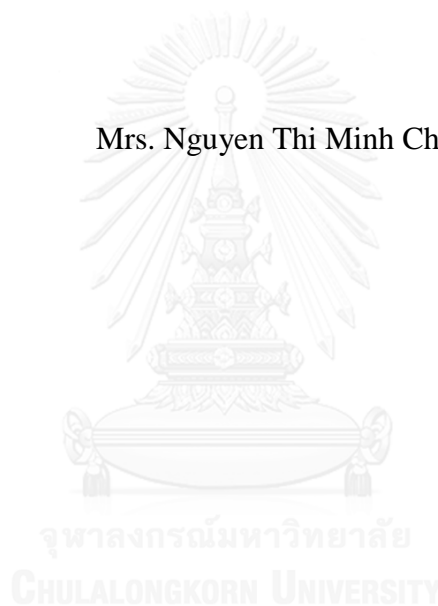


THE EFFECT OF SUPPORTIVE EDUCATIVE NURSING PROGRAM ON HbA1c
LEVEL IN VIETNAMESE WITH UNCONTROLLED
TYPE 2 DIABETES MELLITUS

Mrs. Nguyen Thi Minh Chinh



บทคัดย่อและแฟ้มข้อมูลฉบับเต็มของวิทยานิพนธ์ตั้งแต่ปีการศึกษา 2554 ที่ให้บริการในคลังปัญญาจุฬาฯ (CUIR)
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ผลของโปรแกรมการพยาบาลแบบสนับสนุนและให้ความรู้ต่อระดับน้ำตาลเฉลี่ยสะสมในเลือด
ในผู้ป่วยเบาหวานชนิดที่ 2 ที่ควบคุมโรคไม่ได้ ในชาวเวียดนาม



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 ผลของโปรแกรมการพยาบาลแบบสนับสนุนและให้ความรู้ต่อระดับน้ำตาลเฉลี่ยสะสมใน
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 พยาบาลแบบสนับสนุนและให้ความรู้ต่อระดับ HbA1c ในผู้ป่วยโรคเบาหวานชนิดที่ 2
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 คน แบ่งกลุ่มแบบสุ่มเป็นกลุ่มทดลองจำนวน 46 คน
 ซึ่งได้รับโปรแกรมการพยาบาลแบบให้ความรู้เป็นเวลาต่อเนื่อง 5
 สัปดาห์และโทรศัพท์ติดตามเพื่อให้การสนับสนุน เป็นเวลา 11 สัปดาห์ ส่วนกลุ่มควบคุมจำนวน
 46 คน ได้รับการพยาบาลตามปกติ กลุ่มตัวอย่างได้รับการเจาะเลือดเพื่อประเมินระดับ HbA1c
 ในเบื้องต้นและภายหลังการได้รับโปรแกรม 3 เดือน โดยมีกลุ่มตัวอย่างทั้งหมด 84 คน
 ที่เข้าร่วมการวิจัยจนเสร็จสิ้น แบ่งเป็นกลุ่มทดลองจำนวน 41 คน และกลุ่มควบคุมจำนวน 43 คน

ผลการศึกษาพบว่า ค่าเฉลี่ยของระดับ HbA1c
 ในกลุ่มทดลองลดลงอย่างมีนัยสำคัญในเดือนที่ 3
 ภายหลังได้รับโปรแกรมการพยาบาลแบบสนับสนุนและให้ความรู้ ($t=5.53, p<.05$)
 ค่าเฉลี่ยของระดับ HbA1c ในกลุ่มทดลองต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญในเดือนที่ 3
 เมื่อเทียบกับผลการตรวจระดับน้ำตาลในเลือดเบื้องต้น ($t=3.27, p<.05$)
 โปรแกรมการพยาบาลแบบสนับสนุนและให้ความรู้ร่วมกับการมีส่วนร่วมอย่างจริงจังของพยาบาล
 เป็นแนวทางที่ดีที่จะช่วยเพิ่มความสามารถในการดูแลตนเองของผู้ป่วยในการควบคุมระดับน้ำตาล
 ในกระแสเลือดได้

สาขาวิชา พยาบาลศาสตร์

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ลายมือชื่อนิติกร

ลายมือชื่อ อ.ที่ปรึกษาหลัก

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NGUYEN THI MINH CHINH: THE EFFECT OF SUPPORTIVE EDUCATIVE NURSING PROGRAM ON HbA1c LEVEL IN VIETNAMESE WITH UNCONTROLLED TYPE 2 DIABETES MELLITUS. ADVISOR: ASSOC. PROF. SUREEPORN THANASILP, D.N.S., CO-ADVISOR: ASST. PROF. SUNIDA PREECHAWONG, Ph.D., 167 pp.

A randomized controlled trial aimed to determine the effect of a supportive educative nursing program (SENP) on Glycated hemoglobin (HbA1c) level in Vietnamese with uncontrolled type 2 diabetic mellitus was conducted in outpatient clinic at Namdinh General Hospital, Vietnam, from October 2015 to January 2016. Ninety two persons with uncontrolled type 2 diabetes aged over 18 years were randomly allocated to two groups: intervention (n= 46), and control (n=46). The experimental group received supportive educative nursing program which consisted of 5 weekly sessions of education and 11 weekly telephone calls. The control group received only routine care. A blood sample was analyzed to determine HbA1c level at baseline and 3 months after. Totally eighty four people with type 2 diabetes: intervention (n=41) and control group (n=43) completed study. The finding showed that the mean of HbA1c level in experimental group was significantly decreased at 3 months after undergoing program ($t=5.53$, $p<.05$). The mean of HbA1c level at 3 months after baseline in the experimental group was significantly lower than that of the control group ($t=3.27$, $p<.05$). The supportive educative nursing program with active participation strategy is the best method to help patients increase their self-care agency in order to improve their glyceemic control.

Field of Study: Nursing Science

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Student's Signature

Advisor's Signature

Co-Advisor's Signature

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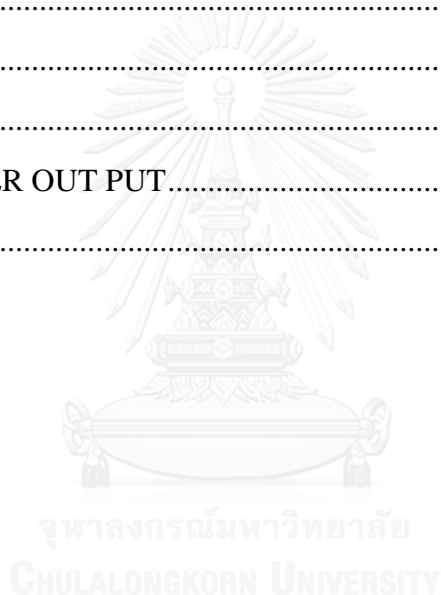
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CHAPTER I

INTRODUCTION

Background and significance of the study

Diabetes is becoming a pandemic with increased need for health care (WHO, 2016). In Vietnam, the prevalence of diabetes was increased dramatically and is estimated to reach 8 million of people with diabetes in 2025 between the ages of 30 to 60 years (Ministry of Health, 2016). Since 2006, diabetes has become the fourth cause of death (Ta, 2006). Mortality from diabetes-related complications is due to poorly controlled diabetes. The financial expenditure related to diabetes care is estimated to be about 3 to 6% of the total nation budgets for healthcare (Ministry of Health, 2016).

Type 2 diabetes is the most common type of diabetes. In type 2 diabetes, body cells cannot metabolize glucose properly, because they are resistant to insulin and/or the pancreas do not produce enough insulin for the body's needs. This leads to an abnormally high blood glucose level which related to many serious complications (American Diabetes Association, 2016). Therefore, controlling blood glucose level are important factors in delaying the onset and progression of diabetes-related complications (Stratton et al., 2000). The blood glucose level is controlled as glycated hemoglobin (HbA1c) level equal or less than 7%. (American Diabetes Association, 2016).

Controlling and prevention of diabetic long term complications as well as reduction of healthcare cost were reflected through controlling the HbA1c level in patients with type 2 diabetes (Woolf et al., 2000). Each 1% reduction in HbA1c level was associated with reductions in risk of deaths related to diabetes (21%), myocardial

infarction (14%), and microvascular complications (37%) (Stratton et al., 2000). Conversely, if the HbA1c level increased by 1%, it was associated with 7% increase in expected health care cost (Gilmer, O'Connor, Manning, & Rush, 1997). Additionally, the strikingly greater risk of death from cardiovascular disease, ischemic heart disease, and all causes mortality when the HbA1c level increased over 7% (Khaw et al., 2004).

However, since 2008, the Vietnamese Government has added nearly 15 million dollars for prevention and control of diabetes (Ministry of Health, 2016). Despite this increase in budget, 81.5% of patients with type 2 diabetes had HbA1c levels higher than 7% (Luong & Nguyen, 2012). In addition, 61.2% of type 2 diabetic patients have complications including cardiovascular complications (43.6%), neurologic complications (50.8%), and renal complications (35.5%) (Pham, Nguyen, & Nguyen, 2012). The mean treatment cost for patients with diabetic complications was 3.2 times higher than that of patients with noncomplications (Pham et al., 2012). The incidence and consequences of uncontrolled HbA1c level suggested need more strategies in diabetes care to improve glycemic control for Vietnamese patients.

Previous studies showed that the reason for poorly controlling HbA1c level was in concern with health behavior (Shrivastava, Shrivastava, & Ramasamy, 2013). Treatment of diabetes is a 24-hour-a-day activity and often include changes in lifestyle, therefore; patients with type 2 diabetes, must take responsibility for their own disease and adopt recommended health behaviors (Beaser & Campbell, 2005). Patients must be able to initiate and perform actions on their own behalf to meet the therapeutic regimen of a healthy diet, exercise, blood glucose monitoring, and taking medication in order to attain the goal of diabetes treatment –controlling HbA1c level (Funnell & Anderson, 2004).

According to a systematic review and meta-analysis, self-care was related factor in controlling HbA1c level in people with type 2 diabetes (Shrivastava et al., 2013). A study from Gao et al. (2013) also reported that self-care is related with HbA1c levels. Based on their analyses, a significant predictor of poor controlling HbA1c levels in type 2 diabetes patients is self-care (Gao et al., 2013). In addition, this result was similarly found in other correlational studies where self-care in diabetes was negatively correlated with HbA1c level in type 2 diabetic patients (Kamuhabwa & Charles, 2014; Khattab, Khader, Al-Khawaldeh, & Ajlouni, 2010). Moreover, the similar results was found in a descriptive study on 400 Vietnamese type 2 diabetes patients. The self-care was the major factor related to HbA1c levels (Nguyen & Nguyen, 2014).

One of the basic theories in nursing for diabetic patients, is Orem's self-care theory (Orem, 2001). This theory expresses the idea that human being are individuals who have some degree of self-thought. The patient is not just a passive recipient of health services, but a strong, reliable and responsible being with power to make decisions related to self-care. In applying this theory to type 2 diabetic patients, they need to increase their knowledge about diabetes self-care principles including continuous control of HbA1c level to prevent early and late complications of the disease, which ensures a longer life for the patient and a reduction in health care costs. Undoubtedly, achieving such goals requires dynamic and continuous public participation. Without patient education and self-care, health care costs will continue to increase, and quality of life for the patients will suffer further decline (American Diabetes Association, 2016).

Diabetes is one of the diseases where the main treatment is the patient's responsibility. Therefore, conducting patient education on self-care can reduce

problems caused by the disease appears to be essential. Unfortunately, existing self-care interventions to decrease HbA1c level in type 2 diabetes had the effect size as modest (ES =0.36; 95% CI 0.21–0.51) (Minet, Moller, Vach, Wagner, & Henriksen, 2010). The reviews and meta-analyses on effect strategies for decreasing HbA1c levels in type 2 diabetes patients have found that the interventions are inadequately described in the studies (Fan & Sidani, 2009). A few of the studies reported using theoretical frameworks as the basic for planning the interventions (Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003). Using the intervention based theory would be useful to deeply understand the application of the study's findings in clinical practice (Burns, & Grove, 2009). Thus, interventions guided by a theoretical framework needs to be conduct on decreasing HbA1c levels in type 2 diabetes patients.

Moreover, most of studies lack of a control group and randomization in research design (Fan & Sidani, 2009; Likiratcharoen, 2000). It is difficult to draw a conclusion about the effectiveness of the programs. Furthermore, most of researchers used fasting plasma glucose as indicators, which may include on error concerning in long-term of glycemic control (Keeratiyutawong, Hanucharurnkul, Boonchay, Phumleng, & Muangkae, 2005).

In Vietnam, common nursing activities in the outpatient department for type 2 diabetic patients include measuring blood pressure and body weight, providing general care according to medical instruction, and giving basic information related to the medical treatment after the patient receive treatment from the physician. Diabetes self-management may cause feelings of burnout in the patients because it requires the patients to continually keep track of their self-care. The majority of problems of diabetes self-care concern the difficulty of ensuring long-term maintenance of behavior change.

Currently, little attention has been made by health professionals to facilitate self-care activities into the nursing program for type 2 diabetes outpatients in Vietnamese studies. Only one quasi - experimental one group pretest-posttest study was found (Trần & Nguyễn, 2009). This study used a program with didactic method focusing on the general knowledge of disease and compliance to the treatment regimen on one week. However, Glasgow et al (2001) suggested that successful diabetes self-care program should provide consistent follow-up procedures in program (Glasgow et al., 2001). Furthermore, in systematic review indicated that diabetes education was most effective when combined with health-care provider interaction, medication adjustment and reinforcement of educational messages (Norris, Engelgau, & Narayan, 2001). Besides that, Whittemore et al (2000) and D'Eramo-Melkus et al (2004) indicated that cultural sensitivities were one of the important contributing elements for effectiveness of diabetes intervention program (D'Eramo-Melkus et al., 2004; Whittemore, 2000).

A randomized controlled trial was aimed to test the effect of a nursing program on controlling HbA1c level in Vietnamese type 2 diabetes patients. This program was guided by Orem's conceptual model of nursing to help patients in learning, managing their diabetes self-care tasks, and encouraging behavior change. This program was based on cultural sensitivities to build the content to facilitate with Vietnamese culture and context. The program expected that can help patients increasing their ability in performing their self-care tasks. From that, this intervention expects to help patients control their disease complications and delays their disease progress. Moreover, this program can be used as guidelines for nurses in enhancing HbA1c level control in this group of patients.

