Using a Randomised Controlled Trial to Test the Effectiveness of a Family-Oriented, Theoretically Based, Diabetes Self-Management Education Program to Improve Glycaemia, Self-Management and Self-Efficacy of Individuals with Type 2 Diabetes Mellitus Living in Rural Thailand

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A thesis submitted in total fulfilment of the requirements of the degree of

Doctor of Philosophy (PhD)

School of Nursing, Midwifery and Paramedicine

Faculty of Health Sciences

Australian Catholic University

March 2018

Candidate's Statement of Authorship and Sources

This thesis contains no material that has been extracted in whole or in part from a thesis that I have submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant ethics/safety committees (where required).

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Contribution to Jointly Published Work

It is acknowledged that I received co-operation from a research team and have been mentored and supported by this team's members and others at the Australian Catholic University for my research training and work. However, the body of work for this program of research was conceptualised by me and undertaken for my PhD and is therefore my own intellectual property.

As is the nature of research, a number of researchers contributed in part to publications included in this thesis; however, the actual research undertaken and the preparation of manuscripts for publication were solely my own work (except where duly acknowledged). It is acknowledged that all co-authors of jointly published papers included in this thesis provided their consent for the inclusion of each paper in this thesis, and that the co-authors accept my contribution to the paper as so described in the statement of contribution to jointly published work by others. All other work included in this thesis that is not part of a published paper, or one that has been accepted for publication, is entirely my own work, except where duly acknowledged. My contribution, and the contributions of others to each of the published papers included in this thesis, is outlined in the following statements.

Publications/Submitted Papers by the Candidate

This thesis includes a number of published/submitted manuscripts. To date, one paper has been published and two have been submitted to a journal for consideration. The details of these publications are outlined below.

Chapter 3 – Research Methodology

Wichit, N., Courtney, M., Mnatzaganian, G., Schulz, P., & Johnson, M. (2017). A randomised controlled trial of a family-supported diabetes self-management program: Study protocol. Manuscript submitted for publication in the *International Journal of Diabetes in Developing Countries.*

Chapter 4 – Efficacy of a Family-Oriented Self-Management Program

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017a). Randomised 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. *Diabetes Research & Clinical Practice*, 123, 37–48. doi: 10.1016/j.diabres.2016.11.013

Chapter 5 – Development and Testing of Research Instruments

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017). Psychometric testing of the family-carer diabetes management self-efficacy scale. *Health and Social Care in Community*, 2017; 00:1–10. doi.org/10.1111/hsc.12511

Statement of Contribution to Jointly Published Work – Chapter 3

Wichit, N., Courtney, M., Mnatzaganian, G., Schulz, P., & Johnson, M. (2017). A randomised controlled trial of a family-supported diabetes self-management program: Study protocol. Manuscript submitted for publication in the *International Journal of Diabetes in Developing Countries*.

Nutchanath Wichit	Conception and design of the literature search
	Drafting of the article and revising it for critically important intellectual content
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George Mnatzaganian	Provision of advice on conception of study
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	Approval of the final version for publication
Paula Schulz	Provision of advice on conception of study
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Date: 07/08/2017 Date: 07/08/2017

Statement of Contribution to Jointly Published Work – Chapter 4

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017a). 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. *Diabetes Research & Clinical Practice*, 123, 37-48. doi: 10.1016/j.diabres.2016.11.013

Nutchanath Wichit	Conception and design of the literature search and data analysis
	Collection and analysis of data
	Drafting of the article and revising it for critically important intellectual content
	Approval of the final version for publication and submission of the article to the journal for publication
George Mnatzaganian	Provision of advice on conception of study and data analysis
	Provision of critical revisions to draft versions for important intellectual content
	Approval of the final version for publication
Mary Courtney	Provision of critical revisions to draft versions for important intellectual content
	Approval of the final version for publication
Paula Schulz	Provision of critical revisions to draft versions for important intellectual content
	Approval of the final version for publication
Maree Johnson	Provision of advice on conception of study
	Provision of critical revisions to draft versions for important intellectual content
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Statement of Contribution to Jointly Published Work – Chapter 5

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017b). Psychometric testing of the family-carer diabetes management self-efficacy scale. Manuscript submitted for publication in the *Health and Social Care in Community*.

Nutchanath Wichit	Conception and design of the literature search and data analysis
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Signed: 

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Professional Editing Assistance

Editor Brenton Thomas, from Fresh Eyes Australia, provided editing assistance in accordance with the requirements of the university-endorsed *Guidelines for Editing of Research Theses*, which form part of the Australian Standards for Editing Practices.

Acknowledgements

I cannot believe that I am now finally at this stage after this long journey. This thesis represents my research training. The completion of this thesis would not have been possible without the amazing contributions and support of so many people, and I am sincerely grateful to all those who have helped me on this journey.

First, I would like to express my sincere gratitude to my supervisors, Professor Maree Johnson, Dr George Mnatzaganian, and Associate Professor Paula Schulz. I am an international student and the English language is not my mother tongue. Culture and language differences did make my journey that much more difficult. However, all my supervisors encouraged me constantly in working towards this final goal. They were always supportive and patient, providing valuable feedback with helpful suggestions. They were excellent supervisors and I would like to thank them for the expertise and wisdom that each one of them provided to me throughout my candidature. Another supervisor that I must also thank is Professor Mary Courtney, who was my principal supervisor for two years (2013-2015). I deeply appreciated the knowledge she shared, as well as her support, guidance and encouragement.

I wish to acknowledge the International Student Office of the Australian Catholic University for its support and assistance with my English language competency, especially Kate D'Orazio and Stella Link. To all my friends in Australia, both international and Thai, I thank you for your friendship and support that helped me in times of loneliness and when I felt homesick.

I am extremely grateful to the support of Suratthani Rajabhat University, who through awarding a scholarship to me gave me the opportunity to study as a full-time student in Australia. Moreover, I would like to acknowledge the support of the School of Nursing, Midwifery and Paramedicine at the Australian Catholic University for the financial research support schemes it offers to HDR students, which provided some financial support for this research study.

Finally, I am grateful to my parents for their love and inspiration, and to my sisters for looking after my parents in my absence from home, and for their financial support. Without their support, none of this would have been achievable.

Table of Contents

List of Figures

List of Tables

Acronyms and Abbreviations

ADA	American Diabetes Association
BMI	Body Mass Index
BP	Blood Pressure
BW	Body Weight
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CVD	Cardiovascular Disease
DKQ	Diabetes Knowledge Questionnaire
DM	Diabetes Mellitus
DMSES	Diabetes Management Self-Efficacy Scale
DKA	Diabetic Ketoacidosis
DSME	Diabetes Self-Management Education program
F-DMSES	Family Diabetes Management Self-Efficacy Scale
GDM	Gestational Diabetes Mellitus
HbA1c	Glycosylated Haemoglobin
HHS	Hyperosmolar Hyperglycaemic State
T1DM	Type 1 Diabetes Mellitus
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
T2DM	Type 2 Diabetes Mellitus

PTES	Perceived Therapeutic Efficacy Scale
RCT	Randomised Controlled Trial
SDSCA	Summary of Diabetes Self-Care Activities measure
SF-12	12-item Short-Form health survey
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization

Definition of Terms

Body mass index (BMI) is a measure of body weight proportional to height, and is calculated by weight in kilograms divided by height in metres squared of an individual.

Blood pressure (BP) is the pressure of the blood within the arteries. Systolic blood pressure of 120 mmHg and diastolic blood pressure of 80 mmHg is considered within normal range (Chobanian et al., 2003).

Carer diabetes management self-efficacy is the confidence of the family-carer to support individuals with diabetes to self-manage their diabetes.

Consolidated standards of reporting trials (CONSORT) is the gold standard in evaluating healthcare interventions. It provides guidelines for reporting and evaluating randomised controlled trials.

Diabetes Mellitus (DM) is a chronic disorder that is caused by the deficiency in insulin secretion, insulin resistance, or both. As a result of this condition the body cannot maintain healthy levels of blood glucose, which, in turn, disrupts the metabolism of carbohydrates, fats, and proteins.

Diabetes Self-Management Education (DSME) is a method of assisting individuals with diabetes in improving knowledge and capability to manage self-care behaviours, including decision-making and problem-solving. The goal is to enhance health outcomes and quality of life with education informed by the best available evidence.

Glycosylated haemoglobin (HbA1c) is a measure of the degree of haemoglobin in erythrocytes. It is expressed as a percentage of total haemoglobin concentration and reflects the exposure of an erythrocyte to glucose. The American Diabetes Association (ADA) defines an HbA1c of ≥ 6.5% as a diagnosis of diabetes and therefore a 5.7 – 6.4% reading for individuals indicates that they have a high risk of developing the disease (American Diabetes Association, 2011).

Hyperglycaemia is a condition resulting from an excessive amount of glucose circulating in the blood plasma (≥ 126 mg/dl when fasting or ≥ 200 mg/dl two hours after meals). The

signs and symptoms of hyperglycaemia include dry mouth, extreme thirst, frequent urination, drowsiness, frequent bed wetting, and stomach pain (International Diabetes Federation, 2015).

Hypoglycaemia is the clinical syndrome resulting from low glucose circulating in the blood plasma (< 70 mg/dl). The signs and symptoms of hyperglycaemia are sweating, trembling, dizziness, mood change, hunger, headache, blurred vision, extreme tired and paleness (Zammitt & Frier, 2005).

Quality of life is the individual's perception of their life and health.

Self-efficacy is defined as the perception of an individual's confidence in their ability to complete a task or accomplish a goal or an outcome in a particular situation (Bandura, 1977).

Type 2 Diabetes Mellitus (T2DM) is a progressive chronic metabolic disease that is categorised by insulin resistance and insulin secretory defectiveness (World Health Organization, 2006).

Abstract

Introduction

Diabetes is increasing in prevalence throughout the world. This increase is also of concern to upper-middle-income countries such as Thailand. Diabetes mellitus develops gradually and is often undetected in the early stages, leading to long-term damage of several organs in the body with related complications. Diabetes self-management education (DSME) has been found to improve knowledge, self-care behaviours, glycaemic control, and quality of life for Thai individuals with type 2 diabetes mellitus (T2DM). Thailand is a country in which family members have a fundamental role in assisting other family members in sickness and in health. Family-oriented interventions, therefore, have the potential to enhance health outcomes for individuals with T2DM. Randomised controlled trials conducted on family-carers of individuals with diabetes in Thailand are limited and none has investigated the potential benefit of a family-oriented DSME program, which includes the family-carer in the intervention.

Aims

The primary aim of this study was to test the effectiveness of a family-oriented, theoretically derived (based on self-efficacy) DSME for Thai individuals living with T2DM. The specific objectives of this research are to develop and deliver a family-oriented DSME for Thai individuals with T2DM and carers; to evaluate the effectiveness of a family-oriented DSME in improving diabetes knowledge, glycaemic control, self-efficacy, self-management, and quality of life among Thai individuals with T2DM; to develop and test the validity and reliability of the family-carer diabetes management self-efficacy scale (F-DMSES) that measures diabetes management self-efficacy among family-carers of Thai individuals with T2DM; and, finally, to measure and compare diabetes management self-efficacy between individuals with T2DM and their carers.

Methods

After developing a family-oriented DSME program, a single-blinded randomised controlled trial was conducted in rural Thailand to examine the effectiveness of the program. One hundred and forty Thai individuals with T2DM (and their carers) were randomly

allocated to intervention and control arms. Those in the intervention group received routine care plus the family-oriented program that included education classes, group discussions, a home visit, and a telephone follow-up. Participants within the control group only received the routine usual care.

The sample size was estimated based on a known effect size (effect size = 0.58) from the primary outcome of diabetes self-management score (Mean difference = 8.35, SD = 14.28) (Wu et al., 2011). 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), and a sample of 140 people (70 per group) was required.

The primary study outcome was diabetes self-management evaluated by the Summary of Diabetes Self-Care Activities measure. The secondary outcomes were diabetes knowledge evaluated by the Diabetes Knowledge Questionnaire, diabetes self-efficacy (efficacy expectation and outcome expectation) evaluated by the Diabetes Management Self-Efficacy Scale and the Perceived Therapeutic Efficacy Scale, quality of life evaluated by the 12-item Short-Form Health Survey, and glycaemic control as shown by HbA1C levels.

Outcome assessments were made overtime (baseline, week 5 and week 13 following intervention) and were evaluated using generalised estimating equations multivariable analyses. The family-carer diabetes management self-efficacy scale (F-DMSES) was developed using forward and backward translations from and to English and Thai languages and its construct and content validity, together with the internal consistency, were tested.

Results

One hundred and forty participants were actually recruited and randomized to the intervention but 134 individuals have completed the three time points in data collection. Intention to-treat analyses were conducted in this study.

Except for age, no between-group significant differences were found in all other baseline characteristics. Diabetes self-efficacy, self-management, and quality of life improved in the intervention group but no improvement was observed in the controls. In the risk-adjusted multivariable models, compared to the controls, participants in the intervention group had significantly better self-efficacy, self-management, outcome

expectations, and diabetes knowledge ($p < 0.001$ for all outcomes). 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 improved in individuals with lower BMIs and in females. No between-group differences were observed in quality of life or glycaemic control. The F-DMSES retained 14 items within 4 factors (general diet and blood glucose monitoring, medications and complications, diet in differing situations, and weight control and physical activities), and explained 72.2% of the total variance in the overarching construct. Internal consistency was high ($\alpha = 0.89$). The F-DMSES was also able to measure change over time following the intervention, with an effect size of 0.9. Diabetes knowledge and management self-efficacy in family-carers improved over time. These aspects were also improved in individuals with T2DM when compared to their carers.

Conclusions

The family-oriented DSME program improved self-efficacy, self-management and quality of life, which in turn could decrease HbA1c levels. The F-DMSES is a valid and reliable self-administered instrument that measures the diabetes management self-efficacy of family-carers of individuals with T2DM, which can be used in clinical and research situations. Better carer diabetes knowledge improved the self-management of individuals with T2DM and greater family-carer diabetes management self-efficacy increased the diabetes management self-efficacy of individuals with T2DM. Family-carers can play an important role in supporting individuals with T2DM living in Thailand and should be formally included within educational programs. Family-carers also have the potential to provide compensatory care when required.

Chapter 1

Introduction

1.1 Overview

Diabetes mellitus is a global public health problem, resulting in considerable morbidity and mortality, and in most countries in the world, this condition is continuing to increase in prevalence. Type 2 Diabetes Mellitus (T2DM), the focus of this thesis, is often referred to as a genetic or lifestyle factors disease. A combination of these factors can cause insulin resistance, resulting from an imbalance in diet and exercise that diminishes the effectiveness of insulin. As a Thai health professional, I have witnessed a rapid increase in the number of cases attending the community hospital in Suratthani Province in Thailand. Enhancing diabetes self-management in individuals with T2DM, improving their self-efficacy and quality of life is a challenge for local health care professionals.

While there is an increasing health service demand, there is also substantial evidence of the effectiveness of educational interventions to reduce complications and enhance self-management of T2DM. The research for this study has sought to develop an educational intervention program based on the best available evidence. Second, this investigation designed a rigorous approach to the evaluation of the effectiveness of the program. Third, a randomised controlled trial was conducted to determine the effectiveness of this educational intervention program on key clinical and psychosocial outcomes for health consumers. No study to date has used a controlled trial and involved family-carers directly in intervention programs in Thailand. Additionally, appropriate instruments will be developed and tested to extend the evaluation to the family support.

The seven chapters in this thesis present the three related studies. Chapter 1 introduces the research problem, defines important terms relevant to the thesis, outlines the scope of the study, and details the research significance. In particular, this chapter provides a summary of the background and context of diabetes mellitus, including describing the classification of the varying forms of the disease and the pathophysiology related to these conditions, and then focuses on T2DM. In this chapter, descriptions of the health services currently provided to

manage this prevalent disease across the world, and specifically within in Thailand, will be outlined. As culture plays a significant role in the management of T2DM within Thailand, Thai culture and norms, family support and the essential role of the family-carer in the Thai rural community are explored in this study. Finally, the research study's aims and objectives, research questions, and thesis structure are detailed. A brief overview of current diabetes self-management educational programs and methods of delivery of educational interventions will also be provided, which will be elaborated on in Chapter 2.

1.2 Diabetes Overview

1.2.1 Diabetes mellitus definition, classification, diagnosis and complications. The World Health Organization [WHO] (2006) defines diabetes mellitus (DM) as a metabolic syndrome caused by chronic hyperglycaemia (blood glucose ≥ 126 mg/dl [7.0 mmol/L] when fasting or ≥ 200 mg/dl [11.0 mmol/L] two hours after meals), with disorders of metabolism resulting from an insulin secretory defect or resistance, or both. People often present to primary care settings with diabetes mellitus while displaying different symptoms such as thirst, frequent urination, nocturia (urination at night), occasional blurred vision, weight loss despite excessive eating, dry and itchy skin, and peripheral neurological damage including a tingling feeling in the hands and feet (Alberti & Zimmet, 1998).

Diabetes mellitus is diagnosed by a "casual blood glucose concentration ≥ 200 mg/dl (11.0 mmol/L) or fasting blood glucose concentrations of ≥ 126 mg/dl (7.0 mmol/L) or a value of ≥ 200 mg/dl (11.0 mmol/L) at two hours of an oral glucose tolerance test (OGTT)" (American Diabetes Association, 2011, p. S62). For individuals experiencing chronic hyperglycaemia, there can be substantial long- and short-term damage to bodily organs including impairment, failure of the kidneys, and damage to eyes, blood vessels, nerves, and the heart (American Diabetes Association, 2014).

1.2.1.1 Diabetes classification. The American Diabetes Association (ADA) has provided direction in relation to the classification of the four types of diabetes.

These include "type 1 diabetes, type 2 diabetes, other specific types, and gestational diabetes" (American Diabetes Association, 2011, p. S65).

Type 1 Diabetes Mellitus (formerly known as type 1, T1DM) is caused by "autoimmune b-cell destruction, usually leading to absolute insulin deficiency" (American Diabetes Association, 2017, p S11). Immune-mediated diabetes mellitus and idiopathic diabetes mellitus are two forms of Type 1 diabetes mellitus (American Diabetes Association, 2011). Only about 5 to 10% of all cases of diabetes are type 1; however, it is the major form of diabetes in children and adolescents (International Diabetes Federation, 2015).

Type 2 Diabetes Mellitus (formerly known as type 2, T2DM) is categorised by a defect in insulin secretion and action (American Diabetes Association, 2011). T2DM is the most typical type of diabetes and is diagnosed predominantly in individuals aged 40 years and over. Children and adolescents are now also being diagnosed with T2DM (Pinhas-Hamiel & Zeitler, 2005). This condition is related to a family history of the disease, obesity, physical inactivity, and high calorie intake with low calorie expenditure (Alberti & Zimmet, 1998).

Other specific types of diabetes mellitus refers to the types of diabetes mellitus that have specific underlying causes including "genetic defects of beta-cell function, genetic defects in insulin action, disease of the exocrine pancreas, endocrinopathies, drug- or chemical-induced diabetes, infections, uncommon forms of immune-mediated diabetes, and other genetic syndromes" (American Diabetes Association, 2011, p. S65).

Gestational diabetes mellitus (GDM) is a form of high blood glucose, which is diagnosed in some pregnant women who have not previously been diagnosed with other forms of diabetes. In most cases of gestational diabetes, glucose levels return to normal after delivery; however, in many cases, if it perseveres, it can be diagnosed as T1DM or T2DM (American Diabetes Association, 2011).

This thesis focuses only on T2DM, which accounts for about 90% of all diabetes cases (International Diabetes Federation, 2015). The disease is a major healthcare burden and cause of death worldwide (International Diabetes Federation, 2013). T2DM frequently has a delayed diagnosis and can take approximately four to six years before a clinical diagnosis is reached (Porta et al., 2014). However, dysglycaemia can be present several years before diagnosis and complications such as retinopathy, heart disease, or microalbuminuria may exist at diagnosis (Joshi & Karne, 2007). T2DM develops gradually and is often undetected in the early stages.

Furthermore, individuals diagnosed with T2DM are at risk of long-term organ and tissue damage as the disease progresses, which results in several acute and chronic complications that can also be serious and life threatening.

1.2.2 Diabetes complications. Diabetes can result in various acute and chronic complications, which are mostly responsible for diabetes-related morbidity and mortality. The complications of T2DM have been responsible for the substantial cost of health care services (American Diabetes Association, 2013a).

1.2.2.1 Acute metabolic complications. Diabetic ketoacidosis (DKA) is a life-threatening condition and is defined by insulin insufficiency leading to hyperglycaemia, with increased lipolysis, ketone production, hyperketonemia, and acidosis (Chiasson et al., 2003) It usually develops in people with T1DM; however, it can also be diagnosed in individuals with T2DM when they do not manage their diet and insulin levels appropriately.

Hyperosmolar Hyperglycaemic State (HHS) is defined by the presence of hyperglycemia (Plasma glucose level of 600 mg/dL or greater), hyperosmolarity (effective serum osmolality of 320 mOsm/kg or greater), and dehydration without the presence of ketoacidosis (Chiasson et al., 2003).

Hypoglycaemia (blood glucose < 70 mg/dl) is a dangerous condition and is clinically diagnosed from symptoms of low blood glucose that can continue for several reasons. It is usually a side effect of diabetes treatment such as taking an excessive dose of medication, missing meals, eating less than normal, or over-exercising (Yanai et al., 2015). Symptoms of low blood glucose include sweating, tremor, dizziness, mood changes, hunger, headache, blurry vision, loss of consciousness, and coma (Zammitt & Frier, 2005).

1.2.2.2 Chronic diabetes complications. Individuals living with T2DM are at high risk of developing complications that will affect major organs such as the heart and blood vessels, eyes, kidneys, and nerves.

These chronic complications are major contributing factors to the increased morbidity and mortality associated with T2DM (Deshpande, Harris-Hayes, & Schootman, 2008). Managing

blood glucose levels within a normal range can delay or prevent diabetes complications (Wattana, Srisuphan, Pothiban, & Upchurch, 2007). Therefore, individuals with T2DM require regular blood glucose monitoring. The long-term major complications of diabetes are now presented.

Cardiovascular disease (CVD) is the most common cause of death related to complications from diabetes and is responsible for 65% of the deaths in individuals with T2DM (Gavin III, Peterson, & Warren-Boulton, 2003). Diabetes has the potential to damage blood vessels of vital organs, particularly the heart, which can potentially lead to fatal complications such as coronary artery disease and occlusion and stroke (Ali et al., 2013). Diabetic nephropathy occurs in individuals with T2DM when small blood vessels in the kidneys are damaged by prolonged high blood glucose levels, which leads to an insufficient blood supply and dysfunction. Diabetic neuropathy and lower-extremity amputations result from prolonged hyperglycaemia that can cause damage to the nerves throughout the body. The most commonly affected areas are the extremities, particularly the feet and hands. This damage leads to pain, tingling, and the loss of feeling in the feet and hands. Diabetic retinopathy is a diabetes complication that affects the vessels of the eyes. The blood vessels of the retina are damaged, which results in reduced vision or blindness. Around 2% of individuals develop blindness and around 10% develop a severe visual impairment after 15 years of diabetic symptoms (World Health Organization, 2017).

1.3 Prevalence of Diabetes in Thailand and Its Associated Healthcare Burden

Prevalence rates of diabetes in developing countries, particularly in the Asia–Pacific region, are already high and are expected to rise more quickly than elsewhere. The rapid growth of these economies and the urbanisation that occurred in this region led to changes in lifestyle, which includes less physical activity and more energy consumption (Aekplakorn et al., 2011). In 2013, 382 million individuals worldwide were diagnosed with diabetes, and this number is estimated to increase to 592 million by 2035 (Guariguata et al., 2014). Most individuals with diabetes are living in low- and middle-income countries such as China and India (International Diabetes Federation, 2015).

1.3.1 Diabetes prevalence in Thailand. Diabetes is a common health problem in Thailand, as it is for other countries worldwide. A national diabetes type 2 registry does not exist in Thailand; however, data on the diabetes prevalence rate is often obtained from the national health examination surveys (NHES) (Deerochanawong & Ferrario, 2013). In 1991, the diabetes prevalence was 2.3%, which increased to 6.9% (55% of all diabetes cases were previously undiagnosed) in 2004 (Aekplakorn et al., 2007) and continued to increase to 7.5% in 2009 (Aekplakorn et al., 2011). Moreover, 35.4% of all diabetes cases diagnosed in 2009 were not previously diagnosed (Aekplakorn et al., 2011). This number indicates that the diabetes prevalence had increased from the previous survey.

Both surveys found that the prevalence rates were higher in women than in men, and higher in urban areas compared with rural communities. Fasting blood glucose tests and patients' self-reports were used to determine their diabetes status. Participants who had fasting plasma glucose of ≥ 7.0 mmol/L and had not previously been diagnosed with diabetes, were defined as having "undiagnosed diabetes", and participants who had never been diagnosed and had been taking diabetes medications for the past two weeks were defined as having "diagnosed diabetes". The Bureau of Non Communicable Diseases of Thailand reported that 501,299 new cases of diabetes were diagnosed in 2011, and it is estimated that this may increase to 553,941 new cases per year in 2020. Consequently, the number of people with diabetes is expected to double within six years so that in 2020 the number of people with diabetes will have increased to 8,200,000 cases (Srichang, 2010).

Diabetes mellitus is one of the most common causes of death in Thailand. In 2011, diabetes was the fourth-leading cause of death in the Thai population (World Health Organization, 2010). The disease was the third-leading cause of death in women aged between 15 and 49 years and the first leading cause of death in women aged between 50 and 74 years (Porapakkham et al., 2010). In Thailand, diabetes-specific mortality rates increased from 12.2% in 2008 to 14.9% in 2013 (Bureau of Non Communicable Disease, 2014). The International Diabetes Federation estimates that 180 Thai people die from disorders attributable to diabetes every day (International Diabetes Federation, 2013). The increase in diabetes prevalence and its associated mortality results in a substantial economic and healthcare burden for Thailand (Chatterjee, Riewpaiboon, Piyauthakit, Riewpaiboon, et al., 2011).

1.3.2 The burden of diabetes in Thailand. Thailand is a developing country and is considered an upper-middle-income economy country located in South-East Asia. Diabetes mellitus is a chronic metabolic disorder that requires long-term treatment. Consequently, it contributes to the healthcare burden in Thailand. The chronic nature of the disease, together with its related complications that include cardiovascular disease, diabetic nephropathy, diabetic neuropathy, and diabetic retinopathy, make it very costly. The increase in diabetes prevalence in Thailand affected the Thai economy, resulting in increased government spending to maintain the health of individuals living with the disease (Chatterjee, Riewpaiboon, Piyauthakit, Riewpaiboon, et al., 2011).

Diabetes imposes a large economic burden on the Thai healthcare system as people with diabetes are prone to ill-health as a consequence of complications either of short-term for example, wound infection or long-term for example, renal dialysis. The hospitalisation rate for diabetes in Thailand has risen over the years, from 213 per 100 000 of the population in 2003, to 389 per 100 000 in 2008, and continue to increase to 699 per 100 000 in 2013 (Bureau of Non Communicable Disease, 2014). Chatterjee, Riewpaiboon, Piyauthakit, and Riewpaiboon (2011) found that the estimated mean medical costs of diabetes at a district public hospital in Thailand was USD881.47 per person per year in 2008, which comprised 21% of the per capita gross domestic product of Thailand. Of all the costs associated with diabetes, 40% was for direct non-medical costs, 37% for indirect costs, and 23% for direct medical costs (dispensing and medication costs). Informal care accounted for 28% of the total cost (Chatterjee, Riewpaiboon, Piyauthakit, & Riewpaiboon, 2011). Nearly half (49%) the direct medical costs resulted from in-patient hospital care. This demonstrates that an inpatient requiring hospitalisation costs more than an individual managed within outpatient departments (13%) (Chatterjee, Riewpaiboon, Piyauthakit, Riewpaiboon, et al., 2011).

The complications of diabetes have a major effect on diabetes-associated expenditure. Deerochanawong and Ferrario (2013) found that the average expenditure for diabetes for patients with complications was four times that of the cost for people without complications, and the cost was further increased when there were multiple complications. Cardiovascular disease is rated as the first cause of disease burden due to vascular damage, which results in heart failure and corresponding surgery, with lengthy hospital stays and extensive recovery

time. Therefore, initial prevention of diabetes and education for people with diabetes is needed to prevent disease progression and the devastating complications and the concomitant burden on the Thai economy.

1.4 Diabetes Management in Thailand

It is a great challenge for healthcare providers, researchers, people with diabetes and policymakers to manage diabetes given the dramatic growth in the prevalence of diabetes that has occurred in Thailand. The majority of healthcare services in Thailand are in the public sector and are delivered by the Ministry of Public Health, which is then followed by the private medical sector (or clinics) and not-for-profit health organisations. Public healthcare services include regional hospitals (> 500 beds), general hospitals (120–500 beds), community hospitals (10–120 beds), and health-promoting hospitals at district level. In Thailand, the level of accessibility to healthcare services depends on the socioeconomic circumstances of a person and location of residence. People living in a rural setting commonly receive healthcare services that include health prevention, health promotion, medical care, and rehabilitation from health-promoting hospitals and community (primary) hospitals, where there are staff shortages, high workloads, and limited resources. Nurses and midwives provide healthcare services in health centres, which are mainly concerned with primary care. Interestingly, patients receiving diabetes treatment in secondary or tertiary hospitals are more likely to have better diabetes control compared to patients receiving treatment in primary hospitals (Rungsin, 2012).

In order to reduce the problem of health inequity in Thailand, three different national healthcare insurance schemes are in place that potentially impact on the management of T2DM. First, in 1978 the public health insurance scheme, the Civil Servant Medical Benefit Scheme (CSMBS) was established to cover all government employees and their dependants (including spouses and parents), where the employee does not have more than two children under the age of 18. In 1990, a social security scheme (SSS) was established that covered workers who have an illness not related to work, and covers every company with more than one employee. Finally in 2002, the Thai government launched its most recent scheme, the Universal Coverage Scheme (UCS), for the rest of the people who were uninsured. This scheme aims to remove financial barriers to accessing health services by limiting payment to 30 baht or one dollar

(exchange rate of 30 baht = USD1.00) per episode of service. Thailand now has 99.47% of its entire population covered under one of the three schemes: under the CSMBS, about 5 million (8% of the population); under the SSS, about 10 million (16% of the population); and under the UCS scheme, about 47 million (75% of the population) (Thammatach-aree, 2011). Although diabetes treatment is universal and easy to access for Thai people, after the introduction of the UCS, achievement of the HbA1c target in members of the CSMBS (30%) was higher than members of the UCS (7.0%). It is important to note that of those people who reached the HbA1c target of less than 7%, the majority received treatment in secondary or tertiary hospitals (Tatsanavivat, Thavornpitak, & Pongchaiyakul, 2012).

In 2011, the Ministry of Public Health, the Office of National Economics, and the Social Development Board and Institute of Nutrition launched the Healthy Lifestyle Strategic Plan 2011-2020, aiming to decrease the prevalence of lifestyle diseases by reducing obesity and increasing physical activity, complications, disability, mortality and expenditure of five major chronic diseases such as diabetes, hypertension, ischemic heart disease, stroke and cancer (Thammatach-aree, 2011). Although some strategies for diabetes were converted to an action plan (i.e., mobile screening for individuals in rural communities and an education program on diabetes for health care providers), other diabetes strategies had no action plan developed to guide implementation (Deerochanawong & Ferrario, 2013).

In 2014, the Diabetes Association of Thailand, together with the Endocrine Society of Thailand, the National Health Security Office, and the Ministry of Public Health of Thailand, launched clinical practice guidelines for diabetes for healthcare providers in order to improve the quality of treatment for diabetes (Diabetes Association of Thailand, 2014). The guidelines contained information relating to general knowledge about diabetes, a screening strategy for those at high risk of developing diabetes, information on screening tests and diagnosis methods relating to diabetes, information on treatment and management of complications, and guidelines for self-management education for T2DM. For the screening strategy, all Thai people who fall into the following categories: (1) ≥ 35 years old; (2) BMI ≥ 25 Kg/m^2 with a family history of diabetes; (3) having high blood pressure or taking hypertension medications; (4) having hyperlipidemia or taking hyperlipidemia medications; (5) diagnosed with gestation diabetes; (6) having impaired fasting glucose (IFG); (7) having cardiovascular disease; or (8)

having polycystic ovarian syndrome are considered high risk and are included in the screening strategy (Diabetes Association of Thailand, 2014).

Further to the screening for high-risk individuals, those people who meet any of the eight criteria (as set out above) are requested by healthcare professionals to follow up with a fasting plasma glucose test once a year. People who have a fasting plasma glucose reading of 100–125 mg/dl (5.6-6.95 mmol/L)are diagnosed with impaired fasting glucose, and require health behaviour change and annual follow-up. Those with a fasting blood glucose reading ≥ 126 mg/dl (7 mmol/L) require a repeat fasting blood glucose test. If the repeated fasting blood glucose reading remains ≥ 126 mg/dl (7 mmol/L), then diabetes is diagnosed (Diabetes Association of Thailand, 2014). The Thai National Health Examination Survey IV in 2009 found that one in three of all newly diagnosed diabetes sufferers had not previously been diagnosed (Aekplakorn et al., 2011). Therefore the screening test is useful to detect and diagnose individuals with T2DM early. Early identification of individuals with no overt signs and symptoms of diabetes may potentially reduce the risk of subsequent complications.

According to the Thai clinical practice guidelines for diabetes, newly diagnosed cases in primary care settings need to start treatment immediately in order to delay the onset of complications related to diabetes. Patients and their carers are included in the process of setting treatment goals. Patients need to follow up at the clinic at least every one to four weeks for healthcare behaviour education, treatment follow-up, and medication adjustment until plasma glucose is within the recommended range (Fasting plasma glucose < 130 mg/dl [7.2mmol/L] and HbA1c < 7%). Body weight, blood pressure, and plasma glucose measurements are provided at each follow-up as well as the review and assessment of diet, exercise, and medication. HbA1c, lipid profiles, physical check-up, eyes and feet examination, cardiovascular disease and nephropathy assessment, combined with the influenza vaccine, are offered annually to patients (Diabetes Association of Thailand, 2014). Although several clinical practice guidelines for diabetes recommend HbA1c targets of less than 7%, the recommended HbA1c targets should be personalized especially for people who are older, who have had the disease for many years, or have complications (Paschou & Leslie, 2013).

There is a clear requirement for diabetes education to be delivered to individuals who are at high risk of diabetes to prevent the development of the disease; however, a significant proportion of education is directed at supporting individuals already diagnosed with T2DM who require ongoing monitoring and support. The goal of education is to improve knowledge, promote better self-management, and enhance quality of life, as well as prevent acute and chronic complications. The education process consists of assessment, goal setting, planning, implementation, and evaluation that use a patient-centred care method (Diabetes Association of Thailand, 2014). The specific content of diabetes education includes general knowledge of diabetes, dietary therapy, physical activities, medications, blood glucose monitoring, the management of hypoglycaemia and hyperglycaemia, diabetes-related complications, general health care, foot care and diabetes care for special occasions such as holidays, pregnancy, parties, and sick days.

All newly diagnosed people are provided with diabetes education, and self-care support is delivered to groups or individuals by healthcare providers (Diabetes Association of Thailand, 2014). Even though Thailand has guidelines for diabetes care and these guidelines are instructive and available to healthcare centres across Thailand, there is no study that has evaluated the effectiveness of the guidelines and there is no evidence indicating how many healthcare centres have implemented the guidelines.

1.5 Cultural Context and Its Influence on Diabetes

Cultural and religious beliefs influence an individual's perspectives of diabetes self-care (Shakibazadeh et al., 2011). An understanding of cultures has potential benefit for the healthcare professional to develop diabetes self-management educational interventions based on cultural considerations. Given the importance of dietary changes, which are often culturally influenced, this focus on social culture may be crucial. Culturally appropriate DSME has the potential to be more effective in improving HbA1c and knowledge (Hawthorne, Robles, Cannings-John, & Edwards, 2010).

Thai society has its own practices and beliefs that are complex and very different from Western societies. Thai family life is also often more closely knit than in Western cultures. The majority of the Thai population is Buddhist (94–95%), with minorities following Muslim (5–6%) and Christian (1%) faiths. Buddhism is not only the dominant religion of Thailand but it also provides a principal philosophy that is followed by most Thais (Sowattanangoon, Kotchabhakdi, & Petrie, 2009). Such values and beliefs directly influence diabetes management, behaviours and glycaemic control (Sowattanangoon et al., 2009). Thai people are religious and spiritual. Both religion and spirituality influence coping strategies in people with chronic disease. These can help people to overcome the distress and difficulties of chronic illness (Yodchai, Dunning, Savage, & Hutchinson, 2017).

1.5.1 Thai culture and norms. According to Buddhist teachings, children are expected to take care of their parents when they are old, which is an important part of the Thai culture (Nantsupawat, Kamnuansilapa, Sritanyarat, & Wongthanawasu, 2010). The Thai family is based on a hierarchical system, with the parents at the top and the children, who are taught to honour their parents, below.

Traditionally, Thai people believe that because they received care from their parents when they were young, it is very considerate of them to reciprocate this care when their parents are aged. For example, children often care for their parents when they become old or unwell. Children who fail to support their elderly parents, or who provide inadequate care, are considered to be “ungrateful” people. Therefore, it is very unusual to find older Thai people abandoned by their families (Thanakwang, 2008). Children, whether they live close by or not, provide support in the form of regular visits, financial assistance, provision of food, transportation for medical care, and assistance with other caretaking tasks. This close parent–child relationship, regular family contact and strong family ties – which are underpinned by the value of gratitude – are common to Thai kinship including extended families. Grandparents receive great respect from younger generations and play an instructor role in preparing food, learning to work, instigating health practices, and being role models for general good behaviour. They also undertake the role of childcare support, looking after grandchildren and great-

grandchildren. When the elders are not able to earn an adequate living, caused by health problems or lack of physical energy, they are cared for by their children.

Consequently, Thai family relationship support is represented as sharing happiness and suffering in both health and illness (Thanakwang, 2008). Caregivers look after their parents and siblings because of love and attachment based on the familial relationship. Spouses look after each other based on time spent together and a sense of belonging. Therefore, most caregivers in Thai society are informal caregivers who are family members. Most caregivers believe that caring for family members is the responsibility of the family and often lack confidence in people from outside the family who may formally provide care for their family members (Subgranon & Lund, 2000).

1.5.2 Family support and T2DM. Living with T2DM is an issue for both the individual and the family. Most patients live with their family members. Interactions with close family members can enhance both the physical and psychological health of individuals who are living with a chronic disease. Family support for people with T2DM can benefit their health by buffering stress and enhancing self-efficacy (the belief in an individual's confidence in their ability) (Miller & DiMatteo, 2013). Previous studies have found that individuals with high levels of support from their family increased their diabetes self-care behaviours, had greater diabetes medication adherence and improved glycaemic control (Mayberry & Osborn, 2012; Vaccaro, Exebio, Zarini, & Huffman, 2014). Additionally, family members can stimulate new healthy lifestyle behaviours and aid in the maintenance of behavioural changes such as improved physical activity and a reduced intake of fats and carbohydrates (Barrera, Toobert, & Strycker, 2014). Enhanced social support is related to positive healthcare activities and wellbeing amongst individuals with T2DM (McEwen, Pasvogel, Gallegos, & Barrera, 2010; Schiøtz, Bøgelund, Almdal, Jensen, & Willaing, 2012). The association between family support and self-management behaviours is significant and family support with practical assistance can ease the problems of living with this chronic disease (Miller & DiMatteo, 2013; Rosland et al., 2008).

From a Thai cultural perspective, people are more likely to rely on family members and less likely to live alone (Thanakwang, 2009). Family members are key personnel in helping people with diabetes manage their ill-health. Family members help each other in several ways –

for example, by supporting activities of daily living and providing financial and emotional support. Consequently, a person who has a greater social support network is more likely to live successfully compared to those who have less social support. A Thai kinship network is very strong, and this kinship support has a clear and direct influence on a person's sense of wellbeing and, indirectly, has an effect on health-promoting behaviours (Thanakwang, 2008). Economic and social changes within Thai communities have influenced the living arrangements of the elderly, with Thai families changing from extended families to nuclear families. Although Thai family arrangements and social structure aspects have altered in the Thai population over the past few decades, family members continue to be the foundation of support for ageing people (Knodel & Chayovan, 2008). Furthermore, support from family members reduces the need for healthcare providers (Crotty et al., 2015). Family-supported interventions can enhance the self-management abilities of individuals living with T2DM. Therefore, involving family members who can provide physical and mental support to individuals with diabetes should be promoted to enhance the individual's self-management abilities and competency. This element of family support is an essential component of the proposed educational intervention, which is central to the research presented in this thesis.

1.5.3 Role of family-carer support. Family plays a significant role in both coping and symptom management. Aspects of physical and mental support from family members influence the physical and mental wellbeing of individuals living with chronic disease (Martire, 2005). One study found incorporating asthma management practices into family routines can improve medication adherence and reduce asthma morbidity (Fedele et al., 2014).

Although family-carers are considered key support for individuals with chronic diseases, family-carers often encounter physical, mental and financial challenges when trying to provide quality care for their loved one. Caring for people living with chronic disease may cause burnout, stress and worsening mental and physical health for carers. In particular, carers who are older, with potential increased risk of some alterations in mobility or instrumental activities of daily living may experience negative effects on their wellbeing. However, the caring relationship can also lead to an improvement in relationships with the person being cared for.

A great many family-carers provide unpaid care to their family members, which includes bathing, dressing, transportation, financial and emotional support, meal preparation, and attending to medical tasks. Some family-carers take on their roles without any training in how to provide care and have not had previous experience in the role. The inclusion of carers in chronic disease management is challenging for healthcare providers who are seeking to understand the importance of including family support in self-care behaviour educational programs and find suitable methods that improve the carer role without addition substantial carer burden.

1.5.4 Role of family-carer support in diabetes. Informal carers who are family members can undertake diabetes self-management activities with the person who has the disease and thereby assist in reducing the deleterious effects on glycaemic control (Vaccaro et al., 2014). Family members can offer many forms of assistance; however, the major type of assistance is instrumental support such as driving patients to appointments and ensuring they follow meal plans, undertake foot and eye care, increase their physical activity, monitor their blood glucose levels, and take their medications. These supports have been demonstrated to improve the self-care behaviours of the individual with T2DM (Tabasi, Madarshahian, Nikoo, Hassanabadi, & Mahmoudirad, 2014; Vaccaro et al., 2014). Families also provide emotional, informational and appraisal support (Mayberry & Osborn, 2012). This type of support has been shown topromote adherence to self-care behaviours (Tabasi et al., 2014). Conversely, non-supportive actions from family members have been shown to result in less adherence to diabetes self-care behaviours, with the consequence being that the individual has poorer glucose control (Baig, Benitez, Quinn, & Burnet, 2015).

Purchasing groceries, creating meal plans, and cooking meals are vital functions of family members that impact on healthy behaviours (Denham, Ware, Raffle, & Leach, 2011). Healthy behaviours can be hampered when there is family conflict or when non-supportive family members prepare unhealthy meals. Song, Lee, and Shim (2010) studied self-management adherence in Korea and found that wives stated that reminders from their husbands to follow their diabetes treatment were most supportive in maintaining healthy behaviours. Husbands said that meal preparation and dietary monitoring from their wives was most beneficial.

As an individual's diabetes self-management is strongly related to the attention provided to them by an informal carer, diabetes self-management education should focus not only on the people with T2DM but also on the family-carers given the positive support they are able provide to the family member with diabetes. Through the education programs, family-carers can decrease the psychological stress that can result from caring for a relative who has diabetes, as well as improve their own health behaviours towards the individual with T2DM. The participation of patients with T2DM in the education programs may also improve their health behaviours.

1.6 Diabetes Self-Management Education (DSME) Programs in Thailand

Diabetes self-management education (DSME) refers to a method of assisting individuals with diabetes to improve their self-care behaviours, decision-making and problem-solving, and enhance their health indicators and quality of life through the provision of evidence-based health information (Funnell et al., 2009). Several systematic reviews have indicated that self-management interventions are positively related to diabetes knowledge, metabolic control, healthcare behaviours, and quality of life in individuals with T2DM (Chrvala, Sherr, & Lipman, 2016; Cui, Wu, Mao, Wang, & Nie, 2016; Minet, Moller, Vach, Wagner, & Henriksen, 2010; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012).

Thirteen studies relating to DSME programs in Thailand have been analysed during a systematic review of the existing literature. Most of these studies on DSME programs have confirmed the effectiveness of these programs in improving health indicators, self-care behaviours and quality of life for individuals living with diabetes (Jaipakdee, Jiamjarasrangsi, Lohsoonthorn, & Lertmaharit, 2015; Keeratiyutawong, Hanucharurnkul, Melkus, Panpakdee, & Vorapongsathorn, 2006; Saengtipbovorn & Taneepanichskul, 2015; Wattana et al., 2007; Wongrochananan, Jiamjarasrangsi, Tuicomepee, & Buranarach, 2013); however, none of them included the formal education of the family-carer as part of the research.

DSME programs in Thailand have been based on a variety of theories relevant to behaviour change that include cognitive behaviour therapy, the health belief model, the Orem self-care theory, self-efficacy, self-help groups, and social cognitive theory. These theory-based DSME programs were found to improve physical and behavioural outcomes (Keeratiyutawong

et al., 2006; Saengtipbovorn & Taneepanichskul, 2014; Sukwatjanee et al., 2011; Wattana et al., 2007). Some studies are based on one or two theories, although there were some studies without a theoretical foundation.

The strategies used by DSME included face-to-face interaction (education classes, group discussions, home visits), an automated telephone-link system, computer-assisted instruction, electronic mail, and phone calls (Jaipakdee et al., 2015; Keeratiyutawong et al., 2006; Kulnawan et al., 2011; Wattana et al., 2007; Wongrochananan et al., 2013). Some studies adopted only one delivery strategy, but most of the studies considered a combination of strategies.

The introduction demonstrated that the rate increase of T2DM in the Thai population has been substantial, and that the Public Health Ministry of Thailand's approach to managing new and existing cases of diabetes is clearly defined. There is extensive screening proposed for high-risk conditions that may develop into T2DM, and there is also an urgent need for primary care settings to provide comprehensive educational interventions for both patients and their family-carers.

The setting for this study was a community hospital in rural Thailand. The study will involve testing an educational intervention, which will include the family-carer from a household of an individual with T2DM. The goal is to respond to cultural norms and ultimately deliver improved self-management behaviours and improved psychological outcomes for both the carer and the individual with T2DM. Such an intervention, therefore, may mitigate the need for health professional services to be delivered as frequently to the individual with diabetes, while at the same time be able to reduce the development of costly complications from T2DM.

1.7 Significance of the Study

The introduction presented evidence indicating that the diabetes prevalence rate, and its associated mortality rate, has been increasing dramatically in Thailand. The complications arising from diabetes have a substantial impact on the expenditure for diabetes care and have created an economic burden for the country. The prevention of disease progression and the risk of complications related to diabetes, therefore, require urgent attention to lower the high costs related to diabetes health care in Thailand.

Diabetes self-management is broadly recognised as having the capacity to decrease the risk and delay the development of complications related to diabetes, which can reduce the cost of diabetes care. This thesis details the outcomes of developing a family-oriented DSME program based on self-efficacy theory, which included family members in the process of learning. It was envisaged that by including family members in the formal education process, several benefits would be achieved for both the family members and the individuals with diabetes. The study involved family-carers attending the education classes and group discussions, together with the individuals with T2DM, in order to gain the knowledge and confidence to assist their relatives to manage their conditions more effectively. The expectation of this comprehensive program is that it will deliver improved health benefits for both the individual with T2DM and their family-carer.

The management of diabetes affects the health of the individual with T2DM as well as the health of their family members. The program developed in this research study may be of benefit to both the carer and the individual living with diabetes as well as having the potential to improve relationships and reduce family conflict. Family members may also benefit from the reduced psychological and physical distress of having to deal with their family members' experiences of having T2DM, and may also improve their own healthcare behaviours through participating in the DSME programs. Additionally, family members at high risk of developing diabetes may reduce the probability of acquiring the disease by practising enhanced healthcare behaviours. There is the potential for family members to obtain sufficient information regarding the condition to change their own behaviours, or their children's behaviours, to avoid other family members developing the disease. Therefore, involving family members in obtaining knowledge about diabetes and educating them on matters of self-care ability and perceived self-efficacy related to the disease to assist individuals with T2DM may be the critical point in diabetes self-management.

