FACTORS AFFECTING HIV-INFECTED PATIENTS' INTENTION IN CLINICAL TRIAL PARTICIPATION

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FACTORS AFFECTING HIV-INFECTED PATIENTS' INTENTION IN CLINICAL TRIAL PARTICIPATION

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ABSTRACT

The number of clinical trials has been increasing dramatically in Asia due to several reasons. Many researchers have been discovering the reasons why some patients decide to participate in these trials, but there is not enough evidence that such an inquiry has been studied in the Thai population. This research was to identify factors affecting the intention of HIV-infected patients to participate in a clinical trial by using the Health Belief Model (HBM). A structured questionnaire was developed in accordance with the six major variables in the HBM. There were 280 patients aged between 18 – 60 years with asymptomatic HIV infection who presented at one academic hospital, Bangkok, Thailand during May to July 2013 who responded to the questionnaire.

About 76.4% of the respondents decided to join the clinical trial study; whereas 23.6% refused to join. The logistic regression results show that education, perceived susceptibility, perceived benefits, perceived barriers, cues to action and self-efficacy were predicting factors of the intention to participate in the clinical trial.

KEY WORDS: CLINICAL TRIAL PARTICIPATION / HIV / THE HEALTH BELIEF MODEL

103 pages

ปัจจัยที่มีผลต่อความตั้งใจเข้าร่วมโครงการวิจัยทางคลินิกในผู้ป่วยติดเชื้อเอชไอวี
FACTORS AFFECTING HIV-INFECTED PATIENTS' INTENTION IN CLINICAL TRIAL PARTICIPATION

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บทคัดย่อ

จำนวนโครงการวิจัยทางคลินิกในแถบทวีปเอเชียมีจำนวนมากขึ้นอันเนื่องมาจากหลายสาเหตุ ปัจจุบันมีงานวิจัยมากมายที่กำลังศึกษาหาเหตุผลว่าทำไมผู้ป่วยถึงตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก แต่หลักฐานที่บ่งชี้ว่ามีการศึกษาวิจัยเหล่านี้ในประเทศไทยนั้นมีไม่เพียงพอ งานวิจัยนี้มีวัตถุประสงค์เพื่อศึกษาปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิกในผู้ติดเชื้อเอชไอวี โดยใช้กรอบแนวคิดแบบแผนความเชื่อด้านสุขภาพในการพัฒนาแบบสอบถาม ซึ่งประกอบด้วย 6 ตัวแปรหลักในแบบแผนความเชื่อด้านสุขภาพ การวิจัยนี้ศึกษากับผู้ติดเชื้อเอชไอวีอายุระหว่าง 18 – 60 ปี ที่ยังไม่มีอาการแสดง จำนวน 280 ราย ณ โรงพยาบาลแห่งหนึ่งในกรุงเทพมหานคร ระหว่างเดือนพฤษภาคม ถึง กรกฎาคม พ.ศ. 2556

ผลการวิจัยพบว่าผู้ติดเชื้อเอชไอวีที่ตั้งใจเข้าร่วมโครงการวิจัยทางคลินิกร้อยละ 76.4 และปฏิเสธอีกร้อยละ 23.6 ผลสถิติการถดถอยโลจิสติกส์พบว่า ตัวแปรสำคัญที่มีผลกระทบต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก ได้แก่ ระดับการศึกษา การรับรู้โอกาสเสี่ยง การรับรู้ประโยชน์ การรับรู้อุปสรรค การรับรู้สิ่งเร้า และการรับรู้ความสามารถของตนเอง

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LIST OF ABBREVIATIONS

Abbreviation	
AIDS	Acute Immunodeficiency Diseases
CDC	Center of Disease Control
FDMA	Food and Drug Administration Modernization Act
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HBM	Health Belief Model
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRIS	Immune Reconstitution Inflammatory Syndrome
NAAT	Nucleic Acid Amplification Testing
NIH	The US National Institute of Health
NNRTIs	Non-nucleoside Reverse Transcriptase Inhibitors
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
OR	Odds Ratio
PIs	Protease Inhibitors
PPE	Pruritic Popular Eruption
SOP	Standard Operating Procedures

CHAPTER I
INTRODUCTION

1.1 Rationale and Background

In recent years drug development industry has been expanding globally. The number of industry-sponsored clinical trials has been widely spreading from North America and Europe to Asia. As a result of this developing, clinical trial registration website (Clinicaltrials.gov) was firstly initiated by the US National Institute of Health (NIH) in February 2000 to respond to an accord of the Food and Drug Administration Modernization Act of 1997 (FDAMA). [1, 2]

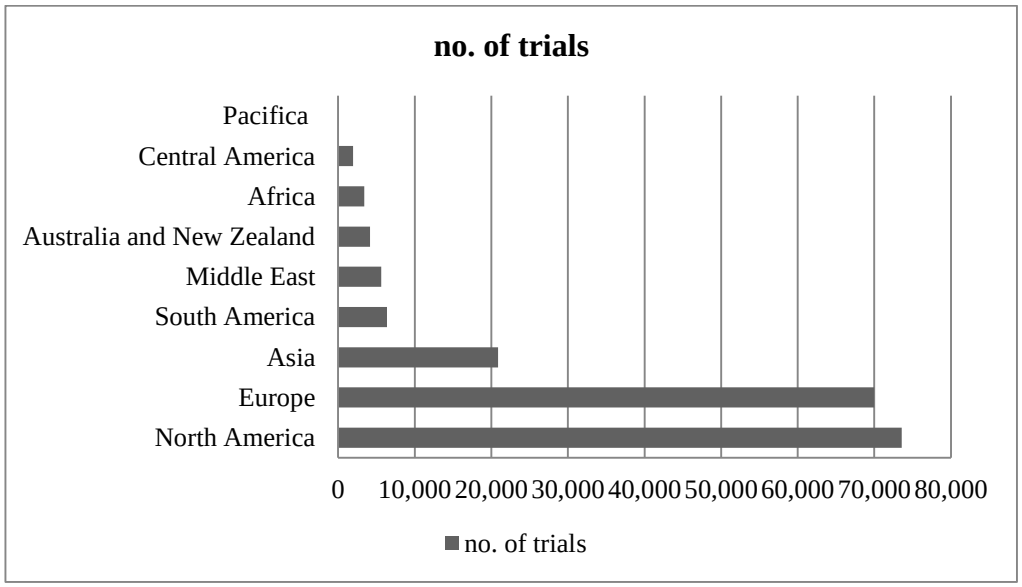

Figure 1.1 The Number of Clinical Trials Conducted Worldwide
Source: Clinicaltrials.gov (data as of June 2012)

The graph in Figure 1.1 provided the overall number of clinical trial conducted worldwide in June 2012. About 20,897 (11.23%) clinical trials were registered in Asian countries. Henderson (2010) and Varawalla (2010) have investigated why several western pharmaceutical companies and health organizations

have been interested to initiate clinical trials in Asia. Six reasons were concluded as follows: (1) the large population size, (2) less differences in ethnic, races and living habits, (3) potential market for pharmaceutical products, (4) pool of naïve patients, (5) availability of experienced medical professionals, and (6) cost saving. [3, 4] Adequate sample size improves the reliability of research data and high recruitment rate in large population will shorten time for drug development. Furthermore, the ethnic diversity of Asian is relatively small when compared with US and European. Asia has become one of the world fastest growing in pharmaceutical markets because of high demands of medications, eligible naïve patients, well-trained medical staff and cost saving.

According to Figure 1.2, the majority of clinical trials approximately 57.95% have been conducted in East Asia whereby 3,439 studies have been conducted in South Korea, 2,998 studies have been studied in China and about 2,355 studies have been performed in Japan. It was found that oncology trials (non-small-cell lung cancer and breast cancer) have been mostly conducted followed by bipolar disorder, and type 2 diabetes mellitus [1, 5].

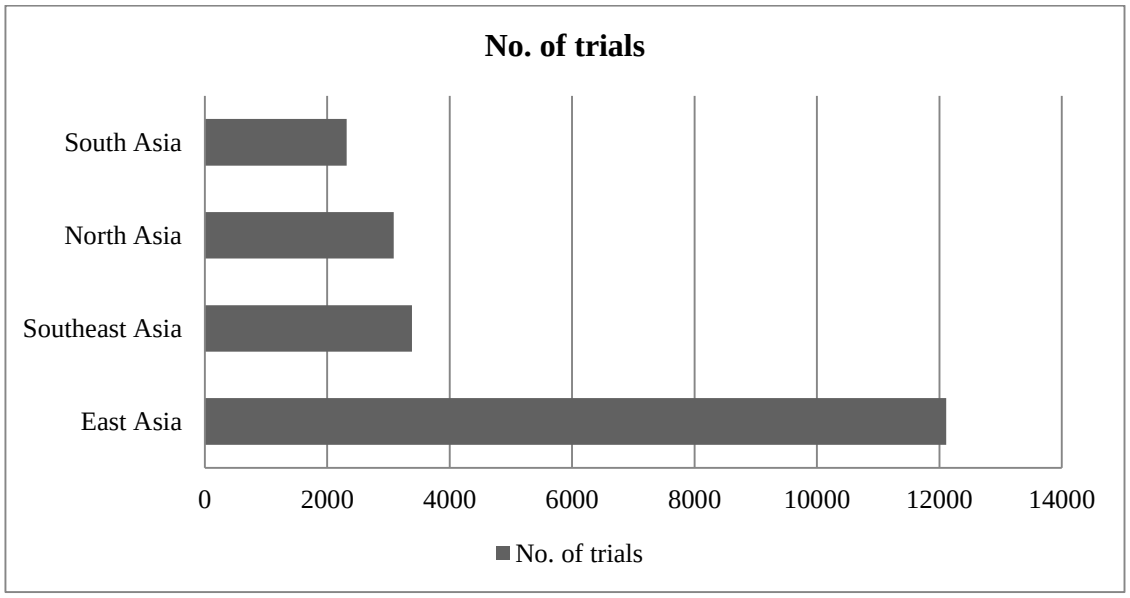

Figure 1.2 The Number of Clinical Trials Conducted in Asia
Source: Clinicaltrials.gov (data as of June 2012)

As can be seen in Figure 1.2 and 1.3, Southeast Asia has become the second in the number of studies whereby 3,383 studies have been registered. Within

three years, May 2009 to June 2012, the number of clinical trials has been increasing from 1,194 studies to 3,383 studies.(1) About 1,095 studies (32.37%) have been initiated in Thailand followed by Singapore, Philippines and Malaysia. Of those initiated, most trials were phase III randomized double blind trials and the majority of therapeutic diseases in this region are cancer and hematologic diseases followed by cardiovascular diseases except for Thailand where Acquired Immunodeficiency Disease is the second highest.(5) In February 19, 2013, approximately 161 HIV clinical studies were registered in clinicaltrials.gov.(2)

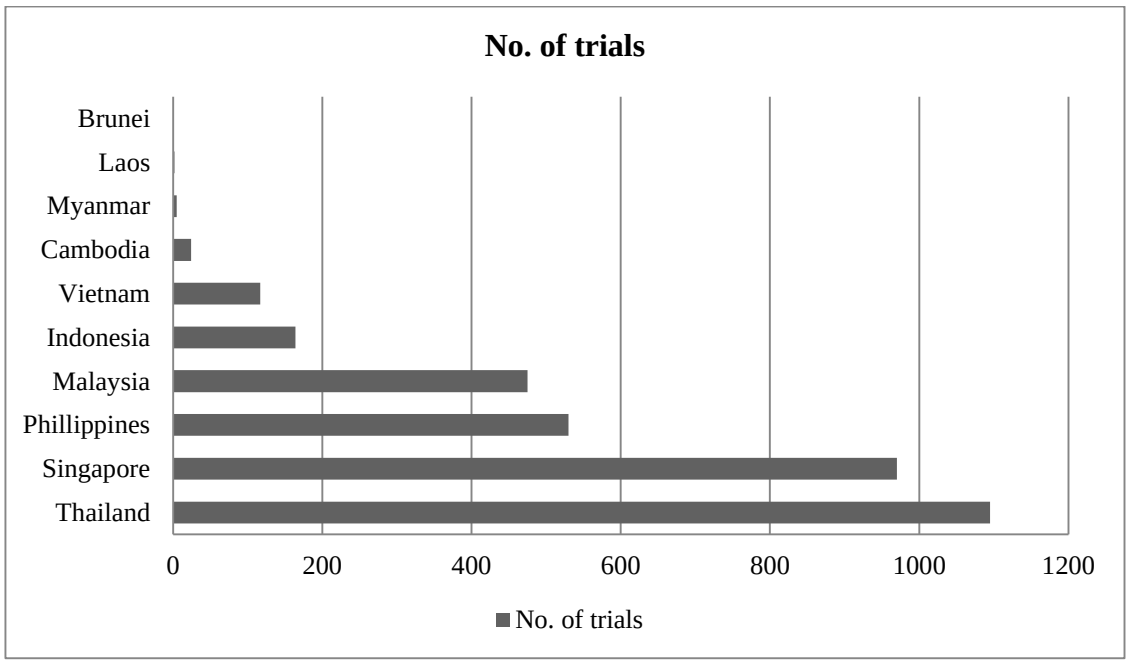

Figure 1.3 The Number of Clinical Trials Conducted in Southeast Asia
Source: Clinicaltrials.gov (data as of June 2012)

The context of developing countries is different from developed countries; for example, history, economy, healthcare system, cultures, politics, wealth and power. As a result of these differences, developing countries specific issues are unique. One of major concerns identified in developing countries is to ensure that the rights, safety and well-being of trial subjects must be protected in compliance with Good Clinical Practice (GCP); however, illiteracy, poverty, and inadequate healthcare system appear to make trial participants become vulnerable. In addition to paternal relationship between trial subjects and research physicians, some trial subjects might

not be aware of their rights to freely make decision to join the clinical trial.[1] In other words, this relationship might be used to influence the patients to join the clinical trial [6, 7].

According to the results from some previous studies, motivating factors and barriers have been interpreted differently in particular population. [8-20] Thus, factors affecting clinical trial participation identified previously in other countries might not be properly applied for Thai population. Since the research about these factors cannot be found in Thai literatures, examining these motivating factors and barriers in Thai population will provide basic knowledge about clinical trial participation related factors through the application of the Health Belief Model (HBM).

This cross-sectional research was designed to determine the relationship between patients' characteristic, their perception and intention in clinical trial participation using HBM. This study was done in one academic hospital in Bangkok in order to examine these factors. The HIV-infected patients were recruited to allow adequate sample population due to high number of clinical trials. The HBM was used as the theoretical and conceptual framework for the study because this model can answer why patients take actions relating to their health condition and to predict the patients' health behavior.

1.2 Research Questions

1. What factors in the HBM affecting the intention of HIV-infected patients to participate in the clinical trial?

2. What are the relationship between patients' characteristics and their intention to participate in the clinical trial?

3. What are the relationship between patients' perception according to the HBM and their intention to participate in the clinical trial?

1.3 Research Objectives

1. To identify what factors in the HBM affecting the intention to participate in the clinical trial in HIV-infected patients.

2. To determine the relationship between HIV-infected patients' characteristics and the intention to participate in the clinical trial.

3. To determine the relationship between HIV-infected patients' perception according to the HBM and the intention to participate in the clinical trial.

1.4 Hypotheses

There were 13 hypotheses proposed for this research based on the other previous studies summarized in table 2.3.

H1: Male patients intend to participate in the clinical trial higher than female patients.

H2: Older patients intend to participate in the clinical trial higher than younger patients.

H3: Married patients intend to participate in the clinical trial higher than single or divorce patients.

H4: Low income population intends to participate in the clinical trial higher than high income population.

H5: Low educated patients intend to participate in the clinical trial higher than higher educated patients.

H6: Occupation is not related to the intention to participate in the clinical trial.

H7: Patients without or do not use health insurance coverage intend to participate in the clinical trial higher than patients with health insurance coverage.

H8: Patients with high perceived susceptibility intend to participate in the clinical trial higher than log perceived susceptibility.

H9: Patients with high perceived severity intend to participate in the clinical trial higher than low perceived severity.

H10: Patients with high perceived benefits intend to participate in the clinical trial higher than low perceived benefits.

H11: Patients with low perceived barriers intend to participate in the clinical trial higher than high perceived barriers.

H12: Patients with low cues to action intend to participate in the clinical trial higher than high cues to action.

H13: Patients with high self-efficacy intend to participate in the clinical trial higher than low self-efficacy.

1.5 Scope and Limitation of Research

This study focused on HIV-infected patients' intention leading to clinical trial participation. Only those who have been receiving antiretroviral therapy at the infectious clinic of one academic hospital in Bangkok and met eligibility criteria were the subjects of this research. The questionnaire was adapted to determine the relationship between patients' characteristics and the intention to participate in the clinical trial as well as patients' perception and their intention.

This research design; however, had limitations. The best practice to identify factors affecting decision to participate in the clinical trial should be conducted after the decisions had been made. Conversely, there was no new clinical trial initiated during the period of our study; however, based on the Theory of Planned Behavior (TPB) proposed by Ajzen (1991), belief was related to actions that can be predicted through attitudes and intentions [21].

1.6 Operation Definition of Terms

1.6.1 Patients' Intention to Participate in the Clinical Trial refers to the HIV-infected patients' intention to participate in the future clinical trial in one academic hospital in Bangkok based on the assumption that higher intention would lead to higher participation. The patients' intention was assessed by measuring the intention of clinical trial participation. The intention was divided in 10 levels from 1 to 10 [16].

1.6.2 HIV-infected patients refer to the HIV-infected patients who presented at the infectious clinic in an academic hospital in Bangkok during May to July 2013 and met all eligibility criteria specified in this research.

1.6.3 Health Belief Model refers to six constructs of the HBM and other related variables that affect the intention of research population to participate the in clinical trial.

1.6.3.1 Perceived susceptibility refers to HIV-infected patients' beliefs about the possibility of experiencing a risk of having AIDS defining illness during the completion of the questionnaire; e.g. awareness of the importance of antiretroviral therapy compliance, follow-up on health conditions, having blood test for $CD4^+$ and viral load and health maintenance. HIV-infected patients' risk behaviors were self-evaluated in four points Likert's scale.

1.6.3.2 Perceived severity to clinical trial participation refers to HIV-infected patients' feeling concerning about the seriousness of their HIV infection condition if they participate or do not participate in the clinical trial. HIV-infected patients' personal health concerns about medical and clinical consequences including social consequences were self-assessed in four points Likert's scale.

1.6.3.3 Perceived benefits refer to HIV-infected patients' beliefs that expected benefits that they might receive from being a volunteer in the clinical trial would reduce their risks or seriousness of getting AIDS defining illness. The expected benefits were evaluated in three dimensions: health benefits, economic benefits and knowledge benefits. Four points Likert's scale was used.

1.6.3.4 Perceived barriers refer to HIV-infected patients' beliefs about negative aspects of expected risks and discomforts that they might receive from being a volunteer in the clinical trial. HIV-infected patients' evaluation about the expected risks, physical and emotional discomforts including trusts in clinical researchers and study site were measured in four points Likert's scale.

1.6.3.5 Cues to action refer to any inducers both internal and external which initiate the readiness of HIV-infected patients to make decision to participate in the clinical trial. Experiencing receiving clinical trial information and

recommendations from physicians and family members were assessed in four points Likert's scale.