Objectives of the Study

General objective

1. To determine the effect of a supportive educative nursing program on HbA1c level in Vietnamese with uncontrolled type 2 diabetes mellitus

Specific objective

1. To compare HbA1c level of Vietnamese with uncontrolled type 2 diabetes mellitus before and after receiving the supportive educative nursing program

2. To compare HbA1c level in Vietnamese with uncontrolled type 2 diabetes who receive the supportive educative nursing program and those who receive routine care

Research Questions

1. What are the differences in HbA1c level in Vietnamese with uncontrolled type 2 diabetes mellitus before and after receiving a supportive educative nursing program?

2. What are the differences in HbA1c level between Vietnamese with uncontrolled type 2 diabetes mellitus who receive supportive educative nursing program and those who receive only routine care?

Theoretical framework

In this research study, Orem's Self-Care Deficit Nursing Theory (SCDNT) (2001) was utilized as the theoretical framework. Orem's general theory is made up of three related theories: the theory of self-care, the theory of self-care deficit, and the theory of nursing systems (Orem, 2001). The study utilized Orem's related theory of self-care, which describes how and why people care for themselves to improve their well-being (Marriner-Tomey & Alligood, 2006).

The theory of self-care states that self-care is a human regulatory function that individuals must perform themselves to maintain life, health, development, and well-being (Marriner-Tomey & Alligood, 2006). Self-care must be learned and performed deliberately and continuously to regulate function related to regulatory requirements (Marriner-Tomey & Alligood, 2006). Regulatory requirements are related to stages of growth and development, states of health, levels of energy expenditure, and environmental factors (Marriner-Tomey & Alligood, 2006).

The theory of self-care deficit is related to the limitations of mature or maturing persons to perform self-care (Marriner-Tomey & Alligood, 2006). Self-care is defined as the relationship between one's therapeutic self-care demands and their powers of self-care agency, or self-care ability (Marriner-Tomey & Alligood, 2006). Self-care deficit is the limitations or inability of an individual to provide self-care performance or measures (Marriner-Tomey & Alligood, 2006). The development of self-care agency constitutes the development of self-care capabilities (Marriner-Tomey & Alligood, 2006).

In the early 1970's, Orem identified the concept of self-care agency as a condition which is characteristic of human beings to initiate and sustain self-care, but it was only defined and conceptualized by Orem in the 1980 and 1990s. According to Orem (1991), self-care agency is defined as "the complex acquired ability to meet one's continuing requirements for care that regulates life processes, maintains and promotes integrity of human structure and functioning and human development, and promotes wellbeing" (Orem, 1991). This concept is used throughout the theory to interpret an individual's capabilities for self-care actions to achieve a goal-oriented outcome.

Self-care agency is described by Orem (1980, 1985, and 1991) as having three types of personal trait components: foundational, enabling, and operational. Foundational traits include personal capabilities regarding sensation, perception, memory, and orientation. Any disturbance in one of these capabilities affects one's deliberate actions. Enabling traits are the self-care agency power components consisting of the specific personal capabilities to engage in self-care such as knowledge, self-care skills, health value, energy, mobility, motivation, decision-making, interpersonal skills, persistence, and purposeful goals. Operational traits are the personal capabilities for recognition of personal and environmental conditions and factors significant to one's self-care actions (estimative operations); judgment and decision-making about what one can, should, and actually does do (transitional operations); and the actual performance of self-care actions (productive operations) (Orem, 1980, 1985, 1991).

Self-care agency is one of the key concepts in Orem's SCDNT and it is acquired throughout the lifespan. Orem also emphasized that personal and environmental basic conditioning factors influence self-care agency as well as self-care needs. Orem listed ten basic conditioning factors: age, gender, developmental level, health state, sociocultural orientation, health care system, family system, patterns of living, environmental factors, and the availability and adequacy of resources. The conditioning factors are too broad; any personal, environmental, and health-related factors may influence the development and exercise of self-care agency (e.g. one's knowledge, skills, experience, resources, interest, desire, goals orientation, or disturbance of human integrity functioning such as memory, perception, sensation, orientations, and organic conditions). Orem's conceptualization of self-care agency suggests that the reason that

individuals do not act appropriately may not be because they do not know how to perform self-care actions but, rather, because self-care agency varies with one's physical, cognitive, and psychosocial development.

The theory of nursing systems proposes that nursing is the human action or action systems for persons with health associated limitations of self-care (Marriner-Tomey & Alligood, 2006). Helping methods related to nursing were defined as a series of actions that, if performed, would overcome or compensate for the health related limitations of an individual's self-care (Marriner-Tomey & Alligood, 2006). Nurses use the helping methods singularly or in combination to assist the person in their self-care (Marriner-Tomey & Alligood, 2006). These helping methods include acting for or doing for another, guiding and directing, providing physical or psychological support, providing and maintaining an environment that supports personal development, and teaching (Marriner-Tomey & Alligood, 2006). Nursing agency includes deliberate action, including intentionality, and operations of diagnosis, prescription, and regulation (Marriner-Tomey & Alligood, 2006). The goal of nursing agency is to compensate or overcome known or emerging health-associated limitations for patients regarding their self-care (Marriner-Tomey & Alligood, 2006). Self-care agency is the acquired ability of mature persons to know and meet the requirements of human functioning and development (Marriner-Tomey & Alligood, 2006). Self-care agency is the result of developmental processes, and is promoted when the person is able to perform the self-care that is required to support human functioning, development, and health (Slusher, 1999). The researcher collected data from the sample population, related to their self-care agency or their ability to provide diabetic care for themselves. All individuals are assumed to have self-care requisites, required actions that regulate

factors that affect human functioning, development and health (Slusher, 1999). Self-care requisites are formulated and expressed insights about actions to be performed that are known or hypothesized to be necessary in the maintenance of life, healthful functioning, continuing personal development and well-being. They are the reasons why self-care is undertaken (Orem, 2001).

Orem divides self-care requisites in three parts: universal, developmental and health deviation. In all self-care requisites, health deviation self-care requisites are needs resulting from illness, injury and disease or its treatment. “The characteristics of health deviation as conditions extending over time determine the kinds of care demands that individuals experiences as they live with the effects of pathological conditions and live through their durations” (Orem, 2001). If one understands the health deviation self-care requisites of the patient, goals can be established that attribute towards health maintenance, healthful functioning, personal development and well-being. The goals also drive actions (care measures) needed to meet therapeutic self-care demand.

Therapeutic self-care demand “consists of the summation of care measures necessary at specific times or over a duration of time for meeting all of an individual’s known self-care requisites” specifically for existent conditions and circumstances using actions and methods that create a balance between health, life, and well-being (Marriner-Tomey & Alligood, 2006).

Persons perform deliberate actions that are directed to their own care needs thereby producing actions termed as self-care, however, in some situations the needs of the individual will exceed that person’s abilities to care for themselves. Nursing, then, is the institutional vehicle by which care is administered to the person with a self-care deficit. With that, Orem developed the theory of nursing systems to which

describes the series of actions a nurse must take to meet the patient's self-care requisites and self-care demands as determined by the patient. Orem created three variations in the nursing system. The supportive-educative- the patient can meet self-care demands, but needs help in decision-making, behavior control or knowledge acquisition.

In type 2 diabetes outpatients, self-care requisites is health deviation self-care requisites that are the needs resulting from abnormal blood glucose and diabetes treatment regimens. The goals of diabetes care aim to keep blood glucose level at a normal or near normal level and preventing long-term diabetes complications. To achieve these goals, therapeutic self-care demand need be met. Therapeutic self-care demands in type 2 diabetes patients consists of self-care actions which include diabetic patients monitoring blood glucose, eating nutritiously, doing exercise, and taking medications appropriately over time. It also includes interpreting health measurement data (HbA1c levels) and using the results for self-care decision-making.

The study attempted to identify and examine areas of self-care deficit and self-care demands in the sample population, in order to set an appropriate short term goals and long term goal. From that, nurse can provides diabetes knowledge to improve patient's understanding and belief on their abilities and capacities to be confident in performing self-care behaviors to achieve target HbA1c level. Moreover, nurse enhance patient's self-care agency to perform and maintain all knowledge and information that they receive at education process. Nurse support person with type 2 diabetes by using the weekly telephone call to explore the patient's perform self-care, their problems and their solutions last 7 days. Nurse guide patients to recognize their problems and choose the big problem that they must be priority to resolve. Then, patients be supported to

take the best solution for that problem, motivate to use appropriate environment supports, and encourage to apply this solution.

The contents of the supportive educative nursing program were developed according to Diabetes Education Standard from American Diabetes Association (American Diabetes Association, 2016) and review from existing diabetes education program and Vietnamese situation. This program was delivered through the actions of 1) assessing self-care deficit and self-care demands, 2) providing good environment, 3) teaching knowledge and skills related exercise, diet, medication, blood glucose monitoring, 4) supporting and motivating the beliefs and values to maintain self-care 5) evaluating the obstacles and problems during the intervention. In this study, HbA1c was considered as a product of individual's confidential to perform diabetes treatment regimen in daily life. In summary, this program was designed as theory-based intervention program for HbA1c level control in type 2 diabetes outpatients as show in **Figure 1**.

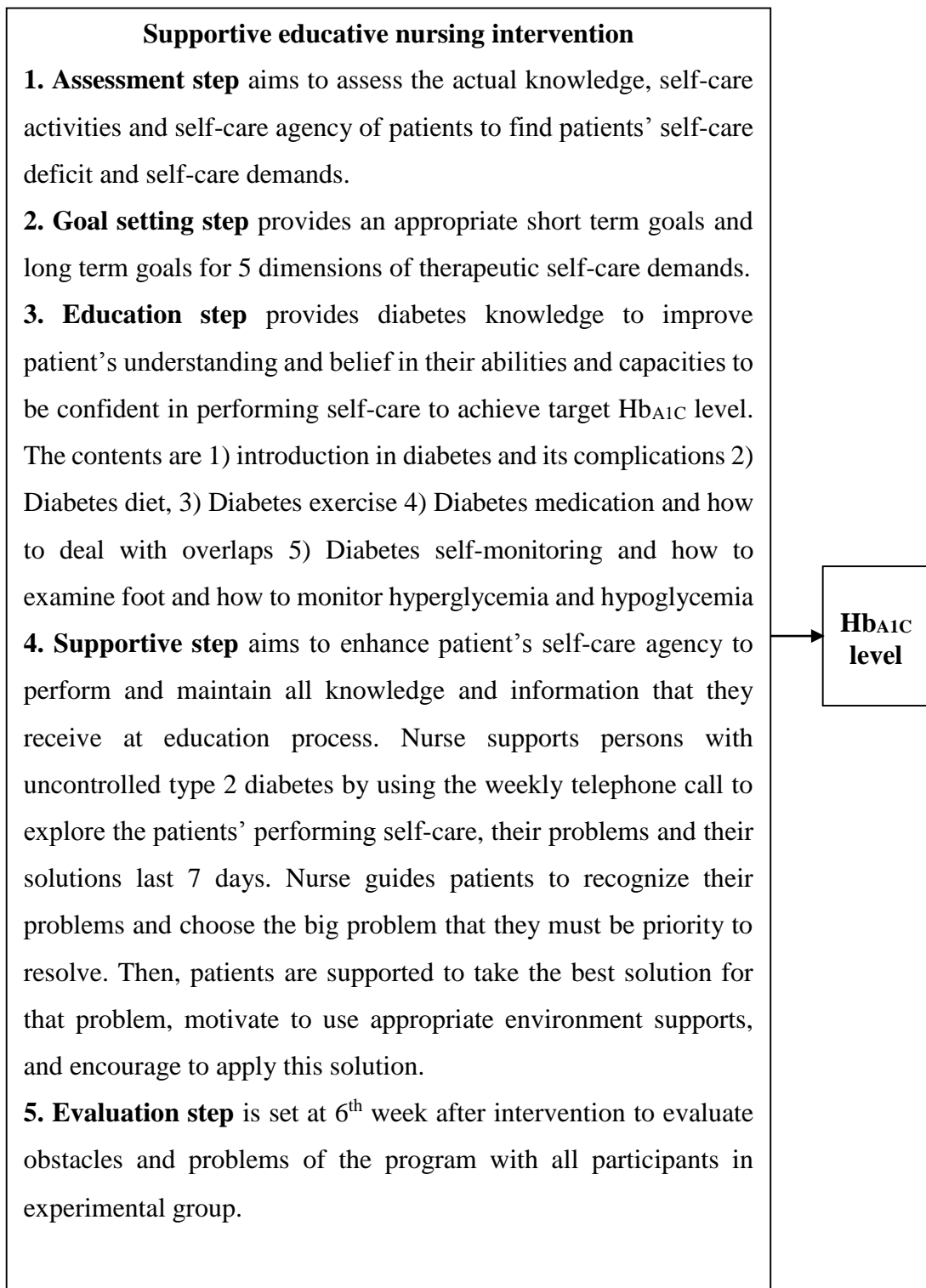


Figure 1: Theoretical framework of supportive educative nursing intervention on HbA1c level in uncontrolled type 2 diabetes patients

Hypotheses and rationales

Self-care was the best and significant predicting factor of HbA1c level (Gao et al., 2013; Khattab et al., 2010). Type 2 diabetes patients need to maintain their self-care behaviors to control their HbA1c level and prevent diabetic complications. The diabetes self-care behaviors included diet, exercise, glucose monitoring and intake of oral medications (Shrivastava et al., 2013). The patients need to develop self-care agency in order to maintain their self-care behaviors (Orem, 2001). In this study, an intervention based on Orem's conceptual framework was proposed to enhance patients' self-care agency through educating and supporting patients the knowledge and practice self-care actions such as diet control, doing exercise, self-monitoring and medication taking. Moreover, this program used telephone follow-up to motivate and maintain patients' self-care behaviors by providing consistency helping patients solve their health problems and overlaps in self-care activities and stress in adhere self-care behaviors. From that, this program help patients maintain their HbA1c level with the acceptable range. The HbA1c reflected the mean plasma glucose concentration and over the previous 2 to 3 months (Cooper, Mullis, & Stewart, 1991). It proposed that longer period assessment, more exactly HbA1c level can reflect. As that reason, this study proposed following hypotheses:

Hypothesis 1: The participants with uncontrolled type 2 diabetes mellitus in the experimental group had lower HbA1c level after 3 months receiving a supportive educative nursing program than that of before.

