Factors Related to Decision-Making Towards Participation in Clinical Trials in Diabetes Patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Miss Rakjit Kanlayanatam

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Public Health Program in Public Health
College of Public Health Sciences
Chulalongkorn University
Academic Year 2015

ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกในผู้ป่วยโรคเบาหวาน โรงพยาบาลจุฬาลงกรณ์ กรุงเทพมหานคร ประเทศไทย

นางสาวรักจิต กัลยาณะธรรม

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาสาธารณสุขศาสตรมหาบัณฑิต
สาขาวิชาสาธารณสุขศาสตร์
วิทยาลัยวิทยาศาสตร์สาธารณสุข จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2558

Thesis Title	Factors Related to Decision-Making Towards Participation in Clinical Trials in Diabetes Patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand
By	Miss Rakjit Kanlayanatam
Field of Study	Public Health
Thesis Advisor	Assistant Professor Naowarat Kanchanakhan, Ph.D.

Accepted by the College of Public Health Sciences, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

.....Dean of the College of Public Health Sciences
(Associate Professor Sathirakorn Pongpanich, Ph.D.)

THESIS COMMITTEE

.....Chairman
(Associate Professor Ratana Somrongthong, Ph.D.)
.....Thesis Advisor
(Assistant Professor Naowarat Kanchanakhan, Ph.D.)
.....Examiner
(Professor Surasak Taneepanichskul, M.D.)
.....External Examiner
(Nanta Auamkul, M.D.)

รักจิต กัลยาณะธรรม : ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกในผู้ป่วยโรคเบาหวาน โรงพยาบาลจุฬาลงกรณ์ กรุงเทพมหานคร ประเทศไทย (Factors Related to Decision-Making Towards Participation in Clinical Trials in Diabetes Patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ. ดร. เนาวรัตน์ กาญจนาคาร, 79 หน้า.

ในปัจจุบัน การดำเนินการศึกษาวิจัยทางคลินิกในประเทศไทยมีอัตราเพิ่มขึ้นและเติบโตอย่างต่อเนื่อง ซึ่งมีผลทำให้จำนวนผู้ป่วยที่เข้าร่วมในการศึกษาวิจัยทางคลินิกมีจำนวนเพิ่มมากขึ้นตามไปด้วย ทั้งนี้ทำให้ผู้ป่วยคนไทยเข้ามามีส่วนเกี่ยวข้องจากการเข้าร่วมการศึกษาวิจัยมากขึ้นในทศวรรษนี้ นอกจากความเสี่ยงและประโยชน์จากการเข้าร่วมการศึกษาวิจัยทางคลินิก พบว่ามีปัจจัยอื่นๆ ที่มีผลต่อการตัดสินใจเข้าร่วมหรือไม่เข้าร่วมการศึกษาวิจัยทางคลินิก

การศึกษาวิจัยนี้เป็นการศึกษาวิจัยแบบ cross-sectional descriptive study ซึ่งเก็บข้อมูลโดยใช้แบบสอบถามเพื่อหาปัจจัยที่มีผลต่อกระบวนการตัดสินใจเกี่ยวกับการเข้าร่วมการศึกษาวิจัยทางคลินิก การศึกษาวิจัยนี้จะดำเนินการศึกษาในผู้ป่วยโรคเบาหวานในโรงพยาบาลจุฬาลงกรณ์ กรุงเทพ ประเทศไทย โดยมีจำนวนผู้ป่วยโรคเบาหวานที่เข้าร่วมการศึกษาวิจัยจำนวน 110 ราย การศึกษานี้ใช้การวิเคราะห์ข้อมูลแบบ Multiple logistic regression เพื่อหาปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกระยะที่ 3 ผลที่ได้จากการวิเคราะห์ข้อมูลแบบ Multiple logistic regression ได้แสดงให้เห็นผลอย่างมีนัยสำคัญว่า ความรู้เกี่ยวกับการศึกษาวิจัยทางคลินิก ($p=0.007$), ทัศนคติเกี่ยวกับการเข้าร่วมการศึกษาวิจัยทางคลินิก ($p<0.001$) และสถานภาพสมรสเป็นปัจจัยที่มีผลต่อการเข้าร่วมการศึกษาวิจัยทางคลินิก ($p=0.025$) ในการศึกษาวิจัยนี้คาดว่าจะได้รับข้อมูลเกี่ยวกับปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกในผู้ป่วยโรคเบาหวานในโรงพยาบาลจุฬาลงกรณ์ หวังว่าผลที่ได้จากการวิจัยนี้จะสร้างความแตกต่างในการศึกษาเกี่ยวกับความรู้และทัศนคติเกี่ยวกับการเข้าร่วมการศึกษาวิจัยทางคลินิก

สาขาวิชา สาธารณสุขศาสตร์ ลายมือชื่อนิสิต .....

ปีการศึกษา 2558 ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

5578843553 : MAJOR PUBLIC HEALTH
KEYWORDS:

RAKJIT KANLAYANATAM: Factors Related to Decision-Making Towards Participation in Clinical Trials in Diabetes Patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand. ADVISOR: ASST. PROF. NAOWARAT KANCHANAKHAN, Ph.D., 79 pp.

Presently, the proportion of clinical trials conducted in Thailand is continuously increased and growth. This reflects number of patients in clinical trial is also increased which brings Thai patients are more involved in clinical trial participation in this decade. Beyond the risks and benefits from clinical trial participation, there are other influential factors that influence patients to decide to participate or decline to participate in the clinical trials.

A descriptive, cross-sectional research design through self-questionnaire data collection method described factors related to the decision making process regarding participation in clinical trials. The study was conducted in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The sample consisted of 110 diabetes patients. Multiple logistic regression analysis was used to examine factors that influence phase III clinical trial participation.

Logistic regression analyses showed that the factors best explaining participation were knowledge about clinical trial ($p=0.007$), attitude towards clinical trial participation ($p<0.001$), and patient with single status ($p=0.025$).

This research is expected to collect some information about the factors related to decision-making towards participation in clinical trials in diabetes patients at the King Chulalongkorn Memorial Hospital. The results of this research can make a difference in the study towards patients' knowledge and attitude towards clinical trial participation.

Field of Study: Public Health Student's Signature .....

Academic Year: 2015 Advisor's Signature .....

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to my advisor, Assistant Professor Naowarat Kanchanakhan, Ph.D., for her invaluable support, suggestions and encouragement throughout the research.

My gratitude is extended to my Thesis Committee: Professor Surasak Taneepanichskul, M.D, Nanta Auamkul, M.D., and Associate Professor Ratana Somrongthong, Ph.D. for their comments and guidance to improve my thesis.

I would also like to extend my appreciation to Associate Professor Sompongse Suwanwalaikorn, M.D. for his advice, interest, and giving me the opportunity to make this research possible. My sincere appreciation is extended to Associate Professor Thiti Snabboon, M.D., Head of Division of Endocrinology and Metabolism, Department of Medicine, Faculty of Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital, for giving me permission to commence this research for data collection process in the hospital. I also would like to thank to friendly nurses and staffs from Out-patient Endocrinology Metabolism and Thyroid Clinic, for their help and hospitality during data collection process.

Special thanks and appreciation to Pinyadarat Areerob, M.D. for her kind support and useful comments to improve my thesis, and special thanks to all my friends those who gave me great help in difficult times and encouragement along the way of my study in master's degree.

Finally, this research could not have been accomplished without the help, support, and encouragement of the people mentioned above. They are a part of this successful journey of my life that I will be always grateful.

CONTENTS

Page

Page

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CRO	Contract Research Organization
CSMBS	Civil Servant Medical Benefit Scheme
CT	Clinical Trial
DM	Diabetes Mellitus
DHEW	Department of Health, Education, and Welfare
EC	Ethics Committee
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IDF	International Diabetes Federation
IND	Investigational New Drug
IRB	Institutional Review Board
MoPH	Ministry of Public Health
OPD	Out-patient Department
PI	Principal Investigator
RCT	Randomized Clinical Trial
UC	Universal Health Coverage
WHO	World Health Organization

CHAPTER I
INTRODUCTION

1.1 Background

An increasing number of clinical trials have been conducted in clinical practice, which aims in providing evidence for the efficacy and safety of investigational new drug or treatment. Over the past decade, the number of clinical trials in Asian countries has increased rapidly due to the importance of evidence based on ethnic diversity and cost-effectiveness in clinical trials. Nowadays (year 2015), Thailand is one of the most rapidly growing in Southeast Asian countries, ranking as the 1st most active industry-sponsored clinical trial countries [1,739 studies of total 3,956 studies in Southeast Asia, as of 25 June 2015] (clinicaltrials.gov, 2015). The globalization of clinical trials can bring both benefits and risks to research subjects. Depending on the study design, during participating in clinical trial patients may be asked to receive an investigational new drug (IND) or alternative treatment as either mono therapy or combination with a standardized regimen, to accept treatment assignment by randomization, to undergo additional study procedures, laboratory tests, exams, and interviews, and, in the blinded trial, to remain unaware of what drug they are taking for the duration of the study.

Although the risks resulting from participation is not known and there may be other side effects of drug or study procedures that may happen that are not known, it is evident that subjects or sick volunteers often participate in clinical trials for many reasons; for example hope for better treatment, financial, and altruism. However, beyond the risks and benefits from clinical trial participation, there are other influential factors that influence patients to decide to participate or decline to participate in the clinical trials.

In Thailand, the clinical trials are increasingly being conducted in developing countries and the proportion of clinical trials conducted in Thailand is continuously increased and growth. This reflects number of patients in clinical trial is also increased which brings Thai patients are more involved in clinical trial participation in this decade. Investigating the efficacy and safety of any new drugs in clinical research, the patient

is pivotal as they are treated with interventional study in order to deliver the study outcome for future development of drug, therapies, treatment, and new techniques. These interventions may be medical products, such as drugs or devices; procedures; or changes to patients' behavior, for example, diet. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including no intervention). Consequently, in aspects of ethics and human rights, all clinical trials must be conducted according to the ICH-GCP to ensure that the patient is always well-being and safe during participating in the clinical trials; patient's comprehension should be enhanced with a clear understanding of clinical trial participation before their decision to enter a clinical study. There are several factors affect patient decision making about whether or not to join in a clinical trial and understanding the decision to participate or decline a clinical trial is important to enhance health professionals (investigator, nurse, etc.) to provide better support their patients in the decision making process. Therefore, assessing patient's knowledge and attitude about clinical trial before patient participation and learning more about the factors related to patients' decision-making towards participation in clinical trials need to be more focused.

The previous studies reported that patients' knowledge and attitudes on clinical trials that are a part of influential factors for their decision-making to participate in clinical trials. The factors are varied in individual patients depending on; for example patients' health status, socio-demographic characteristics, medical insurance plan, and their experience in clinical trial participation (Biedrzycki, 2010) (Avis, Smith, Link, Hortobagyi, & Rivera, 2006). Even patients decide to take part in clinical trials with many reasons, however it was found that patients' knowledge about clinical trial and attitude were related to their decision-making for clinical trial participation (Hutchison, Cowan, McMahon, & Paul, 2011) and other influential factors is necessary to be investigated in future study. Furthermore, a previous study reported that patients who had a high level of understanding of clinical trials were likely to have a more positive attitude toward participation than were those with lower levels of understanding, which impacted their decision-making to participate in clinical trials respectively. This means the positive attitudes can lead to decide for participating in the clinical trial (Comis,

Miller, Aldige, Krebs, & Stoval, 2003). The relationship between attitudes and decision-making in patients for participation in clinical trials is correlation. In previous studies also reported the positive attitudes is a major factor for patients' decision-making to participate in clinical trials (Comis et al., 2003). However, the difference of individual demographic data, knowledge, and understanding of clinical trial is still varied and it is the factors related to decision-making in patients.

There are several studies to find out the factors that influences to clinical trial participation and it was a part of corresponding to study-related and diseases which are mostly involved in patients with cancer. There are various factors associated with participation in clinical trials that was reported in several studies. The specific cancer trials and cancer patients were frequently studied in the literature which may be a gap in research because of limited study area. Mostly cancer patient participated in clinical trials with alternative treatment reason, patients' health status, medical insurance plan, and economic purpose which was not broaden to non-clinical trial patient or patient in different therapeutic area those who may have more alternative and the clinical trial is not their best option. Therefore, to further research in non-clinical study specific and in different therapeutic area beyond cancer patient is recommended to be more focused.

The King Chulalongkorn Memorial Hospital is a public and university hospital, where is affiliated to the Faculty of Medicine, Chulalongkorn University in Bangkok. This hospital consists of 1,479-bed general hospital with approximately 1,400,000 patients that are divided into 1,320,240 out-patients, and 51,187 in-patients (Hospital, 2014). Currently, there are numerous clinical trials in different therapeutic area conducted in the hospital, including clinical trials in diabetes patients. In pharmaceutical industry and clinical research field in Thailand, the King Chulalongkorn Memorial Hospital is one of top 5 leading university hospital where is selected to conduct the clinical trials with these reasons: a large number of patient, potential investigators who expertise in various therapeutic area, fully equipped facilities. Hence, the King Chulalongkorn Memorial Hospital is selected for this research.

There are a small number of researches to study and explore the factors affecting decision-making for clinical trial participation in Thailand; hence this research is expected to collect some information about the factors related to decision-making towards participation in clinical trials in diabetes patients at the King Chulalongkorn Memorial Hospital. The results of this research can make a difference in the study towards patients' knowledge and attitude towards clinical trial participation.

1.2 Research Questions

1. What are the factors related to decision-making of diabetes patients regarding participation in phase III clinical trials at King Chulalongkorn Memorial Hospital in Bangkok, Thailand?
2. What is the level of knowledge and attitude towards participation in phase III clinical trial in diabetes patients?

1.3 Objectives

1.3.1 General Objective

To identify the factors related to decision-making towards participation in phase III clinical trials in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand.