This theoretically based program will be developed to improve adherence to medication regimes, increase attendance at medical appointments, increase the frequency of blood glucose monitoring, raise awareness of the necessity for strict dietary and exercise requirements, and improve glycaemic control by using a variety of educational strategies and resources. These educational and supportive approaches included face-to-face educational classes, diabetes

workbooks, group discussions, skill-practising section, telephone follow-ups, and home visits. In using these multi-component educational resources, the objective is for individuals and their carers to enhance their confidence and ability to manage diabetes. Consequently, the introduction of the program may assist in reducing the burgeoning costs of health services involved in managing the complications of diabetes within the Thai population.

The research study will develop an educational intervention program for a community hospital in a rural setting, where there are limited resources in terms of healthcare professionals. This educational program could also be suitable for other primary care settings in Thailand as it could be easily modified and extended to adapt to other rural settings and healthcare professionals could be trained to effectively implement the program. Consequently, the program could reduce the costs of complications related to T2DM within the local and extended Thai community.

For healthcare professionals, the availability of a rigorously tested educational intervention program that considers the cultural context of Thai families is critically important. The educational program may reduce the workload of healthcare providers and increase their confidence to utilise the program. For medical officers providing ongoing care to individuals with T2DM, the introduction of a structured comprehensive education program may reduce the burden on healthcare providers to deliver this form of education as the program will also equip another member of the family with knowledge and skills to assist their relative who has T2DM.

To the researcher's knowledge, this was the first trial in Thailand to include a family member formally within the education intervention program. While various studies have been published on diabetes management in Thailand, only a few studies have focused on DSME, and no study has included family members in the health intervention. Although the clinical practice guidelines for diabetes state that the carer should be provided with information related to diabetes, educators tend to disregard the role of the family-carer. Education delivered with family involvement could positively affect diabetes self-management outcomes. The results of this study will indicate the benefits of establishing a family-oriented diabetes self-management program in rural Thailand and, therefore could be introduced to other rural communities.

1.8 Research Aims and Objectives

The research study aims to develop, implement and evaluate the effectiveness of a family-oriented diabetes self-management program for Thai individuals living with T2DM and their carers. The specific objectives of the study are presented below:

- To develop and deliver a family-oriented diabetes self-management program for Thai individuals living with T2DM and their carers.
- To evaluate the effectiveness of a family-oriented diabetes self-management program in improving diabetes knowledge, glycaemic control, self-efficacy, self-management, and quality of life among Thai individuals living with T2DM.
- To develop and test the validity and reliability of the family-carer diabetes management self-efficacy scale (F-DMSES) that measures diabetes management self-efficacy (DMSE) among family-carers of Thai individuals with T2DM.

1.9 Research Questions/Hypotheses

Chapter 4 research hypotheses

Within-group comparisons for the intervention group

H1: For individuals with T2DM receiving the family-oriented DSME intervention, there will have been an improvement in diabetes knowledge (measured by the diabetes knowledge questionnaire [DKQ]), self-efficacy (measured by the diabetes management self-efficacy scale [DMSES] and perceived therapeutic efficacy scale [PTES]), self-management (measured by the summary of diabetes self-care activities measure [SDSCA]), HbA1c, and quality of life (measured by the 12-Item Short Form Survey [SF-12]) at week 5 and at week 13 when compared to the baseline.

Within-group comparisons for the control group

H2: For individuals with T2DM receiving the usual care, there will have been no improvement in diabetes knowledge (measured by the DKQ), self-efficacy (measured by the DMSES and PTES), self-management (measured by the SDSCA), HbA1c, and quality of life (measured by the SF-12) at week 5 and at week 13 when compared to the baseline.

Between-group comparisons

H3: Individuals with T2DM receiving the family-oriented DSME intervention will have diabetes knowledge higher scores (measured with the DKQ), self-efficacy (measured by the DMSES and PTES), and self-management (measured by the SDSCA) at week 5 and at week 13 compared to the scores of those who receive usual care.

H4: Individuals with T2DM receiving the family-oriented DSME intervention will achieve an HbA1c target of 7.0% at week 5 and at week 13 compared to the HbA1c target of those who receive usual care.

H5: Individuals with T2DM receiving the family-oriented DSME intervention will demonstrate an increased quality of life (measured by the SF-12) at week 5 and at week 13 compared to the quality of life of those who receive usual care.

Chapter 5 research question

Is the family-carer diabetes management self-efficacy scale (F-DMSES) a valid and reliable measure of diabetes management self-efficacy undertaken by family-carers of Thai individuals with T2DM?

Chapter 6 research questions

What is the difference between the diabetes management self-efficacy of a family-carer (measured by the F-DMSES) and the diabetes management self-efficacy (measured by the DMSES) of the individual with T2DM?

What is the relationship between the family-carer diabetes management self-efficacy (measured by the F-DMSES) and diabetes knowledge (measured by the DKQ) of the family-carer, and the diabetes self-management (measured by the SDSCA) of the individual with T2DM?

1.10 Thesis Structure

This thesis consists of seven chapters that present the three studies, with the addition of a reference list and appendices. There are three manuscripts presented in three chapters, one

of which is published in a peer-reviewed scientific journal. The other two manuscripts are currently under review. Each of these publications and manuscripts presents a body of original work developed and designed to provide new knowledge in diabetes care for clinical nurses, diabetes educators, health service providers, and researchers.

Chapter 2 provides an overview of the literature and extends on the information provided in this Introduction chapter by further examining diabetes in Thailand and its management; the diabetes management education programs provided in the health services in Thailand and the outcome measurements of the self-management program; and the role and outcomes for family-carers of individuals living with T2DM. The literature also highlights the gaps in the effectiveness of a family-oriented program for individuals living with T2DM in Thailand as well as the literature search strategy.

Chapter 3 presents the methodology for Study 1 (the main randomised controlled trial) and a manuscript describing the study protocol for the randomised controlled trial of the family-oriented DSME program. This manuscript is currently under review by the *International Journal of Diabetes in Developing Countries* and its title is "A randomised controlled trial of a family-supported diabetes self-management program: Study protocol". The design of the family-oriented DSME program is described in detail including explanations of design selection, ethical considerations, development of the family-oriented DSME program and its theoretical grounding. The description of the conduct of the trial is also provided including the research setting, randomisation and blinding, data management and collection, and outcome measures and the statistical analysis approach.

Chapter 4 presents the results of Study 1. The manuscript reports findings of the testing of the effectiveness of a family-oriented DSME program, which has been published in *Diabetes Research and Clinical Practice* journal and its title is "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". The study describes the changes in the outcomes of the research (diabetes knowledge, glycaemic control, self-efficacy, self-management, and quality of life) among individuals with T2DM at one- and three-month intervals.

Chapter 5 describes the findings of Study 2. This chapter examines the development and validity and reliability testing of the family-carer diabetes management self-efficacy scale (F-DMSES). This scale assesses the diabetes management self-efficacy of family-carers of individuals with T2DM who participated in this study. The manuscript's title is "Psychometric testing of the family-carer diabetes management self-efficacy scale", and it has been has been published in the *Social Health Care in the Community* journal.

Chapter 6 presents the findings of Study 3, which compares individuals with T2DM and family-carers on their diabetes management self-efficacy scale scores. The exploration of the relationship between the diabetes self-management of individuals with T2DM and the family-carers' diabetes management self-efficacy, together with the family-carer's diabetes knowledge, is also detailed in this chapter. This chapter will also provide some understanding regarding the additional impact of the carer on self-care abilities of the individual with T2DM.

Chapter 7 discusses the findings of all the studies and provides an overall summary of the methodology issues that have not been addressed elsewhere, as well as outlining the limitations and strengths of the research and the implications of the research findings for future practice and research.

Chapter 2

Literature Review

2.1 Introduction

Chapter 1 presented an overview of the thesis as well as an introduction to key terms relevant to the study, and the prevalence of T2DM and its current health management in Thailand. This chapter reviews the contemporary literature relating to diabetes management and the effectiveness of current interventions. DSME programs and their outcomes are discussed in this chapter together with family-based educational interventions. The gaps in the literature relevant to this thesis are also outlined, which provide positioning for this thesis and direction.

Finally in this chapter, theoretical frameworks and conceptual models that have been applied to educational interventions relating to changing behaviour in individuals living with T2DM are examined, and a case for the use of self-efficacy theory in the development of the DSME program, the intervention that forms the basis for this thesis, is presented.

2.2 Literature Search Strategy

In January 2017, a final literature search, using four electronic databases was undertaken for all relevant articles. These databases were the cumulative index to nursing and allied health literature (CINAHL complete), the online medical literature analysis and retrieval system (MEDLINE complete), EMBASE, and PubMed. Only articles published in English were included. The search strategy was based on an analysis of medical subject headings (MeSH) such as “Type 2 diabetes mellitus”, “non–insulin dependent diabetes mellitus”, “NIDDM” or “type 2 diabetes mellitus”, and “self-management” or “self-care”, and covered the period from January 2000 to January 2017. In total, 15,557 articles were retrieved from all four databases. Given this large number of articles, the literature search was further refined to between January 2010 and January 2017. This search produced 8,415 articles for the seven-year period, with an unusually high number of publications on the topic of diabetes self-management. As systematic reviews indicate the highest level of evidence and include numerous studies, the literature review in this chapter will focus on examining these reviews. Seventy-seven of them were identified and contained within the reviews were 1,899 intervention studies.

2.3 The Prevalence and Management of Diabetes Mellitus

2.3.1 Diabetes prevalence. Diabetes mellitus has become a worldwide public health problem that is one of the most common chronic diseases that affects approximately 415 million individuals worldwide, which represents one in 11 adults (International Diabetes Federation, 2015). This number is predicted to increase to 642 million by the year 2040 (International Diabetes Federation, 2015). In 2015, the prevalence was higher in men (215.2 million) than women (199.5 million) and greater in urban areas (International Diabetes Federation, 2015). The prevalence of diabetes is increasing more rapidly in low- and middle-income countries when compared to high-income countries. The incidence is highest in developing countries, especially in Asia. China and India have the highest numbers of individuals with diabetes – 109.6 and 69.2 million respectively (International Diabetes Federation, 2015). Four hundred and forty-one million African adults and 660 million European adults (between 20 and 79 years of age) are suffering from diabetes. An estimated 1.2 million (5.1%) Australian adults aged 18 years and over had diabetes in 2014–15 and the prevalence was higher in men (7%) than in women (5%), with 10% of all deaths attributable to diabetes (Australian Institute of Health and Welfare, 2017). Consequently, diabetes has become a serious health problem globally. Although early diagnosis of diabetes is inexpensive, large numbers of the world's population have impaired glucose tolerance and remain undiagnosed, which has led to chronic complications and considerable healthcare and economic burdens for many countries.

T2DM is a leading cause of death and healthcare burden in both developed and developing countries. The International Diabetes Federation reported that 5.1 million adults died from causes attributable to diabetes in 2013 (that is, one person dies from diabetes every six seconds) (International Diabetes Federation, 2015) and more than 21 million live births were affected by women experiencing diabetes during pregnancy in 2013 (International Diabetes Federation, 2013). Diabetes was the eighth-leading cause of death in both sexes and the fifth-leading cause of death in women in 2012 (International Diabetes Federation, 2013). The number of female deaths was greater than the number of male deaths (International Diabetes Federation, 2015). The highest number of deaths related to diabetes was found in the western Pacific area, especially in China (1.3 million), India (1.1 million), Indonesia (0.4 million), and in Russia (0.2 million) (International Diabetes Federation, 2015).

Diabetes is a significant cause of increased healthcare expenditure, mortality, morbidity, and economic burden worldwide. In 2015, 11.6% (USD673 billion) of the total global health expenditure was spent on services related to diabetes (International Diabetes Federation, 2015). The United States of America (USA) was the top-ranked country for expenditure, spending USD320 billion on diabetes-related services (International Diabetes Federation, 2015). Consequently, the incidence of diabetes places a huge economic burden on individuals, families, and national health systems. Given the high cost of the disease, a considerable amount of research has been devoted to how to best manage the condition.

2.3.2 Diabetes management. Diabetes self-management has been broadly documented as a significant practice for improving an individual's behaviours and health status (Zhao, Suhonen, Koskinen, & Leino-Kilpi, 2016). The American Diabetes Association stated that enabling individuals with diabetes to self-manage is central to providing a high standard of diabetes care (American Diabetes Association, 2013b).

Systematic reviews have shown that people with diabetes who have better self-management abilities and knowledge of their disease also have better control of their blood glucose and practise healthier food habits compared to those who have low self-management skills (Klein, Jackson, Street, Whitacre, & Klein, 2013). Furthermore, results from several systematic reviews confirm that effective DSME has led to better clinical and behavioural outcomes as well as reduced costs compared to the usual care practices currently being provided by healthcare professionals (Alves de Vasconcelos et al., 2013; Nuti et al., 2015; Ricci-Cabello, Ruiz-Perez, Nevot-Cordero, et al., 2013).

There are several clinical practice guidelines for DSME including the *International Guidelines for T2DM* (International Diabetes Federation, 2014), *National Evidence-Based Guidelines for Patient Education in Type 2 Diabetes* (The Diabetes Unit Menzies Centre for Health Policy, 2009), *Standards of Medical Care in Diabetes* by the American Diabetes Association (Marathe, Gao, & Close, 2017), and *Type 2 Diabetes in Adults: Management* (National Institute for Health and Care Excellence, 2015). Most of the accepted guidelines present the strategies for screening and diagnosis, care delivery, education, lifestyle management, monitoring, complication screening and prevention. Although various standards for diabetes self-management have been developed, complications related to

diabetes continue to increase and the self-care ability among individuals with diabetes remains unsatisfactory (Shrivastava, Shrivastava, & Ramasamy, 2013).

2.4 Diabetes Self-Management Education Program (DSME)

The diabetes self-management education program (DSME) is designed for people living with diabetes and focuses on empowering people through supporting informed decision-making, self-care activities, and problem-solving in order to enhance biological and behavioural outcomes as well as quality of life (Lepard, Joseph, Agne, & Cherrington, 2015; Marathe et al., 2017). Diabetes self-management is generally acknowledged as a central approach to increase an individual's management behaviours and physical and mental health status (Houle et al., 2015; Sherifali, Bai, Kenny, Warren, & Ali, 2015). Results from several systematic reviews and meta-analyses indicate that effective DSME improves healthy behaviours and glycaemic control, and knowledge of diabetes, as well as reducing the risk of all-cause mortality and costs of hospital admission and readmission for individuals living with diabetes (He et al., 2016; Netten et al., 2016; Zhao et al., 2016). Additionally, DSME delays the onset and progress of diabetes-related complications and improves self-efficacy and quality of life (Klein et al., 2013; Lepard et al., 2015; Tanash, Fitzsimons, Coates, & Deaton, 2016).

In order to improve the effectiveness of DSME, the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics introduced the National Standards for DSME in 2015. The National Standards suggest that DSME should provide a clear mission statement and goals, resources for external stakeholders and access to experts to promote program quality. Further, DSME providers should assess the target population to reduce the barriers to education, deliver the program with instructional staff using the guidelines to facilitate education, include individual patient assessment focused on behaviour change, ensure ongoing follow-up support, and ongoing measurement of patient self-efficacy and success, and program evaluation and subsequent improvement (Powers et al., 2015). Diabetes educators, healthcare providers and researchers have attempted to define best practice for DSME in following these standards. Consequently, numerous DSME programs have been developed based on different theories and strategies. A number of aspects of DSME interventions have been demonstrated to improve health outcomes, including a clear theoretical framework, delivery and teaching

methods (face to face, versus web link), intensity (how many educational sessions and topics to provide), the duration of interventions (how long do they continue for), and the nature of the educational content. An exploration of each of these key components is now presented.

2.4.1 Theoretical basis for education intervention. Various theoretical frameworks have been developed to provide diabetes self-management educational programs such as the health belief model, social cognitive theory, social ecological theory, social support, the transtheoretical model/stages of change model, symptom-focused model, and the chronic care model (Arambepola et al., 2016; Pal et al., 2014; Steinsbekk et al., 2012). Most of the theoretical frameworks used for diabetes self-management are social and behaviour theories that focus on behaviour change and the maintenance of new behaviours in order to improve healthy behaviours and glycaemic control (Gucciardi, Chan, Manuel, & Sidani, 2013). Zhao et al. (2016) conducted a systematic review and meta-analysis of 20 randomised controlled trials (RCTs) on theory-based self-management educational interventions among people living with T2DM and found that DSME based on one or more theories was effective in enhancing glycaemic control, self-efficacy, self-care behaviours and diabetes knowledge compared to usual care methods that have no theory base. Similarly, Hadjiconstantinou et al. (2016) stated that theory-based DSME programs are more beneficial compared to DSME without a theoretical basis.

The self-efficacy theory, which is a part of the social cognitive theory, is widely used to understand how individuals gain confidence in their ability to initiate certain behavioural changes (Bandura, 1977). Bandura states that self-efficacy is the most effective predictor of behavioural change, so individuals with a higher level of self-efficacy are more likely to succeed when faced with difficulties compared to those with a lower level of self-efficacy (Bandura, 1986). There are two cognitive components in self-efficacy – self-efficacy or efficacy expectation, and outcome expectation (Bandura, 1977). Self-efficacy is defined as an individual's confidence in their ability to generate the behaviour, while outcome expectation is defined as an individual's belief that the given behaviours will provide the desired result (Bandura, 1977). Consequently, individuals will perform certain behaviours when they believe that such behaviours will provide the desired result. Both cognitive components of self-efficacy (efficacy expectation and outcome expectation) are essential for desirable behaviours. Therefore, utilising self-efficacy to improve self-care behaviours among individuals with diabetes is broadly accepted in educational intervention programs, and

those programs based on self-efficacy have been found to enhance self-management behaviours among individuals with T2DM (Sharoni & Wu, 2012; Walker, Smalls, Hernandez-Tejada, Campbell, & Egede, 2014). Various studies have found that self-efficacy is a predictor of metabolic control and is also positively associated with improved adherence to treatment regimens (ALAboudi, Hassali, Shafie, & Saleem, 2016; DePalma, Trahan, Eliza, & Wagner, 2015).

The health belief model (HBM) is an individual's perceptions of the benefits of either taking action or avoiding certain behaviour (Jalilian, Motlagh, Solhi, & Gharibnavaz, 2014). It has been widely used for prevention and in interventions that focus on reducing high-risk behaviours. Individuals are more likely to practise healthy behaviours if they perceive that the behaviour is beneficial, they are at risk, and the disease is severe. The model improves an individual's concern about the prevention and detection of diseases. Individuals with T2DM will adhere to treatment regimens if they perceive that diabetes could have serious complications, and that following medical recommendations can reduce or delay the onset of complications related to diabetes. DSME based on the HBM significantly improves glycaemic control, diabetes knowledge, practice and attitude towards diabetes self-management, and self-efficacy (Mohamed, Al-Lenjawi, Amuna, Zotor, & Elmahdi, 2013). Furthermore, utilising the HBM provides benefits in relation to the prevention of complications related to diabetes (Jalilian et al., 2014).

The transtheoretical model (TTM) or stages of change model (SOC) is another model that is often applied to interventions that focus on behaviour change. The model describes how individuals change their behaviour. It focuses on long-term changes in health behaviour that involve multiple actions and adaptations over time, where the individual moves through the five stages of "change readiness" – precontemplation, contemplation, preparation, action and maintenance (Prochaska, 2013). People who have progressed further through the five stages tend to have improved physical activity, self-efficacy and self-liberation (Kirk, MacMillan, & Webster, 2010). This model is generally used to guide interventions for dietary and physical activity, changes which are critical for diabetes self-management (Partapsingh, Maharaj, & Rawlins, 2011). Utilising the model for diabetes self-management, the current stage of the change readiness in an individual is identified and that person is then provided with appropriate counselling strategies. Advocates of TTM believe that people at varying stages have different counselling needs that will enable them to move forward through the

various change stages to practise healthier behaviours (Salmela, Poskiparta, Kasila, Vahasarja, & Vanhala, 2009). For example, an individual might start from being unconcerned or unaware of the impact of their current health behaviours *(precontemplation)* and then move to considering a change in their behaviours *(contemplation)* after becoming motivated to engage in change. Then from that position of intending to change their health behaviours, they receive behavioural-skills training to do so *(preparation)*, which then enables them to adjust their health behaviours *(action)* using specific interventions or guidelines. Once the individual has adjusted their behaviours, they then need to sustain these new health behaviours in order to avoid a relapse *(maintenance)* (Salmela et al., 2009).

The social cognitive theory was developed by Albert Bandura from social learning theory and describes learning as being embedded in a social context, with a dynamic interaction of personal factors, environmental influences, and behaviour (Bandura, 1977). It has been widely used in health promotion, prevention and management of diseases because the theory focuses on maintaining the new behaviour in addition to initiating or learning the new behaviour. Underpinning the theory is the concept that individuals learn through their own experiences and observe the actions of others, which results in new behaviours being performed (Bandura, 1977). Rosal et al. (2011) postulate that social cognitive theory-based interventions enhance knowledge of diabetes, self-care behaviours, and self-efficacy in individuals living with T2DM.

Moreover, using DSME that is underpinned by theory helps the facilitator or researcher to understand why people do or do not practise healthy behaviours, and therefore the information needed to design an effective intervention can be identified. A recent study indicated that DSME with theoretical foundations is more likely to be beneficial when compared to routine care (Hadjiconstantinou et al., 2016; Zhao et al., 2016). However, results from a systematic review of 15 studies found that only one in three of them demonstrated a specific theoretical framework to guide their program (Lepard et al., 2015).

2.4.2 Delivery strategies for education. The review of the literature indicates that various strategies have been applied to develop diabetes self-management education. These include community-based, couple-orientation, group-based, telemedicine, videoconference-based, internet-based, web-based, and computer-based strategies. Such strategies have tended to provide a beneficial outcome for diabetes self-management behaviours and physical outcomes.

Currently, technological approaches are widely used in healthcare systems to assist healthcare professionals, particularly in health education programs. The mobile or cell phone is a communication device that is now part of the daily life of individuals of all ages. People can use the short messages service (SMS) or direct calls at any time to any place, which is useful for providing good accessibility and for reaching individuals who have difficulties travelling to programs. To use a mobile phone is convenient, simple and inexpensive. Numerous studies indicate that mobile phones have been used for remote electronic diabetes education – such as for medication adherence, follow-up reminders, and blood glucose measurement – which can improve glycaemic control, clinical results, and self-care changes in diet, medication and exercise (Hou, Carter, Hewitt, Francisa, & Mayor, 2016; Liang et al., 2011; Saffari, Ghanizadeh, & Koenig, 2014). Cui et al. (2016) conducted a systematic review and meta-analysis of mobile health interventions using smartphone applications and found that such applications were related to a significant decrease in HbA1c, with a pooled effect on HbA1c reduction of –0.4% (–4.37 mmol/mol), and improved behavioural outcomes.

Information technology-based interventions such as internet-based, web-based, and computer-based interventions are gradually being used to manage healthcare delivery and chronic disease management as these methods provide easier access to health care for patients as well as facilitating communication between patients and the healthcare provider. Several systematic reviews have demonstrated the potential benefits of information technology-based interventions on diabetes self-management, which include the improvement of blood glucose monitoring, medication taking, and healthy eating (Alharbi et al., 2016; Chen & Wilkosz, 2014; El-Gayar, Timsina, Nawar, & Eid, 2013; Hadjiconstantinou et al., 2016; Mushcab, Kernohan, Wallace, & Martin, 2015). Furthermore, a systemic review and meta-analysis of computer-based DSME programs to enhance self-management in individuals living with T2DM has indicated the potential benefit of these interventions to

change self-care behaviours and enhance adherence to treatment regimens. However, the benefit was greater for mobile phone-based interventions when compared to computer-based interventions (Pal et al., 2013). Connelly, Kirk, Masthoff, and MacRury (2013) conducted a systematic review on the use of technology supporting physical activity in T2DM management and found that using information technology can enhance physical activity. The use of modern communications technologies to deliver DSME programs is also recommended by the *Global Guidelines for Type 2 Diabetes* (International Diabetes Federation, 2014). A systematic review of 39 interventions found that approximately 70% (27) were delivered via face-to-face interactions, while only 13% were delivered by telecommunications and 7% by a combination of both (Ricci-Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014). Although information technology-based interventions are low-cost strategies, they have limited utility in rural settings due to the poverty and limited internet access in such areas, which results in such interventions being less effective (Skillman, Andrilla, Patterson, Fenton, & Ostergard, 2015).

Although technological approaches provide a powerful instrument for healthcare delivery, individual face-to-face sessions, group sessions, and a combination of both types of sessions, remain the most effective means of improving diabetes self-management. Findings from systematic reviews report that two in three studies were delivered in a group setting and most of those studies indicated significant improvement in HbA1c levels (Dube, Van den Broucke, Housiaux, Dhoore, & Rendall-Mkosi, 2015). Moreover, other studies state that group-based diabetes self-management programs demonstrate a significant improvement in glycaemic control, knowledge of diabetes, self-care abilities and quality of life among individuals living with T2DM (Heinrich, Schaper, & Vries, 2010; Steinsbekk et al., 2012). Similarly, one-on-one interventions also effectively improve glycaemic control (Ricci-Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014).

A combination of group-based interventions in education classes, with individual sessions at a follow-up, was selected in this study in order to provide individuals with T2DM with an opportunity to meet others with diabetes and to discuss diabetes self-management within their peer group. The individual sessions provided participants with the chance to discuss personal difficulties with the educator and for regular reinforcement of improved behaviours. This approach was supported by a recent study, which indicated that a combination approach to DSME appeared to lead to an improvement in HBA1c levels

compared to when group, individual, and remote interventions were used separately (Chrvala et al., 2016). It is also noted that tailoring the education to the individual's health literacy, learning style, age and interests is also recommended (Schapira et al., 2017).

2.4.3 Measuring the outcomes of the self-management program. Different study outcomes have been reported. These include biological outcomes, cognitive outcomes, behavioural outcomes, and emotional and knowledge outcomes in relation to interventions to improve T2DM. The level of HbA1c was the outcome measure most frequently reported in the literature (Torenholt, Schwennesen, & Willaing, 2014), followed by blood pressure, BMI or weight, and serum lipid.

According to the National Institute for Health and Care Excellence's *Guidelines for Type 2 Diabetes Management in Adults*, HbA1c should be routinely measured (National Institute for Health and Care Excellence, 2015) as it is an important indicator of glycaemic control. HbA1c should be measured in individuals with T2DM at three and six monthly intervals until the level of HbA1c is stable. The target for HbA1c levels in adults with T2DM taking a hypoglycaemic agent is 53 mmol/mol (new IFCC units) (7.0%, old DCCT units) (National Institute for Health and Care Excellence, 2015).

Fasting blood glucose (FBG) is the amount of blood glucose present when individuals have fasted. It is another indicator of glycaemic control and is the recommended marker for routine diabetes screening and diagnostic criteria. It is a more reliable indicator to distinguish between a diabetic and a non-diabetic state than HbA1c and is easier to interpret (Ghazanfari, Haghdoost, Alizadeh, Atapour, & Zolala, 2010). Moreover, the fasting blood glucose level is not affected by the variations in the length of erythrocyte lifespan (approximately 120 days) (Sacks, 2011). Therefore, HbA1c levels provide a measurement of the average glucose concentration over the preceding eight to 12 weeks while fasting blood glucose readings indicate the level of blood glucose in the previous two to three weeks. The normal range for blood glucose is 70 to 100 mg/dl. Individuals having levels of 100 to 126 mg/dl are classified as having impaired fasting glucose (IFG) and are diagnosed with diabetes when fasting blood glucose levels of ≥ 126 mg/dl are reached (American Diabetes Association, 2014).

Although HbA1c is not recommended for routine screening tests, it is an important predictor of microvascular complications related to diabetes, especially cardiovascular

disease and retinopathy (Ghazanfari et al., 2010). Therefore, HbA1c is preferable for monitoring individuals with diabetes as it is more time flexible and informative in long-term conditions.

A systematic review of 52 studies found that the level of HbA1c was the primary outcome measure in 34 of them (Sapkota, Brien, Greenfield, & Aslani, 2015). Most of the studies found that the levels of HbA1c and fasting blood glucose had improved significantly in the intervention groups when compared to the levels in the control groups (Alves de Vasconcelos et al., 2013; Chrvala et al., 2016; Cotter, Durant, Agne, & Cherrington, 2014; Mushcab et al., 2015; Zhao et al., 2016). Torenholt et al. (2014) found that the HbA1c levels of individuals who had participated in the DSME program had decreased in nine out of 10 studies. DSME programs were also considered to have contributed to a decrease in systolic and diastolic blood pressure, total cholesterol, triglyceride and low-density lipoprotein as well as an increasing high-density lipoprotein (Sherifali et al., 2015). The relationship between DSME and a reduction in BMI or weight has not been consistent, although many studies found that the DSME interventions were associated with a reduction in BMI or weight (Lepard et al., 2015). However, in the meta-analysis of one major study, which consisted of 20 RCTs with 5802 participants, researchers found that the DSME interventions were not associated with a reduction in BMI (Zhao et al., 2016).

Knowledge and cognitive outcomes measured included diabetes knowledge and self-efficacy and most studies demonstrate that these factors are positively related to DSME interventions (Pal et al., 2014; Zhao et al., 2016). Furthermore, results from the meta-analyses of 16 trials with 3545 participants indicated that interactive self-management enhances self-efficacy among individuals with poorly controlled diabetes (Cheng, Sit, Choi, Chair, et al., 2016). Quality of life was also measured as an outcome of DSME interventions, and there were slight but significant improvements in the quality of life of most participants (Cotter et al., 2014; Hadjiconstantinou et al., 2016; Zhao et al., 2016); however, the results from one meta-analysis found no improvement in the participants' quality of life (Cheng, Sit, Choi, Chair, et al., 2016). Social support was found to have significantly improved after individuals had participated in DSME interventions (Hadjiconstantinou et al., 2016). Significant improvements in emotional outcomes such as distress and depression after receiving DSME, have been found in a systematic review and meta-analysis of 16 RCTs (Hadjiconstantinou et al., 2016).

After participation in a DSME intervention, individuals demonstrated a significant improvement in their overall self-care or particular self-care activities (that is, physical activity or diet control) (Pal et al., 2014; Zhao et al., 2016). Lepard et al. (2015) state that approximately half of the studies reviewed (8/15) measured the outcomes of diabetes self-care behaviours and four of them found improvement in self-care behaviour in the intervention group. Cotter et al. (2014) conducted a systematic review of internet interventions supporting diabetes management and found that nearly all the studies (8/9) measured change in physical activities. Adherence was measured in several studies as a self-care behavioural outcome, and included adherence to medication, meal plans, physical activities, foot care, and blood glucose monitoring. Farmer et al. (2016) report that a systematic review of 11 trials examining the influence of monitoring, with brief messages on medication adherence, found only two trials had no significant differences in medication adherence between the intervention and control groups.

In conclusion, after DSME interventions the level of HbA1c is the common primary outcome measured, which is then followed by the measurement of other physical and psychological outcomes, and these are assessed within this study. Other biological outcomes such as blood pressure, BMI, and lipid profiles are also considered along with the fasting blood glucose.

2.4.4 Content and intensity of the educational intervention. Although DSME intervention is well accepted in improving biological and behavioural outcomes for individuals with diabetes, the features of the different interventions also affect the likelihood of an improvement in those outcomes (Samuel-Hodge et al., 2009). A recent systematic review of 37 studies using DSME approaches indicates that teaching methods in DSME affect study outcomes (Ricci-Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014).

Diverse teaching methods have been used to develop behaviour change techniques in DSME including providing feedback on performance, action plans, goal-setting skills, problem-solving, and lifestyle changes, and these methods have been associated with significant reductions in the levels of HbA1c and improvements to quality of life (Cheng, Sit, Choi, Chair, et al., 2016; Jonkman, Schuurmans, Groenwold, Hoes, & Trappenburg, 2016). Although the benefits of these methods were found to improve outcomes, a face-to-face (group or individual) didactic method alone was still used in 82% of interventions (Ricci-

Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014). Most of the educational content in DSME is focused on the important elements of diabetes self-care such as diet, physical activities, self-monitored blood glucose, general knowledge of diabetes, and medication adherence (Liang et al., 2011; Ricci-Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014). The scope of content is defined in international clinical guidelines (Haas et al., 2014). The recommended content for this DSME intervention is derived from a selection of existing standards, which is presented in Table 1.

Table 1
Content for Specific Clinical Guidelines for Education Interventions for T2DM

Standard	Content
Thai clinical practice guidelines[a].	General knowledge of diabetes, diet management, exercise, hypoglycaemic medications, blood glucose monitoring, addressing hypoglycaemia, diabetes complications, foot care, and diabetes care in specific situations such as pregnancy.
International standards for education of diabetes health professionals[b].	Prevention of diabetes, pathophysiology and diagnosis of diabetes, monitoring diabetes self-management, exercise, diet, hypoglycaemic medications, use of insulin, addresses hypoglycaemia and other complications, role of DSME, managing diabetes during special situation such as pregnancy.
National standards for diabetes self-management education and support[c].	The diabetes care process and treatment options, diet, medications, monitoring blood glucose, physical activity, detecting, and addressing acute and chronic complications.
National evidence-based guidelines for patient education in type 2 diabetes[d].	Knowledge and understanding of diabetes, adherence to medical treatment, dietary habits, foot care, exercise, self-monitoring of blood glucose, complications, psychological adjustment and self-determination, and health service utilisation.

[a]Diabetes Association of Thailand. [b]International Diabetes Federation. [c]The American Association of Diabetes Educators and the American Diabetes Association. [d]The National Health and Medical Research Council, Australia.

The number and length of education sessions influences the outcome of DSME interventions. A diabetes self-management education program that delivers fewer than 10 contact hours results in limited improvement in glycaemic control, whereas a program that delivers 10 or more contact hours results in a significant decrease in the levels of HbA1c and all-cause mortality risk related diabetes (Chrvala et al., 2016; Pillay et al., 2015). Furthermore, other studies found that interventions operating daily were more effective in

reducing HbA1c levels compared with weekly interventions (Liang et al., 2011). Similarly Lepard et al. (2015) confirm that interventions with more contact hours are associated with increased improvements in outcomes. However, He et al. (2016) found only 11 of 42 (26.2%) DSME interventions offered educational sessions with more than 10 contact hours.

The wide range of follow-up periods, in addition to the duration of the program delivery period, have been found to influence the changes in HbA1c levels. Previous studies have indicated that follow-up periods of fewer than six months did not result in researchers observing reduced HbA1c levels (Liang et al., 2011). Additionally, in DSME programs with longer follow-up periods (≥1.5 years), a reduction in all-cause mortality risk in individuals suffering with diabetes has been observed (He et al., 2016). However, the impact of the duration of DSME programs on study outcomes remains inconsistent. The total study duration has varied, from 10 weeks to four years, but most studies that have been conducted over a three-month period indicated an improvement in study outcomes (Sapkota et al., 2015). However, a meta-analysis of 20 DSME interventions revealed that the total duration of the intervention, the number of sessions, and the duration of each session did not significantly correlate with alterations in glycaemic control (Ricci-Cabello, Ruiz-Perez, Rojas-Garcia, et al., 2014). The trial period for this research study will be 13 weeks.

2.5 Education Adapted to Cultural Tailoring

Cultural differences, such as beliefs, behaviour patterns, illness, and attitude to medications, are important concerns for the development of a DSME intervention. Cultural appropriateness has been identified as important to reduce discrimination between ethnic minorities and to address cultural beliefs related to health management (Dauvrin, Lorant, & d'Hoore, 2015; Ferguson, Swan, & Smaldone, 2015). The most commonly used cultural component is cultural tailoring (Dauvrin et al., 2015). Cultural tailoring is defined as an intervention that is developed and delivered using the essential elements from a different method for the specific group or individual case based on the unique characteristics of their cultural origins (Archibald, 2011). Several studies used culturally adapted education techniques and found that culturally appropriate interventions provided greater benefits in terms of enhancing metabolic control, diabetes knowledge, self-management ability of diet, and physical activity when compared to usual care methods (Dauvrin et al., 2015; Hawthorne et al., 2010; Radhakrishnan, 2012; Rosal et al., 2011).

In addition to improved physical markers, culturally tailored educational programs have also resulted in improved psychosocial behavioural outcomes such as quality of life and participant satisfaction (Joo, 2014). Hu, Wallace, McCoy, and Amirehsani (2014) conducted a family-based diabetes intervention that was culturally tailored and their findings revealed that such educational interventions had positive results on blood glucose monitoring, blood pressure, diabetes self-efficacy, diabetes self-management (on diet and foot care), and quality of life (both physical and mental components).

2.6 Diabetes Family-Based Educational Intervention

An individual's family affects the individual's self-care in both the physical and emotional aspects of management such as daily eating, physical activities, problem-solving, addressing barriers, and decision-making. Conversely, diabetes and its treatment also have an influence on the family routine in many ways. Individuals with diabetes in Thailand mostly live in households with their families. This familial environment has a strong effect on diabetes self-management and has been found to influence the improvement in individual well-being, decision-making, and healthcare behaviours (Baig et al., 2015). A variety of family-based interventions have been developed. Some studies involved the individual's partner in the program (Martire, Schulz, Helgeson, Small, & Saghafi, 2010; Trief et al., 2011), while other studies also incorporated an individual's children, their siblings, and other household members (García-Huidobro, Bittner, Brahm, & Puschel, 2011; Hartmann, Bäzner, Wild, Eisler, & Herzog, 2010; C. Kang et al., 2010).

Family support has been found to positively influence an individual's self-care behaviours and to improve glycaemic control, whereas a lack of support from family members has often led to a lower level of adherence to a medication regime by an individual with diabetes (Baig et al., 2015). Recent studies indicate that family members can enhance an individual's ability to self-care (Mayberry & Osborn, 2012; Rintala, Jaatinen, Paavilainen, & Astedt-Kurki, 2013). Family-based interventions present significant benefits to individuals with diabetes (Torenholt et al., 2014) by providing psychological support as well as facilitating the development of healthy family behaviours (Hu et al., 2014). Family-based interventions also enhance diabetes knowledge, self-efficacy, self-care ability, glycaemic control and quality of life among individuals with T2DM (Baig et al., 2015; García-Huidobro et al., 2011; Hu et al., 2014; Shi et al., 2016).

The influence of family members can have both positive and negative effects on care outcomes and self-care behaviours for individuals with diabetes. For example, a spouse's issues with the diet of their partner who has diabetes can contribute to the greater physical and psychological suffering among individuals with T2DM (Stephens et al., 2013). Findings from the study by Stephens et al. (2013) reveal an inconsistency regarding the benefit of family-based interventions (Stephens et al., 2013). Although various studies have indicated that family-based interventions improve diabetes self-management, the study by Kang et al. (2010) found no significant improvement in glycaemic control and plasma lipid profiles.

2.7 Diabetes Self-Management Education Programs in the Thai Population

Diabetes self-management educational programs present a challenging issue for researchers, diabetes educators, and policy makers in Thailand. Although numerous studies on diabetes management in Thailand have been conducted, only 13 published studies on DSME have been identified through the literature search for this thesis. Various theoretical models and concepts have been used to develop the diabetes self-management educational programs and inform either the content or the delivery strategies. Of those 13 studies, 11 of them (84.6%) had a theoretical basis, with only two studies not presenting the theory that was used to underpin the study. The theories and concepts used in these studies included cognitive behaviour theory, the health belief model, medical nutrition therapy, the Orem self-care theory, patient-centred care, self-efficacy, self-help groups, self-monitoring, and the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework (Chaveepojnkamjorn, Pichainarong, Schelp, & Mahaweerawat, 2009; Jaipakdee et al., 2015; Keeratiyutawong et al., 2006; Kulnawan et al., 2011; Ngaosuwan & Osataphan, 2015; Partiprajak, Hanucharurnkul, Piaseu, Brooten, & Nityasuddhi, 2011; Prueksaritanond, Tubtimtes, Asavanich, & Tiewtranon, 2004; Saengtipbovorn & Taneepanichskul, 2014; Sukwatjanee et al., 2011; Suppapitiporn, Chindavijak, & Onsanit, 2005; Suriyawongpaisal, Tansirisithikul, Sakulpipat, Charoensuk, & Aekplakorn, 2016; Wattana et al., 2007).

Medical nutrition therapy (MNT) is defined as the process of nutrition care. Its components are nutrition assessment, diagnostic therapy, counselling services, and monitoring and evaluation, all delivered by a registered dietitian or nutrition professional (American Diabetes Association, 2008). MNT aims to promote healthy eating behaviours, address nutritional problems, maintain a desirable eating pattern, and deliver practical tools

for meal planning (Evert et al., 2013). MNT is crucial for individuals living with diabetes and also for those with pre-diabetes. The national standards for diabetes self-management education and support consider the prominence of healthy eating as one of the core curriculum topics in DSME (Haas et al., 2014). Furthermore, the American Diabetes Association (ADA) states that diet is an important aspect of self-care behaviour so individuals with diabetes or pre-diabetes should be provided individualised MNT by a registered dietitian or nutrition professional in order to accomplish their treatment goals (American Association of Diabetes Educators, 2009). Findings from one RCT indicate the effectiveness of MNT in lowering HbA1c levels, and improving fasting blood glucose and weight levels (Al-Shookri, Khor, Chan, Loke, & Al-Maskari, 2012). Ngaosuwan and Osataphan (2015) conducted an RCT to evaluate the effect of MNT when combined with blood glucose self-monitoring in Thai individuals with T2DM, and found that the intervention had significantly enhanced glycaemic control, when compared to the glycaemic control of the control group, and seven participants in the intervention group had reduced or had discontinued oral hypoglycaemic agents by the end of the program.

The Orem self-care theory consists of three related theories that include self-care, self-care deficits, and nursing systems. The theory of self-care is described as “the practices of activities that individuals initiate and perform on their own behalf to maintain life, health and well-being” (Orem, 1991, p. 117). The theory assists individuals to understand what is required for self-care, and how individuals can learn and perform the duties by themselves without the influence of others (Orem, 2001).

As a diagnosis of diabetes causes a disturbance to normal daily routines and requires an adjustment of lifestyle that incorporates new self-care needs, DSME can play a significant role in diabetes care. DSME facilitates the learning of diabetes self-care actions by individuals who are managing their diabetes. Once these self-care actions are learnt, the individuals can undertake them to maintain their glucose levels. The self-care theory model for diabetes has been found to enhance diabetes self-care management and glycaemic control (Sousa & Zauszniewski, 2005). Keeratiyutawong et al. (2006) conducted an RCT to evaluate the effectiveness of a DSME program using the Orem self-care theory and cognitive behaviour therapy among Thai individuals with T2DM and found that the DSME program led to improvements in the knowledge of diabetes, self-care activities, and quality of life.

Patient-centred care (PCC) or patient-centred approach is broadly acknowledged as a core value of DSME by the national guidelines (Diabetes Association of Thailand, 2014; National Institute for Health and Care Excellence, 2015; The Royal Australian College of General Practitioners, 2016). PCC is defined as "an approach to providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions" (Institute of Medicine, 2001, p. 6).

Healthcare professionals organise and outline the choices of treatment to the individual with diabetes, and the individual becomes involved in the medical decision-making relating to their treatment regime. Although this approach is appropriate for individuals living with T2DM, a patient-centred approach to diabetes requires a knowledge of all aspects of goal-setting, decision-making, self-care, and problem-solving. A previous study indicated that PCC enhances medication adherence among individuals with T2DM, which in turn can improve glycaemic control (Robinson, Callister, Berry, & Dearing, 2008). Prueksaritanond et al. (2004) developed a PPC program for Thai individuals with T2DM and indicated that the program enhances glycaemic control through the improvement of eating and exercise behaviours.

Self-efficacy is another approach that has been used for DSME in the Thai population (the details of the model have been described in Section 2.3.1). Wattana et al. (2007) evaluated the impact of a DSME program on metabolic control, coronary heart disease risk, and quality of life in Thai individuals with T2DM using self-efficacy. Self-efficacy was applied in all delivery strategies of the education program including the didactic education class, group discussions, and home visits, as well as being described in the education manual. Findings from the study indicate that the DSME program, which is based on self-efficacy, was effective in enhancing glycaemic control and quality of life as well as decreasing the risk of chronic health disease in Thai individuals with T2DM (Wattana et al., 2007).

The RE-AIM framework was developed to assist healthcare professionals to translate evidence-based recommendations and guidelines to specific implementation issues (Glasgow, Nelson, Strycker, & King, 2006). It consists of five elements: "reach" (representative of target population), "effectiveness" (resulting in positive changes for participants' self-management and quality of life), "adoption" (representative settings and clinicians), "implementation" (consistency of implementation of strategies), and

"maintenance" (self-management in participants and sustained delivery within the setting level) (Glasgow et al., 2011, p. 2). Jaipakdee et al. (2015) conducted an RCT evaluating the effectiveness of a DSME program based on the RE-AIM framework. This study utilised computer-assisted instruction in DSME to deliver an education session on disease knowledge, which was then followed by face-to-face education on skill development facilitated by a registered nurse, who also provided psychological support. Researchers found that an intervention program based on the RE-AIM framework, together with a combination of technological and face-to-face approaches, was successful in improving glycaemic control, quality of life and healthcare behaviours (Jaipakdee et al., 2015).

In summary, several theories and concepts have been applied to DSME's development and delivery strategies, as well as its design and evaluation, in order to achieve best practice for diabetes management in Thailand. Both face-to-face sessions and technology assisted instruction or a combination of these have been utilised as well as individual or group-based approaches, or a combination of both, in order to improve the physical, psychological, and behavioural outcomes for individuals with diabetes. Glycaemic control (HbA1c) was the primary outcome most frequently measured in these studies, followed by diabetes self-management and quality of life.

2.8 Incorporating Self-Efficacy and Family Context in Diabetes Self-Management Program

The social cognitive theory is a learning theory relevant to health communication that describes how people obtain and maintain certain behavioural patterns. According to Bandura's social cognitive theory, personal factors, behaviours, and environmental factors are key factors that interact to influence behavioural change. Environmental factors are external to the person providing opportunities and support, whereas behavioural factors result from knowledge and skill to perform a given behaviour by promoting mastery learning through skills training (Bandura, 1977). Environment is an external factor that can influence an individual's behaviour and includes both social and physical environments. The social environment consists of family members, friends and colleagues while the physical environment contains a range of factors such as temperature, place, or foods (Bandura, 1986). A recent study found that diabetes self-management behaviours are affected by personal and environmental factors (Luo et al., 2015). The intervention of this study focused

on the social environment, in particular family members that influence self-management behaviours among individuals with T2DM.

The self-efficacy model was derived from social learning theory, which is a theoretical framework to explain human behaviour (Bandura, 1977). As noted previously, self-efficacy is the level of confidence an individual has in their ability to perform a particular task in order to accomplish a specific goal (Bandura, 1977). According to social theory, perceived self-efficacy is the confidence of an individual to complete a particular course of action. The greater the perceived efficacy, the more vigorous and persistent individuals will be in engaging in behaviour that they believe will be beneficial in the long term, even in the face of barriers (Bandura, 1997; Lenz & Shortridge-Baggett, 2002). According to Bandura, self-efficacy has two basic principles: the expectation of personal mastery (efficacy expectation or self-efficacy) and success (outcome expectation) (Bandura, 1977, 1986). These two aspects of self-efficacy come together in terms of the characteristics of the person, the behaviour of the person and the socio-structural factors that directly influence the outcome behaviour.

Efficacy expectation or self-efficacy is an individual's judgement about their ability to achieve a goal, or the belief that person has regarding their capability to complete a task that will influence their activities in daily life. Individuals with a higher efficacy belief are more confident in their capacity to execute behaviour, while individuals with low self-efficacy are not, and therefore may not learn or accomplish the desired behaviour. An individual's beliefs about their perceived self-efficacy have an influence on their goals and accomplishments (Bandura, 1977). Outcome expectation is an individual's expectation of the outcomes that will result from their behaviour (Bandura, 1997). Individuals are motivated to accomplish behaviours when they believe that the given behaviours will generate a desired result (Bandura, 1986).

It has been established that greater self-efficacy is related to better health and higher achievement (Bandura, 2004). Self-efficacy has been shown to be the best predictor for health indicators and a significant predictor for several health behaviours – for example, cessation of smoking, weight control, diet control, and alcohol consumption (Lenz & Shortridge-Baggett, 2002). From a diabetes perspective, several studies have found that individuals with greater levels of self-efficacy developed greater adherence to diabetes

treatment and better managed their diabetes (DePalma et al., 2015; Greenberger, Freier Dror, Lev, & Hazan Hazoref, 2014; Walker et al., 2014). Moreover, Greenberger et al. (2014) state that self-efficacy has both a direct influence on glycaemic control and indirectly enhances self-management, which also contributes to improved glycaemic control.