Under Orem's theory, person with type 2 diabetes have health deviation self-care requisites that make them have therapeutic self-care demands in order to improve their wellbeing. To respond to this self-care demands of patients, nurse must use

professional care to enhance patients' ability to perform diabetes self-care in order to control their HbA1c level. The supportive educative nursing system help nurse empower patients to take care themselves. Nurse use a combination of helping techniques: teaching, support, guidance, motivating and providing to make patients be stronger confidence and to support patients an appropriate environment. By using those approaches, nurse enhance patients' self-care agency, from that, patients can improve their wellbeing by reducing their HbA1c level.

Hypothesis 2: The participants with uncontrolled type 2 diabetes mellitus in the experimental group had lower HbA1c level after 3 months than those in the control group.

The participants in experimental group receive the supportive educative nursing program that extra to routine care. The supportive educative nursing program was a self-care education program that provide specific diabetes self-care knowledge and skills, moreover, as appropriate environment for learning, caring were supported to patients by nurse that help patients be comfortable, confident and stronger in performing, enhancing and maintaining self-care activity at home. From that, the participants in experimental group had lower HbA1c level at 3 months than that of the control group.

Scope of the Study

A randomized controlled trial aimed to determine the effect of a supportive – educative nursing program on HbA1c level in persons with uncontrolled type 2 diabetes. The participants in this study were uncontrolled type 2 diabetes patients in Outpatient clinic at Namdinh General hospital who had diagnosed with type 2 diabetes at least 6 weeks, had fasting plasma glucose level over 130 mg/dL at nearly past 6 weeks

checking at hospital before entering the research, aged over 18 years, were prescribed with one kind diabetes medication, and without active severe complications or other serious diseases. The participants were randomly assigned into either experimental or control group. The experimental group was received supportive – educative nursing program and the control group was received routine care. The outcome measured HbA1c level at baseline and three months after.

Operational Definitions

1) **Hb_{A1C}** Glycated hemoglobin (HbA1c) referred to substances which are formed by any carbohydrate binding to hemoglobin in the red blood cell. The HbA1c presented the degree to which hemoglobin is glycosylated in erythrocytes and is expressed as a percentage of total hemoglobin concentration. The HbA1c level was determined by analyzing the patient's blood sample under a Biorad Diamat automated glycosylated hemoglobin analyzer (Biorad Laboratories, Hemel Hempstead, Hertfordshire, U.K.) with the Cation exchange chromatography method at the laboratory in Namdinh General Hospital.

2) **Supportive – educative nursing program** referred to the program that provided knowledge and telephone call follow up to motivate the diabetes self-care behavior based on Orem's theory to help type 2 diabetes outpatients enhance their self-care agency from that they have ability to perform the diabetes treatment regimen for at least 7 days per weeks, within 5 self-care activities that need to apply at home, to improve their HbA1c level control. The approaches were weekly training program within 5 weeks and telephone calls for follow-ups 11 times over 11 weeks from the beginning of study. The patients' self-care was measured by the Diabetes Appraisal of

Self-Care Agency Scale – Revised (DASAS-R) (Sousa, Zauszniewski, Zeller, & Neese, 2008).

3) Routine care was a common nursing activities in the outpatient department at Namdinh General Hospital, Vietnam for type 2 diabetes patients when they visited physician. These activities included providing assessing the vital sign, providing general knowledge on care according to medical instruction and giving basic information related medical treatment after patient receive treatment from the physician. The knowledge and information were given in the morning on the day of the physician's visit while the patients wait for laboratory results at the hall of clinic.

4) Person with uncontrolled type 2 diabetes mellitus were Vietnamese people who had medically diagnosed with type 2 diabetes at least 6 weeks and had fasting plasma glucose level over 130 mg/dL at nearly past 6 weeks checking at hospital before entering the program, in adult and older adult aged, both male and female.

Expected benefits

The program was a supportive-educative system that help the patient with knowledge acquisition, behavior control or change and decision-making. It based on what the patient needs and what the patient was able to do. Therefore, this program helps patients have deeply understand their current situation and recognize the benefit resources and the barriers in performing their self-care activities. From that, the patients can realized the direction that they should do to help them improve their conditions. By guiding, helping, supporting and motivating, nurse help person with type 2 diabetes mellitus be confident and more powerful to perform their self-care. Performing self-care helps person with type 2 diabetes mellitus control their HbA1c level. The study findings were contributed to the body of knowledge in nursing science as it provided a new

knowledge for clinical nursing practice and demonstrated any benefit of supportive-educative nursing program in patients with diabetes and newly completing a diabetes education program.



CHAPTER II

LITERATURE REVIEW

Literature was reviewed the literature in five areas. The first was the overview of type 2 diabetes mellitus. The second was the outcomes of uncontrolled type 2 diabetes care. The third was the therapeutic self-care demands of persons with uncontrolled type 2 diabetes mellitus. The fourth was factors related to HbA1c level. The last was intervention for improving HbA1c level control in uncontrolled type 2 diabetes patients.

1. The nature of type 2 diabetes mellitus

Type 2 diabetes, previously referred to as “non–insulin-dependent diabetes” or “adult-onset diabetes,” accounts for 90–95% of all diabetes. This form encompasses individuals who have insulin resistance and usually relative (rather than absolute) insulin deficiency (American Diabetes Association, 2016).

Diagnostic criteria for diabetes mellitus by the American Diabetes Association (ADA) are using independently to establish the diagnosis: (1) symptoms of diabetes plus random plasma glucose of 200 mg/dl (11.1 mmol/l) or more, (2) a fasting plasma glucose (FPG) of 126 mg/dl. (7.0 mmol/l) or more on more than one occasion, and (3) a 75g oral glucose tolerance test (OGTT) with a 2 hour value of 200 mg/dl (11.1 mmol/l) or more. The classic symptoms of diabetes include polyuria, polydipsia, and unexpected weight loss. Susceptibility to certain infections may also accompany chronic hyperglycemia (American Diabetes Association, 2016).

Type 2 diabetes, once known as adult-onset or noninsulin-dependent diabetes, is a chronic condition that affects the way body metabolizes sugar (glucose), body's main source of fuel. With type 2 diabetes, body either resists the effects of insulin — a

hormone that regulates the movement of sugar into cells — or doesn't produce enough insulin to maintain a normal glucose level. The insulin deficiencies can cause high blood glucose levels, which can contribute to ongoing health problems and complications. Untreated, type 2 diabetes can be life-threatening.

More common in adults and older adults, type 2 diabetes increasingly affects children as childhood obesity increases. There's no cure for type 2 diabetes, but patients can manage the condition by eating well, exercising and maintaining a healthy weight. If diet and exercise don't control your blood sugar, you may need diabetes medications or insulin therapy.

Now, diabetes is one of the most common diseases in the world. Diabetes is increasing very fast. In 1995 it was 135 million diabetic patient, predicted in 2010 would be approximately 221 million people with diabetes, but the actual in 2006 has exceeded forecasts – there was 246 million diabetic patients. In 2009, the International Diabetes Federation estimates that 285 million people around the world have diabetes. This total is expected to rise to 438 million within 20 years. Each year a further 7 million people develop diabetes (American Diabetes Association, 2016).

In Vietnam, the prevalence of diabetes doubled between 1994 and 2003 (Ta, 2006). Diabetes disease situation tends to increase especially in major cities. According to the results of a survey in 1999, the prevalence of diabetes in Hanoi, Hue, and Ho Chi Minh City respectively 1.2%, 0.96% and 2.52%, respectively. In 2012, the prevalence of diabetes in urban areas of four cities is 4.0%, the rate of glucose tolerance disorders was 7.0%. According to the results of Ta et al (2012) the prevalence of diabetes in the whole country is 5.7%. According to the report of Ministry of Health, the prevalence of diabetes was dramatically increased with 211% in past decade. The patients with

diabetic complications was 60% of diabetes patients in which there were 150 of cases death related to diabetes. Currently, the prevalence of diabetes in whole country is 6% (Ministry of Health, 2016).

The goal of treatment in type 2 diabetes is to achieve and maintain optimal blood glucose, lipid, and blood pressure (BP) levels to prevent or delay chronic complications of diabetes (American Diabetes Association, 2012). Many people with type 2 diabetes can achieve blood glucose control by following a nutritious meal plan and exercise program, losing excess weight, implementing necessary self-care behaviors, and taking oral medications, although others may need supplemental insulin (Centers for Disease Control and Prevention, 2014). Diet and physical activity are central to the management and prevention of type 2 diabetes because they help treat the associated glucose, lipid, blood pressure control abnormalities, as well as aid in weight loss and maintenance. When medications are used to control type 2 diabetes, they should augment lifestyle improvements, not replace them.

2. The outcome of uncontrolled type 2 diabetes mellitus care

The outcome of diabetes care was controlling the HbA1c level at acceptable range

2.1 Definition of HbA1c

Glycated hemoglobin (HbA1c) refers to substances which are formed by any carbohydrate binding to hemoglobin in the red blood cell. Glycohaemoglobin is also used as an alternative term to glycated hemoglobin.

The HbA1c fraction is the major part of glycated hemoglobin and is formed by the binding of glucose to the N valine terminal of the β chain of hemoglobin. This occurs in a two-step process. The initial and rapid process takes minutes to hours

to form an aldimine complex (Schiff base), a reaction which is reversible. Over subsequent days to weeks this unstable aldimine complex undergoes an Amadori rearrangement to form the stable ketoamine HbA1c. Glucose binding (glycation) occurs slowly and continuously over the life span of a red blood cell (120 days) (Cooper et al., 1991).

Because erythrocytes are freely permeable to glucose, the HbA1c level provides a glycemic history of the previous 120 days, the average erythrocyte life span. The HbA1c reflects the time averaged blood glucose over the preceding 1-3 months incorporating both pre- and postprandial glycemia (American Diabetes Association, 2016). In this study, in order to enhance the validity of findings, HbA1c was used to measure blood glucose level at 3 months to determine the status of glucose control in patients with type 2 diabetes. The patient was defined as having glycemic control when their HbA1c level is equal or less than 7%. The HbA1c is highly correlated to long-term complications of diabetes (retinopathy, nephropathy and neuropathy) (Stratton et al., 2000).

2.2 The consequences of uncontrolled HbA1c level

The Center for Disease Control (2009) reported high HbA1c level could lead to health complications such as heart disease, blindness, stroke, hypertension, kidney failure, poor dental health, nerve damage and peripheral vascular disease. If not treated early, diabetes can quickly progress and as a result cause death from diabetes-related complications. In 6 cohort studies including 27,996 participants with nonfasting glucose measurements, the results were demonstrated that each 1 mmol/l lower usual fasting glucose was associated with a 21% (95% CI 18–24%) lower risk of total stroke and a 23% (19–27%) lower risk of total ischemic heart disease (Asia Pacific Cohort

Studies Collaboration, 2004). Additional researches showed that there was a 16% reduction in cardiovascular events (combined fatal or nonfatal myocardial infarction and sudden death) when glycemic control as measured by HbA1c was accurate. Moreover, after 10 years of follow-up, those originally randomized to intensive glycemic control had significant long-term reductions in myocardial infarction and in all-cause mortality (13% and 27%, respectively) (Holman, Paul, Bethel, Matthews, & Neil, 2008).

In Vietnamese diabetes has become the fourth cause of death since 2006 (Ta, 2006). Currently, there were 61.2% of type 2 diabetes patients have severe complications in which included 43.6% of cardiovascular complications, 50.8% of neurologic complications, and 35.5% of renal complications (Pham et al., 2012). From that, the healthcare cost became a big issue in Vietnam, since 2008 the Vietnamese Government has added nearly 15 million dollars for prevention and control of diabetes (Ministry of Health, 2016). Moreover, the length in hospital of patients with diabetic complications was 2.2 times higher than that of people with other diseases (Ta, 2006).

2.3 Measurements of HbA1c

To date, the main analytical methods used for the measurement of HbA1c are: cation exchange chromatography, affinity chromatography, immunoassay and capillary electrophoresis. The European Reference Laboratory External Quality Program showed that in Europe, some 75% of laboratories use ion-exchange HPLC, 23% immunochemistry, and only a few use affinity chromatography, although this may change with the introduction of new affinity chromatography and capillary electrophoresis analyzers to the market in the coming years.

In Namdinh General Hospital, the HbA1c is tested by using Cation exchange chromatography. Therefore, we concern about how to get accuracy of this method measure HbA1c.

Cation exchange chromatography. HbA1c has a subtle difference in their isoelectric points and can be separated on this basis. In 1971, Trivelli and co-workers described a separation on shortened ion-exchange columns, in which the fast fractions was removed with 0.055 mmol/L phosphate buffer, pH 6.70; the remaining hemoglobin was removed with 0.15 mmol/L phosphate buffer, pH 6.42. The absorbance of the fractions eluted from the column was measured at 415nm and the fractions expressed as a percentage of the total. Later, automated high-performance liquid chromatography (HPLC) systems was developed. After many generations, several systems (major suppliers: Tosoh, Bio-Rad, and ARKRAY/Menarini) have reached a high level of performance. These methods do not suffer from interference by the Schiff base or carbamylated haemoglobin but may be prone to interference from haemoglobin variants, which may co-elute with the peaks of interest.

For the sensitivity and specificity of HbA1c, the New Hoorn study showed, that using a cut point of ≥ 42 mmol/mol (6.0 %), 50% of patients who had tested positive for diabetes using fasting plasma glucose or 2h post glucose load values would not be positive by HbA1c value. The study authors suggested that at ≥ 40 mmol/mol.

HbA1c had a sensitivity of 72% and specificity of 91% for the diagnosis of diabetes (van 't Riet et al., 2010). The values are similar to those of the NHANES (National Health and Nutrition Examination Survey) study, which reported that HbA1c would only detect 30% of those diagnosed with diabetes by any criteria.

According to the WHO systematic review on the use of HbA1c in the diagnosis of type 2 diabetes, in the DETECT 2 (Evaluation of Screening and Early Detection Strategies for Type 2 Diabetes and Impaired Glucose Tolerance) collaborative study, the optimal cut-points for detecting diabetes-specific retinopathy in all participants were plasma glucose concentrations of 6.5 mmol/L (fasting) and 12.4 mmol/L (2 h post glucose administration), and 6.3% for HbA1c. At these cut points the areas under the ROC curves, sensitivities and specificities were 0.87, 82% and 81%, respectively, for fasting plasma glucose; 0.89, 83% and 83% for 2h plasma glucose, and 0.90, 86% and 86%, respectively, for HbA1c (WHO, 2016).