1.3.2 Specific Objectives

1. To determine the level of knowledge about phase III clinical trials in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand.
2. To determine the level of attitude towards participation in clinical trials in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand.
3. To identify the relationship between socio-demographic characteristics of patients and patients' decision-making for participating in phase III clinical trials.
4. To identify the relationship between patients' knowledge about clinical trials and patients' decision-making for participating in phase III clinical trials at King Chulalongkorn Memorial Hospital, Bangkok, Thailand.
5. To identify the relationship between patients' attitude towards clinical trial participation and patients' decision-making for participating in phase III clinical trials at King Chulalongkorn Memorial Hospital, Bangkok, Thailand.

6. To identify the relationship between socio-demographic characteristics of patients, patients' knowledge about clinical trials, patients' attitude towards clinical trial participation, and patients' decision-making for participation in phase III clinical trials.

1.4 Hypothesis

1. There is a relationship between socio-demographic characteristics of patients and patients' decision-making to participate in phase III clinical trials.
2. There is a relationship between patients' knowledge about clinical trials and patients' decision-making to participate in phase III clinical trials.
3. There is a relationship between patients' attitude towards clinical trial participation and patients' decision-making to participate in phase III clinical trials.
4. There is a relationship between socio-demographic characteristics of patients, patients' knowledge about clinical trials, patients' attitude towards clinical trial participation, and patients' decision-making for participation in phase III clinical trials.

1.5 Variable in research

Independent variable

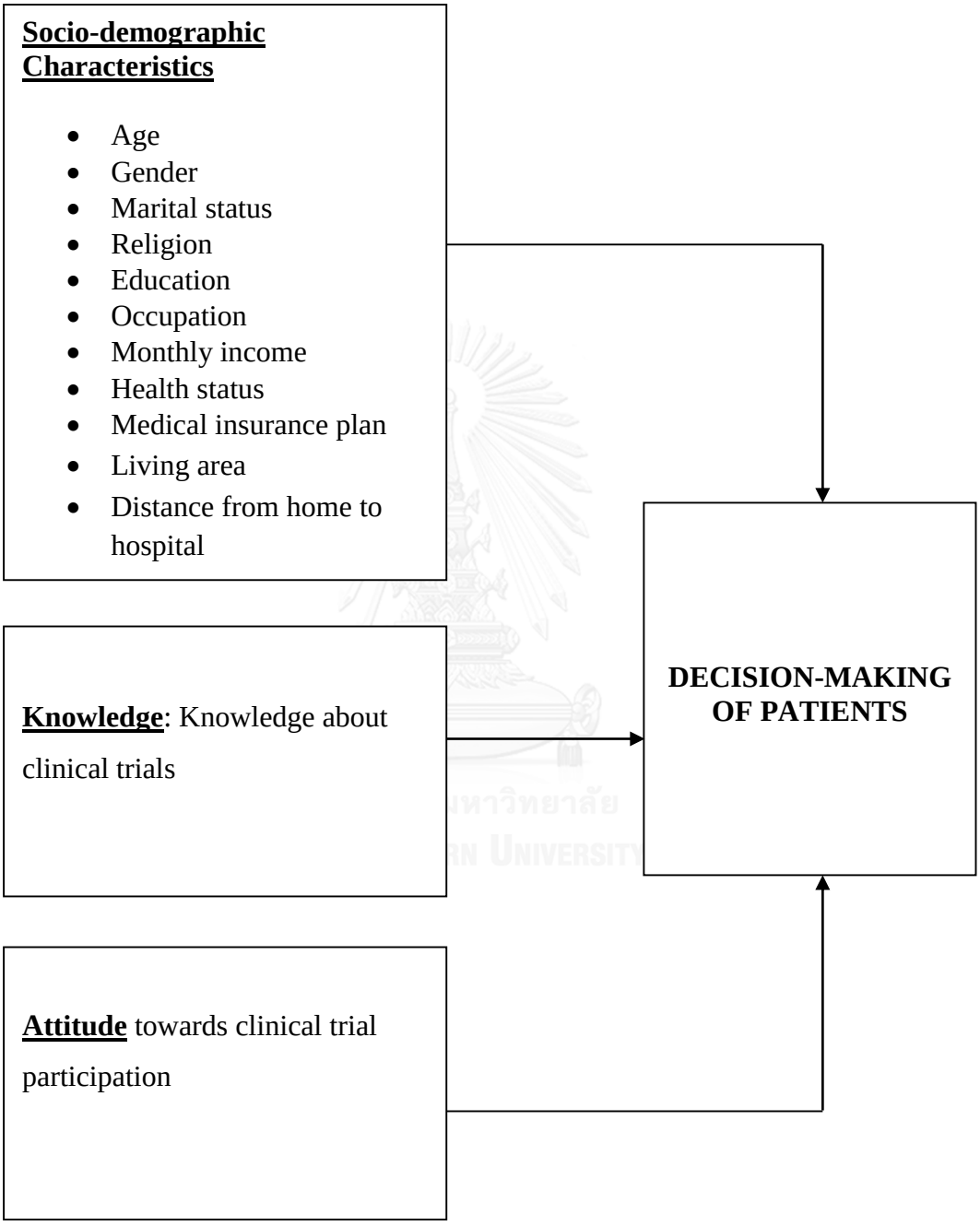
1. Socio-demographic characteristics of patient include:
   - Age
   - Gender
   - Marital status
   - Religion
   - Education
   - Occupation
   - Monthly income
   - Health status
   - Medical insurance plan
   - Living area
   - Distance from home to hospital
2. Knowledge about clinical trials
3. Attitude towards clinical trial participation

Dependent variables

- Patients' decision-making to participate in phase III clinical trials

1.6 Conceptual Framework

Independent Variables



1.7 Operational Definitions

Clinical Trials:

Any phase III clinical trials which is the most rigorous and extensive type of scientific clinical investigation of a new treatment. The number of patients in phase III is larger than other phases which become a large number of patients who participate in clinical trial phase III.

Diabetes Patients/ Patients:

Patients who have been diagnosed as diabetes, and have not currently participated in any clinical trials or during last 6 months at the King Chulalongkorn Memorial Hospital.

Factors related to decision-making

This refers to the factors that influence patients' decision to participate or not participate in phase III clinical trials.

Knowledge

Knowing the basic information about clinical trials.

Attitude towards clinical trial participation means beliefs, needs and values on clinical trial participation.

Decision-making of patients:

This refers to diabetes patients' decision to participate in any phase III clinical trials.

CHAPTER II
LITERATURE REVIEW

2.1 Clinical Trials

Clinical trial is an experiment study which involves patients and is designed to elucidate the most appropriate treatment of future patients with a given medical condition (Pocock, 1983).

Depending on product type and development stage, investigators initially enroll volunteers and/or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. As positive safety and efficacy data are gathered, the number of patients typically increases. Clinical trials can vary in size, and can involve a single research entity in one country or multiple entities in multiple countries. Every clinical trial is led by a principal investigator, who is often a medical doctor. Clinical trials also have a research team that may include doctors, nurses, social workers, and other health care professionals. The clinical trials are usually borne by the sponsor, which may be a governmental organization or a pharmaceutical, biotechnology or medical device company. When the required support exceeds the sponsor's capacity, the trial may be managed by an outsourced partner, such as a contract research organization or an academic clinical trials unit. During the trial, investigators recruit patients with the predetermined characteristics, administer the treatment(s) and collect data on the patients' health for a defined time period.

2.1.1 Types of Clinical Trial

The clinical trial (drug trials within the pharmaceutical industry) is classified into four main phases of experimentation. Each phase of the drug approval process is treated as a separate clinical trial. The drug-development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases 0, 1, 2, and 3, it will usually be approved by the national regulatory authority for use in the

general population. These four phases are a general guideline on how the clinical trials research programme for a new treatment in a specific disease might develop (Pocock, 1983).

Phase 0: Pharmacodynamics and Pharmacokinetics
Phase 1: Clinical Pharmacology and Toxicity (Screening for safety)
Phase 2: Initial Clinical Investigation for Treatment Effect (Establishing the efficacy of the drug, usually against a placebo)
Phase 3: Full-scale Evaluation of Treatment (Final confirmation of safety and efficacy)
Phase 4: Post-marketing Surveillance (Sentry studies during sales)

Each phase has a different purpose and helps scientists answer a different question:

Phase 0 trials are the first-in-human trials. Single sub-therapeutic doses of the study drug are given to a small number of subjects (10 to 15) to gather preliminary data on the agent's pharmacodynamics (what the drug does to the body) and pharmacokinetics (what the body does to the drugs).

In Phase 1 trials, researchers test an experimental drug or treatment in a small group of people (20–80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In Phase 2 trials, the experimental treatment is given to a larger group of people (100–300) to see if it is effective and to further evaluate its safety.

In Phase 3 trials, the treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.

In Phase 4 trials, post-marketing studies delineate additional information, including the treatment's risks, benefits, and optimal use.

The phase 3 trials is the most precise and extensive type of scientific clinical investigation of a new treatment. As above-mentioned, the number of patients in phase III is larger than other phases which become a large number of patients who participate in clinical trial phase III.

Examples of clinical trial goals include assessing the safety and (relative) effectiveness of a medication or device:

- On a specific kind of patient (e.g., patients who have been diagnosed with Diabetes Mellitus)
- At a different dose (e.g., 10-mg dose instead of 5-mg dose)
- For a new indication
- Is more effective for the patient's condition than the standard therapy
- Relative to two or more already approved/common interventions for that disease (e.g., device A vs. device B, therapy A vs. therapy B)

2.1.2 Current Situation of Clinical Trials

In worldwide regarding clinical trials, an increasing number of clinical trials (CT) are being conducted in clinical practice, aimed at providing evidence for the efficacy and safety of new agents or treatment. Over the past decade, the number of clinical trials in Asian countries has increased rapidly due to the importance of evidence based on ethnic diversity and cost-effectiveness in clinical trials and new drugs development for improving people's health and efficacy of treatment. The globalization of clinical trials can bring both benefits and risk to research subjects. Potential risk includes an insufficient informed consent process as a result of inadequate regulatory oversight of research activities regarding ethical issues in emerging countries.

When conducting the clinical trials, Good Clinical Practice (GCP) is one of the most important tools for ensuring the protection of patient rights in clinical trials all over the

world. In Thailand, all study sites and Principal Investigator follow GCP which is under supervision and monitoring by IRB/IEC of each institution and subject's comprehension on clinical trial that he/she will participate is also important before informed consent process.

2.1.3 Trends of Clinical Trials in Thailand

The ClinicalTrials.gov, a web-based resource, maintained by the National Library of Medicine (NLM) at the U.S. National Institutes of Health (NIH) shows the number of registered CT studies as of 25 Jun 2015; there are 1,739 studies to be conducted in Thailand, which is the highest number in Southeast Asian Region [3,956 studies in total] (Health, 2015). This data represents a significantly high growth in clinical trials in Thailand. If compared to other countries within the same region, Thailand is a leading country in clinical trial development due to they have full with potential principal investigator, capacity of study center, and sufficient patient pool to conduct the trials in different therapeutic area, including diabetes.

2.2 Diabetes

Presently, diabetes is a chronic disease that is growing problem among people in worldwide. From statistical trends (*IDF Diabetes Atlas, Sixth Edition*), 382 million people have diabetes in 2013; by 2035 this will rise to 592 million and the number of people with type 2 diabetes is increasing in every country. The 80% of people with diabetes live in low- and middle-income countries which Thailand included (IDF, 2014).

Type 2 diabetes mellitus accounts for 90 to 95% of all cases of diabetes and is an increasingly prevalent disease with an estimated 180 million people affected worldwide. Its incidence is expected to double during the next twenty years. Complications induced by hyperglycemia are currently the most frequent cause of adult-onset loss of vision, renal failure, and amputation in the industrialized world. Diabetes is also associated with macrovascular complications with a 2- to 5-fold increase in cardiovascular disease risk. The high frequency of complications leads to a significant reduction of life expectancy (IDF, 2014).

2.2.1 Treatment

Generally, glycemic control is a key factor for diabetes treatment and currently available anti-diabetic agents are not sufficient to maintain long term glycaemic control. Hence, management of diabetes in providing greater efficacy of treatment in diabetic patient is continuously developed in medical field for discovering a new drug that would be more efficacy and better response to metabolic mechanism in diabetic patient than the existing medicine and treatment; in addition to find a new techniques in therapeutic procedure in order to prolong glucose control and decrease complications in the patient.

2.2.2 Current Situation of Diabetes in Thailand

Data derived from Thailand Health Profile 2008-2010, it showed the number and percentage of deaths among Thai people, diabetes stands on the top 12 causes of death; especially in female that is in the top 5 causes of death. Also, the prevalence of chronic diseases that are major health problems among Thai people during 1991-2009 includes hypertension, hyperlipidemia, and diabetes. Based on data, the prevalence of diabetes had risen every year and increased at 6.9% in 2008-2009 (Ministry of Public Health, 2011). Diabetes is one of chronic diseases that are major health problems among Thai people 1991-2009 with its prevalence has been risen every year as well as rate of hospitalization of patients with diabetes (Ministry of Public Health, 2011).

2.3 Concept and Definition of Decision-making

2.3.1 Definition of decision-making

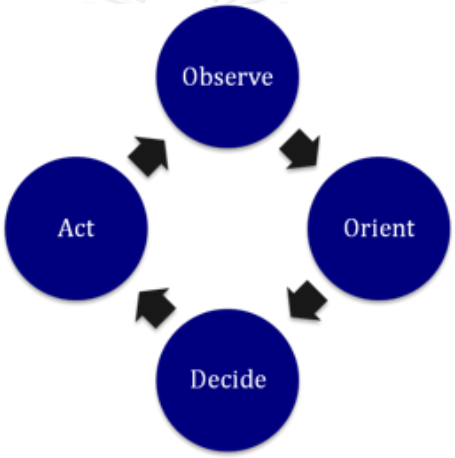
“Making a decision involves a choice among alternatives. A decision is the point at which a choice is made between alternative and options” (Fitzgerald, 2002).