1.6.3.6 Self-efficacy refers to HIV-infected patients' beliefs how much they can comply with clinical trial requirements by measuring the confidence level. Clinical trial requirements consist of visiting the trial site, follow clinical study procedures (blood collection and adverse events recording), and complying with study drug regimen.

1.7 Theoretical and Conceptual Framework

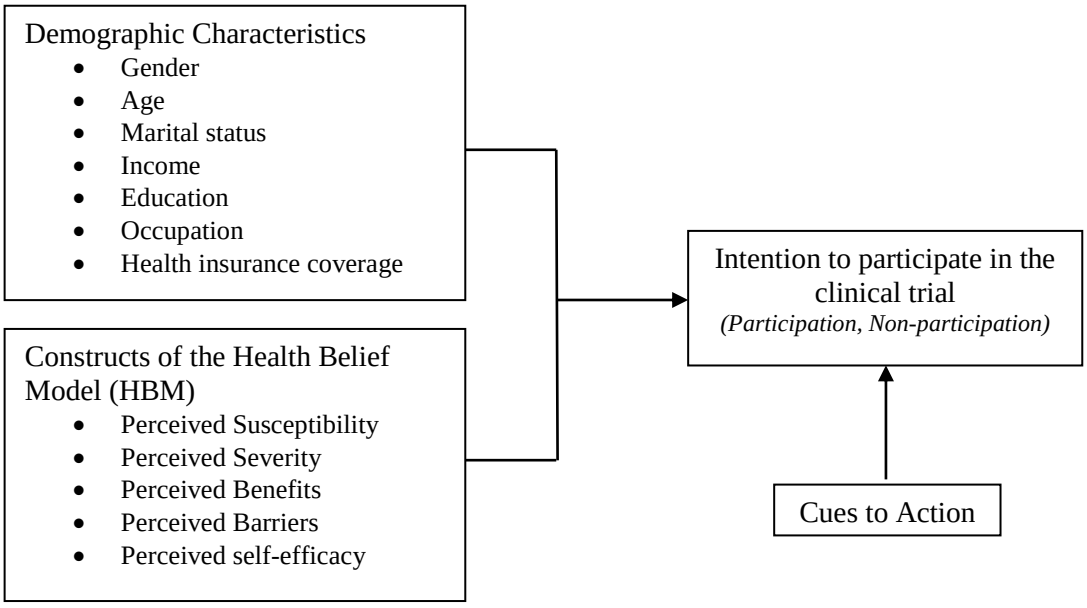

Figure 1.4 Health Belief Model theoretical and conceptual framework applied to intention to participate in the clinical trial of HIV-infected patient

Source: The conceptual framework adopted from the Health Belief Model; Health Behavior and Health Education: Theory, Research, and Practice; 4th edition; San Francisco; Jossey-Bass Publishers 2008 [22]

CHAPTER II
LITERATURE REVIEW

This research was to examine the factors relating to the intention to participate in the clinical trial of HIV-infected patients. The literature review addressed the concepts, theories and other documents related to clinical trials, the HBM and HIV-infected patients are as follows:

2.1 Clinical trials

2.2 Clinical trial participation

2.3 The Health Belief Model (HBM)

2.4 Clinical management for HIV-infected patients and AIDS patients

2.5 Related and variables related to clinical trial participation

2.1 Clinical Trials

2.1.1 Definition

According to Meinert (1986), clinical trial was initially defined as a well-planned experiment in human subjects to evaluate the efficacy of the investigational products by comparing the outcomes between tested group and control group until the end of the trial over the same time period.[23] Then in April 1990 when International Conference on Harmonization (ICH) was established, clinical trial is officially defined as any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The ICH's definition of clinical trial has been widely accepted internationally [24].

2.1.2 Classification and Description of Clinical Trials

The classification of clinical trial is determined by features and purposes. ICH classifies it into four phases as follows [24]:

2.1.2.1 Phase I study is to explore the tolerability, safety, pharmacokinetics and pharmacodynamic of the investigational products whether it is worthwhile for further investigation. The absorption, distribution, metabolism, and excretion of tested drug are measured. First administration of a new therapy to human subjects happens at this phase. Healthy volunteers and patients with mild severity of illness are also involved in phase I study.

2.1.2.2 Phase II study is to further investigate to collect dose-response relationship data. Pathophysiology of diseases is addressed including adverse reaction and potential impact of new study endpoints. Therapeutic regimens and target population may be evaluated for further studies. Phase I and phase II emphasize on the proof of concept about drug toxicity and clinical complications.

2.1.2.3 Phase III study is to proof the evidence accumulated from phase II. The determination of the investigational products in large-scale comparative trial versus standard of care or placebo is performed. This phase is to proof whether the new therapy should replace current treatments. Dose-response relationship including drug usage in wider population may be further explored at this stage. Data accumulated from phase I, II and III are required for drug registration,

2.1.2.4 Phase IV or Post-marketing study begins after drug approval. This phase focuses on gathering additional data about safety and impact of new treatments as well as rate of drug usage. The registered new therapy is used in clinical practice with safety monitoring based on reported adverse events. Drug development for new indications is also classified as phase IV trial.

2.1.3 Clinical Trial Life Cycle

The clinical trial consists of six main stages as follows [23]:

2.1.3.1 Initial design stage: According to the ICH guidelines, study design is a mandatory step to the success of the study. Every single components of the clinical study protocol such as the sample size calculation, comparative drugs, and study objectives are clearly identified. Safety monitoring process, laboratory

specimen handling and following-up premature withdrawal patients are indicated in this protocol [24, 25].

2.1.3.2 Protocol development stage: A well-designed protocol is mandatory to ensure the success of the clinical trial. As described by Chow (2004) and ICH guideline, a protocol is a documented plan that direct the researchers to conduct the clinical study. The well-designed protocol should clearly describe about the study objective, methodology as well as data analysis. The study background and rationale including references should be clearly stated [24, 26].

2.1.3.3 Patient recruitment stage: Patient recruitment stage starts after getting the approval from the Ethics Committees and the Regulatory Authorities. It is responsibilities of the sponsor to ensure that all essential documents and facilities are ready to recruit the patient after site initiation. Once the first patient is recruited, data collection and monitoring are implemented at the trial site. Since the multi-center studies have been conducted globally, the variety of subject and its recruitment rate are high. The systematic bias is also reduced. Thus, selecting the high performing sites is necessary for a successful study [27]. The recruitment process and related factors are described in section 2.2.

2.1.3.4 Treatment and follow-up stage: Once the trial sites are approved to enroll the subject, the investigational products are administered according to the protocol. The trials are monitored periodically by the sponsor's representatives to ensure that they are conducted in compliance with the GCP, Standard Operating Procedures (SOPs), regulatory requirements and the protocol. This process is to ensure that the subject's rights, safety and well-being are protected and data are integrity. After the treatment period ends, the safety of the subjects are followed up until at the end of the study or until the subjects discontinue or early withdraw from the study [27].

2.1.3.5 Patient close-out stage: After all subjects completed the treatment and follow-up period and clinical data are verified with the source documents and frozen by data manager, the trial sites are ready to be closed. [27]

2.1.3.6 Termination stage: The trial sites or the protocol itself can be terminated at any stage of the trial for both positive and negative reasons. The positive reasons may be; for example, overall enrollment and statistical stopping criteria were met. The negative reasons may be the investigational product was found

to be unsafe, not effective, the protocol is too difficult to comply, and investigators die, retire or move to other places, etc. [27].

2.2 Clinical Trial Participation

2.2.1 Recruitment Process

Patient recruitment is a process of considering patients' eligibility of the study and asking for clinical trial participation. The successful of recruitment depends on an adequate budget, a clear recruitment strategy and periodic monitoring. The recruitment process is described in Figure 2.1. The potential patients are approached whether they are willing to participate in the clinical trial. Then the patients are asked to sign and date on the informed consent form prior to screening to check eligibility criteria. If the patients are eligible, they will be enrolled in the clinical trial.

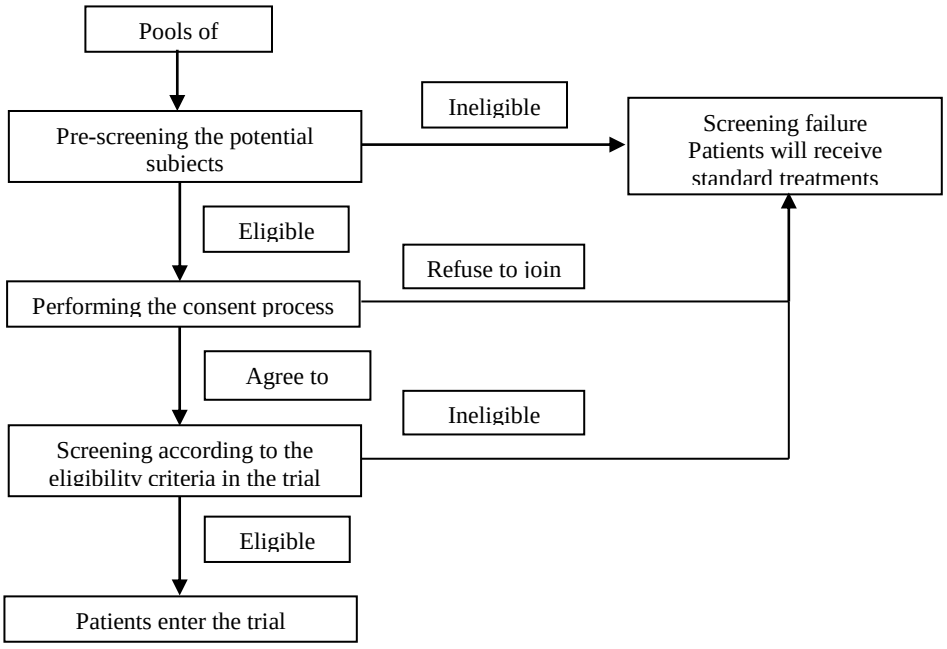

Figure 2.1 Patient Recruitment and Participation in a Clinical Trial (Spilker; 1996)[28]

2.2.2 Patient Recruitment Related Factors

The factors influencing subject recruitment suggested by Spilker (1996) are presented in table 2.1. These factors were categorized into four groups: patients, trial sites, study designs and others [28].

Table 2.1 Selected Factors that Influence Patient Recruitment

	Factors
Patients	• Socioeconomic composition of the patient pool
	• Degree of health concerns of the patients
	• Number of patients contacted via telephone, letter or direct approach, etc.
Trial Sites	• Resources of time, staff, and budget available to devote to this effort
	• Location of the trial site relative to patients' home or work
Study Design	• Nature of appeal to patients to enroll in the study
	• Specific requirements and demands of the study
	• Amount of remuneration or other benefits
Others	• Source of patient referral: medical sources, other clinical trials, laboratories, blood banks.
	• Specific place where mass screening occurs.

Source: Spilker (1996), Patient recruitment, Guide to clinical trial, Pennsylvania, Lippincott-Raven Publishers [28].

2.3 The Health Belief Model (HBM)

The HBM is derived from psychological theories of decision making about alternative behavior. It is used to explain how and why individuals take action to their illness condition [22]. The theoretical conditions proposed by the HBM are as follows [29]:

1. The individuals' determining their perception of the susceptibility of diseases and their perception of the severity of the medical/clinical consequences to stimulate the readiness to take action that relates to their health condition.

2. The individuals' evaluation of efficacy and feasibility of their health conditions considered with the barriers and the perceptions of psychological of the proposed actions.

3. Internal and external triggers must stimulate the health related behavior.

2.3.1 The Origins of the Health Belief Model

The HBM was initially implemented by Hochbaum and associates from the US Public Health Service. This model is to examine why individuals refuse to join tuberculosis screening program. In the early of 1950s, Academic Social Psychology developed this model based on their perspectives that "behavior is an operation of subjective value of an outcome and of the subjective probability that a particular action will reach that outcome" [30-33].

After that the HBM was re-formulated based on the concept that (1) the health related behavior is the desire to recover from illness or to avoid illness and (2) the health related action will prevent individuals from illness. The model was later acknowledged as the individuals' estimates of personnel susceptibility to illness and severity of an illness and its possibility to reduce their threats [34].

2.3.2 The Components of the Health Belief Model

Six key components in the HBM consist of perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy. The concepts and linkages are shown in Figure 2.2 [30].

2.3.2.1 Perceived susceptibility: Perceived susceptibility assesses individuals' perception about the possibility to get risk of contracting a health condition. For patients, the perception includes the patients' estimates of re-susceptibility, acceptance of the diagnosis, and susceptibility to illness in general. This term is also defined as "individuals' acceptance of personal susceptibility to their health conditions". The meaning of perceived susceptibility may vary in patients with different level of severity. Patients with moderate severity may deny the possibility of

getting diseases; whereas, patients with moderate severity may accept their susceptibility by admitted to the possibility of a disease occurrence. This component partly depends on knowledge [22, 35].

2.3.2.2 Perceived severity: Feeling concerning the seriousness of getting diseases if leaving it untreated. Perceived severity is measured by evaluate the clinical and social consequences. Clinical consequences include but not limited to disability, pain and death. Social consequences are the social relationship with family members, colleagues and others. Perceived severity is also defined as "Individual's opinion about the seriousness of a disease condition as well as its consequences". The degree of seriousness is measured by considering the kinds of difficulties the individual beliefs about illness is created for them and about the level of emotional arousal. This component partly depends on knowledge [22, 35].

2.3.2.3 Perceived benefits: The individuals' beliefs in the effectiveness of actions in decreasing disease threats. An appropriate level of beliefs in perceived threat that individuals expressing will not accept any health related actions until they judge that recommended action is effective. Perceived benefits is also defined as "Individuals' belief of the potency of the recommended actions in reducing disease threats" [35].

2.3.2.4 Perceived barriers: The individuals' beliefs in any potential negative aspects that may be an obstacle to undertaking the recommended behavior; for example, time consuming, unpleasant and painful, risks of having negative adverse effects, inconvenience etc. Thus, the combined levels of susceptibility and severity that energy or force to act and the perception of benefits provide a preferred path of action. Perceived barriers is also defined as "Individuals' opinions of the physical and psychological costs of the recommended action" [22, 35].

2.3.2.5 Cues to action: A stimulus that triggers appropriate health behavior to take action [32]. Hochbaum (1958) proposed that there are other factors can potentiate the readiness to take action; for example, bodily and environmental events [31]. Mass media, reminders, recommendations from family members and friends can be considered as triggers. The intensity of a cue required to stimulate behavior depends the levels of susceptibility and severity. This term is also defined as "Pathway to initiate individuals' readiness" [22, 35].

2.3.2.6 Self-efficacy: Self-efficacy was initially defined by Bandura in 1977 as "Beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments". Another definition of self-efficacy is "A personal belief how much control they can manage in situations". This self-efficacy concept was introduced in order to increase an explanatory power to the HBM [33, 36, 37]. Self-efficacy affects individuals' reaction to respond to the situations that they are challenging. If people believe that they cannot control those situations, they will tend to avoid or escape from those situations. Self-efficacy is traditionally measured by rating the degree of confidence in performing a specific task [38]. It induces the choice of activities and affects coping efforts once it is initiated. This can be explained that people usually tend to avoid or escape the situations that they believe their coping skills cannot control that situation; whereas, they get involved in activities if they judged themselves that they can handle it.

2.3.2.7 Other variables appear to influence health related behavior are as follows [22, 34, 35]:

- General characteristic factors (age, gender, ethnic, etc.)
- Sociopsychological factors (self-efficacy, social support etc.).
- Socioeconomics factors (household income, education, etc.) [39]
- Knowledge about the disease.

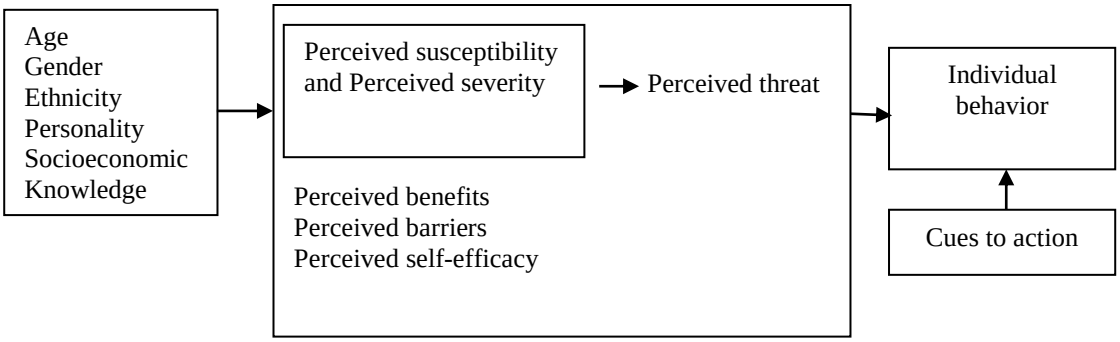

Figure 2.2 The Health Belief Model Components and Linkages

Source: The Health Belief Model; Health Behavior and Health Education: Theory, Research, and Practice; 4th edition; San Francisco; Jossey-Bass Publishers 2008 [22].

2.4 Clinical Management for HIV-infected and AIDS Patients

2.4.1 Laboratory Testing for HIV Infection

Laboratory testing is mandatory to confirm the HIV infection by anti-HIV and viral detection. The positive result is confirmed only for patients whom having reactive result from all different three techniques. If they have nonreactive result from the first test, the negative result is reported. In case of all three different techniques show intermediate result, repeating the blood testing within two weeks, three and six months are recommended. If the repeated result is still intermediate, the negative result is finally reported.

2.4.1.1 Anti-HIV detection: Three different techniques used to detect antibody to HIV are as follows: ELISA is one of immunological techniques to measure both antigen and antibody to HIV. This technique consists of three methods: Indirect Enzyme Immunoassay, Competitive Enzyme Immunoassay, and Antigen Double Sandwich Immunoassay. The result is reported as "Reactive" and "Nonreactive". Simple test is a technique to detect antibody to HIV by Gelatin Particle Agglutination. The result is reported as "Reactive" and "Nonreactive". Rapid test is a rapid technique that can detect antibody to HIV within 30 minutes. The result can be interpreted easily without special instruments.

2.4.1.2 HIV viral testing: ELISA technique is to detect p24 antigen of HIV in acute phase. Nucleic Acid Amplification Testing (NAAT) is a genetic detection technique which is used to detect proviral DNA or RNA in infected cells.

2.4.2 Treatments for HIV-infected patients

Before initiation of antiretroviral therapy in naïve patients, $CD4^+$ and viral load are measured to evaluate the HIV-infected patients' health conditions. Too early initiation of antiretroviral therapy may lead to Immune Reconstitution Inflammatory Syndrome (IRIS). Antiretroviral therapy is used to control viral load and restore $CD4^+$ level and reduce risks of getting opportunistic infection. In Thailand, clinical signs and symptoms and $CD4^+$ are used for consideration as shown in Table 2.2.

Table 2.2 Indications for Initiation of Antiretroviral Therapy in Thailand

Clinical signs and symptoms	$CD4^+$ level (cell/µl)	Recommendation
AIDS defining illness	Any level	Initiation of antiretroviral therapy
Specific signs and symptoms*	Any level	Initiation of antiretroviral therapy
No clinical signs and symptoms	≤ 350	Initiation of antiretroviral therapy
No clinical signs and symptoms	More than 350	Follow-up for clinical signs and symptoms and $CD4^+$ level every (six) 6 months

Source: National Guideline on HIV/AIDS Diagnosis and Treatment: Thailand 2010[40]

*Specific clinical signs and symptoms are defined as oral candidiasis, Pruritic Popular Eruption (PPE), unspecified chronic fever, unspecified chronic diarrhea up to 14 days, weight loss more than 10% within three months and herpes zoster more than two dermatomes, etc. Opportunistic infection prophylaxis will be given if these signs and symptoms are detected.