2.4 The prevalence of uncontrolled HbA1c level

In serial cross-sectional surveys analyzed pooled data from the National Health and Nutrition Examination Surveys (NHANES). Glycated hemoglobin was measured in 4,926 non-pregnant adults aged ≥ 18 years with self-reported diabetes. The results showed that the people with diabetes achieved HbA1c $< 7\%$ was 43.1%, 44.1%, 57.0% and 52.5% during 1988-1994, 1999-2000, 2003-2006 and 2007-2010, respectively (Stark Casagrande, Fradkin, Saydah, Rust, & Cowie, 2013). The authors concluded that poor HbA1c level control still is time consistently prevalent among patients with diabetes.

The same situation as in Vietnam, cross-sectional survey of 330 patients with type 2 diabetes in the Central region of Vietnam between 2006 and 2009 indicated that over 85% of person with type 2 diabetes mellitus had poor HbA1c level control (Doan & Pham, 2009). Similarly, the poor glycemic control in type 2 diabetes was illustrated in another study in 262 type 2 person with type 2 diabetes mellitus in a provincial hospital in the North region, Vietnam. The person with type 2 diabetes

mellitus had $HbA1c \leq 7\%$ was only 19.5% (Luong & Nguyen, 2012). Those evidenced that the glycemic control in type 2 diabetes in Vietnam is far from optimal and needs more attention.

3. The therapeutic self-care demands of person with uncontrolled type 2 diabetes mellitus

Under Orem's theory all individuals with type 2 diabetes are assumed to have health deviation self-care requisites. In order to control their HbA1c level, person with type 2 diabetes need to meet the self-care therapeutic demands. In diabetes, the self-care therapeutic demands includes diet control, physical exercise, taking medicine and self-monitoring

3.1 Diet control

The major problem for patients with diabetes type 2 is known as the controlling diet. Patients perceived that their poor diet control related to many factors such as blood glucose level unrelated to dietary control, feeling bored with diabetes control, getting used to the taste of food, and difficulty in limiting sweet foods (Keeratiyutawong, Thampanichawat, Melkus, Khuwatsamrit, & Youngpradith, 2003). In addition, the evidences showed that the appropriate amount of food intake or inconsistently practicing dietary control in some patients also related to diet control in type 2 diabetes patients. The problem of dietary control usually occurred because of energy expenditure inconsistency in each day (American Diabetes Association, 2012). Patients should be informed about food sources and amount of food intake that is appropriate for individual patients by nurse. Food list exchange should be taught. Moreover, barriers to dietary control should be discussed and encourage to solve their problems and practice self- motivation to maintain their diet control. Persons with

diabetes can improve their health through healthy food choices and physical activity as well as consideration of personal and cultural preferences and lifestyle choices of each individual (American Diabetes Association, 2012).

Carbohydrates

The ADA (2012) suggests 50% of the total caloric intake should be from carbohydrate sources. Carbohydrates refer to sugars, starch, and fiber. People with diabetes are encouraged to choose a variety of fiber-containing foods, such as whole grains, fruits, and vegetables, because they provide vitamins, minerals, fiber, and other substances important for good health (Hu, van Dam, & Liu, 2001). There is evidence to support that a high-fiber diet significantly improves blood glucose control and reduces plasma cholesterol levels in patients with diabetes compared with a low-fiber diet. In addition, a high-fiber diet does not increase plasma insulin and triglyceride concentrations, despite the higher consumption of carbohydrates (Hu et al., 2001)

Fruits and milk have been shown to have lower glycemic responses than most starches (American Diabetes Association, 2012; Hu et al., 2001). The sweeteners that have calories from carbohydrate, like fruit juice concentrate, molasses, honey, and corn syrup, have direct effects on blood glucose similar to sucrose and offer no advantage to persons with diabetes (Strain, 2001). Nonnutritive sweeteners are encouraged for people with diabetes to add increased variety to their food choices. No adverse effects from using saccharin, aspartame, acesulfame K and sucralose have been demonstrated in humans for many years over a wide range of dosages (American Diabetes Association, 2012).

Protein

The ADA (2012) suggests 10 to 20% of total caloric intake be from protein sources. Protein refers to meats, fish, beans, and egg. Recent research has focused on the type of protein and its effect on the kidney. Diet using soy protein has been shown to reduce hyperfiltration of the kidneys in individual with diabetes (Strain, 2001). For preventing kidney disease, vegetable protein such as beans and legumes is recommended as a substitute for animal protein (Friesen, 2002).

Fat

The amount of fat that should be consume in the diet has been liberalized to 30% of the total calories (American Diabetes Association, 2012). The primary dietary fat goal in persons with diabetes is to limit saturated fat and dietary cholesterol intake. Less than 10% of energy intake should be derived from saturated fats. Sources of saturated fat are animal fats, meats, butter fat, coconut oil, and palm oil (Friesen, 2002). The recommended cholesterol intake is less than 300 mg/day for patients with normal plasma cholesterol concentrations (American Diabetes Association, 2012). Polyunsaturated fat recommendation is less than 10% of total calories. Sources are corn, safflower, sunflower, soybean, and sesame seed. Monounsaturated fats like olive oil and canola oil, have been shown not to increase the LDL cholesterol and may improve glycemic control, triglyceride and HDL cholesterol levels. A result of meta- analysis of fish oil consumption from clinical trials showed that fish oil has no adverse effects on GHb in diabetes patients and lower triglyceride levels effectively by almost 30%. Omega-3 Fatty acids reduce serum lipids and lipoproteins, impair platelet aggregation, increase cell membrane fluidity, and lower

blood pressure in humans. Omega 3 fatty acids from fish and other kinds of seafood are recommended three times per week (Strain, 2001).

Sodium

Several meta-analyses and reviews have documented the relationship between sodium intake and blood pressure. The mean effect of a moderate sodium restriction is reported to be a reduction of 5 mmHg for systolic and 2 mmHg for diastolic blood pressure in hypertensive patients and a reduction of 3 mmHg for systolic and 1 mmHg for diastolic blood pressure in normotensive people. The goal should be to reduce sodium intake to 2,400 mg or sodium chloride (salt) to 6,000 mg/day (American Diabetes Association, 2012).

Alcohol

It is noted that alcohol is not metabolized to glucose and can inhibit gluconeogenesis. Alcohol can have both hypoglycemic and hyperglycemic effects in people with diabetes. Alcohol slightly enhances the meal-induced insulin secretion resulting in lower blood glucose concentrations the next morning. Moderate alcohol intake taken with a meal has been shown to have little or no effect on postprandial glycemic excursions. The evidence-based nutrition principles recommended no more than two drinks per day for men and no more than one drink per day for women. One drink, or alcoholic beverage, is commonly defined as 360 ml of beer, 150 ml of wine, or 45 ml of distilled spirits, each of which contains 15 g of alcohol. If alcohol is not consumed with food and the patient is taking medication to lower blood glucose, hypoglycemia may occur. Alcohol, if taken, should be taken with food. The use of alcohol is also contraindicated with certain medications, particularly metformin which is frequently prescribed for type 2 diabetes, since alcohol can increase

the effects of metformin on lactate metabolism which increases the risk of lactic acidosis (Strain, 2001).

3.2 Physical exercise

Lack of physical exercise and obesity are major contributory factors to insulin resistance. The potential benefits of regular physical activity in patients with diabetes include improvements in insulin sensitivity and glycemic control, reduction in cardiovascular risk, improvements in blood pressure, lipid profile and weight loss (Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006).

A systematic review and meta-analysis were conducted on the effects of structured exercise interventions in clinical trials of ≥ 8 weeks duration on HbA1c in people with type 2 diabetes. Post intervention HbA1c was significantly lower in exercise than control groups (7.65 vs. 8.31%, weighted mean difference -0.66% ; $P < 0.001$). Meta-regression confirmed that the beneficial effect of exercise on HbA1c was independent of any effect on body weight. Therefore, structured exercise programs had a statistically and clinically significant beneficial effect on glycemic control (Boule, Haddad, Kenny, Wells, & Sigal, 2001).

A subsequent meta-analysis by the same authors showed that exercise intensity predicted post intervention weighted mean difference in HbA1c ($r = -0.91$, $P = 0.002$) to a larger extent than exercise volume ($r = -0.46$, $P = 0.26$). These results provide support for encouraging type 2 diabetic individuals who are already exercising at moderate intensity to consider increasing the intensity of their exercise in order to obtain additional benefits in both aerobic fitness and glycemic control (Boule, Kenny, Haddad, Wells, & Sigal, 2003).

A careful medical history and physical examination should focus on the

symptoms and signs of disease affecting the heart and blood vessels, eyes, kidneys, feet, and nervous system before increasing usual patterns of physical activity or an exercise program (American Diabetes Association, 2012). Aerobic physical activity should be recommended; for example, walking, jogging, swimming, dancing and cycling, and other endurance activities, depending on individual preference. Individuals must be taught to monitor closely for blisters and other potential damage to their feet both before and after physical activity. Proper hydration is also essential, as dehydration can affect blood glucose levels and heart function adversely. Adequate hydration prior to physical activity is recommended, i.e. 500 ml of fluid consumed 2 hour before physical activity. During physical activity, fluid should be taken early and frequently in an amount sufficient to compensate for losses in sweat reflected in body weight loss (American Diabetes Association, 2012).

A standard recommendation for patients with diabetes is that physical activity includes a proper warm-up and cool-down period. A warm-up should consist of 5 to 10 minutes of aerobic activity at a low-intensity level. The warm-up session is to prepare the skeletal muscles, heart, and lungs for a progressive increase in exercise intensity. After the activity session, a cool-down of 5 to 10 min should be structured similar to the warm-up. This help gradually reduce the heart rate down to the pre-exercise level and reduce the risk of post exercise hypotension and arrhythmias. It is recommended for patients with diabetes to engage in aerobic exercise roughly every other day or 3 to 5 days each week (American Diabetes Association, 2012).

For patients who cannot exercise for any reason increasing energy expenditure whenever they have chance is recommended, example of increasing physical activities are walking to the market, going up and down stairs, cleaning the

house, and gardening.

3.3 Self-monitoring

Self-monitoring skills for detecting hyperglycemic or hypoglycemic symptoms are important skills for patients with diabetes. Hyperglycemia and hypoglycemia can cause numerous physical symptoms in patient with diabetes mellitus. A patient should learn how to observe his or her physiological responses to glucose change and learn how to interpret those symptoms as well as how to cope when those symptoms and other symptoms related to diabetes complications occur such as foot ulcer, and fungal infection. Furthermore, food intake awareness, and increased physical activities should be encouraged through self-motivation. Keeratiyutawong et al. (2003) reported that patients with type 2 diabetes tended to rely on their subjective feeling of physical symptoms and their direct experiences of self-care rather than believe suggestions from health care providers. However, a problem arises when symptoms are not easily recognized or are interpreted inaccurately.

Therefore, self-monitoring is a necessary skill of patients with diabetes for evaluation of their health status at any time. Patients with diabetes should learn to monitor themselves everyday regarding food intake, symptoms of hyperglycemia or hypoglycemia, and check their body's skin.

3.4 Medication-taking

The problems of drug administration usually occurred in patients with diabetes. Most patients with diabetes do not take medicines following the prescription for many reasons (Ta, 2006). Because patients must take medications everyday, they occasionally miss their medication. Moreover, the individuals may have many medicines to take because of having other comorbidity diseases; thus, they sometimes

forget or feel too bored to take their medication (Keeratiyutawong et al., 2003). Another reason for failure to take prescribed medication is that Vietnamese patients often take traditional medicines such as herbs instead. Others take both the traditional medicine and the prescription drugs. Egede et al. (2002) studied the prevalence and pattern of complementary and alternative medicine in the U.S. individuals with diabetes. They found that more than one a half times as many individuals with diabetes use CAM as individuals without diabetes (Egede, Ye, Zheng, & Silverstein, 2002).

Patients with diabetes should learn about the action of drugs, how to take medications, and the side effects of their medications. Moreover, nurses should explore patients' problems about medication taking and solve those problems with patients

4. Factors related to HbA1c level

In literature illustrated that there were many factors predict on HbA1c level in type 2 diabetes. According to a systematic review and meta-analysis, there were three groups of related factors on HbA1c level which are patient related factors, disease related factors, and treatment related factors (Sanal, Nair, & Adhikari, 2011). Patients related factors include age (Juarez et al., 2012) , gender, body mass index (BMI), level of knowledge on diabetes (Sanal et al., 2011). Disease related factors included duration of diabetes (Adham, Froelicher, Batieha, & Ajlouni, 2010) and diabetic complications (Sanal et al., 2011). Adherence to diet, to exercise, to glucose monitoring and to intake of oral drugs which are essential self-care behaviors in people with diabetes (Shrivastava et al., 2013) were included in treatment related factors (Khattab et al., 2010).

In longitudinal observational data was collected on 573 patients with type 2 diabetes to determine predictors of HbA1c. The results of the mixed effects model

showed that patients who were uninsured, had diabetes for a longer period of time, used insulin or multiple oral agents, or had high cholesterol had higher HbA1c values over time indicating poorer glycemic control. The younger patients also had poorer control (Benoit, Fleming, Philis-Tsimikas, & Ji, 2005).

Moreover, Sanal et al (2011) conducted a systematic review and meta-analysis in 21 studies on factors related to diabetes control with outcome as HbA1c in type 2 diabetes patients. The results showed that elderly people and males had better control on diabetes. Presence of coronary heart disease and non-adherence to self-care (diet, exercise, medication and glucose monitoring) were the factors associated with poor control of diabetes.

The results of a recent study determined the predicted pathways linking factors to glycemic control, showed that there were significant negative direct effects from diabetes self-care ($\beta = -0.21$, $p = .007$) to HbA1c, and positive direct effects from duration of diabetes ($\beta = 0.32$, $p = .005$) and waist-to-hip ratio ($\beta = 0.15$, $p = .009$) to HbA1c. Self-efficacy had no direct effect on HbA1c; although it had an indirect effect on HbA1c ($\beta = -0.06$) through diabetes self-care (Gao et al., 2013).