2.3.2 Decision-making Concept

The OODA Loop model was developed by John Boyd (Boyd, J.R. (1987). It consists of the 4 components and steps as follows:

- Observe
- Orient
- Decide
- Act

Figure 1 Decision-Making Concept, OODA Loop Model



(John Boyd, 1987)

Learning from the OODA Loop Model, before decision is made, gathering information called “Observation” is a part of component that is a step into decision and actions. Another component, “Orientation”– it helps to turn information into knowledge. And knowledge is the real predictor of making good decisions. Another component called “Decision” that considers options and decides. And lastly, “Action” that follows decision and it is the last step of the Decision Loop before circulating to the observation as cycle.

In this concept - the OODA Loop model, there are also 5 main forces that influence the decisions:

1. Cultural traditions
2. Genetic heritage
3. The ability to analyze and synthesize
4. Previous experience level
5. New information coming in

Based on this concept, it was adapted to the conceptual framework of this study; socio-demographic characteristics, knowledge and attitudes which are independent variables in the study could be a force that influences patient's decision, similar to the model components – observation, orientation, decision, and action. To further study on what are the factors that influence patient's decision-making, hence this model is interestingly used and applied.

2.4 Treatment and Research Decision Making Model

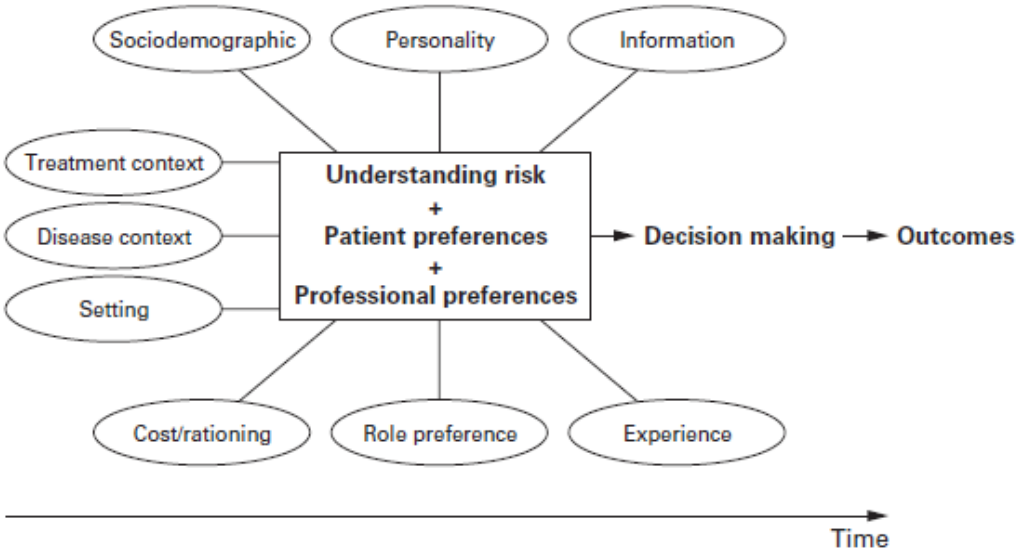


Figure 2 Treatment and Research Decision Making Model
(Bowling & Ebrahim, 2001)

Decision making involving in treatment and research is a multi-factorial process. Bowling and Ebrahim identified 12 factors that impact decision making for treatment and perceptions of risk through their Treatment Decision Making Model as shown in

the Figure 2, a comprehensive analysis of all variable mentioned would require a large sample size that is not feasible for a thesis proposal. The key factors to be explored and adapted to this study are socio-demographic, information, experience, patients' understandings of risks, and patient preferences which influence decision-making for clinical trial participation. These variables were selected based on Bowling and Ebrahim's model and relevant literature on factors that influences decision-making for clinical trial participation. The modification of the model permitted a more focused research study.

Based on the literature on Treatment Decision Making Model (Bowling & Ebrahim, 2001) which was used for measuring for patients' preferences for treatment and perceptions of risk; the Treatment Decision Making Model (Bowling & Ebrahim, 2001) was also adapted to this study. The researcher considers this model as a knowledge-based for developing how relationship among socio-demographics, information (considered as Knowledge), experience, patients' understandings of risks, and patient preferences (considered as Attitude), which are factors related to patients' decision-making decisions to participate in the clinical trials.

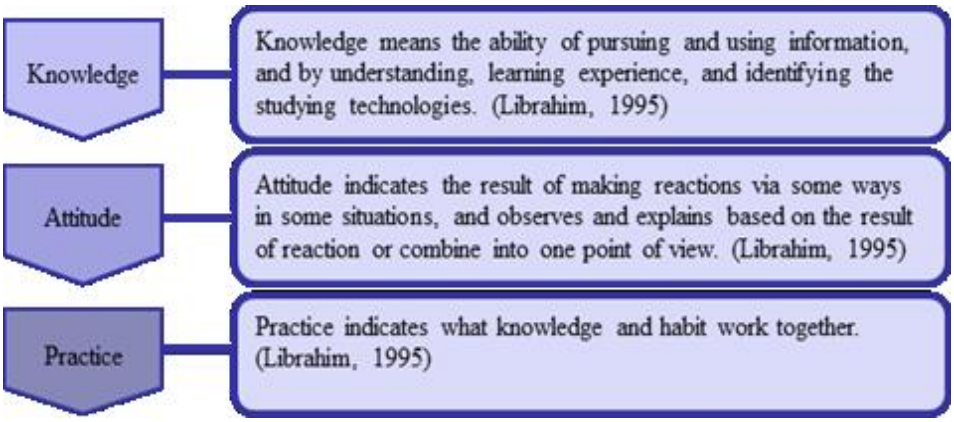
2.5 KAP Concept and Definition of Knowledge and Attitude

2.5.1 KAP Concept

KAP is the abbreviations of Knowledge, Attitude, and Practice which knowledge is a set of understandings; attitude is a way of being, a position; and practice or behavior is the observable actions of an individual in response to a stimulus (Gumucio, 2011).

The statement about KAP survey, which is described by the WHO, is a representative study of a specific population to collect information on what is known, believed and done in relation to a particular topic (WHO, 2008).

Figure 3 The influence diagram of knowledge, attitude and practice



(Badran, 1995)

2.5.2 Definition of Knowledge

Ibrahim G. Badran defines knowledge is "*the capacity to acquire, retain and use information; a mixture of comprehension, experience, discernment and skill*" based on David Hume's (Hume, 2003). According to a study of Brucks (Brucks, 1986), the knowledge is "a complicated construction characterized by the structure and the content of the information stored in the memory". Whilst the structure refers to the way the knowledge is represented and celebrated in memory, the content states to the information related to an object which is stored. In the literature, this first dimension, Knowledge, provides three various factors, in turn of general knowledge, information source and responsibility awareness.

2.5.3 Definition of Attitude

Definition of attitude is a "Readiness of the psyche to act or react in a certain way" (Jung, 1971). Moreover, attitudes are also a function of behavioral beliefs; it means if a personal trusts the performance of a particular behavior will lead to a positive result, then this individual will develop a favorable attitude towards such behavior (Ajzen, 1985).

2.5.4 Definition of Practice

With regards to Practice describing, a quote from Ibrahim's study (Badran, 1995) that "*by practice we mean the application of rules and knowledge that leads to action*".

2.6 Related Research Studies

The "Research Participation: Decision making and Outcomes in Cancer Clinical Trial" by Johns Hopkins University, a cross-sectional descriptive study with a mailed survey data collection method described factors related to the decision making process regarding participation in a cancer clinical trial and satisfaction with this decision (Biedrzycki, 2010). The independent variables (socio-demographic, patients' preferences, understanding risks, information, etc.) and one of dependent variables (decision to accept or decline research participation), which are similar to this research, so it could be a good literature as evidence-based to support future research. However, Barbara et al studied in 200 patients with advanced gastrointestinal cancer and investigated patients' participation in cancer clinical trials in phases I, II, and III. Some points due to study limitation that may be considered to be investigated in future research; for example health care insurance coverage, out-of-pocket expenses, and availability of clinical trials to explore the variable of cost/rationing.

A study on motivations of patients with diabetes to participate in a general antibiotic research study, but not to investigate motivations of diabetes patients to participate in diabetes trials. This study is two controlled-group (diabetes patient and patient with no illness) to compare the reason and willingness to participate in a research study by using the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Appelbaum & Grisso, 2001), Mini-Mental State Examination (MMSE), and Short-Form-36 (SF-36) as measurement. The MacCAT-CR that consists of 6 domains, is a well-validated and used instrument to assess decision-making capacity and it can be adapted to provide information about specific research protocols in addition to assess patients' understanding, appreciation, reasoning and choice (Geppert et al., 2014). The MacCAT-CR that is used to ask patients about the motivations for their decisions about participating in the research study, it is provided the following 6 reasons:

1. Money/desire for payment (MONEY)
2. General and specific risks associated with research (RISK)
3. Aversion to research and procedures (AVERSION)
4. Motives related to receiving treatment (e.g. better treatment) (BETTER TREATMENT)
5. Altruism (ALTRUISM)
6. Other responses

As a result, the reason given by 2 groups regarding willingness or unwillingness to participate in research did not significantly differ. 75% giving reasons for better treatment, 63% altruism, none mentioned money. Patients with diabetes who would not participate in research, 94% risk, and 89% expressed aversion to research. Due to the similarity of patients' motivation between medical and mental ill patients and non-ill patient in this study, further study to focus more closely regarding the individual perceptions and values of patients directly involved in clinical research rather than their diagnoses may be investigated. Furthermore, the motivation to participate in research between ill patient and non-ill patient which may have a gap and varied by their disease. However, further study that more focuses with the similar criterion and a single group would be explored.

A study on "Reasons given by patients for participating, or not, in Phase 1 cancer trials", it reported that 40 patients completed the questionnaire. Patients were generally optimistic with few concerns on the experimental study in Phase 1 trials. Most 36/40 (90%) consented to trial entry. 51% thought the trial was the only treatment option available. The 4 main reasons for trial entry included expectation of some medical benefit (21%), trial the best available option (21%), to maintain hope (15%) and to help with research (13%). Only 1 patient gave altruism as their main reason for trial participation (Catt, Langridge, Fallowfield, Talbot, & Jenkins, 2011).

A study found that there were significant differences between 2 groups between patient subject and healthy subject in gender, age, education, the phase of CTs and the investigated drugs of CTs which they participated. The major point learned from this study is the outcome of participant's decision-making to participate in clinical trial, and

to know participant's knowledge of clinical trials. This study also reported that the patients were also significantly influenced by medical staff (medical doctor or nurse at the hospital) when making a participation decision which is phenomenon originated from the unique Korean cultural factor emphasizing patient compliance to medical personnel and this may be a weakness of clinical trials in Asian countries. Furthermore, sufficient information about clinical trial, understanding of the risks and benefits of their participation, and level of understanding of CTs are influential factors to decision to participate in clinical trials (Chu et al., 2012).

2.6.1 Factors influencing decision-making for clinical trial participation

A study, the "Factors Associated with Participation in Breast Cancer Treatment Clinical Trials" (Avis et al., 2006). The authors investigated the factors related to CT participation among women who were invited to participate in a CT for breast cancer. Data collection from the study was collected during the telephone interview. The factors that were explored the association with patients' participation in Breast Cancer Clinical Trial is the following:

1) Socio-demographic factors
2) Medical factors
3) Knowledge of Clinical Trials – A list of 22 items (4-point scale - definitely true, probably true, probably false, or definitely false)
4)) was developed to assess knowledge of clinical trials
5) Attitudes toward clinical trials
6) Factors in personal decision
7) Feelings about knowing about CTs

The result of the study, 57.8% of women agreed to participate in the CT for which they were being recruited. And it was also found that women recruited for phase II trials were much more likely to accept participation than women recruited for phase I or III trials. Aspect of knowledge about CTs, it showed that it was not related to participation because all study women received educational materials, and knowledge. This finding is consistent with the findings of Davis et al, who found that a booklet improved cancer patients' knowledge about CTs. Research participants were limited for women

who declined trial participation at the time of trial recruitment which their decision may be influenced by different factors compared with women more open to participation.

Hutchison studied the factors affecting patients' decisions for randomized cancer clinical trial participation with 2 main points; 1) to determine patients' perceptions about important factors in their decision, by asking them directly, 2) to determine the effect of other factors contributing to the decision, that patients may be unaware of, for example understanding/misunderstanding of trial information, physician influence (Hutchison et al., 2011). The 173 patients with colorectal, breast or lung cancer who are clinically eligible for entry into a randomised cancer treatment trial (in different trial), were asked to complete the Clinical l Trial Decision Questionnaire (CTDQ) developed by Jenkins and Fallow field to assess patients' reasons for accepting or declining participation in a trial. The 148 patients who completed the CTDQ and 125 patients who had agreed to take part in a clinical trial and 23 who refused. This represented 98% of the total sample who said 'yes' to a clinical trial (125/128) and 72% of the patients who said 'no' (23/32).

In this study, demographic and baseline characteristics (gender, tumor type [breast, colorectal, lung], age, type of treatment in trial, type of trial [2 or more active treatment arms, Supportive care / no treatment arm]) were also investigated. A part of CTDQ (Yes/No questions) is related to whether or not patients agreed to take part in the clinical trial. At the bottom of the questionnaire, patients were asked to pick out their most important reason for agreeing or not agreeing to take part in the clinical trial. However, the study is limited to randomised cancer treatment trial and cancer patient only, and the questions in the CTDQ is quite difficult for adaptation to this thesis research due to it is applicable to trial participant only, but it gave some idea for further research study.

2.6.2 Patients' attitude towards participation in clinical trials

Although the study results were approximately 32% of American adults indicate that they would be very willing to participate in a cancer clinical trial if asked. However, in the literature point from other studies, even the data about attitudes were shown in positive, there are still several reasons for patients' decision due to many patients hold mistaken views of the nature of clinical trials, and that many significantly overestimate the efficacy of standard therapies in making their decision. Beyond the attitudes, patients also concerned the value and benefit of clinical trials. For example, over half of the patients in the Cassileth study, (CASSILETH, ZUPKIS, SUTTON-SMITH, & MARCH, 1980) chose getting the best medical care as the reason for considering clinical trial participation. It is important to continue to study the decision-making process by patients and the role played by physicians in presenting and explaining the clinical trial option.