AIDS defining illness is defined by CDC classification as follows:

- Candidiasis of bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical cancer, invasive
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (more than 1 month)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with loss of vision)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcer(s) (more than 1 month); or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (more than 1 month)
- Kaposi's sarcoma

- Lymphoma, Burkitt's (or equivalent term)
- Lymphoma, immunoblastic (or equivalent)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *M. kansasii*, disseminated or extrapulmonary
- Mycobacterium tuberculosis, any site (pulmonary or extrapulmonary)
- Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis* pneumonia
- Pneumonia, recurrent
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain
- Wasting syndrome due to HIV
- Peniciliosis (for Thailand)

Antiretroviral therapy marketed in Thailand has four categories as follows:

- *Nucleoside Reverse Transcriptase Inhibitors (NRTIs)* such as Zidovudine (AZT), Stavudine (d4T), Lamivudine (3TC), Didanosine (ddI), Abacavir (ABC) and Tenofovir (TDF) including fixed dose combination.
- *Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)* such as Nevirapine (NVP) and Efavirenz (EFV) including fixed dose combination.
- *Protease Inhibitors (Pis)* such as Indinavir (IDV), Ritonavir (RTV), Nelfinavir (NFV), Saquinavir soft gel capsule (SQV-sgc), Lopinavir/ritonavir (LPV/r), Atazanavir (ATV)
- *Fusion Inhibitors* such as Enfuvirtide.

2.5 Research and Variables Related to Clinical Trial Participation

Recently, the HBM has been widely used to understand the human behaviour in several studies including clinical trial participation. The literatures

involving the HBM and clinical trial participation were reviewed and summarized to identify common variables used in this research study as presented in table 2.3.

Calnan conducted the research to examine how far the Health Belief Model can predict the participation in the breast cancer early detection program. Health motivation, value of illness threat reduction, probability that compliant, state of health, social support, practice of breast self-examination were assessed by interviewing with the questionnaire. Sociodemographic characteristics data including social class, education, age, marital status and employment status were collected. The result showed that the intention to attend was the strongest discriminator between attendance and non-attendance. Data was also reported that marital status and age were important to explore how people thought about their health condition. Calnan suggested exploring the relationship between marital status and age with the perception of health behaviour [(41)].

Gorkin et al (1996) applied the Health Belief Model in relationship between personal demographic, psychosocial, environmental variables of and the decision to enrol post myocardial infarction patients. The result indicated that the medical insurance coverage, gender and personal health concern were related to the decision to participate in the trial; whereas education had no relationship with the decision making. The study discussion also revealed that well receiving clinical trial information or knowledge during the informed consent process lead to clinical trial participation [(19)].

Verheggen and van Wijimen (1996) examined information disclosure and trial participation by reviewing the empirical literatures on informed consent from 1979 to 1995. Verheggen and van Wijimen summarized that investigators, patients and characteristics of clinical trial design are associated with clinical trial participation. Attitude and motivation of investigators to refer patients, attitude and motivation of the patients to make a decision to participate in the trial as well as clinical trial design are also key factors. Four behavioural concepts influencing trial participation were reported. Possibility of getting risk and perceived health condition, perceived benefits of treatments and having knowledge as well as expected costs, inconvenience and trial duration are considered as behavioural concepts that influence trial participation [(17)].

A study conducted by Zimet et al (1997) to test the relationship of health belief to intention to receive HIV vaccine among university undergraduates. The result discovered that the investigational products effectiveness influenced the rate of vaccination. The susceptibility, benefits and fear of the investigational products were significantly correlated to the acceptance of immunization [(42)].

Verheggen et al. (1998) studied determinants of clinical trial participation by interviewing patients who did and did not consent to participate in the trial using the Health Belief Model. These two groups of patients were interviewed after they were asked by the investigator to join the trial. Expected physical and emotional benefits, risks, and time-consuming were assessed. These variables were found to depend on patients' opinion about medical care and healthcare professionals and how patients consider about their diseases. The result concluded that beliefs in the reduction of patients' disease threats and the evaluations of clinical trial the patient was approached for; were related to health behaviour prediction. Moreover, the result also revealed that the reason why the patients participate in the trial between long-term patients and short-term patients was different [(16)].

Ross et al (1999) systematically reviewed 78 trials that published on Medline, Embase and CINAHL for ten years (1986 - 1996) to identify the barriers of clinical trial participation excluding phase I and II trials as no enough supporting evidence. Expected barriers concluded by Ross are but not limited to additional procedures, appointments, transportation, expenses, fear of treatment, preferences for a particular treatment and informed consent concerns. On the other hand, the investigators and site staff themselves act as barriers; such as inadequate training, time constraint, patients' concerns, fear of the impact on physician-patient relationship, loss of professional autonomy, informed consent process, lack of rewards and recognition and insufficiently interesting questions [(43)].

Rojavin et al (2006) studied factors that motivated dyspepsia patients to enter into clinical trial. The motivated factors included intention to help develop new drug, receiving treatment and access to high level of the professional care. However, the result indicated that the financial benefits were not a major motivator in this trial [(12)].

Mills et al (2006) examined the obstacles to HIV pharmacological trials by systematic reviewing 97 studies both qualitative and quantitative literatures published on the trustworthy database such as AMED, Campbell Collaboration, CINAHL, Cochrane Library, Embase, ERIC, Medline and UK National Health Service Economic Evaluation Database including unpublished sources such as clinicaltrials.gov website and the UK National Research Register during 1975 to 2004. The common barriers were concluded that fear of side effects, suspicions about drug itself, mistrust in researchers, interference with everyday life/changes in routine, transportation obstacles, confidentiality issues and lack of anonymity became the major concerns for HIV patients to enter the trial [(44)].

Newman et al (2007) studied the impact of HIV vaccine trial attributed on willingness of healthy volunteers living in vulnerable communities located in the United States. The research indicated that fear on the risk of infection from HIV vaccine, AIDS stigma were major concerns. In addition, unbelief in clinical research system to treat the volunteers if they were infected was also a barrier[(11)].

Marcantonio et al (2008) identified the barriers and motivators of clinical research study participation in vulnerable older patients living in the United States. The research concluded that free parking and flexible appointments were incentives and repeated study procedure, the duration of procedure and transportation were barriers of the participation [(10)].

Baquet et al (2008) studied factors associated with trial enrolment in African American and other underrepresented populations. The result concluded that patients, healthcare professionals, investigators, structure and organization play a key role in clinical trial participation. Patients' demographic and socioeconomic status including patient/community awareness influences the decision to participate in trials. The healthcare professionals reported that they do not know how to access such trials because of having limited information on available clinical trials. Lack of basic knowledge on the clinical research role, concern about losing patients, lack of administrative support and reimbursement concerns influence patients to trials were reported as the barriers. Factors related to the investigators include failure to recognize the importance of culturally approaches, distrust of academic institutions and researchers by patients, lack of training in explaining complex research protocol to

low iterate patients, and failure to implement patient recruitment strategies are barriers reported from the investigators. Structural and organizational factors consist of inconvenient time of subject appointments, logistic arrangements, lack of adequate support from sponsors, and insufficient community-based infrastructure and trial design factors [45].

Robiner et al (2009) described that study period, frequency and number of study visits/procedures, travelling to study site, missing work, and study procedure related physical discomfort are concluded to be the most problematic to clinical trial participation in double-blind placebo-controlled diabetes trial [46].

Stunkel and Grady (2011) reviewed the existing literatures published in PubMed that studied regarding the decision making, motivations and willingness of clinical research participants in order to examine whether monetary compensation was a principal motivator for healthy volunteers to enter the clinical trial. Six studies conducted in the United States, six studies conducted in Europe and one study conducted in Malawi were systematic reviewed. The result discovered that financial reward was a good aspect of participating. Some studies found that non-volunteers preferred financial motivations rather than volunteers; whereas others concluded the opposite result; non-volunteers were less likely seeking for financial motivations. In addition, the research reported that age, education, and social circumstances were correlated to influence on how important money was needed. However, the possibility to take risks from clinical trial participation was still an important concern for who decided to be in the trial [47].

James et al (2012) explored the use of health belief model to develop culturally suitable for weight-management program. The result explored that obesity might be led by culture and genetics. The expected benefits the patients received from losing weight in the weight management program were reducing their disease threats and improving appearance. Motivators were being diagnosed, physical appearance and cost saving. Barriers could be lack of reliable information, no social support and no motivation [20].

Chu et al (2012) compared the view between the patients and the healthy volunteers on clinical trial participation in South Korea to understand the decision of research participants to enter the clinical trial. The discussion stated that paternal

relationship affected the decision making of patients rather than healthy volunteers. Attitudes of research participants and knowledge regarding the clinical trial were influential factors on the successful of the recruitment. The main purpose for participation was economic benefits for both groups, but health benefits were reported in patient group. Poor communication between the physician and patients was judged to be one of the barriers of trial participation [9].

Park et al (2012) discovered the motivators and barriers influencing the willingness of injected drug users to participate in HIV vaccine trial. Altruism or willingness to help others and protection from HIV infection were key motivators; whereas monetary payments was found as a motivator only in a small group. The safety and side effects of HIV vaccine were defined as barriers. Time constraint was a main reason for non-participants [8].

Yörük et al (2012) discovered that the negative perception from the community regarding "the guinea pig" attitude prevented Turkish patients not to participate in the trial [48].

The factors from the other research studies has been summarized in table 2.3 can be categorized based on the HBM; demographic, perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy.

Table 2.3 The Summary of Factors Associated with Programs or Interventions of Participation

Author/Year	Theory based	Variables	Program of Participation
Calnan (1984) [41]	HBM	Intention to attend Marital status Age	Breast cancer early detection program
Gorkin et al (1996) [19]	HBM	Medical insurance coverage Personal health concern Receiving clinical trial information Gender	Post myocardial infarction trial
Verheggen and van Wijimen (1996)[17]	None	Possibility of getting risk Perceived health condition Perceived benefits Knowledge Costs Inconvenience Trial duration	Literature reviewing
Zimet et al (1997)[42]	HBM	Effectiveness of investigational products Perceived susceptibility Perceived benefits Fear of investigational products	HIV vaccine trial
Verheggen (1998)[16]	HBM	Beliefs in the reduction of disease threats Beliefs in evaluation of clinical trial	Surgery trial Dermatology trial ENT trial Internal medicine trial Urology trial Cardiology trial Pulmonary trial Orthopedics trial Radiology trial Anesthesiology trial

Table 2.3 The Summary of Factors Associated with Programs or Interventions of Participation (cont.)

Author/Year	Theory based	Variables	Program of Participation
Ross et al (1999)[43]	None Literature reviewing	Additional procedures Appointments Transportation Expenses Fear of treatment Informed consent concern	Randomized controlled-trial
Rojavin et al (2006)[12]	None (Descriptive analysis)	Intention to help develop new drug Receiving treatment Access to high level of professional care	Dyspepsia trial
Mills et al (2006)[44]	None (Systematic reviewing)	Fear of side effects Suspicions about drug Confidentiality Lack of anonymity	HIV drug trial
Newman et al (2007)[11]	None (Descriptive analysis)	Fear of the risk of infection Stigma Unbelief in clinical research system	HIV vaccine trial
Marcantonio et al (2008)[10]	None (Descriptive analysis)	Free parking Flexible appointments Repeated study procedure Duration of study procedure	Trials recruiting elderly patients
Baquet et al (2008)[45]	None (Literature review)	Patients' demographic and socioeconomic status Awareness	Cancer trial

Table 2.3 The Summary of Factors Associated with Programs or Interventions of Participation (cont.)

Author/Year	Theory based	Variables	Program of Participation
Robiner et al (2009)[46]	HBM	Study period Frequency of visits and procedures Travelling Missing work Physical discomfort	Diabetes trial
Stunkel and Grady (2011)[47]	None (Literature review)	Financial rewards Age Education Social circumstances Risks of clinical trial	Trials recruiting healthy volunteers
James et al (2012)[20]	HBM	Being diagnosed Physical appearance Cost saving	Weight management program
Chu et al (2012)[9]	None (Descriptive analysis)	Attitude about trial Knowledge about trial Economic benefits Health benefits Poor communication	Phase I trial Bioequivalence trial
Park et al (2012)[8]	None (Descriptive analysis)	Altruism Monetary payments The safety and side effects Time-constraint	HIV vaccine trial
Yörük et al (2012)[48]	None (Descriptive analysis)	Guinea pig attitude	Oncology trial Pulmonary trial Neurology trial Orthopedics trial Endocrinology trial Cardiology trial Cardiovascular trial Urology trial

As summarized in table 2.3, the variables concluded by previous research studies were varied depends on the population and therapeutic area. Variables from some research were similar to each other. All variables were categorized into each construct of the HBM based on the questionnaire developed by Gorkin et al (1996) and Verheggen and van Wijimen (1996) [19,17].

CHAPTER III
RESEARCH METHODS

This chapter described the research methods of this study. This chapter addressed the research design, research population and sampling techniques, instruments, validity and reliability testing, ethical consideration, data collection and data analysis.

3.1 Research Design

This is a cross-sectional study design to investigate the factors related to the intention of the HIV-infected patients to participate in future clinical trials based on the HBM.

3.2 Research Population and Sampling Techniques

3.2.1 Population and Sample

The target population was HIV-infected patients aged between 18 – 60 years presented at the out-patient department at one academic hospital in Bangkok during May to July 2013. Patients aged less than 18 years or older than 60 years were excluded to avoid recruiting the vulnerable population.

3.2.2 Sample Size Calculation

The sample size for logistic regression was calculated using the model proposed by Whittemore (1981).[49] Since the number of studies about factors affecting clinical trial participation in Thai population was limited, the probability used in this equation was referred from the research about HIV-1 vaccine trial in young Thai men population.

According to the study by Jenkins et al (2000), the results were reported that perceived risks of getting HIV (*OR* = 1.84) and perceived benefits are major factors of the willingness to join the trial. Perceived benefits consists of altruism (helping Thai society (*OR* = 1.72) and recognition from family (*OR* = 1.23)) including tangible benefits (*OR* = 1.33). [50] Perceived benefits as tangible incentives were used for sample size calculation in this research.

Dependent variables in this research were the intention to clinical trial participation (Y = 1) and non-participation (Y = 0). Perceived benefits in high level (X = 0) and in low level (X = 1) were considered as independent variable in this formula.[49] The sample size was calculated by considering various odds ratio from 1.2 to 2.0.

Sample Size Formula proposed by Whittemore (1981)[49]

$$n = (1 + 2P_0) \times \frac{\left(Z_{1-\alpha}\sqrt{\frac{1}{1-\pi}+\frac{1}{\pi}} + Z_{1-\theta}\sqrt{\frac{1}{1-\pi}+\frac{1}{\pi e^{\beta_1^*}}}\right)^2}{P_0\beta_1^{*2}}$$

The appropriate sample size used in this research was 262.14 or approximately 262 patients plus 10% missing data. Total number of patients was 288 patients with odds ratio at 2.0.

n = Total number of HIV-infected patients needed for this research.

$Z_{1-\alpha}$ = The significance level for one-sided test at 0.05 level = 1.645

$Z_{1-\theta}$ = The power of analysis at 80% = 0.842

$e^{\beta_1^*}$ = Odds ratio of perceived tangible incentives and participate in clinical trial. = 1.49 or approximately 1.50

P_0 = The assumed response probability of HIV-infected patients who decided to participate in the clinical trial with high perceived benefits. The numbers used for calculation were from the research conducted by Jenkins (2000). [50]

$$= \frac{No.of\ patients\ who\ participated\ in\ the\ trial\ with\ perceived\ tangible\ incentives}{No.of\ patients\ who\ perceived\ tangible\ incentives}$$

$$= \frac{416\ patients}{1{,}453\ patients} = 0.286$$

π = The assumed response probability of HIV-infected patients who have high perceived benefits. The numbers used for calculation were from the research conducted by Jenkins (2000).[50]

$$= \frac{No.of\ patients\ with\ perceived\ tangible\ incentives}{Total\ no.of\ patients}$$

$$= \frac{1{,}037\ patients}{2{,}674\ patients} = 0.388$$

3.2.3 Sample Inclusion and Exclusion Criteria

All HIV-infected patients who visited the hospital were pre-screened by registered nurses. Then they were screened for eligibility criteria by reviewing the medical records and interviewing. Only eligible patients were included in the study.

3.2.3.1 Inclusion Criteria

- Patients with positive HIV confirmed by laboratory testing.
- Never participate in the clinical trials.
- Male or female aged between 18 – 60 years old on the day of questionnaire completion.
- Receiving antiretroviral therapy.
- Able to communicate in Thai and complete the questionnaire.

3.2.3.2 Exclusion Criteria

- Required inpatient hospitalization or immediate treatments as decided by the physician.
- Experienced to participate in the clinical trial which provided antiretroviral therapy as investigational products.
- Refused to participate in this study.
- Diagnosed having active AIDS defining illness as defined in CDC classification.

3.3 Research Instruments

The self-administrated questionnaire was adapted from the research studied by Verheggen (1998) and Gorkin (1996) [16, 19].

Total of 38 items were designed to assess the HIV-infected patients' beliefs, general characteristics, and the intention to participate in the clinical trial for six domains as follows:

General characteristics	7	items
Perceived susceptibility	4	items
Perceived severity	4	items
Perceived benefits	6	items
Perceived barriers	11	items
Cues to action	4	items
Self-efficacy	5	items
Intention to clinical trial participation	1	item

3.3.1 General characteristics

There were seven items of the questionnaire to obtain information about general characteristics including age, gender, marital status, occupation, income, education and health insurance coverage.

3.3.2 The variables in the Health Belief Model

The questionnaire was developed according to the definitions and concepts of the HBM from Verheggen (1998) and Gorkin (1996) as shown in table 3.1 to 3.6.[16, 19] The HBM variables; perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy were measured by Likert's four points rating scale questionnaire. Sum score was calculated and used for data analysis.

	Positive statement	Negative statement
Strongly Agree	4	1
Agree	3	2
Disagree	2	3
Strongly Disagree	1	4

Sum score of the HBM variables was categorized into three perception levels as follows:

High level of perception	≥ 80%
Moderate level of perception	60% - 79%
Low level of perception	≤ 59%

3.3.2.1 Perceived susceptibility: there were four items to measure individuals' beliefs about the possibility of getting AIDS defining illness by assessing their risk behavior. Question 1.1 assesses the patients' awareness of the importance of antiretroviral therapy. Question 1.2 assesses the patients' awareness of health condition follow-up. Question 1.3 assesses the patients' awareness of blood tests and question 1.4 assesses the patient's awareness of the importance of health maintenance.

Table 3.1 Definition and Concepts of Perceived Susceptibility Questions and Scoring

		Scoring
Q1.1	Patients' awareness of the importance of antiretroviral therapy compliance in order to prevent drug resistance.	Positive
Q1.2	Patients' awareness of the importance of follow-up on their health conditions periodically.	Positive
Q1.3	Patients' awareness of the importance of having blood test for $CD4^+$ and viral load periodically.	Positive
Q1.4	Patients' awareness of the importance of health maintenance.	Positive

3.3.2.2 Perceived severity: there were five items to understand individuals' feeling concerning about their seriousness of HIV infection condition if they participate or do not participate in the clinical trial. Question 2.1 and 2.2 assess the physical and mental health concern on clinical consequences; whereas question 2.3 and 2.4 assess social consequences.