The presence of family members is a significant component in an individual's social environment and therefore has the potential to impact on individual behaviours. The association between an individual and their social environment, which includes family members and friends, as well as culture and social context, is a multilevel structure of support for managing a disease (Glasgow, Hampson, Strycker, & Ruggiero, 1997). Positive support from the family plays an important role in an individual's ability to make healthier choices and can also provide practical support. A recent study found that family support assists individuals with T2DM to enhance their medication adherence, which resulted in better glycaemic control and increased cognitive status (Tabasi et al., 2014). Although support from the family can have a positive health outcome on the management of disease among individuals with diabetes, it can also produce negative health outcomes. For example, competing demands between individuals and family-carers have been shown to be a barrier to self-management of diabetes (Miller & DiMatteo, 2013). Thus, the involvement of family members in the intervention program may help both individuals and carers in their understanding of diabetes self-care, which will result in better glycaemic control.

The findings from the literature review indicate a significant association between self-efficacy and diabetes self-care behaviours that can be enhanced by an intervention program based on self-efficacy. Therefore, utilising self-efficacy to develop DSME programs in order to enhance diabetes self-care, and hence achieve better control of blood glucose in individuals with T2DM should be considered. Diabetes educators and healthcare providers should integrate the self-efficacy theory into their teaching methods in order to assist individuals to develop their own strategies for long-term diabetes management and improved quality of life. Furthermore, there are a limited number of published research studies directly involving family members in diabetes intervention, especially in Thailand. No study has compared family-oriented interventions and patient-oriented interventions in diabetes patients. Involving close family members such as a spouse, children and siblings in an intervention based on self-efficacy theory for individuals with T2DM in Thailand is part of this study's intervention program.

The theoretical framework for the study was developed from self–efficacy and social cognitive theory (Bandura, 1977; Shortridge-Baggett & Van Der Bijl, 1996). This model demonstrates the relationship between efficacy expectations, behaviour, outcome expectations, and outcomes related to this thesis. The framework (see Figure 1) details the potential factors affecting individuals and family members, such as socio-structural, and efficacy expectations, which are linked as direct influences on behaviour (self-care activities), while behaviour (self-care activities) and outcome expectations are linked as direct influences on outcomes such as self-efficacy towards management of T2DM, quality of life, diabetes self-management, family diabetes management self-efficacy, diabetes knowledge and glycaemic control. Additionally, information sources are linked as a *direct* influence on efficacy expectation; outcomes and behaviour are linked as an *indirect* influence on individuals and family members. It can be seen from the theoretical framework of this study, perceived self-efficacy has an influence on diabetes self-care activities. Individuals with strong self-efficacy usually have a higher score on diabetes self-care activities. However, family-carer self-efficacy may have also had an influence on an individual's self-managed care and contributed to the individual's high score.

Self-efficacy and family-focused approaches were applied to develop the family-oriented diabetes self-management program that underpins this study. Information sources were utilised in education classes (teaching method or content), group discussions, the home visit, telephone follow-up, as well as workbooks (performance accomplishment, vicarious experiences, verbal persuasion) to develop a diabetes education program that would lead to higher efficacy expectation.

The family-oriented DSME program will be delivered to participants in the intervention group in order to improve efficacy expectation and increase the utilisation of diabetes self-care activities. The underlying premise is that the demographics and the perceptions of participants, together with high diabetes efficacy expectations, would result in better diabetes self-management. The self-efficacy of the family-carer would assist the individual with T2DM in managing their diabetes and influence their self-care behaviours.

The intention of the intervention program for the study was also to educate the carers of participants in the intervention group in order to improve their diabetes management self-efficacy. Participants who develop greater adherence to self-care activities

are likely to have higher levels of perceived outcome expectations and are thus more likely to have better biological and behavioural health outcomes.

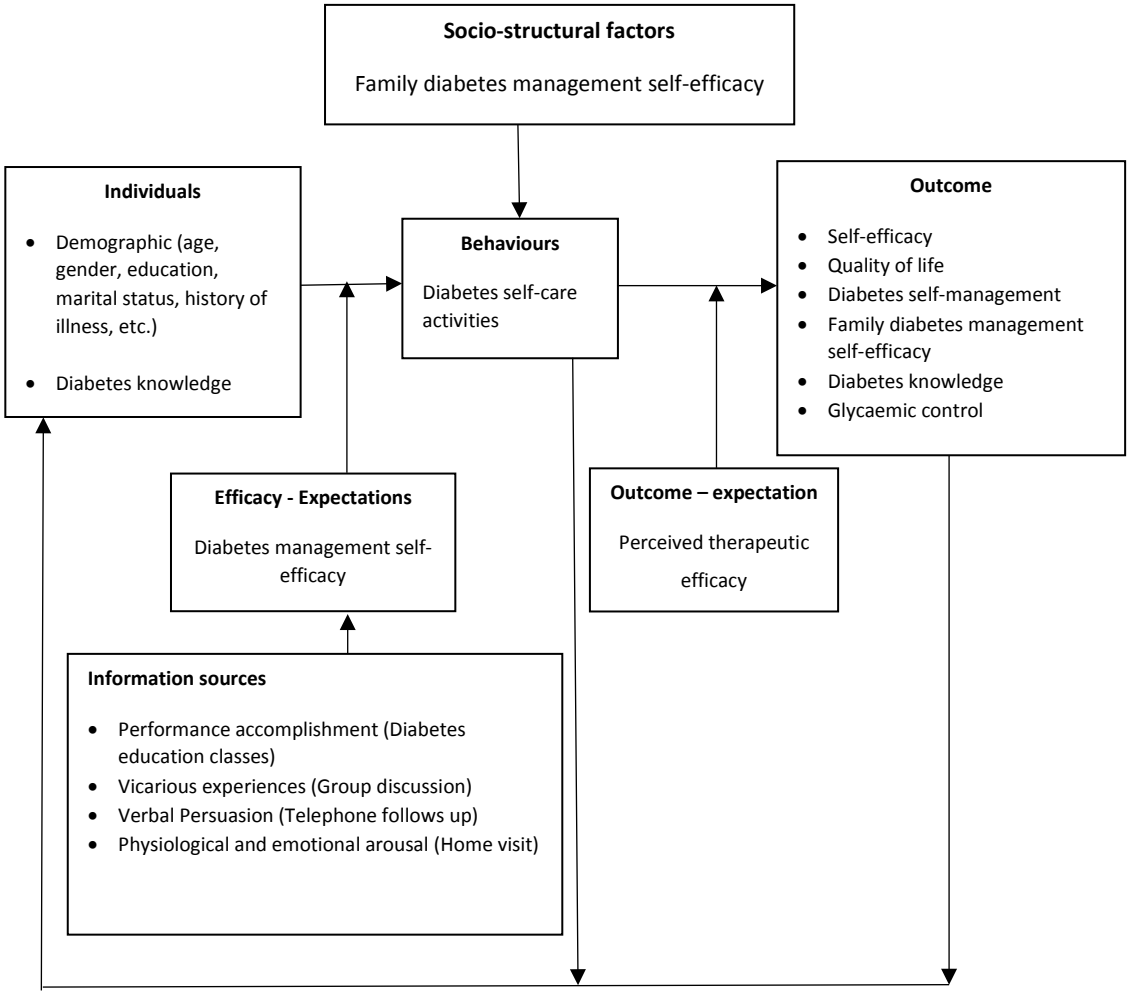

Figure 1. Theoretical framework. Developed based on Bandura, 1977 and Shortridge-Baggett and Van Der Bijl, 1996.

2.9 Key Findings from the Literature Review Relevant to this Thesis

Findings from the literature review have shown the diversity of diabetes self-management educational programs developed to help individuals with diabetes to enhance their knowledge, self-care ability, glycaemic control, and physical health and quality of life, as well as reduce their complications and the mortality rate from the disease. A wide range of theories, models, and concepts have been used to guide the many intervention studies, particularly behavioural theories targeting healthy behaviours and their maintenance. Although this review found beneficial effects of DSME based on theories presented in many of the studies, theoretical frameworks were absent from some studies.

After conducting the literature review, it was decided that self-efficacy, with consistent positive outcomes and family-involvement, would be used to guide the development of the DSME intervention program that is the basis of this thesis.

Empirical evidence has demonstrated the effectiveness of various strategies used to deliver DSME including technological-based approaches, group-based teaching, and one-to-one teaching. Most of the results from DSME studies using those methods indicated the beneficial effects on clinical and for behavioural outcomes. The intervention presented in this thesis combines a number of delivery strategies including group and individual sessions, face-to-face and remote electronic (mobile phone) approaches, education, and training classes. This study also includes details of education facilitation, ongoing follow-up support, and ongoing measurement to improve participants' outcomes and to increase their self-management.

Glycaemic control (HbA1c) is the most common outcome measured from DSME programs as the maintenance of HbA1c within normal limits is the primary goal of treatment of individuals living with T2DM. In addition, HbA1c is a predictor of complications related to diabetes. Diabetes self-management is also an important behavioural outcome to measure as it provides an indication of the ability of individuals to master self-care and self-management behaviours, both of which are positively associated with glycaemic control. Diabetes knowledge and self-efficacy are also positively related to the improvement in glycaemic control and therefore these outcomes are included in the review of the effectiveness of the intervention. The thesis focuses on diabetes self-management as a primary outcome; however, this comprehensive program was also designed to measure the improvement in all biological, cognitive, and behavioural outcomes.

Although several national and international guidelines have been used to guide the scope of the content in DSME programs, the information in those guidelines is similar, focusing on critical elements of diabetes self-care such as general knowledge in diabetes, diet management, physical activities, blood glucose monitoring, medications, complications monitoring and management, foot care, and diabetes management in special circumstances. DSME programs that provide 10 or more contact hours seem to provide the best possibility of improvement in metabolic control and reduce the risk of complications related to diabetes. Similarly, this review of the literature has revealed that there is a wide range of

periods of evaluation and follow-up; however, most studies were conducted over a period of three months. A follow-up period of 13 weeks is proposed for the intervention for this study.

The content of this family-oriented DSME program was developed following both national and international guidelines covering the main elements of diabetes self-care including the definition and classification of diabetes, signs and symptoms of diabetes, complications of diabetes and its management, blood glucose monitoring, diet management, exercise, and foot care. Approximately 10 contact hours in total were delivered through three education classes, three group discussion and training sessions, one home visit, and one telephone follow-up call. The study will be evaluated at three intervals: the beginning, the middle, and at the end of the education component of the program, thereby providing an indication of the effectiveness of the program from the first month after commencement to the completion of the DSME program 13 weeks later.

Tailoring DSME intervention programs to take into account aspects of culture, including consideration of cultural beliefs and customs, family participation, diet patterns, language, and values, has been found to improve metabolic control and behavioural and psychosocial outcomes. Similarly, the review of the literature has confirmed that family members can influence the diabetes self-management of patients when the family represents a model for good health behaviours. Family members who are closest to individuals with T2DM are more likely to contribute to daily activities. Consequently, the quality and type of family interactions influence the health status of individuals with T2DM, especially their glycaemic control.

The family-oriented DSME program undertaken in this study is designed to take into account the cultural norms of the Thai community, where family members play an essential role in supporting other people in their family. Moreover, this program's education classes will be delivered in the local language and the educational workbook (described in Chapter 3) was presented in simple language with appropriate pictures. Such cultural tailoring of the DSME program may help individuals to reduce the barriers present in diabetes management and increase their self-care abilities.

In conclusion, the key components of a DSME program derived from this review influenced the design and development of the DSME program that is the subject of this thesis and the evaluation of its effectiveness. This comprehensive program was developed

to include an appropriate theoretical foundation with appropriate content and intensity, a variety of delivery strategies, an adequate period for delivery and evaluation of the program and a suitable follow-up period. This culturally derived program is deemed to be suitable for individuals with T2DM in a rural community of Thailand with the aim of improving their self-management of diabetes and other associated health outcomes.

2.10 Summary

The literature review presented in this chapter has examined the status of diabetes and diabetes management worldwide and has described the search strategies undertaken to deliver a comprehensive summary of diabetes self-management educational programs in terms of theory, content and intensity, delivery strategies, and appropriate outcome measurement. Family-oriented intervention programs and cultural tailoring have also been outlined in this chapter.

The overall findings demonstrated the effectiveness of DSME intervention programs in enhancing biological indicators, health behaviours and social cognitive outcomes. The importance of incorporating self-efficacy theory and the family context in diabetes self-management programs has also been described in this chapter. This thesis focuses on self-management as the primary outcome but will consider other measures of glycaemic control as well.

The following chapter outlines the methodology (Study 1) and the development of a family-carer DSME program for individuals living with diabetes in rural Thailand.

Chapter 3

Study 1 Methodology

3.1 Introduction

Chapter 1 provided the background and significance of the study including the prevalence and the pathogenesis of T2DM. Chapter 2 provided evidence of the effectiveness of DSME programs for T2DM and introduced the theoretical framework for the intervention that is based on the self-efficacy theory (Bandura, 1977). Few RCTs have been conducted to evaluate the effectiveness of family-carer involvement in DSME in other countries (García-Huidobro et al., 2011; Kang et al., 2010), and prior to this study, no such study had been conducted in Thailand despite the strong kinship and family ties that exist in Thai communities. This chapter describes the rationale for the selection of the methodology and provides details of the design, sample and setting, and the outcome measures. Details of how the outcomes are to be measured, the data collection procedures, data management, and the data analysis approaches are also presented. Finally, ethical considerations in relation to this trial will be outlined.

3.2 Selection of the Design

For this study, the randomised controlled trial design was chosen to evaluate the effectiveness of the family-oriented DSME program in improving diabetes knowledge, glycaemic control, quality of life, self-efficacy and self-management of people living with T2DM. Descriptive designs such as correlational or cross-sectional designs were not appropriate as these designs detect the association between variables, with no manipulation of the independent variables. Although quasi-experimental designs involve manipulation, the lack of a comparison group or randomisation can result in bias occurring in the sample (Polit & Beck, 2004).

The randomised controlled trial was first conducted and reported on in 1747 by James Lind, a surgeon working on a ship (Bhatt, 2010). Lind conducted a controlled clinical trial to explore the treatment of scurvy for two groups of ill sailors, who received either a cider beverage or oranges and lemons (Bothwell & Podolsky, 2016; Collier, 2009). The first broadly conducted randomised controlled trial, which was published in 1948 by the British Medical Research Council (MRC), investigated the efficacy of streptomycin for the treatment

of pulmonary tuberculosis (Bhatt, 2010). RCTs were documented as the standard method for "rational therapeutics" in medicine (Meldrum, 2000).

The parallel study, also called "between patient" or "non-crossover", is defined as an experimental study in which participants are allocated to either a treatment group(s) or a control group. Except for treatments which differ between groups, all participants are exposed to the same procedures during the study (Turner, 2013). It is the most common form of clinical design and is frequently used for comparing the outcomes of treatments in two groups (Hopewell, Dutton, Yu, Chan, & Altman, 2010). This is particularly relevant where there is a new treatment being compared to a routine treatment or a comparative or a control treatment. A parallel-group RCT design is universally regarded as the "gold standard" as it minimises bias through the process of random assignment and blinding (Ofori-Asenso & Agyeman, 2015). Therefore, the parallel-group RCT design was selected to test the effectiveness of the intervention undertaken for this study.

There are several critical elements of a randomised controlled trial: randomisation, manipulation of an intervention, blinding, sample selection, and data collection (West & Spring, 2014). The methods of the study are described on pages eight and nine of the paper written by Wichit, Courtney, Mnatzaganian, Schulz, and Johnson (2017) – which has been submitted for publication but the following section provides more detail on the elements of the design that have not been described in the protocol paper.

3.3 Randomisation

Randomisation or random allocation is a technique that reduces participant selection bias between intervention and control groups and has been widely used in human clinical trials (Torgerson & Roberts, 1999). Randomisation is a procedure that is central to an RCT, ensuring participants have an equal chance of being allocated to either an intervention or a control group. Randomisation aims to balance baseline characteristics between the two groups in order to avoid the effects from complicating factors that could impact on the study outcomes (Suresh, 2011). There are numerous benefits of randomisation such as avoiding systematic bias being introduced into the groups, eliminating *a priori* knowledge of group assignments, and supporting the achievement of underlying assumptions of statistical tests for significant differences between outcomes (Kang, Ragan, & Park, 2008). Strict adherence

to random allocation techniques is essential to confirm the appropriate testing of the effectiveness or efficacy of an intervention.

There are several methods of generating random numbers including simple randomisation (table of random numbers, computer-generated set of random numbers, tossing a coin, shuffling a deck of cards, or throwing a die), block randomisation, stratified randomisation, and covariate adaptive randomisation (Kang et al., 2008). The simple randomisation method is easy to use and it can be trusted to generate similar numbers of participants in each group for large clinical research projects, while the block randomisation method ensures a balance in sample size across groups at all times, even in small sample sizes (Suresh, 2011). Although simple randomisation can be problematic for small sample sizes, resulting in an unequal number of participants among groups, computer-generated random numbers can address this problem.

Allocation concealment is another critical element to reduce selection bias. Random allocation should be completed independently of the research team and the use of sequentially numbered, sealed, opaque envelopes with the assignment inside is recognised as being an effective method of concealment (Tharyan & Adhikari, 2007).

In this study, an unpredictable sequence of random numbers was computer generated to randomly allocate participants to either the intervention or the control group. The sealed envelopes for allocation were prepared by clinical staff, who were independent of the research team, which thereby confirmed that the group allocation of participants was not known prior to assignment. Once a participant had consented to enter a trial, an envelope was opened and the participant was assigned to either the intervention or control grouping.

3.4 Blinding

Blinding is another aspect to minimise bias as study, where participants, data collectors, and investigators or healthcare providers remain unaware of the allocated intervention (what group they are in). This reduces the opportunity for clinicians or researchers to be influenced by the knowledge of group allocations (Bang, Ni, & Davis, 2004; Day & Altman, 2000). Furthermore, adequate blinding not only reduces bias in subject allocation but also increases the retention rate of participants in a trial (Schulz & Grimes,

2002; Viera & Bangdiwala, 2007). In clinical trials, there are three forms of blinding: single-blind, double-blind, and triple blind (Misra, 2012). A single-blinded trial is a trial where only the study participant is unaware of their treatment allocation; a double-blinded trial is a trial where both study participant and researcher are unaware of the assignment of the participants to the treatment allocations; and a triple-blinded trial is a trial where the participant, the researcher, and the person analysing the data are all unaware of the assignment of participants (Misra, 2012). The double-blinded method is most commonly used for clinical trials; however, the single-blinded randomised controlled trial was the appropriate method for testing the effectiveness of the intervention program for this study.

Participants were blinded to the allocation. In this study, data collectors, recruitment support staff, staff managing the random allocation, and healthcare providers were also blinded as these staff could have potentially influenced the outcomes if they knew the allocations. Participants were also blinded as to their group assignment. Participants who knew that they were assigned to receive a new treatment could have increased their expectations for that treatment, while those assigned a routine treatment may have felt that they were unlikely to improve and therefore may have withdrawn from the study (Schulz & Grimes, 2002). Thus, applying a blinding process to the trial is important as it can reduce perceptions of the impact of the treatment on the mental or physical responses of the participants (Schulz & Grimes, 2002).

A parallel RCT was the most suitable method for this study as manipulation of the independent variable (family-oriented DSME) was required. Furthermore, the RCT's design using the element of randomisation ensures all potential participants have equal probability of being included in either the intervention or control group. This randomisation reduces selection bias that could indirectly affect study outcomes; that is, participants who have better clinical features could be inadvertently selected for the intervention, resulting in improved outcomes which may or may not be related to the intervention. Randomisation also minimises the possibility that the relationship between the intervention and improved outcomes could be caused by a third factor (which may or may not have been measured) linked to both the intervention and the outcome (Sibbald & Roland, 1998).

RCTs can be generally considered as effectiveness (pragmatic) trials or efficacy (explanatory) trials (Wasan, 2014). There are many different aspects between the two types

of trial. First, an effectiveness trial usually attempts to find an answer to whether an intervention will work under usual conditions in a real clinical setting, whereas an efficacy trial attempts to test if an intervention will work under ideal circumstances or in an ideal setting. Thus, the control condition for effectiveness trials is usual care, whereas the control condition for efficacy trials is a placebo or perfect condition. Second, the study population of an efficacy trial is the homogenous population with numerous exclusion criteria applied, whereas the study population for an effectiveness trial is often the heterogeneous population, with few to no exclusion criteria applied. Finally, effectiveness trials require representative usual providers, whereas efficacy trials require highly experienced providers (Singal, Higgins, & Waljee, 2014). Therefore, effectiveness research is more appropriate for healthcare interventions in clinical settings, whereas efficacy research is more suitable for pharmaceutical trials under specific conditions.

The research study for this thesis was an effectiveness trial that tested the effect of a family-oriented DSME program conducted under pragmatic conditions in a clinical setting. Participants in both groups received their routine diabetes care from staff at the diabetes clinic; however, a family-oriented DSME program was included for the intervention group, where family-carers attended the education sessions delivered by the program. The population in this study was heterogeneous with limited exclusion criteria.

3.5 Bias

There are many forms of bias that can lead to incorrect conclusions being drawn in relation to the effects of an intervention (Sackett, 1979). Some forms of bias in clinical trials are well known including “selection bias, performance bias, detection bias, attrition bias, and reporting bias” (Higgins & Green, 2011, p195).

Allocation or selection bias can occur when there is a systematic difference in the enrolment of participants at the baseline; however, RCTs can minimise this bias through randomisation and allocation concealment, which increases the probability that the baseline characteristics are balanced in terms of both known and unknown factors (Kahan, Rehal, & Cro, 2015). Performance bias is a systematic difference between the intervention and control groups in the treatment that has resulted from variations in the offered treatment or other exposure factors (Higgins & Green, 2011). Detection bias is a systematic error that occurs in the evaluation of outcome measures when data collectors or trial participants are

aware of group allocations (Sedgwick, 2011). Consequently, the blinding of participants and data collectors should reduce the possibility of performance or detection bias (Higgins & Green, 2011). Attrition bias is the systematic difference in the dropout rate between two groups (Higgins & Green, 2011). This can be addressed through the careful reporting of dropouts from both the intervention and control groups.

In this research study, the randomisation procedures used minimised selection bias as each participant had equal probability of being enrolled in either the intervention or control group, and recruiters were unaware of group allocation. There was careful attention to allocation concealment, and recruiters were unable to access the allocation listing for groups. Also, opaque envelopes were used to conceal the allocation numbers that had been prepared by clinical staff independently of the investigator. Participants and data collectors were blinded to reduce performance and detection bias. To prevent attrition bias, the trial was designed for participants to have a follow-up assessment on the same day with a physician, as well as making telephone calls to the participants to support their attendance at follow-up data collection points.

3.6 Reporting a Randomised Controlled Trial

A randomised controlled trial (RCT) was conducted to evaluate the effect of a family-oriented DSME program for Thai individuals with T2DM. The study examined the difference between individuals with T2DM who participated in a family-oriented diabetes self-management program (intervention group) compared to those who received the usual form of care (control group). The methods used for the development and evaluation of the effectiveness of this program are also detailed in the study protocol publication (Wichit, Courtney, et al., 2017). The following discussion provides details of the method and adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al., 2010; Schulz, Altman, & Moher, 2010).

Although randomisation eliminates selection bias, the power and the quality of the trial results is determined by how accurately the RCT is reported. Many RCTs omit to report critical trial information – for example, allocation concealment, sample size calculations, primary outcomes, and random sequence generation (Chan & Altman, 2005). Consequently, a reader may not be able to evaluate the validity of the trial and its findings. In 1996, a group of researchers and journal editors launched the Consolidated Standards of Reporting Trials

(CONSORT) statement to increase the quality of reporting of RCTs. This statement was revised in 2001 and 2010 (Moher et al., 2010; Moher, Schulz, Altman, & Group, 2005; Schulz et al., 2010).

Previous studies have demonstrated that prior to the update of the CONSORT Statement in 2001, more than half of the trial reports had provided inadequate details of critical methodological information (Chan & Altman, 2005). Even though reporting of trials published between 2000 and 2006 had improved after revision of the CONSORT statement, several trial reports had still neglected to include critical methodological details and were therefore deemed to be below an acceptable standard (Hopewell et al., 2010). Hopewell et al. (2010) found that the quality of reporting improved for details of the allocation concealment, random sequence generation, study outcome, and sample size calculation; however, there were no differences in the details of the blinding.

In 2010, the latest version of the CONSORT statement was published, which contained a 25-item checklist (many with sub-items) and a diagram showing the flow of participants through a trial. This version assists researchers to better assess and report on their RCT methodology (Moher et al., 2010). The checklist items provide details of the research methodology, reporting design, analysis, and interpretation of a trial that should be included in the report. Additionally, the flow diagram demonstrates the flow (available population, loss of participants at varying stages of the trial) of all participants in the study (Moher et al., 2012). To avoid methodological biases, the methodology of the current study adhered to the CONSORT statement explanations and elaborations of RCTs for non-pharmacological treatments (Moher et al., 2012). The researcher for this study used the CONSORT item checklist for reporting on the study's trial (see Appendix G).

An RCT is considered the highest level of experimental design and produces the highest level of objective evidence compared to other designs because many of the sources of bias have been removed from the process of the study in order to improve its accuracy (Gugiu & Ristei Gugiu, 2010). The RCT is acknowledged as a critical resource for the evidence-based practice of medicine (Gugiu & Ristei Gugiu, 2010). Therefore, the RCT is considered the gold standard for a clinical trial as it provides the most effective method of minimising bias (Sullivan, 2011).

The design of the randomised controlled trial for this study was a parallel-group study design that consisted of an intervention group and a control group. Participants were randomly allocated to either the intervention (received family-oriented DSME) or the control group (received routine care) using a computer-generated sequence of random numbers that ensured there was equal probability of a participant being assigned to either group, thereby reducing selection bias. An opaque envelope with the concealed allocations was prepared independent of the investigators. Participants were blinded from their group assignment in order to minimise bias, although the potential for contamination within the clinic was evident. Study outcomes were measured at the baseline, at week 5, and at week 13 of the RCT.

3.7 Sample

The study sample was drawn from individuals diagnosed with T2DM who lived in the Thachang District and attended the diabetes outpatient clinic at Thachang Hospital for follow-up care. Patients were invited to participate in the research project via a flyer posted on the hospital's noticeboard by the investigator. The selection criteria for inclusion in the trial were that individuals with T2DM were (1) aged 35 years or older; (2) had a fasting plasma glucose level of more than 140 mg% in at least two follow-up clinic visits (a month apart); (3) were willing to participate in the trial and to receive home visits; (4) had a telephone at home; and (5) lived with a family member (co-resident). People with T2DM who were being treated with insulin or who had severe complications (for example, retinopathy or stroke) were not considered suitable for the trial and excluded.

The sample size for the study was calculated based on power analysis, which contains four components: the level of significance or alpha (α), sample size, population effect size (ES), and power (1-β). The sample size was calculated based on a known effect size of the primary outcome variable (diabetes self-management) from a previous study (Wu et al., 2011). After calculation, it was determined that a sample size of 100 (50 per group) participants was required. However, in this study the researcher anticipated that there was a situation where a participant may drop out. The researcher took this into account by adding 30% into the sample size. Therefore the number of subjects needed in this study is 140 people (70 per group). The details of sample and sample size estimations are described in the protocol paper (Wichit, Courtney, et al., 2017), which is in section 3.13 of this chapter.

3.8 Setting

Further details, beyond those described in the protocol paper (Wichit, Courtney, et al., 2017) are outlined to appropriately contextualise the findings of this thesis. The RCT for this study was conducted at Thachang Hospital and at patients' homes in Thachang District in Suratthani Province, Thailand. Thachang Hospital is a community hospital with 30 in-patient beds and provides health services to people in 46 villages located in the Thachang District and surrounding area. This hospital, located in the north of the province, is 40 kilometres from the Suratthani city and serves a population of 32,618 people. There are four general physicians and 72 healthcare providers working at the hospital. This community hospital provides curative care, health promotion, rehabilitation, and disease prevention services. The services for outpatients with diabetes are provided at the diabetes clinic in the outpatient department (OD). The diabetes clinic is open only on Tuesdays and Wednesdays from 7.00 am to 12.00 pm. Outpatients' travel time to the clinic can be as little as 10 minutes or up to one hour, and they get there using public transport or private vehicles. The patients at the clinic are often from poor rural locations that usually have limited telephone or internet access.

The community hospital runs healthcare programs using standard procedures established by Thailand's Ministry of Public Health. The diabetes clinic follows the Diabetes Clinical Practice Guidelines 2014 that were established by the Diabetes Association, the Endocrine Association, and the Institute of Medical Research and Technology Assessment and National Health Security Office (NHSO) (Diabetes Association of Thailand, 2014). The following section outlines the clinical services or the usual care that is provided for diabetes management in the clinic.

People with diabetes usually arrive at the hospital between 6.00 am and 7.00 am for blood glucose checking at the laboratory department. Vital signs, body weight and height are measured. To prevent diabetes complications, lipid profile, kidney function, electrocardiography, chest x-ray, retinopathy, and feet are also monitored annually. While waiting to see the physician, general health education is provided individually to the patients by a nurse who works at the diabetes clinic or by a healthcare provider. Individual health education is provided for new cases as well as for patients who have, according to institutional guidelines, uncontrolled blood glucose levels. The program is unstructured and

has no lesson plan or theoretical foundation. For new cases of diabetes, the individuals receive advice on a one-to-one basis, as well as a booklet on diabetes knowledge. The booklet includes diabetes and hypertension information, the personal information of the patient, and a monitoring record sheet with details of their body weight, BMI, blood pressure, blood glucose levels, pulse rate, treatment received and the time of their next appointment. Patients with diabetes see the physician for approximately 10 to 15 minutes for a physical examination, advice and treatment. They then see a nurse at the front desk to make their next appointment. After their appointment with the physician, patients then receive their medication and advice from the pharmacist at the hospital regarding how they should administer the medication to themselves. Diabetes patients return to the hospital for a follow-up check every month.

3.9 Intervention: Development of a Family-Oriented DSME Program for Individuals with T2DM and Their Carers Living in Rural Thailand

A detailed description of the family-oriented DSME program is outlined in the paper "A randomised controlled trial of a family-supported diabetes self-management program: Study protocol" (Wichit, Courtney, et al., 2017). The education program that formed the basis of the intervention focused on the five elements of diabetes self-management, which include coping with diabetes-related complications, blood glucose monitoring, diet, foot hygiene, and physical activity. The intervention program of this study aimed to enhance diabetes self-management in individuals with T2DM by delivering an educational intervention program that had been developed and was delivered using self-efficacy theory and associated facilitation strategies. The teaching strategies used to deliver this intervention included 3 education classes, 3 group sessions, 1 follow-up telephone calls and 1 home visits. The delivery strategy was designed by the lead investigator without the involvement of people with T2DM and their carers. The strategy included education sessions and booster sessions. Booster sessions influence knowledge and metabolic control outcomes (Fan & Sidani, 2009). In order to improve clinical outcomes, the facilitator contacted the participants every two weeks providing all education sessions and booster sessions. Intervention fidelity was integrated into the study design, with structured lesson plans of prescribed content and activities, delivered consistently by the lead investigator (the facilitator) to people with T2DM and their carers.

In this program, the family member is formally involved in the education process, not only education classes but also in the follow up, group discussion, and home visit. The facilitator has deliberately focused on educating the family member which is different from other diabetes self-management programs.

The specific content and timing of the delivery of the intervention is presented in Table 2. The educational components were delivered over three sessions using a booklet format. The intervals for the delivery of the intervention program were every two weeks and included the education sessions, a home visit, and a telephone follow-up call. The intervention program was delivered by a registered nurse who was experienced in the management of diabetes. The same educator delivered each session to all the participants.

Table 2
Summary of the Intervention Program

Week	Timing (minutes)	Self-efficacy model application	Main content
1	30	Physiological information and affective information	General overview of diabetes: the meaning, types, signs and symptoms, complications and prevention, signs and symptoms of acute complications of diabetes
	30	Performance accomplishments	Self-treatment for hyperglycaemia and hypoglycaemia
	45	Vicarious experience	Blood glucose monitoring and its purposes
	60	Performance accomplishment	Blood glucose monitoring practice
	15	Goal setting	Counselling and identifying the problems and barriers to self-blood glucose testing
3	30-60	Verbal persuasion, physiological and affective information	Clarifying individual problems, reinforcing behaviour changes, problem-solving, anticipation of barriers and maintenance of new behaviour
5	30	Physiological and affective information	Self-assessment, benefits of healthy diet education
	30	Verbal persuasion	Tips for making healthy eating choices
	30	Performance accomplishments	Diabetes diet, creating meal plans, and eating away from home when on holidays or at special occasions
	15	Vicarious	Demonstration of role model who had a healthy diet
	60	Performance accomplishment	Practising the creation of a meal plan

Week	Timing (minutes)	Self-efficacy model application	Main content
	15	Goal setting	Counselling and identifying the problems and barriers
7	15-30	Verbal persuasion	Telephone follow-up call for encouraging problem-solving, counselling and identifying individual problems and barriers
9	45	Verbal persuasion, physiological and affective information	Self-assessment, important benefits of physical activity and exercise
	30	Physiological and affective information	Exercising precaution and staying safe in exercise
	30	Performance accomplishment	Foot care
	60	Vicarious and verbal persuasion	Practise foot exercises
	15	Goal setting	Encouragement and reinforcement

3.9.1 Diabetes booklets. There were three diabetes self-management booklets used in this intervention. These booklets were produced using the self-efficacy model. The content of the booklets was developed from the Clinical Practice Guidelines for Diabetes Thailand (Diabetes Association of Thailand, 2014), clinical guidelines from the National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2015), and the National Health and Medical Research Council Australia (The Diabetes Unit Menzies Centre for Health Policy, 2009). The three diabetes booklets explained the main aspects of understanding how to manage diabetes.

The three booklets were developed in an easy and basic approach for individuals with T2DM and their carers using pictures that reflected the Thai cultural context, as well as having reflective questions that were designed to encourage discussion between the individuals with T2DM and their carer/support person to enhance self-efficacy. The three diabetes self-management booklets were first produced in the English language by the investigator and were then reviewed by a panel of experts on diabetes self-management. The panel provided suggestions and comments on the three sessions in the education program as well as the lesson plans for each session. The booklets were reviewed by two experts in diabetes self-management and self-efficacy. The experts provided feedback on additional content and suggested strategies to improve the application of self-efficacy in the

intervention, including information on the global standard of diabetes care that would enhance self-efficacy.

The investigator revised the booklets and resubmitted them to the panel for final review. The booklets were translated into the Thai language by bilingual translators after approval by the panel. Three experts in diabetes self-management in Thailand (a diabetes educator, a nursing teacher, and a diabetes clinical nurse) were asked to provide feedback on the cultural validity and language accuracy of the booklets. The booklets were further revised following this feedback and then resubmitted again to these experts. The booklets were then verified for readability and ease of understanding by three individuals with T2DM and their carers, who stated that the resources were useful in enhancing knowledge and self-care ability as well as being supportive in the management of diabetes.

The diabetes self-management booklet 1, handed out to the participants at the beginning of the program, provided information on general diabetes knowledge including the meaning, type, signs and symptoms, acute and chronic complications, as well as coping strategies and blood glucose testing. A self-workbook was included in the booklet that required the participants to self-assess issues such as their confidence in diabetes management, their understanding of the benefits of self-management of diabetes and their diabetes knowledge. In each section, participants were requested to evaluate themselves, for example, by describing the type of diabetes they had, their understanding of why they had diabetes, describing the signs and symptoms they had prior to diagnosis, and explaining the signs or symptoms of the diabetes-related complications they had experienced.

The diabetes self-management booklet 2, handed out at week 5, focused on diet (five groups of food, why diet control, tips for making healthy eating choices, foods to avoid, foods to limit, and foods to eat freely). This booklet also included a self-workbook for participants, which at the beginning of the session, asked participants to answer the question “how confident are you in your ability to choose the appropriate foods for diabetes” and to write down all the foods they had eaten the previous day. The education session on diet was then delivered and the participants were asked to assess their food list and choose the most appropriate dishes for diabetes.

The diabetes self-management booklet 3, handed out at week 9, covered physical activities and foot care including the important benefits of physical activity, preparing for

exercise and physical activity, exercise precautions and staying safe with exercise, foot care, foot exercise, and strengthening muscles. This booklet included a self-workbook that assessed participants' activities. Participants were asked about their weekly exercise frequency, what were the barriers to undertaking exercise, suggestions for overcoming those barriers, frequency of feet assessment, and setting goals for physical activity. The topics of each chapter are outlined in Table 3 and examples of the booklets are presented in Appendix F.

Table 3
Examples of Questions in intervention program

Booklet	Topic	Example Question
1	Introduction	How confident are you in your diabetes self-management?
		Why you should manage your diabetes?
	Meaning of diabetes	How much do you know about diabetes?
	Types of diabetes	What kind of diabetes do you have?
	Signs and symptoms of diabetes	Please circle the signs and symptoms you had before you found out about your diabetes?
	Diabetes complications	Did you have those signs and symptoms after you got diabetes? Please describe
		How did you solve the problem?
	Glucose monitoring	What is your target range for blood glucose?
		What should you do to achieve your goal?
2	Introduction	Please write down all the foods you ate yesterday?
		Please write the group name of the following foods?
	Benefits of diet control	Why should you control your diet?
	Tips for making healthy eating choices	How confident are you in your ability to choose appropriate foods for diabetes?
	Diabetes diet	Which dish is most appropriate for your diabetes?
		Can you create your food for three days?
		How confident are you in following your meal plan?
		What are the barriers to eating a diabetes diet?
3	Introduction	On how many days of the week do you take part in at least 30 minutes of exercise?
		What kind of activities you do? (For participant who does)

Booklet	Topic	Example Question
		What are the barriers that are stopping you from doing exercise? (For participant who does not)
	Important benefits of physical activity	How do physical activities help you to control diabetes?
	Preparing for exercise and physical activity	How do you prepare yourself before doing exercise?
	Exercise precaution and staying safe in exercise	How do you prepare yourself before doing exercise?
	Foot care	Did you check your feet today?
		How can you keep your feet healthy?
	Foot exercise and muscle strengthening	How many days do you plan to do exercise in one week?
		How can you overcome any barriers? Can you write down your specific barrier, then an idea that can help you to stay on track?

3.9.1.1 Self-efficacy and social cognitive theory applied. The family-oriented DSME program was developed by this investigator based on self-efficacy theory for diabetes self-management (Bandura, 1977).

According to Bandura's social cognitive theory, four information sources affect behavioural changes in perceived self-efficacy and outcome expectations. These four sources – performance accomplishment, vicarious experience, verbal persuasion, and physiological information – together with the two elements of the self-efficacy theory (efficacy expectation and outcome expectation) were used to develop the DSME intervention program for this research study. According to Bandura (1997), combining all multiple information sources of self-efficacy is the best way to improve the self-efficacy of individuals.

Performance accomplishment is where the participants learn special skills for enhancing their confidence and changing their behaviours, which include practice in meal planning, physical activities, monitoring signs and symptom and problem-solving. Vicarious experience is where participants who have performed appropriate behaviours are encouraged to be an example to other participants in how to develop desired behaviours. For instance, participants exhibiting appropriate behaviours shared their experiences with others in the class regarding how to achieve the desired target of fasting blood glucose

levels. Verbal persuasion is where participants are encouraged and supported to undertake more self-management activities. Finally, the physiological information resource is where participants learn ways to identify emotional problems and strategies to overcome problems.

Diabetes education classes that aimed to enhance self-efficacy were provided at three points during the intervention program (baseline, week 5, and week 9). Participants and their carers were divided into small groups (8–12 dyads per group). The main objective of the sessions was to enhance the confidence of participants and carers to carry out the necessary behaviours so that would enable the individuals with diabetes to self-manage their disease satisfactorily. The facilitator utilised self-efficacy counselling skills to enhance participants' confidence, which included asking and answering questions, identifying problems, setting goals, providing follow-up support, conducting group discussions, asking stimulating questions, discussing successes and failures, and assessing the extent of behaviour changes (Wang, Li, Chang, Courtney, & Chang, 2007).

At the beginning of each session, participants (carers and individuals with T2DM) were asked to evaluate their confidence by responding to the question, "how confident are you in your diabetes self-management" and rating their confidence levels on a scale from 1 to 10. Counselling skills were used during the session as well as teaching and facilitation practices. During the sessions, the individuals with diabetes and their carers participated in the education classes, which included reviewing the diabetes self-management workbook, asking and answering questions, sharing experiences, assessing confidence levels, and learning new knowledge. During each session, the facilitator observed the verbal and non-verbal responses of participants. At the end of each session, participants were again asked to evaluate their confidence in identifying any change in their levels of confidence. Participants were also asked to set their own goals as well as design their personal action plans. Successful achievement of goals and the barriers encountered in trying to achieve the goals were reported at the beginning of the next class.

The second class was delivered at week 5 and used the same approach as the first class, with the addition of a discussion on the success and barriers experienced at the beginning of the second class. Successful people who performed appropriate behaviours were promoted as role models for other participants to learn from, which encouraged

learning from vicarious experience. The facilitator interviewed participants who did not meet their goals to identify the barriers they had encountered and discuss the strategies they needed to employ to overcome those barriers. The distribution of physiological information was encouraged through the discussion of cognitive and emotional issues, problem-solving, and the sharing of experiences, as well as the counselling being delivered, which focused on identifying problems and barriers. During the last 30 minutes of each education session, participants with T2DM were encouraged to enhance their self-efficacy skills and goal-setting skills through discussion with their carers.

3.9.2 Group discussion. Group discussions were established after education classes to promote self-confidence of participants at the baseline, week 5, and week 9. The group discussion was approximately 1 hour per session. Each group discussion commenced with an activity that required participants to formulate an action plan and set individual goals. The group process commenced with target group recruitment, facilitation of communication within the groups and analysis of group discussion (Stewart & Shamdasani, 2014).

Performance accomplishment was encouraged by providing training to develop the necessary skills for diabetes management to promote confidence, as positive and negative experiences of individuals can impact on their ability to achieve given tasks. Participants were trained in blood glucose testing, creating meal plans, and undertaking foot and muscle strength exercises at the baseline, week 5 and week 9 intervals respectively. In those sessions, for example, the facilitator demonstrated self-blood glucose testing and then the participants learnt how to perform that test on themselves.

Vicarious experiences were promoted when less successful participants observed successful participants undertake a task – for example, blood glucose testing. Seeing a peer successfully undertake a task reinforced the idea that learning such a task was achievable and therefore promoted higher self-efficacy. Self-efficacy was encouraged using verbal persuasion that related to the participant's performance or capability to perform given tasks. Utilising verbal persuasion in a positive way encouraged participants, with the consequence being that they would have a better chance of success. For example, the facilitator might say to the participant "You can do it" or "I have confidence in you".

Perceived emotional arousal influences beliefs of efficacy so physiological feedback or self-evaluation was promoted. Participants were taught about physical and emotional

problems and each problem was discussed during group discussions. Problem-solving, facing barriers and maintaining new behaviours were emphasised. It is important that participants perceived themselves as having the ability to learn about diabetes and to understand the benefits of diabetes self-management in order to feel more capable of managing the condition and, therefore, develop higher beliefs of self-efficacy. With such beliefs, the participants could overcome problems and demonstrate their confidence in problem-solving. For example, after the facilitator outlined to the participants the scenario about acute complications related to diabetes, they were then asked how they would deal with such complications.

3.9.3 Home visits. Participants participated in an individual session of approximately 30 minutes during a home visit at week 3 to clarify individual problems and reinforce behaviour changes.

This session promoted problem-solving and overcoming barriers, maintaining new behaviours, continuing education, and making adjustments to achieve goals. The facilitator (registered nurse) also used the opportunity to catch up with other family members and provide diabetes knowledge to them.

3.9.4 Telephone follow-up calls. Telephone follow-ups were provided by the facilitator in week 7. The purpose of the telephone follow-up was to monitor the progress of the participant in engaging in appropriate self-management behaviours. This was an individual session that encouraged problem-solving, and provided counselling and support to overcome problems and barriers, and foster continued performance accomplishment. The focuses of the unstructured follow-up calls was decided by the facilitator and people with T2DM and was related to problem-solving barriers to achieving self-management behaviours.

At the end of the data collection period, the usual care group also received one diabetes self-management education class, delivered by the facilitator, plus the diabetes self-management booklets 1 to 3. Family carers were not included in this session.

3.10 Study Outcomes and Measurement

The primary study outcome was diabetes self-management, which was evaluated by the Summary of Diabetes Self-care Activities Scale (scores ranged from 0 - 140) (Toobert,

Hampson, & Glasgow, 2000). The secondary outcomes were diabetes knowledge, evaluated by the Diabetes Knowledge Questionnaire (scores ranged from 0 - 24) (Garcia, Villagomez, Brown, Kouzekanani, & Hanis, 2001); diabetes self-efficacy (efficacy expectation and outcome expectation), evaluated by the Diabetes Management Self-efficacy Scale (scores ranged from 20 - 100) (van der Bijl, Poelgeest-Eeltink, & Shortridge-Baggett, 1999) and the Perceived Therapeutic Efficacy Scale (scores ranged from 10 - 50) (Dunbar-Jacob, 2000); quality of life, evaluated by the 12-item Short-Form Health Survey (Ware, Kosinski, & Keller, 1996); and glycaemic control as shown by HbA1c levels extracted from medical records.

The outcomes for family-carers were diabetes knowledge evaluated by the diabetes knowledge questionnaire (Garcia et al., 2001) and family-carer diabetes management self-efficacy evaluated by the family diabetes management self-efficacy scale. The study outcomes are more fully described in the study protocol paper (Wichit, Courtney, et al., 2017) detailed in section 3.13 and also within the findings of the randomised controlled trial in section 4.3 (Wichit, Mnatzaganian, Courtney, Schulz, & Johnson, 2017a).

3.11 Data Management and Analysis

Data were collected by a trained registered nurse. Hard copies of the surveys were given to the investigator and all data entry was undertaken by the investigator. All data were organised and coded before being entered into a computer file and re-checked with the information from the original questionnaires until no differences were found. All data were saved onto two USBs at the completion of the data entry phase and a hard copy of the data which was kept in a locked filing cabinet. The computer was password protected and a lockout screensaver was installed. Data checking and cleaning was undertaken by the researcher, as well as checks for out-of-range values and corrections. Data recoding was completed prior to the analysis.

Data analysis was conducted using SPSS version 23 (IBM Corp, 2015). Descriptive analysis was conducted of participants' demographic and clinical data, diabetes knowledge, HbA1c levels, outcome expectations, self-efficacy, self-management and quality of life of the individual with T2DM, as well as family-carer diabetes management self-efficacy. Mean and standard deviation were used to examine the continuous variables, whereas percentages were used for categorical data.

Baseline characteristics (such as age, gender, marital status, occupation, income, education, comorbidity, complication, BMI, FBS, duration of illness, HbA1c and BP) of the intervention and control groups were compared using the non-parametric Mann-Whitney test for continuous variables, whereas Chi-square tests were used for proportional differences. Within-group comparisons were analysed using the non-parametric Friedman test.

Prior to modelling, analytics were undertaken to determine the distribution and normality of the data for independent and dependent variables, which included the plotting of histograms, the transformation of data using logs and square roots, and the checking of residuals. However, most of the study variables were not normally distributed after transformation. Although log transformation is widely used in biomedical and psychosocial research to deal with skewed data, the results of standard statistical tests performed on log-transformed data are often not relevant for the original data (Feng et al., 2014). Therefore, non-parametric statistics were used for interferential statistics.

Regression analyses are statistical methods used for assessing the relationship between one or more dependent variables and one or more independent variables (Tabachnick & Fidell, 2007). In this study, repeated assessments over time were undertaken and the generalised estimating equations (GEE) (Hardin & Hilbe, 2007) approach was used to model each study outcome to predict the relationship of the variables while accounting for correlated data within the repeated measures study design.

The marginal model (population-averaged model) is the method used for modelling the population-averaged response, depending only on the covariates of interest (Heagerty & Zeger, 2000). The GEE approach, presented by Liang and Zeger (1986), is the most common procedure in marginal models representing an extension of the generalised linear modelling (GLM), and GEE can accommodate correlated data with binary, discrete, or continuous outcomes. GEE delivers a non-likelihood based or quasi-likelihood procedure to model related data, specifying one of a variety of possible working correlation matrix structures to account for the within-subject correlations.