A study on Patients' Attitudes and Preferences About Participation and Recruitment Strategies in Clinical Trials. This study is to assess attitudes of patients about participation in clinical trials and total 485 patients were approached to answer study survey, but no patient diagnosis-specific. The 78-question survey comprises 5 specific areas: 1) basic demographic information, 2) information from patients about their knowledge of access to clinical trials and their previous participation, 3) attitudes of patients about participating in clinical trials, 4) preferences of patients about the recruitment, and 5) beliefs of patients about the integrity of clinical trials. The 400 (82%) of the 485 patients who completed the survey. Most 271 patients (68%) showed interest (strongly agree or agree) in participating in clinical trials. However, only 97 patients (24%) were interested in participating in trials if the intervention had potential adverse effects (SOOD et al., 2009).

A study on the preferences of patients with breast cancer towards decision-making for participating or not in RCT by comparing 3 groups (RCT-acceptance group, RCT-refusal group, and RCT-not-proposed group). The results of the study show that the attitudes of patients about their CT participation depended on their experience of previous RCT. The patients with previous RCT experience showed greater willingness

to participate in a further RCT as they obtained sufficient information about clinical trials before (e.g. randomization). In this study, the patients' attitudes towards randomization were found to be an important factor determining participation in a RCT. The RCT-acceptance group had more positive attitudes towards randomization than the RCT-not-proposed group (Mancini et al., 2007).

A study reported a large proportion of patients in the UK appear willing to participate in clinical trials; and the principal motivations for clinical trial participation were to benefits others, to improve their own treatment, and to comply with a request from medical staff (Bevan, CHEE, McGHEE, & McINNES, 1993).

A study on "*Perceptions of Participation in a Phase I, II, or III Clinical Trial among African American Patients with Cancer: What Do Refusers Say?*" (Richard F. Brown et al., 2013). The 22 patients with cancer, participants who declined to participate in cancer clinical trials within last 3 months were approached to be interviewed and asked about demographic and disease information, psychosocial factors, and patients' experience with clinical trials. Subsequently, 2 months later, participants completed a questionnaire that asked about their trial decision. Semi-structured Patient Interview that was used in the study involving in this research includes:

- **Demographic and disease information** (Participant characteristics: sex, age, race/ethnicity, religion, education, employment, income level, living situation, primary tumor site, and the phase of trial offered.
- **Questions about Trials (Patient knowledge and beliefs about clinical trials):** Participants were asked trial-specific questions about their knowledge, beliefs, and attitudes about clinical trials; who described clinical trials; how they experienced this communication; and what factors went into their decision not to participate. Patients were also questioned about the potential for different decision support tools, a decision aid, informational video, patient navigator, or a question prompt list to aid their levels of trial knowledge and make trial decisions. The Research Assistant provided descriptions and examples of each of these during the interview.

The results from the study in aspect of Patient Knowledge and Beliefs about Clinical Trials, 9 (41%) in 22 participants stated that they had no prior knowledge or opinions about clinical trials. Patients who did have previous knowledge viewed trials as necessary to advance cancer treatment. And some were less confident that they would personally benefit from joining a trial. Aspect of the factors influencing the decision not to participate, 12 participants (55%) declined participation for many reasons. Many 11 participants (50%) had a primary concern on potential adverse effects of the treatments received as part of a clinical trial. Some preferred the standard care than the trial treatment because there was greater knowledge about treatment effectiveness and long-term adverse effects. There was additional concern about being able to tolerate adverse effects. Some participants were concerned that they would experience increased adverse effects if they were to receive the clinical trial treatment in addition to standard care. However, Participants reported positive attitudes to trials in general. Most participants were motivated to join a trial by a sense of altruism. These participants wanted to assist future patients make treatment decisions by contributing to the evidence base for new medications.

In summary, previously various studies reported that patients' knowledge, understanding, and particularly attitudes towards CT is influential factor to patient's decision-making for participating in clinical trials. However, the cancer patients in the previous studies were mostly studied and interviewed about their attitudes, views and understanding of cancer clinical trials they participate. The results derived from these studies may be limited in aspects of cancer patient only. Obviously, patients' attitudes to participation in cancer clinical trials were often positive due to patient may make their decision to participate in CT due to alternative treatment reason or just to take better medical care than the standard care they are receiving to prolong their life or prevent suffering from their cancer.

2.6.3 Previous study in Thailand

A Thai research studied volunteers' comprehension about informed consent for the clinical trial that they participated, and explored factors associated with volunteers' comprehension. The previous study similarly is a well-knowledge based to this research in term of patients' comprehension (knowledge of clinical trial), and attitudes towards participation in clinical trial. However, the study was specific-focused on CT participant with malaria and clinical research-specific purpose supporting that clinical research to explore CT participant's comprehension when they participated in clinical trial, which is similar to other studies and not extent to non-CT participant approach in a new different patient's view (Kaewpoonsri, 2006).

Unfortunately, the literature is limited in this area for Thailand and only a minority of clinical research papers report reasons for the factors that influence patient with illness and non-illness to participate in the phase III clinical trial.

CHAPTER III
RESEARCH METHODOLOGY

3.1 Research Design

Research design is a cross-sectional descriptive study with the purpose to study the factors related to patients' decision-making for participation in clinical trials and investigate patients' knowledge about clinical trial and attitude towards clinical trial participation.

3.2 Site of Study

The study was conducted at the Out-patient Endocrinology Metabolism and Thyroid Clinic, Department of Medicine, Faculty of Medicine, Chulalongkorn University King Chulalongkorn Memorial Hospital in Bangkok, Thailand.

3.3 Study Population

The target population for this study is out-patients with diabetes who visit OPD of Endocrinology Metabolism and Thyroid Clinic, Department of Medicine, Faculty of Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital.

Inclusion Criteria

1. The diabetes patient has voluntarily signed the Informed Consent Form.
2. Male or female aged 18-80 years.

Exclusion Criteria

1. The patient has previously been answered the questionnaire during the study period.
2. The patient with severe symptoms and unconscious condition.
3. The patient who is currently participating and had previously participated in any clinical trials during last 6 months.

3.4 Sample size

The sample size was determined using Fisher's (1998) formula the following:

$$n = \frac{z^2 \times p \times (1-p)}{d^2}$$

where:

n = desired sample size

z = standard normal deviate - set at 1.96 at 95% confidence level

p = proportion of diabetes patient = 0.5 (reference)

q = 1-p

d = Error in estimating population = 0.1

There is no previous study to survey factors related to decision-making towards participation in clinical trials in diabetes patients in Thailand before, thus the proportion of diabetes patient is estimated at 50% (p = 0.5) and d = 0.1. Therefore, the desired sample size was calculated as follows:

$$n = \frac{1.96^2 \times 0.5 \times (1 - 0.5)}{0.1^2}$$

n = 96

To compensate for 10% incomplete data (96 + 10%), therefore **110 patients** are required and approached for the study.

3.5 Sampling Technique

A convenient sample of individual patients was recruited from Out-patient Endocrinology Metabolism and Thyroid Clinic in this study.

3.6 Measurement Tools

To investigate the factors related to patients' decision-making towards participation in clinical trials, a self-administered questionnaire (see Appendix A) was used. This structured questionnaire was used as measurement tools.

Designing the questionnaire that was used in this study, it was adapted from the literature and the existing questionnaires from the previous studies with similar points to focus on assessment of patients' knowledge on clinical trial and attitude towards clinical trial participation (Catt et al., 2011) (Chu et al., 2012) (Hutchison et al., 2011).

3.6.1 Questionnaire constructions

The questionnaire consists of 4 sections as follows:

Section 1: Socio-demographic characteristics and general information of patient.
This part consists of (13) items.

Section 2: Knowledge about clinical trial
This part consists of (12) items.

Section 3: Attitude towards clinical trial participation
This part consists of (10) items.

Section 4: Decision-making to participate in clinical trial
This part consists of (4) items.

3.6.2 Measurement Methods

The measurement methods for each variable are as follows:

Section 1: Socio-demographic characteristics and general information of patient.

This section comprises 13 questions about patient's socio-demographic data including gender, age, marital status, religion, education, occupation, monthly income, health status, health insurance plan, living area, transportation, travel time from home to hospital, and patients' status of clinical trial participation in the past.

Section 2: Knowledge about clinical trials

This section consists of 12 components to assess patients' knowledge about clinical trials. Each item is Yes / No choice.

Section 3: Attitude towards clinical trial participation

This section consists of 10 items, which are on the 5-point Likert scale to measure patients' attitude towards participation in clinical trials. The 5-point Likert scale is divided into 5 levels of response (Strongly Agree, Agree, Neutral, Disagree, and Strongly Disagree).

Section 4: Decision-making to participate in clinical trial

This section of questionnaire aims to explore whether patients will participate in clinical trial or not. It comprises four questions in the following:

Question 1: Will you participate in the clinical trial in the future?

Question 2: What is your main reason for participating in the clinical trial?

Question 3: Who is the most influential person in your decision-making to participate in the clinical trial?

Question 4: What is your information source about clinical trials?

This section is to focus on what are the influential factors related to patients' decision-making to participate and decline participating in a clinical trial, in addition to explore patients' reason to participate or not participate.

3.7 Validity and Reliability

3.7.1 Validity Test

The content of the questionnaire was reviewed by the Experts.

3.7.2 Reliability Test

The questionnaire was pilot-tested and retested with 30 sampling patients at least, whose socio-demographic data and criteria is equivalent to study population. Cronbach's alpha coefficient was used to measure reliability of the questionnaire for attitude. Reliability test result is 0.734.

3.8 Data Collection

Data collection was implemented through self-administered questionnaire and face-to-face interview for some case in elderly patients. All questionnaires are administered in Thai language. Data collection can be conducted after the patient has signed the Informed Consent Form and consented to disclose his/her participation in clinical trials.

The Research Assistants were assigned by the Researcher for collecting the information (hardcopy questionnaire) and approach for interview in some case with elderly patients. All Research Assistants were trained by the researcher to have a professional and unbiased approach for the data collection process. In this study, to ensure that the Research Assistants understand well about clinical trials due to patients' confidentiality is sensitive, they were trained about background, general procedures, confidentiality of clinical trial by the researcher before starting data collection process.

All patients were approached from the out-patient who visited the OPD of Endocrinology, Metabolism and Thyroid Clinic, Department of Medicine, Faculty of Medicine, Chulalongkorn University, King Chulalongkorn Memorial Hospital. Every patient was requested to fill the questionnaire. Patients took time about 15-20 minutes to complete a questionnaire. For the diabetes patients routinely come to the clinic (out-patient clinic of hospital) as usual and receive treatment from the hospital according to the existing procedure as standard of care.

Timing of Data Collection

The times of data collection was morning on weekdays (Monday, Tuesday, Thursday, and Friday) at OPD (waiting area) of Endocrinology Metabolism and Thyroid Clinic, King Chulalongkorn Memorial Hospital. Data collection for this research was conducted over a period of 2 weeks during 5-17 November 2015.

3.9 Data Analysis

Data analysis was performed through the SPSS statistical package.

Descriptive statistics: Statistics was used to describe and analyze the socio-demographic characteristics, knowledge, and attitude data in this study. It includes central tendency (mean, median) and dispersion (standard deviation, 95% CI), frequency and percentage.

Analytical statistics:

Univariate analysis and multiple logistic regression model were used for data analysis in this research and the multiple regression equation is as follows:

$$Y=a + b_1X_1 + b_2X_2 + b_3X_3$$

Y is the value of the Dependent variable (Y)

a (Alpha) is the Constant or intercept

b_1 is the Slope (Beta coefficient) for X_1

X_1 First independent variable that is explaining the variance in Y

b_2 is the Slope (Beta coefficient) for X_2

X_2 Second independent variable that is explaining the variance in Y

b_3 is the Slope (Beta coefficient) for X_3

X_3 Third independent variable that is explaining the variance in Y

Y= Patients' decision-making

X_1 = Socio-demographic characteristics

X_2 = Knowledge about clinical trial

X_3 = Attitude towards clinical trial participation

Coding, Scoring and Classification:

To measure all variables, the criteria of coding and scoring to each item and classification of variables are as follows:

- **Knowledge about clinical trials**

There are 12 Yes/No questions in this section. The questions focus on assessing patients' knowledge on clinical trials.

- The correct answer get: 1 score
- The wrong answer get: 0 score

The total score is 12 and the scores varied from 0-12. The patients' knowledge will be classified into 3 levels with cut-off point (Bloom, 1956) as follows.

- Poor 0-7 points (< 60%)
- Moderate 8-10 points (60-80%)
- Good 11-12 points (> 80%)

- **Attitude towards clinical trial participation**

The answers were categorized into 5 levels (5-point Likert scale): Strongly agree, Agree, Neutral, Disagree, and Strongly disagree. The below table describes score of the Likert scale.

Table 1 Score of the Likert scale for statements

Statement		**Negative statement**
Choice	**Score**	**Score**
Strongly Agree	5	1
Agree	4	2
Neutral	3	3
Disagree	2	4
Strongly disagree	1	5

The scores is range from 10 to 50. The patients' attitude will be classified into 3 levels with cut-off point (Bloom, 1956) as follows.

- Poor attitude 10-29 points (< 60%)
- Moderate attitude 30-39 points (60-80%)
- Good/High attitude 40-50 points (> 80%)

- **Decision-making to participate in clinical trial**

This section comprises one key statement (Yes/No choice) to explore whether patients will participate in clinical trial or not. The remaining 3 statements are supportively set to survey patients' reason to participate or not participate in the trials.

- Answer YES (participate) get: 1 score
- Answer NO (not to participate) get: 0 score

3.10 Ethical Consideration

This research was approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University for ethical review before conducting this survey research; and informed consent form was also approved by them. Written informed consent was obtained from all participants; and they are always reassured of confidentiality and anonymity.

Prior to patient participation in this study, written informed consent was obtained by the Researcher or designated Research Assistants from each patient in the waiting area of OPD, Endocrinology Metabolism and Thyroid Clinic. The purpose of the study, methods, how many questions and estimated time of completing a questionnaire, the anticipated benefits, and that study participation is voluntary for the patients must be explained to the patients. The patients must be given sufficient time to consider whether to participate in the study.