Table 3.2 Definition and Concepts of Perceived Severity Questions and Scoring

		Scoring
Q2.1	Patients' feeling concerning about clinical trial participation.	Negative
Q2.2	Patients' feeling concerning about their health condition if they decided not to participate in the clinical trial.	Negative
Q2.3	Patients' feeling concerning about social stigma if they decided to participate in the clinical trial.	Negative
Q2.4	Patients' feeling concerning about their relationship with family members, friends or colleagues if they decided to participate in the clinical trial.	Negative

3.3.2.3 Perceived benefits: there were six items to measure individuals' beliefs that expected benefits of voluntary in clinical trial that they might receive from being a volunteer in the clinical trial would reduce their risks or seriousness of experiencing AIDS defining illness. Questions 3.1 to 3.3 assess health benefits such as getting more health maintenance, accessing to professional care and receiving more effective treatments. Question 3.4 and 3.5 assess economic benefits such as compensation and free treatments. Question 3.6 assesses knowledge benefits for society gained from the result of the clinical research.

Table 3.3 Definition and Concepts of Perceived Benefits Questions and Scoring

		Scoring
Q3.1	Patients' beliefs of getting more physical and mental health maintenance from being a volunteer in the clinical trial when compared to nonparticipation.	Positive
Q3.2	Patients' beliefs about access to high level of the professional care provided by study doctors and study nurses in the clinical trial in comparison with standard of care.	Positive
Q3.3	Patients' beliefs about the effectiveness of treatments provided by the clinical trial.	Positive
Q3.4	Patients' expectations about receiving money or travel compensation from the clinical trial.	Positive
Q3.5	Patients' expectations about cost saving by receiving free treatments provided by the clinical trial.	Positive
Q3.6	Patients' altruistic idea that future patients may benefit from the results of the trial.	Positive

3.3.2.4 Perceived barriers: there were eleven items were to identify individuals' beliefs about negative aspects of expected risks and discomforts that they might receive from being a volunteer in the clinical trial. These items consist of expected risks, physical and emotional discomforts, including mistrusts in clinical researchers and institutes. Question 4.1 and 4.2 assess expected risks might have from investigational products and/or study procedures. Questions 4.3 to 4.5 assess physical discomforts such as any burden on daily life, time-consuming and transportation. Question 4.6 to 4.9 assess potential emotional discomforts might occur on patients such as confidentiality violation, attitude about being a guinea pig, attitude about experiments on patients, and negative implication of participatory refusal. Question 4.10 and 4.11 assess patients' trusts on the investigator and/or institute.

Table 3.4 Definition and Concepts of Perceived Barriers Questions and Scoring

		Scoring
Q4.1	Patients' beliefs of the risks by undergoing new, untested treatment in the clinical trial.	Negative
Q4.2	Patients' beliefs of the risks by receiving study procedure such as blood collection.	Negative
Q4.3	Patients' beliefs of the burden imposed upon daily life by participating in the trial.	Negative
Q4.4	Patients' beliefs that clinical trial participation is time-consuming.	Negative
Q4.5	Patients' beliefs of their physical discomforts in travelling to the study site.	Negative
Q4.6	Patients' beliefs of the emotional discomfort in telling the study team any personal sensitive information.	Negative
Q4.7	Patients' negative beliefs that a volunteer is a guinea pig.	Negative
Q4.8	Patients' beliefs towards medical experiments on patients.	Negative
Q4.9	Patients' beliefs of negative implications will have on the non-trial treatment if refuse to participate.	Negative
Q4.10	Patients' beliefs about their trusts in the medical competence of the investigators in controlling and reducing risks of the investigational products.	Positive
Q4.11	Patients' beliefs about their trusts in university/hospital.	Positive

3.3.2.5 Cues to action: there were five items to identify any stimulus that the patient needs to trigger their readiness to participate in the trial. Question 5.1 to 5.3 asks any recommendations needed from physicians, family members and friends. Question 5.4 assesses the need to obtain the clinical trial information and question 5.5 assesses for the need to get knowledge of the clinical trial.

Table 3.5 Definition and Concepts of Cues to Action Questions and Scoring

		Scoring
Q5.1	Patients' receiving recommendations to participate in the clinical trial from physicians.	Positive
Q5.2	Patients' receiving recommendations to participate in the clinical trial from their family members.	Positive
Q5.3	Patients' receiving recommendations to participate in the clinical trial from their friends.	Positive
Q5.4	Patients' receiving clinical trial information.	Positive

3.3.2.6 Self-efficacy: there were five items were to measure individuals' confidence level to comply with clinical trial requirements. Question 6.1 assesses whether the patients can visit the study site regularly. Question 6.2 and 6.3 assess whether the patients can perform study activities. Question 6.4 assesses if the patients can take study medications according to the study protocol. Question 6.5 assesses whether the patients are willing to provide the investigator their personnel information.

Table 3.6 Definition and Concepts of Self-efficacy Questions and Scoring

		Scoring
Q6.1	Patients' beliefs about their confidence to visit the study site regularly as specified in the clinical trial.	Positive
Q6.2	Patients' beliefs about their confidence to be willing to have blood collection as specified in the clinical trial.	Positive
Q6.3	Patients' beliefs about their confidence to record events on their health conditions and medications receiving during clinical trial participation.	Positive
Q6.4	Patients' beliefs about their confidence to take study drug as specified in the clinical trial.	Positive
Q6.5	Patients' beliefs about their confidence to provide the study staff their personal information.	Positive

3.3.3 The Intention to Participate in the Clinical Trial.

One question was to ask the patients whether they intend to participate in the clinical trial. One was entered for participation and zero for non-participation. The intention level was measured from 1 to 10.

3.4 Validity and Reliability Test

3.4.1 Validity Test

Contents of the questionnaire were reviewed by three experts for its completeness and clarity of the language using face validity.

3.4.2 Reliability Test

The reliability of the constructs of the HBM was tested for internal consistency using Cronbach's alpha. Any items having Cronbach's alpha coefficient less than 0.70 will be deleted or revised according to George and Mallery (2003).[51]

There were 30 HIV-infected patients visited the HIV out-patient clinic of one academic hospital in May 2013. They were asked to complete the research questionnaire to try out for reliability test. The results were reported as follows:

3.4.2.1 Perceived susceptibility: there were four questions included in the questionnaire. The Cronbach's alpha was 0.906.

3.4.2.2 Perceived severity: the Cronbach's alpha was 0.705. There were four questions included in the questionnaire.

3.4.2.3 Perceived benefits: there were six questions included in the questionnaire. The Cronbach's alpha was 0.917.

3.4.2.4 Perceived barriers: there were 11 questions included in the questionnaire. The Cronbach's alpha was 0.776.

3.4.2.5 Cues to action: there were four remaining questions were included in the questionnaire. The Cronbach's alpha was 0.745.

3.4.2.6 Self-efficacy: there were five questions included in the questionnaire. The Cronbach's alpha was 0.926.

Table 3.7 The Reliability Test of the Research Questionnaire

	Perceived Susceptibility	Perceived Severity	Perceived Benefits	Perceived Barriers	Cues to Action	Self-Efficacy
Items (*n*)	4	4	6	11	4	5
Valid Cases (*N*)	30	26	27	27	30	29
Cronbach's alpha	0.906	0.705	0.917	0.776	0.745	0.926
Standardized alpha	0.906	0.280	0.919	0.751	0.721	0.930

3.5 Ethical Consideration

The official letter to conduct the research from Faculty of Graduate Studies, Mahidol University and the research proposal were submitted to the Ethical Review Committee of an academic hospital in Bangkok in March 2013. The approval letter no. MURA2013/248 dated 06 April 2013 was obtained from the Ethical Review Committee, and then the letter was submitted to the Office of Research for approval of data collection. The approval letter no. sor thor 0517.0617/688 dated 15 May 2013 was obtained from the Office of Research. The head of department of medicine and the head of division of infectious diseases were notified regarding the research.

According to the GCP, the informed consent form (ICF) was generated and approved by the Ethical Review Committee before using. The informed consent process was performed before asking the HIV-infected patients to complete the research questionnaire.

To protect the confidentiality of all research respondents, the questionnaire was identified by the research identification number. Only the researcher can access through the respondents' documents. All research records were stored in the safe place until the publication was completely done. The respondents' personal information and identities will not be disclosed to the public.

3.6 Data Collection

Data collection started in May 2013 after getting all approval letters. The HIV-infected patient was referred individually from the clinic to the researcher by the registered nurse after pre-screening. There were approximately 10 – 20 patients were screened per day based on the doctor schedule.

The researcher educated the HIV-infected patient about the clinical trial and reviewed the medical record to check for eligibility criteria. The HIV-infected patient was asked whether he/she was willing to complete the research questionnaire. Then the HIV-infected patient was asked to sign and date on the ICF. The researcher instructed the patient on how to complete the questionnaire and answered all questions that the patient had. After that let the patient completed the questionnaire for 15 minutes. The completed questionnaires were checked for completeness before leaving the patients.

3.7 Data Analysis

3.7.1 Descriptive Statistics

Descriptive statistic was used to describe the characteristics of the respondents including gender, age group, marital status, education, income, occupation and health insurance coverage.

Mean and standard deviation were used for analyzing the variables of the HBM which included perceived susceptibility, perceived severity, perceived benefits, perceived barriers, cues to action and self-efficacy.

3.7.2 Bivariate Analysis

Cross-tabulation with chi-square analysis was used to compare the differences between each group of general characteristics and clinical trial participation. Cross-tabulation was presented in the joint frequency distribution table to determine whether the variables are associated with clinical trial participation or independent.

3.7.3 Logistic Regression Analysis

Logistic regression analysis was used to examine the relationship between the independent variables (general characteristics and the variables in the HBM) and the binary dependent variables (clinical trial participation).

Multivariate logistic regression was computed by forward stepwise likelihood ratio function. Only significant variables with *p*-value less than 0.05 were included in the model. Hosmer-Lemeshow goodness of fit test was performed to ensure that model can be used.

$$\ln\left(\frac{Participation}{Non-participation}\right) = \alpha + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_n x_n$$

Figure 3.1 Logistic Regression Model

CHAPTER IV
RESULTS

This chapter presents the results of the research by descriptive and logistic regression analysis. The first section was a descriptive analysis of general characteristics of the respondents, including the association with clinical trial participation. The second section describes the factors affecting HIV-infected patients' intention to participate in the clinical trial using the HBM. The last section presents the results of multivariate logistic regression analysis of these variables and clinical trial participation.

4.1 The Characteristics of Respondents

There were total of 280 HIV-infected patients enrolled as respondents in this study. The respondents visited at the out-patient department at one academic hospital in Bangkok during May to July 2013. About 53.6% of HIV-infected patients were male; whereas 46.4% were female.

The HIV-infected patients who age in between 18 to 60 years were selected as sample population in order to avoid vulnerable populations. The respondents were classified into four groups according to their age. The majority of respondents were in 31 – 40 years age group about 34.6% and 38.6% in 41 – 50 years. About 14.3% were in 18 – 30 years and 12.5% in 51 – 60 years age group.

About 41.8% of the respondents are married and 40.4% are single, and 8.9% were divorced and widowed.

For education, most respondents finished their junior high school or lower about and finished their bachelor degree or higher about 31.8% and 33.2% respectively. There were 24.3% finished their senior high school or vocational certificate and 10.7% for high vocational certificate or diploma.

According to income, there were 36.4% of the respondents earned less than or equal to 10,000 THB and 37.2% earned 10,001 – 20,000 THB. There were 18.2% earned in between 20,000 – 30,000 THB and only 8.2% earned more than 30,001 THB per month.

Most of the respondents in this research were self-employed about 36.0% , second comes were government officers about 22.9%, employees about 16.4%; and unemployed about 13.2%. Only 3.6% were agriculturist and 7.9% were freelance or other occupations.

Health insurance coverage for the Thai citizens were provided by different providers. About 64.6% of the respondents had medical insurance both public and private insurance schemes. For public insurance including Civil Servant Medical Benefit Scheme (CSMBS), Universal Coverage (UC) and Social Security Scheme (SSS); however about 35.4% of the respondents had to pay out-of-pocket (OOP) for their medications.

Table 4.1 Characteristics of the Respondents

	Number (n = 280)	**Percentage (%)**
Gender		
Male	150	53.6
Female	130	46.4
Age (years old)		
18 – 30	40	14.3
31 – 40	97	34.6
41 – 50	108	38.6
51 – 60	35	12.5
Marital status		
Single	113	40.4
Married	117	41.8
Divorced	25	8.9
Widowed	25	8.9

Table 4.1 Characteristics of the Respondents (cont.)

	Number (n = 280)	Percentage (%)
Highest education		
Junior High School or lower	89	31.8
Senior High School/ Vocational	68	24.3
High Vocational/Diploma	30	10.7
Bachelor Degree or Higher	93	33.2
Monthly income (THB)		
≤ 10,000 THB	102	36.4
10,001 – 20,000 THB	104	37.2
20,001 – 30,000 THB	51	18.2
30,001 or more	23	8.2
Occupation		
Government Officers	64	22.9
Employees	46	16.4
Self-employed	101	36.0
Farmers	10	3.6
Unemployed	37	13.2
Others	22	7.9
Health insurance coverage		
No	99	35.4
Yes	181	64.6

There were 214 or 76.4% of the respondents intended to participate in the clinical trial at the academic hospital setting of this study in Bangkok. The intention level ranged from 1 to 10. The mean level of the intention was 7.61 with a standard deviation at 2.18. About 30.4% of the respondents had the highest intention level at 10; while 32.7% had intention level at level 5 and above as presented in table 4.2.

Table 4.2 The Intention Level of Clinical Trial Participation

Intention level	Number (n = 214)	Percentage (%)
Level 1	4	1.9
Level 2	2	0.9
Level 3	1	0.5
Level 4	5	2.3
Level 5	33	15.4
Level 6	15	7.0
Level 7	37	17.3
Level 8	34	15.9
Level 9	18	8.4
Level 10	65	30.4
Overall scale	Mean = 7.61, SD = 2.18, Min = 1, Max = 10	

4.1.1 Gender

There were 80.7% of male and 71.5% of female respondents intended to participate in the trial. The chi-square testing revealed that there was no significant association between gender and clinical trial participation as shown in table 4.3 (p = 0.073).

Table 4.3 Gender and Clinical Trial Participation

Gender	Total number (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
Male	150	29 (19.3%)	121 (80.7%)	
Female	130	37 (28.5%)	93 (71.5%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.073

4.1.2 Age

There were 65.0% of respondents who aged between 18 to 30 years intended to participate in the trial (Table 4.4). The percentage of the respondents aged between 31 - 40 years, 41 – 50 and 51 – 60 years who intended to join the future clinical trial were 80.4%, 75.0% and 82.9% respectively. The chi-square testing for statistically significant revealed that age of respondents was not associated with the intention to participate in the clinical trial (p = 0.197). This implied that no relationship between each age group and clinical trial participation.

Table 4.4 Age and Clinical Trial Participation

Age (years old)	**Total numbers (%)**	**Clinical Trial Participation**		***p*-value**
		Non-Participation (%)	**Participation (%)**	
18 – 30	40	14 (35.0%)	26 (65.0%)	
31 – 40	97	19 (19.6%)	78 (80.4%)	
41 – 50	108	27 (25.0%)	81 (75.0%)	
51 – 60	35	6 (17.1%)	29 (82.9%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.197

4.1.3 Marital Status

The result of cross-tabulation and chi-square revealed that there was no significant relationship between marital status and clinical trial participation (p = 0.493) and there were no differences among the four marital status group in their intention to participate in the clinical trial as shown in table 4.5.

Table 4.5 Marital Status and Clinical Trial Participation

Marital status	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
Single	113	28 (24.8%)	85 (75.2%)	
Married	117	30 (25.6%)	87 (74.4%)	
Divorced	25	3 (12.0%)	22 (88.0%)	
Widowed	25	5 (20.0%)	20 (80.0%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.493

4.1.4 Education

There were 82.0%, 76.5%, 70.0% and 73.1% of the respondents who finished junior high school or lower, senior high school or vocational certificate, high vocational or diploma group, and bachelor degree or higher group intended to join the clinical trial respectively. The results showed that there was no significant relationship between education and clinical trial participation (p = 0.424) and there were no differences among the four education group in their intention to participate in the clinical trial as presented in table 4.6.

Table 4.6 Education and Clinical Trial Participation

Education	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
Junior High School or lower	89	16 (18.0%)	73 (82.0%)	
Senior High School/ Vocational	68	16 (23.5%)	52 (76.5%)	

Table 4.6 Education and Clinical Trial Participation (cont.)

Education	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
High Vocational/ Diploma	30	9 (30.0%)	21 (70.0%)	
Bachelor Degree or Higher	93	25 (26.9%)	68 (73.1%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.424

4.1.5 Income

The respondents with different income level who intended to participate in the clinical trial were 81.4% earned less than 10,000 THB, 76.9% earned 10,001 – 20,000 THB, 68.6% earned 20,001 – 30,000 THB, and 69.6% earned higher than 30,000 THB respectively. While those who not intend to join were 23.1%, 31.4% and 30.4% earned less than 10,000 THB, 10,001 – 20,000 THB, 20,001 – 30,000 THB and higher than 30,000 THB respectively.

The chi-square testing showed that that there was no significant relationship between income level and clinical trial participation ($p = 0.293$) and there were no differences among the four income level in their intention to participate in the clinical trial as presented in table 4.7.

Table 4.7 Income and Clinical Trial Participation

Income (THB)	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
≤ 10,000	102	19 (18.6%)	83 (81.4%)	
10,001 – 20,000	104	24 (23.1%)	80 (76.9%)	
20,001 – 30,000	51	16 (31.4%)	35 (68.6%)	

Table 4.7 Income and Clinical Trial Participation (cont.)

Income (THB)	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
30,001 or more	23	7 (30.4%)	16 (69.6%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.293

4.1.6 Occupation

Among the study sample population, there were 76.6% of government officers, 65.2% of employees, 76.2% of self-employed, 70.0% of farmers, 89.2% of unemployed and 81.8% of freelancers or other occupations intended to participate in the clinical trial. The results showed that there was no significant relationship between occupation and clinical trial participation (p = 0.210) and there were no differences among these five occupation groups in their intention to participate in the clinical trial as presented in table 4.8.

Table 4.8 Occupation and Clinical Trial Participation

Occupation	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
Government Officers	64	15 (23.4%)	49 (76.6%)	
Employees	46	16 (34.8%)	30 (65.2%)	
Self-employed	101	24 (23.8%)	77 (76.2%)	
Farmers	10	3 (30.0%)	7 (70.0%)	
Unemployed	37	4 (10.8%)	33 (89.2%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.210

4.1.7 Health Insurance Coverage

About 73.7% and 77.9% of the respondents who did not have and had medical insurance coverage respectively intended to join the clinical trial whereas 26.3% and 22.1% of the respondents who did not have and had medical insurance coverage refused to join the clinical trial. The chi-square testing showed that there was no association between medical insurance coverage and clinical trial participation (p = 0.433) and there were no differences among these two groups in their intention to participate in the clinical trial as presented in table 4.9.