There are several advantages to using GEE – for example, the GEE is less restrictive in relation to the assumptions of traditional regression models (Ghisletta & Spini, 2004; Hardin & Hilbe, 2007). In addition, the GEE method can be applied to non-normal distributions and

incomplete data sets as well as unbalanced data (Zeger, Liang, & Albert, 1988; Ghisletta & Spini, 2004). GEE is a procedure that does not require the correct specification of the multivariate distribution but only the mean structure (Ziegler & Vens, 2010). Although, the GEE approach has advantages, there are several limitations to using GEE. It uses quasi-likelihood estimation so likelihood-based methods are not appropriate for testing fit. The AIC (Akaike's Information Criterion) statistic cannot be directly estimated using GEE since AIC is based on maximum likelihood estimation and GEE is non-likelihood-based. However, GEE provides an alternative method that is used to compare the best fitting model which is the QIC or the quasi-likelihood under the Independence model Criterion. When using QIC to compare two structures or two models, the model with the smaller statistic is preferred. Additionally, empirical-based standard errors may underestimate the true ones. However, this last point is not correct in large sample sizes (Khajeh-Kazemi et al., 2011).

The intervention and control groups were compared over time in adjusted models that accounted for age, gender, BMI, education, occupation, income, duration of illness, presence of diabetes-related complications, presence of comorbidities, blood pressure, diabetes knowledge, self-efficacy (efficacy expectation and outcome expectation), self-management, quality of life (mental and physical), and HbA1c.

The analysis was conducted using intention-to-treat (ITT) and per-protocol (PP) approaches. ITT compares study arms which includes all participants assigned after randomisation, whereas PP includes only participants who completed the protocol (Ranganathan, Pramesh, & Aggarwal, 2016; Sedgwick, 2015). ITT analysis is recommended because it tends to minimise bias when incomplete information is associated with the study outcome. This approach also maintains a balance of baseline data and preserves sample size due to dropouts, which may reduce the sample size and statistical power (Ranganathan et al., 2016). The last-observation-carried-forward method is recommended for use in cases of missing data (Gupta, 2011). Furthermore, the CONSORT statement notes that both ITT and PP analyses should be used for improving the quality of RCT reporting (Moher et al., 2012).

3.12 Ethical Considerations

Ethical considerations seek to maximise possible benefits and minimise possible harm to participants (Resnik, 2011). Ethical considerations were taken into account for various parts of the study such as planning, conceptualisation, execution, analysis of data,

and publication. For example, participants in the intervention program would have expected a benefit from the new treatment but they may have become distressed due to the possibility of exposure to undesirable effects from the new treatment. Consequently, studies should attempt to minimise risks and provide benefits for participants in the program.

The researcher sought ethical approval for this study from the Human Research Ethics Committee of the Australian Catholic University and the Suratthani Public Health Office in Thailand. Subsequently, approval was obtained and the Australian Catholic University's approval number was 2014-222Q (Appendix B.1) and the Suratthani Public Health Office's document number was ST0032.009/4824 (see Appendix B.2). This trial was registered with the Australian New Zealand Clinical Trials Registry, registration number ACTRN12615001249549 (see Appendix D). The data collection procedures covered all aspects of human rights protection.

The researcher provided a complete verbal explanation of the purpose of the study, the process of the study, its methods, risks and benefits, as well as the protection of confidentiality and the provision of anonymity. In addition, participants received an information letter (Appendix E) concerning the study and all the questions they had regarding the study were answered. Participants were informed that their participation in the study was voluntary, and that they could refuse to participate or withdraw from the study at any time if they wished without it affecting the health services they were receiving. Participants were reassured that there would be no impact to their standard treatment, and participation or non-participation in the study would not affect their relationship with the hospital staff or the doctor treating them. Prior to data collection, participants who had agreed to participate were asked to sign the consent form (Appendix C). A copy of the consent form and information sheet was then provided to the participants, which contained details of how to contact the investigator should they wish to withdraw.

The research was low risk for participation; however, participants were informed that the diabetes clinic manager would accept referrals from them for counselling, medical or other support if they were suffering from any distress from participation in the program. As participants were receiving a predominantly educational intervention and no invasive procedures, or pharmacological interventions were administered, this study was considered

a low-risk intervention (National Health and Medical Research Council, 2014). Throughout this study, there were no adverse events that affected the participants.

For the follow-up telephone calls and the home visits, establishing rapport was important and as the lead investigator was delivering the intervention, the participants were comfortable with the investigator following up with them on the telephone and visiting them in their home. The investigator was considerate and respectful of the participants' private home space and all participants provided a warm welcome when the investigator visited their home. When visiting participants, the investigator notified the hospital community staff of her location and the likely duration of the visit.

3.13 Publication Relevant to the Thesis

Wichit, N., Courtney, M., Mnatzaganian, G., Schulz, P., & Johnson, M. (2017). A randomised controlled trial of a family-supported diabetes self-management program: Study protocol. Manuscript submitted for publication in the *International Journal of Diabetes in Developing Countries*.

A randomised controlled trial of a family-supported diabetes self-management program: Study protocol

ABSTRACT

Aims: To evaluate the effectiveness of a nurse-led family-supported self-management intervention on diabetes self-management, self-efficacy, knowledge, quality of life, and glycaemic control.

Background: Living with type 2 diabetes mellitus is a challenge for patients and carers. Self-management education programs have delivered promising outcomes, however the additional benefit of involving a family member has not been explored.

Designs: A single-blinded randomised controlled trial.

Methods: One hundred and forty people with Type 2 diabetes will be randomised into intervention and control groups. The intervention group will receive the nurse-led family-supported self-management education program (based on the Self-Efficacy Theory)—3 education classes, 3 sessions of group discussion, a 30-60 minute home visit, and a 10-30 minute telephone follow-up call. The control group will only receive routine care. Baseline data will be collected with follow-up collections at 1 and 3 months. The primary outcome will be the improvement of diabetes self-management ability. Multivariable generalised estimating equations approach will be used to explore differences in the groups over time.

Conclusion: This study will be the first trial investigating the effectiveness of an evidence-based diabetes self-management intervention—aspects of Self-Efficacy Theory and family involvement—tailored for people with type 2 diabetes, living in rural communities in Thailand.

Keywords: carer, diabetes, nurse-led, protocol, self-efficacy, self-management

INTRODUCTION

Diabetes mellitus is one of the most common chronic diseases in both developed and developing countries with approximately 56 million people in Europe and 72 million people in South-East Asia being affected [1]. In 2013, Type 2 Diabetes Mellitus (T2DM) represented the predominant form of diabetes accounting for 85% to 95 % of all cases [1].

The prevalence of diabetes (all forms) within Thailand was 7.5% in a 2009 report [2]. Most individuals being treated for diabetes manage to control their blood glucose levels with 28.5% remaining uncontrolled and susceptible to major complications. Interventions that are uniquely adapted to the needs of the Thai population are a health imperative if the economic burden of the condition is to be contained. Within this study setting (rural community in Thailand), unstructured education is provided to newly diagnosed individuals with T2DM, however, a structured education program that minimises health service use long-term, was required. In addition, rural communities pose challenging environments to the delivery of health services. We describe in this protocol an intervention that brings together the key elements of evidence-based self-management programs—aspects of Self-Efficacy Theory, self-management, and family involvement—to deliver an intervention designed for people with T2DM, living in rural communities. This paper provides particular insights into the key elements of self-management education, a comprehensive set of instruments and clinical outcomes to evaluate an education program, and issues of delivery and follow-up of these programs.

Diabetes self-management education (DSME) refers to methods of assisting people living with T2DM, to improve their diabetes knowledge, quality of life, and glycaemic control, as well as preventing the development and progression of diabetes-related complications [3-5]. Varying characteristics of these educational programs have been considered within interventions including use of a theoretical framework, group versus individual sessions, use of technology, intensity of the delivery (number of hours or sessions provided), and follow-up strategies with telephone and home visit support.

Theoretical foundation of diabetes education

Several theoretical frameworks have been used to develop the educational content and/or deliver strategies within either DSME or other education programs. Systematic

reviews of DSME programs have described the use of such theories as: health belief model, self-efficacy, social cognitive theory, social support, and trans-theoretical model [6]. These theories focus predominantly on changing behaviour related to lifestyle factors (diet and exercise) and encourage effective blood glucose monitoring [6].

Self-efficacy, derived from social cognitive theory, is another concept which is broadly acknowledged as enhancing an individual's confidence in their ability to initiate certain behavioural change even in the face of barriers [7]. Various studies have found that self-efficacy is a predictor of metabolic control and is positively related to improved self-management [8, 9]. Self-Efficacy Theory will be used as the foundation for this DSME intervention.

Group versus individual delivery

Varying approaches to delivery of DSME have been described in several systematic reviews [10]. In particular, there is a predominance of individual face-to-face sessions and/or group sessions. Studies using group-based diabetes self-management programs have demonstrated a significant improvement of glycaemic control, knowledge of diabetes, self-management behaviours and quality of life among people living with T2DM [11, 12], although no differences in behavioural outcomes were found [11]. Conversely, other studies have found one-to-one strategies improved glycaemic control compared to group formats [10]. However, group-based DSME is an inexpensive method and has advantages for patients who may live in isolated rural communities. For a rural community in Thailand, the opportunity to meet and discuss how others are managing their T2DM may prove effective. In this study, we propose a combination of group-based education classes with individual sessions delivered at follow-up.

Intensity of the educational intervention

DSME is well established as improving self-management behaviours and glycaemic control, however the quality (contact hours and other features) of the intervention is also related to improved outcomes [13]. Greater improvement in HbA1c levels was found in an intensive intervention (12 group sessions, monthly telephone contact, 3 encouragement postcards) compared to minimal intervention (pamphlets by mail) [13]. DSME programs offering 11 or more contact hours resulted in greater improvements in glycaemic control,

while 10 or fewer contact hours delivered only slight improvements in controls [14]. However, a meta-analysis of 20 randomised controlled trials found total duration of intervention, number of sessions, and duration of each session did not influence alterations in glycaemic control [10].

Use of technologies to deliver education

Various promising technologies have been used to improve diabetes self-management including computer-based, social-media, telemedicine, and web-based education. A systematic review found that glycaemic control ability in the intervention group (received telephone calls) was better than the control group [5]. Furthermore, a systematic review of computer-based interventions demonstrated enhanced self-care behaviours and adherence to treatment regimens using these interventions [15]. However, a meta-regression of 20 randomised controlled trials found better improvements of glycaemic control were observed in educational programs provided face-to-face [10].

Follow-up support

Follow-up support, such as regular telephone contact or home visits, encourages and reinforces developing self-care behaviours [16]. Telephone follow-up (weekly and/or biweekly) support, after an initial DSME program combined with mobile coaching, was found to reduce HbA1c levels [16] and enhance mental health related quality of life [17]. Telephone support is likely to be helpful to people with T2DM living in rural communities where there are difficulties in being transported to local health facilities. Transportation difficulties have been found to be a barrier to self-care for people with T2DM [18].

Home visits are an effective educational health care strategy [18], and in this study will provide an opportunity for individualised education. Home health care and telephone support among diabetes patients have been found to be beneficial in preventing readmission [19]. Both telephone support and home visits will be included in this study.

Family involvement in T2DM

Family-based interventions are effective in enhancing diabetes related-knowledge, self-efficacy, self-care ability, glycaemic control and quality of life among individuals living with T2DM [20, 21]. Although most studies show the benefits of family-based interventions,

one study found no significant decrease in blood glucose levels between family and non-family involvement [22]. Within Thai society, family members play a key role in providing physcial, mental and socio-economic support [23], although studies within rural communities, where the benefit may be increased, have not been undertaken. Family memberss will form a key component of the DSME program to be implemented in this study.

In the Thai healthcare system, nurses play a major role in offering diabetes care for individuals with T2DM. However, nurses are often unable to meet the high demand for care with only 35% of the primary care units in Thailand providing comprehensive service delivery [24]. It was envisaged that the additional support provided by family members, if found effective, may reduce the demand for nursing services. Nurses have been identified in the literature as key health professionals in the delivery of diabetes education to patients in acute and primary care settings. A review of the effects of nurse-led care in diabetes found that nurses were delivering education, individualised care, promotion of self-care, and other content, resulting in improved glycaemic control and symptom management [25]. A nurse-led intervention is supported in this study.

Although several self-management diabetes educational interventions have been conducted in Thailand, none of those studies has incorporated family members as part of the education intervention. This trial will be the first trial in Thailand evaluating the effectiveness of an evidence-based DSME intervention, based on Self-Efficacy Theory, which includes the family member within the intervention, with telephone and home visit follow-up, to enhance diabetes self-management for people from rural Thai communities. In addition, we will explore the family member's perceived improvement in their abilities to support the person with T2DM which may result from participating in the intervention. We hypothesise that this evidence-based, family-supported self-management program can improve diabetes knowledge, self-efficacy, self-management, glycaemic control, and quality of life among Thai individuals living with T2DM, compared to those receiving standard care.

METHODS

Aims

The aim of the study was to test the efficacy of a nurse-led family-supported self-management education program for individuals living with T2DM living in a rural Thai community with follow up assessments at one and three months.

Design

A prospective single-blinded randomised controlled trial is defined in accordance to Consolidated Standards of Reporting Trials (CONSORT) guidelines. The setting will be the diabetes clinics within a 30 bed rural community hospital, in Surattani Province, Thailand.

Sample size calculation

The sample size was estimated based on a known effect size (effect size = 0.58) from the primary outcome of diabetes self-management score (Mean difference = 8.35, SD = 14.28) [9]. 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), and a sample of 100 people (50 per group) is required.

Participant eligibility

Participants for the study will be individuals diagnosed with T2DM attending the community hospital and their family member. All participants will need to be literate in the Thai language. The lead author (NW) who is a Thai National and a registered nurse will deliver the intervention. The inclusion criteria are individuals: 1) being ≥ 35 years old with a diagnosis of T2DM (diagnosed by a physician ≥ 6 months as recorded in patient's medical file); 2) having a fasting plasma sugar level more than 140 mg% in at least two follow up clinic visits (a month apart); 3) willing to participate in the trial and to receive home visits; 4) having a telephone at home; and 5) with a family member who lives with them. The exclusion criteria includes people with T2DM: who are being treated with insulin, who have severe complications (e.g. retinopathy, stroke), or who are too unwell to participate in the program.

The participants in the intervention group will be asked to bring their family member to attend the diabetes education program. Family members in this trial are defined as a person who supports and helps participants in activities of daily living for example, in preparing meals, managing medication, escorting the person to the hospital, and providing financial support.

Recruitment and Randomisation

The registered nurse at the Diabetes Clinic in the community hospital will identify the participants for enrolment based on the inclusion criteria. These participants will be listed on a database. Participants meeting the eligibility criteria, attending the Diabetes Clinic, will receive an information sheet and verbal explanation of the study by the lead researcher. Participants' consent forms will be signed prior to participants being randomised to either the treatment or control group. Participants will be able to ask questions regarding this study at any time and can withdraw anytime they wish.

A computer-generated sequence of random numbers will be used for both the intervention and control groups. Envelopes will then be placed with the allocated number obscured and will be prepared independent of the research team. The concealed sealed envelopes will be placed in the clinic area. Once the participant has consented to the study, the sealed envelope indicating the group allocation will be opened and the participant will be allocated to the intervention or control group. Data collectors and health care providers will be blinded to the allocation however the lead author will not be blinded. Baseline data including: demographics (age, body weight, body mass index, education level, gender, height, marital status, occupational, income, religion, people in household), disease and complications (duration of disease, comorbidity, complications, blood pressure, fasting blood glucose) and medications, will be collected from the patient healthcare record.

Outcome measures

The primary outcome of the study will be diabetes self-management measured by the Summary of Diabetes Self-Care Activities measure (SDSCA) [26]. The secondary outcomes for participants will be: diabetes knowledge measured by the Diabetes Knowledge Questionnaire (DKQ-24) [27], diabetes self-efficacy measured by the Diabetes Management Self-Efficacy Scale (DMSES) [28] and the Perceived therapeutic Efficacy Scale (PTES) [29],

glycaemic control as shown by HbA1c levels, and quality of life evaluated by the 12-item Short-Form Health Survey (SF-12) [30]. For the family member, the outcome will be diabetes knowledge measured by the Diabetes Knowledge Questionnaire (DKQ-24) [27] and family member's diabetes management self-efficacy measured by the Family Diabetes Management Self-Efficacy Scale (F-DMSES) (Table 1).

Table 1: Outcomes variables and Measures

Variable	Questionnaires/Scales
Primary outcome	
Self-management	Summary of diabetes self-care activities measure (SDSCA)
Secondary outcomes	
Self-efficacy	Diabetes management self-efficacy scale (DMSES)
	Perceived therapeutic efficacy scale (PTES)
Diabetes knowledge	Diabetes knowledge questionnaire (DKQ-24)
Hemoglobin A1C levels	The clinical and demographic data questionnaire
Quality of life	The 12-item short-form health survey (SF-12)
Family-carer diabetes knowledge	Diabetes knowledge questionnaire (DKQ-24)
Family-carer diabetes self-efficacy	Family diabetes management self-efficacy scale (F-DMSES)

DSME intervention

This DSME program was developed based on the Self-Efficacy Theory [7]. According to Bandura's Social Cognitive Theory, perceived self-efficacy and outcome expectation affect behaviour change through four information sources—performance accomplishment, vicarious experience, verbal persuasion, and physiological information [7]. Performance accomplishment is where the participants learn special skills for enhancing confidence and changing behaviours including practicing meal planning, engaging in physical activities, monitoring signs and symptoms and problem-solving. Vicarious experience encourages participants who perform appropriate behaviours to be models (demonstrating desired behaviours) for other participants. Verbal persuasion supports participants to undertake more self-management activities. Finally, in physiological information, participants learn ways to identify emotional issues and find solutions.

Diabetes education classes to enhance self-efficacy will be offered within 3 sessions (at baseline, week 5 and week 9) of 3 hours duration using the supportive approaches outlined (performance accomplishment, sharing experiences [vicarious experience], verbal persuasion, and self-evaluation). Participants and their carers will be divided into small groups (8-12 dyads per group). The main goal of the sessions will be to enhance the confidence of participants to carry out necessary behaviours to achieve their own goals. The facilitator will utilise self-efficacy counselling skills to enhance participants' confidence including asking and answering questions, identifying problems, setting goals, maintaining contact with participants, brainstorming solutions, considering past efforts, acknowledging successes and failures, reassessing confidence, and finally checking behaviour changes [31]. The purpose of the home visit in week 3 and the telephone follow-up in week 7 is to encourage participants to maintain their new behaviours. The contact hours (including home visits and telephone calls) will range from 10 to 11 hours approximately, dependent on the individual needs of the participant.

The three Diabetes Self-management Booklets developed for use in this intervention are based on clinical guidelines from the National Institute for Health and Care Excellence [32], National Health and Medical Research Council Australia [33] and Clinical Practice Guideline for Diabetes Thailand [34]. The first booklet (presented at Session 1) provides information on general diabetes knowledge including the meaning, type, signs and symptoms, complications and blood glucose checking. The second booklet (Session 2) will detail the required diet. The third booklet (Session 3) will focus on physical activities and foot care.

Intervention group

The participants and their family member in the intervention group will receive the standard care by clinical staff as well as the nurse-led family-carer supported diabetes self-management education program. The intervention includes: 1) three diabetes self-management education classes with group discussions using three Diabetes Self-Management Booklets delivered on the 1st, 5th, and 9th week; 2) a home visit in the 3rd week, and 3) telephone follow-up in the 7th week (Figure 1). Unlike the control group, participants in the intervention group will be supported by family members who will also

receive education about care provision during the three education sessions mentioned above.

Control group

Participants will receive the standard care (including health assessment, blood glucose monitoring, physical examination, and medication support) from clinical staff in the Diabetes Clinic. Individual health education is provided for new cases as well as individuals with uncontrolled blood glucose following the Thai Clinical Practice Guidelines [34], however, education is unstructured. Family members in the control group will not receive any formal structured education. After the completion of the trial, a two-hour diabetes education class and the Diabetes Self-management Booklets will be offered to the control group.

Data collection

Before randomisation all participants and carers in the intervention group will be asked to complete baseline questionnaires. The follow-up assessment questionnaires will be collected at the 5th and 13th week after entering the program at the diabetes clinic while participants return to hospital for follow-up every 4 weeks. Questionnaires will take approximately 30 minutes to complete. All baseline and assessment questionnaires will be administered by research assistants who will be blinded to study group allocation. If participants or their carers suffer any distress or psychological injury as a result of this research project, participants will be advised to contact the Diabetes Clinic manager as soon as possible.

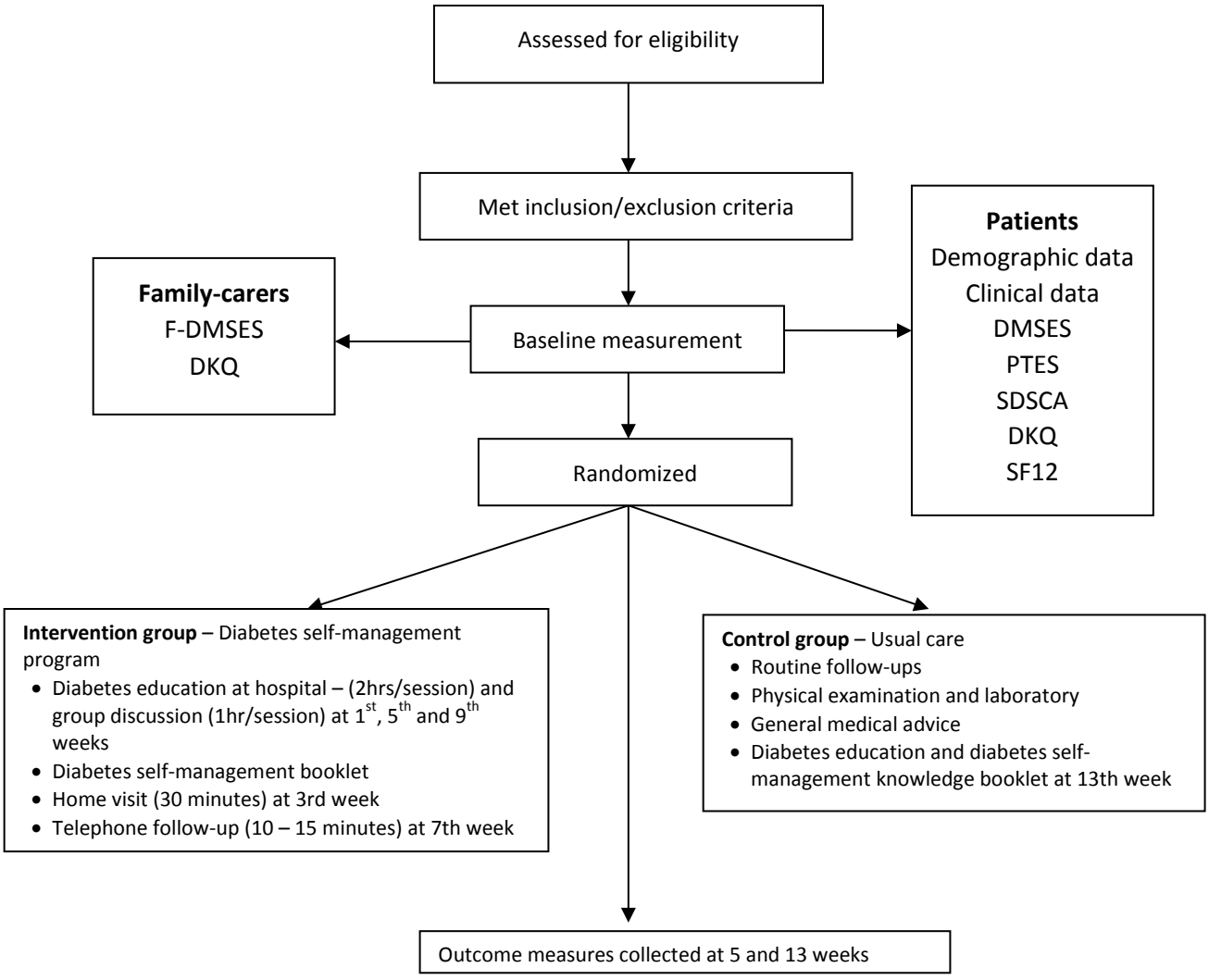

Figure 1 Flow of participants

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), F-DMSES (Family diabetes management self-efficacy scale)

Validity and reliability of instruments

Questionnaires (DMESE, SDSCA, and SF-12) previously translated into the Thai language and validated will be used in the trial. Questionnaires (DKQ-24, PTES) without Thai language versions will be translated from the English language version into a Thai language version using a forward and back-translation technique.

The SDSCA includes 11 items relating to how often diabetes self-care activities – diet, exercise, blood glucose checking, foot care, and smoking status – were performed over the past 7 days [26]. The Thai version of SDSCA was translated and tested for reliability on 30 Thai individuals living with T2DM. The average inter-item correlation scores within components was high (r = 0.43) and the test–retest reliability was 0.89 [35].

The DKQ-24, elicits information about the disease and complications, and has a demonstrated Cronbach's alpha of 0.78 indicating internal consistency [27].

PTES was developed to measure participant confidence on outcome expectation [29]. Individuals with T2DM accomplish self-management behaviours, which reach the required outcomes (outcome expectation). Outcome expectations provide the motivation for certain behaviours. This instrument contains 10 items that are rated on a 5 point scale. The PTES has demonstrated internal consistency (alpha 0.94 - 0.96) and test-retest reliability (0.64-0.80) [29, 36].

DMSES is a self-administered questionnaire consisting of 20 items. Higher scores indicate better diabetes management self-efficacy. The internal consistency of the English version was 0.81 and the reliability was 0.79 [28]. The Thai language version of DMSES will be used in the current trial. Content validity of the DMSES Thai version has been assured with a reported content validity index of 0.96, internal consistency with a Cronbach's alpha of 0.95, and test-retest reliability of ICC = 0.69 [37].

The Short-Form Health Survey (SF-12) contains 12 items with a response scale ranging from 2 to 6 [30]. The 12 items cover self-assessment of health, physical functioning, physical role limitation, mental role limitation, social functioning, mental health, and pain. The summary score indicates physical (PCS-12) and mental (MCS-12) functioning. Higher scores indicate greater quality of life. The Thai version has been tested demonstrated internal consistency ($\alpha = 0.83$) [38].

The F-DMSES is a self-assessment Likert scale with 20 items. It was developed by the author to assess the family member's confidence in assisting an individual with T2DM to manage their diabetes. The F-DMSES was adapted from the Diabetes Management Self-Efficacy Scale [28].

Ethical Considerations

Ethics approvals were obtained from the Australian Catholic University's Human Research Ethics Committee in October 2014, approval number 2014-222Q and Suratthani Public Health Office in Thailand, document number ST0032.009/4824. Written consent will be obtained from all participants and family members. The trial has been registered in the Australian New Zealand Clinical Trials Registry, registration number ACTRN12615001249549. Date registered: November 16, 2015.

Data management

Data entry will be checked by two researchers with logit checks for out-of-range scores being undertaken. Data management procedures are defined and held with the research team available upon request. All data will be confidential and anonymous. Data will be stored with no identifiable information of any participant. All data files will be password protected and all hardcopies of data will be stored in a locked cabinet when not in use.

Data analysis

Continuous data such as the study outcome measures will be modelled using a multivariable Generalized Estimating Equations regression (that will account for correlated data within this repeated measures design). The intervention and control arms will be compared in adjusted and non-adjusted models. The adjusted models will account for age, gender, body mass index, education, occupation, income, duration of illness, baseline HbA1c levels, presence of DM-related complications, presence of comorbidities, and systolic blood pressure at baseline. Statistical significance will be set at a P-value of < 0.05 (two-sided).

DISCUSSION

Diabetes mellitus remains a challenging condition for many nations throughout the world. Countries like Thailand are also experiencing the increased economic and social burden related to T2DM [39]. The cultural and family ties of the Thai people provide an opportunity to explore how family members can support the health outcomes of individuals living with T2DM within a rural community. This intervention, developed from existing evidence and adapted for this rural setting, will use rigorous methods to evaluate its effectiveness.

This study protocol considers a range of valid and reliable measures, including adaptations for Thai language and culture, to adequately identify the relevant changes in ability and clinical outcomes, including the improvement in family member's ability to assist self-management. A single-blinded RCT prospective design has been chosen to ensure results are comparable to existing trials, while providing the strongest possible evidence of effectiveness.

The primary outcome measure of this study is diabetes self-management, and therefore the application of Self-Efficacy Theory, which enhances perceptions of ability to self-manage, is well-considered. The greater the perceived efficacy, the more vigorous and persistent individuals will be to engage in the required behaviour, even in the face of barriers [7]. Higher self-efficacy is also related to improved glycaemic control, medication adherence, and quality of life [8, 9]. These studies confirm that interventions based on Self-Efficacy Theory are associated with better self-management among individuals living with T2DM, and this theory and related education strategies, form the distinct DSME program proposed within this protocol. The study findings will contribute to knowledge relating to the application of Self-Efficacy Theory in the management of chronic conditions.

The additional benefit of a nurse-led family support in the self-management of health conditions is emerging in the literature. This study provides further knowledge on how family-carers benefit people living with chronic conditions within differing contexts. A systematic review of 19 randomised controlled trials reveals the effectiveness of family interventions in improving diabetes knowledge and glycaemic control [22]. Participants who had family members' involvement were more likely to have greater improvement of glycaemic control than those participants who did not have family members' involvement

[20, 22]. Martire noted that nearly half of the 12 randomised controlled trials demonstrated that a family intervention was more beneficial than patient interventions, with one adverse finding that a family-oriented intervention led to reduced self-efficacy and increased fatigue [40].

These studies confirm that a nurse-led family-supported intervention enhances diabetes self-management behaviours. A Thai community can provide a unique setting in which a family-supported approach can be introduced, whereby the intervention protocol in this study complements existing family and religious traditions about children supporting parents. Where family support persons are children there is also the opportunity to teach potential new individuals living with diabetes within the family how to avoid the condition. In addition, engaging family support for individuals with T2DM has the potential to reduce the demands on nurse educators and health services by providing additional support and reducing complications [41].

Limitations

The conduct of this trial in a community-based hospital within a rural setting may not represent all individuals with Type 2 diabetes in Thailand particularly those from urban settings. In addition the trial necessarily excludes the most severe cases. In this study we will explore the family member's perceived improvement in their abilities to support the person with T2DM, however, the unique contribution of the family member, to the outcome measures will not be examined. We will be unable to control for the impact of family members on the control group, which may occur inadvertently.

CONCLUSION

T2DM remains a major health concern worldwide and the advancing knowledge base originating in westernized countries may be significantly informed by studies conducted in rural communities with limited resources. We have outlined in this protocol an intervention that brings together the key elements of evidence-based DSME programs—aspects of Self-Efficacy Theory, self-management, and family involvement—to deliver an intervention appropriate for people, with T2DM, living in rural communities in Thailand. Comparisons of the findings from this study, with other findings can inform all health educators, but particularly those within small rural communities.

DISCLOSURE

The authors declare that they have no competing interests.

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3.14 Summary

This chapter outlined the methods used to conduct this randomised controlled trial to evaluate a family-oriented DSME program including the development of the program. Additionally, the critical elements of an RCT, data management and analysis, and ethical considerations have been described. Population, sample, sample size calculation, outcome measures, and procedures for data collection were also presented in the protocol paper in section 3.13 (Wichit, Courtney, et al., 2017).

Chapter 4 presents the findings of the RCT used in this study to test the effectiveness of a theoretically derived, family-oriented DSME program for individuals with T2DM living in rural Thailand which included three follow-up intervals (baseline, week 5 and week 9).

Chapter 4

Study 1 – Results of a Randomised Controlled Trial to Test the Effectiveness of a Theoretically Derived, Family-Oriented Diabetes Self-Management Program for Individuals with T2DM Living in Rural Thailand

4.1 Introduction

The protocol for the RCT of a family-oriented DSME program to improve diabetes knowledge, self-efficacy, glycaemic control and quality of life for individuals living with T2DM in rural Thailand was presented in Chapter 3 (Wichit, Courtney, et al., 2017). Chapter 4 provides details of the intervention and control sample characteristics, and the findings of the trial in relation to primary and secondary outcomes. The peer-reviewed publication of the results utilising a randomised controlled trial design is included in this chapter (Wichit,Mnatzaganian, et al., 2017a). This chapter was designed to answer the following research hypotheses:

Within-group comparisons for the intervention group

H1: For individuals with T2DM receiving the family-oriented DSME intervention, there will have been an improvement in diabetes knowledge (measured by the diabetes knowledge questionnaire [DKQ]), self-efficacy (measured by the diabetes management self-efficacy scale [DMSES] and perceived therapeutic efficacy scale [PTES]), self-management (measured by the summary of diabetes self-care activities measure [SDSCA]), HbA1c, and quality of life (measured by the 12-Item Short Form Survey [SF-12]) at week 5 and at week 13 when compared to the baseline.

Within-group comparisons for the control group

H2: For individuals with T2DM receiving the usual care, there will have been no improvement in diabetes knowledge (measured by the DKQ), self-efficacy (measured by the DMSES and PTES), self-management (measured by the SDSCA), HbA1c, and quality of life (measured by the SF-12) at week 5 and at week 13 when compared to the baseline.

Between-group comparisons

H3: Individuals with T2DM receiving the family-oriented DSME intervention will have diabetes knowledge higher scores (measured with the DKQ), self-efficacy (measured by the DMSES and PTES), and self-management (measured by the SDSCA) at week 5 and at week 13 compared to the scores of those who receive usual care.

H4: Individuals with T2DM receiving the family-oriented DSME intervention will achieve an HbA1c target of 7.0% at week 5 and at week 13 compared to the HbA1c target of those who receive usual care.

H5: Individuals with T2DM receiving the family-oriented DSME intervention will demonstrate an increased quality of life (measured by the SF-12) at week 5 and at week 13 compared to the quality of life of those who receive usual care.

4.2 Description of Study Sample

A total of 153 individuals were assessed for eligibility, however, nine did not meet the inclusion criteria and four refused to participate. After the assessment process, 140 people with T2DM agreed to participate and signed the consent form. When their baseline measurements were completed, participants were randomly allocated to either the control or the intervention group utilising a computer-generated sequence of random numbers. Consequently, 70 participants were allocated to the control group and 70 were allocated to the intervention group. Of the 70 participants in the control group, three participants did not continue with the program during the follow-up phase due to personal reasons, thereby reducing the number of participants in the control group at week 5 and at week 13 to 67. In the intervention group, 67 participants completed the study. Two participants did not continue with the program during the follow-up phase at week 4 due to either leaving the district or having transportation problems. Additionally, one participant required insulin treatment at week 9. The final number of participants in the intervention group at week 5 and at week 13 was 68 and 67 participants respectively.

The baseline data of 140 participants were analysed. Most participants were female (72.9%) and married (80%). The average age was 58.4 (SD = 11.4) years and the average income of participants was over 25,000 baht per month (20.7%). Most had primary school education (71.4%). The majority of participants were farmers (41.4%). Four in five (81.4%)

participants had existing comorbidities and 14.3% had complications related to diabetes. The average duration of diabetes was 5.7 years (SD = 4.5).

Seventy carers of individuals with T2DM in the intervention group agreed to participate. Sixty-seven (95.7%) participants completed the study. More than half of the carers were female (51.4%) and most were either spouses (51.4%) or children (40.0%) of individuals with T2DM. No demographic data, other than the gender and role of the participants, was collected, although all carers were 18 years or older.

Findings from the trial indicated that participation in the family-oriented diabetes self-management program significantly improved diabetes self-efficacy, self-management, and quality of life in the intervention group. No improvement was evident in the control group (Wichit, Mnatzaganian, et al., 2017a). Further findings are presented in the detail of the relevant publication, which is presented in the following section.

4.3 Publication Relevant to this Thesis

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017a). 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. Diabetes Research & Clinical Practice, 123, 37-48. doi: 10.1016/j.diabres.2016.11.013

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

ABSTRACT

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 (β=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 glycaemic control, however, in the risk-adjusted multivariable models, higher self-management scores were associated with significantly 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.

Keywords: Health outcome, Family-oriented, Self-management, Type 2 diabetes, Randomized controlled trial.

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 glycaemic 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 glycaemic 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 utilised [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 to 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 (Figure 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 (α = 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 (α = 0.78) [37]. The SF-12 (Thai), with 12 items, had scores from 0–100 points, with higher scores reflecting better quality of life. The internal consistency of the Thai version of SF-12 is good with α =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 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 =< 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 Figure 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).

Table 1: Baseline characteristics of individuals randomised 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 = < 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

* Within group comparisons were analysed using the non-parametric Friedman test. Statistical significance was determined at *p* value = < 0.05.

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)

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 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).

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

* Between-group comparisons were analysed using the non-parametric Mann-Whitney test. Statistical significance was determined at *p* value = < 0.05.

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)

Table 4: Prediction of individual patient outcomes over time by baseline variables: repeated measures Generalized Estimating Equations in seven multivariable analyses* – intention 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††							
Agent1	-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
Agent2	-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

* 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 consisted of the three trial points in time: Baseline, week 5, and week 13

Abbreviations: Agent1 (Taking one hypoglycaemic agent), Agent2 (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)

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 – -0.2, $p = 0.006$), outcome expectations by 0.1 points ($\beta = 0.1$, Wald 95% CI -0.3 – 0.0, $p = 0.02$), and also decreased physical health by 0.2 points ($\beta = 0.2$, Wald 95% CI -0.3 – -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 – -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 – -0.9, $p = 0.02$), diabetes knowledge by 1.9 points ($\beta = 1.9$, Wald 95% CI -3.1 – 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 – -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 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 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 week 13 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% (53mmol/mol) [23] to minimise the risk of developing complications. Study participants were encouraged to achieve and maintain the goal of a HbA1c level of 7.0% (53mmol/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 centre, 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 behaviour 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 and disclosure

All authors have no conflicts of interest relevant to this study.

Acknowledgments

The authors would like to thank all participants and their family members for participating and contributing to this study .Special thanks go to Mrs .Wilaiwan

Boonkumkrong at Thachang Hospital who helped with study coordination and management.

This study was supported by the Australian Catholic University.

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4.4 Summary

This chapter presented the results of an RCT evaluating the effectiveness of a family-oriented DSME program in improving diabetes knowledge, self-efficacy, glycaemic control and quality of life of individuals living with T2DM in rural Thailand. Six hypotheses were examined and answered.

The results support the hypothesis that except for outcome expectation, no between-group significant differences were found in diabetes knowledge, self-efficacy, self-management, HbA1c and physical and mental components of quality of life at baseline. Participants allocated to the control group had significantly higher outcome expectations compared to participants in the intervention group.

After receiving the family-oriented DSME intervention, there was an improvement in diabetes knowledge, self-efficacy and outcome expectation, self-management, and physical and mental components of quality of life. However, there was no change observed in HbA1c levels. Although several studies found diabetes self-management programs improve glycaemic control (Klein et al., 2013; Lou, Wu, Dai, Cao, & Ruan, 2011; Pimouguet, Le Goff, Thiébaut, Dartigues, & Helmer, 2011), others found that HbA1c did not significantly improve through diabetes self-management intervention (Graco et al., 2012; Lorig, Ritter, Villa, & Armas, 2009). For this study, no differences in HbA1c levels were observed.

Although there was no improvement in self-efficacy and outcome expectation, self-management, and quality of life (both physical and mental components) in individuals with T2DM allocated to the control group who continued receiving the usual care, a significant rise in HbA1c levels was observed. However, diabetes knowledge did improve over time in the control group.

Diabetes knowledge, self-efficacy, outcome expectation, and self-management improved for the participants in the intervention group compared to the control group at week 5 and week 13. Although participants' levels of HbA1c in the intervention group remained stable at 7.0% at the baseline and at week 13, the average HbA1c levels for participants in the control

group were higher at week 13 compared to the baseline. Participants in the intervention group were still within the normal range of glycaemic control measured by an HbA1c level of 7.0 %.

Participants allocated to the intervention group performed better in the physical and mental components of quality of life at week 5 compared to the control group but there was no significant difference between the two components in the intervention group participants. However, at week 13 there was a significant difference in the mental QOL component of participants in the intervention group compared to participants in the control group, but no difference was observed between the physical QOL components of the two groups.

The next chapter will provide further information about the measurement and comparison of diabetes management self-efficacy between family-carers and individuals with T2DM as well as present an evaluation of the psychometric testing of the family-carer diabetes management self-efficacy scale (F-DMSES) administered to carers in this randomised controlled trial.

Chapter 5

Study 2 – Development and Testing of the Family-Carer Diabetes Management Self-Efficacy Scale

5.1 Introduction

Previous chapters described the problem and the impetus for the randomised controlled trial that is central to the thesis. An important aspect of the trial was the inclusion of a family member as a carer. Although the DSME intervention program specifically targeted the family-carer to be included within the educational framework that was being delivered to individuals with T2DM, there were no available instruments at the time to measure the family member's perceived diabetes management self-efficacy. The premise of this study was that the family member's ability would be related to that of the individual with T2DM.

Consequently, this chapter presents the design, validity and reliability testing of the family-carer diabetes management self-efficacy scale (F-DMSES) that was specifically developed for this DSME intervention program. Carer diabetes management self-efficacy was assessed using the F-DMSES, which consisted of 20 items in a self-report questionnaire. The instrument was adapted from the diabetes management self-efficacy scale (DMSES) (van der Bijl et al., 1999), and a full description of the psychometric aspects of this scale are presented in the publication by Wichit, Mnatzaganian, Courtney, Schulz, and Johnson (2017b).

5.2 Research Question

Is the family-carer diabetes management self-efficacy scale (F-DMSES) a valid and reliable measure of diabetes management self-efficacy undertaken by family-carers of Thai individuals with T2DM?

5.3 Methods

A subgroup of 70 carers participating in the RCT of this study also completed the F-DMSES's self-reporting questionnaire. A full description of the family-carers of individuals with T2DM who participated in this psychometric testing trial is available in the manuscript submitted for publication, which is detailed in section 5.4 (Wichit, Mnatzaganian, et al., 2017b).

Fourteen items of the F-DMSES were developed and tested for validity and consistency. A content validity index (CVI) and a principal component analysis (PCA) were used to test the content and construct validity of the instrument, whereas the Cronbach's alpha test was used to examine internal consistency. There are several key aspects to consider when establishing a new psychometric scale, particularly aspects of reliability and validity.

5.3.1 Reliability. Reliability is a key standard of the quality of a quantitative instrument and the degree to which the instrument consistently and accurately measures the underlying construct (Polit & Beck, 2004). There are several aspects that can be used to assess the reliability of an instrument including: internal consistency, stability and equivalence (Polit & Beck, 2004). Internal consistency (homogeneity) refers to the degree to which all items in the instrument measure one construct (Heale & Twycross, 2015). Cronbach's alpha measures the average inter-correlation among the items on the scale and it is widely used to examine the internal consistency of a scale (Kimberlin & Winetrstein, 2008).

The coefficient of internal consistency is a number between 0 and 1 and the value of 0.7 and higher is considered acceptable reliability (Bolarinwa, 2015). Stability refers to the correlation of the two sets of testing scores that is administered at two different points of time for the same individuals under similar conditions (Kimberlin & Winetrstein, 2008). Stability demonstrates the instrument's ability to produce consistent results from one test to the next test. High correlation between the scores from each test indicates strong stability (correlation coefficient values of 0.5 and higher are considered strong correlation) (Heale & Twycross, 2015).

5.3.2 Validity. Validity is also a criterion used to evaluate the quality of a quantitative instrument and the degree to which it consistently and accurately measures the construct under investigation (Polit & Beck, 2004). There are several types of validity: content and construct are commonly used. Content validity refers to the degree to which the measurement instrument provides an adequate and representative sample of all the items possible for the specific construct under question (Kimberlin & Winetrstein, 2008).

Content validity is most often measured by the judgment of people who are experts in the construct being measured. The experts are usually asked to evaluate each item of the

instrument and to provide feedback about how well the items captured the construct. Their feedback is analysed and an informed decision can be made about the quality of each item. Relevant and appropriate items representing the construct are two critical aspects evaluates of each item of the instrument. In addition, how well the items adequately measure all aspects of the construct is considered. The Content Validity Index (CVI) is commonly used and is the proportion of item relevance rated by content experts (Polit & Beck, 2006). Experts rate items on a four-point scale (from 1 = not relevant to 4 = very relevant) and a CVI score of 0.78 or higher is acceptable (Polit, Beck, & Owen, 2007).

Factor analysis (FA) is another statistical technique that estimates the construct validity of an instrument (Goodwin, 1999). FA is used to identify and group a large set of variables into underlying dimensions called factors (Polit & Beck, 2004). There are two phases of factor analysis: factor extraction (condensing variables into a smaller number of factors) and factor rotation (moving the axes of the factors for the best construct). A PCA with a Varimix rotation was selected to explore the underlying construct of the F-DMSES. A PCA is a multivariate statistical method and it is broadly used for factor extraction (Polit & Beck, 2004). The PCA identifies "a new set of variables, called the principal components, which are linear combinations of the original variables" (Ringnér, 2008, p 303). Varimax rotation represents an orthogonal rotation and is the most common rotation option in factor analysis (Abdi & Williams, 2010). The following publication describes the psychometric testing of the F-DMSES.

5.4 Publication Relevant to this Thesis

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017b). Psychometric testing of the Family-Carer Diabetes Management Self-Efficacy Scale. Health and Social Care in Community, first published 6 November 2017. DOI:10.1111/hsc.12511

Psychometric testing of the Family-Carer Diabetes Management Self-Efficacy Scale

ABSTRACT

The aim of the study was to develop and test the construct and content validity, internal consistency of the Family-Carer Diabetes Management Self-Efficacy Scale (F-DMSES). A sample of 70 Thai individuals who cared for those living with type 2 diabetes mellitus (T2DM) in a rural community in Thailand was included in the study. Data were collected by a questionnaire survey in January of 2014. The F-DMSES was initially derived from the Diabetes Management Self-Efficacy Scale, with subsequent forward and backward translations from and to English and Thai languages. The psychometric properties (content, construct, and internal consistency) of the Thai version were explored using the Content Validity Index approach, exploratory factor analysis, and Cronbach's alpha test. The F-DMSES initially designed with 20 items, was reduced to 14 items within 4 factors (general diet and blood glucose monitoring, medications and complications, diet in differing situations, and weight control and physical activities), and explained 72.2% of the total variance in the overarching construct. Internal consistency was supported ($\alpha = 0.89$). The F-DMSES was also able to measure change over time following an intervention, with an effect size of 0.9. The F-DMSES is a valid and reliable self-administered instrument that measures the diabetes management self-efficacy of family-carers of individuals with T2DM. This instrument can be used in practice and clinical trials to assess the impact of family-carers on the health outcomes of individuals with T2DM.

Keywords: Type2 diabetes; Family-Carer, Diabetes Management, Self-Efficacy, Instrument

What is known about this topic?

- Appropriate diabetes self-management may improve glycaemic control and quality of life for individuals with T2DM.
- Positive social or family support has been found to improve health outcomes in many chronic conditions, including T2DM.
- Several instruments currently exist to measure self-management ability, although no instrument was found to measure family-carer's support in T2DM.

What this paper adds?

- The F-DMSES is a brief, valid, and reliable instrument measuring family-carer diabetes management self-efficacy.
- This instrument can be used in both clinical practice and intervention studies to assess and monitor the impact of the family-carer on an individual's ability to manage their T2DM.

INTRODUCTION

The ability of patients to self-manage the essential aspects of their diabetes care including blood glucose control, hypoglycaemic medications, diet and exercise, has been associated with improved health outcomes and reduced complications (Wattana *et al.*, 2007). This is particularly relevant to patients living with Type 2 Diabetes Mellitus (T2DM). Various systematic reviews and meta-analyses have shown that self-management interventions for individuals with T2DM can improve health outcomes such as lowering haemoglobin A1C, lipids, and blood pressure levels, and increasing diabetes knowledge and self-management behaviours (Sherifali *et al.*, 2015, Pimouguet *et al.*, 2011, Lou *et al.*, 2011, Minet *et al.*, 2010, Heinrich *et al.*, 2010, Cochran and Conn, 2008). Additionally, improved self-management is associated with delays in onset or reduced risk of diabetes complications (Kent *et al.*, 2013, Boren *et al.*, 2007). Self-management and self-care are terms that are often used interchangeably, however, there are distinct differences. Self-management relates to a cooperative partnership between healthcare professionals, community, patients, and their carers to improve specific skills, namely six self-management skills—problem solving, decision making, resource utilization, the formation of a patient–provider partnership, action planning, and self-tailoring (Lorig & Holman, 2003). Self-care refers to the behaviours used by individuals living with T2DM, such as accessing available resources, to improve their health and wellbeing (Omisakin & Ncama, 2011).