This study was conducted in compliance with the ethical considerations in research based on 3 Principles of Belmont Report (DHEW Publication No. (OS) 78-0014, and http://www.hhs.gov) which is the following details.

1) Respect for person

The signed informed consent from each patient is required to obtain prior to participating in this study after adequate explanation of the aims, methods, and anticipated benefits of the study. The Researcher or designated Research Assistant will also explain that patients are completely free to refuse to enter the study or to withdraw from it at any time, for any reason. In aspect of confidentiality, patients are always

reassured of confidentiality and anonymity. The information collected will not identify patient's name, only by a Research ID number. Patient's name will not be used in any study reports, and these reports will be used for research purposes only.

2) Beneficence/non-maleficence

There will be no cost to patient for participating and completing the questionnaire in this study. Taking part in this study may benefit patient in aspect of learning a new knowledge about clinical trials or clinical research participation. The results of the study might help people with a similar condition in the future.

3. Justice

There is no bias in this study due to it is clear inclusion and exclusion criteria and patient participation is voluntary. A convenient sample of individual patients is recruited from out-patient department in this study.

3.11 Expected Benefit

- This study will be a new knowledge in clinical research and pharmaceutical industry in Thailand.
- Study outcome will be beneficial to health professionals in clinical research field (Investigator, Study Nurse, etc.) to improve clinical trial process involving the subjects, especially obtaining informed consent process.
- To know patients' knowledge and attitudes about clinical trial participation, it would minimize the gap between doctor and patient in order to provide more information about clinical trial to their patients for better understanding and knowledge building.
- Information about the factors influencing patients' decision to participate in clinical trials may be used for clinical research development in the hospital.
- Study outcome will be a primary data for future studies with a larger sample size.
- Study outcome will be a knowledge-based in clinical research area in Thailand for further studies.

CHAPTER IV
RESULTS

This cross-sectional descriptive study aims to identify the factors related to decision-making towards participation in phase III clinical trials in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The 110 patients were approached to complete the structured questionnaire during 5-17 November 2015. This chapter presents the findings from data analysis which are categorized into 3 parts in the following details.

4.1 Descriptive Findings
4.2 Univariate Analysis
4.3 Multiple Logistic Regression Models

4.1 Descriptive Findings

4.1.1 Socio-demographic characteristics of diabetes patients

Table 2 describes the socio-demographic characteristics of diabetes patients from OPD of Endocrinology Metabolism and Thyroid Clinic, King Chulalongkorn Memorial Hospital, Bangkok, Thailand. This socio-demographic factor includes age, gender, marital status, religion, education, occupation, monthly income, health status, medical insurance plan, living area, and distance from home to hospital. Majority of the patients were female in the age group "61-80 years" (46%) and minority were in the age group "18-30 years" (11%) and living in Bangkok (85.5%). Collected data describes patient with diabetes (56.4%) and patient with concomitant disease (43.6%).

Table 2 Socio-Demographic Characteristics of Diabetes Patients

Characteristics	No. of Patients (n=110)	Percentage (%)
Age, years		
18 - 30	11	10
31 - 40	22	20
41 - 60	31	28.2
61 - 80	46	41.8
Gender		
Male	21	19.1
Female	89	80.9
Marital status		
Single	13	11.8
Married	81	73.6
Widow	15	13.6
Separate	1	0.9
Religion		
Buddhism	106	96.4
Christian	2	1.8
Muslim	2	1.8

Characteristics	No. of Patients (n=110)	Percentage (%)
Education level		
≤ Primary school	34	30.9
High school	21	19.1
Certificate/Diploma	13	11.8
> Bachelor's degree	42	38.2
Occupation		
Agriculture	1	0.9
Employee	24	21.8
Self-employed	15	13.6
Government Officer	7	6.4
Dependent	38	34.5
Others (housewife, retiree)	25	22.7
Income per month (THB)		
< 10,000	37	33.6
10,000-30,000	51	46.4
30,000-50,000	11	10.0
> 50,000	11	10.0
Health status		
Diabetes	62	56.4
Concomitant disease	48	43.6
Medical insurance plan		
National Health Security or 30 Baht scheme	17	15.5
Civil Servant Medical Benefit Scheme (CSMBS)	37	33.6
Social Security Scheme (SSS)	24	21.8
Private Insurance	3	2.7
Others (no insurance, pay out of own pocket)	29	26.4

Characteristics	No. of Patients (n=110)	Percentage (%)
Living area		
Bangkok	94	85.5
Other provinces	16	14.5
Travel from home to hospital		
Bus	29	26.4
Taxi	23	20.9
Own vehicle	44	40.0
Others (Skytrain, airplane, motorbike, bicycle)	14	12.7
Travel time from home to hospital		
≤ 2 hours	101	91.8
> 2 hours	9	8.2

4.1.2 Knowledge about clinical trials

The knowledge about clinical trials of diabetes patients was measured by setting with 10 true statements and 2 false statements in the questionnaire. The full score is 12 points. The Median of knowledge score of diabetes patients is 10 points and the minimum and maximum score is 4 and 12 points respectively.

Table 3 Number and percentage distribution of correct answer to each question of knowledge about clinical trials

	Statement	Correct Number (n=110)	Correct Percentage (%)
1	The objective of the clinical trial is to study the new drug or a new diabetes treatment?	104	94.5
2	Do you think clinical trials have benefit?	109	99.1
3	Are you required to sign Informed Consent Form before participating in any clinical trials?	84	76.4
4	Every person who participates in a clinical trial receives the new drug or treatment.	81	73.6

	Statement	Correct	
		Number (n=110)	Percentage (%)
5	You cannot participate in clinical trial if you are not eligible, even though you want to	70	63.6
6	Your decision to participate in clinical trials is voluntary.	102	92.7
7	You will receive payment for participating in clinical trial.*	87	79.1
8	The results from clinical trials may help improving the treatment for future patients who suffer from the same illness as you.	108	98.2
9	You can withdraw from the clinical trial at any time after your participation.	104	94.5
10	It is possible you may get side effects of the treatment or risk or discomfort during participation in clinical trial.	96	87.3
11	Will your information be kept confidentially if you participate in clinical trial?	104	94.5
12	The physician can convince or persuade you to participate in clinical trials.*	31	28.2

**False statement*

Level of knowledge about clinical trials in diabetes patients as shown in Table 4, the most of patients had rather moderate and good knowledge on clinical trials (70.9% and 23.6%).

Table 4 Level of knowledge about clinical trials

Level of knowledge		Number (n=110)	Percentage (%)
Low level of knowledge	(<60%)	6	5.5
Moderate level of knowledge	(60-80%)	78	70.9
High level of knowledge	(>80%)	26	23.6

4.1.3 Attitude towards clinical trial participation

Table 5-6 shows the level of attitude towards clinical trial participation in diabetes patients. The attitude towards clinical trial participation of patients was measured by using 10 statements with 5-point Likert scale.

Table 5 Percentage distribution of attitude towards clinical trial participation

	Statement	Percentage (n=110)				
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	The clinical trials have benefit	16.4	77.3	4.5	1.8	0.0
2	I think clinical trial is the best option available	5.5	55.5	28.2	10.9	0.0
3	I have no choice to participate in clinical trial	29	26.4	35.5	34.5	3.6
4	I think clinical trials are safe	4.5	43.6	42.7	9.1	0.0
5	I would participate in clinical trial in the future	4.5	44.5	40.9	10.0	0.0
6	I do not fear to take an investigational new drug or treatment	4.5	45.5	36.4	12.7	0.9
7	Other people with would benefit from the results of the clinical trial	11.8	63.6	15.5	9.1	0.0
8	I trust the doctor treating me	10.9	73.6	15.5	0.0	0.0
9	I want to help with the research	9.1	66.4	20.0	4.5	0.0
10	I feel like a ‘guinea pig’ if participating in clinical trial	2.7	32.7	31.8	30.9	1.8

The range of attitude score is 10-50 points, the mean was 35.33 (SD=4.0003)

Table 6 Level of attitude towards clinical trial participation

Level of Attitude		Number (n=110)	Percentage (%)
Low level of attitude	(<60%)	2	1.8
Moderate level of attitude	(60-80%)	20	18.2
High level of attitude	(>80%)	88	80.0

4.1.4 Decision-making to participate in phase III clinical trials

The proportion of patient's decision-making for clinical trial participation was acceptance rate at 50.9% and decline rate at 49.1% as shown in Table 7.

Table 7 Percentage distribution of patients' decision to participate in phase III clinical trials

Statement	Accepted (%)	Declined (%)
Will you participate in the clinical trial in the future?	56 (50.9%)	54 (49.1%)

Table 8 Percentage distribution of 1) Main reason given by patients for clinical trial participation, 2) The most influential person for participating in the clinical trials, and 3) information source about clinical trials

	Statement	Number (n=110)	Percentage (%)
1	**Who is the most influential person in your decision-making process to participate in the clinical trial?**		
	Myself	79	71.8
	Family members (spouse, children, parents, sibling, relatives)	22	20.0
	Friends or acquaintance	-	-
	Medical staffs (my doctor or nurse, others)	9	8.2
2	**What is your main reason for participating in the clinical trial?**		
	Economic benefits (free drug, test fee support)	4	3.6
	Therapeutic benefits (advance benefit of new drug application)	67	60.9
	Complying with physicians' opinion or requested by medical staff (Relationship with medical staff)	8	7.3
	Helping the future of clinical trials	27	24.5
	Others (Don’t know)	4	3.6
3	**What is your information source about clinical trials?**		
	Relatives/friends/former trial participants	22	20.0
	Posters or booklets in a hospital	2	1.8
	Internet	6	5.5
	Hospital staff (doctor, nurse)	44	40.0
	Others (never known before)	36	32.7

4.2 Univariate Analysis

Table 9-11 describes the relationship between decision-making of patient and categorical variables below.

- Relationship between socio-demographic characteristics of patients and their decision-making for participating in phase III clinical trials.
- Relationship between patients' knowledge about clinical trials and their decision-making in participating in phase III clinical trials
- Relationship between patients' attitude towards clinical trial participation and their decision-making in participating in phase III clinical trials

Table 9 Relationship between socio-demographic characteristics of diabetes patients and clinical trial participation

Variable	No. of Patients	Accepted		Declined		p-value
		No.	%	No.	%	
Age, year						**0.001***
18 - 30	11	11	19.6	0	0.0	
31 - 40	22	7	12.5	15	27.8	
41 - 60	31	18	32.1	13	24.1	
61 - 80	46	20	35.7	26	48.1	
Gender						**0.525**
Male	21	12	21.4	9	16.7	
Female	89	44	78.6	45	83.3	
Marital status						**0.174**
Single	13	9	16.1	4	7.4	
Married	81	37	66.1	44	81.5	
Widow, Separate	16	10	17.9	6	11.1	
Religion						**1.000**
Buddhism	106	54	96.4	52	96.3	
Others	4	2	3.7	2	3.6	

Variable	No. of Patients	Accepted		Declined		p-value
		No.	%	No.	%	
Education						**0.484**
≤ Primary school	34	14	25.0	20	37.0	
High school	21	11	19.6	10	18.5	
Certificate/Diploma	13	8	14.3	5	9.3	
≥ Bachelor's degree	42	23	41.1	19	35.2	
Occupation						**0.477**
Employee	24	11	19.6	13	24.1	
Self-employed	15	6	10.7	9	16.7	
Government Officer	7	5	8.9	2	3.7	
Dependent	38	18	32.1	20	37.0	
Others	26	16	28.6	10	18.5	
Monthly income (THB)						**0.484**
< 10,000	37	21	37.5	16	29.6	
10,000-30,000	51	24	42.9	27	50.0	
30,000-50,000	11	4	7.1	7	13.0	
> 50,000	11	7	12.5	4	7.4	
Health status						**0.548**
Diabetes	62	30	53.6	32	59.3	
Concomitant disease	48	26	46.4	22	40.7	
Medical insurance plan						**0.281**
UC	17	12	21.4	5	9.3	
CSMBS	37	19	33.9	18	33.3	
SSS	24	13	23.2	11	20.4	
Private Insurance	3	1	1.8	2	3.7	
Others	29	11	19.6	18	33.3	
Living area						**0.644**
Bangkok	94	47	83.9	47	87.0	
Other provinces	16	9	16.1	7	13.0	

Variable	No. of Patients	Accepted		Declined		p-value
		No.	%	No.	%	
Transportation						**0.046***
Bus	29	19	33.9	10	18.5	
Taxi	23	10	17.9	13	24.1	
Own vehicle	44	17	30.4	27	50.0	
Others	14	10	17.9	4	7.4	
Travel time from home to hospital (hour)						**0.162**
≤ 2 hours	101	49	87.5	52	96.3	
>2 hours	9	7	12.5	2	3.7	

**Statistically significant association at p-value < 0.05*

Table 10 shows relationship between patients' knowledge on clinical trials (knowledge full score 12 points) and their decision-making for clinical trial participation, the mean score was 10.05 (SD=1.29) falling to moderate level of knowledge was associated with acceptance of clinical trial participation (n= 56). Mean score of CT refusal was 9.28 (SD=1.38). As a result, moderate level of knowledge about clinical trials was highly related to decision-making for clinical trial participation in diabetes patients (p=0.001 by Chi-square).

Table 10 Relationship between Knowledge and Clinical Trial Participation

Variable	Accepted		Declined		p-value
	No.	%	No.	%	
Knowledge score: Mean ± SD	10.05 ± 1.29		9.28 ± 1.38		**0.003**[a]
Low level of knowledge	1	1.8	5	9.3	**0.001**[b]
Moderate level of knowledge	34	60.7	44	81.5	
High level of knowledge	21	37.5	5	9.3	

a Two-sample t-test

b Pearson's chi-square test

Table 11 shows relationship between patients' attitude towards clinical trial participation (attitude score range 10-50 points) and their decision-making for clinical trial participation, the mean score was 36.88 (SD=3.45) as Good Attitude which was associated with acceptance of clinical trial participation (n= 56). As a result, good attitude was highly related to decision-making for clinical trial participation in diabetes patients (p=<0.001 by Chi-square).