Table 4.9 Health Insurance Coverage and Clinical Trial Participation

Health insurance coverage	Total numbers (%)	Clinical Trial Participation		*p*-value
		Non-Participation (%)	Participation (%)	
No	99	26 (26.3%)	73 (73.7%)	
Yes	181	40 (22.1%)	141 (77.9%)	
Total	280 (100%)	66 (23.6%)	214 (76.4%)	0.433

4.2 Descriptive Analysis of the Health Belief Model Score

The questions were created according to the HBM. The respondents were asked if they agreed or disagreed with the statements in the questionnaire, then the overall score of each HBM constructs was classified into three levels; low, moderate and high as presented in table 4.10 to 4.21.

4.2.1 Perceived Susceptibility

The perceived susceptibility measures the risk behavior response to get AIDS defining illness. One case was missing from data analysis. The perceived susceptibility score ranges from 4 to 16 (*Min* = 8, *Max* = 16). The mean score of perceived susceptibility score was 14.61 points with a standard deviation of 1.57 as

shown in table 4.10. The measurement of risk behavior to get AIDS defining illness of perceived susceptibility was described as follows:

4.2.1.1 Awareness of antiretroviral therapy compliance: there were 66.1% of respondents strongly agreed and 31.4% agreed that the compliance of antiretroviral therapy was important for postponing of getting AIDS defining illness. There were only 0.4% of respondents strongly disagreed and 2.1% disagreed.

4.2.1.2 Awareness of health condition follow-up: there were 67.1% of respondents strongly agreed and 30.0% agreed that following-up the health condition periodically was important; whereas about 1.1% of respondents were strongly disagreed and 1.8% disagreed.

4.2.1.3 Awareness of blood test follow-up: most respondents about 63.1% were strongly agreed and 33.3% agreed that following-up $CD4^+$ and viral load by blood testing periodically were necessary for postponing of getting AIDS defining illness. There were about 0.4% of respondents strongly disagreed and 3.2% disagreed.

4.2.1.4 Awareness of health maintenance: About 76.8% of respondents were strongly agreed and 22.1% agreed that health maintenance by doing exercise regularly was important to slow-down the occurrence of AIDS defining illness. There were 1.1% of respondents disagreed and no one strongly disagreed.

Table 4.10 Descriptive Analysis of Perceived Susceptibility Responses (n = 279)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' awareness of the importance of antiretroviral therapy compliance in order to prevent drug resistance.	1 (0.4%)	6 (2.1%)	88 (31.4%)	185 (66.1%)
Patients' awareness of the importance of follow-up on their health conditions periodically.	3 (1.1%)	5 (1.8%)	84 (30.0%)	188 (67.1%)

Table 4.10 Descriptive Analysis of Perceived Susceptibility Responses (n = 279) (cont.)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' awareness of the importance of having blood test for $CD4^+$ and viral load periodically.	1 (0.4%)	9 (3.2%)	93 (33.3%)	176 (63.1%)
Patients' awareness of the importance of health maintenance.	0	3 (1.1%)	62 (22.1%)	215 (76.8%)
Overall score	Mean = 14.61 SD = 1.57 Min = 8 Max = 16			

Sum score of perceived susceptibility was divided into three levels; low, moderate and high as follows:

13 – 16 points	High level of perceived susceptibility
10 – 12 points	Moderate level of perceived susceptibility
4 – 9 points	Low level of perceived susceptibility

From table 4.11, there were 87.1% of the respondents had high level of perceived susceptibility. About 12.5% of respondents had moderate level and approximately 0.4% had low level of perceived susceptibility.

Table 4.11 Descriptive Analysis of Perceived Susceptibility Level (n = 279)

Perceived susceptibility level	Frequency (n)	Percentage (%)
High	243	87.1
Moderate	35	12.5
Low	1	0.4
Overall score	279	100.0

4.2.2 Perceived Severity

The assessment of the seriousness of health condition; whether the respondents participated or did not participate in the trial was performed by measuring their medical/clinical and social consequences. The perceived severity score ranges from 4 to 16 (*Min* = 4, *Max* = 16). The mean score of perceived severity was 11.02 points with a standard deviation of 2.98 as shown in table 4.12. The assessment of perceived severity was described as follows:

4.2.2.1 Feeling concerning about clinical trial participation: there were 33.2% of respondents agreed and 13.4% strongly agreed that they were worry about clinical trial participation. About 31.8% of respondents were disagreed and 21.7% strongly disagreed.

4.2.2.2 Feeling concerning about health condition if not participate: most respondents were disagreed (32.7%) and strongly disagreed (27.0%) that their health condition would get worse if they participated in the trial; whereas, about 23.7% of respondents were agreed and 16.5% strongly agreed.

4.2.2.3 Feeling concerning about social stigma if participate: most respondents were disagreed (35.1%) and strongly disagreed (32.6%) that they would have social stigma by being in the clinical trial. There were 20.7% of respondents agreed and 11.6% strongly agreed.

4.2.2.4 Relationship with others if participate: most of respondents were disagreed (35.1%) and strongly disagreed (30.5%) that they would have problems in their relationship with other people. However, there were only 18.6% of respondents agreed and 15.8% strongly agreed.

Table 4.12 Descriptive Analysis of Perceived Severity Responses (n = 271)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' feeling concerning about clinical trial participation.	60 (21.7%)	88 (31.8%)	92 (33.2%)	37 (13.4%)

Table 4.12 Descriptive Analysis of Perceived Severity Responses (n = 271) (cont.)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' feeling concerning about their health condition if they decided not to participate in the clinical trial.	75 (27.0%)	91 (32.7%)	66 (23.7%)	46 (16.5%)
Patients' feeling concerning about social stigma if they decided to participate in the clinical trial.	90 (32.6%)	97 (35.1%)	57 (20.7%)	32 (11.6%)
Patients' feeling concerning about their relationship with family members, friends or colleagues if they decided to participate in the clinical trial.	85 (30.5%)	98 (35.1%)	52 (18.6%)	44 (15.8%)
Overall score	Mean = 11.02 SD = 2.98 Min = 4 Max = 16			

Sum score of perceived severity was divided into three levels; low, moderate and high as follows:

13 – 16 points	High level of perceived severity
10 – 12 points	Moderate level of perceived severity
4 – 9 points	Low level of perceived severity

Table 4.13 presented the frequency and percentage of perceived severity level. There were approximately 33.6% of respondents had high level of perceived severity and 38.0% had moderate level. About 28.4% of respondents had low level of perceived severity.

Table 4.13 Descriptive Analysis of Perceived Severity Level (n = 271)

Perceived severity level	Frequency (n)	Percentage (%)
High	91	33.6
Moderate	103	38.0
Low	77	28.4
Overall score	271	100.0

4.2.3 Perceived Benefits

Perceived benefits measures the benefits that respondents expected to receive if they participated in the trial. The perceived benefits score ranges from 6 to 24 (*Min* = 7, *Max* = 24). The mean score of perceived benefits was 18.56 points with a standard deviation of 3.09 as shown in table 4.14. The responses for perceived benefits were described as follows:

4.2.3.1 Getting more physical and mental health maintenance: most respondents were strongly agreed (37.1%) and agree (44.6%) that they would get more physical and mental health maintenance if they decided to participate in the trial. About 14.7% of respondents and 3.6% were disagreed and strongly disagreed respectively.

4.2.3.2 Access to high level of professional care: most respondents were strongly agreed (41.6%) and agreed (40.9%) that being in the clinical trial, the respondents can access the high level of professional care if compared with standard of care. There were 13.3% of respondents disagreed and 4.3% strongly disagreed.

4.2.3.3 Effectiveness of study treatments: there were 32.1% of respondents strongly believed and 52.5% believed that the investigational products provided by clinical trials were effective. About 14.3% of respondents were disagreed and 1.1% strongly disagreed.

4.2.3.4 Compensation: most respondents were disagreed (34.5%) and strongly disagreed (21.8%) that they did not expect to receive money or travel compensation to be a study volunteer. About 27.3% of respondents were agreed

and 26.4% of respondents strongly agreed that they should receive money or travel compensation.

4.2.3.5 Free treatments: most respondents were agreed (38.8%) and strongly agreed (32.0%) that they expected to receive free treatments provided by the clinical study. About 20.5% of respondents were disagreed and 8.6% strongly disagreed.

4.2.3.6 Altruism: most respondents were strongly agreed (73.6%) and agreed (23.9%) that the study results would cause benefits to future patients; whereas, there were only 1.8% of respondents disagreed and 0.7% strongly disagreed.

Table 4.14 Descriptive Analysis of Perceived Benefits Responses (n = 271)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' beliefs of getting more physical and mental health maintenance from being a volunteer in the clinical trial when compared to nonparticipation.	10 (3.6%)	41 (14.7%)	124 (44.6%)	103 (37.1%)
Patients' beliefs about access to high level of the professional care provided by study doctors and study nurses in the clinical trial in comparison with standard of care.	12 (4.3%)	37 (13.3%)	114 (40.9%)	116 (41.6%)
Patients' beliefs about the effectiveness of treatments provided by the clinical trial.	3 (1.1%)	40 (14.3%)	147 (52.5%)	90 (32.1%)
Patients' expectations about receiving money or travel compensation from the clinical trial.	60 (21.8%)	95 (34.5%)	75 (27.3%)	45 (26.4%)
Patients' expectations about cost saving by receiving free treatments provided by the clinical trial.	24 (8.6%)	57 (20.5%)	108 (38.8%)	89 (32.0%)

Table 4.14 Descriptive Analysis of Perceived Benefits Responses (n = 271) (cont.)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' altruistic idea that future patients may benefit from the results of the trial.	2 (0.7%)	5 (1.8%)	67 (23.9%)	206 (73.6%)
Overall score	Mean = 18.56 SD = 3.09 Min = 7 Max = 24			

Sum score of perceived benefits was divided into three levels; low, moderate and high as follows:

19 – 24 points	High level of perceived benefits
15 – 18 points	Moderate level of perceived benefits
6 – 14 points	Low level of perceived benefits

Table 4.15 showed the frequency and percentage of perceived benefits level. Most of respondents had high level of perceived benefits (53.1%); whereas about 37.6% had moderate level and 9.2% had low level of perceived benefits.

Table 4.15 Descriptive Analysis of Perceived Benefits Level (n = 271)

Perceived benefits level	Frequency (n)	Percentage (%)
High	144	53.1
Moderate	102	37.6
Low	25	9.2
Overall score	271	100.0

4.2.4 Perceived Barriers

The respondents were measured about the obstacles or discomforts that might prevent the respondents from clinical trial participation. The perceived barriers score ranges from 11 to 44 (*Min* = 17, *Max* = 44). The mean score of perceived

barriers score was 30.94 points with a standard deviation of 5.73 as shown in table 4.16. The responses for perceived barriers were described as follows:

4.2.4.1 Risks of new and untested treatments: most respondents were agreed (37.2%) and strongly agreed (16.2%) that the risks of untested drug might be an obstacle. There were 34.7% of respondents disagreed and 11.9% strongly disagreed.

4.2.4.2 Risks of study procedures: most respondents were disagreed (34.7%) and strongly disagreed (11.9%) that study procedures such as blood collection could be their barriers; whereas about 23.0% of respondents were agreed and 8.6% strongly agreed.

4.2.4.3 Burden imposed upon daily life: there were about 37.3% disagreed, 12.9% strongly disagreed, 32.3% disagreed and 17.6% strongly disagreed that participating in the clinical trial burdens their daily life.

4.2.4.4 Time-consuming: most respondents were disagreed (39.3%) and strongly disagreed (27.1%) that participating in the trial is time-consuming; however, about 26.1% of respondents were agreed and 7.5% strongly agreed.

4.2.4.5 Transportation: most of respondents were disagreed (37.1%) and strongly disagreed (21.4%) that travelling to the site might be an obstacle of clinical trial participation while about 28.9% of respondents were agreed and 12.5% strongly agreed.

4.2.4.6 Personal information: most respondents were disagreed (39.4%) and strongly disagreed (22.2%) that providing the study staff their personal and sensitive information could be a barrier to clinical trial participation. However, there were 25.4% of respondents agreed and 12.9% strongly agreed.

4.2.4.7 Guinea pig attitude: most respondents were disagreed (33.5%) and strongly disagreed (19.8%) that being a volunteer was a guinea pig; whereas about 30.6% of respondents were agreed and 16.2% strongly agreed.

4.2.4.8 Drug experiments on patients: most respondents were disagreed (43.0%) and strongly disagreed (15.4%) that clinical trials should not test a new drug on patients; however, about 28.7% of respondents were agreed and 22.9% strongly agreed.

4.2.4.9 Negative implications: most respondents were disagreed (33.2%) and strongly disagreed (31.4%) that if they refused to join the study, they could get any negative implications. There were about 21.3% of respondents agreed and 14.1% strongly agreed.

4.2.4.10 Trust in investigators: most respondents were agreed (55.8%) and strongly agreed (31.3%) that they trusted in the investigators; however, there were only 10.1% of respondents disagreed and 2.9% strongly disagreed.

4.2.4.11 Trust in the institute: most respondents were strongly agreed (78.2%) and agreed (19.3%) that they trusted in an academic hospital in Bangkok; however, there were about 1.8% of respondents disagreed and 0.7% strongly disagreed.

Table 4.16 Descriptive Analysis of Perceived Barriers Responses (n = 267)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' beliefs of the risks by undergoing new, untested treatment in the clinical trial.	33 (11.9%)	96 (34.7%)	103 (37.2%)	45 (16.2%)
Patients' beliefs of the risks by receiving study procedure such as blood collection.	67 (24.1%)	123 (44.2%)	64 (23.0%)	24 (8.6%)
Patients' beliefs of the burden imposed upon daily life by participating in the trial.	49 (17.6%)	90 (32.3%)	104 (37.3%)	36 (12.9%)
Patients' beliefs that clinical trial participation is time-consuming.	76 (27.1%)	110 (39.3%)	73 (26.1%)	21 (7.5%)
Patients' beliefs of their physical discomforts in travelling to the study site.	60 (21.4%)	104 (37.1%)	81 (28.9%)	35 (12.5%)
Patients' beliefs of the emotional discomfort in telling the study team any personal sensitive information.	62 (22.2%)	110 (39.4%)	71 (25.4%)	36 (12.9%)
Patients' negative beliefs that a volunteer is a guinea pig.	55 (19.8%)	93 (33.5%)	85 (30.6%)	45 (16.2%)

Table 4.16 Descriptive Analysis of Perceived Barriers Responses (n = 267) (cont.)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' beliefs towards medical experiments on patients.	42 (15.4%)	117 (43.0%)	78 (28.7%)	35 (12.9%)
Patients' beliefs of negative implications will have on the non-trial treatment if refuse to participate.	87 (31.4%)	92 (33.2%)	59 (21.3%)	39 (14.1%)
Patients' beliefs about their trusts in the medical competence of the investigators in controlling and reducing risks of the investigational products.	8 (2.9%)	28 (10.1%)	155 (55.8%)	87 (31.3%)
Patients' beliefs about their trusts in university/hospital.	2 (0.7%)	5 (1.8%)	54 (19.3%)	219 (78.2%)
Overall score	Mean = 30.94 SD = 5.73 Min = 17 Max = 44			

Sum score of perceived barriers was divided into three levels; low, moderate and high as follows:

35 – 44 points	High level of perceived barriers
27 – 34 points	Moderate level of perceived barriers
11 – 26 points	Low level of perceived barriers

Table 4.17 showed the frequency and percentage of perceived barriers level. Most of respondents had moderate level of perceived barriers (53.2%); whereas about 25.5% had high level and 21.3% had low level of perceived barriers.

Table 4.17 Descriptive Analysis of Perceived Barriers Level (n = 267)

Perceived barriers level	Frequency (n)	Percentage (%)
High	68	25.5
Moderate	142	53.2
Low	57	21.3
Overall score	267	100.0

4.2.5 Cues to Action

Cues to action measures whether respondents required any triggers to stimulate their decision making such as recommendations and clinical trial information. The cues to action scores ranges from 4 to 16 (*Min* = 4, *Max* = 16). The mean score of cues to action was 12.75 points with a standard deviation of 2.50 as presented in table 4.18. The responses of cues to action were described as follows:

4.2.5.1 Recommendations from physicians: most respondents were strongly agreed (43.9%) and agreed (42.9%) that they need recommendations from physicians prior to make a decision in clinical trial participation. There were only 10.0% of respondents disagreed and 3.2% and strongly disagreed.

4.2.5.2 Recommendations from family members: there were respondents about 30.1% agreed and 28.0% strongly agreed that they needed recommendations from their family members prior to make a decision in clinical trial participation; whereas there were respondents about 25.4% disagreed and 16.5% strongly disagreed.

4.2.5.3 Recommendations from friends: most respondents were strongly agreed (48.4%) and agreed (41.6%) that they need recommendations from their friends prior to make a decision to join the study; whereas, there were about 8.2% disagreed and 1.8% strongly disagreed.

4.2.5.4 Clinical trial information: most respondents were strongly agreed (47.1%) and agreed (47.1%) that clinical trial information was required to make a decision to join the study; while there were respondents only 4.3% disagreed and 1.4% strongly disagreed.

Table 4.18 Descriptive Analysis of Cues to Action Responses (n = 276)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' receiving recommendations to participate in the clinical trial from physicians.	9 (3.2%)	28 (10.0%)	120 (42.9%)	123 (43.9%)
Patients' receiving recommendations to participate in the clinical trial from their family members.	46 (16.5%)	71 (25.4%)	84 (30.1%)	78 (28.0%)
Patients' receiving recommendations to participate in the clinical trial from their friends.	5 (1.8%)	23 (8.2%)	116 (41.6%)	135 (48.4%)
Patients' receiving clinical trial information.	4 (1.4%)	12 (4.3%)	131 (47.1%)	131 (47.1%)
Overall score	Mean = 12.75 SD = 2.50 Min = 4 Max = 16			

Sum score of cues to action was divided into three levels; low, moderate and high as follows:

13 – 16 points	High level of cues to action
10 – 12 points	Moderate level of cues to action
4 – 9 points	Low level of cues to action

Table 4.19 showed the frequency and percentage of cues to action level. There were 53.6% of respondents had high level of cues to action; whereas approximately 37.3% had moderate level and 9.1% had low level of cues to action.

Table 4.19 Descriptive Analysis of Cues to Action Level (n = 276)

Cues to action level	Frequency (n)	Percentage (%)
High	148	53.6
Moderate	103	37.3
Low	25	9.1
Overall score	276	100.0

4.2.6 Self-efficacy

Self-efficacy was assessed whether the respondents are confident to comply with the clinical trial specific requirements. The self-efficacy scores ranges from 5 to 20 (*Min* = 5, *Max* = 20). The mean score of self-efficacy was 15.53 with a standard deviation of 2.94 as presented in table 4.20. The responses of self-efficacy were described as follows:

4.2.6.1 Visit schedule: most respondents were agreed (41.6%) and strongly agreed (22.9%) that they were confident that they could visit the study site as required by the study; whereas there were respondents about 25.1% disagreed and 10.6% strongly disagreed.

4.2.6.2 Blood collection: most respondents were agreed (55.8%) and strongly agreed (29.1%) that they were confident that they could have blood tests regularly according to the study protocol and there were respondents about 11.2% disagreed and 4.0% strongly disagreed.

4.2.6.3 Study data recording: most respondents were agreed (53.9%) and strongly agreed (35.0%) that they were confident to record any study related events such as health conditions and medications. There were respondents about 9.6% disagreed and 2.1% strongly disagreed.