According to Bandura's Social Cognitive Theory, family members are a significant component of the individual's social environment and therefore have a potential impact on individual behaviours (Bandura, 1998). The relationship between an individual and their environments, especially family and society, is a fundamental support that enhances coping mechanisms with a chronic disease (Glasgow et al., 1997). Family support is an important aspect of diabetes care and self-management (Gao *et al.*, 2013, Vaccaro *et al.*, 2014, Rintala *et al.*, 2013) especially in a country like Thailand which places family at the centre of its culture. Family social support can help people living with diabetes increase their adherence to treatments and decrease their risk of developing complications (Miller & DiMatteo, 2013, Mayberry & Osborn, 2012, Rad et al., 2013). In Thailand, an estimated 3.2 million people currently live with diabetes (i.e., 6.4% of the adult population) and it is estimated that by 2035, an additional 1.1 million

Thai adults will develop diabetes (International Diabetes Federation, 2013). Including family members in diabetes care and management may improve the self-efficacy, diabetes knowledge, diabetes self-care among those living with this condition (Shields *et al.*, 2012, Baig *et al.*, 2015, Hu *et al.*, 2014), and improve clinical health outcomes (Hartmann *et al.*, 2010).

Within a recently conducted randomised controlled trial (RCT), we have shown how a family-oriented self-management program improved self-management, self-efficacy, diabetes knowledge, and quality of life among Thai individuals with T2DM (Wichit *et al.*, 2017). This RCT incorporated family members into the intervention meetings, classes, and home visits. The RCT intervention promoted self-efficacy in family members to assist patients with T2DM in diabetes management. There is increasing evidence that family-oriented diabetes self-management programs are effective (García-Huidobro *et al.*, 2011, Keogh *et al.*, 2011). However, most of the currently used family education interventions for diabetes focus on incorporating parents into the treatment and management of the diabetes of their children and limited interventions focus on adult patients and their family members (Baig *et al.*, 2015). Furthermore, no study was identified in the literature that had measured the family-carers' perceptions of their ability to perform the behaviours required to assist another to manage diabetes (for another) or their confidence to do so (self-efficacy). However, the Diabetes Management Self-Efficacy was an established valid and reliable instrument used to measure these constructs in patients with T2DM and was frequently used in experimental studies (van der Bijl *et al.*, 1999).

To self-manage diabetes, individuals need essential knowledge on the pathophysiology and complications of diabetes and an understanding of the behaviours or tasks required of self-management. Self-efficacy is also important referring to the confidence and belief in the ability of a person to adhere to particular behaviours and perform certain tasks that help individuals to achieve a specific goal (Bandura, 1977). Self-efficacy related to T2DM refers to the confidence to conduct such activities as blood glucose monitoring, diet planning, and participating in physical exercise. Individuals with lower levels of self-efficacy are more likely to perceive diabetes self-care activities as a problem (Weijman *et al.*, 2004). Higher self-efficacy has been shown to be effective in improving glycaemic control, diabetes management, health outcomes,

and enhancing quality of life (Walker *et al.*, 2014, DePalma *et al.*, 2015, van de Laar and van der Bijl, 2001, Ha *et al.*, 2014, Greenberger *et al.*, 2014, Yoo *et al.*, 2011).

Including family-carers in diabetes self-management education can improve the carers' confidence and ability to assist their family members with T2DM to manage the disease. Consequently, family-carers of individuals with T2DM who have greater levels of self-efficacy in performing specific required tasks are more likely to have greater levels of success in overcoming barriers and actively supporting specific self-management tasks.

The self-efficacy model has been broadly applied to studies of people with chronic diseases, eg., arthritis, diabetes, hypertension, and dementia (Yoo *et al.*, 2011). In this study this model will be used to describe the perceived self-efficacy of family caregivers. Existing family-carer self-efficacy scales have been developed with other chronic diseases (dementia, cancer, chronic hearth disease) and Type 1 diabetes. Zeiss and others (1999) developed the Caregiving Self-Efficacy Scale for dementia patients and found the benefits of exploring caregiver's self-efficacy. Similarly, Wallston and others (2007) developed the Perceived Diabetes Self Management Scale (PDSMS) to assess the role of parental self-efficacy on adolescents with type 1 diabetes and found that better scores on the PDSMS were related to enhanced self-care and glycaemic control for the adolescent. No instrument was located that measured family-carer self-efficacy for individuals with T2DM, the focus of this study.

The aim of this study was to develop and test the content, construct, internal consistency and ability of the instrument to measure change self-efficacy over time, of an instrument measuring family-carer diabetes management and self-efficacy.

METHODS

Design

The original RCT included data collection at baseline and two follow-up points at the 5th week and the 13th week following a family-oriented self-management intervention that aimed to improve self-efficacy, glycaemic control and quality of life among Thai individuals with T2DM.

Aspects of validity and reliability examined in this study relied on data collected at baseline. The analysis of change in efficacy over time used all three data collection points.

Sample

Seventy family-carers of individuals with T2DM, who were involved in the original RCT, living in a rural Thai community, were included in this analysis. The inclusion criteria were as follows: 1) living with individuals with T2DM in same residency, 2) being a spouse, child, grandchild, sibling, or friend of individuals with T2DM, and 3) aged ≥ 18 years old. A full description of outcomes of the RCT (Wichit et al., 2017) is available elsewhere.

Ethical considerations

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.

Data collection and procedure

Data collection was commenced after individuals provided informed written consent to participate in this study. An invitation to participate was sent by the researcher in the Diabetes Clinic, Thachang Hospital, Thailand. An information sheet was provided together with verbal explanation. Participants who agreed to participate in the study signed the consent form prior to data collection. Data collection was conducted by research assistants who were especially trained for this purpose. Baseline measurement was undertaken in January 2015 followed by follow up measurement at Week 5 (test-retest reliability) and at Week 5 and Week 13 (changes overtime).

Instrument translation development

Instrument construction commenced with the clarification of the concept of family-carer diabetes management self-efficacy. Family-carer diabetes management self-efficacy was defined as a judgment and belief of family members about their capability to perform tasks in

helping their kin to manage their diabetes. In this study, *family-carer* was defined a person who supports and assists the individual in activities of daily living including preparing meals, managing medication, escorts to hospital, and providing financial, mental and physical support.

The Family-Carer Diabetes Management Self-Efficacy Scale (F-DMSES) was modified from the Diabetes Management Self-Efficacy Scale (DMSES) (van der Bijl *et al.*, 1999). The DMSES was chosen as it is a psychometrically sound instrument that comprehensively measures an individuals' confidence (efficacy expectation) to undertake the self-care activities required to manage T2DM (van der Bijl *et al.*, 1999). The F-DMSES was constructed to measure similar efficacy expectation in family-carers to support people living with T2DM including: blood sugar monitoring, diet selection, adjusting diet in various situations, and fundamental health assessment. By using the DMSES as the basis for the F-DMSES, direct comparisons to specific self-care activities could be made between the carer and the individual with T2DM.

The F-DMSES was first generated in the English language and then forward and backward translations techniques were used (Brislin, 1970, Chapman and Carter, 1979). Permission to use the DMSES was sought and obtained from the creator (van der Bijl *et al.*, 1999). Two bilingual translators independently translated the scale from English into the Thai language. This was followed by another review and verification by a bilingual (English and Thai) researcher and two translators who assessed the concepts and the appropriate use of language. The cultural appropriation of the F-DMSES was further reviewed by 4 experts: a diabetes clinical nurse with expertise in patient diabetes education, a diabetes educator, and two teachers of nursing. At a later stage, two independent bilingual translators translated the Thai version of F-DMSES back to the English language. The translations were compared with the original to identify and amend any incorrect use of language and potential misinterpretations. The initial version of the instrument consisted of 20 items.

Instrument validation

Content validity

Content validity of the instrument was assessed by using a two-stage (Development and Judgement-Quantification stage) process (Lynn, 1986). The instrument was developed and

reviewed twice by three expert panels. The expert panel consisted of health professionals (Nurse practitioners) who were experienced in diabetes care (n =2), or the conceptual underpinnings of Self-Efficacy Theory (Nursing lecturer) (n =1). Experts assessed the tool on a 4-point scale: 4=highly relevant, 3= quite relevant, 2= somewhat relevant and 1= not relevant, consistent with the categories outlined in the procedure detailed by Grant and Davis (Grant and Davis, 1997). For each item in the questionnaire, the experts recommended how to rephrase the sentences. The content validity index (CVI) was calculated for each item and the overall score. A CVI score of at least 0.78 (Grant and Davis, 1997) or higher is recommended. Initially F-DMSESF contained 20 items; however, four out of these did not meet the targeted CVI score of 0.78. We introduced some minor changes in the wording of various items. For example, item 3 "To correct their blood sugar when the blood sugar value is too low", was re-worded to read: "To correct their blood sugar when the blood sugar value is too low, such as fainting, sweating and rapid heartbeat". Item 7 was modified to read: "To examine their feet for skin problems, for example pale, cyanosis, bruise, or inflammation". The scale was accordingly modified and re-assessed by the experts. The final total average CVI score 0.93 was obtained confirming the content validity of the instrument.

Pilot testing

The final modified Thai version of the scale was pilot tested on 15 individuals who cared for relatives living with T2DM recruited from another diabetes clinic to further detect and clarify language difficulties and to estimate administration time of the questionnaire. This step confirmed the items were easily read and time required completing the scale ranged from 15 to 20 minutes. This sample was also asked to complete the scale on two occasions. The items within the final version of the instrument can be seen in Table 1.

Analysis

A principal component analysis (PCA) with varimax rotation was used to explore the underlying construct. The varimax approach is an orthogonal rotation option that assumes that the items tested are not highly correlated (Tabachnick and Fidell, 2007). Several steps in this analysis were considered to achieve the best fitting solution with a parsimonious approach to

the selection of items and domains reflecting the underlying construct. These included: a review of the eigenvalues and scree plot with the 1.0 point of a sharp decline or diminishing variance explained being used to select the number of factors (Polit and Beck, 2004). Second, the retention and location of items with a specific factor was guided by a cut-off point of 0.6 or more for factor loadings, with the avoidance of items that cross-loaded on two or more factors (Tabachnick and Fidell, 2007). Finally, the solution obtained was reviewed to ensure that items related to the overarching factor were meaningful and items were deleted if they did not present a meaningful solution. Bartlett's and Kaiser-Meyer-Olkin (KMO) test was used to test the overall significance of all correlations within the correlation matrix, thus measuring sampling adequacy. A KMO of greater than 0.6 confirms sampling adequacy (Kaiser, 1958).

Internal consistency and stability

Internal consistency was examined by calculating Cronbach's alpha, using the value of >= 0.8 as acceptable (George & Mallery, 2003). A Cronbach's alpha of each subscale and the overall F-DMSES were calculated to examine internal consistency of the scale.

Stability or the test-retest reliability of the F-DMSES was measured by the Intra-Class Correlation (ICC) coefficient. ICC values between 0.5 and 0.75 indicate moderate reliability and between 0.75 and 0.9 indicate good reliability, while those greater than 0.9 indicate excellent reliability (Portney & Watkins, 2015). Agreement between the repeated measured scores was further assessed using the Bland-Altman method (Bland & Altman, 1986) which is a graphical method by which the mean differences of the repeated scores are plotted against the averages of the sets of scores.

A repeated measures ANOVA test was conducted to compare mean differences of F-DMSES scores over the three points in time. The effect size of F-DMSES was calculated demonstrating effect of the intervention. The Cohen's d effect size was used (Cohen, 1977).

Table1: The 20 items of original version of Family-Carer Diabetes Management Self-Efficacy Scale.

I am confident in helping my family member:

		Yes Definitely	Probably Yes	Maybe Yes/No	Probably No	Definitely Not
1	To check their blood sugar level if necessary	☐	☐	☐	☐	☐
2	To correct their blood sugar when the blood sugar value is too high for example frequent urination, increased thirst, or fatigue.	☐	☐	☐	☐	☐
3	To correct their blood sugar when the blood sugar value is too low for example rapid heartbeat, fainting, or sweating.	☐	☐	☐	☐	☐
4	To select the right foods	☐	☐	☐	☐	☐
5	To select different foods but stay within their diabetes diet.	☐	☐	☐	☐	☐
6	To keep their weight under control.	☐	☐	☐	☐	☐
7	To examine their feet for skin problems for example pale, cyanosis, bruise, or inflammation.	☐	☐	☐	☐	☐
8	To get sufficient physical activities, for example, taking a walk or biking.	☐	☐	☐	☐	☐
9	To adjust their diet when they are ill	☐	☐	☐	☐	☐
10	To follow their diet most of the time.	☐	☐	☐	☐	☐
11	To take extra physical activities, when the doctor advises them to do so.	☐	☐	☐	☐	☐
12	To adjust their diet when they are taking extra physical activities.	☐	☐	☐	☐	☐
13	To follow their diet when they are away from home.	☐	☐	☐	☐	☐
14	To adjust their diet when they are away from home.	☐	☐	☐	☐	☐
15	To follow their diet when they are on vacation.	☐	☐	☐	☐	☐
16	To follow their diet when they are at a reception/party.	☐	☐	☐	☐	☐
17	To adjust their diet when they are under stress or tension.	☐	☐	☐	☐	☐
18	To visit the doctor once a year to monitor their diabetes.	☐	☐	☐	☐	☐
19	To take their medicine as prescribed.	☐	☐	☐	☐	☐
20	To adjust their medication when they are ill.	☐	☐	☐	☐	☐

FINDINGS

Research population

Seventy carers of individuals with T2DM agreed to take part and 67 (95.7%) participants completed the study. More than half of the participants were female (51.4%) and most of them were spouses (51.4%) or children (40.0%) of patients with T2DM. No demographic data on participants beyond gender and role of participants were collected, although all carers were 18 years or older.

Construct validity

Sampling adequacy was supported and measured by KMO and Bartlett's test, at 0.78 with a statistically significant test of Sphericity (*p* value <0.001). A scree plot identified four potential factors with an eigenvalue of 1.00.

The principal component analysis, using a varimax rotation, identified four factors—general diet and sugar monitoring, medication and complication, diet in different situations, and weight control and physical activities—that explained 69.2% of the total sample variance for the F-DMSES. Six items of the F-DMSES were removed (3 items were cross-loaded and 3 items were not meaningful in relation to the overarching factor) still maintaining the same previously identified factors which now explained 72.2% of the total variance (Tables 2 and 3). The four constructs with their 14 items accounted for 42.9%, 11.7%, 10.3%, and 7.3% of the variance respectively, with acceptable factor loadings higher than 0.6 for all retained items.

Table 2: Eigenvalues and variance explained for factors identified from the principal-component factor analysis for the F-DMSES (n = 70).

Factor number	Eigenvalue	Percentiles of Variance	Cumulative percentiles
1	6.00	42.88	42.88
2	1.64	11.71	54.59
3	1.44	10.25	64.84
4	1.02	7.31	72.16

Table 3: Factor loadings for the 4 extracted factors after varimax rotation (n=70)

Items	Factor 1	Factor 2	Factor 3	Factor 4
I am <u>confident</u> in helping my family member				
Factor 1 (General diet and blood glucose monitoring)				
1. To check their blood sugar level if necessary	0.71			
4. To select the right foods	0.67			
9. To adjust their diet when they are ill	0.77			
10. To follow their diet most of the time.	0.69			
12. To adjust their diet when they are taking extra physical activities.	0.77			
13. To follow their diet when they are away from home.	0.68			
Factor 2 (Medication)				
18. To visit the doctor once a year to monitor their diabetes.		0.86		
19. To take their medicine as prescribed.		0.86		
20. To adjust their medication when they are ill.		0.78		
Factor 3 (Diet in different situations)				
15. To follow their diet when they are on vacation.			0.77	
16. To follow their diet when they are at a reception/party.			0.83	
17. To adjust their diet when they are under stress or tension.			0.77	
Factor 4 (Weight control and physical activities)				
6. To keep their weight under control.				0.89
8. To get sufficient physical activities, for example, taking a walk or biking.				0.76

* Items 2, 5, and 14 were cross-loaded and item 3, 7, and 11 were not meaningful in relation to the overarching factor.

Internal consistency

The Cronbach's alpha coefficient calculated for the 14 items forming the scale was 0.89. The average of inter-item correlation was 0.41 (ranging from 0.06 to 0.78). Cronbach's alpha coefficients for the subscales identified during testing of the F-DMSES for construct validity were 0.85 for general diet and sugar monitoring, 0.87 for medication and complication, 0.83 for diet in different situations, and 0.70 for weight control and physical activities (Table 4).

Table 4: Internal consistency results for subscales and total scale for the F-DMSES (n=70).

Instrument	Number of items	Cronbach's alpha
F-DMSES	14	0.89
General diet and sugar monitoring (Items 1, 4, 9, 10, 12, 13)	6	0.85
Medication and complication (Items 18, 19, 20)	3	0.87
Diet in different situations (Items 15, 16, 17)	3	0.83
Weight control and physical activities (Items 6, 8)	2	0.70

Stability

The Intra-Class Correlations coefficient (ICC), using a two-way mixed-effect model absolute agreement approach, was 0.56 indicating moderate reliability.

The Bland-Altman plot, as shown in Figure 1, shows agreement between the repeatedly measured F-DMSES scores, with a mean difference of 15.12, 95% confidence interval -0.4, +30.64. Only 4 observations were outside the limits of agreement and most observations were within 2 standard deviations of the mean, indicating a good level of agreement among observations over time. Also no proportional bias was detected.

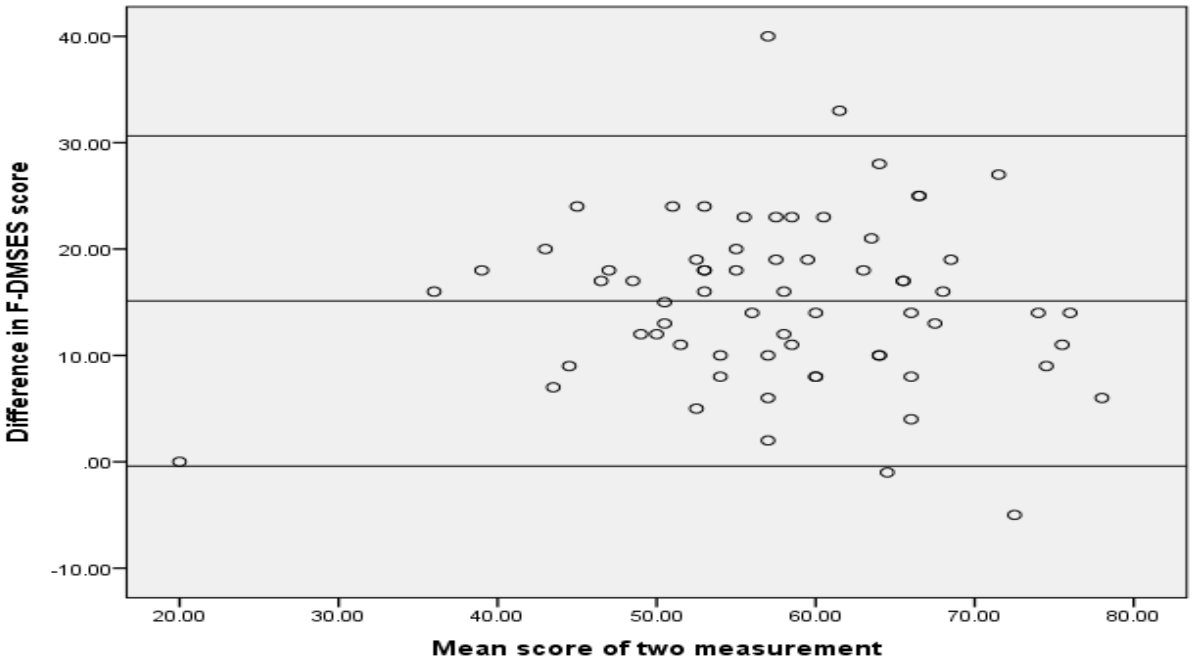

Figure1. Bland-Altman plot of F-DMSES score

Changes overtime of F-DMSES

Table 5 shows the mean scores of family-carer diabetes management self-efficacy significantly improved over time (p<0.001), following an educational intervention as noted in the original RCT (Wichit *et al.*, 2017), demonstrating the scale is sensitive to change overtime. Of the 70 participants, 67 (95.7%) completed the study. Of those 67 participants, 64 family-carers (95.5%) improved over study time in diabetes management self-efficacy skills compared to their baseline measures, one family-carer (1.49%) remained stable, and two carers (3.0%) deteriorated. The effect size of F-DMSES changed scores was 0.9 demonstrating a large effect of the intervention.

A repeated measures ANOVA test with a Greenhouse-Geisser correction showed statistically significant differences in mean F-DMSES scores over time (F (10706.35, 109.0) = 193.79, p< 0.001). Post hoc tests using the Bonferroni correction revealed that the educational intervention produced an improvement in family-carer diabetes management self-efficacy in all points in time, comparing baseline to either week 5 or week 13, and comparing week 5 to week 13, in all p < 0.001.

Table 5: Differences overtime for F-DMES at baseline, Week 5 and Week 13 following intervention (n = 70).

Variable	Baseline (n=70)	Week5 (n=68)	Week 13 (n=67)	*p*-value[‡]	Effect size[*]
Carer diabetes management self-efficacy (F-DMSES)	50.21 (10.98)	65.33 (10.98)	66.03 (11.40)	<0.001	0.9

[*] Effect size = $M_1 - M_2/SD_{pooled}$

[†] Within group comparisons were analyzed using a non-parametric Friedman test. [‡] Statistical significance was determined at p-value=<0.05.

DISCUSSION

Numerous studies use family members to provide additional support to individuals suffering from T2DM (Baig *et al.*, 2015, Hu *et al.*, 2014, Keogh *et al.*, 2011) or chronic disease management (Rosland *et al.*, 2010). Previous research has established relationships between higher levels of carer self-efficacy and better health-related outcomes (Crellin *et al.*, 2014, Au *et al.*, 2009). This study aimed to develop and test the psychometric properties of a newly developed F- DMSES in a sample of family-carers living in a rural Thai community. This instrument validation study included a sample of family-carers that were part of a larger RCT that examined the effectiveness of a family-oriented theoretically derived intervention to improve the health outcomes of Thai people suffering from T2DM (Wichit *et al.*, 2017).

Instrument Validity and Reliability

The development of the items within this F-DMSES logically followed from the DMSES which measures a similar construct within patients with diabetes. The F-DMSES has established reliability and validity for this instrument in 70 diabetes carers. We found 4 factors—general diet and blood glucose monitoring, medications and complications, diet in differing situations, and weight control and physical activities—within 14 items of F-DMESE (explaining 72.2% variance in the overarching construct). Bijl and others also derived 4 factors—nutrition specific and weight, nutrition general and medical treatment, physical exercise, and blood sugar (van der Bijl *et al.*, 1999) within 20 items (explaining 74.1% variance). Similarly 4 factors were

developed for the DMSES Chinese version for patients with T2DM: nutrition, blood sugar and feet check, physical exercise and weight, and medical treatment, (explaining 68.3% variance) (Wu *et al.*, 2008). The findings confirm the 4 domains of self-care management required for individuals suffering from T2DM and in this case their family-carers (explaining 72.2% variance). No doubt the use of the DMSES as the basis for these other instruments has contributed to this outcome; however the domains do reflect the key aspects of the management of T2DM.

Internal consistency was also assured (alpha = 0.89). The reliability of F-DMSES is greater than that found for the DMSES in Dutch language (van der Bijl *et al.*, 1999) whereas closely related to coefficients for the Australian (McDowell *et al.*, 2005) and the Chinese version of the DMSES (Wu *et al.*, 2008). The test-retest reliability was conducted over a four week period with a strong correlation demonstrated ($r = 0.74$, $p < 0.001$). Finally, the ability of the instrument to be measure change following an intervention was determined, with an effect size of 0.9 confirming the sensitivity of the instrument to change. This instrument would be a valuable instrument to measure the impact of family involvement on patient outcomes within experimental studies.

Results of the present study support the use of the F-DMSES as an assessment tool in clinical and research settings. We suggest that researchers use two instruments to measure both the patient (DMSES) and family-carer (F-DMSES) self-management self-efficacy. Both of these instruments could be used in any intervention study that includes both the individual with T2DM and the carer in the study, to increase the impact on patient outcomes. Although the scales are likely to be related, only further studies of larger samples can determine the unique impact that family-carers can have on the clinical outcomes of people living with T2DM.

The F-DMSES offers a simple, effective way to assess carer self-efficacy in diabetes management. The use of the F-DMSES reported in this study will assist health care providers to identify carers at risk and to develop appropriate interventions to assist them with their carer role. The F-DMSES is a self-administered instrument, with 14 items, taking 15 minutes to complete. Diabetes educators or any clinicians working with individuals living with T2DM could use this scale to assess the ability of family-carer to support the person with T2DM on specific self-management behaviours. Family-carers, particularly where the individuals with T2DM may

have limited ability, often attend education sessions with the person with T2DM. Self-efficacy of those carers could be assessed overtime, to see if they are gaining confidence in their ability to support the self-management of the person with diabetes. Where there is limited improvement in a domain for example, general diet and blood glucose monitoring, measures can be made to improve those skills. Optimal performance involves both skills and confidence in order to achieve a specific goal. Interventions that allow individuals the opportunity to develop skills and practice them in their actual carer environment have the highest likelihood of success (Bandura, 1997).

Assessing the self-efficacy of carers of individuals with diabetes is important for clinical purposes to design effective interventions and monitor changes in medical outcomes over time, as carers with low self-efficacy may need more support from their health care provider. To our knowledge, our developed instrument is the first diabetes management self-efficacy scale that measures self-efficacy among carers of individuals with T2DM. Existing measures of diabetes self-efficacy only focus on the patient or parents of youth with Type 1 diabetes. Other family involvement programs use different types of scales measuring the role of family such as parental self-efficacy for diabetes management in young children (Marchante *et al.*, 2014), or Self-Care Self-Efficacy and Problem-Solving Self-Efficacy scales that measure coping skills among caregivers (Zeiss *et al.*, 1999). Our scale was developed to measure particularly family-carer confidence in assisting individuals with T2DM. Empirical studies have shown the effectiveness of family involvement interventions among individual with T2DM in improvement of medication adherence, physical and mental health outcome (Miller and DiMatteo, 2013, Keogh *et al.*, 2011, Kang *et al.*, 2010) however the lack of any tool to assess their likely contribution to the individuals T2DM, has limited the assessment of the precise contribution of the family member.

LIMITATIONS

Although the adequacy of the sample has been demonstrated in the findings, the sample size was nonetheless small. Principal component analysis has been undertaken, further confirmatory factor analysis using another larger sample is recommended. Further testing of this scale in other language and cultural groups is required.

CONCLUSIONS

The F-DMSES (Thai) has been found to be a valid and reliable measure of family-carer self-management self-efficacy within a sample of Thai carers. The instrument can be used in clinical practice to assess the ability and confidence of carers to support the self-management behaviours required of individuals with T2DM. This instrument is also sensitive to change making the F-DMSES suitable for intervention studies. This scale could be used in combination with the DMSES to determine the unique contribution carers make to the health outcomes of persons with T2DM.

Authors' contribution

NW, MC and PS generated and developed the scale in English language. NW collected data. NW, MJ and GM analysed and interpreted of data. All authors were involved in the drafting and revising of the article includes critically important intellectual content, and all authors approved the final version to be published.

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5.5 Summary

This chapter has presented the findings related to the process of developing and testing the new F-DMSES instrument. The F-DMSES is a self-reporting instrument developed to evaluate diabetes management self-efficacy in carers. This study confirmed that F-DMSES is a valid (demonstrating content and construct validity) and reliable (internally consistent) to measure the self-efficacy of family members caring for Thai individuals with T2DM.

The next chapter will compare diabetes knowledge and management self-efficacy between the family-carer and individuals with T2DM to explore the relationship between the two groups.

Chapter 6

Study 3 – Measuring and Comparing Diabetes Management Self-Efficacy between Family-Carers and Individuals with Type 2 Diabetes Mellitus

6.1 Introduction

According to the social cognitive theory described in Chapter 2, the environment is one of three factors that influence an individual's behaviour. The role of the family is one component of the social environment (Bandura, 1977). Self-efficacy, derived from social learning theory, is based on the premise that individuals with greater self-efficacy are more likely to accomplish their goals and be more persistent in the face of difficulties compared to those with lower self-efficacy (Bandura, 1997). Therefore, carers of individuals with T2DM who have a greater level of self-efficacy for performing the task of caring are more likely to have a greater level of success in overcoming the barriers and achieving a level of support for specific self-management tasks. Moreover, family-carers with a higher level of self-efficacy may experience lower physical and mental distress as well as improved wellbeing (Hampton, 2015).

A recent systematic review indicated that the environment is associated with diabetes self-management behaviours (Luo et al., 2015). Furthermore, numerous studies have confirmed that diabetes self-management behaviours are affected by family members (Baig et al., 2015; Rintala et al., 2013; Shi et al., 2016).

Type 2 diabetes mellitus could also be considered a family disease because of the central role family members play in an individual's diabetes self-management. Family members assist with diet management, physical activities encouragement, blood glucose monitoring, medication administration, problem-solving and coping with the disease. In addition, if individuals with T2DM are not able to perform their activities of daily life, family members can provide self-management activities such as food preparation, dressing, cleaning, transportation for medical appointments, and communicating with healthcare providers. Thus, family-carers should be included in DSME programs to enhance their confidence and ability to assist family members with T2DM to manage their disease. Consequently, the involvement of family

members in DSME improves biological, behavioural and cognitive outcomes for individuals with T2DM (Baig et al., 2015; Rintala et al., 2013; Shi et al., 2016; Sinclair et al., 2013).

Several studies across diverse countries (China, Japan, Korea, and Thailand) have outlined the specific role of family-carers in relation to diabetes self-management with the supportive self-care behaviours performed being meal preparation, exercise monitoring, taking medications, blood glucose monitoring, psychological counseling, observing and addressing complications and other aspects (Charoen, Pakdevong, & Namvongprom, 2010; Choi, 2009; Kang et al., 2010; Shi et al., 2016; Watanabe et al., 2010).

6.2 Aim

The study aimed to (1) evaluate family-oriented DSME in improving the family-carer diabetes management self-efficacy and family-carer diabetes knowledge; (2) compare diabetes management self-efficacy between family-carers and individuals with T2DM; and (3) explore the relationship between individuals with T2DMs' diabetes self-management and family-carers' diabetes management self-efficacy, together with family-carer diabetes knowledge.

6.3 Research Questions/Hypotheses

What is the difference between the diabetes management self-efficacy of a family-carer (measured by the F-DMSES) and the diabetes management self-efficacy (measured by the DMSES) of the individual with T2DM?

What is the relationship between the family-carer diabetes management self-efficacy (measured by the F-DMSES) and diabetes knowledge (measured by the DKQ) of the family-carer and the diabetes self-management (measured by the SDSCA) of the individual with T2DM?

6.4 Method

The sample for the study was drawn from the main study, the RCT conducted to test the effectiveness of a DSME program for Thai individuals with T2DM. Seventy individuals living with T2DM and the 70 family-carers of those individuals, all living in the Thachang District, a rural community in Thailand, were included in the analysis. A full description of the sample of both

family-carers and individuals with T2DM is available in the protocol paper (Wichit, Courtney, et al., 2017).

To address the aims of the study, the non-parametric Friedman test was used to evaluate the effectiveness of family-oriented DSME in improving a family-carer's diabetes management self-efficacy and their diabetes knowledge. Comparisons between the individuals with T2DM and family-carer diabetes management self-efficacy over time were analysed using the non-parametric Mann-Whitney U test. Generalised estimating equations (GEE) were used to model each study outcomes while accounting for correlated data within the repeated measures study design.

6.5 Results

The comparison of carer diabetes knowledge and carer diabetes management self-efficacy over time (baseline, week 5, week 13 after enrolment) were conducted and analysed. The results of the within-group comparisons showed carer diabetes knowledge and diabetes management self-efficacy improved over time (baseline to Week5, and Week 13) (p-value < 0.05, in each outcome) (Table 4.)

Table 4
The Mean (SD) for Family-Carer Management Self-Efficacy at Baseline, Week 5 and Week 13 Following Intervention (n = 70)

Outcome Variable	Baseline	Week 5	Week 13	p-value[a]
Carer diabetes management self-efficacy	50.21	65.33	66.03	<0.001
(F-DMSES)	(10.98)	(10.98)	(11.40)	
Diabetes knowledge:	8.10	16.31	14.16	<0.001
(DKS)	(4.39)	(4.23)	(3.98)	

Note: Within-group comparisons were analysed using the non-parametric Friedman test.

[a]Statistical significance was determined at p-value ≤0.05.

Comparing individuals with T2DM and their family-carers on diabetes management self-efficacy found that the total score of DMSE in individuals with T2DM were significantly better

than for the family-carers at all three points of time (p = 0.008, 0.02, and < 0.001 respectively). At the baseline, except for exercise and medication activities, no significant differences were found between individuals with T2DM and their family-carers in all aspects of self-care activities. Between-group comparisons at week 5 and at week 13 indicated that diet, foot care, and self-monitoring were better understood by the individuals with T2DM than the family-carers. However, no between-group differences were seen in exercise at week 5 and in medication at week 13 (Table 5).

Table 5

Comparisons of Diabetes Management Self-Efficacy between Individuals with T2DM and Family-Carers: Baseline, Week 5, and Week 13 (n = 70).

Self-Care Activities	Baseline			Week 5			Week 13		
	Patient	Carer	*P*[a]	Patient	Carer	*P*[a]	Patient	Carer	*P*[a]
Total score mean (SD)	55.6 (12.0)	49.9 (10.7)	0.008	69.8 (11.9)	65.3 (11.0)	0.02	76.0 (9.4)	66.0 (11.4)	<0.001
Diet, mean (SD)	23.4 (5.9)	20.9 (5.0)	0.3	29.3 (6.5)	27.0 (5.4)	0.02	31.3 (4.6)	26.9 (5.4)	<0.001
Exercise, mean (SD)	8.2 (2.0)	7.6 (1.7)	0.05	9.6 (2.0)	9.25 (1.9)	0.4	10.8 (1.7)	9.3 (1.9)	<0.001
Foot care, mean (SD)	2.8 (1.3)	2.6 (1.0)	0.5	3.8 (0.8)	3.5 (0.7)	0.02	4.4 (0.8)	3.4 (0.8)	<0.001
Medication, mean (SD)	11.5 (2.0)	9.6 (2.3)	<0.001	13.2 (1.7)	12.5 (2.1)	0.04	14.0 (1.5)	12.6 (2.2)	0.2
Self-monitoring, mean (SD)	9.8 (3.3)	9.2 (2.9)	0.2	14.0 (2.8)	13.1 (2.3)	0.03	15.5 (2.5)	13.9 (2.5)	<0.001

Note: Between-group comparisons were analysed using the non-parametric Mann-Whitney test.

[a]Statistical significance was determined at *p* value = < 0.05.

Modelling

Using GEE, two separate multivariable models were constructed for diabetes management self-efficacy (DMSES) and diabetes self-management of individuals (SDSCA) with

T2DM while adjusting for baseline variables (Table 6). Family-carer diabetes knowledge (F-DK) significantly improved the diabetes self-management (SDSCA) scores of individuals with T2DM by 0.6 points (β = 0.6, Wald 95% CI 0.1 – 1.0, p = 0.02). Greater family-carer management self-efficacy (F-DMSES) significantly increased the individual with T2DM self-efficacy (DMSES) scores by 0.3 points (β = 0.3, Wald 95% CI 0.05 – 0.5, p = 0.01).

Table 6

Prediction of Individual with T2DM DMSES[a] and SDSCA[b] Over Time by Baseline Variables (n = 70)

Variables	Model 1	Model 2
	DMSES β (Wald 95% CI), *p*	SDSCA β (Wald 95% CI), *p*
Family-carer diabetes knowledge (F-DK)	0.05 (–0.3, 0.4), 0.8	0.6 (0.1, 1.0), 0.02
Family-carer diabetes management self-efficacy (F-DMSES)	0.3 (0.05, 0.5), 0.01	0.08 (–0.1, 0.3), 0.5

[a]Diabetes management self-efficacy scale

[b]Summary of diabetes self-care activities

Note: Besides listed variables in the 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.

6.6 Discussion

The results of the family-oriented DSME intervention program of this study, which is based on self-efficacy theory, indicate there was a direct improvement in self-efficacy for family-carers of individuals with T2DM, which in turn has increased the diabetes management self-efficacy of individuals with T2DM. These improvements were consistent and increased over time. The level of knowledge for family-carers was high, therefore, the family-carer could have a major role in supporting an individual with T2DM.

The study findings contributed to existing research. They demonstrated that the presence of a family-carer can influence an individual's behaviours (Bandura, 1997). The study found diabetes management self-efficacy for the individual with T2DM was better than their family-carer's. This is the first study to formally include family-carers in a DSME program in Thailand. The study found family-carers can make a unique positive contribution to the overall

diabetes self-management activities of individuals with T2DM. Despite diabetes clinical guidelines stating that carers of individuals with T2DM should be included in DSME, diabetes educators have tended to ignore that recommendation and provided DSME only for the individuals with T2DM.

This family-oriented DSME intervention program improved diabetes management self-efficacy in family-carers and diabetes management self-efficacy in individuals with T2DM. Furthermore, the higher diabetes management self-efficacy of the family-carers contributed to the improved self-efficacy of individuals with T2DM. Improved diabetes knowledge and diabetes management self-efficacy in carers can help individuals with T2DM and their carers to reduce the psychological distress associated with managing a long-term chronic condition. This in part may be explained as addressing either their limited knowledge about diabetes or not knowing how to support their loved one. This role may also improve interpersonal relationships. An aspect of the impact on relationships and the carer is a topic for future research beyond the scope of this study.

6.7 Summary

This chapter presented an evaluation of family-carer diabetes self-efficacy and diabetes knowledge. The findings of the study indicate that diabetes management self-efficacy and diabetes knowledge of the family-carers improved over time, which supports the hypothesis that the participation of family-carers in formal DSME programs will benefit individuals with T2DM. The comparison of diabetes management self-efficacy between family-carers and individuals with T2DM indicated that diabetes management self-efficacy in individuals with T2DM was better than for the family-carers. Although the scores for family-carers' self-efficacy were lower than individuals with T2DM, the scores for self-efficacy in family carers remained high (66.0 of 100) indicating that family carers have sufficient ability to provide compensatory care when required.

The discussion of the overall study findings will be presented in the next chapter. Chapter 7 will indicate how the results of current study relate to those of previous studies and the associated literature. The strengths and limitations will be outlined, as will the implications

of the study for patients, healthcare providers and policymakers. Finally, the conclusions of the thesis will be presented.

Chapter 7

Discussion and Conclusion

7.1 Introduction

Chapter 6 demonstrated the effects of family-oriented DSME in improving family-carer diabetes management self-efficacy and knowledge. Further, differences in diabetes management self-efficacy between family-carers and individuals with T2DM, were also compared.

The purpose of Chapter 7 is to discuss the evidence from this series of studies in response to the research questions and hypotheses and aims of the research. Chapter 7 begins with an overview of the key aspects of the investigation, followed by a discussion of the research findings and, finally, the strengths and limitations of the study will be highlighted and the implications of the findings for practice will be considered as well as recommendations for further research.

The central purpose of this thesis was to examine the effectiveness of a family-oriented DSME program for Thai individuals living with T2DM.

7.2 Overview

7.2.1 Setting and cultural context. The Thai culture, the background setting for this series of DSME studies, provided a unique context in which to consider the study's findings. The study was conducted in a rural area where there is strong kinship and family ties. People living in this setting are respectful and help each other.

Healthcare professionals are always called *Mhoa* (Doctor) irrespective of whether they are physicians, nurses, pharmacists or laboratory technicians. Consequently, people who are working in the health industry receive much respect from patients. The relationship between healthcare providers and consumers is usually informal, especially with older people, who consider the healthcare providers to be their children. Healthcare providers also respect their patients and provide care as if they were their relatives, friends or siblings.

The diabetes clinic located in the Thachang Hospital, where the study took place, is located in the centre of Thachang District, so travelling time to the hospital for participants in the study varied from between five and 60 minutes. Those living nearby got to the hospital by walking or by motorcycle, while those who lived a distance away travelled to the hospital by car or public transport. Carers brought patients to the hospital if the patient was not able to get there themselves, or the carer might have dropped them at the hospital in the morning then picked them up at a later time.

7.2.2 Educational intervention and theoretical framework. The education program (both lesson and booklet) was developed in English and then translated into Thai, following a rigorous process over several months. The education program that was finally produced was culturally valid and the language used was appropriate.

Participants in the program acknowledged that the program was very beneficial in that it provided them with new knowledge and practical skills that enabled them to self-manage their diabetes. Additionally, healthcare providers recognised that the lesson plans and booklets that were developed for this research project were based on self-efficacy theory and were comprehensive and easy to use in the diabetes clinic. The education classes were offered in the morning when the participants were waiting to see the physician. However, being worried about missing their position in the queue to see the physician, may have diminished the participants' focus on the education classes. Participants in the intervention and the control groups waited to see the physician in the same location. This may have provided an opportunity for information of the intervention to be shared between participants from both groups and, therefore, contamination may have occurred.

The theoretical framework of this intervention program was based on self-efficacy theory and was successful in improving diabetes knowledge, self-efficacy and self-management. This research utilised self-efficacy and social cognitive theory in a variety of delivery strategies, which included education classes, group discussions, home visits, and telephone follow-ups. The findings of the study support the findings of Zhao et al. (2016) and Hadjiconstantinou et al. (2016) that a DSME program that had been developed with a strong theoretical foundation was more effective in improving health and behavioural outcomes compared to a DSME program

that had no theoretical foundation (Hadjiconstantinou et al., 2016; Zhao et al., 2016). Similar to this research, several other studies had also applied self-efficacy model and Social Cognitive Theory to develop DSME programs and found that the model was beneficial in enhancing diabetes self-management (Sharoni & Wu, 2012; Walker et al., 2014).

The concepts of Social Cognitive Theory such as the self-efficacy component, were found to be effective in shaping this educational intervention, and this finding contributes to the work of other studies in further demonstrating the beneficial effect of using self-efficacy conceptualisations in intervention programs to improve the healthy behaviours of individuals with T2DM.

7.2.3 Sampling issues. After approval was obtained, the researcher contacted the Director of the Thachang Hospital and the purpose and procedures of the proposed study were explained to the hospital's healthcare teams. A notice regarding the study was then placed on the noticeboard at the diabetes clinic, inviting patients to participate in the setting of the diabetes clinic. Many patients expressed interest in participating, however, some of them did not meet the selection criteria. Some individuals with T2DM were not included in the sample due to their fasting blood glucose levels being less than 140 mg/dl, they had no carer living with them, or they had severe complications such as a history of stroke or chronic renal failure. Consequently, these selection criteria would have introduced some bias into the sample because more severe cases of T2DM had been excluded.

Due to the positive relationship between the healthcare professionals and the patients attending the diabetes clinic, the retention rate of participants in the study was high (134/140, 95.7%) and the withdrawal rate was low (6/140, 4.3%). Participants were willing to receive home visits and were most welcoming when the investigator called on them. Other family members, who did not participate in the program, took part in the conversation and asked questions about their loved ones regarding diabetes self-management. Both family-carers and individuals with T2DM found the program very useful and anecdotally reported that they had never received this type of program before in their community. Formal review (beyond the initial development review) of the participants' responses to the intervention was not included as part of this research study but will be undertaken in the near future.

7.2.4 Using the randomised controlled trial design. A randomised controlled trial design was chosen for this study as this method provides the "gold standard" of evidence of the effectiveness of an intervention. Randomisation was used for participant assignment to the intervention and control groups in order to avoid selection bias. Furthermore, randomisation ensures the validity of the statistics used for the analysis of a study's outcomes (Kang et al., 2008).

A parallel-group RCT was selected to assess the effectiveness of family-oriented DSME. Except for the family-oriented DSME program, both groups received the same procedure and equal treatment (routine care and follow-up measurement). Randomisation reduced selection bias. Computer-generated simple random numbers addressed the problem of having a possible unequal number of participants between the groups. The computer-generated unpredictable sequence of random numbers and the allocation concealment were completed by clinical staff independent of the investigator team. The random numbers indicating a participant's assignment to either the intervention or control group were placed into sealed opaque envelopes and were given to participants after completion of their baseline measurements. This randomisation process led to a balance of baseline characteristics between the two groups (Suresh, 2011). The results show that no significant differences were found in most of the baseline demographics between the intervention and control groups except for age.

To minimise study bias, a single-blind design was chosen for this study. Participants were enrolled by clinical staff, who were unaware of the participant's assignment to either of the two groups. In addition, the data collectors were also blinded. After completing the baseline measurements, the participants were assigned to either the intervention or control group. The participants were also unaware of their study allocation. All the healthcare professionals in the diabetes clinic were blinded as well. However, the lead investigator, who was the person entering and analysing the data, was not blinded. As mentioned previously, the possible contamination of the participants in the intervention and control groups could have occurred as a result of both groups waiting for treatment and medication in the same area of the clinic, which would have given an opportunity to share knowledge and information among

themselves. Consequently, such scenarios should be avoided, if possible, in further studies using randomised controlled trials.

This study was designed to capture data during a three-month period, with follow-up assessments at weeks 5 and 13. However, as the HbA1c levels may not have changed within those three months, the National Institute for Health and Care Excellence suggested measuring this clinical outcome at three- and six-monthly intervals (National Institute for Health and Care Excellence, 2015).

This study's high participant retention rate, with only a 4.3% withdrawal rate, could be attributed to the researcher arranging follow-up measurements on the same day as a participant's appointment with the physician, or it could be due to the follow-up support strategies (home visits and telephone calls), which encouraged participants to continue with the program.

7.3 The Effectiveness of the Theoretically Derived, Family-Oriented DSME Intervention for Thai Individuals Living with T2DM

Diabetes management is a challenging task for healthcare professionals worldwide, including Thailand, where the country is faced with increasing diabetes prevalence in the population (Aekplakorn et al., 2011). Self-management care is essential for individuals with T2DM as they need to learn various diabetes self-care behaviours that will help them better manage their health. Several systematic reviews have indicated that DSME programs produce improvements in the knowledge, quality of life, and glycaemic control, as well as the delay of the onset of complications related to diabetes, in individuals with T2DM (Klein et al., 2013; Pimouguet et al., 2011; Wattana et al., 2007).

The self-efficacy model is generally accepted and focuses on behaviour change, which can be employed as a predictor of improved self-management. An individual with a greater perceived sense of self-efficacy will perform better when attempting to accomplish a specific goal, even in the face of adversity or barriers (King et al., 2010). Numerous studies have found that DSME programs based on self-efficacy improve self-management (DePalma et al., 2015; Sharoni & Wu, 2012; Walker et al., 2014). Substantial evidence has demonstrated that

improving self-efficacy in people with diabetes provides a positive influence in the development of self-management techniques and continuing glycaemic control.

Within Thai rural communities there are very strong kinship and family ties. Family-carers often play a significant role in enhancing the healthcare behaviours and wellbeing among their family members including diabetes self-management behaviours for individuals with T2DM. Family education interventions have shown the potential to help patients and family members manage chronic illnesses (Shields, Finley, & Chawla, 2012), and also improve the caregivers' quality of life (Corry, While, Neenan, & Smith, 2015). Family-carers are key individuals who can influence the self-care behaviours of individuals with T2DM (Rintala et al., 2013). Family-carers can assist such individuals with several activities relating to diabetes self-care: diet, physical activities, blood glucose monitoring, and medication administration (Baig et al., 2015). A recent study that focused on family-based interventions for individuals with T2DM confirmed that such interventions develop self-efficacy, a sense of social support, knowledge of diabetes, and self-care ability of diabetes (Baig et al., 2015). This was similar to the systematic review of randomised controlled trials, which demonstrated that involving family members in DSME is productive in enhancing the knowledge of diabetes and glycaemic control within the family unit (Armour, Norris, Jack, Zhang, & Fisher, 2005). The research undertaken for this thesis confirms that a family-oriented DSME intervention program benefits the diabetes self-management ability of individuals with T2DM. The unique nature of Thai rural communities facilitated the ability of this research study to provide an opportunity for healthcare professionals to use a family-oriented approach to enhance diabetes self-management behaviours.

On comparing the results of this study to other Thai studies, the mean scores for the SDSCA were found to be higher in a study by Keeratiyutawong, Hanucharurnkul, Melkus, Panpakdee, and Vorapongsathorn (2006), working with individuals with T2DM only, compared to this study. The reasons for these differences are unclear. Family members may uniquely benefit from this education programme, by reducing their own psychological distress regarding their family member's diabetes and by improving their own health behaviours.