Table 11 Relationship between Attitude and Clinical Trial Participation

Variable	Accepted		Declined		p-value
	No.	%	No.	%	
Attitude score: Mean ± SD	36.88 ± 3.45		33.72 ± 3.92		**<0.001**[a]
Low level of attitude	0	0.0	2	3.7	**<0.001**[b]
Moderate level of attitude	3	5.4	19	35.2	**<0.001**[c]
High level of attitude	53	94.6	35	64.8	

a Two-sample t-test

b Pearson's chi-square test

(By grouping low and moderate attitude row because of too small number)

c Fisher's exact test

Table 12 Main Reason for Acceptance to Participate in Clinical Trial

Main reason	Accepted (%)	Declined (%)
Economic benefits	1 (1.8)	3 (5.6)
Therapeutic benefits	37 (66.1)	30 (55.6)
Complying with physicians' opinion or requested by medical staff	3 (5.4)	5 (9.3)
Helping the future of clinical trials	15 (26.8)	12 (22.2)
Others (Don't know)	0 (0.0)	4 (7.4)

Table 13 The Most Influential Person for Patients' Decision to Participate in Clinical Trials

Statement	Accepted (%)	Declined (%)
Myself	40 (71.4)	39 (72.2)
Family members	10 (17.9)	12 (22.2)
Medical staffs	6 (10.7)	3 (5.6)

4.3 Multiple Logistic Regression Models

To identify the relationship between socio-demographic characteristics of patients, patients' knowledge about clinical trial, patients' attitude towards clinical trial participation, and their decision-making for participation in phase III clinical trials, multiple logistic regression models was used for analysis. A total of 12 variables (x variables) were included in the first multiple logistic regression model (Table 14). Using backward elimination (with log-likelihood ratio test), the final model comprised only 3 variables i.e., marital status (Married, Single, Widow/Separated), knowledge score and attitude score as shown in Table 15.

Table 14 Logistic Regression Model of Acceptance to Participate in Clinical Trials (Model 1)

Variables	b	p-value	Adjusted OR	95% CI
Age, year				
18 - 40	1.719	0.120	5.58	0.64 - 48.72
41 - 60	1.679	0.050	5.36	0.10 - 28.72
61 - 80	-	-	1	-
Gender				
Male	0.055	0.951	1.06	0.19 - 6.03
Female	-	-	1	-
Marital status				
Single	1.384	0.216	3.99	0.45 – 35.71
Married	-	-	1	-
Widow, Separate	2.185	0.014	8.90	1.56 – 50.82
Education				
≤ Primary school	-	-	1	-
High school	1.096	0.269	3.00	0.43 – 20.86
Certificate/Diploma	0.734	0.452	2.08	0.31 – 14.09
≥ Bachelor's degree	0.673	0.439	1.96	0.36 - 10.76

Variables	b	p-value	Adjusted OR	95% CI
Occupation				
Employee	-	-	1	-
Self-employed	-0.036	0.971	0.97	0.14 – 6.58
Government Officer	2.145	0.240	8.54	0.24 – 306.76
Dependent	0.192	0.854	1.21	0.16 – 9.37
Others	0.754	0.507	2.13	0.23 – 19.65
Monthly income (THB)				
< 10,000	-	-	1	-
10,000 - 30,000	-0.909	0.300	0.40	0.72 – 2.25
30,000 - 50,000	-0.929	0.434	0.40	0.04 – 4.06
> 50,000	0.672	0.566	1.96	0.20 – 19.40
Health status				
Diabetes	-	-	1	-
Concomitant disease	0.578	0.376	1.78	0.50 – 6.42
Medical insurance plan				
UC	-	-	1	-
CSMBS	0.377	0.719	1.46	0.19 – 11.35
SSS	0.138	0.897	1.15	0.14 – 9.32
Private Insurance	-0.803	0.667	0.45	0.02 – 17.45
Others	-1.019	0.300	0.36	0.05 – 2.48
Living area				
Bangkok	-	-	1	-
Other provinces	-0.806	0.442	0.45	0.06 – 3.49
Transportation				
Bus	0.972	0.207	2.64	0.59 – 11.97
Taxi	0.436	0.568	1.55	0.35 – 6.90
Own vehicle	-	-	1	-
Others	1.575	0.113	4.83	0.69 – 33.92
Knowledge score	0.662	0.10	1.94	1.17 – 3.21
Attitude score	0.267	**0.001***	1.31	1.11 – 1.54

**Statistically significant at p-value < 0.05*

Table 15 Multiple Logistic Regression Model of Acceptance to Participate in Clinical Trials (Model 2)

Variables	b	p-value	Adjusted OR	95% CI
Attitude score	0.268	<0.001	1.31	1.13 - 1.51
Knowledge score	0.541	0.007	1.72	1.16 - 2.55
Marital status				
Single	1.620	0.025	5.05	1.22 – 20.91
Widow, Separate	1.286	0.076	3.62	0.87 – 15.01

In line with the Logistic Regression Model 2 (Table 15) containing only statistically significant 3 variables (attitude score, knowledge score, and marital status), so the regression equation is;

ln odds of acceptance to participate in clinical trials
= -15.059
+ 0.268*Attitude score
+ 0.541*Knowledge score
+ 1.620*(Single)
+ 1.286*(Widow/Separated)

Where

If single, then Single = 1, Widow/Separated = 0

If Widow/Separated, then Single = 0, Widow/Separated = 1

CHAPTER V
DISCUSION AND CONCLUSIONS

5.1 Discussion

This cross-sectional descriptive study was conducted in diabetes patients at King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The study aims to identify the factors related to decision-making towards participation in phase III clinical trials in diabetes patients (n=110) and determine the level of patients' knowledge and attitude about clinical trials and explore relationship of all independent variables (demographic characteristics, knowledge about clinical trials, and attitude towards clinical trial participation) with dependent variable (decision-making of patients).

The major findings of this study were the proportion of patient's decision-making for clinical trial participation with acceptance rate at 50.9% and refusal rate at 49.1%. Majority of diabetes patients was range 61-80 years and female. This study reported some factors that were associated with a positive decision making outcome (say 'yes' to join the trial). Good knowledge and attitude on clinical trial participation was significantly associated with patients' acceptance of CT participation. Collected data also represented diabetes patients with good knowledge at 60.7% and high level of attitude at 94.6% influencing their acceptance to participate in the clinical trial.

Obviously, attitude were significantly associated with decision-making for CT participation ($p<0.001$) which were a factor related to patients' decision-making to take part in the trial. This result was a evidence to support the previous studies that reported the positive attitudes is a major factor for patients' decision-making to participate in clinical trials (Comis et al., 2003). It was also indicated that the attitude could predict future behavior according to Kraus's study, Attitudes and the Prediction of Behavior (Kraus, 1995).

It was interestingly reported in this study that the most frequency of incorrect response to a question on patient knowledge assessment was "*The physician can convince or persuade you to participate in clinical trials*" which represented 28.2% (31/110) for correct response. This implied mostly patients (71.8%) always trust in their doctor and the doctor can convince them to join the trials; it described patient's belief and point of view to their doctor. Similar to another study, (Hutchison et al., 2011) reported that 47.2% of patients discussed with doctor for their decision to take part in the clinical trial.

However, in this study, the proportion of acceptance (50.9%) and refusal (49.1%) rate of clinical trial participation was not significant difference in this small sample size. Therefore, to further study in a larger sample size with same criteria will help to confirm the result of this study.

Limitation

A total of 110 patients in this study is a small sample size and limited power. The study was conducted at only one public hospital in the center of Bangkok and findings cannot be extended to other hospitals in different region of Thailand. The target population in this research was only out-patient with diabetes diagnosis which is not extent to in-patient and another disease indication. Therefore, the factors to influence in-patient and patients in other diseases for clinical trial participation were not identified and their knowledge and attitude towards clinical trial participation was not investigated.

5.2 Conclusions

A total of 110 diabetes patients completed the structured questionnaire in the study and they have never participated in a clinical trial during last 6 months or currently participating in any clinical trials. This study reported that 50.9% of the patients will participate in the phase III clinical trial if they will be asked to join in the future. Majority of the patients were female in the age group "61-80 years" (46%) living in Bangkok (85.5%). Collected data represented patient's health status

as diabetes (56.4%) and diabetes with concomitant disease (43.6%). Mostly patients (60.9%) gave reason of therapeutic benefits (hope to get better treatment) as their main reason for clinical trial participation. 79 of 110 patients (71.8%) decided to participate in the trial by themselves and 20% by family. Interestingly, 27 of 110 patients (24.5%) is optimistic with altruism reason.

Overall knowledge about clinical trials indicated that 70.9% of patients had moderate knowledge on clinical trials and 23.6% had good knowledge. Another findings of attitude towards clinical trial participation in this study, it showed that 80% of patients had good attitude and low attitude represented just only 1.8%.

Logistic regression analyses showed that the factors best explaining participation were knowledge about clinical trial ($p=0.007$), attitude towards clinical trial participation ($p<0.001$), and patient with single status ($p=0.025$). Furthermore, the data findings also represented the significant relationship between age and decision for CT participation ($p=0.001$), transportation and decision ($p=0.046$), and relationship between moderate knowledge and decision for CT participation ($p=0.003$), and relationship between good attitude and decision for CT participation ($p<0.001$) respectively.

5.3 Recommendations

1. Study outcome is a primary data for future studies with a larger sample size and further studies in different therapeutic area is recommended.

2. Based on the Treatment and Research Decision Making Model (Bowling & Ebrahim, 2001) containing a multi-factorial process, grouping variable or investigation of all influential factors from this model should be further studied.

APPENDIX

APPENDIX A

QUESTIONNAIRE

The following box to be filled in by Researcher or Research Assistant

Name of Researcher / Research Assistant:
……
Research ID number: ☐☐☐

Date: ……/……/……...

SECTION 1: Socio-Demographic Characteristics and General Information
Please tick ☑ in the box or fill in the blanks as required.

1. Have you ever participated in a clinical trial for last 6 months or currently participating in any clinical trials?

   ☐ Yes (When? Please specify month/year)……../……...

   ☐ No (Please go to question #2)

2. Age

   ☐ 18 - 30 years old ☐ 31 - 40 years old

   ☐ 41 - 60 years old ☐ 61 - 80 years old

3. Gender

   ☐ Male ☐ Female

4. Marital status

   ☐ Single ☐ Married

   ☐ Widow ☐ Separate

5. Religion

☐ Buddhism ☐ Christian

☐ Muslim ☐ Others, please specify…….

6. Education level

☐ Primary school and lower ☐ High school

☐ Certificate/Diploma ☐ Bachelor's degree and higher

7. Occupation

☐ Agriculture ☐ Employee

☐ Self-employed ☐ Government Officer

☐ Dependent ☐ Other, please specify……

8. Income per month (Baht)

☐ Less than < 10,000 ☐ 10,000-30,000

☐ 30,000-50,000 ☐ More than > 50,000

9. What is your health problem? ……

Are you diabetes patient?

☐ Yes ☐ No

10. What is your health insurance plan?

☐ National Health Security or 30 Baht scheme

☐ Civil Servant Medical Benefit Scheme (CSMBS)

☐ Social Security Scheme (SSS)

☐ Private Insurance

☐ Others, please specify…….

11. Where do you live?

☐ Bangkok, please specify area ……

☐ Other provinces, please specify……..

12. How do you travel from home to the hospital?

☐ by bus ☐ by taxi

☐ by your own vehicle ☐Other, please specify…….

13. How long does it take from your home to the hospital?

……..…hour

SECTION 2: Knowledge about clinical trial

Please tick ☑ in the box that matches your opinion.

1. The objective of the clinical trial is to study the new drug or a new diabetes treatment?

☐ Yes ☐ No

2. Do you think clinical trials have benefit?

☐ Yes ☐ No

3. Are you required to sign Informed Consent Form before participating in any clinical trials?

☐ Yes ☐ No

4. Every person who participates in a clinical trial receives the new drug or treatment.

☐ Yes ☐ No

5. You cannot participate in clinical trial if you are not eligible, even though you want to.

☐ Yes ☐ No

6. Your decision to participate in clinical trials is voluntary.

☐ Yes ☐ No

7. You will receive payment for participating in clinical trial.

☐ Yes ☐ No

8. The results from clinical trials may help improving the treatment for future patients who suffer from the same illness as you.

☐ Yes ☐ No

9. You can withdraw from the clinical trial at any time after your participation.

☐ Yes ☐ No

10. It is possible you may get side effects of the treatment or risk or discomfort during participation in clinical trial.

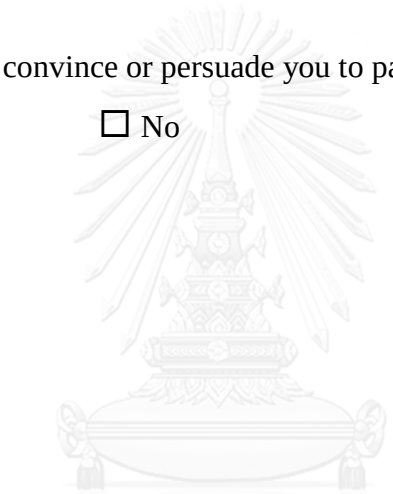
☐ Yes ☐ No

11. Will your information be kept confidentially if you participate in clinical trial?

☐ Yes ☐ No

12. The physician can convince or persuade you to participate in clinical trials.

☐ Yes ☐ No



SECTION 3: Attitude towards clinical trial participation

Please fill ✓ in the column which is the closest to your thoughts in the following statements.

Statements	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The clinical trials have benefit					
2. I think clinical trial is the best option available					
3. I have no choice to participate in clinical trial					
4. I think clinical trials are safe					
5. I would participate in clinical trial in the future					
6. I do not fear to take an investigational new drug or treatment					
7. Other people with would benefit from the results of the clinical trial					
8. I trust the doctor treating me					
9. I want to help with the research					
10. I feel like a 'guinea pig' if participating in clinical trial					

SECTION 4: Decision-making to participate in clinical trials

Please tick ☑ in the box that matches your opinion.