Actually, in diabetes care diabetes outpatients carried out 95% or more of the daily self-care of diabetes (Anderson, 1995). Individuals with diabetes have been shown to make a dramatic impact on the progression and development of their disease by participating in their own care (Shrivastava et al., 2013). Evidence supports that patients with diabetes who adhered to self-care behaviors have good glycemic control (Compeán Ortiz, Gallegos Cabriales, González González, & Gómez Meza, 2010; Gao et al., 2013; Khattab et al., 2010; Sousa, Zauszniewski, Musil, Price Lea, & Davis, 2005). Patients with diabetes should be responsible for their activities regarding diet,

exercise, self-monitoring, foot care, and medication-taking. Improvement of those diabetes self-care areas in each session produced better controlling HbA1c level, and prevent long term complications.

In Vietnam, the results of study on 400 type 2 diabetes patients who treated in Outpatient clinic at Namdinh General Hospital. This study aimed to determine the relationship between three groups of related factors and HbA1c level. The results were found the age has positive effect on HbA1c level. The diabetes duration of disease, self-care had negative effect on HbA1c level (Nguyen & Nguyen, 2014).

Summary, there are many factors related to control HbA1c level in patients with type 2 diabetes. In those factors, the self-care is most important factor that predict on control HbA1c level in this group of patients.

4.1. Definition of self-care agency

The concept of self-care agency was developed by Orem (1980) as a component of Self-Care Deficit Nursing Theory (SCDNT). According to Orem, self-care agency is an individual's capabilities to recognize his or her needs, to evaluate personal and environmental resources, to determine and perform self-care actions to achieve a desired outcome. Self-care agency appears to be affected by personal and environmental factors, which interfere with its development and maintenance. The exercise of self-care agency leads to the achievement of goal-oriented outcomes.

4.2 Measurement of self-care agency

There were several self-care agency assessment tools which can be found in the international literature, including the Exercise of Self-care Agency (ESCA) (Kearney & Fleischer, 1979), the Denyes Self-care Agency Instrument (DSCAI) (Denyes, 1980), the Self-As-Career Inventory (SCI) (Geden & Taylor, 1991),

and the Appraisal of Self-care Agency Scale (ASAS) (Evers et al., 1986). The most widely used of these tools are the ASAS and its reduced version the ASAS-R (Sousa, 2002).

The Appraisal of Self-care Agency Scale (ASAS) (Evers et al., 1986) was developed based on Orem's widely used in the SCDNT, which emphasizes patient responsibility for self-care behaviors, and aims to evaluate patient awareness of health needs and promotes self-care (Evers et al., 1986). In its original version, the ASAS comprised 24 items responded in a five-point Likert scale ranging from 1 (totally disagree) to 5 (totally agree). According to the authors, the ASAS is a one-dimensional measure which provides a general and non-specific appraisal of self-care agency (Evers et al., 1986). This tool has been used and validated in several countries, including The Netherlands (Evers et al., 1986), Norway (Lorensen, Holter, Evers, Isenberg, & van Achterberg, 1993), Switzerland (Soderhamn, Evers, & Hamrin, 1996), and Hong Kong (Fok, Alexander, Wong, & McFadyen, 2002). Despite its widespread use, some authors have shown that the original version has a complex factor structure which may compromise the tool's construct validity. Sousa et al. (2008), for example, evaluated the factor structure of the ASAS in a sample of American adults with diabetes mellitus (N = 141). Seven factors were retained using the eigenvalue > 1 factor retention criterion. However, after performing the scree plot test the authors found that two factors were the most representative of the data set and, after forcing a two-factor solution, four items were excluded from further analysis due to unacceptable communality estimates. After initially obtaining a nine-factor solution the authors forced a two-factor solution, as suggested by Sousa et al. (2008), and found that six items did not load on any factor. In light of these problems, a refinement study of the

original 24-item ASAS was conducted with a general sample of American adults ($N = 629$). First, exploratory factor analysis was conducted with part of the sample ($n = 240$) and the authors found a three-factor solution that explained 51.3% of variance. However, only two items loaded on the third factor, suggesting inadequacies. Moreover, the item-total and/or inter-item correlations of four items loaded on factor 1 and three items on factor 2 were then excluded because they did not achieve minimum criteria of $r = 0.30$. The authors conducted further exploratory factor analysis of the 15 remaining items and obtained the following three-factor solution once again: factor I - having capacity for self-care (eigenvalue = 6.06, $\alpha = 0.86$); factor II – developing capacity for self-care (eigenvalue, 2.07, $\alpha = 0.83$; factor III); lacking capacity for self-care (eigenvalue = 1.14, $\alpha = 0.79$). Total explained variance was 61.7%. In this revised model, each scale item had strong factor loadings ranging from 0.52 to 0.81. Goodness-of-fit of the revised version (ASASR) was tested by comparing the results of a confirmatory factor analysis conducted with the other part of the sample ($n = 389$) with the goodness of-fit indexes of the one-dimensional and three factors structure of the original 24-item version (ASAS). The ASAS-R showed excellent fit [$\chi^2/d.f = 1.97$, goodness of fit index (GFI) = 0.94, adjusted goodness of fit index (AGFI) = 0.92, comparative fit index (CFI) = 0.96, Tucker-Lewis index (TLI) = 0.95, root mean square error of approximation (RMSEA) = 0.05, root-mean square residual (RMR) = 0.05], while the one-dimensional and the three-factor versions of the original ASAS did not achieve acceptable fit (Sousa et al., 2008).

The ASAS-R has been shown to be a reliable assessment tool. The DASAS-R is a 15-item measure designed to assess individuals' self-care agency, conceptualized as the ability to enhance health-promoting behaviors and disease

management as applicable to medical personnel and individuals with chronic diseases. The DASAS-R was employed as a measure of self-care agency that should correlate to an individual's ability to care for others as well as for him or herself. Items were evaluated according to how well the statement described the individual. Responses were scored on a five-point scale: 1 (totally disagree) to 5 (totally agree). Scores on the DASAS-R scale can range from 15 to 75, with higher scores indicating greater self-care agency. The convergent validity of the DASAS-R has been reported to range from $r = .46$ to $.61$, and Cronbach's alpha was $r = .89$ (Sousa et al., 2008).

5. Intervention for improving HbA1c level control in uncontrolled type 2 diabetes

Interventions controlling HbA1c level in type 2 diabetes have been used in many kind of diabetes education. The diabetes educations include educational, behavioral, and psychological and mix those methods interventions. Diabetes education has moved from a compliance -based approach to an empowerment approach. Traditional diabetes education focused on patient adherence to the treatment recommendations of health-care professionals (Wens et al., 2008). Patients with diabetes played a passive role while the health-care provider was an expert who could make a decision regarding diabetes treatment for the patients (Ellis et al., 2004). Under this philosophy, the primary diabetes educational program used a didactic method focusing on the acquisition of knowledge and compliance to the regimen (Ellis et al., 2004; Wens et al., 2008).

Gary et al. (2003) reported a meta-analysis of 18 randomized controlled trials. The studies on the effects of educational and behavioral interventions were retrieved. All intervention types had mild to moderate positive effects which decreased between the 1 month and 26 months follow-up. A reduction (0.43%) was in HbA1c in favor of intervention. In addition, Ismail et al (2004) reviewed and analyzed 12 psychological

therapies in type 2 diabetes. The results indicated that had a significant reduction in HbA1c level (Ismail, Winkley, & Rabe-Hesketh, 2004). Those things illustrated that the educational, behavioral and psychosocial intervention had an effective diabetes education program. Gary and colleagues suggested that future research should design a more quality and rigorous methodology and assess the cost benefits of the program.

Fan & Sidani (2009) reported a meta-analysis of 50 randomized controlled trials conducted on the effect of diabetes education between 1990 and 2006. The results indicated that the behavioral interventions had the largest effect ($ES = 0.63$) in comparing with psychological interventions ($ES=0.40$), and mixed interventions ($ES=0.50$) on HbA1c level. The finding suggested that the behavioral interventions involving patient empowerment with participation and collaboration should involve in a diabetes education program as one of strategies to improve knowledge, change behaviors, in order to enable to control glycemic level in type 2 diabetes patients.

Additionally, Norris's et al (2002) review of diabetes self-management education concluded that behavior change strategies should be incorporated into diabetes education to promote lifestyle change. Moreover, diabetes education was most effective when combined with health-care provider interaction, medication adjustment and reinforcement of educational messages (Norris, Lau, Smith, Schmid, & Engelgau, 2002).

However, several meta-analyses and systematic review showed the inconsistency of improvement in HbA1c control was found in previous studies (Hunt, 2013; Loveman, Frampton, & Clegg, 2008; Minet et al., 2010). Some studies reported statistically significant reducing of HbA1c in the intervention groups compared with control groups. On the other hand, some others found that there were no statistically

significant differences in HbA1c between intervention and control groups, despite what seem to be relatively large differences in mean levels of HbA1c in some of the studies (Loveman et al., 2008; Minet et al., 2010). Besides that, in current systematic review showed that some studies noted improvements in outcomes for both intervention and control groups (Hunt, 2013). Actually, most of previous studies lack of describing content of intervention, and lack of describing the homogeneous sample before enter study. Therefore, it should have new strategy which is conducted with homogeneous sample to clarify clearly the different of effectiveness of intervention between experimental and control group.

In a meta-analysis on element in diabetes education illustrated that shifting from a medically oriented approach to patient oriented approach is an effective strategy for improving both the physiology and psychology of living with diabetes. Multiple strategies in diabetes educational programs such as teaching, discussing, goal setting, problem solving, coping strategies, maintaining self-motivation, and practicing some skills were used for enhancing patients' knowledge and modifying unhealthy lifestyles (Fan & Sidani, 2009). This finding illustrated the benefit of multiple approaches; didactic instruction, skill training, and behavioral modification in diabetes educational programs.

Cultural sensitivity should be emphasized when developing a diabetes intervention program (Whittemore, 2000). D'Eramo-Melkus et al. (2004) conducted a pilot feasibility testing of a culturally competent intervention consisting of education and care for black women with type 2 diabetes mellitus using a one group, pretest posttest quasi-experimental design. Twenty-five black women with type 2 diabetes attended the 6 week diabetes intervention program which was designed in a culturally

sensitive manner. The program focused on problem solving, counter conditioning, stimulus control, and decision-making for goal attainment. The results showed that glycemic control was improved from baseline to 3 months. This concerned with cultural sensitivity increased the effectiveness of the program.

A recent systematic review and meta-analysis of randomized controlled trials and clinical controlled trials evaluated the effectiveness of individual patient education on metabolic control (Duke, Colagiuri, & Colagiuri, 2009). This review included nine studies involving 1359 participants, six studies compared individual education to usual care and three compared individual education to group education (361 participants). In the six studies comparing individual face-to-face education to usual care, individual education did not significantly improve HbA1c over a 12 to 18 month period. In three others, the group education showed improvement glycemic control comparing with individual education group (Duke et al., 2009).

Deakin et al (2005) conducted a meta-analysis of 11 randomized controlled trials on the effect of group-based diabetes education programs. The results showed that the high improvement in HbA1c. The authors concluded that group-based patient education in people with type 2 diabetes is effective in improving HbA1c level control (Deakin, McShane, Cade, & Williams, 2005). However, the desirable size for a group depended on many factors such as the age of members, type of group, the problem to be explored, and experience of the leader (Corey & Corey, 1992).

The effectiveness of supportive – educative nursing intervention was evidenced in some studies in Thailand. Likiratcharoen (2000) analyzed 57 studies of supportive-educative nursing systems in diabetes education programs in Thailand. The results indicated that the average effect size for metabolic control was medium (0.60).

However, most of the previous studies lacked a control group and randomization in research design and therefore it was difficult to draw a conclusion about the effectiveness of the intervention programs. Moreover, the strategies for sustaining behavioral changes were not mentioned clearly in the conceptual basis of the program intervention.

Hanucharunkul et al. (2001) developed a supportive – educative program by using the participatory action research. This one-day program provided information on diabetes knowledge and self-care management through a lecture, discussion, practice, videotape recording, and pamphlets and was followed by small group meetings once a month, for 3 months. The results indicated that mean score of FPG level decreased significantly each month (Hanucharunkul, Achananupap, Plodnaimuang, & Pramokul, 2001). Boonchaury (2001), Phumleng (2002), and Muangkae (2002) replicated the study of Hanucharunkul et al. (2001) in the whole of Thailand, respectively. The findings were consistent with the findings of Hanucharunkul et al. (2001). However, those studies did not have a control group, most of the time was spent in a didactic method and they used fasting plasma glucose (FPG) as an indicator of the outcome, which may include on error concerning glyceamic control interpretation (Boonchaury, 2001; Hanucharunkul et al., 2001; Keeratiyutawong et al., 2005; Muangkae, 2002; Phumleng, 2002).

Keeratiyutawong et al (2005) conducted a quasi-experimental one-group pre-posttest design of 127 outpatients with uncontrolled type 2 diabetes. A one day workshop of the diabetes education program based on Orem theory and cognitive behavioral theory were carried out in this study. A program provided information on diabetes knowledge and self-care activities as well as nurses' motivation through a

lecture, discussion, practice, videotape recording, and pamphlets and was followed by small group meetings once a month, for 3 months. The results showed that the mean fasting blood sugar (FBS) level from month 1 to 4 ($p < .01$) (Keeratiyutawong et al., 2005). The researchers suggested that a rigorous methodology, using a control group design, and using other glycemic index should be considered for further study.

Navicharern et al. (2009) conducted a quasi-experiential design in forty participants with type 2 diabetes. The diabetes education program with multifaceted nursing-coaching intervention was conducted in 12 weeks. The results indicated that the mean average of HbA1c of the experimental group was significantly lower than that of the control group ($p < 0.5$) (Navicharern, Aunguroch, & Thanasilp, 2009). However, this study was conducted with purposive small sample size in two various places, which may include in error concerning homogeneous of samples and threats of external validities.