To ensure that results for the control and intervention groups could be compared as the intervention program progressed, key confounding and key outcome measures were undertaken of the two groups at the baseline (the commencement of the intervention program). Except for outcome expectation, there were no significant differences in any of the measurements taken at the baseline between the intervention and control groups. Outcome expectation in the control group was greater than for the intervention group at the baseline.

7.3.1 Within-group comparisons. For the intervention group, the findings from this study show that diabetes knowledge, self-efficacy, and self-management behaviours had significantly improved over time through the delivery of the family-oriented DSME program, although no improvement in HbA1c levels and quality of life were observed in the this group. These results support Wu's study that examined the effects of a self-efficacy program for individuals with T2DM in Taiwan (Wu et al., 2011). Wu developed a self-efficacy-enhancing intervention program and tested the effectiveness of such a program with individuals who had diabetes in Taiwan. The results indicated that an improvement in self-efficacy and self-care behaviours had significantly improved overtime in the intervention group at the three- and six-month intervals when compared to the baseline (Wu et al., 2011). Similarly, Walker et al. (2014) evaluated the impact of self-efficacy on metabolic control, self-care ability, and quality of life for individuals with T2DM, and conclude that self-efficacy is associated to an improvement in metabolic control, self-care ability, and quality of life.

In the study control group, except for diabetes knowledge, no significant differences were found in any of the outcomes at weeks 5 and 13 when compared to the baseline for individuals who had been receiving the usual care for diabetes throughout the randomised controlled trial. Diabetes knowledge in the control group had improved at weeks 5 and 13 when compared to the baseline measurement, which could be explained by the potential contamination factor alluded to previously when the two groups were together in the waiting area of the clinic. It was also noticed that the curiosity of participants receiving the usual care for diabetes was triggered by the information in the questionnaires as they tried to ascertain the knowledge themselves in order to improve their scores at the next measurement point. Some participants stated that when they could not answer the questions at the first

measurement point they realised that the answers to the questions were important for people with T2DM. They then attempted to understand and seek out the correct answers from other resources.

7.3.2 Changes in diabetes knowledge, self-efficacy and self-management. Between-group comparisons were analysed to compare the effectiveness of the family-oriented DSME program in the intervention and the control groups. The findings from this study demonstrate that there is potential for improvement in diabetes self-management through family-oriented DSME programs based on self-efficacy. The family-oriented DSME program delivered as part of this research study proved to be effective in the treatment of diabetes given that participants in the intervention group had significantly higher scores in diabetes knowledge, self-efficacy, and self-management when compared to the scores of those in the control group at week 5 and at week 13 after the commencement of the program.

The results of this study confirm the benefits of DSME in encouraging improvements in diabetes self-care activities. Correspondingly, several other researchers had found that self-efficacy theory had contributed to self-management (King et al., 2010; Walker et al., 2014; Wu et al., 2007; Yoo, Kim, Jang, & You, 2011). Wu et al. (2007) revealed the results of a self-efficacy program for those with T2DM in Taiwan and found that the self-efficacy model could be used as a framework for diabetes education programs. Yoo et al. (2011) also found that a self-efficacy-enhancing intervention could be beneficial for patients with diabetes who set out to improve their self-management behaviours and health status.

Additionally, Zhao et al. (2016) conducted a systematic review and meta-analysis of 20 RCTs with 5802 participants, which indicated that theory-based DSME is more effective in enhancing diabetes knowledge, self-efficacy, and self-management behaviours. Their findings are consistent with those from a systematic review of diabetes self-management undertaken by Lepard et al. Lepard et al. (2015) indicate that interventions based on behavioural theories for individuals with T2DM living in rural areas are more likely to demonstrate improvements in diabetes knowledge, self-management and glycaemic control compared to the control group.

This study has proved that DSME based on self-efficacy and social cognitive theory is effective in improving diabetes knowledge, self-efficacy, and self-management for individuals with T2DM. Therefore, self-efficacy theory should be used to guide the development of a DSME program in either the study design or implementation phase.

7.3.3 Changes in glycaemic control. While numerous studies have previously demonstrated that self-efficacy improves glycaemic control (Klein et al., 2013; Lou et al., 2011; Pimouguet et al., 2011; Sherifali et al., 2015), the findings from this study indicate that there were no differences in the mean scores of glycaemic control between the intervention and control groups at week 13. However, differences were observed in the glycaemic control of participants within each of the groups at week 13: in the intervention group, the average HbA1c levels of participants remained stable (7%) throughout the 13 weeks; in the control group, the average HbA1c levels of participants increased from 6.3% at the baseline to 7.3% at week 13. It should be noted that both groups were approaching normal levels for HbA1c.

The findings of this study support the work of other researchers. Lorig et al. (2009) conducted an RCT examining the effectiveness of a community-based DSME among 345 individuals with T2DM and found that there was no significant improvement in glycaemic control between the participants in the intervention group and the control group after 12 months of the program. These results were different to those from a study conducted by Wattana et al. (2007) which found improved glycaemic control and enhanced quality of life in individuals with T2DM in the intervention group. Moreover, several other systematic reviews found significant improvement in the glycaemic control of participants who had received DSME compared to participants who had continued to receive the usual care (Alves de Vasconcelos et al., 2013; Chrvala et al., 2016; Torenholt et al., 2014; Zhao et al., 2016).

Although the study findings did not uncover significant differences in the glycaemic control between participants in the intervention and control groups, participants in the intervention group still managed to achieve a normal range of glycaemic control (HbA1c levels of 7%). It may be that this was affected by the average HbA1c levels in participants who entered the trial. The duration of the intervention program might be another reason for the non-observation of improvement in the glycaemic control of participants in the intervention group

as the final follow-up measurement was at three months after enrolment, whereas the recommended time for follow-up measurement of HbA1c levels should be at three- and six-month intervals after the final educational intervention is delivered (at week 13 education was still being delivered) as recommended by the National Institute for Health and Care Excellence (2015). Considerable debate exists as to whether a target of 7% is appropriate as the international standard, given substantial glucose variability (Siegelaar, Holleman, Hoekstra, & DeVries, 2010). In this study sample, further reductions of 0.4 -0.5% in HbA1c, may not of been desirable, particularly in the elderly.

7.3.4 Changes in quality of life. The results of this study's intervention program reveal that at week 5 there were no significant differences in the physical and mental aspects of quality of life between participants who had received the family-oriented DSME and those who had received the usual care. However, the mental health aspects relating to quality of life were significantly better in the intervention group than those same aspects in the control group at week 13.

This study also did not identify any elements of the DSME program that could be considered to have influenced the physical health aspects of quality of life. This finding was similar to a meta-analysis of the effectiveness of interactive self-management interventions for individuals with poorly controlled T2DM conducted by Cheng, Sit, Choi, Li, et al. (2016). The meta-analysis of the four studies that had 792 participants in total indicated that there had been no improvement in the participants' quality of life (Cheng, Sit, Choi, Chair, et al., 2016). In addition, Elzen, Slaets, Snijders, and Steverink (2007) studied the effects of chronic disease self-management programs among ageing people and found no significant differences in the physical component of quality of life between their study's intervention and control groups. However, evidence from another systematic review of nine studies indi(46.7 and 54.1 respectively)cated that an internet-based DSME program had improved the quality of life for individuals with T2DM (Cotter et al., 2014). As well, a systematic review and meta-analysis of 22 RCTs with a total of 5802 participants that used theory-based DSME was conducted by Zhao et al. (2016), who found the program improved the quality of life of individuals with T2DM.

No improvement in the quality of life in individuals with T2DM was demonstrated. This may be explained by the initial high quality of life scores found for participants at baseline for both the physical and mental dimensions (46.7 and 54.1 respectively). These high scores may imply that the participants had relatively high quality of life and some adjustment to the condition had occurred. These high scores would represent a ceiling effect on this variable that is unlikely to be amenable to further statistically significant increases.

7.4 Family-Carer Diabetes Management Self-Efficacy Scale (F-DMSES) Psychometric Testing

Several studies have focused on developing a self-efficacy scale based on self-efficacy and social cognitive theory for carers – for example, the revised scale for caregiving self-efficacy developed by Steffen, McKibbin, Zeiss, Gallagher-Thompson, and Bandura (2002), which was used for family members of dementia-disorder patients. Family caregivers' self-efficacy has also been developed by Fortinsky, Kercher, and Burant (2002) for managing patients with dementia. However, those studies did not focus on self-care and were developed by measuring the specific disease. No scale specified the particular task of the carer in diabetes self-care. Hence, a family-carer diabetes management self-efficacy scale (F-DMSES) to measure diabetes management self-efficacy in carers was required. This new scale for the family-carer was developed by modifying the diabetes management self-efficacy scale (DMSES) (van der Bijl et al., 1999), which is used to measure the self-efficacy of individuals with T2DM, with a focus on comprehensive self-care activities.

This new instrument for measuring the diabetes management self-efficacy of carers was developed in English and then translated into Thai to test its validity and reliability for use with carers of Thai individuals with T2DM. The meaning of each item in the instrument was considered when it was being translated into the Thai language for use in the Thai culture. The back-translation technique is a well acknowledged method for translating instruments in health research (Brislin, 1970). In this study, translation and back-translation techniques were used, which were then followed by further review and verification by bilingual experts in order to confirm that the meaning of each item corresponded in both languages. Consequently, the Thai version of the F-DSMES was developed. Psychometric testing of the F-DMSES confirmed the

content and construct validity, and the internal consistency of the instrument. The development of the F-DMSES now provides new opportunities for measuring and monitoring the family-carer's potential of supporting individuals with T2DM.

7.5 Comparing the DMSES for the Individual with T2DM with the Family-Carer

A comparison of the scores of the perceived abilities of the individual and the carer was undertaken as part of this research. The findings revealed that the individuals with T2DM achieved higher scores than the family-carers, which was to be expected, although the family-carer's knowledge could adequately assist the individual with T2DM if required. The results indicate that the family-oriented DSME program based on self-efficacy theory could improve self-efficacy not only in individuals with T2DM but also in the family-carers of individuals with T2DM. Other studies have also described the benefits of self-efficacy for individuals with T2DM (King et al., 2010; Walker, Smalls, Hernandez-Tejada, Campbell, & Egede, 2014). The findings of this study are similar to those of other studies in terms of both individuals with T2DM and their family-carers benefiting from the self-efficacy model.

Although no significant differences were observed in DMSES/F-DMSES at baseline between individuals with T2DM and family-carers in most aspects of diabetes self-management (except medication), however, the total scores of DMSES were significantly different between individuals and family-carers at baseline. Individuals had higher scores in DMSES compared to family-carers at baseline. No significant differences were seen in scores of the perceived exercise activities (a domain within the DMSES/F-DMSES) at the second point of measurement. There were no significant differences in medication (a domain within the DMSES/F-DMSES) between individuals and family-carers in week 13. However, the scores of F-DMSES increased over time after participation in the intervention. Additionally, in the risk-adjusted multivariable model, higher F-DMSES scores were associated with significantly increased DMSES scores in the individual with T2DM, although the gain was small. This study supports the findings of the study of Barrera et al. (2014), who found that family members could encourage increased physical activity in individuals with T2DM.

7.6 Strengths of the Study

This study has a number of strengths. First, to the knowledge of the researcher, the single-blinded randomised controlled clinical trial that was conducted for this study was the first trial in Thailand to incorporate family members in an intervention program. Moreover, this RCT study adhered to the CONSORT statement ensuring the comprehensive reporting of the RCT. The research has supported the current literature in that a culturally appropriate health education program delivered to individuals with T2DM and their carers is effective, particularly in improving diabetes knowledge (Hawthorne et al., 2010). Second, the education program of the intervention was theoretically based and its framework of study, lesson plan, booklets, and teaching methods was based on self-efficacy and social cognitive theory.

The findings of this study have confirmed that theory-based self-management educational interventions are effective in enhancing self-efficacy and diabetes knowledge when compared to the results of the usual care that is normally provided (Zhao et al., 2016), although they did not reveal that the glycaemic control (HbA1c) of the participants with T2DMhad improved as a result of the intervention. The intervention program contained a variety of educational resources that were delivered through diverse teaching strategies, which included diabetes management booklets, face-to-face education classes, group discussions and the practising of skills, home visits and follow-up telephone calls. The program contained multiple components and encouraged participants and carers to increase their knowledge, attitude and self-management ability.

7.7 Limitations of the Study

Although the program was successful in improving diabetes knowledge, self-efficacy, and self-management, it had several limitations, which are detailed in this section.

The DSME intervention program was expected to be delivered over a three-month period, with follow-up assessments at weeks 5 and 13 after commencement, but the last education class and group discussion occurred at week 9. Therefore, the second point of measurement was undertaken prior to the final education class being conducted. It is recommended, therefore, that the measurement interval or the length of the time to the

follow-up in subsequent studies should be increased to enable the effectiveness of the intervention in relation to glycaemic control to be measured 12 weeks after the final educational intervention. Follow-up measurement of the intervention should be undertaken six months to one year after its conclusion to examine the effects on glycaemic control of long-term behavioural change. It would be a positive outcome for this intervention, if participants remained at target HbA1c, even as the condition progresses over 2 to 5 years. Further follow-up research extending to two or five years is recommended.

Another limitation was that the number and dosage of hypoglycaemic agents taken by participants were not standardised for the intervention and control groups. Thus, standardisation of the hypoglycaemic drug is recommended if the measurement of HBA1c levels is to be included in future research. Given the potential effects and varying doses of hypoglycaemic agents throughout the 13-week period of this intervention, the HbA1c outcomes may have been influenced, although normal levels were predominant.

Lack of external validity (applicability or generalisability) is another limitation of this RCT. Low external validity has always been a limitation in many RCTs due to the constrained selection process of patients, which is based on strict eligibility criteria and exclusion of patients at risk of complications. Consequently, the results of trials may be less generalizable. The effectiveness of this study's family-oriented DSME program (which was conducted in a small rural community) may not necessarily represent the circumstances of all diabetes patients in Thailand. To further validate these results in larger samples or urban areas and different cultures, more research is needed. It would also be beneficial to conduct a similar study in other Asian countries that have family structures like Thailand's.

Another limitation is that the study was designed to exclude individuals with T2DM who were being treated with insulin for severe diabetes-related complications and therefore the intervention program sample size was not representative of all possible cases of individuals with T2DM. A person with diabetes was not involved in development of the booklets, therefore the booklets may not reflect what sufferers actually want. Future educational interventions should involve the carer and people with T2DM in the design of the content of booklet rather than only

the review the booklets after design is completed. In this study, the researcher was the facilitator of the intervention, and this may of influenced the desire of participants to improve.

In addition, the Family-Carer Diabetes Management Self-Efficacy Scale, does not address the psychological aspects of caring or inter-personal relationships with the person with T2DM. A further instrument measuring carer distress or psychological health could be used, or further qualitative research could be undertaken to develop additional items for the F-DMSES.

Finally, the sample used to compare the family-carer and individual with T2DM self-efficacy was chosen from the intervention group of the main RCT, which was limited (n = 70). Further testing of this scale in a larger sample and in other languages and cultural groups is recommended.

7.8 Implications for Practice

7.8.1 Implication for patients. The evidence presented in this thesis demonstrates the effectiveness of a diabetes self-management education program that has as its basis the concept of self-efficacy theory. Four information sources of the theory were applied to teaching strategies and education materials and were found to be successful in improving diabetes self-management, self-efficacy, and knowledge. Therefore, providing DSME that is underpinned by self-efficacy theory is an effective method for assisting individuals with T2DM to manage their diabetes. The intervention program for this study was conducted in a rural area of Thailand, where it had a profound impact on the individuals with T2DM who were living there. Given its success, the replication of this program for type 1 diabetes mellitus populations might also be beneficial, or it could be modified for the treatment of other chronic diseases such as stroke, hypertension or heart disease. This program has proved that it can deliver beneficial outcomes for patients and their carers.

Limitations to accessing healthcare services have been found to be a problem in rural settings, especially for rural Thai communities. Findings from the study indicate that this culturally tailored, family-oriented DSME program was effective in improving the healthcare behaviours and diabetes knowledge of individuals with T2DM and their family-carers.

Consequently, the presence of informed carers within the family unit and local community may reduce the burden for healthcare professionals, particularly with regard to long-term care. In addition, acute health problems that occur within a local community may be able to be quickly addressed by informed and available local carers.

7.8.2 Implication for healthcare providers. Thailand's guidelines for best practice for individuals with diabetes emphasise the importance of including the carer within the education process. In reality, this is frequently not undertaken. The findings from this study further confirm the beneficial outcomes of formally including a carer in DSME programs. The program can be easily used by healthcare professionals to train the individual with T2DM and their family-carer to achieve the best possible outcomes, thus meeting the requirements of best practice as stated in the guidelines.

The intervention program for this study incorporated self-efficacy t into a pragmatic plan that enabled the healthcare providers and diabetes educators at the Thachang Hospital's diabetes clinic to effectively deliver DSME to the patients with T2DM that participated in the study. Consequently, such a program will make it easier for other healthcare providers or diabetes educators to understand and deliver DSME to other rural communities. The family-oriented DSME program provides enhanced family support that can reduce the constant need for the intervention of healthcare professionals for individuals with T2DM and thereby has the potential to decrease their workloads due to patients being less dependent upon professional health care providers.

The newly developed F-DMSES is a valid and reliable tool, which can be used by healthcare professionals and researchers in the field or in a clinical setting to evaluate the self-efficacy ability of carers. The scale is relatively short and easy to administer by either healthcare professionals or assistants. This instrument can be used at critical points during the education process to assess the level of diabetes self-efficacy and knowledge of the family-carer and identify areas for improvement.

7.8.3 Implication for policymakers. The findings from this research confirm that including a family-carer into a DSME program can improve the diabetes self-management of individuals with T2DM. Therefore, policymakers should promote this culturally tailored program to other clinics, hospital directors and government. The usefulness of a theoretical foundation in health education programs, especially self-efficacy theory, should be included in nursing educational curriculums for nursing students. Continuing education (short courses) in DSME for practising nurses should also be provided in nursing education programs in order to promote the program more generally. The use of theoretically derived health education interventions should form part of public health education programs as well as medical, nursing and allied health undergraduate and postgraduate educational programs.

7.9 Conclusions

T2DM is a major health concern worldwide, including Thailand with its increasing morbidity and mortality. Thailand has its own clinical practice guidelines for diabetes management; however, the percentage of individuals with poorly controlled of T2DM remains high, resulting in a considerable cost burden to the nation. The study for this thesis has presented an effective theoretically derived, family-oriented DSME program, which was specifically targeted for Thai rural communities. It was a randomised controlled trial that included for the first time family-carers participating in a DSME program together with individuals with T2DM. The findings from this research study confirm that involving family-carers in a DSME program produces improvements in diabetes knowledge and self-efficacy for both the family-carer and the individual with T2DM, which in turn leads to better self-management behaviours practised by the person in the home with diabetes.

This study has also produced a valid and reliable scale for measuring diabetes management self-efficacy of carers of people with T2DM. The scale can be used in both clinical and research settings, with both Thai and English language versions available. The research for this study also revealed a positive relationship between carer diabetes management self-efficacy and diabetes management self-efficacy of family members with T2DM. Additionally, the diabetes knowledge of the carer was positively related to the diabetes self-management of individuals with T2DM.

The findings of this study have the potential to positively affect not only individuals with T2DM but also carers and healthcare providers, especially in other rural communities where there is limited access to healthcare services.

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Appendices

Appendix A: List of publication/Submitted papers by the candidate

A.1 Publication papers by the candidate

Wichit, N., Mnatzaganian, G., Courtney, M., Schulz, P., & Johnson, M. (2017). 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. Diabetes Research & Clinical Practice, 123, 37-48. doi: http://dx.doi.org/10.1016/j.diabres.2016.11.013

DIABETES RESEARCH AND CLINICAL PRACTICE 123 (2017) 37–48

Contents available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

International Diabetes Federation

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

Nutchanath Wichit [a,b,*], *George Mnatzaganian* [c,d], *Mary Courtney* [a], *Paula Schulz* [a], *Maree Johnson* [d,e]

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ARTICLE INFO

Article history:
Received 27 May 2016
Received in revised form
14 November 2016
Accepted 15 November 2016
Available online 19 November 2016

Keywords:
Health outcome
Family-oriented
Self-management
Type 2 diabetes
Randomized controlled trial

ABSTRACT

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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http://dx.doi.org/10.1016/j.diabres.2016.11.013
0168-8227/© 2016 The Authors. Published by Elsevier Ireland Ltd.
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Title: 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

Status: Published in Diabetes Research & Clinical Practice

Statement of contribution of authors:

I acknowledge that my contribution to the above paper is 55%.

Nutchanath Wichit

I acknowledge that my contribution to the above paper is 18%.

Dr.George Mnatzaganian

I acknowledge that my contribution to the above paper is 3%.

Professor Mary Courtney

I acknowledge that my contribution to the above paper is 4%.

Associate Professor Paula Schulz

I acknowledge that my contribution to the above paper is 20%.

Professor. Maree Johnson

A.2 Publication papers by the candidate

Wichit N., Mnatzaganian G., Courtney M., Schulz P., & Johnson M. (2017) Psychometric testing of the Family-Carer Diabetes Management Self-Efficacy Scale. *Health Soc Care Community*. 00:1–10. https://doi.org/10.1111/hsc.12511

Accepted: 11 October 2017
DOI: 10.1111/hsc.12511

ORIGINAL ARTICLE

WILEY Health and Social Care in the community

Psychometric testing of the Family-Carer Diabetes Management Self-Efficacy Scale

Nutchanath Wichit MSc[1,2] | George Mnatzaganian PhD[3] | Mary Courtney PhD[1] | Paula Schulz DPsych[1] | Maree Johnson PhD[4,5]

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Funding information
Australian Catholic University

Abstract

The aim of this study was to develop and test the construct and content validity, internal consistency of the Family-Carer Diabetes Management Self-Efficacy Scale (F-DMSES). A sample of 70 Thai individuals who cared for those living with type 2 diabetes mellitus (T2DM) in a rural community in Thailand was included in the study. Data were collected by a questionnaire survey in January 2014. The F-DMSES was initially derived from the DMSES, with subsequent forward and backward translations from and to English and Thai languages. The psychometric properties (content, construct and internal consistency) of the Thai version were explored using the Content Validity Index approach, exploratory factor analysis and Cronbach's alpha test. The F-DMSES initially designed with 20 items was reduced to 14 items within four factors (general diet and blood glucose monitoring, medications and complications, diet in differing situations, and weight control and physical activities), and explained 72.2% of the total variance in overarching construct. Internal consistency was supported (α = 0.89). The F-DMSES was also able to measure change over time following an intervention, with an effect size of 0.9. The F-DMSES is a valid and reliable self-administered instrument that measures the diabetes management self-efficacy of family-carers of individuals with T2DM. This instrument can be used in practice and clinical trials to assess the impact of family-carers on the health outcomes of individuals with T2DM.

KEYWORDS
diabetes management, family-carers, instrument, self-efficacy, Type 2 diabetes

1 | INTRODUCTION

The ability of patients to self-manage the essential aspects of their diabetes care including blood glucose control, hypoglycaemic medications, diet and exercise has been associated with improved health outcomes and reduced complications (Wattana, Srisuphan, Pothiban, & Upchurch, 2007). This is particularly relevant to patients living with type 2 diabetes mellitus (T2DM). Various systematic reviews and meta-analyses have shown that self-management interventions for individuals with T2DM can improve health outcomes such as lowering haemoglobin A1C, lipids and blood pressure levels, and increasing diabetes knowledge and self-management behaviours (Cochran & Conn, 2008; Heinrich, Schaper, & de Vries, 2010; Lou, Wu, Dai, Cao, & Ruan, 2011; Minet, Moller, Vach, Wagner, & Henriksen, 2010; Pimouguet, Le Goff, Thiébaut, Dartigues, & Helmer, 2011; Sherifali, Bai, Kenny, Warren, & Ali, 2015). In addition, improved self-management is associated with delays in onset or reduced risk of diabetes complications (Boren, Gunlock, Schaefer, & Albright, 2007; Kent et al., 2013). Self-management and self-care are terms that are often used interchangeably; however, there are distinct differences. Self-management

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Title: Psychometric testing of the Family-Carer Diabetes Management Self-Efficacy Scale.

Status: Published in in Health and Social Care in Community.

Statement of contribution of authors:

I acknowledge that my contribution to the above paper is 60%.

Nutchanath Wichit

I acknowledge that my contribution to the above paper is 10%.

Dr.George Mnatzaganian

I acknowledge that my contribution to the above paper is 5%.

Professor Mary Courtney

I acknowledge that my contribution to the above paper is 5%.

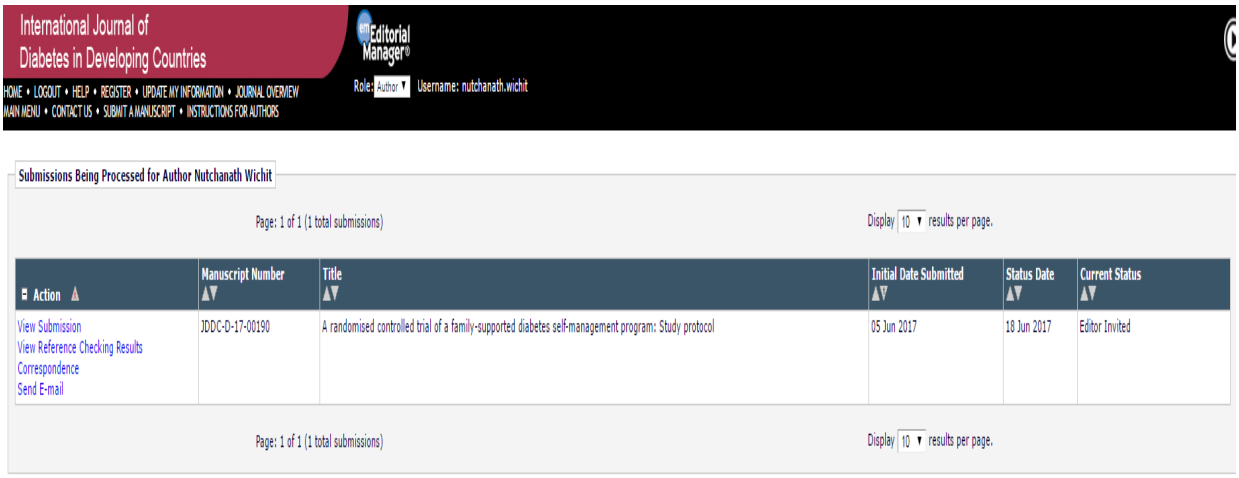
Associate Professor Paula Schulz

I acknowledge that my contribution to the above paper is 20%.

Professor. Maree Johnson

A.3 Submitted papers by the candidate

Wichit, N., Courtney, M., Mnatzaganian, G., Schulz, P., & Johnson, M. (2017a). A randomised controlled trial of a family-supported diabetes self-management program: Study protocol. Manuscript submitted for publication in the International Journal of Diabetes in Developing Countries.



Title: A randomised controlled trial of a family-supported diabetes self-management program: Study protocol

Status: Submitted for publication in the International Journal of Diabetes in Developing Countries.

Statement of contribution of authors:

I acknowledge that my contribution to the above paper is 65%.

Nutchanath Wichit

I acknowledge that my contribution to the above paper is 7%.

Professor. Mary Courtney

I acknowledge that my contribution to the above paper is 5%.

Dr.George Mnatzaganian

I acknowledge that my contribution to the above paper is 3%.

Associate Professor Paula Schulz

I acknowledge that my contribution to the above paper is 20%.

Professor. Maree Johnson

Appendix B: Ethics approval

B.1 Australian Catholic University Human Research Ethics Committee

ACU
AUSTRALIAN CATHOLIC UNIVERSITY

Human Research Ethics Committee
Committee Approval Form

Principal Investigator/Supervisor: Professor Mary Courtney

Co-Investigators: N/A

Student Researcher: : Ms Nutchanath Wichit (HDR student)

Ethics approval has been granted for the following project:
Effectiveness of a self-management program for people with type 2 diabetes and their carer in improving self-efficacy, quality of life and self-management in Thailand

for the period: 30/09/2014-31/01/2015

Human Research Ethics Committee (HREC) Register Number: 2014 222Q

Special Condition/s of Approval
Prior to commencement of your research, the following permissions are required to be submitted to the ACU HREC:
Thachang Hospital

The following standard conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

(i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
- security of records
- compliance with approved consent procedures and documentation
- compliance with special conditions, and

(ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed: .... Date: .... 02/10/2014.....
(Research Services Officer, McAuley Campus)

U:\Ethics\APPLICATIONS\Ethics Applications 2014\2014 222Q Courtney\2014 222Q Approval Formbris 2014.doc

B.2 Suratthani Public Health Office in Thailand

ที่ สฎ ๐๐๓๒.๐๐๙/๔๗๒๔

สำนักงานสาธารณสุขจังหวัดสุราษฎร์ธานี
ถนนการุณราษฎร์ อำเภอเมืองฯ
จังหวัดสุราษฎร์ธานี ๘๔๐๐๐

๓๐ ตุลาคม ๒๕๕๗

เรื่อง การขออนุเคราะห์สถานที่เก็บข้อมูลทำวิจัย

เรียน คณบดีคณะพยาบาลศาสตร์ มหาวิทยาลัยราชภัฏสุราษฎร์ธานี

อ้างถึง หนังสือที่ ศธ ๐๕๐๑.๑๒/๑๘๑/๕๗ ลงวันที่ ๒๒ ตุลาคม ๒๕๕๗

ตามหนังสือที่อ้างถึง ทางมหาวิทยาลัยราชภัฏสุราษฎร์ธานี คณะพยาบาลศาสตร์ ด้วยนางสาวนุชนาถ วิชิต อาจารย์ประจำสาขาการพยาบาลอนามัยชุมชน กำลังศึกษาระดับปริญญาเอก หลักสูตรปรัชญาดุษฎีบัณฑิต สาขาการพยาบาล ณ Australian Catholic University,Campus Brisbane ประเทศออสเตรเลีย มีความประสงค์จะเก็บข้อมูลการวิจัยในคลินิคผู้ป่วยเบาหวานของโรงพยาบาลท่าฉาง นั้น

ในการนี้ สำนักงานสาธารณสุขจังหวัดสุราษฎร์ธานี ได้พิจารณาแล้วยินดีอนุญาตให้ นางสาวนุชนาถ วิชิต อาจารย์ประจำสาขาการพยาบาลอนามัยชุมชน สามารถดำเนินการเก็บข้อมูลเพื่อการวิจัยโดยใช้แบบสอบถาม ได้

จึงเรียนมาเพื่อทราบ และพิจารณาดำเนินการ

ขอแสดงความนับถือ

(นายสามารถ สุนเธียรศักดิ์)
นักวิชาการสาธารณสุขชำนาญการพิเศษ ปฏิบัติราชการแทน
นายแพทย์สาธารณสุขจังหวัดสุราษฎร์ธานี

งานพัฒนาทรัพยากรบุคคล
โทร ๐ ๗๗๒๗ ๒๗๘๔ ต่อ ๑๑๕
โทรสาร ๐ ๗๗๒๘ ๑๒๐๓

B.3 Thanchang Hospital

431 M.1 Thachang, Thachang

Surattani, 84150

8 January 2014

Dear Professor Mary Courtney.

Yes, I support this PhD study of Miss Nutchanath Wichit. Title of study is "Effectiveness of self - management for persons with type 2 diabetes following the implementation of self-efficacy enhancing intervention program in Thailand". Subject to gain ethical approval from Australian Catholic University.

ข้าพเจ้ายินดีให้การสนับสนุนการวิจัยของ นางสาว นุชนาถ วิชิต หัวข้อการศึกษา "Effectiveness of self - management for persons with type 2 diabetes following the implementation of self-efficacy enhancing intervention program in Thailand" โดยที่งานวิจัยนี้จะต้องผ่านการรับรองโดยคณะกรรมการจริยธรรมการวิจัยในคนของ Australian Catholic University ก่อน

(.....)

Sara[illegible] MD

Director of Thachang Hospital

Appendix C: Participant Consent Form

C.1 The English version of an individual participant consent form

PARTICIPANT CONSENT FORM

Title of project Improving the self-management of people with type 2 diabetes in Thailand

Principle Investigator Professor Mary Courtney

Student Researcher Nutchanath Wichit, Ph.D. candidate

I ..... *(the participant)* have read and understood the information provided in the letter to Participants. Any questions I have asked have been answered to my satisfaction.

I agree to:

- Participate in this study which will last for three months.
- Complete a baseline assessment questionnaire.
- Complete follow-up questionnaire at 1 months and 3 months after commencement.
- Participate in the diabetes education program which may include a home visit and telephone follow-up.
- give permission for the researcher to access my medical record.

I realise I can withdraw my consent at any time, if it is not convenient for me, without comment or penalty. I agree that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

NAME OF PARTICIPANT: .....

SIGNATURE ..... DATE .....

NAME OF PRINCIPAL INVESTIGATOR:.....Professor Mary Courtney.....

SIGNATURE ..... DATE .....

NAME OF STUDENT RESEARCHER:.....Nutchanath Wichit.....

SIGNATURE ..... DATE .....

C.2 The Thai version of an individual participant consent form

เอกสารยินยอมเข้าร่วมโครงการวิจัย (ผู้ป่วย)

หัวข้อโครงการวิจัย การพัฒนาโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ ในประเทศไทย

ผู้วิจัยหลัก Professor Mary Courtney

นักศึกษา นางสาวนุชนาถ วิชิต

ข้าพเจ้า..... (ผู้เข้าร่วมวิจัย) ได้อ่านและเข้าใจเอกสารชี้แจงรายละเอียดโครงการดีแล้วทุกประการ ข้าพเจ้าพอใจคำตอบในทุกคำถามที่ข้าพเจ้าได้ถาม และข้าพเจ้ายินยอม

- เข้าร่วมโครงการวิจัยซึ่งใช้ระยะเวลาทั้งหมด ๓ เดือน
- ตอบแบบสอบถามเบื้องต้นก่อนเริ่มต้นโครงการ
- ตอบแบบสอบถามเพื่อประเมินติดตามเมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการ
- เข้าร่วมโปรแกรมการให้ความรู้เรื่องการจัดการตัวเองของผู้ป่วยเบาหวานชนิดที่ ๒ ซึ่งอาจจะรวมถึงการเยี่ยมบ้าน และการติดตามทางโทรศัพย์
- ให้ผู้วิจัยสามารถเข้าถึงข้อมูลทางการรักษาจากบันทึกทางการแพทย์

ข้าพเจ้าทราบว่าสามารถถอนตัวออกจากการวิจัยนี้ได้ตลอดเวลา ถ้าข้าพเจ้าไม่สะดวกโดยไม่มีผลกระทบใดๆ ต่อข้าพเจ้า นอกจากนี้ผู้วิจัยจะเปิดเผยข้อมูลของข้าพเจ้าเพื่อประโยชน์ในการวิจัย และหรือทางวิชาการ โดยไม่ระบุชื่อ/หรือส่วนที่ทำให้รู้ว่าเป็นข้อมูลข่าวสารของข้าพเจ้า.

ชื่อผู้เข้าร่วมโครงการวิจัย: .....

ลงนาม..... วันที่.....

ชื่อผู้วิจัยหลัก:.....Professor Mary Courtney.....

ลงนาม ..... วันที่ .....

ชื่อนักศึกษาผู้วิจัย:.....NutchanathWichit.....

ลงนาม ..... วันที่.....

C.3 The English version of a carer participant consent form

CARER PARTICIPANT CONSENT FORM

Titleof project Improving the self-management of persons with type 2 diabetes in Thailand

Principle Investigator Professor Mary Courtney

Student Researcher NutchanathWichit, Ph.D. candidate

I ..... *(the participant)* the carer of .....*(patient)* have read and understood the information provided in the letter to Participants. Any questions I have asked have been answered to my satisfaction.

I agree to:

- Participate in this study which will last for three months.
- Complete a baseline assessment questionnaire.
- Complete follow-up questionnaire at 1 months and 3 months after commencement.
- Participatethe diabetes education program which may include a home visit and telephone follow-up.

I realise I can withdraw my consent at any time, if it is not convenient for me, without comment or penalty. I agree that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

NAME OF PARTICIPANT: .....

SIGNATURE ..... DATE .....

NAME OF PRINCIPAL INVESTIGATOR:.....Professor Mary Courtney.....

SIGNATURE ..... DATE .....

NAME OF STUDENT RESEARCHER:.....NutchanathWichit.....

SIGNATURE ..... DATE .....

C.4 The Thai version of a carer participant consent form

เอกสารยินยอมเข้าร่วมโครงการวิจัย (สำหรับผู้ดูแล)

หัวข้อโครงการวิจัย การพัฒนาโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ ในประเทศไทย

ผู้วิจัยหลัก Professor Mary Courtney

นักศึกษา นางสาวนุชนาถ วิชิต

ข้าพเจ้า..... (ผู้เข้าร่วมวิจัย) เป็นผู้ดูแลผู้ป่วยเบาหวาน ชื่อ..... (ผู้ป่วย) ได้อ่านและเข้าใจเอกสารชี้แจงรายละเอียดโครงการดีแล้วทุกประการ ข้าพเจ้าพอใจคำตอบในทุกคำถามที่ข้าพเจ้าได้ถาม และข้าพเจ้ายินยอม

- เข้าร่วมโครงการวิจัยซึ่งใช้ระยะเวลาทั้งหมด ๓ เดือน
- ตอบแบบสอบถามเบื้องต้นก่อนเริ่มต้นโครงการ
- ตอบแบบสอบถามเพื่อประเมินติดตามเมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการ
- เข้าร่วมโปรแกรมการให้ความรู้เรื่องการจัดการตัวเองของผู้ป่วยเบาหวานชนิดที่ ๒ ซึ่งอาจจะรวมถึงการเยี่ยมบ้าน และการติดตามทางโทรศัพท์

ข้าพเจ้าทราบว่าสามารถถอนตัวออกจากการวิจัยนี้ได้ตลอดเวลา ถ้าข้าพเจ้าไม่สะดวกโดยไม่มีผลกระทบใดๆ ต่อข้าพเจ้า นอกจากนี้ผู้วิจัยจะเปิดเผยข้อมูลของข้าพเจ้าเพื่อประโยชน์ในการวิจัย และหรือทางวิชาการ โดยไม่ระบุชื่อ/หรือส่วนที่ทำให้รู้ว่าเป็นข้อมูลข่าวสารของข้าพเจ้า.

ชื่อผู้เข้าร่วมโครงการวิจัย: .....

ลงนาม..... วันที่.....

ชื่อผู้วิจัยหลัก:.....Professor Mary Courtney.....

ลงนาม ..... วันที่ .....

ชื่อนักศึกษาผู้วิจัย:.....NutchanathWichit.....

ลงนาม ..... วันที่.....

Appendix D: ANZCTR Trial Registration

Trial Registered on ANZCTR

Trial ID	**ACTRN12615001249549**
Ethics application status	**Approved**
Date submitted	**11/11/2015**
Date registered	**16/11/2015**
Type of registration	**Retrospectively registered**
Registered by	**Nutchanath Wichit**
Web address of trial	**http://www.ANZCTR.org.au/ACTRN12615001249549.aspx**
Public title	**Effectiveness of a self-management program on people with type 2 diabetes**
Study title in 'Participant- Intervention - Comparator- Outcome (PICO)' format	**Effectiveness of a self-management program on people with type 2 diabetes and their care giver in improving self-efficacy, quality of life and self-management in Thailand**
Secondary ID [1]	**None**
Health condition(s) or problem(s) studied:	**Diabetes Mellitus**
Condition category	**Condition code**
Public Health	**Health promotion/education**
Metabolic and Endocrine	**Diabetes**

Appendix E: Participant Information Letter

E.1 The English version of an individual participant information letter

PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Improving the self-management of person with type 2 diabetes in Thailand

PRINCIPAL INVESTIGATOR: Professor Mary Courtney

STUDENT RESEARCHER: NutchanathWichit

STUDENT'S DEGREE: Ph.D. candidate

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

- This research aims to develop and trial a self-management program for people with type 2 diabetes.
- You are invited to take part in this research project because you have diagnosis of type 2 diabetes. I hope this study can enhance the capability of people with diabetes to self–manage and control their blood glucose.

Who is undertaking the project?

This project is being conducted by Nutchanath Wichit and as a part of a Doctor Philosophy at Australian Catholic University under the supervision of Professor Mary Courtney.

Are there any risks associated with participating in this project?

You may feel some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. We do not anticipate any major Adverse Event that might be occurring in the course of the research as a nature or the intervention education. However, if patients and carers become upset or anxious because raising the self-management topic, then the researcher will start exploration about self-management. In addition, the hospital will provide participants and carer a counselling session if you experience any undue fear or anxiety and treat you without extra cost.

What will I be asked to do?

- Prior to commencement, the researcher will verbally inform you about the research project, explain the project and then ask you to provide written consent to participate and to allow the researcher access to your medical records. If you agree to participate in the project, your involvement will be for a three month period. However, you are free to withdraw from this research at any time, if it is not convenient for you, without comment or penalty.
- At the beginning you will complete a baseline assessment questionnaire.
- You will receive the diabetes education program provided by the researcher program which may include group discussion, a home visit and telephone follow-up.
- At 1month and 3 months after commencement, you will be asked to complete follow-up questionnaire.

How much time will the project take?

- Your involvement will be for a three month period. However, you are free to withdraw from this research at any time, if it is not convenient for you, without comment or penalty.
- Completing the questionnaire will take approximately twenty minutes at the beginning and at 1 month and 3 months after commencement. There are no costs associated with participating in this research project, nor will you be paid.
- Participants will receive the diabetes education program 1hours per session at 1st ,5th and 9th week.
- Participants might be asked to participate in 1 hour a group discussion at 5th, and 9th weeks.
- 30 minutes a home visit at 3rd week and 15-20 minutes telephone follow-up at 7th week.

What are the benefits of the research project?

We cannot guarantee or promise you will receive any benefits from this research. However, you will receive the diabetes education program which may helps you to manage yourself for type 2 diabetes mellitus. In addition, the results may have benefit for future patients with diabetes to assist them in improving self-management.

Can I withdraw from the study?

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences. If you do not want to take part, you do not have to. If you decide to take part, you will be given this Participant Information to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the hospital and your treatment.

Will anyone else know the results of the project?

- Data from the questionnaire transcribed to electronic database, will not contain any identifying information. The database will be stored in a file on the G drive that only the researcher will have access to.
- The questionnaire will be kept in a locked filing cabinet that only the researcher will have access to. Once the questionnaires are no longer required they will be placed in boxes and put into secure storage for a period of seven years, after which they will be destroyed.
- The data will be analysed as group data.
- The group results will be made known to the hospital manager or educator.
- Data from questionnaires will only be used for the purpose of this study. It is anticipate the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. All data will be reported an aggregated data. No individual data will be reported.
- It is expected that the results will be published in peer-reviewed journals. No individual will be identified in any publication.
- Your name will not be included on any questionnaire.
- A code number will be used on the questionnaire to match your before and after response.

Will I be able to find out the results of the project?

Once all the data has been entered it will be analysed as group data. Your individual data will not be able to be traced back to you. The group results will be made known to the hospital manager or educator.

Who do I contact if I have questions about the project?

For further information you can contact the researcher anytime:

NutchanathWichit, Ph.D. candidate

Address: 94 M.3 Thachang, Suratthani, 84150

Ph: +61449522117, +66874628935

Email: nunoi_m@hotmail.com, S00148850@myacu.edu.au

or the local site staff you can contact if you have a compliant:

WilaiwanBoonkumkrong, DiabeteClinic manager

Address: 431 M.1 Thachang, Suratthani, 84150

Ph: +6677389124

What if I have a complaint or any concerns?

The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University. If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics

c/o Office of the Deputy Vice Chancellor (Research)

Australian Catholic University

North Sydney Campus

PO Box 968

NORTH SYDNEY, NSW 2059

Ph.: 029739 2519

Fax: 02 9739 2870

Email: res.ethics@acu.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

If you decide you want to take part in the research project, you will be asked to fill out the attached.The researcher will verbally inform you about the research project, explain the project and then ask you to provide written consent to participate and returning it to the researcher. If you agree to participate in the project, your involvement will be for a three month period.

Yours sincerely,

RESEARCHER NAME .....Nutchanath Wichit.....

Signature.....Date.....