1. Will you participate in the clinical trial in the future?

☐ Yes ☐ No

2. Who is the most influential person in your decision-making process to participate in the clinical trial?

☐ Myself

☐ Family members (spouse, children, parents, sibling, relatives)

☐ Friends or acquaintance

☐ Medical staffs (my doctor or nurse, others)

☐ Others, please specify……

3. What is your main reason for participating in the clinical trial?

☐ Economic benefits (free drug, test fee support)

☐ Therapeutic benefits (advance benefit of new drug application)

☐ Complying with physicians' opinion or requested by medical staff (Relationship with medical staff)

☐ Helping the future of clinical trials

☐ Others, please specify……

4. What is your information source about clinical trials?

☐ Relatives/friends/former trial participants

☐ Posters or booklets in a hospital

☐ Internet

☐ Hospital staff (doctor, nurse etc.)

☐ Others, please specify……..

QUESTIONNAIRE (Thai version)
แบบสอบถาม

ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกในผู้ป่วยโรคเบาหวาน โรงพยาบาลจุฬาลงกรณ์ กรุงเทพมหานคร ประเทศไทย

ชื่อผู้วิจัย / ผู้ช่วยวิจัย: .....
รหัสผู้เข้าร่วมโครงการวิจัย: ☐☐☐
วันที่: ...../...../.....

เรียน ผู้เข้าร่วมโครงการวิจัยทุกท่าน

จุดประสงค์ของการศึกษาวิจัยนี้คือ เพื่อหาปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกระยะที่ 3 ในผู้ป่วยโรคเบาหวาน ณ โรงพยาบาลจุฬาลงกรณ์ กรุงเทพ ประเทศไทย ซึ่งผลของการวิจัยนี้จะเป็นข้อมูลที่มีคุณประโยชน์ต่องานวิจัยทางคลินิก และเป็นองค์ความรู้ใหม่สำหรับการวิจัยทางคลินิกในโรงพยาบาลจุฬาลงกรณ์และอุตสาหกรรมยาในประเทศไทย รวมทั้งเป็นข้อมูลสำหรับบุคลากรทางการแพทย์ (เช่น แพทย์ผู้วิจัย พยาบาล ผู้กำกับดูแลการวิจัย ผู้สนับสนุนการวิจัย) ที่กำลังดำเนินการวิจัยทางคลินิกอยู่ในปัจจุบัน

ทั้งนี้ ข้อมูลของการวิจัยและข้อมูลจากคำตอบของท่านจะถูกปกปิดเป็นความลับและจะไม่มีการเปิดเผยชื่อของท่านแต่อย่างใด การวิเคราะห์และการรายงานข้อมูลที่ได้จากการวิจัยนี้เพื่อวัตถุประสงค์ทางวิชาการและใช้สำหรับการวิจัยเท่านั้น คำตอบของท่านจะไม่มีผลใด ๆ ต่อการรักษาของท่านในโรงพยาบาลแห่งนี้

ขอขอบคุณที่สละเวลาของท่านในการตอบแบบสอบถามในครั้งนี้

นางสาวรักจิต กัลยาณะธรรม และคณะผู้วิจัย
นิสิตปริญญาโท วิทยาลัยวิทยาศาสตร์สาธารณสุข
จุฬาลงกรณ์มหาวิทยาลัย

ส่วนที่ 1: ลักษณะทางสังคมประชากรและข้อมูลทั่วไป
โปรดทำเครื่องหมาย ☑ ลงในช่อง หรือเติมข้อความลงในช่องว่าง

1. ท่านเคยเข้าร่วมการศึกษาวิจัยทางคลินิกในช่วง 6 เดือนที่ผ่านมา หรือกำลังเข้าร่วมโครงการใดๆ อยู่หรือไม่

☐ เคย (เข้าร่วมเมื่อใด กรุณาระบุ เดือน/ปี)……../……...

☐ ไม่เคย (กรุณาไปที่คำถามข้อที่ 2)

2. อายุ

☐ 18 - 30 ปี ☐ 31 - 40 ปี

☐ 41 - 60 ปี ☐ 61 - 80 ปี

3. เพศ

☐ ชาย ☐ หญิง

4. สถานภาพสมรส

☐ โสด ☐ แต่งงาน

☐ หม้าย ☐ แยกกันอยู่

5. ศาสนา

☐ พุทธ ☐ คริสต์

☐ อิสลาม ☐ อื่นๆ , โปรดระบุ…….

6. ระดับการศึกษา

☐ ประถมศึกษา หรือน้อยกว่า ☐ มัธยมศึกษา

☐ ปวช / ปวส ☐ ปริญญาตรี หรือสูงกว่า

☐ อื่นๆ , โปรดระบุ…….

7. อาชีพ

☐ เกษตรกรรม ☐ ลูกจ้าง/พนักงานบริษัท

☐ ธุรกิจส่วนตัว ☐ ข้าราชการ

☐ ว่างงาน ☐ อื่นๆ โปรดระบุ…….

8. รายได้ต่อเดือน (บาท)

☐ น้อยกว่า < 10,000 บาท ☐ 10,000 - 30,000 บาท

☐ 30,000 - 50,000 บาท ☐ มากกว่า > 50,000 บาท

9. ท่านมีปัญหาสุขภาพอะไรบ้าง ……

ท่านเป็นโรคเบาหวานหรือไม่?

☐ ใช่ ☐ ไม่ใช่

10. อะไรคือแผนประกันสุขภาพของท่าน

☐ โครงการหลักประกันสุขภาพถ้วนหน้า หรือสิทธิโครงการ 30 บาท

☐ สิทธิสวัสดิการรักษาพยาบาลข้าราชการ

☐ ประกันสังคม

☐ ประกันสุขภาพส่วนบุคคล

☐ อื่นๆ , โปรดระบุ……..

11. ท่านพักอยู่ที่ไหน?

☐ กรุงเทพ โปรดระบุ เขตพื้นที่ ……

☐ ต่างจังหวัด โปรดระบุจังหวัด ……..

12. ท่านเดินทางจากที่บ้านมาโรงพยาบาลอย่างไร

☐ รถโดยสารประจำทาง ☐ รถแท็กซี่

☐ รถยนต์ส่วนตัว ☐ อื่นๆ โปรดระบุ.....

13. ท่านใช้เวลาเดินทางจากบ้านของท่านมายังโรงพยาบาลนานเท่าใด

.....ชั่วโมง

ส่วนที่ 2: ความรู้เกี่ยวกับการศึกษาวิจัยทางคลินิก

โปรดทำเครื่องหมาย ☑ ลงในช่อง ที่ตรงกับความคิดเห็นของท่าน

1. วัตถุประสงค์ของการศึกษาวิจัยทางคลินิกคือ การศึกษายาใหม่หรือการรักษาแบบใหม่ที่ใช้รักษาโรคเบาหวาน

☐ ใช่ ☐ ไม่ใช่

2. ท่านคิดว่าการศึกษาวิจัยทางคลินิกมีประโยชน์ใช่หรือไม่

☐ ใช่ ☐ ไม่ใช่

3. ท่านจำเป็นต้องลงลายมือชื่อในเอกสารให้คำยินยอมก่อนที่จะเข้าร่วมการศึกษาวิจัยทางคลินิกใดๆ ก็ตามใช่หรือไม่

☐ ใช่ ☐ ไม่ใช่

4. ทุกๆ คนที่เข้าร่วมการศึกษาวิจัยทางคลินิกจะได้รับการรักษาด้วยยาใหม่หรือการรักษาแบบใหม่

☐ ใช่ ☐ ไม่ใช่

5. ท่านไม่สามารถเข้าร่วมการศึกษาวิจัยทางคลินิกได้หากท่านมีคุณสมบัติไม่ตรงตามเกณฑ์ แม้ว่าท่านจะอยากเข้าร่วมก็ตาม

☐ ใช่ ☐ ไม่ใช่

6. การตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกเป็นไปด้วยความสมัครใจใช่หรือไม่

☐ ใช่ ☐ ไม่ใช่

7. ท่านจะได้รับเงินค่าตอบแทนเพื่อเข้าร่วมการศึกษาวิจัยทางคลินิกใช่หรือไม่

☐ ใช่ ☐ ไม่ใช่

8. ผลที่ได้จากการศึกษาวิจัยทางคลินิกอาจช่วยรักษาผู้ป่วยที่เป็นโรคเดียวกับท่านได้ดีขึ้นในอนาคต

☐ ใช่ ☐ ไม่ใช่

9. ท่านสามารถถอนตัวออกจากศึกษาวิจัยทางคลินิกได้เมื่อใดก็ได้ทุกเมื่อหลังจากเข้าร่วม การศึกษาวิจัย

☐ ใช่ ☐ ไม่ใช่

10. มีความเป็นไปได้ที่ท่านอาจได้รับผลข้างเคียงจากการรักษาหรือมีความเสี่ยงหรือรู้สึก ไม่สบายตัวในระหว่างที่เข้าร่วมการศึกษาวิจัย

☐ ใช่ ☐ ไม่ใช่

11. ข้อมูลส่วนตัวของท่านจะถูกเก็บรักษาไว้เป็นความลับหากท่านเข้าร่วมการศึกษาวิจัยทางคลินิก

☐ ใช่ ☐ ไม่ใช่

12. แพทย์สามารถโน้มน้าวหรือชักจูงท่านให้เข้าร่วมการศึกษาวิจัยทางคลินิกได้

☐ ใช่ ☐ ไม่ใช่

ส่วนที่ 3: ทัศนคติเกี่ยวกับการเข้าร่วมการศึกษาวิจัยทางคลินิก

โปรดทำเครื่องหมาย ✓ ลงในช่องที่ใกล้เคียงกับความคิดของท่านมากที่สุด

ข้อความ	เห็นด้วยอย่างยิ่ง	เห็นด้วย	ไม่แน่ใจ	ไม่เห็นด้วย	ไม่เห็นด้วยอย่างยิ่ง
1. การศึกษาวิจัยทางคลินิกมีประโยชน์					
2. ข้าพเจ้าคิดว่าการศึกษาวิจัยทางคลินิกเป็นทางเลือกที่ดีที่สุดที่มี					
3. ข้าพเจ้าไม่มีทางเลือกในการเข้าร่วมการศึกษาวิจัย ทางคลินิก					
4. ข้าพเจ้าคิดว่าการศึกษาวิจัยทางคลินิกปลอดภัย					
5. ข้าพเจ้าจะเข้าร่วมการศึกษาวิจัยทางคลินิกในอนาคต					
6. ข้าพเจ้าไม่กลัวที่จะได้รับยาใหม่ที่ใช้ในการศึกษาวิจัยหรือได้รับการรักษาจากการศึกษาวิจัย					
7. ผู้อื่นจะได้ประโยชน์จากผลของการศึกษาวิจัยทางคลินิก					
8. ข้าพเจ้าไว้ใจแพทย์ที่รักษาข้าพเจ้า					
9. ข้าพเจ้าต้องการช่วยสนับสนุนงานวิจัย					
10. ข้าพเจ้ารู้สึกเหมือนเป็น ‘หนูทดลอง’ หากเข้าร่วมการศึกษาวิจัยทางคลินิก					

ส่วนที่ 4: การตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิก

โปรดทำเครื่องหมาย ☑ ลงในช่องที่ตรงกับความคิดเห็นของท่าน

1. ท่านจะเข้าร่วมการศึกษาวิจัยทางคลินิกในอนาคตหรือไม่

☐ เข้าร่วม ☐ ไม่เข้าร่วม

2. ใครมีอิทธิพลต่อการตัดสินใจเข้าร่วมในการศึกษาวิจัยทางคลินิกของท่านมากที่สุด

☐ ตัดสินใจด้วยตัวเอง

☐ ครอบครัว (คู่สมรส บุตร พี่น้อง ญาติ)

☐ เพื่อนหรือคนรู้จัก

☐ เจ้าหน้าที่ทางการแพทย์ (แพทย์หรือพยาบาลประจำตัวข้าพเจ้า)

☐ อื่นๆ โปรดระบุ.....

3. อะไรคือเหตุผลหลักของท่านในการเข้าร่วมการศึกษาวิจัยทางคลินิก

☐ ผลประโยชน์ทางการเงิน (ได้รับยาโดยไม่เสียค่าใช้จ่ายใดๆ ได้รับการสนับสนุนค่าตรวจ)

☐ ผลประโยชน์ทางการรักษา (ได้รับยาตัวใหม่ที่ได้ประโยชน์มากขึ้น))

☐ ทำตามความเห็นของแพทย์หรือเจ้าหน้าที่ทางการแพทย์ร้องขอ

(มีสัมพันธภาพที่ดีกับเจ้าหน้าที่ทางการแพทย์)

☐ เพื่อช่วยสนับสนุนงานวิจัยทางคลินิกในอนาคต

☐ อื่นๆ โปรดระบุ.....

4. อะไรคือแหล่งข้อมูลเกี่ยวกับการศึกษาวิจัยทางคลินิกของท่าน

☐ ญาติพี่น้อง / เพื่อน / ผู้ที่เคยเข้าร่วมการศึกษาวิจัยทางคลินิก

☐ แผ่นโปสเตอร์ หรือแผ่นพับในโรงพยาบาล

☐ อินเตอร์เน็ต (Internet)

☐ เจ้าหน้าที่โรงพยาบาล (เช่น หมอ พยาบาล ฯลฯ)

☐ อื่นๆ โปรดระบุ……..

Appendix B
Informed Consent Form

 **คณะแพทยศาสตร์** **จุฬาลงกรณ์มหาวิทยาลัย**	**AF 10-05/4.0** **เอกสารแสดงความยินยอมเข้าร่วมในโครงการวิจัย**

วันให้คำยินยอม วันที่.....เดือน.....พ.ศ.....