Diabetes care may cause feeling of burnout in a patient because it required the patients to keep track of self-care all through their life. The majority of problems of diabetes self-care concerned the difficulty of ensuring long-term maintenance of behavior change. Glasgow et al (2001) suggested successful diabetes education program should provide consistent follow-up procedure in program. Evidence supported the ideal that telephone consultations reduced cost and missed appointments, and increased frequency of contact and satisfaction in patients with mode of communication (Car & Sheikh, 2003). In addition, telephone support has been found to be beneficial in improving of adherence to drug treatment and self-care in patient with type 2 diabetes. Telephone follow-up was a strategy for following self-care practices of patients at home. Nurses can help patients to solve their problem and give advices about diabetes care.

Moreover, patients can consult nurses about their health problems or self-care problems at a low cost. Thus strategy may enhance patient's motivation and maintain their self-care.

Norris et al (2002) reviewed a total of 31 studies of published randomized controlled trials to evaluate the effectiveness of diabetes educations in type 2 diabetes. On average, individuals who received the intervention had reduced HbA1c by 0.76% more than the control group at immediate follow-up; by 0.26% in 1-3 months of follow-up; and by 0.26% at ≥ 4 months of follow-up. HbA1c decreased more with additional contact time between patient and educator, a 1% decrease was noted for every additional 23.6h of contact. The authors concluded that diabetes education improves HbA1c levels at immediate follow-up, with increased contact time improving the effect.

In Vietnam, a didactic teaching of patients with diabetes was studied in diabetes educational research (Trần & Nguyễn, 2009). This study was a one group pretest posttest design with 161 patients by purposive sampling. The program used multimedia such as slides and posters on general diabetes knowledge to educate on one day only. In this study, the theory guided for intervention was not mentioned. From that, a new program which was built on self-care and focused on type 2 diabetes outpatients should be conducted. Moreover, a study with a rigorous methodology and a control group design was concerned by researcher.

In summary, a patient with type 2 diabetes mellitus should learn to control their disease and prevent long term complications with diet, exercise, self-monitoring, foot care, and medication-taking. Diabetes education programs should shift from a didactic method, in order to increase patients' participation, and encourage patients' self-control

and behavior change. A diabetes education program, based on Orem's self-care theory, designed for improving self-care knowledge and skill abilities can help patients change and maintain their self-care behaviors over time. In addition, there was evidence to support the idea that group interventions and telephone follow-up were the effective strategies for diabetes programs, which were cost effective. Finally, the research findings from meta-analyses suggested an emphasis on a rigorous research design in a diabetes education program.



CHAPTER III: METHODOLOGY

Research design

This study was a randomized controlled trial (RCT) design. This design is the one of powerful methods for testing hypotheses about cause and effect relationships between independent and dependent variables (Polit & Hungler, 1999). The treatment was the supportive-educative nursing program. The outcome was HbA1c level.



Figure 2: A randomized controlled trial design

R: Randomization

O₁: HbA1c level in experimental group at baseline.

O₂: HbA1c level in experimental group at 3 months after.

X: The Supportive Educative Nursing Program.

O₃: HbA1c level in control group at baseline.

O₄: HbA1c level in control group at 3 months after.

Research setting

The study was conducted at Namdinh General Hospital, a province hospital, in the Northern part of Vietnam. This hospital was selected as a setting for this study. In report in 2012 showed that the prevalence of diabetes in the Northern part of Vietnam is one of the highest prevalence (6% population) in whole country (Nation Endocrinology Hospital, 2012). The policy of the Ministry of Health is to improve the potential of province hospitals to take care of patients with diabetes mellitus; therefore,

health education for patients with diabetes has been established at outpatient clinics and all patients have to go there to get treatment. According to hospital's report, there were about more than 2,000 person with type 2 diabetes mellitus who are receiving national management chronic diseases in outpatient clinic in Namdinh General Hospital in 2013, this number showed the higher prevalence of type 2 diabetes in Namdinh in comparing with that in other provinces (Ta, 2006). Also this hospital has a diabetes education service for routine care.

Population and Sample

Population: Vietnamese with uncontrolled type 2 diabetes mellitus aged over 18 years receiving national management chronic diseases in outpatient clinic in Namdinh General Hospital, Vietnam.

Sample: The study sample were Vietnamese with uncontrolled type 2 diabetes mellitus aged over 18 years in outpatient clinics of Namdinh General Hospital in Vietnam. In addition, the inclusion criteria were as follows:

- (1) Who had been diagnosed with type 2 diabetes at least 6 weeks;
- (2) Who had fasting plasma glucose level over 130 mg/dL at nearly past 6 weeks checking at hospital before entering the research.
- (3) Who was prescribed with one kind diabetes medication and not received insulin therapy
- (4) Who did not have diabetes-related complications (end stage renal disease, heart failure, lower extremity amputation), or other serious illness, or hemoglobinopathies, or alcoholism, or any blood diseases
- (5) Who were able to read Vietnamese language.

Sample size

The sample size in this study was based on the effect size from meta-analysis of elements in diabetes education intervention (Fan & Sidani, 2009). It was found that the average effect size of glycemic control was medium ($d = 0.63$). The sample size of this study was adequate when based on a power level of 0.8, an alpha of 0.05. The sample size should be at least 39 participants per group (Cohen, 1988). Previous studies with a 3 months follow-up, found the main reason for attrition was quit from intervention with rate 8.69% (Likiratcharoen, 2000). This study followed the participants as same time as Likiratcharoen's (2000) study. Therefore, this study needed 42 of participants per group which assumed an attrition rate of 9%.

One hundred and fifteen persons with type 2 diabetes mellitus who met the criteria were approached to participate in this study, and 92 persons agreed to join. Only 23 potential persons (20.0%) refused participation. Chi square test and independent sample t test were calculated for comparing the characteristics between the persons who enrolled and did not enroll in the study. Significant differences were not found on demographic data and dependent variable between the persons who enrolled and did not enroll in the study.

Of the participants, forty six participants were in the intervention group and forty six participants were in the control group. Eight participants (8.7%) dropped from the study: five (10.9%) from the intervention group, and three (6.5%) from the control group. The reasons for withdrawal were moving to another province, busy with their work or their life, and working on a ship. Significant differences were not found on demographic data and all dependent variables between the persons who

participating and who withdrew. Finally, 84 participants, 41 in the intervention group and 43 in the control group were further analyzed (see figure 3).

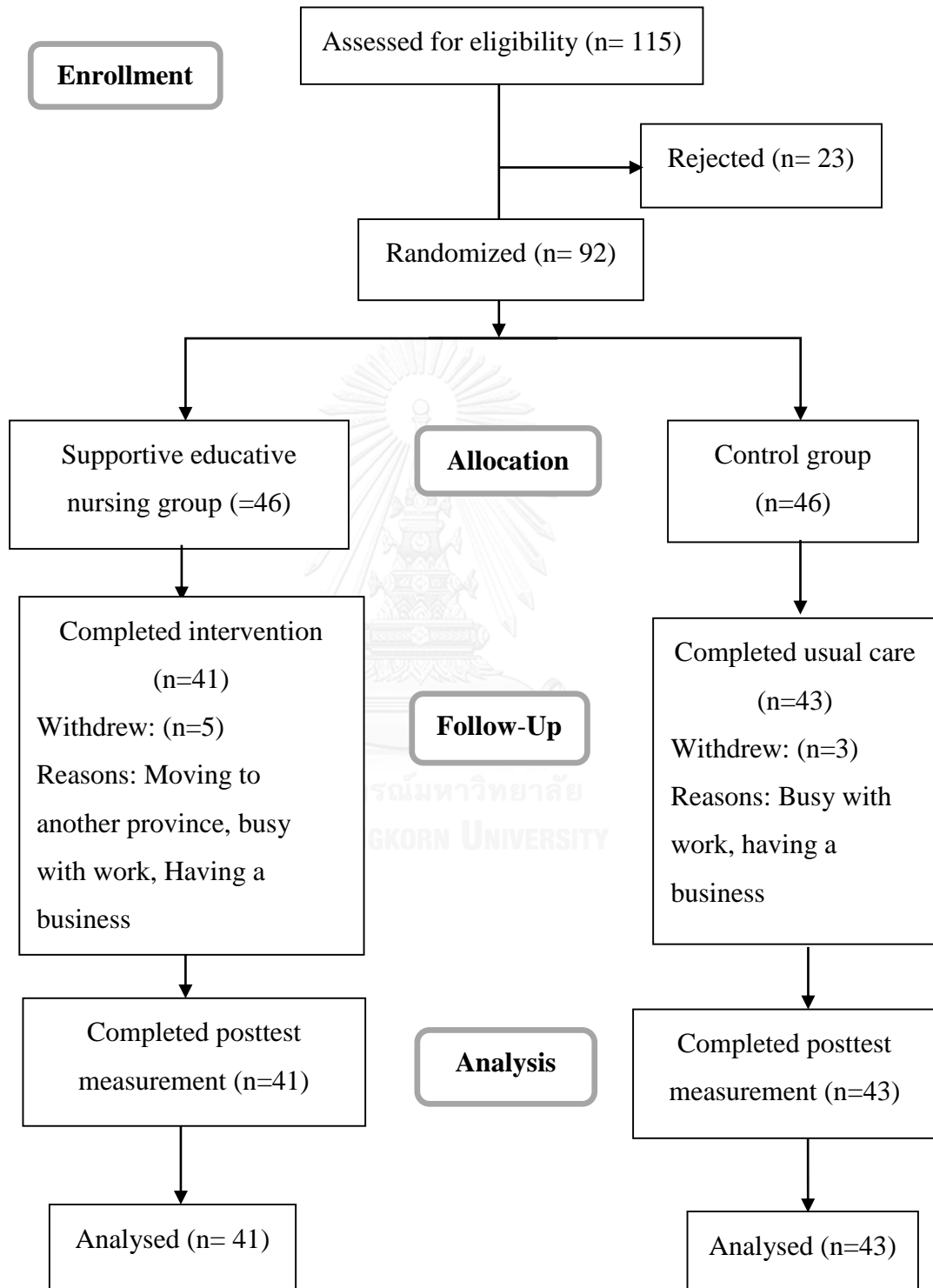


Figure 3: The flow chart of participants through the study.

Group assignment

The researcher approached the persons who met the study criteria at the outpatient clinic. Potential participants were informed of the study purpose and procedures. If agreement, persons were asked to sign an informed consent form. After that, they were randomly assigned to either an experimental or a control group using matching pair with two factors age and duration of disease. This method was used to perform a minimization procedure that adjusted the randomization probabilities to balance age and duration of disease between the intervention and control groups. Longer period of time and younger patients also had poorer control HbA1c level (Benoit et al., 2005). Therefore, this method ensured that these individuals were evenly distributed between the two randomized groups. Then, the allocation of the groups was conducted by using the lottery which was put in the sealed envelope. Both researcher and participants did not know the group that the participants were be in. The participants in both groups were taken blood sample test to determine the HbA1c level, and were given an appointment at the clinic.

Research instruments

In this study, three kinds of instruments were used for data collection, intervention and validity check. For data collection, the personal information sheet and blood sample were used. The supportive educative nursing program was used as intervention. Lastly, the Diabetes Appraisal of Self-Care Agency Scale –Revised was used for validity check.

1. Instruments for data collection

1.1. The Personal Information Sheet

The Personal Information Sheet was used to obtain the demographic characteristic of the participants such as age, gender, marital status, level of education, occupation, residence, monthly incomes, duration of disease, and family medical history (*see Appendix F*).

1.2. The Biorad Diamat automated glycosylated hemoglobin analyzer to measure HbA1c level

Blood sample was collected from all patients to determine of HbA1c level at laboratory in Namdinh General Hospital. The blood sample was analyzed by a Biorad Diamat automated glycosylated hemoglobin analyzer with the Cation exchange chromatography method. The analyzer is maintained by the Viet Thai Company twice a year to ensure that it worked properly. HbA1c had a subtle difference in their isoelectric points and could be separated on this basis. These methods did not suffer from interference by the Schiff based or carbamylated haemoglobin but could be prone to interference from haemoglobin variants, which may co-elute with the peaks of interest.

The quality and validity of measuring HbA1c level were ensured by controlling the factors that effect to the results of this measurement. Firstly, the person who had hemoglobinopathies was not recruited into study. This participant selection ensured this measurement was not interfered from hemoglobinopathies (WHO, 2016). The secondly, the processing of blood was conducted within 3 hours from taking blood sample. The literature showed that using assay for HbA1c level should keep blood sample avoid conditions for more than 12hr at temperatures $> 23^{\circ}\text{C}$

(WHO, 2016). Moreover, participants were took a blood sample by only one nurse who had five year experience in taking blood sample. Every participants were undertook the same procedure which was promulgated by Namdinh General Hospital. The blood samples were analyzed by only one technician who had five year experience in using Biorad Diamat automated glycosylated hemoglobin analyzer. Additionally, the blood sample was measured blind to group allocation.

In this study, the HbA1c was firstly categorized as good control, fair control and poor control with HbA1c level $\leq 7\%$, >7 to $\leq 10\%$ and $>10\%$ respectively. Secondly, to have general view of glycemc control, the HbA1c level was generally categorized as $>7\%$ and $\leq 7\%$ with poor glycemc control and good glycemc control (American Diabetes Association, 2016). The HbA1c level was measured two times for each participants in each group, first time was one day before the intervention (pre-test), and the last one (post-test) was 12th week after pre-test.

2. Instrument for intervention

The intervention of this study was supportive educative nursing program (SENP). This was an education program and was developed based on Orem' conceptual model and Diabetes Education Standard from American Diabetes Association (American Diabetes Association, 2016), International Standard for Diabetes Education (Belton, 2003), literature review and Vietnamese situation; with main goal to improve HbA1c level control among uncontrolled type 2 diabetes patients. The patient's self-care deficits and self-care demands were explored after assessment of the individual's diabetes self-care knowledge, skills and self-care agency. The researcher synthesized self-care deficits, self-care demands and self-care agency of all

participants, then, based on those information, the content of education part and the guideline for telephone call were developed.