4.2.6.4 Confidential information: most respondents were agreed (53.2%) and strongly agreed (33.2%) that they were confident to provide their confidential information. There were respondents about 9.3% disagreed and 4.3% strongly disagreed.

Table 4.20 Descriptive Analysis of Self-efficacy Responses (n = 277)

Statement	Frequency (%)			
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Patients' beliefs about their confidence to visit the study site regularly as specified in the clinical trial.	29 (10.6%)	70 (25.1%)	116 (41.6%)	64 (22.9%)
Patients' beliefs about their confidence to visit the study site regularly as specified in the clinical trial.	29 (10.6%)	70 (25.1%)	116 (41.6%)	64 (22.9%)
Patients' beliefs about their confidence to be willing to have blood collection as specified in the clinical trial.	11 (4.0%)	31 (11.2%)	155 (55.8%)	81 (29.1%)
Patients' beliefs about their confidence to record events on their health conditions and medications receiving during clinical trial participation.	4 (1.4%)	27 (9.6%)	151 (53.9%)	98 (35.0%)
Patients' beliefs about their confidence to take study drug as specified in the clinical trial.	6 (2.1%)	26 (9.3%)	138 (49.3%)	110 (39.3%)
Patients' beliefs about their confidence to provide the study staff their personal information.	12 (4.3%)	26 (9.3%)	149 (53.2%)	93 (33.2%)
Overall score	Mean = 15.53 SD = 2.94 Min 5 Max = 20			

Sum score of self-efficacy was divided into three levels; low, moderate and high as follows:

16 – 20 points	High level of self-efficacy
12 – 15 points	Moderate level of self-efficacy
5 – 11 points	Low level of self-efficacy

Table 4.21 presented the frequency and percentage of self-efficacy level. There were 50.9% of respondents had moderate level of self-efficacy; whereas approximately 41.9% had high level and 7.2% had low level of self-efficacy.

Table 4.21 Descriptive Analysis of Self-efficacy Level (n = 277)

Self-efficacy level	Frequency (n)	Percentage (%)
High	116	41.9
Moderate	141	50.9
Low	20	7.2
Overall score	277	100.0

4.3 The Factors Affecting the Clinical Trial Participation

Two types of logistic regression analysis were computed to identify the factors affecting the intention of clinical trial participation. The first one was that the overall score of each HBM constructs and the respondents' characteristics were entered into the analysis; while the second computing were performed by using the level of HBM constructs as ranking into high, moderate and low and the respondents' characteristics were entered.

4.3.1 Multivariate Logistic Regression Analysis of the HBM Score

The results of multivariate analysis of all potential variables entered in the logistic regression analysis were presented in table 4.22. The categorical data was re-coded into binary format using the first value as the reference. The results from multivariate logistic regression with stepwise likelihood ratio function presented that education, perceived susceptibility, perceived benefits, perceived barriers, and self-efficacy were significantly included in the logistic regression model while the other variables were excluded. There were significant relationships between clinical trial participation and the above variables.

4.3.1.1 Education level: to analyze the categorical variables like education level, the dummy variable needed to be created by setting junior high school or lower education group as the reference variable in this analysis. Data interpretation was comparing each education group with the reference group. The *p*-value of education level was 0.041 which indicated that education level was one of

potential predictors to the intention of clinical trial participation as seen in table 4.22. The results showed that senior high school or vocational group (*OR* = 0.328, *95%CI* [0.108 – 0.995], p = 0.049) and high vocational or diploma (*OR* = 0.151, *95%CI* [0.039 – 0.590], p = 0.007) were significantly different from junior high school or lower education group; whereas bachelor degree or higher education group was not significantly different from junior high school or lower education group (*OR* = 0.514, *95%CI* [0.198 – 1.337], p = 0.172). The chance of clinical trial participation for the respondents who finished senior high school or vocational, high vocational or diploma and bachelor degree or higher were less than junior high school or lower education group 0.328, 0.151, and 0.514 times respectively.

4.3.1.2 Perceived susceptibility: the logistic regression analysis showed that perceived susceptibility was one of the factors affecting the intention of clinical trial participation. The results showed that one point changed in perceived susceptibility would decrease the log-odds of clinical trial participation by 0.457 with the chance of clinical trial participation at 0.633 times. (*OR* =0.633, *95%CI* [0.482 – 0.832], p = 0.001).

4.3.1.3 Perceived benefits: the logistic regression analysis showed that perceived benefits was one of the predicting factors of the intention of clinical trial participation. The results showed that one point changed in perceived benefits would increase the log-odds of clinical trial participation by 0.352 with the chance of clinical trial participation at 1.422 times (*OR* = 1.422, *95%CI* [1.227 – 1.647], $p < 0.001$).

4.3.1.4 Perceived barriers: the logistic regression revealed that perceived barriers was factor affecting the intention of clinical trial participation. The results showed that one point changed in perceived barriers would increase the log-odds of clinical trial participation by 0.088 with the chance of clinical trial participation at 1.092 times. (*OR* = 1.092, *95%CI* [1.017 – 1.173], p = 0.016).

4.3.1.5 Self-efficacy: the logistic regression analysis indicated that self-efficacy was one of the factors predicting the intention of clinical trial participation. The results showed that one point changed in self-efficacy would increase the log-odds of clinical trial participation by a factor of 0.403 with the chance

of clinical trial participation at 1.496 times (*OR* = 1.496, *95%CI* [1.281 – 1.747], $p < 0.001$).

Table 4.22 Multivariate Logistic Regression Analysis of General Characteristics and the Variables in the HBM

	ß	**S.E.**	***p***	**OR**	**95% CI OR**	
					Lower	**Upper**
Education			0.041			
Junior high school or lower						
Senior high school or vocational	-1.114	0.566	0.049	0.328	0.108	0.995
High vocational or diploma	-1.891	0.696	0.007	0.151	0.039	0.59
Bachelor degree or higher	-0.666	0.488	0.172	0.514	0.198	1.337
Health Belief Model						
Perceived Susceptibility	- 0.457	0.139	0.001	0.633	0.482	0.832
Perceived Benefits	0.352	0.075	<0.001	1.422	1.227	1.647
Perceived Barriers	0.088	0.037	0.016	1.092	1.017	1.173
Self-Efficacy	0.403	0.079	<0.001	1.496	1.281	1.747
Constant	-6.278	2.624	0.017	0.002		

Hosmer-Lemeshow goodness of fit was tested. The result shows that this equation fits well (p = 0.051) with percentage of prediction at 82.2%. The logistic regression equation was presented below.

$$\ln\left(\frac{Participation}{Non-participation}\right)$$
$$= -6.278 - 1.114\ (senior\ highscjhool\ or\ vocational)$$
$$- 1.891\ (high\ vocational\ or\ diplma)$$
$$- 0.666\ (bachelor\ degree\ or\ higher)$$
$$- 0.457\ (perceived\ susceptibility) + 0.352\ (perceived\ benefits)$$
$$+ 0.088\ (perceived\ barriers) + 0.403\ (self-efficacy)$$

4.3.2 Multivariate Logistic Regression Analysis of the Perception Level in the HBM

The sum score of each constructs in the HBM was categorized into three levels; low, moderate and high perception level. These perception levels were re-coded into binary format using the first value as the reference. All general characteristic variables and perception levels of all constructs in the HBM were computed using the multivariate logistic regression analysis with forward stepwise likelihood ratio function. The results showed that perceived benefits, cues to action and self-efficacy were potential predicting factors of the intention to participate in the clinical. These variables were included in the logistic regression equation as presented in table 4.23 except the general characteristics.

4.3.2.1 Perceived benefits: low level of perceived benefits was set as the reference value. The *p*-value of perceived benefits level was <0.001 which indicated that perceived benefits was one of factors affecting the intention of clinical trial participation. The results showed that moderate level of perceived benefits (*OR* = 2.387, *95% CI* [0.840 – 6.782], *p* = 0.102) was not different from the reference value; whereas the high level of perceived benefits were significantly different (*OR* = 14.828, *95% CI* [4.707 – 46.708], *p* <0.001). The results can be concluded that the respondents who had high level of perceived benefits would have more chance to participate in the clinical trial more than those who had low level about 14.828 times.

4.3.2.2 Cues to action: low level of cues to action was set as the reference value. The *p*-value of cues to action level was 0.014 which indicated that cues to action was one of the predicting factors of the intention to participate in the clinical trial. The results; however, showed that moderate level of cues to action (*OR* = 0.315, *95% CI* [0.056 – 1.772], *p* = 0.190) was not different from the low level. On the other hand, high level of cues to action (*OR* = 0.130, *95% CI* [0.023 – 0.722], *p* = 0.020) was significantly different from the low level. The chance of clinical trial participation in high level of cues to action would be less likely to participate in the trial 0.130 times than the low level group.

4.3.2.3 Self-efficacy: low level of self-efficacy was set as the reference value. The p-value of self-efficacy level was <0.001 which indicated that self-efficacy was a factor affecting the intention to participate in the clinical trial. The

results showed that moderate level of self-efficacy (*OR* = 12.525, *95% CI* [3.205 – 48.945], *p* <0.001) and the high level groups (*OR* = 36.294, *95% CI* [8.286 – 158.968], *p* <0.001) were significantly different from the low level group. The results revealed that the respondents who had moderate and high level of self-efficacy were more likely to participate in the clinical trial than those who had low level about 12.525 times and 36.294 times respectively.

Table 4.23 Multivariate Logistic Regression Analysis of General Characteristics and the Perception Level of the HBM

	ß	**S.E.**	***p***	**OR**	**95% CI OR**	
					Lower	**Upper**
Perceived benefits level			<0.001			
Moderate	0.870	.533	.102	2.387	.840	6.782
High	2.696	.585	<0.001	14.828	4.707	46.708
Cues to action level			0.014			
Moderate	-1.155	.881	.190	.315	.056	1.772
High	-2.043	.876	.020	.130	.023	.722
Self-efficacy level			<0.001			
Moderate	2.528	.695	<0.001	12.525	3.205	48.945
High	3.592	.754	<0.001	36.294	8.286	158.968
Constant	-1.359	.927	.143	.257		

Hosmer-Lemeshow goodness of fit was tested. The result shows that this equation fits well (*p* = 0.076) with percentage of prediction at 81.8%. The logistic regression equation was presented below.

$$\ln\left(\frac{Participation}{Non-participation}\right)$$
$$= -1.359 + 0.870\ (moderate\ level\ of\ perceived\ benefits)$$
$$+\ 2.696\ (high\ level\ of\ perceived\ benefits)$$
$$-\ 1.155\ (moderate\ level\ of\ cues\ to\ action)$$
$$-\ 2.043\ (high\ level\ of\ cues\ to\ action)$$
$$+\ 2.528\ (moderate\ level\ of\ self-efficacy)$$
$$+\ 3.592\ (high\ level\ of\ self-efficacy)$$

4.4 Hypotheses testing

There were no statistical significant evidences supported the relationship between genders, age, marital status, perceived severity and the intention of clinical trial participation. However, the results indicated that education, perceived susceptibility, perceived benefits, perceived barriers, cues to action and self-efficacy were statistically significant related to the intention of clinical trial participation in HIV-infected patients at one academic hospital in Bangkok. The hypotheses testing were summarized in table 4.24.

Table 4.24 The Summary of Hypotheses Testing

No.	Hypotheses	Results
H1	Male patients intend to participate in the clinical trial higher than female patients.	Reject
H2	Older patients intend to participate in the clinical trial higher than younger patients.	Reject
H3	Married patients intend to participate in the clinical trial higher than single or divorce patients.	Reject
H4	Low income population intends to participate in the clinical trial higher than high income population.	Reject
H5	Low educated patients intend to participate in the clinical trial higher than higher educated patients.	Reject

Table 4.24 The Summary of Hypotheses Testing (cont.)

No.	Hypotheses	Results
H6	Occupation is not related to the intention to participate in the clinical trial.	Accept
H7	Patients without or do not use health insurance coverage intend to participate in the clinical trial higher than patients with health insurance coverage.	Reject
H8	Patients with high perceived susceptibility intend to participate in the clinical trial higher than log perceived susceptibility.	Reject
H9	Patients with high perceived severity intend to participate in the clinical trial higher than low perceived severity.	Reject
H10	Patients with high perceived benefits intend to participate in the clinical trial higher than low perceived benefits.	Accept
H11	Patients with low perceived barriers intend to participate in the clinical trial higher than high perceived barriers.	Reject
H12	Patients with low cues to action intend to participate in the clinical trial higher than high cues to action.	Accept
H13	Patients with high self-efficacy intend to participate in the clinical trial higher than low self-efficacy.	Accept

CHAPTER V
DISCUSSION

From the statistical analysis of the variables in the multivariate logistic regression, we discovered that education, perceived susceptibility, perceived benefits, perceived barriers, cues to action and self-efficacy were potential predictors of the intention to participate in the clinical trial.

5.1 The General Characteristics and Clinical Trial Participation

The majority of respondents were age in between 31 – 50 years. Most of them were either single or married. We found that most of respondents graduated from junior high school or lower and bachelor degree or higher and earned less than or equal to 20,000 THB. More than 50% of respondents had the medical insurance coverage provided by public and private insurance schemes i.e. Civil Servant Medical Benefit Scheme (CSMBS), Universal Coverage (UC) and Social Security Scheme (SSS). From the descriptive analysis, about 76.4% of respondents intended to participate in the clinical trial with high intention level (level 5 to 10); however, the percentage of clinical trial participation among each group of general characteristic variables was not significantly different.

From previous research studied by Gorkin et al (1996) reported that gender difference was a significant factor of clinical trial participation. They found that the percentage of clinical trial participation in post myocardial infarction trial between men and women were big difference. In contrast, this research showed that the percentage of clinical trial participation between both sexes was almost equivalence. Gorkin concluded that women perceived the post myocardial infarction trial as a form of invasive procedures with aggressive treatments that women usually refuse based on the previous data in cardiology research.[19, 52, 53] Regarding HIV treatments, receiving anti-retroviral therapy as well as following-up $CD4^+$ and the viral load were non-

invasive treatments when comparing with post myocardial infarction treatments, so gender should not affect the intention to participate in the HIV trials.

While the results from this research showed that age and marital status were not related to clinical trial participation, Calnan (1984) highlighted the importance of age and marital status to breast cancer screening program and the further research about the relationship between these two factors and participation in the program were required. Calnan proposed that age and marital status might be associated with the decision making process on how patients thought about their health condition.[41] However, we noticed that the research population in Calnan's study was healthy volunteers; while in this research was HIV-infected patients. Not only the research population that was different but also the research design; Calnan's research was screening program but this research was clinical trial. This finding revealed that the differences of population might be related to people's beliefs about their health. This conclusion was supported by a previous study performed by Chu (2012) that patient population could be more vulnerable than healthy volunteer in several dimensions such as sources of information, influential person and purpose of clinical trial participation.[9] Furthermore, another study performed by Gorkin (1996) also concluded that there were no differences in parameters of marital status between enrollees and non-enrollees.[19]

The results from cross-tabulation analysis showed that there was no difference among four education groups in the percentage of clinical trial participation as presented in table 4.6; however, this result contradicted what we found in the logistic regression analysis as education was included in the model. Referring to the result from the logistic regression analysis, we found that junior high school or lower education group and bachelor degree or higher education group were not significantly different in clinical trial participation; whereas, senior high school or vocational education group and high vocational or diploma education group were different from the reference group (junior high school or lower). From the finding that the lowest and highest level of education had no differences in the percentage of participation, it was not clear to state that education was actually related to clinical trial participation. Surprisingly, Gorkin (1996) reported that there were no significant differences in education between enrollees and non-enrollees; whereas Stunkel and Grady (2011)

stated that education was indirectly related to participation through how people thought about monetary compensation as a motivator in the clinical trial.[47] In contrast, education was excluded in the regression model when perception level was computed instead of perception score. Only the HBM variables were included. This finding revealed that education might not be a strong predictor when comparing with perception level.

In Thailand, the compensation for the research subjects for their time and travelling cost was required by the Ethics Committees. This requirement led to an assumption that monetary compensation might influence the patients and healthy volunteer to join the clinical trial especially in low income population. Surprisingly, the result from cross-tabulation and logistic regression analysis presented that income was not related to clinical trial participation. This finding was inconsistent with the research conducted by Stunkel and Grady (2011) who proposed that although monetary payment was one of motivations but the research participants considered other benefits as well as risks.[47] In addition, Park (2012) reported that money was a motivator only in the small group of healthy volunteers in the HIV vaccine trial.[8] Since the research population in this study was HIV-infected patients, there were several benefits that the patients expected to receive from joining the clinical trial such as receiving high level of professional care, receiving effective treatments and saving cost.

Regarding health insurance coverage, most of respondents reported that they had Civil Servant Medical Benefit Scheme (CSMBS) for government officers, Social Security Scheme (SSS) and private health insurance for business employees. Some respondents reported that they needed to pay by themselves even if they had Universal Coverage (UC) that the government provided to all Thai citizens. From the data analysis, health insurance coverage was not related to clinical trial participation. This finding was consistent with the result concluded by Gorkin (1996).[19] Universal Coverage (UC) provided by National Health Security Office (NHSO) covered the cost for HIV/AIDS treatments including laboratory testing; however, anti-retroviral therapy covered by UC was limited.[54] The reason why patients who already had medical insurance coverage still intended to join the clinical trial was that patients might see benefits other than cost saving as presented by Stunkel and Grady (2011).[47]

5.2 The Perception of the HIV-Infected Patients and Clinical Trial Participation

From the logistic regression analysis, we found that several variables in the HBM were potential factors relating to clinical trial participation, i.e. perceived susceptibility, perceived benefits, perceived barriers, cues to action and self-efficacy.

Regarding perceived susceptibility, most of respondents perceived susceptibility in high level (87.1%). From table 4.22, one point increased in perceived susceptibility score would decrease the odd of clinical trial participation 0.633 times. Table 4.23; however, presented that perceived susceptibility level was not in the model. Although this finding indicated that perceived susceptibility level might not affect the intention of clinical trial participation but the overall of perceived susceptibility score could be a potential factor that the patients who perceived susceptibility in high level would be less likely to join the clinical trial.

Perceived severity was excluded from the logistic regression equation due to non-significant result. The results revealed that the percentage of perceived severity in low, moderate and high level were quite equivalence. This finding might be a result of the invalidate questionnaire that did not well measure perceived severity enough. By the way, we found that 67.7% of respondents did not believe that participating in the clinical trial was social stigma and 65.6% of respondents did not concern about their social relationship if they participated in the trial.