E.2 The Thai version of an individual information letter

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย (ผู้ป่วย)

(PARTICIPANT INFORMATION LETTER)

โครงการวิจัย : การพัฒนาโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ ในประเทศไทย

ผู้วิจัยหลัก: Professor Mary Courtney

นักศึกษาผู้วิจัย: นางสาวนุชนาถ วิชิต (นักศึกษาปริญญาเอก)

เรียนผู้เข้าร่วมโครงการ

คุณได้รับเชิญเข้าร่วมโครงการวิจัยดังรายละเอียดด้านล่าง

วัตถุประสงค์ของโครงการวิจัย

- เพื่อพัฒนาและ ประเมินผลของโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ ในประเทศไทย
- คุณได้รับเชิญเข้าร่วมในโครงการวิจัยนี้เนื่องจากคุณได้รับการวินิจฉัยว่าเป็นเบาหวานชนิดที่ ๒
- ผู้วิจัยหวังว่าการวิจัยนี้จะสามารถเพิ่มความสามารถของผู้ป่วยเบาหวานในการจัดการตนเองในการควบคุมระดับน้ำตาลในเลือดและพัฒนาคุณภาพชีวิตของผู้ป่วยเบาหวานชนิดที่ ๒

ผู้ดำเนินการวิจัย

โครงการวิจัยนี้ดำเนินการ โดย นางสาวนุชนาถ วิชิต ซึ่งกำลังศึกษาระดับปริญญาเอกด้านการพยาบาลที่มหาวิทยาลัย Australian Catholic University ประเทศออสเตรเลีย ภายใต้การดูแลของ Professor Mary Courtney อันตรายหรือความเสี่ยงที่อาจเกิดขึ้นในการเข้าร่วมการวิจัยครั้งนี้

ท่านอาจจะรู้สึกว่าบางคำถามอาจทำให้ท่านคับข้องใจ แต่ถ้าท่านมีความประสงค์จะไม่ตอบคำถามใดท่านสามารถข้ามคำถามนั้นไปสู่คำถามอัดไปได้เลย หรือท่านสามารถที่จะหยุดตอบแบบสอบถามได้ทันทีเมื่อท่านไปต้องการตอบ ถ้าท่านมีความคับข้องใจหรือกระทบกระเทือนทางด้านจิตใจ ท่านสามารถปรึกษาทีมผู้วิจัยได้ทันที ท่านจะได้รับการช่วยเหลือและรักษาอย่างเหมาะสม

สิ่งที่ผู้วิจัยจะขอให้ผู้เข้าร่วมโครงการวิจัยปฏิบัติ ได้แก่

- ก่อนเข้าร่วมโครงการ ผู้วิจัยจะอธิบายวัตถุประสงค์และรายละเอียดโครงการวิจัย หลังจากนั้นขอให้ผู้ที่ยินยอมเข้าร่วมโครงการวิจัยเซ็นต์ชื่อในเอกสารยินยอมเข้าร่วมโครงการวิจัย
- ก่อนเริ่มต้นโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเบื้องต้น
- เมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเพื่อประเมินติดตามโดยแต่ละครั้งจะใช้แบบสอบถามชุดเดิม
- ผู้เข้าร่วมการวิจัยจะได้รับการแบ่งออกเป็น ๒ กลุ่ม ผู้เข้าร่วมการวิจัยในกลุ่มทดลอง จะได้รับการดูแลตามปกติตามแนวทางของโรงพยาบาล และจะได้เข้าร่วมโปรแกรมการให้ความรู้เรื่องการจัดการตัวเองของผู้ป่วยเบาหวานชนิดที่ ๒ ซึ่งจะรวมถึงการเยี่ยมบ้าน และการติดตามทางโทรศัพท์ ผู้เข้าร่วมการวิจัยในกลุ่มควบคุมจะได้การดูแลตามปกติตามแนวทางของโรงพยาบาล อย่างไรก็ตามท่านไม่สามารถเลือกได้ว่าต้องการอยู่ในกลุ่มทดลอง หรือกลุ่มควบคุม

ระยะเวลาในการเข้าร่วมโครงการ

- การเข้าร่วมโครงการของคุณจะใช้ระยะเวลาทั้งหมด ๓ เดือน อย่างไรก็ตามผู้ร่วมโครงการวิจัยมีสิทธิ์ถอนตัวออกจากโครงการวิจัยได้ทุกเวลาโดยไม่ส่งผลกระทบใดๆกับวิถีชีวิต หรือไม่กระทบต่อการรักษา
- การตอบแบบสอบถามจะใช้ระยะเวลาทั้งหมดประมาณ ๒๐ นาที โดยที่คุณจะไม่ได้รับค่าตอบแทนหรือเสียค่าใช้จ่ายใดๆ
- ผู้เข้าร่วมวิจัยอาจจะได้รับเชิญให้เข้าร่วมรับฟังการให้ความรู้เรื่องการจัดการตนเองสำหรับผู้ป่วยเบาหวาน ๑ ชั่วโมงต่อครั้ง จำนวน ๓ ครั้ง
- ผู้เข้าร่วมวิจัยอาจจะได้รับเชิญให้เข้าร่วมการสนทนากลุ่มย่อย เรื่องการจัดการตนเองสำหรับผู้ป่วยเบาหวาน ๑ ชั่วโมงต่อครั้ง จำนวน ๓ ครั้ง, การเยี่ยมบ้าน ๑ ครั้ง เป็นเวลาประมาณ ๓๐ นาที และ การโทรศัพย์ติดตาม ๑ ครั้ง
- เมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเพื่อประเมินติดตามโดยแต่ละครั้งจะใช้แบบสอบถามชุดเดิม

ประโยชน์ที่จะได้รับสำหรับผู้เข้าร่วมโครงการวิจัย

ผู้วิจัยไม่สามารถรับประกันหรือสัญญาว่าผู้เข้าร่วมโครงการวิจัยจะได้รับประโยชน์จากการเข้าร่วมโครงการวิจัยนี้ แต่อย่างไรก็ตามผู้เข้าร่วมวิจัยจะได้เข้าร่วมและรับความรู้จากโปรแกรมการจัดการดูแลตนเองสำหรับผู้ป่วยเบาหวาน และโปรแกรมนี้อาจจะเป็นประโยชน์ต่อผู้ป่วยเบาหวานในอนาคต ในการช่วยพัฒนาการจัดการตนเองของผู้ป่วย

การถอนตัวจากโครงการวิจัย

- ผู้เข้าร่วมการวิจัยในโครงการนี้ล้วนมาจากความสมัครใจ ถ้าท่านยินยอมเข้าร่วมการวิจัยแล้วท่านมีสิทธิ์ถอนตัวออกจากโครงการวิจัยได้ทุกเวลาโดยไม่ส่งผลกระทบใดๆกับวิถีชีวิต หรือไม่กระทบต่อการรักษา ถ้าคุณตัดสินใจจะเข้าร่วมการวิจัยให้คุณเก็บเอกสารฉบับนี้ไว้

การเก็บข้อมูลการวิจัย

- ข้อมูลจากแบบสอบถามจะถูกแปลงเป็นรหัส และเก็บรักษาไว้ในคอมพิวเตอร์เป็นความลับ มีเพียงผู้วิจัยเท่านั้นที่สามารถเข้าถึงได้
- แบบสอบถามจะถูกเก็บเป็นความลับผู้วิจัยปิดล็อคและเก็บกุญแจไว้ มีเพียงผู้วิจัยเท่านั้นที่สามารถเข้าถึงได้ และจะถูกเก็บไว้เป็นเวลา ๗ ปี หลังจากนั้นจะถูกทำลาย
- ข้อมูลจากแบบสอบถามจะถูกทำการวิเคราะห์แต่จะเป็นรายงานรวม ไม่แยกเป็นแต่ละคน
- ข้อมูลโดยรวมจากแบบสอบถามอาจจะถูกแจ้งให้เจ้าหน้าที่พยาบาลที่คลินิคเบาหวานรับทราบ
- ผู้วิจัยจะเปิดเผยข้อมูลเพื่อประโยชน์ในทางวิชาการ โดยไม่ระบุชื่อ ข้อมูลส่วนตัวของผู้เข้าร่วมโครงการวิจัยจะถูกเก็บรักษาไว้ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล

การรายงานผลการวิจัย

- หลังจากข้อมูลทั้งหมดถูกป้องเข้าคอมพิวเตอร์ ข้อมูลจะได้รับการวิเคราะห์โดยโปรแกรมคอมพิวเตอร์ในลักษณะข้อมูลเป็นกลุ่มข้อมูล ข้อมูลส่วนตัวของท่านจะไม่สามารถกลับมาชี้ตัวท่านได้ ข้อมูลโดยรวมจากแบบสอบถามอาจจะถูกแจ้งให้เจ้าหน้าที่พยาบาลที่คลินิคเบาหวานรับทราบ

บุคคลที่ท่านสามารถติดต่อได้

ถ้าท่านต้องการทราบรายละเอียดเพิ่มเติมติดต่อผู้วิจัยได้ตลอดเวลา

นางสาวนุชนาถ วิชิต (นักศึกษาปริญญาเอก)

ที่อยู่ ๔๔ หมู่ ๓ ต.ท่าฉาง อ.ท่าฉาง จ.สุราษฎร์ธานี

โทรศัพย์ ๐๘๗-๔๖๒๘๔๓๕

อีเมล: nunoi_m@hotmail.com, S00148850@myacu.edu.au

หรือติดต่อเจ้าหน้าที่โรงพยาบาล

คุณวิไลวรรณ บุญคุ้มครอง (หัวหน้าคลินิคเบาหวาน)

ที่อยู่ โรงพยาบาลท่าฉาง ๔๓๑ หมู่ ๑ ต.ท่าฉาง อ. ท่าฉาง จ.สุราษฎร์ธานี ๘๔๑๕๐

โทรศัพย์ ๐๗๗-๓๘๕๑๒๔

กรณีผู้เข้าร่วมโครงการวิจัยต้องการร้องเรียน

โครงการวิจัยนี้ได้รับการพิจารณาโดยคณะกรรมการการวิจัยในมนุษย์ของมหาวิทยาลัย Australian Catholic University ถ้าท่านต้องการร้องเรียนในการดำเนินการวิจัยท่านสามารถส่งข้อร้องเรียนไปได้ที่ผู้จัดการของคณะกรรมการการวิจัยในมนุษย์ซึ่งเป็นตัวแทนของอธิการบดี

Manager, Ethics

c/o Office of the Deputy Vice Chancellor (Research)

Australian Catholic University

North Sydney Campus

PO Box 968

NORTH SYDNEY, NSW 2059

โทรศัพย์: 029739 2519

แฟ็กซ์: 02 9739 2870

อีเมล: res.ethics@acu.edu.au

ทุกคำร้องเรียนจะได้รับการพิจารณาและตรวจสอบหาความจริง และจะแจ้งผลลัพธ์ให้ท่านทราบ

กรณีท่านต้องการเข้าร่วมการวิจัย

ถ้าท่านตัดสินใจจะเข้าร่วมโครงการวิจัย ผู้วิจัยจะขอให้ท่านกรอกข้อความในเอกสารยินยอมเข้าร่วมการวิจัยที่แนบมาด้วย ผู้วิจัยจะอธิบายรายละเอียดและวัตถุประสงค์ของโครงการให้ท่านทราบด้วยวาจาอีกครั้ง และจะขอให้ท่านลงนามเข้าร่วมการวิจัยและส่งเอกสารยินยอมการเข้าร่วมการวิจัยกลับคืนแก่ผู้วิจัย

ด้วยความเคารพ

ชื่อผู้วิจัย .....นางสาวนุชนาถ วิชิต.....

ลงนาม.....วันที่.....

E.3 The English version of a carer participant information letter

PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Improving the self-management of person with type 2 diabetes in Thailand

PRINCIPAL INVESTIGATOR: Professor Mary Courtney

STUDENT RESEARCHER: Nutchanath Wichit

STUDENT'S DEGREE: Ph.D. candidate

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

- This research aims to develop and trial a self-management program for people with type 2 diabetes.
- You are invited to take part in this research project because you are the carers of a person who has diagnosis of type 2 diabetes. I hope this study can enhance the capability of carers in helping people with type 2 diabetes to self–manage and control their blood glucose.

Who is undertaking the project?

This project is being conducted by Nutchanath Wichit and as a part of a Doctor Philosophy at Australian Catholic University under the supervision of Professor Mary Courtney.

Are there any risks associated with participating in this project?

You may feel some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support. We do not anticipate any major Adverse Event that might be occurring in the course of the research as a nature or the intervention education. However, if patients and carers become upset or anxious because raising the self-management topic, then the researcher will start exploration about self-management. In addition, the hospital will provide participants and carer a counselling session if you experience any undue fear or anxiety and treat you without extra cost.

What will I be asked to do?

- Prior to commencement, the researcher will verbally inform you about the research project, explain the project and then ask you to provide written consent to participate.
- At the beginning you will complete a baseline assessment questionnaire. At 1month and 3 months after commencement, you will be asked to complete follow-up questionnaire.
- You will receive the diabetes education program in diabetes clinic at Thachang Hospital provided by the researcher program which includes group discussion, a home visit and telephone follow-up.

How much time will the project take?

- Your involvement will be for a three month period.
- Completing the questionnaire will take approximately twenty minutes at the beginning and at 1 month and 3 months after commencement. There are no costs associated with participating in this research project, nor will you be paid.
- You will receive the diabetes education program 1 hour per session at 1st, 5th and 9th week.
- You might be asked to participate in 1 hour a group discussion at 5th and 9th weeks.
- 30 minutes a home visit at 3rd week and 15-20 minutes telephone follow-up at 7th week.

What are the benefits of the research project?

We cannot guarantee or promise you will receive any benefits from this research. However, you will receive the diabetes education program which may help you for assistant people with type 2 diabetes to manage their diabetes. In addition, the results may have benefit for future patients with type 2 diabetes and their carers to assist them in improving self-management.

Can I withdraw from the study?

Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences. If you do not want to take part, you do not have to. If you decide to take part, you will be given this Participant Information to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the hospital and patient's treatment.

Will anyone else know the results of the project?

- Data from the questionnaire transcribed to electronic database, will not contain any identifying information. The database will be stored in a file on the G drive that only the researcher will have access to.
- The questionnaire will be kept in a locked filing cabinet that only the researcher will have access to. Once the questionnaires are no longer required they will be placed in boxes and put into secure storage for a period of seven years, after which they will be destroyed.
- The data will be analysed as group data.
- The group results will be made known to the hospital manager or educator.
- Data from questionnaires will only be used for the purpose of this study. It is anticipate the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. All data will be reported an aggregated data. No individual data will be reported.
- It is expected that the results will be published in peer-reviewed journals. No individual will be identified in any publication.
- Your name will not be included on any questionnaire.
- A code number will be used on the questionnaire to match your before and after response.

Will I be able to find out the results of the project?

Once all the data has been entered it will be analysed as group data. Your individual data will not be able to be traced back to you. The group results will be made known to the hospital manager or educator.

Who do I contact if I have questions about the project?

For further information you can contact the researcher anytime:

NutchanathWichit, Ph.D. candidate

Address: 94 M.3 Thachang, Suratthani, 84150

Ph: +61449522117, +66874628935

Email: nunoi_m@hotmail.com, S00148850@myacu.edu.au

or the local site staff you can contact if you have a compliant:

WilaiwanBoonkumkrong, DiabeteClinic manager

Address: 431 M.1 Thachang, Suratthani, 84150

Ph: +6677389124

What if I have a complaint or any concerns?

The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University. If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics
c/o Office of the Deputy Vice Chancellor (Research)
Australian Catholic University
North Sydney Campus
PO Box 968
NORTH SYDNEY, NSW 2059
Ph.: 029739 2519
Fax: 02 9739 2870
Email: res.ethics@acu.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

If you decide you want to take part in the research project, you will be asked to fill out the attached.The researcher will verbally inform you about the research project, explain the project and then ask you to provide written consent to participate and returning it to the researcher. If you agree to participate in the project, your involvement will be for a three month period.

Yours sincerely,

RESEARCHER NAME .....NutchanathWichit.....

Signature.....Date.....

E.4 The Thai version of a carer participant information letter

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย (ผู้ดูแล)

(PARTICIPANT INFORMATION LETTER)

โครงการวิจัย : การพัฒนาโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ ในประเทศไทย

ผู้วิจัยหลัก: Professor Mary Courtney

นักศึกษาผู้วิจัย: นางสาวนุชนาถ วิชิต (นักศึกษาปริญญาเอก)

เรียนผู้เข้าร่วมโครงการ

คุณได้รับเชิญเข้าร่วมโครงการวิจัยดังรายละเอียดด้านล่าง

วัตถุประสงค์ของโครงการวิจัย

- เพื่อพัฒนาและ ประเมินผลของโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ และผู้ดูแลในประเทศไทย
- คุณได้รับเชิญเข้าร่วมในโครงการวิจัยนี้เนื่องจากคุณเป็นผู้ดูแลผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นเบาหวานชนิดที่ ๒
- ผู้วิจัยหวังว่าการวิจัยนี้จะสามารถเพิ่มความสามารถของผู้ดูแลผู้ป่วยเบาหวานในการช่วยผู้ป่วยจัดการตนเองในการควบคุมระดับน้ำตาลในเลือดและพัฒนาคุณภาพชีวิตของผู้ป่วยเบาหวานชนิดที่ ๒

ผู้ดำเนินการวิจัย

โครงการวิจัยนี้ดำเนินการโดย นางสาวนุชนาถ วิชิต ซึ่งกำลังศึกษาระดับปริญญาเอกด้านการพยาบาลที่มหาวิทยาลัย Australian Catholic University ประเทศออสเตรเลีย ภายใต้การดูแลของ Professor Mary Courtney

อันตรายหรือความเสี่ยงที่อาจเกิดขึ้นในการเข้าร่วมการวิจัยครั้งนี้

ท่านอาจจะรู้สึกว่าบางคำถามอาจทำให้ท่านคับข้องใจ แต่ถ้าท่านมีความประสงค์จะไม่ตอบคำถามใดท่านสามารถข้ามคำถามนั้นไปสู่คำถามถัดไปได้เลย หรือท่านสามารถที่จะหยุดตอบแบบสอบถามได้ทันทีเมื่อท่านไปต้องการตอบ ถ้าท่านมีความคับข้องใจหรือกระทบกระเทือนทางด้านจิตใจ ท่านสามารถปรึกษาทีมผู้วิจัยได้ทันที ท่านจะได้รับการช่วยเหลือและรักษาอย่างเหมาะสม

สิ่งที่ผู้วิจัยจะขอให้ผู้เข้าร่วมโครงการวิจัยปฏิบัติ ได้แก่

- ก่อนเข้าร่วมโครงการ ผู้วิจัยจะอธิบายวัตถุประสงค์และรายละเอียดโครงการวิจัย หลังจากนั้นขอให้ผู้ที่ยินยอมเข้าร่วมโครงการวิจัยเซ็นต์ชื่อในเอกสารยินยอมเข้าร่วมโครงการวิจัย

- ก่อนเริ่มต้นโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเบื้องต้น
- เมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเพื่อประเมินติดตามโดยแต่ละครั้งจะใช้แบบสอบถามชุดเดิม
- ผู้เข้าร่วมการวิจัยจะได้เข้าร่วมโปรแกรมการให้ความรู้เรื่องการจัดการตัวเองของผู้ป่วยเบาหวานชนิดที่ ๒ ร่วมกับผู้ป่วยในความดูแลของท่าน ซึ่งจะรวมถึงการเยี่ยมบ้าน และการติดตามทางโทรศัพย์

ระยะเวลาในการเข้าร่วมโครงการ

- การเข้าร่วมโครงการของคุณจะใช้ระยะเวลาทั้งหมด ๓ เดือน อย่างไรก็ตามผู้ร่วมโครงการวิจัยมีสิทธิ์ถอนตัวออกจากโครงการวิจัยได้ทุกเวลาโดยไม่ส่งผลกระทบใดๆกับวิถีชีวิต หรือไม่กระทบต่อการรักษาของตัวท่านและผู้ป่วยในความดูแลของท่าน
- การตอบแบบสอบถามจะใช้ระยะเวลาทั้งหมดประมาณ ๒๐ นาที โดยที่คุณจะไม่ได้รับค่าตอบแทนหรือเสียค่าใช้จ่ายใดๆ
- ผู้เข้าร่วมวิจัยจะได้รับเชิญให้เข้าร่วมรับฟังการให้ความรู้เรื่องการจัดการตนเองสำหรับผู้ป่วยเบาหวาน ๑ ชั่วโมงต่อครั้ง จำนวน ๓ ครั้ง
- ผู้เข้าร่วมวิจัยจะได้รับเชิญให้เข้าร่วมการสนทนากลุ่มย่อย เรื่องการจัดการตนเองสำหรับผู้ป่วยเบาหวาน ๑ ชั่วโมงต่อครั้ง จำนวน ๓ ครั้ง, การเยี่ยมบ้าน ๑ ครั้ง เป็นเวลาประมาณ ๓๐ นาที และ การโทรศัพย์ติดตาม ๑ ครั้ง
- เมื่อสิ้นเดือนที่ ๑ และ เดือนที่ ๓ ของโครงการผู้วิจัยจะขอให้ท่านตอบแบบสอบถามเพื่อประเมินติดตามโดยแต่ละครั้งจะใช้แบบสอบถามชุดเดิม

ประโยชน์ที่จะได้รับสำหรับผู้เข้าร่วมโครงการวิจัย

ผู้วิจัยไม่สามารถรับประกันหรือสัญญาว่าผู้เข้าร่วมโครงการวิจัยจะได้รับประโยชน์จากการเข้าร่วมโครงการวิจัยนี้ แต่อย่างไรก็ตามผู้เข้าร่วมวิจัยจะได้เข้าร่วมและรับความรู้จากโปรแกรมการจัดการดูแลตนเองสำหรับผู้ป่วยเบาหวาน และโปรแกรมนี้อาจจะเป็นประโยชน์ต่อผู้ป่วยเบาหวานในอนาคต ในการช่วยพัฒนาการจัดการตนเองของผู้ป่วย

การถอนตัวจากโครงการวิจัย

- ผู้เข้าร่วมการวิจัยในโครงการนี้ล้วนมาจากความสมัครใจ ถ้าท่านยินยอมเข้าร่วมการวิจัยแล้วท่านมีสิทธิ์ถอนตัวออกจากโครงการวิจัยได้ทุกเวลาโดยไม่ส่งผลกระทบใดๆกับวิถีชีวิต หรือไม่กระทบต่อการรักษาของตัวท่านและบุคคลในความดูแลของท่าน ถ้าท่านตัดสินใจจะเข้าร่วมการวิจัยให้คุณเก็บเอกสารฉบับนี้ไว้

การเก็บข้อมูลการวิจัย

- ข้อมูลจากแบบสอบถามจะถูกแปลงเป็นรหัส และเก็บรักษาไว้ในคอมพิวเตอร์เป็นความลับ มีเพียงผู้วิจัยเท่านั้นที่สามารถเข้าถึงได้
- แบบสอบถามจะถูกเก็บเป็นความลับผู้วิจัยปิดล็อคและเก็บกุญแจไว้ มีเพียงผู้วิจัยเท่านั้นที่สามารถเข้าถึงได้ และจะถูกเก็บไว้เป็นเวลา ๗ ปี หลังจากนั้นจะถูกทำลาย
- ข้อมูลจากแบบสอบถามจะถูกทำการวิเคราะห์แต่จะเป็นรายงานรวม ไม่แยกเป็นแต่ละคน
- ข้อมูลโดยรวมจากแบบสอบถามอาจจะถูกแจ้งให้เจ้าหน้าที่พยาบาลที่คลินิคเบาหวานรับทราบ
- ผู้วิจัยจะเปิดเผยข้อมูลเพื่อประโยชน์ในทางวิชาการโดยไม่ระบุชื่อ ข้อมูลส่วนตัวของผู้เข้าร่วมโครงการวิจัยจะถูกเก็บรักษาไว้ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล

การรายงานผลการวิจัย

- หลังจากข้อมูลทั้งหมดถูกป้องเข้าคอมพิวเตอร์ ข้อมูลจะได้รับการวิเคราะห์โดยโปรแกรมคอมพิวเตอร์ในลักษณะข้อมูลเป็นกลุ่มข้อมูล ข้อมูลส่วนตัวของท่านจะไม่สามารถกลับมาชี้ตัวท่านได้ ข้อมูลโดยรวมจากแบบสอบถามอาจจะถูกแจ้งให้เจ้าหน้าที่พยาบาลที่คลินิคเบาหวานรับทราบ

บุคคลที่ท่านสามารถติดต่อได้

ถ้าท่านต้องการทราบรายละเอียดเพิ่มเติมติดต่อผู้วิจัยได้ตลอดเวลา

นางสาวนุชนาถ วิชิต (นักศึกษาปริญญาเอก)

ที่อยู่ ๔๔ หมู่ ๓ ต.ท่าฉาง อ.ท่าฉาง จ.สุราษฎร์ธานี

โทรศัพย์ ๐๘๗-๔๖๒๘๔๓๕

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หรือติดต่อเจ้าหน้าที่โรงพยาบาล

คุณวิไลวรรณ บุญคุ้มครอง (หัวหน้าคลินิคเบาหวาน)

ที่อยู่ โรงพยาบาลท่าฉาง ๔๓๑ หมู่ ๑ ต.ท่าฉาง อ. ท่าฉาง จ.สุราษฎร์ธานี ๘๔๑๕๐

โทรศัพย์ ๐๗๗-๓๘๕๑๒๔

กรณีผู้เข้าร่วมโครงการวิจัยต้องการร้องเรียน

โครงการวิจัยนี้ได้รับการพิจารณาโดยคณะกรรมการการวิจัยในมนุษย์ของมหาวิทยาลัย Australian Catholic University ถ้าท่านต้องการร้องเรียนในการดำเนินการวิจัยท่านสามารถส่งข้อร้องเรียนไปได้ที่ผู้จัดการของคณะกรรมการการวิจัยในมนุษย์ซึ่งเป็นตัวแทนของอธิการบดี

Manager, Ethics

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ทุกคำร้องเรียนจะ ได้รับการพิจารณาและตรวจสอบหาความจริง และจะแจ้งผลลัพธ์ให้ท่านทราบ

กรณีท่านต้องการเข้าร่วมการวิจัย

ถ้าท่านตัดสินใจจะเข้าร่วมโครงการวิจัย ผู้วิจัยจะขอให้ท่านกรอกข้อความในเอกสารยินยอมเข้าร่วมการวิจัยที่แนบมาด้วย ผู้วิจัยจะอธิบายรายละเอียดและวัตถุประสงค์ของโครงการให้ท่านทราบด้วยวาจาอีกครั้ง และจะขอให้ท่านลงนามเข้าร่วมการวิจัยและส่งเอกสารยินยอมการเข้าร่วมการวิจัยกลับคืนแก่ผู้วิจัย

ด้วยความเคารพ

ชื่อผู้วิจัย .....นางสาวนุชนาถ วิชิต.....

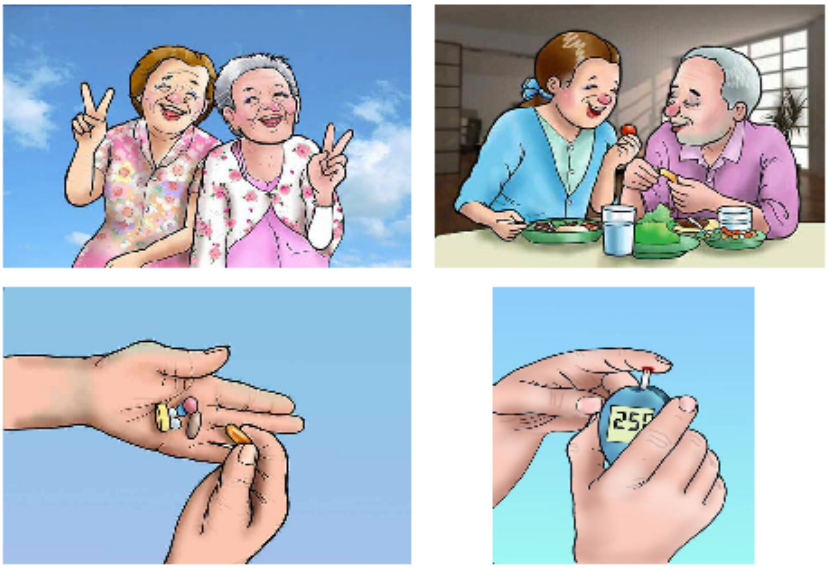
ลงนาม.....**วันที่**.....

Appendix F: Example of Diabetes Workbook

F.1 The English version of an example booklet1

Diabetes Self-management Program

Session 1: General diabetes knowledge



Miss NutchanathWichit

PhD student

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Diabetes Self-management Program

Session 1: General diabetes knowledge

Created by

Miss NutchanathWichit

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Supervisors

Professor Mary Courtney

Associate Professor Paula Schulz

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Preface

This diabetes self-management program developed by the researcher for participants who are participate in the research project "Effectiveness of a self-management program for people with type 2 diabetes and their carer in improving self-efficacy, quality of life and self-management in Thailand".

You have been given this book because you have got diabetes and participate in the Diabetes Self-management program. This book will help you what diabetes is and how it affects your health. It will also help you to make daily decision to manage your diabetes. Share this booklet with your family member and friends so they will understand more about diabetes and they can help you to manage your diabetes as well.

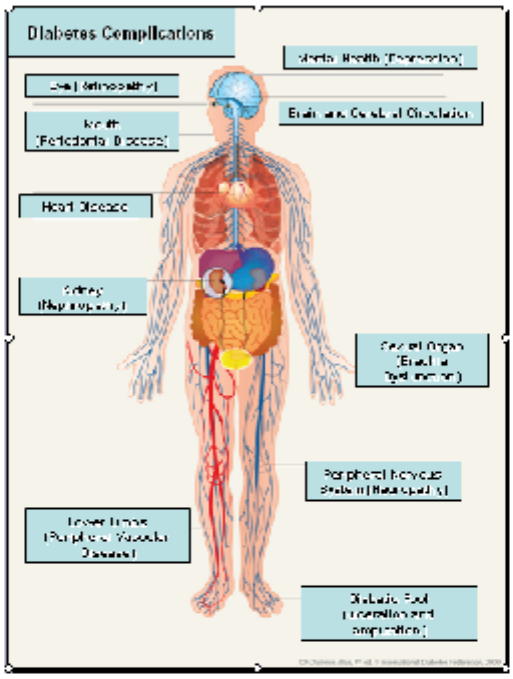
Miss NutchanathWichit

PhD student

3 October 2014

Introduction

Diabetes is non-curable chronic disease with impaired blood glucose tolerance. It is associate with many complications though the progress of microagiopathy and macroagiopathy. Many complications of diabetes can be prevented or delayed through effective management.



Managing your diabetes

Living with chronic condition can be a challenge. Everyday life can distract you from diabetes management. However managing your blood sugar is the key to living well with diabetes. Give yourself time to change habits and learn new information. Learning to self-manage your diabetes takes time and patience but you don't have to go it alone. You will work with health care providers and you family member who can support and advise you increasing a management plan. This book is not home work. It is tools help you to create a diabetes management plan u can stick with.

Direction: Please complete the following question to evaluate your knowledge and confident about diabetes

1. How much you know about diabetes? Please choose number below

Very little Very much

1	2	3	4	5	6	7	8	9	10

2. How confident are you in your diabetes self-management? Please choose number below

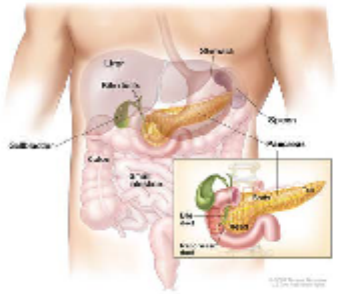
Very little Very much

1	2	3	4	5	6	7	8	9	10

3. Why you should manage your diabetes?

1. Fewer missed day work off
2. Having more energy and a better sense of well-being
   Add a few your own reason here
3. .....
4. .....
5. .....

1.1 What is diabetes?



The food you eat is turned into blood sugar (glucose) for the body to use for energy. The pancreas makes a hormone called insulin to help sugar get into our body. People have diabetes because the body doesn't make enough insulin or the insulin doesn't work the way it should. As a result, the level of sugar in the blood is toohigh.

6

F.2 The English version of an example booklet2

Diabetes Self-management Program

Session 2: Diabetes diet

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Diabetes Self-management Program

Session 2: Diabetes diet

Created by

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PhD student at Australian Catholic University

Supervisors

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Associate Professor Paula Schulz

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Preface

This diabetes self-management program was developed for participants who are undertaking the research project "Effectiveness of a self-management program for people with type 2 diabetes and their carer in improving self-efficacy, quality of life and self-management in Thailand".

You have been given this book because you have diabetes and are undertaking the Diabetes Self-management program. This book will help you understand your diabetes and how it affects your health. It will also help you to make daily decisions to manage your diabetes. Share this booklet with your family members and friends so they will understand more about diabetes and how they can help you to manage your diabetes well.

Miss NutchanathWichit

PhD student

3 October 2014

Please write down all the foods you ate yesterday

Breakfast .....

.....

.....

Lunch .....

.....

.....

Dinner .....

.....

.....

4

Introduction

A key part of managing blood sugar is eating healthy foods every day. Patients do not have to stop eating the foods their like. But they are needed to know how food affects their blood sugar. There are five groups of food (milk, vegetable and fruit, carbohydrate, protein and lipid). Try to eat foods from each of the five food groups every day. The foods in the bottom right corner are high in fat, sugar and salt and should only be eaten sometimes and in small amounts.

Please write the group name of following foods.

1.  .....Vegetable and fruit.....

2.  .....

3.  .....

4.  .....

5.  .....

6

6.  .....

7.  .....

8.  .....

9.  .....

10.  .....

7

F.3 The English version of an example booklet3

Diabetes Self-management

Program

Session3: Physical activity

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Diabetes Self-management Program

Session 3: Physical activity

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You have been given this book because you have diabetes and are undertaking the Diabetes Self-management program. This book will help you understand your diabetes and how it affects your health. It will also help you to make daily decisions to manage your diabetes. Share this booklet with your family members and friends so they will understand more about diabetes and how they can help you to manage your diabetes well.

Miss NutchanathWichit

PhD student

3 November 2014

Introduction

Being physically active every day can help you manage your blood sugar. That's because an active life style can improve your body's ability to use insulin. Daily activity can help delay or prevent complications of diabetes. And it's great way to relieve stress. If you are not normally active, be sure to consult your healthcareprovider before getting started.

On how many in a week you participate in at least 30 minutes of physical activity?
Please choose number below

0	1	2	3	4	5	6	7

What kind of activities you do? (For participant who does)

1. .....
2. .....
3. .....

What is a barrier of doing exercise? (For participant who does not)

1. .....
2. .....
3. .....

Activity and movement can help control your BGL and is good for your heart. It can also make you feel better in yourself

It's good to do at least 30 minutes of exercise every day.

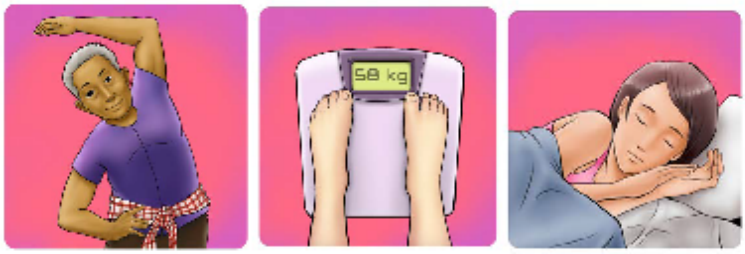
5

Important benefits of physical activity

- Lowers fasting blood glucose and improves insulin action
- Lowers blood pressure

- Lowers cholesterol and triglyceride (blood fat) levels
- Lowers your risk for heart disease and stroke

- Relieves stress and can improve your mood
- Burns calories, which can help you manage your weight



- Improves energy and ability to concentrate
- Helps you sleep better at night

Preparing of exercise and physical activity and concept of exercise

Being prepared and following these general guidelines can help keep you safe and injury-free during exercise.

- Choose appropriate exercise for age and body weightfor example walking
- Protect your feet with shoes that fit properly and are soft and absorbent
- Check for blisters, cuts and reddened areas before and after exercising
- Wear or carry diabetes identification at all times
- Have your glucose meter and supplies with you at all times
- Aim to keep your blood glucose level between 100 to 150 while exercising
- Have a carbohydrate source available to maintain safe blood glucose levels
- Drink enough liquid to replace what you lose from sweating. (You should weigh the same after exercise as you did before.)
- Do exercise at least 20-30 minutes continually and 3-5 days a week
- Warm up before started and calm down before finishing

F.4 The Thai version of an example booklet1

โปรแกรมการจัดการตนเอง ในผู้ป่วยเบาหวานชนิดที่ ๒

ตอนที่ ๑ : ความรู้ทั่วไปเกี่ยวกับโรคเบาหวาน

นางสาวนุชนาถ วิชิต
นักศึกษาปริญญาเอก

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โปรแกรมการจัดตนเองในผู้ป่วยเบาหวานชนิดที่ ๒

ตอนที่ ๑ : ความรู้ทั่วไปเกี่ยวกับโรคเบาหวาน

ผลิตโดย

นางสาวนุชนาถ วิชิต

นักศึกษาปริญญาเอก Australian Catholic University

อาจารย์ที่ปรึกษา

ศาสตราจารย์ ดร. Mary Courtney

ผู้ช่วยศาสตราจารย์ ดร. Professor Paula Schulz

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คำนำ

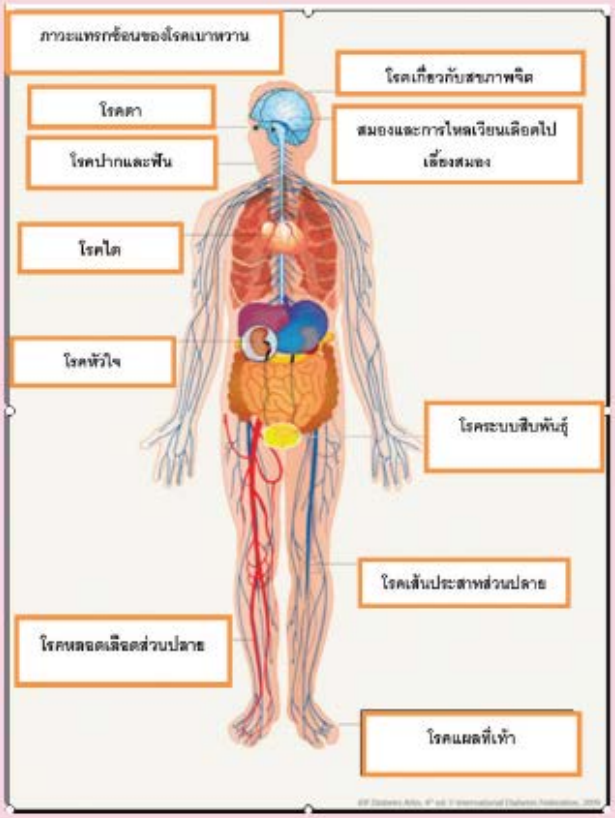
โปรแกรมการจัดการตนเองในผู้ป่วยเบาหวานนี้พัฒนาขึ้นสำหรับบุคคลผู้เข้าร่วมโครงการวิจัยเรื่อง “ประสิทธิภาพของโปรแกรมการจัดการตนเองในผู้ป่วยเบาหวานชนิดที่ ๒ และผู้ดูแล เพื่อการพัฒนาการรับรู้ความสามารถของตนเอง คุณภาพชีวิตและการจัดการตนเองในประเทศไทย”

ท่านได้รับคู่มือฉบับนี้เนื่องจากท่านได้รับการวินิจฉัยว่าเป็นโรคเบาหวานและได้เข้าร่วมโครงการวิจัยการจัดการตนเองในผู้ป่วยเบาหวาน คู่มือฉบับนี้จะช่วยให้ท่านเข้าใจในเรื่องโรคเบาหวานและผลกระทบต่อสุขภาพของท่าน และสามารถช่วยท่านตัดสินใจในการจัดการโรคเบาหวานของท่าน แบ่งปันคู่มือฉบับนี้ให้กับสมาชิกในครอบครัวและเพื่อนของท่าน ซึ่งจะทำให้บุคคลเหล่านั้นเข้าใจในโรคเบาหวานมากขึ้นและสามารถช่วยเหลือท่านในการจัดการกับโรคเบาหวานได้เป็นอย่างดี

นางสาวนุชนาถ วิชิต
นักศึกษาปริญญาเอก
๓ พฤศจิกายน ๒๕๕๗

บทนำ

เบาหวานเป็นโรคเรื้อรังและไม่สามารถรักษาให้หายได้ ซึ่งเป็นความผิดปกติที่ร่างกายไม่สามารถนำน้ำตาลจากการอาหารที่รับประทานไปใช้ได้ตามปกติ จึงทำให้มีปริมาณน้ำตาลในเลือดมากกว่าปกติ ซึ่งจะทำให้เกิดภาวะแทรกซ้อนต่อระบบหลอดเลือดทั้งขนาดเล็กและขนาดใหญ่ ภาวะแทรกซ้อนต่างๆที่เกิดจากโรคเบาหวานสามารถป้องกันได้ถ้ามีการจัดการโรคเบาหวานอย่างมีประสิทธิภาพ



ค่าน้ำตาลในเลือดก่อนรับประทานอาหารเช้า
สำหรับคนปกติจะมีค่าไม่เกิน ๑๑๐ มิลลิกรัมเปอร์เซ็นต์

การจัดการกับโรคเบาหวาน

เป็นสิ่งที่ท้าทายอย่างมากในการมีชีวิตอยู่ร่วมกับโรคเรื้อรังเนื่องจากในการดำเนินชีวิตประจำวันมีโอกาสทำให้ท่านไม่สามารถดำเนินตามแผนการจัดการตัวเองที่วางไว้ได้ อย่างไรก็ตามการจัดการกับปริมาณน้ำตาลในเลือดถือเป็นกุญแจสำคัญในการทำให้ท่านอยู่อย่างเป็นสุขกับโรคเบาหวาน ให้เวลาตัวท่านเองในการปรับเปลี่ยนพฤติกรรมและเรียนรู้ความรู้ใหม่ๆ เพื่อการจัดการโรคเบาหวานที่มีประสิทธิภาพ ในการเรียนรู้การจัดการเบาหวานของท่านอาจจะใช้เวลาและความอดทนแต่ท่านไม่ได้เรียนรู้ตามลำพัง ท่านจะได้รับความร่วมมือจากเจ้าหน้าที่สาธารณสุขและสมาชิกในครอบครัวของท่านผู้ซึ่งสามารถให้ความช่วยเหลือและคำปรึกษาแก่ท่านในการจัดการกับโรคเบาหวาน คู่มือฉบับนี้ไม่ใช่การบ้านแต่เป็นเครื่องมือที่ช่วยท่านในการวางแผนการจัดการตนเองเกี่ยวกับโรคเบาหวาน

คำชี้แจง : กรุณาตอบคำถามต่อไปนี้เพื่อประเมินระดับความรู้และความมั่นใจของท่านเกี่ยวกับโรคเบาหวาน

คำถามที่ ๑

กรุณาเลือกตัวเลขที่แสดงถึงระดับความรู้เกี่ยวกับโรคเบาหวานของท่าน

น้อยมาก มากที่สุด

๑	๒	๓	๔	๕	๖	๗	๘	๙	๑๐

คำถามที่ ๒

กรุณาเลือกตัวเลขที่แสดงถึงระดับความมั่นใจของท่าน ในการจัดการตัวเองเกี่ยวกโรคเบาหวาน

น้อยมาก มากที่สุด

๑	๒	๓	๔	๕	๖	๗	๘	๙	๑๐

คำถามที่ ๓

เพราะเหตุใดท่านจึงควรจะจัดการโรคเบาหวานของท่าน

น้อยมาก มากที่สุด

๑	๒	๓	๔	๕	๖	๗	๘	๙	๑๐

๑. ลดการขาด และลางาน

๒. มีคุณภาพชีวิตที่ดีขึ้น

เพิ่มเหตุผลของท่านลงด้านล่าง

๓. .....

๔. .....

๕. .....

F.5 The Thai version of an example booklet2

โปรแกรมการจัดการตนเอง ในผู้ป่วยเบาหวานชนิดที่ ๒

ตอนที่ ๒ : อาหารเบาหวาน

นางสาวนุชนาถ วิชิต
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โปรแกรมการจัดตนเองในผู้ป่วยเบาหวานชนิดที่ ๒

ตอนที่ ๒ : อาหารผู้ป่วยเบาหวาน

ผลิตโดย

นางสาวนุชนาถ วิชิต

นักศึกษาปริญญาเอก Australian Catholic University

อาจารย์ที่ปรึกษา

ศาสตราจารย์ ดร. Mary Courtney

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คำนำ

โปรแกรมการจัดการตนเองในผู้ป่วยเบาหวานนี้พัฒนาขึ้นสำหรับบุคคลผู้เข้าร่วมโครงการวิจัยเรื่อง “ประสิทธิภาพของโปรแกรมการจัดการตนเองในผู้ป่วยเบาหวานชนิดที่ ๒ และผู้ดูแล เพื่อการพัฒนาการรับรู้ความสามารถของตนเอง คุณภาพชีวิตและการจัดการตนเองในประเทศไทย”

ท่านได้รับคู่มือฉบับนี้เนื่องจากท่านได้รับการวินิจฉัยว่าเป็นโรคเบาหวานและได้เข้าร่วมโครงการวิจัยการจัดการตนเองในผู้ป่วยเบาหวาน คู่มือฉบับนี้จะช่วยให้ท่านเข้าใจในเรื่องโรคเบาหวานและผลกระทบต่อสุขภาพของท่าน และสามารถช่วยท่านตัดสินใจในการจัดการโรคเบาหวานของท่าน แบ่งปันคู่มือฉบับนี้ให้กับสมาชิกในครอบครัวและเพื่อนของท่าน ซึ่งจะทำให้บุคคลเหล่านั้นเข้าใจในโรคเบาหวานมากขึ้นและสามารถช่วยเหลือท่านในการจัดการกับโรคเบาหวานได้เป็นอย่างดี

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กรุณาเขียนรายการอาหารที่ท่านรับประทานเมื่อวาน

มื้อเช้า .....

.....

.....

มื้อเที่ยง .....

.....

.....

เมื้อเย็น .....

.....

.....

บทนำ

การรับประทานอาหารที่มีประโยชน์และถูกหลักการของโรคเบาหวานถือเป็นกุญแจสำคัญในการจัดการตนเองในผู้ป่วยโรคเบาหวาน ท่านไม่จำเป็นต้องหยุดรับประทานอาหารที่ท่านชอบ เพียงแต่ท่านต้องทราบว่าควรรับประทานอย่างไรเพื่อไม่ให้ปริมาณน้ำตาลในเลือดสูงกว่าปกติ อาหารประกอบด้วย ๕ กลุ่มใหญ่ (นม, ผักและผลไม้, แป้ง, เนื้อสัตว์, และไขมัน) พยายามรับประทานอาหารให้ครบทั้ง ๕ หมู่ทุกวัน อาหารในกลุ่มด้านล่างซ้ายมือเป็นพวกไขมัน เกลือ และน้ำตาล ควรรับประทานในปริมาณน้อย

กรุณาเขียนชื่อกลุ่มของรายการอาหารดังต่อไปนี้

๑.ขนุน .....ผักและผลไม้.....

๒.น้ำมันข้าวโพด .....

๓.หมูสับ .....

๔.โยเกิร์ต .....

๕.มันเทศ .....

๖.นมถั่วเหลือง .....

๗.เห็ด .....

๘.ข้าวเหนียว .....

๙.ปลาหมึก .....

๑๐.กะทิ .....

F.6 The Thai version of an example booklet3

โปรแกรมการจัดการตนเอง ในผู้ป่วยเบาหวานชนิดที่ ๒

ตอนที่ ๓ : การออกกำลังกาย

นางสาวนุชนาถ วิชิต
นักศึกษาปริญญาเอก

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ตอนที่ ๓ : ความรู้ทั่วไปเกี่ยวกับโรคเบาหวาน

ผลิตโดย

นางสาวนุชนาถ วิชิต

นักศึกษาปริญญาเอก Australian Catholic University

อาจารย์ที่ปรึกษา

ศาสตราจารย์ ดร. Mary Courtney

ผู้ช่วยศาสตราจารย์ ดร. Professor Paula Schulz

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คำนำ

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บทนำ

การออกกำลังกายเป็นอีกหนึ่งวิธีที่จะช่วยท่านในการจัดการเบาหวาน เนื่องจากการออกกำลังกายหรือกิจกรรมในชีวิตประจำวันสามารถเพิ่มประสิทธิภาพการทำงานของอินซูลิน นอกจากนี้การออกกำลังกายยังช่วยชะลอและป้องกันโรคแทรกซ้อนจากเบาหวานได้อีกด้วย อีกทั้งยังเป็นวิธีการที่ดีในการลดความเครียด ถ้าหากท่านไม่ได้ออกกำลังกายเป็นประจำท่านควรปรึกษาเจ้าหน้าที่ด้านสุขภาพก่อนที่จะเริ่มออกกำลังกาย

ใน ๑ สัปดาห์ ท่านได้ออกกำลังกายอย่างน้อย ๓๐ นาที ต่อวัน เป็นเวลากี่วัน

โปรดเลือกตัวเลขด้านล่าง

๐	๑	๒	๓	๔	๕	๖	๗

ท่านออกกำลังกายโดยวิธีใด?

๑. .....

๒. .....

๓. .....

อะไรคืออุปสรรคที่ทำให้ท่านไม่ได้ออกกำลังกาย?

๑. .....

๒. .....

๓. .....

การออกกำลังกายและการเคลื่อนไหว
สามารถช่วยควบคุมระดับน้ำตาลในเลือดได้
และยังเป็นผลต่อต่อหัวใจท่านอีกด้วย

ประโยชน์ของการออกกำลังกาย

- ทำให้ค่าน้ำตาลในเลือดลดลง และเพิ่มประสิทธิภาพการทำงานของอินซูลิน
- ช่วยลดความดันโลหิต
- ช่วยลดระดับไขมันในเลือด คลอเลสเตอรอลและไตรกลีเซอร์ไรด์

- ลดโอกาสเสี่ยงในการเป็นโรคหัวใจและอัมพาต
- ลดความเครียดและทำให้อารมณ์ดีขึ้น
- ช่วยเผาผลาญพลังงาน ทำให้น้ำหนักลดลง

- ช่วยให้ประสิทธิภาพการนอนหลับดีขึ้น

การเตรียมความพร้อมก่อนการออกกำลังกาย

การเตรียมความพร้อมในการออกกำลังกาย และการปฏิบัติตามคำแนะนำจะช่วยให้ท่านออกกำลังกายด้วยความปลอดภัย ปราศจากการบาดเจ็บระหว่างการออกกำลังกาย

- เลือกกิจกรรมการออกกำลังกายที่เหมาะสมกับอายุ น้ำหนัก และปัญหาสุขภาพของท่าน
- ป้องกันอันตรายบริเวณเท้าโดยการสวมรองเท้าที่พอดี นุ่ม และสบาย
- ตรวจเช็คตุ่มน้ำ บาดแผล หรือจุดแดงก่อนและหลังการออกกำลังกาย
- มีบัตรผู้ป่วยเบาหวานไว้กับตัวเองตลอดเวลา
- รักษาระดับน้ำตาลในเลือดให้อยู่ระหว่าง ๑๐๐–๑๕๐ มก.% ระหว่างการออกกำลังกาย
- พกพาลูกอม หรือท๊อฟฟี่ไว้กับตัวเพื่อป้องกันภาวะน้ำตาลในเลือดต่ำ
- ดื่มน้ำชดเชยปริมาณน้ำที่เสียไประหว่างการออกกำลังกาย (ควรชั่งน้ำหนักก่อนและหลังการออกกำลังกาย)
- ออกกำลังกาย ๒๐-๓๐ นาที อย่างน้อย ๓-๕ วัน ต่อสัปดาห์
- อุ่นเครื่องก่อนเริ่มออกกำลังกายและผ่อนเครื่องก่อนจบการออกกำลังกาย

Appendix G: CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-11
	13b	For each group, losses and exclusions after randomisation, together with reasons	supplemental Figure S1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	supplemental Figure S1
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9-11
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-14
Other information			
Registration	23	Registration number and name of trial registry	1,5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	15

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix H: Questionnaires used in the research program

H.1 The English version of an individual questionnaires

Effectiveness of a self-management program on people with type 2 diabetes and their care giver in improving self-efficacy, quality of life and self-management in Thailand

Instructions

- This questionnaire collects your views about managing issues associated with living with type 2 diabetes.
- This questionnaire contains 7 parts. **Please answer every question** by responding as indicated. Your individual answers will remain confidential and not be shared with anyone else.
- Certain questions may look alike but each one is different. Some questions ask about problems you may not have. That's great, but it is important for us to know. Please answer each question.
- There are no right or wrong answers. If you are unsure how to answer a question please give the best answer you can.
- **Check the questionnaire is complete**. Occasionally a question can be accidentally missed when completing the questionnaire so it would be really helpful if you could take an extra couple of minutes to check that every question has been answered as indicated.
- **Hand in the completed questionnaire.** When you are satisfied that all questions have been answered, please hand the questionnaire back to the data collector.