As an educational program, the supportive educative nursing program also provided knowledge and skill training, and supported telephone calls monitoring by nurse. Using the helping technique in educative part, nurse taught, guided and provided the diabetes self-care knowledge and skills to participants help them understand, believe and be confident to perform self-care activities. Moreover, in supportive part, nurse supported, encouraged and motivated participant maintain their self-care activity. This program abled to enhance self-care agency to perform diabetes self-care behaviors and achieve improving HbA1c level control. The protocol for the supportive educative nursing program was described into two main parts:

1) Education process. This was basic plan and important steps with the purpose to provide diabetes self-care knowledge and diabetes self-care skills to improve patient's understanding and belief their abilities and capacities to be confident in performing self-care behaviors to achieve target HbA1c level. Theme for this education process were:

Session 1: Introduction in diabetes and its complications

Session 2: Diabetes diet

Session 3: Diabetes exercise

Session 4: Using medication in diabetes and how to deal with overlaps

Session 5: Diabetes self-monitoring and how to examine foot and how to monitor hyperglycemia and hypoglycemia

The schedule of this session was conducted as following steps. Firstly, researcher provided all the knowledge and skills related to relevance topic for all participants within 1 hours per each session. Then, the participants were divided into 5 groups (each group had 9 to 10 persons). Each group was discussed to answer the topic guideline as: (1) what is main content of this session? (2) Which part is most difficult to understand? (3) Do you think you can apply the information on this topic to your daily life? (4) Do you need any support from others to apply those information? (5) Who will be your key person in doing this job? (6) What are steps in your plan to apply it? (8) How long do you start doing it?. The group discussion was took within 1 hour. After that, the researcher was collected all information and summarized and concluded the main points that participants must concern and pay more attention on. Patients also received the requirement record for related activity and were reminded to fulfill this record every day. This activity was took within 30 minutes. Lastly, patients were watched a related content video to remind them the content of session. Each video was in 30 minutes. The education process was 5 weekly meetings in meeting room at outpatient clinic in Namdinh General Hospital in 5 weeks. The participants received one manual booklet, one program manual, and one video (VCD). All the content was developed by researcher after finished content validity from the experts who were an expert of nurse educator, clinical nurse, and one physician with specialization in diabetes/metabolic disease.

2) *Support process*. This process was the central of the program for enhancing patient's self-care agency to perform and maintain all knowledge and information that they received at education process. This session was individual session. Each patient was immediately discussed with researcher by telephone call after

first education session. The patient was received telephone call by researcher within 15 to 20 minutes. During telephone call, researcher let patient tell about his/her story related to performing self-care activities last seven days. Content of this conversation was based on the related record that patients received from education session. After that, researcher discussed with patients on following questions as: (1) what is the hardest task in last 7 days? (2) Why did you think that? (3) What is main cause of this difficulty? (4) What is your plan to resolve this problem? (5) Who can help you on that task? (6) How can nurse help you on this?. Based on patient's answer, researcher was guided, supported and motivated them on choosing the best solution for his/her problem. The researcher also encouraged patient in doing and maintaining self-care activities. The research was finished conversation by remind patient on next meeting for education session or testing. This session was conducted within 11 weeks.

3. Validity check instrument

The intervention was checked by using the Diabetes Appraisal of Self-Care Agency Scale – Revised (DASAS-R) (Sousa et al., 2008). The DASAS-R is a 15-item measure designed to assess individuals' self-care agency, conceptualized as the ability to enhance health-promoting behaviors and disease management as applicable to medical personnel and individuals with chronic diseases. The DASAS-R was employed as a measure of self-care agency that should correlate to an individual's ability to care for others as well as for him or herself. Items were evaluated according to how well the statement described the individual. Responses were scored on a five-point scale: 1 (totally disagree) to 5 (totally agree). Scores on the DASAS-R scale can range from 15 to 75, with higher scores indicating greater self - care agency. The

convergent validity of the DASAS-R has been reported to range from $r = .46$ to $.61$, and Cronbach's alpha was $r = .89$ (Sousa et al., 2008).

Our assumption that, the person have self-care agency, he/she can be good in controlling the HbA1c level. The participants were assumed that they had self-care agency unless they did not had less than 80% (60 points) of total self-care agency scores. Self-care is behavior that diabetes patients need have to manage their disease. The people need from 4 to 6 weeks to determine whether behavioral change takes place (Hongu, Kataura, & Block, 2011). Therefore, in this study, the self-care agency was measured from baseline to 6 weeks and 3 months after.

For validity and reliability of this scale in this study, after got the permission of authors (*see appendix B*), the Diabetes Appraisal of Self-Care Agency Scale – Revised (DASAS-R) was translated into Vietnamese by using Brislin's Model (Brislin, 1980). According this model, this scale was translated into the Vietnamese by a bilingual expert at the Language Center, Namdinh University of Nursing. The translated version was reviewed by a Vietnamese healthcare provider to identify ambiguous words and to asses understandable in Vietnamese context and culture. The translated version was changed some words which are appropriate with Vietnamese culture. This change was made after discussion between researcher and expert. The backward translation from Vietnamese version to English version was conducted by a bilingual expert at the Language Center, Namdinh University of Nursing. The original English version and back-translated English version were evaluated by a native English speaker. There had not got any comments on the back-translated version. After that, the final Vietnamese version was validated the content in the Vietnamese context by two graduated nurses who work in diabetes care and were familiar with self-care

concept, three nurse instructors who were familiar with self-care concept and had experience in caring for diabetes patients, and one physician who is lecturer in Namdinh University of Nursing and had experiment in caring for diabetes patients. The experts rated for relevance of each item to self-care concept in Vietnamese culture by using a 4-point Likert scale. This scale included “4 = very relevant”, “3 = fairly relevant”, “2 = little relevant”, and “1 = not relevant at all”. The content validity index (CVI) was calculated as the percentage of items that are rated as relevant. It indicates that the content of the Vietnamese version of scale is valid if CVI is at least .80. In this study, the mean I-CVI of this instrument was 0.91. The S-CVI/UA and mean expert proportion was 0.53 and 0.91, respectively.

The Vietnamese version instrument was test for reliability with thirty Vietnamese people who have the same criteria as participants in the experimental group. In this study, all corrected item-total correlations for the total scale were positive (range 0.28-0.67) within the range recommended 0.30-0.70 (DeVellis, 2003). The total scales mean score was 22.6 (SD 5.5). The mean of inter-item correlations was 0.29 with values ranging from - 0.08-0.73. The Cronbach of this scale was .86 (*see appendix G*).

Research procedures

1. Preparation phase

1.1. Prepare researcher and research assistants

Before implementing the program, the researcher need to have more knowledge and skill related diabetes self-care and diabetes education. For this purposes, the researcher participated in the Competency based Training course of Queensland University of Technology from August 6-20, 2015 at Hanoi Medical University and the conference of the concepts in Nursing science from Asian

Development Bank from July 15 -20, 2015 at Namdinh University of Nursing. Those activities help researcher gain knowledge on using patient centered teaching method, participatory method and self-care concept.

In this study, there were two research assistants, one nurse in diabetes clinic who took a blood sample, one technician in laboratory unit who analyzed blood sample to determine HbA1c level. Both of them were informed the research objectives, procedures and requirements. They were trained on protocol for taking blood sample and analyzing blood sample. The confirmation of researcher assistants' adherence on both protocols was assessed by researcher during the test for experimental and control group.

1.2. Prepare instrument

Assessment phase

The experimental group was asked to answer two questionnaires which were the diabetes knowledge test (Fitzgerald et al., 1998) and the summary diabetes self-care activities scale (Toobert, Hampson, & Glasgow, 2000). The actual knowledge and self-care activities of patients were used to build the content in education in program. Then, participants were completed the Diabetes Appraisal of Self-Care Agency Scale – Revised (DASAS-R) (Sousa et al., 2008). The patients' ability in performing the diabetes self-care was used to guide for development of telephone call content.

Development phase

The manual and media for supportive educative nursing program were developed by researcher (*see appendix D*). The manual included the goals of each session, materials, content, strategies, and detailed guidelines for patient

training, handouts, videos and exercise assignments. The supportive-educative nursing system included a combination of support, guidance, motivation, provision of an environment, and teaching particular knowledge and skills were applied in the program. The presentation, discussion and skills training were the methods which used for each session. Handouts and exercise assignments which were appropriate in each session were distributed. Videos showed how to do each self-care activities were distributed. Moreover, the discussion guidelines for group discussion and telephone discussion were distributed for participants. In addition, a set of written diabetes material was distributed to the participants.

The set of written diabetes material consists of the booklet which deals with the following topics: (1) what diabetes is, (2) diabetes and complications control, (3) diabetes food, (4) diabetes medications, (5) exercise, (6) diabetes self-monitoring, and (7) foot care. The content of videos is (1) what diabetes is, (2) living with quality of life in diabetes, (3) diabetes foods, (4) exercise, and (5) foot care.

Validation phase

After developing, this manual was reviewed by three experts for content validity. The first expert is a medical nurse who is nurse working in diabetes clinic. The second expert is a nursing instructor inn diabetes clinic. Both of them have had 5 years' experience taking care of patients with type 2 diabetes and are post-graduated nurses and are familiar with self-care concept. The third expert is a physician who is an expert on medical care and is familiar with self-care concept. In this study, from experts' recommendations, the content of SENP was changed in some kinds of foods which are familiar with Vietnamese people, example, change Twiss cheese to

butter or cheese. Some parts of this program were in general therefore it was needed to add the detail in foot care, examine the eyes and monitor blood pressure. In Vietnam, patients believed that the diabetes can be cured by using only the medicines, or the energy-dense foods or the traditional medicines, therefore, it was needed to put more strategies to convince them change their behaviors intern of solving problem and decision-making skills. The manual was revised according to the three experts' recommendations.

1.3. Prepare place

After getting the approval of PhD committee for research proposal and Ethics Review Committee for Research Involving Human Research Subjects of the Hanoi School of Public Health, the researcher contacted to director of Namdinh general hospital to get permission to conduct the intervention. After that, the researcher met Head of outpatient unit to get the agreement for experimentation. The room for intervention included table, chairs, and media system was prepared.

2. Procedure

The procedure of this study was different in the experimental group from control group. The procedure was presented as figure 4.

2.1 Procedure in the experimental group

1. After the participants were assigned to the experimental group, they participated following step for intervention:

Assessment step: The participants were assessed the actual knowledge, self-care activities and ability to perform self-care by using diabetes knowledge test (Fitzgerald et al., 1998), diabetes self-care activities questionnaire (Toobert et al., 2000) and the diabetes self-care agency scale (Sousa et al., 2008). The

researcher took face-to-face discussion with each patient in meeting room at outpatient clinic in Namdinh General Hospital. A report was developed to find out the self - care deficit and self - care demands of each patient. The time for each patient, depended on patients' actual knowledge and self-care activities, was around 30 to 90 minutes. In this study, four themes which illustrated patient's self-care deficits were emerged. The first one was lack of knowledge on accurate diet plan, self-monitoring technique and accurate physical activities. The second one was overlap between adherence regimens. The third one was fatigue and anxiety when had to do many things in the same time. Last thing did not have driving force to change and maintain the change and did not have any body to consult in some cases. Based on those information, the content of education part and the guideline for telephone call were developed.

Goal setting step: The researcher help participants set up the main goals for 5 self-care actions. The goals were based on patient own self-care deficit and self-care demands that were specific for each participant's situation. The goals could be changed during time for intervention.

Education step: This was basic plan and important steps with the purpose to provide diabetes self-care knowledge and skills which help patients improve their understanding and belief on their abilities and capacities to be confident in performing self-care behaviors to achieve target HbA1c level. Theme for this education process were: (1): Introduction in diabetes and its complications; (2): Diabetes diet; (3): Diabetes exercise; (4): Using medication in diabetes and how to deal with overlaps; (5): Diabetes self-monitoring and how to examine foot and how to monitor hyperglycemia and hypoglycemia. The schedule of this session was conducted as following steps. Firstly, researcher provided all the knowledge and skills related to

relevance topic for all participants within 1 hours per each session. Then, the participants were divided into 5 groups (each group had 9 to 10 persons). Each group was discussed to answer the topic guideline as: (1) What is main content of this session? (2) Which part is most difficult to understand? (3) Do you think you can apply the information on this topic to your daily life? (4) Do you need any support from others to apply those information? (5) Who will be your key person in doing this job? (6) What are steps in your plan to apply it? (8) How long do you start doing it?. The group discussion was took within 1 hour. After that, the researcher was collected all information and summarized and concluded the main points that participants must concern and pay more attention on. Patients also received the requirement record for related activity and were reminded to fulfill this record every day. This activity was took within 30 minutes. Lastly, patients were watched a related content video to remind them the content of session. Each video was in 30 minutes. The education process was 5 weekly meetings in meeting room at outpatient clinic in Namdinh General Hospital in 5 weeks.

Supportive step: This process was the central of the program for enhancing patient's self-care agency to perform and maintain all knowledge and information that they received at education process. This session was individual session. Each patient was immediately discussed with researcher by telephone call after first education session. The patient was received telephone call by researcher within 15 to 20 minutes. During telephone call, researcher let patient tell about his/her story related to performing self-care activities last seven days. Content of this conversation was based on the related record that patients received from education session. After that, researcher discussed with patients on following questions as: (1)

what is the hardest task in last 7 days? (2) Why did you think that? (3) What is main cause of this difficulty? (4) What is your plan to resolve this problem? (5) Who can help you on that task? (6) How can nurse help you on this?. Based on patient's answer, researcher was guided, supported and motivated them on choosing the best solution for his/her problem. The researcher also encouraged patient in doing and maintaining self-care activities. The research was finished conversation by remind patient on next meeting for education session or testing. This session was conducted within 11 weeks.

Evaluation step: The researcher and participants evaluated and discussed the achievement of long term goal which was related to the short term goal between. The participants were encouraged to share their own feeling and experience during cooperated in the program.

2. The participants attended in training program in a meeting room in outpatient clinic at Namdinh General Hospital. All participants were educated diabetes self-care knowledge and skills by researcher. The program was divided into five weeks with each session per week. Each session was performed within 180 minutes. A set of written diabetes material, a notebook and a pencil were distributed to each participants at the beginning of the program.

3. Parallel with education step, the telephone call was weekly conducted between researcher and each patients during 5 weeks and was continue until 11th week. Each telephone call time was around 10 to 15 minutes. The researcher discussed with patient about their self-care and health problems. Reminding patients for treatment regimens and providing consultation for manage patient's self-care tasks were performed. Researcher encouraged and motivated patient overcome the stress and difficulties to perform their self-care activities.

4. The participants completed the Diabetes Appraisal of self-care Agency Scale- Revised at baseline, 6 weeks and 3 months after to test the patients' self-care agency. The summary of intervention procedure was provided as described in Table 1 (*see Appendix E*).