As presented in table 4.22, perceived benefits and perceived barriers were included into the model as predictors of clinical trial participation. One point increased in perceived benefits score would increase the odds of clinical trial participation at 1.442 times and one point increased in perceived barriers would increase the odds at 1.092 times. However, table 4.23 presented that perceived barriers level was not included; whereas perceived benefits level was still in the model. The patient who perceived benefits in high level would be more likely to participate in the clinical trial 18.145 times than those who perceived benefits in low level. Furthermore, the chance of clinical trial participation between moderate level and low level of perceived benefits were not significantly different. This finding might be a result of the patient did not perceived high enough that they would get benefits from being in the trial. Regarding perceived barriers, most of respondents had moderate level of perceived

barriers and the percentage showed the normal distribution. Basically, the patients would consider about benefits and risks or barriers before making decisions. We found that 81.7% of respondents believed that they would get more physical and mental health maintenance, 82.5% of respondents reported that they would receive high level of the professional care, about 84.6% believed that the investigational products was effective, 70.8% expected to receive free treatments, and 97.5% of respondents believed that the research result would give benefits to the future patients. While most of respondents expected getting benefits, there was a small group of respondents concerned about the barriers. We noticed that only 31.7% of respondents believed they would get risks from research study procedure, 33.6% of respondents reported that clinical trial participation was time-consuming, 38.4% of respondents were not willing to inform their personal confidential information, and 35.4% of respondents believed that they would have negative implications if they refused to join the trial. We also found that most of respondents trusted in their physicians (87.1%) and the hospital (97.5%). Since the benefits and barriers were different among each population and location, these findings should be referred to HIV-infected patients at an academic hospital in Bangkok only.[13]

From the descriptive analysis, the respondents usually agreed that they needed the recommendations from their physicians, friends or family members prior to making a decision. However, the logistic regression analysis presented that cues to action score was not related to clinical trial participation; however, the cues to action level was. Table 4.23 presented that the patient who had high level of cues would be less likely to join the trial 0.130 times than those who had low level. So, the patient who required lots of triggers to make decisions would be less likely to join. However, there were some respondents reported that they did not have to consult their friends or family members because they would like to keep their health condition confidential.

Regarding self-efficacy to clinical trial participation, the data analysis showed that most of respondents believed that they could comply with the study requirements and perceived self-efficacy in moderate level. From table 4.22 and 4.23, the patient who had high and moderate level of self-efficacy would be more likely to join the trial 12.525 times and 36.294 times than those who had low level. We might conclude that if the patients were confident that they could follow the requirements of

the study protocol, they would be more confident to participate in the clinical trial. This finding was consistent with the previous studied by Geyh et al (2012) that self-efficacy was found to be a strong factor related to clinical trial participation than the other factors such as symptoms, social support, and health condition etc.[55]

5.3 Limitations

Since this research question was a new topic in Thailand, the literatures that studied about the factors affecting clinical trial participation were limited especially in Thai population. Only international literatures were only our sources of information. Although the research studies published internationally could provide useful data but the results from some research could not fit Thai population due to cultural differences. So, the questionnaire used in this research was newly adapted from the previous studied in western countries. Although all items in the questionnaire were face validated before using, but some questions needed revising to fit Thai population. However, we found that only quantitative data cannot give detailed information to answer the research questions, and qualitative data was also important for data interpretation. Information sharing by patients about their thoughts and beliefs of clinical trial participation was found to be very useful. We recommended interviewing the patient in the future research.

In addition, during the conducting of this research, there was no new clinical trial initiated. In order to complete this research within limited time, the new HIV trial was generated for questionnaire completion. This new trial included HIV study protocol's general requirements such as study procedures, drug administration, adverse event reporting and frequency of visit schedule based on the researcher's experience. So, the patient's intentions to participate in the clinical trial were measured instead of their decisions. To make the result more reliable, this research should be ideally conducted at the time point of the subject screening and enrollment process of the real clinical trial. The research questionnaire should be completed after the patients already made their decisions whether they agreed to join the clinical trial.

Logistic regression analysis was used to identify the potential predictors of clinical trial participation with binary outcome. The independent variables could be

interval scale or ordinal scale. Computing the raw score of the HBM variables gave more accurate results than using the perception level because categorizing of the HBM variable score could interfere the results if the criteria of categorizing were inappropriate. The logistic regression model resulting from the raw score; however, could not be used in the real life without using the research questionnaire. So, categorizing the perception score into three levels and then analyzing in the logistic regression could give more meaning.

5.4 Recommendations

This research topic was quite new in Thailand, the knowledge concluded from this research results was valuable for clinical research industry in Thailand. According to the results, we knew that education, perceived susceptibility, perceived benefits, perceived barriers, cues to action and self-efficacy were related to clinical trial participation in Thai patients. To improve the subject recruitment, these factors can be applied; for example, providing information and knowledge suitable for low educated patients, allowing patients to ask for recommendations from the others, considering the benefits and barriers, and adjusting the study procedures easier to be followed.

Information provided in the informed consent form should be easy to understand by low educated people. Clinical research professionals should focus on the informed consent process to explain the benefits and risks of the trial until the patients fully understand. The patients should be allowed to ask their friends or family members before making decision. These recommendations are already a global standard practice and every research investigators should comply with. In protocol development stage, we recommend the study protocol writers to discuss with the community representatives from where clinical trials will be conducted to get more information about benefits that they expected to receive from the trial and also barriers. This information is very useful to reduce barriers to improve the recruitment.

Although this research provided some basic results about the factors affecting clinical trial participation in Thai population, but repeating is required because these factors are varied among each particular population. The results from

the other group of patients might give different findings. Interviewing the patients should be performed in parallel with answering the questionnaire in order to obtain the patients' thoughts and beliefs in detail. The research questionnaire should be revised to fit Thai population. We also suggested determining the relationship between the HIV infection condition and clinical trial participation through the HBM.

CHAPTER VI
CONCLUSION

Three major conclusions can be made from this study. The first conclusion is that the proportions of the patients who intended and did not intend to participate in the clinical trial among each group of characteristic variables were not significantly different although the overall percentage of participation was higher than non-participation.

The second conclusion is that the variables in the Health Belief Model were stronger predictors than the patients' characteristic variables. Although education was selected to be in the logistic regression model, but there were no significant differences between the lowest and highest education group in clinical trial participation. Moreover, the result showed that income was not related to clinical trial participation and monetary compensation might not be a motivator for some patients as previously expected.

The third conclusion is that the clinical trial information was essential for the patients to weigh between benefits and barriers before making decision. The benefits that the patients expected to receive from the trial were getting more physical and mental health maintenance, access to high level of the professional care, receiving the effective and free treatments. Some patients; however, were fear of getting risks from the study procedure. To reduce their fear, the clinical research staff should focus on the details of study procedure during the consent process to ensure that the patients were fully understand what they would receive during the trial. Some patients thought that participating in the trial was time-consuming. Although most of clinical trial allow the window period of the study visit to give more flexibility to investigators and the patients, but we recommend the site to effectively prepare for the study procedure, so the visit will not be so long for the patients.

In addition, a small group of patients was not willing to provide their confidential information. This confidentiality point was already included as a part of

informed consent process. The clinical research staff should take this opportunity to make the patients trust and feel comfortable enough to provide their personal data. In Thai population, the paternal relationship between the patients and physicians still existed. Some patients would fully rely on their physicians to make decisions on behalf of the patients because they did not have knowledge about clinical trial and they believed that their physicians would choose the best thing for them. However, some patients were fear to have negative implications if they refused to join the clinical trial.

In conclusion, providing clinical trial information during the informed consent process will give the patients basic knowledge about clinical trial and the clinical trial specific requirements. This step is mandatory for the patients to make decision. The clinical research staff should focus on each component of the informed consent process such as explaining all detailed information, giving time to think and make decision, allowing them to ask their friends or relatives, answering all questions may have, and signing/dating on the informed consent form etc.

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APPENDICES

APPENDIX A

HUMAN RESEACH ETHICS TRAINING

บัณฑิตวิทยาลัย มหาวิทยาลัยมหิดล
ใบรับรอง เพื่อแสดงว่า

ชื่อ – นามสกุล นางสาวศิริวรรณ ฐิติพงศ์ประภัทร รหัสนักศึกษา ๕๔๓๗๕๓๘ PHPH/M
คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

เป็นผู้ผ่านการเรียนชั่วโมง “จริยธรรมการวิจัยในคน”

ในรายวิชา สศบส ๖๑๒ วิธีวิจัยทางด้านการบริหารสาธารณสุข
คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล
เมื่อวันที่ ๑๗ มีนาคม พ.ศ. ๒๕๕๕

ลงนาม
(ผู้ช่วยศาสตราจารย์พีระ ครึกครื้นจิตร)
อาจารย์ผู้รับผิดชอบรายวิชา/ผู้ประสานงานรายวิชา

ลงนาม
(รองศาสตราจารย์ ดร.ฉัตรสุมน พฤฒิภิญโญ)
อาจารย์ผู้สอน

APPENDIX B

DOCUMENTARY PROOF OF ETHICAL CLEARANCE

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
๒๗๐ ถนนพระราม ๖ แขวงทุ่งพญาไท เขตราชเทวี กทม. ๑๐๔๐๐
โทร. ๐-๒๓๕๔-๗๒๗๕, ๐-๒๒๐๑-๑๒๕๖ โทรสาร ๐-๒๓๕๔-๗๒๗๓
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เอกสารรับรองโดยคณะกรรมการจริยธรรมการวิจัยในคน
คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี
มหาวิทยาลัยมหิดล

เลขที่ ๒๕๕๖/๒๑๕

ชื่อโครงการ	ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิกของผู้ป่วยติดเชื้อเอชไอวี
เลขที่โครงการ/รหัส	ID ๐๓–๕๖–๔๗ ย
ชื่อหัวหน้าโครงการ	นางสาวศิริวรรณ ฐิติพงศ์ประภัทร
ที่ทำงาน	ภาควิชาบริหารงานสาธารณสุข คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

ขอรับรองว่าโครงการดังกล่าวข้างต้นได้ผ่านการพิจารณาเห็นชอบโดยสอดคล้องกับแนวปฏิญญา เฮลซิงกิ จากคณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

ลงนาม _____

กรรมการและเลขานุการจริยธรรมการวิจัยในคน (ศาสตราจารย์ แพทย์หญิงดวงฤดี วัฒนศิริชัยกุล)

ลงนาม _____

ประธานกรรมการจริยธรรมการวิจัยในคน (ศาสตราจารย์ นายแพทย์บุญส่ง องค์พิพัฒนกุล)

วันที่รับรอง ๖ เมษายน ๒๕๕๖

ระยะเวลาในการศึกษา ๙ เดือน

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
๒๗๐ ถนนพระราม ๖ แขวงทุ่งพญาไท เขตราชเทวี กทม. ๑๐๔๐๐
โทร. ๐-๒๓๕๔-๗๒๗๕, ๐-๒๒๐๑-๑๒๙๖ โทรสาร ๐-๒๓๕๔-๗๒๓๓

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Documentary Proof of Ethical Clearance
Committee on Human Rights Related to Research Involving Human Subjects
Faculty of Medicine Ramathibodi Hospital, Mahidol University

MURA2013/248

Title of Project	Factors Affecting HIV-Infected Patient' Decision in Clinical Trial Participation
Protocol Number	ID 03-56-47
Principal Investigator	Miss. Siriwan Thitiphongpraphat
Official Address	Department of Public Health Administration Faculty of Public Health Mahidol University

The aforementioned project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki.

Signature of Secretary Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Duangrurdee Wattanasirichaigoon, M.D.
Signature of Chairman Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Boonsong Ongphiphadhanakul, M.D.
Date of Approval	April 6, 2013
Duration of Study	8 Months

APPENDIX C

INFORMED CONSENT FORM

เอกสารประกอบ 4

เอกสารชี้แจงข้อมูล/คำแนะนำแก่ผู้เข้าร่วมการวิจัย

(Patient/Participant Information Sheet)

ชื่อโครงการ

Factors Affecting HIV-Infected Patients' Decision in Clinical Trial Participation

ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิกของผู้ป่วยติดเชื้อเอชไอวี

ชื่อผู้วิจัย

ผู้วิจัยหลัก (นักศึกษาปริญญาโท)

นางสาวศิริวรรณ ฐิติพงศ์ประภัทร

สังกัดภาควิชาบริหารงานสาธารณสุข คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

อาจารย์ที่ปรึกษาวิทยานิพนธ์

อาจารย์ ดร. ภิฤดี ภวนานันท์

สังกัดภาควิชาบริหารงานสาธารณสุข คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

รองศาสตราจารย์ ดร. สุปรียา ตันสกุล

สังกัดภาควิชาสุขศึกษาและพฤติกรรมศาสตร์ คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

รองศาสตราจารย์แพทย์หญิงศศิโสภิณ เกียรติบูรณกุล

สังกัดสาขาวิชาโรคติดเชื้อ ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

มหาวิทยาลัยมหิดล

ผู้ช่วยศาสตราจารย์ ฉัฐกมล ชาญสาธิตพร

สังกัดภาควิชาชีวสถิติ คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

สถานที่วิจัย

สาขาวิชาโรคติดเชื้อ ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

มหาวิทยาลัยมหิดล

270 ถนนพระรามที่ 6 แขวงทุ่งพญาไท เขตราชเทวี กรุงเทพฯ 10400

บุคคลและวิธีการติดต่อเมื่อมีเหตุฉุกเฉินหรือความผิดปกติที่เกี่ยวข้องกับการวิจัย

นางสาวศิริวรรณ ฐิติพงศ์ประภัทร

ภาควิชาบริหารงานสาธารณสุข คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

420/1 ถนนราชวิถี เขตราชเทวี กรุงเทพฯ 10400

โทร. 089-199-0971 (ในและนอกเวลาราชการ)

ผู้สนับสนุนการวิจัย

ไม่มี

ความเป็นมาของโครงการ

โครงการศึกษาวิจัยทางคลินิก เป็นโครงการที่ได้รับการวางแผนมาแล้วอย่างละเอียดรอบคอบ เพื่อค้นหาคำตอบให้กับคำถามสำคัญเกี่ยวกับสุขภาพที่จะสามารถช่วยเหลือผู้คนได้ในอนาคต ซึ่งโครงการศึกษาวิจัยทางคลินิกที่จะกล่าวถึงต่อไปในเอกสารฉบับนี้ คือ โครงการศึกษาวิจัยเพื่อพัฒนายาต้านไวรัสเอชไอวีชนิดใหม่ซึ่งยังไม่เคยวางตลาดขายที่ใดมาก่อน เพื่อเป็นการพิสูจน์ว่ายาต้านไวรัสเอชไอวีชนิดใหม่นั้น มีประสิทธิภาพในการควบคุมโรคได้ และมีความปลอดภัยที่จะใช้ในคน จึงจำเป็นต้องมีการทดลองในสัตว์ทดลองและในคนก่อนที่จะนำมาวางขายเพื่อใช้ในผู้ป่วยทั่วโลก

ในปัจจุบันโครงการวิจัยเพื่อพัฒนายาในประเทศแถบทวีปเอเชีย โดยเฉพาะอย่างยิ่งในประเทศไทยมีจำนวนมากขึ้น เนื่องจากเหตุผลต่างๆ ได้แก่ ประชากรมีจำนวนมาก ความแตกต่างด้านเชื้อชาติและการใช้ชีวิตมีน้อย มีตลาดการค้าขายขนาดใหญ่ มีแหล่งผู้ป่วยจำนวนมาก มีเจ้าหน้าที่ด้านการแพทย์ที่มีประสบการณ์และค่าใช้จ่ายต่ำเมื่อเทียบกับประเทศในแถบทวีปยุโรปและสหรัฐอเมริกา

ทั้งนี้ หากพิจารณาในผู้ป่วยติดเชื้อเอชไอวีจะพบว่า ผู้ป่วยติดเชื้อเอชไอวีบางรายยินยอมตนเป็นอาสาสมัครในโครงการศึกษาวิจัยที่ทดลองยาต้านไวรัสชนิดใหม่ ถึงแม้ว่าผู้ป่วยเหล่านั้นจะสามารถเข้าถึงยาต้านไวรัสเอชไอวีได้อย่างสะดวกก็ตาม ดังนั้น สิ่งที่ส่งผลต่อการตัดสินใจว่าเหตุใดผู้ป่วยติดเชื้อเอชไอวีจึงยินยอมเข้าร่วมโครงการศึกษาวิจัยจึงเป็นคำถามที่น่าสนใจ ปัจจุบันมีการศึกษาปัจจัยที่ส่งผลต่อการตัดสินใจในประเทศแถบตะวันตก ซึ่งปัจจัยที่พบนั้นแตกต่างกันไปในแต่ละประเทศ และยังไม่มีการศึกษาวิจัยประเภทนี้ในผู้ป่วยชาวไทย ดังนั้น การศึกษาปัจจัยที่มีผลต่อการตัดสินใจของผู้ป่วยติดเชื้อเอชไอวียินยอมตนเพื่อเป็นอาสาสมัครในโครงการวิจัยทางคลินิกในผู้ป่วยชาวไทย จะช่วยให้แพทย์ผู้วิจัยสามารถบริหารจัดการอาสาสมัครที่เข้าร่วม

โครงการวิจัยทางคลินิกได้อย่างมีประสิทธิภาพเพื่อให้เกิดประโยชน์สูงสุดแก่ทั้งอาสาสมัครและโครงการวิจัย

วัตถุประสงค์

1. เพื่อศึกษาปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก
2. เพื่อศึกษาความสัมพันธ์ระหว่างปัจจัยความเชื่อด้านสุขภาพ ข้อมูลทั่วไปและการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมการวิจัย

ผู้วิจัยได้ขออนุมัติจากคณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี เพื่อพิจารณาข้อมูลเกี่ยวกับการรักษาของท่านที่บันทึกอยู่ในเวชระเบียน เพื่อใช้ในการคัดเลือกกลุ่มผู้ป่วยที่จะขอทำการศึกษาวิจัย ข้อมูลที่พิจารณา ได้แก่ วันเดือนปีเกิด เพศ ประวัติการเจ็บป่วยอันเนื่องมาจากโรคติดเชื้อเอชไอวี ผลตรวจทางห้องปฏิบัติการ โดยผู้วิจัยจะอ้างอิงข้อมูลโดยใช้หมายเลขประจำตัวผู้ป่วยโรงพยาบาลรามาธิบดี และจะไม่มีการระบุชื่อของท่านลงบนเอกสารงานวิจัย

ทางผู้วิจัยจะขอเรียนเชิญท่าน เพื่อเข้าร่วมการศึกษาในครั้งนี้ ผู้วิจัยจะอธิบายรายละเอียดการศึกษาวิจัยเพื่อให้ท่านได้พิจารณาว่า ยินดีที่จะเข้าร่วมการศึกษาวิจัยครั้งนี้หรือไม่ การตัดสินใจเข้าร่วมการศึกษาวิจัยนี้ ขึ้นอยู่กับการพิจารณาของท่าน ท่านมีสิทธิที่จะปฏิเสธการเข้าร่วมได้ทุกเมื่อ หากท่านยินยอมที่จะเข้าร่วมการศึกษานี้โดยสมัครใจ ผู้วิจัยจะขอให้ท่านเซ็นชื่อและวันที่ลงบนเอกสารฉบับนี้ ท่านจะได้รับเอกสารยินยอมฉบับนี้ 1 ชุด เพื่อเก็บไว้เป็นหลักฐาน

หากท่านสมัครใจเข้าร่วมการศึกษาครั้งนี้ ทีมผู้วิจัยจะขอให้ท่านตอบแบบสอบถาม 3 ชุด จำนวนทั้งหมด 7 หน้า โดยมีหัวข้อดังต่อไปนี้

ชุดที่ 1 ข้อมูลทั่วไป	จำนวน 7 ข้อ
ชุดที่ 2 ความเชื่อด้านสุขภาพต่อการเข้าร่วมโครงการวิจัยทางคลินิก	จำนวน 36 ข้อ
ชุดที่ 3 การตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก	จำนวน 1 ข้อ

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้เข้าร่วมการวิจัย

ท่านอาจไม่ได้รับประโยชน์โดยตรงจากการศึกษาครั้งนี้ อย่างไรก็ตาม ผลการศึกษานี้จะเป็นประโยชน์ต่อผู้วิจัยในการบริหารจัดการผู้ป่วยในโครงการวิจัยได้อย่างมีประสิทธิภาพมากขึ้น รวมทั้ง เพิ่มขีดความสามารถของสถานศึกษาวิจัยเพื่อรองรับจำนวนโครงการวิจัยทางคลินิกที่จะมีจำนวนเพิ่มมากขึ้นในอนาคต

ท่านมีสิทธิที่จะไม่ตอบคำถามบางข้อซึ่งอาจทำให้ท่านไม่สะดวกใจในการตอบ อย่างไรก็ตาม เพื่อความน่าเชื่อถือของผลการศึกษาที่จะเป็นประโยชน์ในอนาคต แบบสอบถามควรได้รับการตอบอย่างครบถ้วนสมบูรณ์

การเก็บข้อมูลเป็นความลับ

หมายเลขประจำตัวอาสาสมัครจะถูกระบุลงในแบบสอบถามและเอกสารที่เกี่ยวข้องต่างๆ เพื่อเป็นการปกป้องข้อมูลส่วนบุคคลของท่าน จะไม่มีการระบุชื่อและนามสกุลของท่านลงบนเอกสาร เอกสารที่สามารถสืบย้อนกลับไปถึงตัวท่านจะถูกเก็บรักษาไว้ในสถานที่ปลอดภัย ณ สถานศึกษาวิจัย โดยมีเพียงทีมผู้วิจัยที่จะสามารถเข้าถึงข้อมูลส่วนบุคคลของท่านได้ หลังจากโครงการศึกษานี้เสร็จสิ้นสมบูรณ์และงานวิจัยครั้งนี้ได้รับการเผยแพร่ทางวิชาการ เอกสารที่สามารถสืบย้อนไปถึงตัวท่านจะถูกนำไปทำลาย เหลือไว้เพียงเอกสารที่ระบุด้วยหมายเลขอาสาสมัครเท่านั้น ทั้งนี้ ข้อมูลส่วนตัวของท่านจะไม่ถูกนำไปเปิดเผยในที่สาธารณะ

ถ้าท่านมีปัญหาข้องใจหรือรู้สึกกังวลใจกับการเข้าร่วมในโครงการวิจัยนี้ ท่านสามารถติดต่อกับประธานกรรมการจริยธรรมการวิจัยในคน สำนักงานวิจัยคณะฯ อาคารวิจัยและสวัสดิการ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี

เอกสารประกอบ 5ก

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

(Informed Consent Form)

ชื่อโครงการ

Factors Affecting HIV-Infected Patients' Decision in Clinical Trial Participation

ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิกของผู้ป่วยติดเชื้อเอชไอวี

ชื่อผู้วิจัย นางสาวศิริวรรณ ฐิติพงศ์ประภัทร

*ชื่อผู้เข้าร่วมการวิจัย .....