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Part 1 Demographics and clinical data

1. Gender ☐ (1) Male ☐ (2) Female

2. Age _____ Date of birth____/____/____(dd/mm/yy)

3. Height _____ cm, Weight_____Kg, BMI_____kg/m

4. Religion ☐ (1) Buddhist ☐ (2) Muslim ☐ (3) Christian

☐ (4) Others_____(please describe)

5. Marital status ☐ (1) Single ☐ (2) Married ☐ (3) Divorced

☐ (4) Widow ☐ (5) Separated

6. Education level ☐ (1) No education ☐ (2) Primary school ☐ (3) Secondary school

☐ (4) Diploma ☐ (5) Bachelor ☐ (6) Master and above

7. Occupation ☐ (1) Housewife ☐ (2) Farmer ☐ (3) Office worker

☐ (4) Professional ☐ (5) Own business ☐ (6) Labour worker

☐ (7) Retired

8. Family income/month (Baht)

☐ (1) Less than 5,000 ☐ (2) 5,000 - 10,000 ☐ (3) 10,001 - 15,000

☐ (4) 15,001 - 20,000 ☐ (5) 20,001 - 25,000 ☐ (6) 25,001 and above

9. Personal living in Household

☐ (1) Spouse ☐ (2) Children ☐ (3) Parents/in laws

☐ (4) Other_____(please describe)

10. Duration of being diagnosed with diabetes_____year_____month

11. Co-morbidity ☐ (1) None ☐ (2) Yes, _____(please describe)

12. Complication of diabetes ☐ (1) None ☐ (2) Yes, _____(please describe)

13. Blood pressure_____mmHg Date ____/____/____(dd/mm/yy)

14. Fasting blood sugar_____mmol/L Date ____/____/____(dd/mm/yy)

15. Hb A1C level_____%

16. Medication

Name_____ Dose_____ Usage_____

Name_____ Dose_____ Usage_____

Name_____ Dose_____ Usage_____

Part 2 Diabetes Management Self-Efficacy Scale (DMSES)

Directions: Please answer each question by checking the answer that describes how convinced you are in managing your diabetes

		Yes Definitely	Probably Yes	Maybe Yes Maybe No	Probably No	Definitely Not
1	I think I'm able to check my blood sugar level if necessary	☐	☐	☐	☐	☐
2	I think I'm able to correct my blood sugar when the blood sugar value is too high.	☐	☐	☐	☐	☐
3	I think I'm able to correct my blood sugar when the blood sugar value is too low.	☐	☐	☐	☐	☐
4	I think I'm able to select the right foods	☐	☐	☐	☐	☐
5	I think I'm able to select different foods but stay within my diabetes diet.	☐	☐	☐	☐	☐
6	I think I'm able to keep my weight under control.	☐	☐	☐	☐	☐
7	I think I'm able to examine my feet for skin problems	☐	☐	☐	☐	☐
8	I think I'm able to get sufficient physical activities, for example, taking a walk or biking.	☐	☐	☐	☐	☐
9	I think I'm able to adjust my diet when I'm ill	☐	☐	☐	☐	☐
10	I think I'm able to follow my diet most of the time.	☐	☐	☐	☐	☐
11	I think I'm able to take extra physical activities, when the doctor advises me to do so.	☐	☐	☐	☐	☐
12	When taking extra physical activities, I think I'm able to adjust my diet.	☐	☐	☐	☐	☐
13	I think I'm able to follow my diet when I am away from home.	☐	☐	☐	☐	☐
14	I think I'm able to adjust my diet when I am away from home.	☐	☐	☐	☐	☐
15	I think I'm able to follow my diet when I am on vacation.	☐	☐	☐	☐	☐
16	I think I'm able to follow my diet when I am at a reception/party.	☐	☐	☐	☐	☐
17	I think I'm able to adjust my diet when I am under stress or tension.	☐	☐	☐	☐	☐
18	I think I'm able to visit the doctor once a year to monitor my diabetes.	☐	☐	☐	☐	☐
19	I think I'm able to take my medicine as prescribed.	☐	☐	☐	☐	☐
20	I think I'm able to adjust my medication when I'm ill.	☐	☐	☐	☐	☐

Part 3 Perceived therapeutic Efficacy Scale (PTES)

Directions: Please answer each question by checking the answer that describes how convinced you are in managing your diabetes

		Yes Definitely	Probably Yes	Maybe Yes Maybe No	Probably No	Definitely Not
1	My level of confidence in the ability of my diabetes medication to control my blood sugar is:	☐	☐	☐	☐	☐
2	My level of confidence in the ability that my diabetes medication can keep my blood sugar at a stable level and prevent it from becoming elevated is:	☐	☐	☐	☐	☐
3	My level of confidence in the ability of my diabetes medication to limit the severity of complications (e.g. eye or foot problems) is:	☐	☐	☐	☐	☐
4	My level of confidence in the ability of my diabetes medication to prevent me getting (more) complications is:	☐	☐	☐	☐	☐
5	My level of confidence in the ability that the maintenance of the dose of my medication can control my diabetes effectively is:	☐	☐	☐	☐	☐
6	My level of confidence in the need to take my medication each day exactly as prescribed to control my diabetes is:	☐	☐	☐	☐	☐
7	My overall level of confidence in the value of the diabetes medication that I am prescribed is:	☐	☐	☐	☐	☐
8	My level of confidence in the ability if medication in general to control my diabetes is:	☐	☐	☐	☐	☐
9	My level of confidence in my health professionals' advice that experts such as doctor or nutritionists give me in my diabetes treatment is:	☐	☐	☐	☐	☐
10	My overall level of confidence in my ability to cope with my diabetes is:	☐	☐	☐	☐	☐

Part 4 Summary of diabetes Self -Care Activities Measure (SDSCA)

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

1	How many of the last SEVEN DAYS did you eat the appropriate quantity of diabetic food to balance your daily energy loss?	0	1	2	3	4	5	6	7
2	How many of the last SEVEN DAYS did you eat snacks between meals?	0	1	2	3	4	5	6	7
3	On how many of the last SEVEN DAYS did you eat high glucose food, such as, sweet drink, sweet fruit (Durian, Mango, Longan, lychee) without consideration?	0	1	2	3	4	5	6	7
4	On how many of the last SEVEN DAYS did you eat high fat food, such as, belly pork, pork legs, duck skin, chicken skin, coconut milk, deep fried food, oyster, calamari, ect?	0	1	2	3	4	5	6	7
5	On how many of the last SEVEN DAYS did you eat your 3 meals on time?	0	1	2	3	4	5	6	7
6	On how many of the last SEVEN DAYS did you use exchange food concept (1 pod of corn instead of 2 ladle of rice)?	0	1	2	3	4	5	6	7
7	On how many of the last SEVEN DAYS did you drink alcohol, such as, more than 1 can of beer, more than half glass of wine?	0	1	2	3	4	5	6	7
8	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).	0	1	2	3	4	5	6	7
9	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking)?	0	1	2	3	4	5	6	7
10	On how many of the last SEVEN DAYS did you reconsider your eating plan?	0	1	2	3	4	5	6	7

11	On how many of the last SEVEN DAYS did you check yourself for signs and symptoms of hypo and hyperglycemia?	0	1	2	3	4	5	6	7
12	On how many of the last SEVEN DAYS did you check your body for auxiliary and groin infection?	0	1	2	3	4	5	6	7
13	On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7
14	On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?	0	1	2	3	4	5	6	7
15	On how many of the last SEVEN DAYS did you check your feet?	0	1	2	3	4	5	6	7
16	On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	0	1	2	3	4	5	6	7
17	On how many of the last SEVEN DAYS did you soak your feet?	0	1	2	3	4	5	6	7
18	On how many of the last SEVEN DAYS did you dry between your toes after washing?	0	1	2	3	4	5	6	7
19	On how many of the last SEVEN DAYS, did you take your recommended number of diabetes medication?	0	1	2	3	4	5	6	7
20	On how many of the last SEVEN DAYS, did you take your diabetic medication on time?	0	1	2	3	4	5	6	7

Part 5 Diabetes Knowledge Scale

Directions: Please answer each question by selecting the answer as indicated for each of the following items:

Item	Question	Yes	No	I don't know
1	Eating too much sugar and other sweet foods is a cause of diabetes.	☐	☐	☐
2	The usual cause of diabetes is lack of effective insulin in the body.	☐	☐	☐
3	Diabetes is caused by failure of the kidneys to keep sugar out of the urine.	☐	☐	☐
4	Kidneys produce insulin.	☐	☐	☐
5	In untreated diabetes, the amount of sugar in the blood usually increases.	☐	☐	☐
6	If I am diabetic, my children have a higher chance of being diabetic.	☐	☐	☐
7	Diabetes can be cured.	☐	☐	☐
8	A fasting blood sugar level of 210 is too high.	☐	☐	☐
9	The best way to check my diabetes is by testing my urine.	☐	☐	☐
10	Regular exercise will increase the need for insulin or other diabetic medication.	☐	☐	☐
11	There are two main types of diabetes: Type 1 (insulin-dependent) and Type 2 (non-insulin-dependent).	☐	☐	☐
12	An insulin reaction is caused by too much food.	☐	☐	☐
13	Medication is more important than diet and exercise to control my diabetes.	☐	☐	☐
14	Diabetes often causes poor circulation.	☐	☐	☐
15	Cuts and abrasions on diabetics heal more slowly.	☐	☐	☐
16	Diabetics should take extra care when cutting their toenails.	☐	☐	☐
17	A person with diabetes should cleanse a cut with iodine and alcohol.	☐	☐	☐
18	The way I prepare my food is as important as the foods I eat.	☐	☐	☐
19	Diabetes can damage my kidneys.	☐	☐	☐
20	Diabetes can cause loss of feeling in my hands, fingers, and feet.	☐	☐	☐
21	Shaking and sweating are signs of high blood sugar.	☐	☐	☐
22	Frequent urination and thirst are signs of low blood sugar.	☐	☐	☐
23	Tight elastic hose or socks are not bad for diabetics.	☐	☐	☐
24	A diabetic diet consists mostly of special foods.	☐	☐	☐

Part 6 Health related quality of life

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
○	○	○	○	○

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○	○	○
b Climbing several flights of stairs	○	○	○

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	○	○	○	○	○
b Were limited in the kind of work or other activities	○	○	○	○	○

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	○	○	○	○	○
b Did work or activities less carefully than usual	○	○	○	○	○

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
○	○	○	○	○

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6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	○	○	○	○	○
b Did you have a lot of energy?	○	○	○	○	○
c Have you felt downhearted and depressed?	○	○	○	○	○

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7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

H.2 The Thai version of an individual questionnaires

ประสิทธิภาพโปรแกรมการจัดการตนเองของผู้ป่วยเบาหวานชนิดที่ ๒ และผู้ดูแล ในการพัฒนาการรับรู้ความสามารถของตนเอง คุณภาพชีวิต และการจัดการตนเองในประเทศไทย

คำชี้แจง

- แบบสอบถามนี้พัฒนาขึ้นเพื่อสอบถามความคิดเห็นของท่านเกี่ยวกับการดำเนินชีวิตด้วยโรคเบาหวานชนิดที่ ๒
- แบบสอบถามนี้ประกอบด้วย ๓ ส่วน กรุณาตอบทุกคำถามตามความคิดของท่าน
- ข้อคำถามมีลักษณะแตกต่างกัน บางคำถามอาจไม่ได้ปัญหาของท่านแต่กรุณาตอบคำถามตามความคิดเห็นของท่าน
- ไม่มีคำตอบที่ผิดหรือถูก ถ้าท่านไม่แน่ใจในคำตอบ กรุณาตอบตามที่ท่านเห็นว่าถูกต้องที่สุด
- ตรวจสอบความสมบูรณ์ของแบบสอบถามอีกครั้งหลังจากตอบแบบสอบถามเสร็จ
- ส่งแบบสอบถามที่สมบูรณ์คืนแก่ผู้รวบรวมแบบสอบถาม หลังจากท่านตอบแบบสอบถามสมบูรณ์และพอใจในคำตอบ

นุชนาถ วิชิต

นักศึกษาปริญญาเอก

มหาวิทยาลัย Australian Catholic ประเทศออสเตรเลีย

ส่วนที่ ๑ ข้อมูลส่วนบุคคลและข้อมูลทางคลินิก

๑. เพศ ☐ (๑)ชาย ☐ (๒) หญิง

๒. อายุ _____ปี วัน เดือน ปี เกิด____/____/____ (วัน/เดือน/ปี)

๓. ความสูง _____ ซม. น้ำหนัก_____กิโลกรัม, ดัชนีมวลกาย_____กิโลกรัม/เมตร^2

๔. ศาสนา ☐ (๑) พุทธ ☐ (๒) อิสลาม ☐ (๓) คริสต์
☐ (๔) อื่นๆ_____(โปรดระบุ)

๕. สถานภาพสมรส ☐ (๑) โสด ☐ (๒) สมรส ☐ (๓) หย่าร้าง
☐ (๔) หม้าย ☐ (๕) แยกกันอยู่

๖. Education level ☐ (๑) ไม่ได้ศึกษา ☐ (๒) ประถมศึกษา ☐ (๓) มัธยมศึกษา
☐ (๔) ประกาศนียบัตร ☐ (๕) ปริญญาตรี ☐ (๖) ปริญญาโท หรือมากกว่า

๗. อาชีพ ☐ (๑) แม่บ้าน ☐ (๒) เกษตรกร ☐ (๓) บริษัทเอกชน
☐ (๔) รับราชการ ☐ (๕) ธุรกิจส่วนตัว ☐ (๖) รับจ้าง กรรมกร
☐ (๗) อื่นๆ ระบุ_____

๘. รายได้ของครอบครัว/เดือน (บาท)
☐ (๑) น้อยกว่า ๕,๐๐๐ ☐ (๒) ๕,๐๐๐ - ๑๐,๐๐๐ ☐ (๓) ๑๐,๐๐๑ - ๑๕,๐๐๐
☐ (๔) ๑๕,๐๐๑ - ๒๐,๐๐๐ ☐ (๕) ๒๐,๐๐๑ - ๒๕,๐๐๐ ☐ (๖) ๒๕,๐๐๑ และ มากกว่า

๙. บุคคลที่อาศัยอยู่ด้วยในบ้าน
☐ (๑) สามี/ภรรยา ☐ (๒) บุตร
☐ (๓) บิดามารดา ☐ (๔) อื่นๆ ระบุ_____

๑๐. ระยะเวลาการเป็นเบาหวาน_____ปี_____เดือน

๑๑. โรคร่วมอื่นๆ ☐ (๑) ไม่มี ☐ (๒) มี, ระบุ_____

๑๒. โรคแทรกซ้อนจากเบาหวาน ☐ (๑) ไม่มี ☐ (๒) มี, ระบุ_____

๑๓. ความดันโลหิต_____mmHgวันที่ ____/____/____(วัน/เดือน/ปี)

๑๔. ประมาณน้ำตาลในเลือด (FBS)_____mmol/Lวันที่ ____/____/____(วัน/เดือน/ปี)

๑๕. ปริมาณน้ำตาลสะสม (Hb A๑C)_____% วันที่ ____/____/____(วัน/เดือน/ปี)

๑๖. ยาที่ได้รับ

ชื่อ_____ ปริมาณ_____ เวลาที่รับประทาน_____

ชื่อ_____ ปริมาณ_____ เวลาที่รับประทาน_____

ชื่อ_____ ปริมาณ_____ เวลาที่รับประทาน_____

ส่วนที่ ๒ แบบวัดการรับรู้สมรรถนะแห่งตนสำหรับการควบคุมและดูแลตนเองในผู้ป่วยโรคเบาหวานชนิดไม่พึ่งอินสุลิน

คำชี้แจง: แบบวัดชุดนี้มีวัตถุประสงค์เพื่อต้องการทราบระดับความมั่นใจในความสามารถที่จะปฏิบัติกิจกรรมเพื่อการควบคุมและดูแลตนเองในโรคเบาหวานขอให้ท่านอ่านข้อความแต่ละข้อความทางด้านซ้ายมือ ประเมินและให้คะแนนความเชื่อมั่นของสถานการณ์ในแต่ละข้อ

ข้อ	สถานการณ์	ระดับความมั่นใจ				
		ไม่มั่นใจเลย	มั่นใจน้อย	มั่นใจปานกลาง	มั่นใจมาก	มั่นใจมากที่สุด
๑	ท่านสามารถตรวจสอบระดับน้ำตาลในเลือดหรือในปัสสาวะได้ด้วยตัวท่านเองถ้าจำเป็นต้องทำ					
๒	ท่านสามารถปรับระดับน้ำตาลในเลือดให้อยู่ในเกณฑ์ปกติได้เมื่อมีอาการของภาวะน้ำตาลในเลือดสูงเกินไป เช่น ปัสสาวะบ่อย กระหายน้ำ อ่อนเพลีย					
๓	ท่านสามารถปรับระดับน้ำตาลในเลือดให้อยู่ในเกณฑ์ปกติได้เมื่อมีอาการของภาวะน้ำตาลในเลือดต่ำเกินไป เช่น ใจสั่น หน้ามืด หรือเหงื่อออกมาก ตัวเย็น					
๔	ท่านสามารถเลือกรับประทานอาหารที่เหมาะสมกับโรคเบาหวานได้อย่างถูกต้อง					
๕	ท่านสามารถเลือกอาหารที่หลากหลายและแตกต่างออกไปแต่ยังเป็นอาหารที่เหมาะกับโรคเบาหวาน					
๖	ท่านสามารถควบคุมน้ำหนักตัวเองให้อยู่ในเกณฑ์ปกติได้					
๗	ท่านสามารถตรวจดูความผิดปกติของผิวหนังบริเวณเท้าด้วยตัวเองได้ เช่น สีผิวซีด หรือเขียวคล้ำ รอยช้ำ บาดแผล หรืออาการอักเสบ					
๘	ท่านสามารถสังเกตอาการผิดปกติทางการมองเห็น เช่น ตาพร่ามัว					
๙	ท่านสามารถออกกำลังกายอย่างเพียงพอที่จะควบคุมระดับน้ำตาลในเลือดได้ เช่น การเดิน หรือ การขี่จักรยาน					
๑๐	เมื่อมีอาการเจ็บป่วยท่านสามารถปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารของตัวเองได้อย่างเหมาะสมกับโรคเบาหวาน					
๑๑	ท่านสามารถดูแลตัวเองให้ได้รับอาหารที่เหมาะสมกับโรคเบาหวานได้เกือบตลอดเวลา					
๑๒	ท่านสามารถเพิ่มการออกกำลังกายได้อีกเมื่อแพทย์แนะนำ					

ข้อ	สถานการณ์	ระดับความมั่นใจ				
		ไม่มั่นใจเลย	มั่นใจน้อย	มั่นใจปานกลาง	มั่นใจมาก	มั่นใจมากที่สุด
๑๓	เมื่อท่านออกกำลังกายหนักท่านสามารถปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารของตัวเองได้อย่างเหมาะสมกับพลังงานที่สูญเสียไป					
๑๔	ท่านสามารถปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารของตัวเองได้อย่างเหมาะสมกับเบาหวานแม้ว่าไม่ได้อยู่ที่บ้าน					
๑๕	ช่วงวันหยุดนักขัตฤกษ์ เทศกาล หรือช่วงพักร้อนท่านสามารถดูแลตัวเองให้ได้รับอาหารเหมาะสมกับโรคเบาหวานได้					
๑๖	เมื่ออยู่ในงานเลี้ยงพบปะสังสรรค์ ท่านสามารถดูแลตัวเองให้ได้รับอาหารให้เหมาะสม กับโรคเบาหวานได้					
๑๗	เมื่ออยู่ในภาวะเครียดหรือภาวะกดดันท่านสามารถปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารของตัวเองได้					
๑๘	ท่านสามารถไปพบแพทย์เป็นประจำตามที่แพทย์นัด เพื่อตรวจเช็คอาการของโรคเบาหวาน					
๑๙	ท่านสามารถรับประทานยาตามที่แพทย์สั่งได้อย่างถูกต้อง					
๒๐	ท่านสามารถปรับการรับประทานยาได้อย่างถูกต้องทุกครั้งเมื่อมีอาการเจ็บป่วย					

ส่วนที่ ๓ แบบวัดการรับรู้สมรรถนะการรักษาโรค (Perceived Therapeutic Efficacy Scale (PTES)

คำชี้แจง: กรุณาตอบคำถามโดยการทำเครื่องหมาย ☒ ในคำตอบที่ตรงกับระดับการรับรู้ของท่านในการจัดการกับโรคเบาหวาน

ข้อ	สถานการณ์	ระดับความมั่นใจ				
		ไม่มั่นใจเลย	มั่นใจน้อย	มั่นใจปานกลาง	มั่นใจมาก	มั่นใจมากที่สุด
๑	ระดับความเชื่อมั่นของฉันต่อความสามารถของยารักษาเบาหวานในการสามารถควบคุมน้ำตาลในเลือด					
๒	ระดับความเชื่อมั่นของฉันต่อยารักษาเบาหวานในการรักษาระดับน้ำตาลให้คงที่และป้องกันการเพิ่มขึ้นของน้ำตาลได้					
๓	ระดับความเชื่อมั่นของต่อยารักษาโรคเบาหวานว่าสามารถจำกัดความรุนแรงของโรคแทรกซ้อนได้ (เช่น ปัญหาเท้าหรือสายตา)					
๔	ระดับความเชื่อมั่นของฉันต่อยารักษาโรคเบาหวานในการสามารถป้องกันไม่ให้เกิดโรคแทรกซ้อนเพิ่มขึ้นได้					
๕	ระดับความเชื่อมั่นของฉันต่อการทานยาตามขนาดแล้วจะสามารถควบคุมโรคเบาหวานได้อย่างมีประสิทธิภาพ					
๖	ระดับความเชื่อมั่นของฉันต่อความจำเป็นในการรับประทานยาตามที่แพทย์กำหนดเป็นประจำทุกวันเพื่อควบคุมโรคเบาหวาน					
๗	ระดับความเชื่อมั่นโดยรวมของฉันต่อคุณประโยชน์ของยารักษาโรคเบาหวานฉันได้รับ					
๘	ระดับความเชื่อมั่นของฉันต่อความสามารถของการรักษาด้วยยาในการควบคุมโรคเบาหวานของฉัน					
๙	ระดับความเชื่อมั่นของฉันต่อคำแนะนำจากผู้เชี่ยวชาญด้านสุขภาพ เช่น แพทย์หรือนักโภชนาการที่ให้แก่ฉันในการรักษาโรคเบาหวาน					
๑๐	ระดับความเชื่อมั่นของฉันโดยรวมด้านความสามารถในการรับมือกับโรคเบาหวาน					

ส่วนที่ ๔ แบบวัดกิจกรรมการดูแลตนเองในผู้เป็นเบาหวาน

ข้อคำถามต่อไปนี้ถามท่านเกี่ยวกับกิจกรรมการดูแลตนเองในช่วง ๗ วันที่ผ่านมา ถ้าในช่วง ๗ วันที่ผ่านมาท่านเจ็บป่วย ให้นึกย้อนหลังไปอีก ๗ วันก่อนช่วงที่ท่านเจ็บป่วย กรุณาใส่เครื่องหมายวงกลม (O) ลงในหมายเลขที่ตรงกับจำนวนวันที่ท่านดูแลตนเอง

ข้อ	การดูแลตนเอง	จำนวนวัน							
๑	การรับประทานอาหาร ในช่วง ๗ วันที่ผ่านมา ท่านกินอาหารในปริมาณที่เหมาะสมกับผู้ป่วยเบาหวาน และเหมาะกับการใช้แรงงานประจำวันของท่านกี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๒	ในช่วง ๗ วันที่ผ่านมา ท่านกินอาหารจุบจิบระหว่างมื้อ กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๓	ในช่วง ๗ วันที่ผ่านมาท่านกินอาหารที่มีน้ำตาลมาก เช่น น้ำหวาน หวานเย็น ผลไม้รสหวานจัดเช่น ทุเรียน มะม่วง ลำไย ลิ้นจี่ ละมุด โดยไม่คำนึงถึงปริมาณที่กินได้กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๔	ในช่วง ๗ วันที่ผ่านมา ท่านกินอาหารไขมันสูง เช่น หมูสามชั้น ขาหมู หนังเป็ด หนังไก่ กะทิ อาหารทอดต่างๆ ไข่แดง หอยนางลม ปลาหมึก กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๕	ในช่วง ๗ วันที่ผ่านมา ท่านกินอาหารตรงเวลาครบ ๓ มื้อ กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๖	ในช่วง ๗ วันที่ผ่านมา ท่านใช้หลักการแลกเปลี่ยนอาหารในการกินอาหารได้กี่วัน (การแลกเปลี่ยนอาหาร เช่น กินข้าวโพด ๑ ฝัก แทนการกินข้าว ๒ ทัพพี กินข้าวเหนียว ๑ ปั้นเท่าไข่ไก่ แทนการกินข้าว ๑ ทัพพี เป็นต้น)	๐	๑	๒	๓	๔	๕	๖	๗
๗	ในช่วง ๗ วันที่ผ่านมา ท่านดื่มเครื่องดื่มที่มีแอลกอฮอล์ เช่น เหล้ามากกว่า ๒ เป็ก เบียร์มากกว่า ๑ กระป๋อง ไวน์ มากกว่าครึ่งแก้ว กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๘	การออกกำลังกาย ในช่วง ๗ วันที่ผ่านมา ท่านมีการออกแรงทำกิจกรรมอย่างต่อเนื่องอย่างน้อย ๓๐ นาที เช่น อู้บ้านจนเหงื่อออก ทำสวน เดิน กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๙	ในช่วง ๗ วันที่ผ่านมา ท่านมีกิจกรรมออกกำลังกายที่เฉพาะเจาะจง เช่น เต้นแอร์โรบิก ว่ายน้ำ วิ่ง ขี่จักรยาน กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๐	การประเมินตนเอง ในช่วง ๗ วันที่ผ่านมา ท่านทบทวนตนเองในเรื่องการกินอาหาร ว่ากินมากเกินไป หรือน้อยเกินไป กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๑	ในช่วง ๗ วันที่ผ่านมาท่านสังเกตตนเองว่ามีอาการน้ำตาลในเลือดสูง เช่น กระหายน้ำบ่อย ปัสสาวะบ่อย ตาพร่ามัว อ่อนเพลีย หรือมีอาการน้ำตาลต่ำ เช่น หิว ใจสั่น เหงื่อแตก กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๒	ในช่วง ๗ วัน ที่ผ่านมา ท่านตรวจร่างกายตนเองตามซอกอับ เช่น รักแร้ ใต้ราวนม ขาหนีบ ว่ามีการติดเชื้อหรือไม่ กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๓	ในช่วง ๗ วัน ที่ผ่านมา ท่านตรวจน้ำตาลในเลือดด้วยตัวเอง กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗

ข้อ	การดูแลตนเอง	จำนวนวัน							
๑๔	ในช่วง ๗ วัน ที่ผ่านมาท่านตรวจน้ำตาลในเลือดด้วยตัวเองตามจำนวนครั้งที่เจ้าหน้าที่พยาบาลแนะนำ กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๕	การดูแลเท้า และสุขอนามัย ในช่วง ๗ วันที่ผ่านมา ท่านตรวจเท้าอย่างละเอียดกี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๖	ในช่วง ๗ วันที่ผ่านมา ก่อนใส่รองเท้าท่านตรวจดูที่รองเท้าว่ามีเศษหิน ทราย หรือของมีคม อยู่ที่รองเท้า กี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๗	ในช่วง ๗ วันที่ผ่านมา ท่านทำความสะอาดเท้าอย่างทั่วถึงกี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๘	ในช่วง ๗ วันที่ผ่านมา ท่านเช็ดซอกเท้าให้แห้งหลังทำความสะอาดเท้ากี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๑๙	การรับประทานยา ในช่วง ๗ วันที่ผ่านมา ท่านกินยาเบาหวานครบทุกมื้อ และตามขนาดที่แพทย์กำหนดกี่วัน	๐	๑	๒	๓	๔	๕	๖	๗
๒๐	ในช่วง ๗ วันที่ผ่านมา ท่านกินยาเบาหวานได้ตรงเวลาทุกมื้อกี่วัน	๐	๑	๒	๓	๔	๕	๖	๗

ส่วนที่ ๕ ความรู้เรื่องโรคเบาหวาน

คำชี้แจง: กรุณาตอบแต่ละคำถามโดยการทำเครื่องหมาย ☒ ในช่องคำตอบ

ข้อ	คำถาม	ใช่	ไม่ใช่	ไม่ทราบ
๑	การรับประทานน้ำตาลและอาหารหวานมากเกินไป เป็นสาเหตุของโรคเบาหวาน			
๒	สาเหตุปกติของโรคเบาหวาน คือ ขาดอินซูลินที่มีประสิทธิภาพในร่างกาย			
๓	โรคเบาหวานเกิดจากความล้มเหลวของไตในการเก็บรักษาน้ำตาลออกจากปัสสาวะ			
๔	ไตผลิตอินซูลิน			
๕	ในโรคเบาหวานที่ไม่ได้รับการรักษา โดยปกติปริมาณน้ำตาลในเลือดเพิ่มขึ้น			
๖	ถ้าฉันเป็นเบาหวาน บุตรของฉันมีโอกาสที่จะเป็นเบาหวานสูงขึ้น			
๗	โรคเบาหวานสามารถรักษาได้			
๘	หลังงดอาหารอย่างน้อย ๘ ชั่วโมง ระดับน้ำตาลในเลือด ๒๑๐ มิลลิกรัม/เดซิลิตร ถือว่าสูงมาก			
๙	วิธีที่ดีที่สุดในการตรวจเช็คโรคเบาหวานคือ การตรวจปัสสาวะ			
๑๐	การออกกำลังสม่ำเสมอจะเพิ่มความต้องการอินซูลินหรือยารักษาโรคเบาหวาน			
๑๑	โรคเบาหวานมีสองประเภทหลักๆ คือประเภทที่ ๑ (ชนิดพึ่งอินซูลิน) และประเภทที่ ๒ (ชนิดไม่พึ่งอินซูลิน)			
๑๒	การออกฤทธิ์ของอินซูลินเกิดขึ้นเพราะกินอาหารมากเกินไป			
๑๓	ในการควบคุมเบาหวาน ยามีความสำคัญมากกว่าอาหารและการออกกำลังกาย			
๑๔	โรคเบาหวานมักก่อให้เกิดการไหลเวียนเลือดไม่ดี			
๑๕	บาดแผลและรอยถลอกในผู้ป่วยเบาหวานหายได้ช้า			
๑๖	ผู้ป่วยเบาหวานควรระวังเป็นมากพิเศษขณะตัดเล็บเท้า			
๑๗	บุคคลที่เป็นโรคเบาหวานควรจะทำความสะอาดบาดแผลด้วยสารละลายไอโอดีนและแอลกอฮอล์			
๑๘	วิธีการเตรียมอาหารมีความสำคัญเท่ากับอาหารที่รับประทาน			
๑๙	โรคเบาหวานสามารถทำลายไตได้			
๒๐	โรคเบาหวานสามารถก่อให้เกิดการสูญเสียความรู้สึกที่มือ นิ้วและเท้า			
๒๑	เหงื่อออก ตัวสั่น เป็นอาการของน้ำตาลในเลือดสูง			
๒๒	การถ่ายปัสสาวะบ่อยและกระหายน้ำเป็นอาการของน้ำตาลในเลือดต่ำ			
๒๓	ถุงน่องหรือถุงเท้าที่แน่นไม่เป็นอันตรายต่อผู้ป่วยเบาหวาน			
๒๔	อาหารสำหรับโรคเบาหวานประกอบด้วยอาหารพิเศษเป็นส่วนใหญ่			

ส่วนที่ ๖ สุขภาพและความผาสุกของคุณ

แบบสอบถามนี้ถามความคิดเห็นของคุณเกี่ยวกับสุขภาพของคุณ ข้อมูลนี้จะช่วยในการบันทึกว่าคุณรู้สึกอย่างไร และคุณสามารถทำกิจกรรมต่างๆ ตามปกติของคุณได้ดีแค่ไหน ***ขอบคุณที่ให้ความร่วมมือในการตอบแบบสอบถามนี้***

ในแต่ละคำถามต่อไปนี้ โปรดทำเครื่องหมาย ☒ ลงในช่องเพียงช่องเดียวที่ตรงกับคำตอบของคุณมากที่สุด

1. โดยทั่วไป คุณจะบอกว่าสุขภาพของคุณ:

ดีที่สุด	ดีมาก	ดี	พอใช้	แย่
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. คำถามต่อไปนี้เป็นคำถามเกี่ยวกับ กิจกรรมที่คุณอาจจะทำในช่วงวันปกติทั่วๆ ไป <u>สุขภาพของคุณในตอนนี้ทำให้คุณถูกจำกัด</u>ในการทำกิจกรรมเหล่านี้หรือไม่ ถ้าใช่ ถูกจำกัดมากน้อยแค่ไหน

	ใช่ ถูกจำกัดมาก ▼	ใช่ ถูกจำกัดเล็กน้อย ▼	ไม่ใช่ ไม่ถูกจำกัดเลย ▼
a. <u>กิจกรรมที่ใช้แรงปานกลาง</u> เช่น การย้ายโต๊ะ การถวาดพื้น การทำสวน การปั่นจักรยาน หรือการว่ายน้ำ	☐ 1	☐ 2	☐ 3
b. การเดินขึ้นบันไดขึ้นสัก <u>2-3</u> ชั้น	☐ 1	☐ 2	☐ 3

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3. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจวัตรประจำวันอื่นๆ อันเนื่องมาจากสุขภาพทางกายของคุณ

	ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นานๆครั้ง	ไม่เคยเลย
a. ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. ถูกจำกัดชนิดของงานหรือกิจกรรมที่คุณสามารถทำได้	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจวัตรประจำวันอื่นๆ ของคุณ อันเนื่องมาจากปัญหาด้านอารมณ์ (เช่น รู้สึกซึมเศร้า หรือ วิตกกังวล)

	ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นานๆครั้ง	ไม่เคยเลย
a. ทำงานหรือกิจวัตรประจำวันอื่นๆ สำเร็จได้น้อยกว่าที่คุณต้องการ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. ทำงานหรือกิจกรรมอื่นๆ ด้วยความระมัดระวังน้อยกว่าปกติ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. ในช่วง 4 สัปดาห์ที่ผ่านมา ความเจ็บปวดมีผลรบกวนการทำงานตามปกติของคุณ (ทั้งงานนอกบ้านและงานบ้าน) มากน้อยแค่ไหน

ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากที่สุด
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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6. คำถามต่อไปนี้จะถามเกี่ยวกับว่าคุณรู้สึกอย่างไร และคุณเป็นอย่างไร ในช่วง 4 สัปดาห์ที่ผ่านมา แต่ละคำถามต่อไปนี้ โปรดเลือกเพียงคำตอบเดียว ที่ใกล้เคียงกับความรู้สึกของคุณมากที่สุด ในช่วง 4 สัปดาห์ที่ผ่านมา ป่อยแค่ไหน ที่...

	ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
a. คุณรู้สึกใจเย็นและสงบ	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. คุณรู้สึกเต็มไปด้วยพลัง	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. คุณรู้สึกท้อแท้และซึมเศร้า	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. ในช่วง 4 สัปดาห์ที่ผ่านมา ป่อยแค่ไหน ที่สุขภาพทางกายหรือปัญหาด้านอารมณ์ของคุณ

ตลอดเวลา	เป็นส่วนใหญ่	เป็นบางครั้ง	นาน ๆ ครั้ง	ไม่เคยเลย
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

มีผลรบกวนกิจกรรมทางสังคมของคุณ (เช่น การไปเยี่ยมเพื่อน หรือ ญาติมิตร เป็นต้น)

ขอบคุณที่ให้ความร่วมมือในการตอบคำถาม

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H.3 The English version of a carer questionnaires

Part 7 Family Diabetes Management Self-Efficacy Scale (F-DMSES)

Directions: Please answer each question by checking the answer that describes how convinced you are in helping your family member to manage their diabetes

I am confident in helping my family member:

		Yes Definitely	Probably Yes	Maybe Yes Maybe No	Probably No	Definitely Not
1	To check their blood sugar level if necessary	☐	☐	☐	☐	☐
2	To correct their blood sugar when the blood sugar value is too high.	☐	☐	☐	☐	☐
3	To correct their blood sugar when the blood sugar value is too low.	☐	☐	☐	☐	☐
4	To select the right foods	☐	☐	☐	☐	☐
5	To select different foods but stay within their diabetes diet.	☐	☐	☐	☐	☐
6	To keep their weight under control.	☐	☐	☐	☐	☐
7	To examine their feet for skin problems	☐	☐	☐	☐	☐
8	To get sufficient physical activities, for example, taking a walk or biking.	☐	☐	☐	☐	☐
9	To adjust their diet when they are ill	☐	☐	☐	☐	☐
10	To follow their diet most of the time.	☐	☐	☐	☐	☐
11	To take extra physical activities, when the doctor advises them to do so.	☐	☐	☐	☐	☐
12	To adjust their diet when they are taking extra physical activities.	☐	☐	☐	☐	☐
13	To follow their diet when they are away from home.	☐	☐	☐	☐	☐
14	To adjust their diet when they are away from home.	☐	☐	☐	☐	☐
15	To follow their diet when they are on vacation.	☐	☐	☐	☐	☐
16	To follow their diet when they are at a reception/party.	☐	☐	☐	☐	☐
17	To adjust their diet when they are under stress or tension.	☐	☐	☐	☐	☐
18	To visit the doctor once a year to monitor their diabetes.	☐	☐	☐	☐	☐
19	To take their medicine as prescribed.	☐	☐	☐	☐	☐
20	To adjust their medication when they are ill.	☐	☐	☐	☐	☐

Part 8 Diabetes Knowledge Scale (For carer)

Directions: Please answer each question by selecting the answer as indicated for each of the following items:

Item	Question	Yes	No	I don't know
1	Eating too much sugar and other sweet foods is a cause of diabetes.	☐	☐	☐
2	The usual cause of diabetes is lack of effective insulin in the body.	☐	☐	☐
3	Diabetes is caused by failure of the kidneys to keep sugar out of the urine.	☐	☐	☐
4	Kidneys produce insulin.	☐	☐	☐
5	In untreated diabetes, the amount of sugar in the blood usually increases.	☐	☐	☐
6	If I am diabetic, my children have a higher chance of being diabetic.	☐	☐	☐
7	Diabetes can be cured.	☐	☐	☐
8	A fasting blood sugar level of 210 is too high.	☐	☐	☐
9	The best way to check my diabetes is by testing my urine.	☐	☐	☐
10	Regular exercise will increase the need for insulin or other diabetic medication.	☐	☐	☐
11	There are two main types of diabetes: Type 1 (insulin-dependent) and Type 2 (non-insulin-dependent).	☐	☐	☐
12	An insulin reaction is caused by too much food.	☐	☐	☐
13	Medication is more important than diet and exercise to control my diabetes.	☐	☐	☐
14	Diabetes often causes poor circulation.	☐	☐	☐
15	Cuts and abrasions on diabetics heal more slowly.	☐	☐	☐
16	Diabetics should take extra care when cutting their toenails.	☐	☐	☐
17	A person with diabetes should cleanse a cut with iodine and alcohol.	☐	☐	☐
18	The way I prepare my food is as important as the foods I eat.	☐	☐	☐
19	Diabetes can damage my kidneys.	☐	☐	☐
20	Diabetes can cause loss of feeling in my hands, fingers, and feet.	☐	☐	☐
21	Shaking and sweating are signs of high blood sugar.	☐	☐	☐
22	Frequent urination and thirst are signs of low blood sugar.	☐	☐	☐
23	Tight elastic hose or socks are not bad for diabetics.	☐	☐	☐
24	A diabetic diet consists mostly of special foods.	☐	☐	☐

H.4 Carer questionnaires (Thai)

ส่วนที่ ๓

แบบวัดการรับรู้สมรรถนะแห่งตนสำหรับสมาชิกในครอบครัวผู้ป่วยโรคเบาหวานในการช่วยเหลือควบคุมและดูแลตนเองในโรคเบาหวานชนิดไม่พึ่งอินสุลิน

คำชี้แจง: แบบวัดชุดนี้มีวัตถุประสงค์เพื่อต้องการทราบระดับความมั่นใจของท่านในความสามารถที่จะช่วยเหลือสมาชิกในครอบครัวปฏิบัติกิจกรรมเพื่อการควบคุมและดูแลตนเองในโรคเบาหวานขอให้ท่านอ่านข้อความแต่ละข้อความทางด้านซ้ายมือประเมินและให้คะแนนความเชื่อมั่นของสถานการณ์ในแต่ละข้อว่า

"ท่านมั่นใจว่าท่านสามารถช่วยเหลือสมาชิกในครอบครัวของท่านในสถานการณ์ต่อไปนี้"

ข้อ	สถานการณ์	ระดับความมั่นใจ				
		ไม่มั่นใจเลย	มั่นใจน้อย	มั่นใจปานกลาง	มั่นใจมาก	มั่นใจมากที่สุด
๑	ตรวจสอบระดับน้ำตาลในเลือดหรือในปัสสาวะของผู้ป่วยได้ถ้าจำเป็นต้องทำ					
๒	ปรับระดับน้ำตาลในเลือดของผู้ป่วยให้อยู่ในเกณฑ์ปกติได้เมื่อมีอาการของภาวะน้ำตาลในเลือดสูงเกินไป เช่น ปัสสาวะบ่อย กระหายน้ำ อ่อนเพลีย หรือเป็นแผลหายช้า					
๓	ปรับระดับน้ำตาลในเลือดของผู้ป่วยให้อยู่ในเกณฑ์ปกติได้เมื่อมีอาการของภาวะน้ำตาลในเลือดต่ำเกินไป เช่น ใจสั่น หน้ามืด หรือเหงื่อออกมาก					
๔	เลือกรับประทานอาหารที่เหมาะสมกับโรคเบาหวานได้อย่างถูกต้อง					
๕	เลือกอาหารที่แตกต่างออกไปแต่ยังเป็นอาหารที่เหมาะกับโรคเบาหวาน					
๖	ควบคุมน้ำหนักตัวผู้ป่วยให้อยู่ในเกณฑ์ปกติได้					
๗	ตรวจดูความผิดปกติของผิวหนังบริเวณเท้าของผู้ป่วยได้ เช่น สิผิวซีด หรือเขียวคล้ำ รอยช้ำ บาดแผล หรืออาการอักเสบ					
๘	สังเกตอาการผิดปกติทางการมองเห็นของผู้ป่วยเช่น ตาพร่ามัว					
๙	ออกกำลังกายอย่างเพียงพอที่จะควบคุมระดับน้ำตาลในเลือดได้ เช่น การเดิน หรือ การขี่จักรยาน					
๑๐	เมื่อผู้ป่วยมีอาการเจ็บป่วยสามารถปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารของผู้ป่วยได้อย่างเหมาะสมกับโรคเบาหวาน					

ข้อ	สถานการณ์	ระดับความมั่นใจ				
		ไม่มั่นใจเลย	มั่นใจน้อย	มั่นใจปานกลาง	มั่นใจมาก	มั่นใจมากที่สุด
๑๑	ดูแลผู้ป่วยให้ได้รับอาหารที่เหมาะสมกับโรคเบาหวานได้เกือบตลอดเวลา					
๑๒	เพิ่มการออกกำลังกายได้อีกตามคำแนะนำจากแพทย์					
๑๓	เมื่อออกกำลังกายหนักสามารถช่วยผู้ป่วยปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารได้อย่างเหมาะสมกับพลังงานที่สูญเสียไป					
๑๔	ช่วยปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารได้อย่างเหมาะสมกับระดับน้ำตาลในเลือดแม้ว่าผู้ป่วยไม่ได้อยู่ที่บ้าน					
๑๕	ในช่วงวันหยุดเทศกาล นักขัตฤกษ์หรือช่วงพักร้อนสามารถดูแลผู้ป่วยให้ได้รับอาหารเหมาะสมกับโรคเบาหวานได้					
๑๖	เมื่ออยู่ในงานเลี้ยงพบปะสังสรรค์ สามารถดูแลผู้ป่วยให้ได้รับอาหารให้เหมาะสม กับโรคเบาหวานได้					
๑๗	เมื่อผู้ป่วยอยู่ในภาวะเครียดหรือภาวะกดดันสามารถช่วยปรับเปลี่ยนชนิดและวิธีการรับประทานอาหารได้					
๑๘	พาไปพบแพทย์เป็นประจำตามที่แพทย์นัด เพื่อตรวจเช็คอาการของโรคเบาหวาน					
๑๙	ให้รับประทานยาตามที่แพทย์สั่งได้อย่างถูกต้อง					
๒๐	ช่วยปรับการรับประทานยาได้อย่างถูกต้องทุกครั้ง เมื่อมีอาการเจ็บป่วย					

ส่วนที่ ๘ ความรู้เรื่องโรคเบาหวาน (สำหรับสมาชิกในครอบครัว)

คำชี้แจง: กรุณาตอบแต่ละคำถามโดยการทำเครื่องหมาย ☒ ในช่องคำตอบ

ข้อ	คำถาม	ใช่	ไม่ใช่	ไม่ทราบ
๑	การรับประทานน้ำตาลและอาหารหวานมากเกินไป เป็นสาเหตุของโรคเบาหวาน			
๒	สาเหตุปกติของโรคเบาหวาน คือ ขาดอินซูลินที่มีประสิทธิภาพในร่างกาย			
๓	โรคเบาหวานเกิดจากความล้มเหลวของไตในการเก็บรักษาน้ำตาลออกจากปัสสาวะ			
๔	ไตผลิตอินซูลิน			
๕	ในโรคเบาหวานที่ไม่ได้รับการรักษา โดยปกติปริมาณน้ำตาลในเลือดเพิ่มขึ้น			
๖	ถ้าฉันเป็นเบาหวาน บุตรของฉันมีโอกาสที่จะเป็นเบาหวานสูงขึ้น			
๗	โรคเบาหวานสามารถรักษาได้			
๘	หลังงดอาหารอย่างน้อย ๘ ชั่วโมง ระดับน้ำตาลในเลือด ๒๐๐ มิลลิกรัม/เดซิลิตร ถือว่าสูงมาก			
๙	วิธีที่ดีที่สุดในการตรวจเช็คโรคเบาหวานคือ การตรวจปัสสาวะ			
๑๐	การออกกำลังสม่ำเสมอจะเพิ่มความต้องการอินซูลินหรือยารักษาโรคเบาหวาน			
๑๑	โรคเบาหวานมีสองประเภทหลักๆ คือประเภทที่ ๑ (ชนิดพึ่งอินซูลิน) และประเภทที่ ๒ (ชนิดไม่พึ่งอินซูลิน)			
๑๒	การออกฤทธิ์ของอินซูลินเกิดขึ้นเพราะกินอาหารมากเกินไป			
๑๓	ในการควบคุมเบาหวาน ยามีความสำคัญมากกว่าอาหารและการออกกำลังกาย			
๑๔	โรคเบาหวานมักก่อให้เกิดการไหลเวียนเลือดไม่ดี			
๑๕	บาดแผลและรอยถลอกในผู้ป่วยเบาหวานหายได้ช้า			
๑๖	ผู้ป่วยเบาหวานควรระวังเป็นมากพิเศษขณะตัดเล็บเท้า			
๑๗	บุคคลที่เป็นโรคเบาหวานควรจะทำความสะอาดบาดแผลด้วยสารละลายไอโอดีนและแอลกอฮอล์			
๑๘	วิธีการเตรียมอาหารมีความสำคัญเท่ากับอาหารที่รับประทาน			
๑๙	โรคเบาหวานสามารถทำลายไตได้			
๒๐	โรคเบาหวานสามารถก่อให้เกิดการสูญเสียความรู้สึกที่มือ นิ้วและเท้า			
๒๑	เหงื่อออก ตัวสั่น เป็นอาการของน้ำตาลในเลือดสูง			
๒๒	การถ่ายปัสสาวะบ่อยและกระหายน้ำเป็นอาการของน้ำตาลในเลือดต่ำ			
๒๓	ถุงน่องหรือถุงเท้าที่แน่นไม่เป็นอันตรายต่อผู้ป่วยเบาหวาน			
๒๔	อาหารสำหรับโรคเบาหวานประกอบด้วยอาหารพิเศษเป็นส่วนใหญ่			