การวิจัยเรื่อง **ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกในผู้ป่วยโรคเบาหวาน โรงพยาบาลจุฬาลงกรณ์ กรุงเทพมหานคร ประเทศไทย**

วัตถุประสงค์หลักของการศึกษาวิจัยนี้คือ เพื่อหาปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิกระยะที่ 3 ในผู้ป่วยโรคเบาหวาน ณ โรงพยาบาลจุฬาลงกรณ์ กรุงเทพ ประเทศไทย

แบบสอบถามสำหรับการวิจัยนี้มีจำนวนคำถามทั้งหมด 39 ข้อคำถาม โดยแบ่งเป็น 4 ส่วน ดังนี้

ส่วนที่ 1 ลักษณะทางสังคมประชากรและข้อมูลทั่วไป	จำนวน 13 ข้อ	ใช้เวลาประมาณ 2 นาที
ส่วนที่ 2 ความรู้เกี่ยวกับการศึกษาวิจัยทางคลินิก	จำนวน 12 ข้อ	ใช้เวลาประมาณ 10 นาที
ส่วนที่ 3 ทัศนคติเกี่ยวกับการเข้าร่วมการศึกษาวิจัยทางคลินิก	จำนวน 10 ข้อ	ใช้เวลาประมาณ 5 นาที
ส่วนที่ 4 การตัดสินใจเข้าร่วมการศึกษาวิจัยทางคลินิก	จำนวน 4 ข้อ	ใช้เวลาประมาณ 3 นาที

ข้อมูลที่ได้จากการวิจัยนี้และข้อมูลจากคำตอบของท่านจะถูกปกปิดเป็นความลับและจะไม่มีการเปิดเผยชื่อของท่านหรือระบุถึงตัวท่านแต่อย่างใด การวิเคราะห์และการรายงานข้อมูลที่ได้จากการวิจัยนี้เพื่อวัตถุประสงค์ทางวิชาการและใช้สำหรับการวิจัยเท่านั้น คำตอบของท่านจะไม่มีผลใด ๆ ต่อการรักษาของท่านในโรงพยาบาลแห่งนี้

ท่านจะไม่ได้รับค่าตอบแทนในการตอบแบบสอบถามในการวิจัยนี้ และการตอบแบบสอบถามของท่านเป็นไปด้วยความสมัครใจ โดยคาดว่าจะใช้เวลากรอกแบบสอบถามประมาณ 15-20 นาที

ข้าพเจ้า นาย/นาง/นางสาว.....

ที่อยู่.....ได้รับสำเนาเอกสารแสดงความยินยอมเข้าร่วมในโครงการวิจัยที่ข้าพเจ้าได้ลงนามและวันที่แล้วจำนวน 1 ฉบับ ทั้งนี้ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย ระยะเวลาของการทำวิจัย ระยะเวลาในการตอบแบบสอบถาม วิธีการวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัย ข้าพเจ้ามีเวลาและโอกาสเพียงพอในการซักถามข้อสงสัยจนมีความเข้าใจอย่างดีแล้ว โดยผู้วิจัยได้ตอบคำถามต่าง ๆ ด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยโดยสมัครใจ โดยข้าพเจ้ายินยอมตอบแบบสอบถามในการวิจัยนี้

ข้าพเจ้ามีสิทธิที่จะบอกเลิกเข้าร่วมในการวิจัยนี้เมื่อใดก็ได้ โดยไม่จำเป็นต้องแจ้งเหตุผลและการบอกเลิก การเข้าร่วมการวิจัยนี้จะไม่มีผลต่อการรักษาโรคหรือสิทธิอื่น ๆ ที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ และจะไม่เปิดเผยชื่อหรือระบุถึงตัวข้าพเจ้า ข้อมูลที่ได้จากการวิจัยนี้จะนำไปใช้เพื่อวัตถุประสงค์สำหรับการวิจัยเท่านั้น และไม่มีข้อมูลใดในการรายงานที่จะนำไปสู่การระบุตัวข้าพเจ้า และข้อมูลจะเปิดเผยได้เฉพาะเมื่อได้รับการยินยอมจากข้าพเจ้าเท่านั้น ผู้วิจัยอาจได้รับอนุญาตให้เข้ามาตรวจและประมวลข้อมูลของข้าพเจ้า ทั้งนี้จะต้องกระทำไปเพื่อวัตถุประสงค์เพื่อตรวจสอบความถูกต้องของข้อมูลเท่านั้น โดยการตกลงที่จะเข้าร่วมการศึกษานี้ข้าพเจ้าได้ให้คำยินยอมที่จะให้มีการตรวจสอบข้อมูลประวัติทางการแพทย์ของข้าพเจ้าได้

ผู้วิจัยรับรองว่าจะไม่มีการเก็บข้อมูลใด ๆ เพิ่มเติม หลังจากที่ข้าพเจ้าขอยกเลิกการเข้าร่วมโครงการวิจัย และต้องการให้ทำลายเอกสารทั้งหมดที่สามารถสืบค้นถึงตัวข้าพเจ้าได้

ข้าพเจ้าเข้าใจว่า ข้าพเจ้ามีสิทธิ์ที่จะตรวจสอบหรือแก้ไขข้อมูลส่วนตัวของข้าพเจ้าและสามารถยกเลิกการให้สิทธิในการใช้ข้อมูลส่วนตัวของข้าพเจ้าได้ โดยต้องแจ้งให้ผู้วิจัยรับทราบ

ข้าพเจ้าได้ตระหนักว่าข้อมูลในการวิจัยรวมถึงข้อมูลทางการแพทย์ของข้าพเจ้าที่ไม่มีการเปิดเผยชื่อจะผ่านกระบวนการต่าง ๆ เช่น การเก็บข้อมูล การบันทึกข้อมูลในแบบบันทึกและในคอมพิวเตอร์ การตรวจสอบ การวิเคราะห์ และการรายงานข้อมูลเพื่อวัตถุประสงค์ทางวิชาการ รวมทั้งการใช้ข้อมูลทางการแพทย์ในอนาคตเท่านั้น

ข้าพเจ้าได้อ่านข้อความข้างต้นและมีความเข้าใจดีทุกประการแล้ว ยินดีเข้าร่วมในการวิจัยด้วยความเต็มใจ จึงได้ลงนามในเอกสารแสดงความยินยอมนี้

.....ลงนามผู้ให้ความยินยอม

(.....) ชื่อผู้ยินยอมตัวบรรจง

วันที่ .....เดือน.....พ.ศ.....

ข้าพเจ้าได้อธิบายถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย ระยะเวลาในการตอบแบบสอบถาม รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดให้ผู้เข้าร่วมในโครงการวิจัยตามนามข้างต้นได้ทราบและมีความเข้าใจดีแล้ว พร้อมลงนามลงในเอกสารแสดงความยินยอมด้วยความเต็มใจ

.....ลงนามผู้ทำวิจัย/ผู้ร่วมการวิจัย

(.....) ชื่อผู้ทำวิจัย ตัวบรรจง

วันที่ .....เดือน.....พ.ศ.....

.....ลงนามพยาน

(.....) ชื่อพยาน ตัวบรรจง

วันที่ .....เดือน.....พ.ศ.....

Appendix C

Time Schedule

Research Activities	**Time Frame (Month)**											
Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Literature review	→	→	→									
Proposal writing		→	→									
Tool development for data collection		→	→									
Validity and reliability test				→	→							
Ethical review/approval					→	→	→					
Data collection								→				
Data analysis									→			
Report writing									→	→		
Publication											→	→
Duration of this study is approximately 12 months												

Appendix D
Budget

	Description	Unit cost (THB)	Quantity	Budget (THB)
1	**Pre-testing** Printing/Photocopy/Binding (Questionnaires)	100	30 sets	3,000
	Stationary	500	1 set	500
	Travel costs for researcher (Gasoline per round trip)	1,000	5 days	5,000
2	**EC submission process** Preparedness for Ethics submission (Printing/Photocopy/Binding/Courier)	1,000	10 sets	10,000
3	**Data Collection** Printing/Photocopy/Binding (Questionnaires + Informed Consent Form)	200	120 sets	24,000
	Travel costs for researcher (Gasoline expense per round trip)	1,000	10 days	10,000
	Meal for researchers (All day)	200	10 days	2,000
	Training for questionnaire use (Printing/Photocopy/Binding) (Questionnaires + Informed Consent Form)	200	3 persons	600
	Hiring place for training	500	1 day	500
4	**Data processing and Data Analysis**	100	120 sets	12,000
5	**Thesis Document Process** Printing/Photocopy/Binding/Courier (Exam + Final submission process)			10,000
6	**Miscellaneous** Telephone, Internet fee, courier fee			2,200
			Total Amount	**79,800**
	(Seventy Nine Thousand Eight Hundred Thai Baht) Total Amount in letters			

REFERENCES

Ajzen, I. (1985). From intentions to actions: A theory of planned behavior. USA: Springer-Verlag Berlin Heidelberg.

Appelbaum, P. S., & Grisso, T. (2001). MacCAT-CR MacArthur Competence Assessment Tool for Clinical Research. *Professional Resource Exchange, Inc*.

Avis, N. E., Smith, K. W., Link, C. L., Hortobagyi, G. N., & Rivera, E. (2006). Factors Associated With Participation in Breast Cancer Treatment Clinical Trials. *JOURNAL OF CLINICAL ONCOLOGY, 24*(12), 1860-1867.

Badran, I. G. (1995). Knowledge, attitude and practice the three pillars of excellence and wisdom: a place in the medical profession. *Eastern Mediteranean Health Journal, 1*(1).

Bevan, E. G., CHEE, L. C., McGHEE, S. M., & McINNES, G. T. (1993). Patients' attitudes to participation in clinical trials. *Br. J. clin. Pharmac., 35*, 204-207.

Biedrzycki, B. A. (2010). *Research Participation: Decision Making and Outcomes in Cancer Clinical Trials*. USA: ProQuest LLC.

Bloom, B. S. (1956). *Taxonomy of Educational Objectives. Vol. 1: Cognitive Domain*. New York, USA: New York: David Mckay.

Bowling, A., & Ebrahim, S. (2001). Measuring patients' preferences for treatment and perceptions of risk. *Quality in Health Care, 10(Suppl I):i2–i8*.

Brucks, M. (1986). A Typology of Consumer Knowledge Content. *Advances in Consumer Research, 13*.

CASSILETH, B. R., ZUPKIS, R. V., SUTTON-SMITH, K., & MARCH, V. (1980). Information and Participation Preferences Among Cancer Patients. *Annals of Internal Medicine, 92*(6).

Catt, S., Langridge, C., Fallowfield, L., Talbot, D. C., & Jenkins, V. (2011). Reasons given by patients for participating, or not, in Phase 1 cancer trials. *Eur J Cancer, 47*(10), 1490-1497. doi:10.1016/j.ejca.2011.02.020

Chu, S. H., Jeong, S. H., Kim, E. J., Park, M. S., Park, K., Nam, M., . . . Yoon, Y. R. (2012). The views of patients and healthy volunteers on participation in clinical trials: an exploratory survey study. *Contemp Clin Trials, 33*(4), 611-619. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/22405971

clinicaltrials.gov. (2015). Available from www.clinicaltrials.gov (2015, 25 June).

Comis, R. L., Miller, J. D., Aldige, C. R., Krebs, L., & Stoval, E. (2003). Public Attitudes Toward Participation in Cancer Clinical Trials. *Journal of Clinical Oncology, 21*(5), 830-835.

Fitzgerald, S. P. (2002). *Decision Making* United Kingdom: Capstone Publishing

Geppert, C., Candilis, P., Baker, S., Lidz, C., Appelbaum, P., & Fletcher, K. (2014). Motivations of Patients with Diabetes to Participate in Research *AJOB Empir Bioeth, 5*(4), 14-21. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/25419533

Gumucio, S. (2011). *The KAP survey model (Knowledge, Attitude & Practices)*: IGC Communigraphie.

Health, U. S. N. I. o. (2015). Trends and charts of number of clinical trials in worldwide.

Hospital, K. C. M. (2014). Hospital information Retrieved from http://www.chulalongkornhospital.go.th/

Hume, D. (2003). *A Treatise of Human Nature*. New York, USA: Dover Publications Inc.

Hutchison, C., Cowan, C., McMahon, T., & Paul, J. (2011). Factors Affecting Patient Decision Making for Randomised Cancer Clinical Trials. *Austra- Asian Journal of Cancer, 10*(2), 125-133.

IDF. (2014). IDF Diabetes Atlas, Sixth Edition. Retrieved from http://www.idf.org/

Jung, C. G. (1971). *Psychological Types*. New Jersey, USA: Princeton University Press.

Kaewpoonsri, N. (2006). Factors related to vulunteer comprehension of informed consent for a clinical trial. *SOUTHEAST ASIAN J TROP MED PUBLIC HEALTH, 37*(5).

Kraus, S. J. (1995). Attitudes and the Prediction of Behavior: A Meta-Analysis of the Empirical Literature. *Pers Soc Psychol Bull, 21*(1).

Mancini, J., Geneve, J., Dalenc, F., Genre, D., Monnier, A., Kerbrat, P., . . . Julian Reynier, C. (2007). Decision-making and breast cancer clinical trials: how experience challenges attitudes. *Contemp Clin Trials, 28*(6), 684-694. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17434812

Ministry of Public Health, T. (2011). *Thailand Health Profile 2008-2010*.

Pocock, S. J. (1983). *CLINICAL TRIALS: A Practical Approach*. England: British Library.

Richard F. Brown, P., PhD, D. L. C., Robert H. Houlihan, D., Maria D. Thomson, P., Pratt, E. C., Amy Sullivan, E., & Laura A. Siminoff, P. (2013). Perceptions of Participation in a Phase I, II, or III Clinical Trial Among African American Patients With Cancer: What Do Refusers Say? *Journal of Oncology Practice 9*(6).

SOOD, A., PRASAD, K., CHHATWANI, L., SHINOZAKI, E., CHA, S. S., LOEHRER, L. L., & WAHNER-ROEDLER, D. L. (2009). Patients' Attitudes and Preferences About Participation and Recruitment Strategies in Clinical Trials. *Mayo Clin Proc., 84*(3), 243-247.

WHO. (2008). *A Guide to Developing Knowledge, Attitude and Practice Surveys* Switzerland: World Health Organization

VITA

Nationality Thai

Place of birth Bangkok, Thailand

Education Master of Public Health (International Program)

Chulalongkorn University

Professional Experience

May 2006 – Present: QUINTILES (THAILAND) CO., LTD.

Regulatory and Site Start-Up Specialist