อายุ .....เลขที่เวชระเบียน .....

คำยินยอมของผู้เข้าร่วมการวิจัย

ข้าพเจ้า นาย/นาง/นางสาว ..... ได้ทราบรายละเอียดของโครงการวิจัยตลอดจนประโยชน์ และข้อเสี่ยงที่จะเกิดขึ้นต่อข้าพเจ้าจากผู้วิจัยแล้วอย่างชัดเจน ไม่มีสิ่งใดปิดบังซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้นข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่เข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ข้าพเจ้าพึงได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ.....(ผู้เข้าร่วมการวิจัย)

.....(พยาน)

.....(พยาน)

วันที่ .....

คำอธิบายของแพทย์หรือผู้วิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ.....(แพทย์หรือผู้วิจัย)

วันที่.....

หมายเหตุ : กรณีผู้เข้าร่วมการวิจัยไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือยินยอมฯ นี้ให้แก่ผู้เข้าร่วมการวิจัยฟังจนเข้าใจดีแล้ว และให้ผู้เข้าร่วมการวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวข้างต้นไว้ด้วย

* ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

APPENDIX D

QUESTIONNAIRE

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

แบบสอบถามความคิดเห็นต่อการศึกษาวิจัยทางคลินิก

หัวข้อวิทยานิพนธ์ ปัจจัยที่มีผลต่อการตัดสินใจเข้าร่วมโครงการวิจัยทางคลินิก

นักศึกษาปริญญาโท นางสาวศิริวรรณ ฐิติพงศ์ประภัทร ภาควิชาบริหารงานสาธารณสุข คณะสาธารณสุขศาสตร์ มหาวิทยาลัยมหิดล

ความรู้ทั่วไปเกี่ยวกับการศึกษาวิจัยทางคลินิก

การศึกษาวิจัยทางคลินิกคืออะไร

การศึกษาวิจัยทางคลินิก คือ การศึกษาที่ได้รับการวางแผนมาแล้วอย่างละเอียดรอบคอบ ศึกษาข้อมูลด้านการแพทย์และการรักษา เพื่อตอบคำถามที่นำมาซึ่งความรู้ที่อาจเป็นประโยชน์ต่อการรักษาผู้ป่วยในอนาคต โดยผู้ป่วยจะได้รับข้อมูลรายละเอียดเกี่ยวกับการศึกษาวิจัย และทางผู้วิจัยจะขอคำยินยอมจากผู้ป่วย การตัดสินใจเข้าร่วมโครงการวิจัยขึ้นอยู่กับผู้ป่วยแต่เพียงผู้เดียวโดยจะได้รับเวลามากพอในการทำความเข้าใจรายละเอียดของโครงการวิจัย หากผู้ป่วยตัดสินใจเข้าร่วมโครงการศึกษาวิจัย ผู้ป่วยจะได้รับการร้องขอให้ลงลายมือชื่อและวันที่ ในเอกสารแสดงความยินยอม ถึงแม้ว่าผู้ป่วยตัดสินใจเข้าร่วมโครงการวิจัยแล้ว ผู้ป่วยมีสิทธิที่จะถอนตัวจากโครงการวิจัยได้ทุกเมื่อถึงแม้ว่าผู้ป่วยตัดสินใจไม่เข้าร่วมโครงการศึกษาวิจัย ผู้ป่วยจะยังคงได้รับการดูแลรักษาตามแนวทางการรักษาตามปกติ

ยาวิจัยคืออะไร

ยาวิจัย คือ ยาที่ใช้ในการศึกษาวิจัย ซึ่งได้รับการทดสอบในสัตว์ทดลองมาก่อนแล้วว่ามีความปลอดภัยในระดับหนึ่ง แต่ก็ยังคงมีความเสี่ยงจากการใช้ยาวิจัยที่ยังไม่สามารถระบุได้ ยาวิจัยส่วนใหญ่เป็นยาที่ยังมิได้วางขายในท้องตลาด แต่มีบางส่วนที่ได้วางขายแล้วโดยใช้เป็นยาเปรียบเทียบ

การดำเนินการวิจัย

อาสาสมัครที่ยินยอมเข้าร่วมการศึกษาวิจัย จะได้รับการสุ่มเพื่อให้ได้รับยาชนิด ก หรือยาชนิด ข โดยที่ทางผู้วิจัยและอาสาสมัครจะไม่ทราบว่าได้รับยาชนิดใด โดยอาสาสมัครจะต้องรับประทานยาตามที่ผู้วิจัยกำหนด นอกจากนี้บางการศึกษาวิจัยอาจมีการเก็บตัวอย่างเลือดเพื่อการติดตามอาการของโรค โดยระยะเวลาการศึกษาวิจัยจะนานประมาณ 3 – 12 เดือน หรืออาจนานหลายปี โดยอาสาสมัครจำเป็นต้องมาพบผู้วิจัยตามหมายกำหนดการทุกครั้ง

ประโยชน์และความเสี่ยงจากการเข้าร่วมการศึกษาวิจัย

อาสาสมัครจะได้รับการติดตาม ดูแลรักษา จากทีมแพทย์ผู้วิจัย ตลอดระยะเวลาที่เข้าร่วมในโครงการวิจัย โดยทางผู้สนับสนุนงานวิจัยจะเป็นผู้ออกค่าใช้จ่ายทั้งหมด อาสาสมัครจะได้รับค่าเดินทางหรือค่าเสียเวลาเป็นเงินจำนวนหนึ่ง

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

ชุดที่ 1 การตัดสินใจเข้าร่วมโครงการศึกษาวิจัยยา

ท่านเคยเป็นอาสาสมัครเข้าร่วมโครงการวิจัยยา มาก่อนหรือไม่ ☐ เคย ☐ ไม่เคย

จากความรู้เกี่ยวกับโครงการศึกษาวิจัยยาที่ท่านได้รับแล้วข้างต้น หากท่านได้รับเชิญให้เข้าร่วมโครงการศึก
ทางคลินิกที่อาจจะมีขึ้น**ในอนาคต** ท่านมีความสนใจที่จะเข้าร่วมโครงการศึกษาวิจัยที่อาจจะมีขึ้น**ในอนาคต**นี้ห
กรุณาเลือกตอบเพียงหนึ่งข้อ

☐ **ไม่สนใจ**เข้าร่วม (0)

☐ สนใจเข้าร่วม (1) โปรดระบุระดับความสนใจ โดยการทำเครื่องหมายกากบาท (X) ลงบน
ตัวเลขด้านล่าง

(สนใจน้อย) 1 ------ 2 ------ 3 ------ 4 ------ 5 ------ 6 ------ 7 ------ 8 ------ 9 ------ 10 (สนใจมาก)

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

ชุดที่ 2 ข้อมูลทั่วไป

1. เพศ

☐ เพศชาย (0) ☐ เพศหญิง (1)

2. อายุ

☐ 18 – 25 ปี (1) ☐ 26 – 30 ปี (2) ☐ 31 – 35 ปี (3) ☐ 36 – 40 ปี (4)

☐ 41 – 45 ปี (5) ☐ 46 – 50 ปี (6) ☐ 51 – 55 ปี (7) ☐ 56 – 60 ปี (8)

3. สถานภาพสมรส

☐ โสด (0) ☐ สมรส (1) ☐ หย่า (2) ☐ หม้าย (3)

4. ระดับการศึกษาสูงสุด

☐ มัธยมศึกษาตอนต้นหรือต่ำกว่า (1) ☐ มัธยมศึกษาตอนปลาย หรือ ปวช (2)

☐ ปวสหรืออนุปริญญา (3) ☐ ปริญญาตรีหรือสูงกว่า (4)

5. รายได้ต่อเดือนของท่าน

☐ น้อยกว่าหรือเท่ากับ 5,000 บาท (1) ☐ 5,001 – 10,000 บาท (2)

☐ 10,001 – 15,000 บาท (3) ☐ 15,001 – 20,000 บาท (4)

☐ 20,001 – 25,000 บาท (5) ☐ 25,001 – 30,000 บาท (6)

☐ มากกว่า 30,000 บาท (7)

6. อาชีพของท่าน

☐ นักเรียน/นักศึกษา (0) ☐ ข้าราชการ (1) ☐ รัฐวิสาหกิจ (2)

☐ ลูกจ้างบริษัทเอกชน (3) ☐ ประกอบธุรกิจส่วนตัวหรือค้าขาย (4)

☐ เกษตรกรรม (5) ☐ ไม่ได้ประกอบอาชีพ (6) ☐ อื่นๆ (7).....

7. ใครเป็นผู้ออกค่าใช้จ่ายค่ารักษาพยาบาลของท่าน

☐ ตัวท่านเอง (0) ☐ ประกันสังคม (1)

☐ ประกันสุขภาพกลุ่ม (1) ☐ ประกันสุขภาพถ้วนหน้า (30 บาท) (1)

☐ สวัสดิการรัฐวิสาหกิจ (1) ☐ สวัสดิการข้าราชการ (1)

☐ อื่นๆ (1).....

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

ชุดที่ 3 ความเชื่อด้านสุขภาพต่อการเข้าร่วมโครงการวิจัยยา กรุณาวงกลม ในช่องที่ตรงกับความรู้สึกของท่านมากที่สุดเพียงหนึ่งช่อง

1 = ไม่เห็นด้วยมากที่สุด 2 = ไม่เห็นด้วย 3 = เห็นด้วย 4 = เห็นด้วยมากที่สุด

ตอนที่ 1 การวัดโอกาสเสี่ยงต่อโรคแทรกซ้อนจากโรคติดเชื้อเอชไอวีและการเข้าร่วมโครงการวิจัยทางคลินิก

	ฉันเชื่อว่า...	**ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด**			
1.*	การรับประทานยาต้านไวรัสอย่างสม่ำเสมอสามารถชะลอการเกิดโรคแทรกซ้อนได้	1	2	3	4
2.*	การมาพบแพทย์ตามกำหนด สามารถชะลอการเกิดโรคแทรกซ้อนได้	1	2	3	4
3.*	การเจาะเลือดตรวจระดับภูมิต้านทานและปริมาณเชื้อไวรัสเป็นประจำสามารถชะลอการเกิดโรคแทรกซ้อนได้	1	2	3	4
4.*	การรักษาสุขภาพร่างกายให้แข็งแรงอยู่เสมอสามารถชะลอการเกิดโรคแทรกซ้อนได้	1	2	3	4

ตอนที่ 2 การวัดความรุนแรงต่อโรคแทรกซ้อนและการเข้าร่วมโครงการวิจัยยา

		ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
1.	ฉันเชื่อว่าการเข้าร่วมโครงการวิจัย ทำให้ฉันรู้สึกกังวลใจ	1	2	3	4
2.	หากฉัน**ไม่**เข้าร่วมโครงการวิจัย ฉันเชื่อว่าอาการป่วยของฉันจะแย่ลง	1	2	3	4
3.	หากฉันเข้าร่วมโครงการวิจัย ฉันเชื่อว่าฉันอาจถูกสังคมรังเกียจ	1	2	3	4
4.	หากฉันเข้าร่วมโครงการวิจัย ฉันเชื่อว่าความสัมพันธ์ของฉันกับสมาชิกในครอบครัว เพื่อนฝูง หรือ เพื่อนร่วมงาน จะมีปัญหาเช่นกัน	1	2	3	4

ตอนที่ 3 การวัดประโยชน์ที่คาดว่าจะได้รับจากการเข้าร่วมโครงการศึกษาวิจัยยา

		ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
1.	ฉันเชื่อว่าการเข้าร่วมโครงการวิจัย จะทำให้ฉันได้รับการดูแลทั้งทางด้านร่างกายและจิตใจดีกว่าผู้ป่วยที่ไม่ได้เข้าร่วมโครงการวิจัย	1	2	3	4
2.	ฉันเชื่อว่าการเข้าร่วมโครงการวิจัย ทำให้ฉันสามารถเข้าถึงการรักษาที่ดีกว่าการรักษาทั่วไป	1	2	3	4

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

		ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
3.	ฉันเชื่อว่ายาวิจัยที่จะได้รับจากการเข้าร่วมโครงการ มีประสิทธิภาพในการรักษาโรค	1	2	3	4
4.	ฉันเชื่อว่าโครงการวิจัยจะให้เงินค่าตอบแทน เช่น ค่าเดินทาง หรือ ค่าเสียเวลา	1	2	3	4
5.	ฉันเชื่อว่าฉันจะได้รับการรักษาโดยไม่เสียค่าใช้จ่าย หากฉันตัดสินใจเข้าร่วมโครงการ	1	2	3	4
6.	ฉันเชื่อว่าความรู้ที่ได้รับจากผลการวิจัยจะเป็นประโยชน์ต่อผู้ป่วยในอนาคต	1	2	3	4

ตอนที่ 4 การวัดผลเสียที่คาดว่าจะได้รับจากการเข้าร่วมโครงการศึกษาวิจัยยา

		ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
1.	ฉันเชื่อว่า ฉันอาจได้รับอันตรายจากยาวิจัยที่เป็นยาชนิดใหม่และไม่เคยทดสอบมาก่อน	1	2	3	4
2.	ฉันเชื่อว่า ฉันอาจได้รับอันตรายจากขั้นตอนการตรวจวินิจฉัยในโครงการวิจัย เช่น การเจาะเลือด	1	2	3	4
3.	ฉันเชื่อว่า การเข้าร่วมโครงการวิจัยอาจส่งผลกระทบต่อชีวิตประจำวันของฉัน เช่น ทำให้เสียงานหรือเสียรายได้	1	2	3	4
4.	ฉันเชื่อว่า การเข้าร่วมโครงการวิจัยทำให้ฉันเสียเวลา	1	2	3	4
5.	ฉันเชื่อว่า ฉันจะได้รับความลำบากในการเดินทางมาที่สถานศึกษาวิจัย	1	2	3	4
6.	ฉันรู้สึกไม่สบายใจหากต้องบอกข้อมูลส่วนตัวให้ผู้วิจัยทราบ	1	2	3	4
7.	ฉันเชื่อว่า ฉันจะเป็นเสมือนหนูทดลองยา	1	2	3	4
8.	ฉันเชื่อว่า ผู้วิจัยไม่ควรทดลองยาวิจัยชนิดใหม่กับฉัน	1	2	3	4
9.	ฉันเชื่อว่า หากฉันปฏิเสธการเข้าร่วมโครงการวิจัย ฉันอาจไม่ได้รับการรักษาที่เหมาะสม	1	2	3	4
10.*	ฉันเชื่อในความสามารถของผู้วิจัยว่าจะสามารถลดความเสี่ยงที่จะเกิดอันตรายจากการได้รับยาวิจัยได้	1	2	3	4
11.*	ฉันเชื่อถือในชื่อเสียงด้านการรักษาของโรงพยาบาลรามาธิบดี	1	2	3	4

หมายเลขอาสาสมัคร _____

วันที่ _____/_____/_____

ตอนที่ 5 การวัดสิ่งเร้าต่อการเข้าร่วมโครงการวิจัยยา

		ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
1.	ฉันควรขอคำแนะนำจากแพทย์ก่อนตัดสินใจว่าจะเข้าร่วมโครงการวิจัย	1	2	3	4
2.	ฉันควรขอคำแนะนำจากสมาชิกในครอบครัวก่อนตัดสินใจว่าจะเข้าร่วมโครงการวิจัย	1	2	3	4
3.	ฉันควรได้รับข้อมูลเกี่ยวกับยาวิจัย ก่อนตัดสินใจว่าจะเข้าร่วมโครงการวิจัย	1	2	3	4
4.	ฉันควรมีความรู้ว่าโครงการวิจัยทางคลินิกคืออะไรจากพยาบาลวิจัย ก่อนตัดสินใจว่าจะเข้าร่วมโครงการวิจัย	1	2	3	4

ตอนที่ 6 การวัดความสามารถของตนเองต่อการเข้าร่วมโครงการวิจัยยา

	ฉันเชื่อว่า...	ไม่เห็นด้วยมากที่สุด – เห็นด้วยมากที่สุด			
1.	ฉันสามารถมาพบผู้วิจัยได้ตามกำหนดการทุกครั้ง	1	2	3	4
2.	ฉันสามารถรับการตรวจเลือดตามที่กำหนดไว้ในโครงการวิจัยได้	1	2	3	4
3.	ฉันสามารถแจ้งอาการป่วยที่ฉันเป็นอยู่และยาที่ได้รับระหว่างเข้าร่วมโครงการวิจัยแก่ผู้วิจัยได้อย่างแม่นยำ	1	2	3	4
4.	ฉันสามารถทานยาวิจัยตรงตามเวลาที่กำหนดไว้ในโครงการวิจัยได้	1	2	3	4
5.	ฉันสามารถบอกข้อมูลส่วนตัวให้แก่ผู้วิจัยได้	1	2	3	4

ขอบพระคุณที่ตอบแบบสอบถาม

BIOGRAPHY

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