5. The cost of blood sample test to determine the HbA1c level was covered. The participants received compensation for travelling expenses to intervention visits and time lost from work about 100.000 VNDs (150 Baht) per session at 12th week. Snacks and water was available during a break.

2.2 Procedure in the control group

1. The participants who were assigned to the control group received a routine care as following steps:

Participants met nurse in individual to receive the code and assess vital signs. Then they waited for physicians' examination at hall of diabetes clinic. At this place, participants were watched the general diabetes care videos without any instructions. The content of those video was "what is diabetes and it complications? What should patients do in term of prevention diabetes complication?". Participants were assessed and took blood sample by nurse in same room before after receiving physician's order. They were continuous watched those videos during the waiting time for laboratory test's results.

When the laboratory test's results came, the participants were received general diabetes care from nurse such as should choose foods with low sweet, should do exercise, should check blood glucose every day, and should take medicine ect. This information was provided within 10 minutes per participant. The process was repeated in same way every month.

2. The patients were taken blood sample to determine HbA1c level at the baseline and at 12th week after. Contact was kept with the control group by telephone call at 11th week to remind them of dates of appointments (The patients was given appointments to visit the outpatient clinic on different dates for the experimental group to prevent participants contamination). The cost of blood sample test to determine the HbA1c level was compensated. Traveling expenses (70.000 VNDs \approx 100 Baht) were paid for participants who came for data collection on a different date from their appointment with the physician.

3. At the end of program, the participants were distributed a set of written materials, booklet and all assignments as same the participants in experimental group received.

Protection of the rights of human subjects

Prior to data collection undergone a procedure to gain approval from the Ethics Review Committee for Research Involving Human Research Subjects of the Hanoi School of Public Health (No.290/2014/YTCC-HD3 on November 11th 2014) (*see appendix A*) and consent letter of chairman of Namdinh General Hospital. The potential people who met the study criteria were informed of the purpose, procedure, benefits, and risks of the study.

The participants were informed that the process of data collection would take around one to two hours and would involve answering questionnaires and drawing blood sample test to determine the HbA1c level at two times. They can refuse to answer any specific question which made them feel uncomfortable. There were not known major risks to participants in this study, only the discomfort of having blood draw. The participants were be assured that they can terminate their participation at any time. They

were also assured that their willingness to participate in the study had no implications for the health care services that they received. Their decision to discontinue participating in the study was not affected their relationship with healthcare providers or their assessment of any services available at the hospital. If they participated willingly, the written informed consent was signed between researcher and participants (*see Appendix C*).

The participants in experimental group were informed to attend in education sessions within 5 weeks and each session was 3 hours. Moreover, they were also informed to have telephone call in every week within 11 weeks. Each telephone call would be in 15 to 20 minutes.

Data collection

The data collection took place from October 2015 to January 2016. After this study got the Permission of the Faculty of nursing of Chulalongkorn University, and approval of the Ethics Review Committee for Research Involving Human Research Subjects, Hanoi School of Public Health (No.290/2014/YTCC-HD3 on November 11th 2014) and Namdinh General of Hospital for the data collection, the procedures for data collection were:

1. Researcher met patients who met the criteria as participants in outpatient clinic, and explained the objectives, procedures, and the protection of human right of the participants. When they agreed to participate, they had to sign the informed consent form. The researcher randomly assigned to put every participants to the intervention group or control group using lottery technique.

2. Data collection for knowledge and self-care activities was at one day before intervention for experimental group to prepare the program.

3. The pretest was at one day before intervention at the hospital. This data collection was blinding between participants and researcher to control confounding factors, decrease bias, and increase validity of the outcomes.

4. Participants in control group received the routine care, while participants in the intervention group received the supportive educative nursing program from the researcher.

5. The HbA1c level post-test was conducted at 12th week after pretest for both groups at the hospital. This data collection was also blinding between participants and researcher to control confounding factors, decrease bias, and increase validity of the outcomes.

6. Researcher checked the questionnaire and cleared the data prior to data analysis.

Data analysis

Data analysis was implemented through the SPSS (version 16.0). Descriptive statistics were used to analyze demographic data by using frequency, percentage, means, and standard deviation. The Chi-square was used to examine for the differences between the experimental and control group on categorical variables. The paired t-test and independent t test were used to analyze the difference in the mean of variables in the group and between groups, respectively. The significance level of all statistical tests was set at .05.

The assumptions for the t test were tested before further analysis. The following assumptions were examined to ensure the validity of statistical calculations.

1. Independence: Observations within each group was be independent because the patients were difference time to take blood sample and they not influence each other.

2. Normality distribution of HbA1c was tested. The dependent variable was accepted as a normal distribution. The skewness and kurtosis values of dependent variable were close to zero. Skewness and Kurtosis value of HbA1c variable had a skewness (0.755) and kurtosis (-0.063), respectively. Fisher's measure of skewness and kurtosis was calculated by dividing the skewness or kurtosis value by the standard error for skewness or kurtosis, $(0.755/0.263 = 2.870, -0.063/0.520 = 0.121$ respectively). Values above -1.96 and below +1.96 are significant at the .05 level (Duffy & Jacobsen, 2001). After transferring the HbA1c level to logarithm of HbA1c, the Fisher's measure of skewness and kurtosis was $0.473/0.263 = 1,798, -0.523/0.520 = - 1.005$. It indicated that this distribution of HbA1c is now closely normal (*see appendix I*).

In this study, the paired t test was used to test the difference mean of HbA1c level within experimental group or within control group. The results of this test were answered for hypothesis 1. The independent t test was used to test difference mean of HbA1c level between experimental and control group. The results of this test were answered for hypothesis 2. To evaluate the proportion of changing in HbA1c level was tested by using Chi-square test. The repeated measurement of ANOVA was used to test the changing of self-care agency scores at baseline, 6 weeks and 3 months.

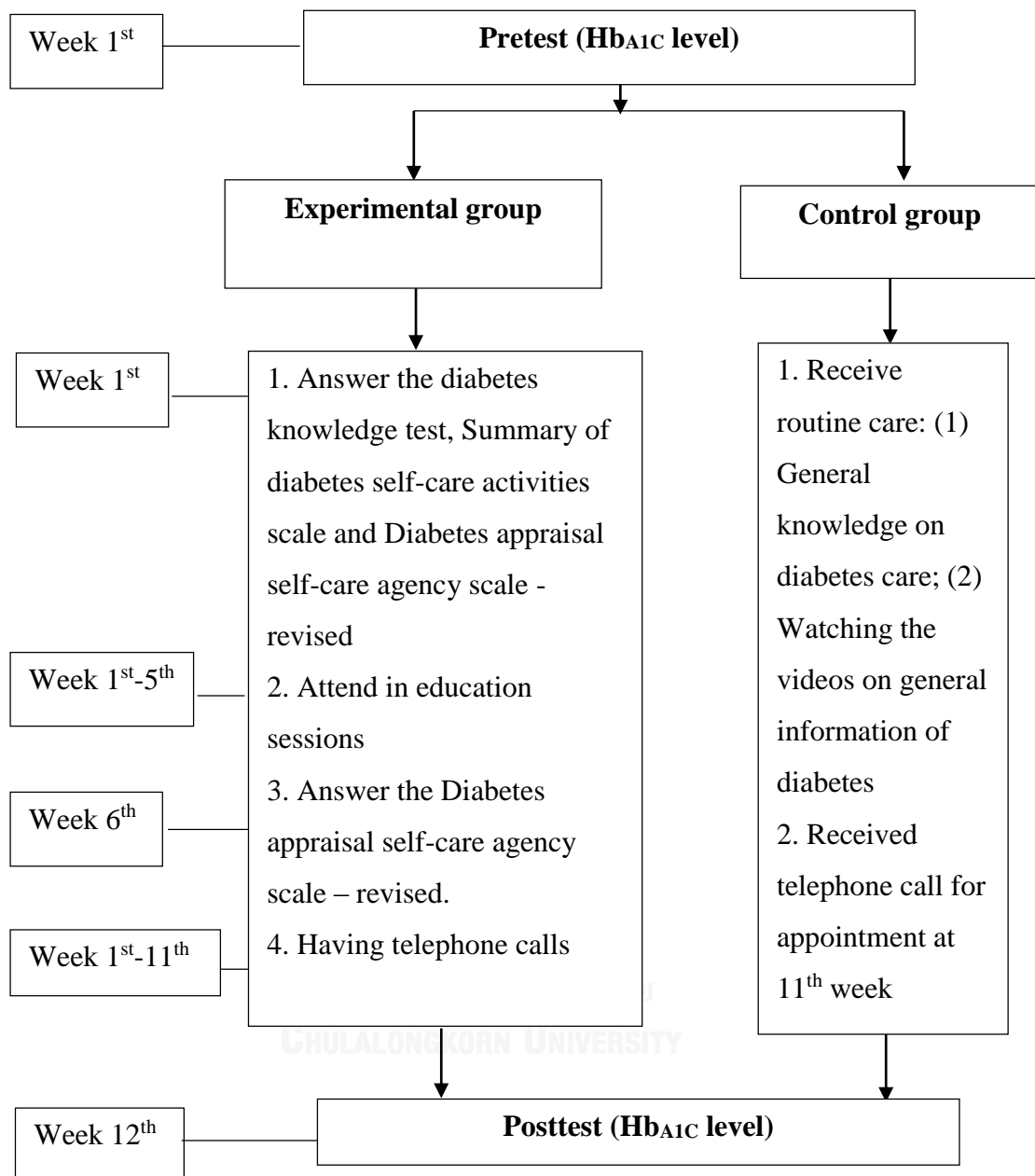


Figure 4: The summary of research procedure

CHAPTER IV

RESULTS

This chapter was presented the results of study on demographic data of participants and the effect of supportive educative nursing program on HbA1c level and also on self-care agency in Vietnamese with uncontrolled type 2 diabetes mellitus. Moreover, the effect size of the supportive educative nursing program on HbA1c level in Vietnamese with uncontrolled type 2 diabetes mellitus was also presented in this part.

1. Characteristics of the sample

This part was demonstrated the comparison of demographic characteristics of the participants in experimental group and control group. The categorical variables were compared with Chi-square test, meanwhile, the t test was used to test the difference mean of variables.

In the table 1 showed that of the 84 participants, approximately 56% of them were female and most were married (76.2%). The major address was urban (70.2%). The participants graduated from secondary and undergraduate degree was highest (34.5%). Over seventy percent of the participants had an income less than 100USD per month. More than a half of family members had diabetes (64.3%). The distribution of demographic variables regarding to gender, marital status, residential area, education, occupation or income and history of family member between intervention and control group were not significant difference ($p > .05$).

Table 1 Comparison of demographic characteristics of the experimental group (n=41) and control groups (n=43) with Chi-square test.

Variables	Experimental	Control Group	χ^2	<i>p-value</i>
	Group (n=41)	(n=43)		
	n (%)	n (%)		
Gender				
Female	21 (51.2)	26 (60.5)	0.72	0.394
Male	20 (48.8)	17 (39.5)		
Marital status				
Single	5 (12.2)	4 (9.3)	0.40	0.817
Married	30 (73.2)	34 (79.1)		
Divorced/widow	6 (14.6)	5 (11.6)		
Residential area				
Urban	32 (78.1)	27 (62.8)	2.34	0.126
Rural	9 (21.9)	16 (37.2)		

Table 1 (Continue) Comparison of demographic characteristics of the experimental group (n=41) and control groups (n=43) with Chi-square test.

Variables	Experimental	Control Group	χ^2	p-value
	Group (n=41)	(n=43)		
	n (%)	n (%)		
Education				
Primary/secondary	14 (34.2)	10 (23.3)	6.84	0.08
Tertiary	12 (29.3)	11 (25.6)		
Colleges/undergraduate	9 (21.9)	20 (46.5)		
Graduate/postgraduate	6 (14.6)	2 (4.6)		
Occupation				
Manual Labour	8 (19.5)	4 (9.3)	3.90	0.272
Governmental officer	13 (31.7)	12 (27.9)		
Business	6 (14.6)	13 (30.2)		
Pensioner	14 (34.2)	14 (32.6)		
Income per month				
Under 50USD/month	15 (36.6)	17 (39.6)	1.85	0.604
50 - <100USD/month	12 (29.3)	16 (37.2)		
100-<200USD/month	11 (26.8)	9 (20.9)		
\geq 200USD/month	3 (7.3)	1 (2.3)		
History of family member				
Yes	15 (36.6)	15 (34.9)	0.26	0.871
No	26 (63.4)	28 (65.1)		

In table 2 showed that the participants' age ranged from 36 to 89 years ($M = 66.05$, $SD = 10.03$). The average duration of diabetes mellitus was 2.37 years ($SD = 1.61$). All participants in this study had uncontrolled HbA1c level ($>7\%$) at baseline. Comparison of the means of the characteristics in the experimental and control groups were done using independent t test on a ratio scale of age, duration of disease and HbA1c level. No significant difference was found in the means of these three variables from the intervention and the control group ($p > .05$).

Table 2 Comparison of demographic characteristics of the experimental group ($n=41$) and control groups ($n=43$) with t test

Item	Experimental Group		Control Group		t test	p -value
	Mean	SD	Mean	SD		
Age	64.98	8.06	67.07	11.60	0.96	0.34
Duration of disease	2.34	1.69	2.40	1.55	0.17	0.86
HbA1c	9.32	1.43	9.33	1.44	-0.06	0.96

2. Results

In this part, the effect of supportive educative nursing program was explored. The tables presented the comparison of HbA1c level in groups before and after 3 months implementation of the program. The comparison of the difference mean of HbA1c level in control group and experimental group were presented. Moreover, the proportion of changing the HbA1c index and categories of controlling HbA1c were also presented. Besides that, the changing in total score of self-care agency and score of each components of self-care agency in experimental group were compared at before, 6 weeks and 3 months after undergoing the program.

Table 3 Comparison of HbA1c level between the experimental (n=41) and control group (n=43) at baseline and 3 months after program implementation, and between baseline and 3 months after the program in each group.

HbA1c level	Control Group (n=43)	Experimental Group (n=41)	<i>Independent t test</i>	p-value
	Mean (SD)	Mean (SD)		
Baseline	9.33 (1.44)	9.32 (1.43)	-0.06	0.96
3 months	9.4 (1.36)	8.47 (1.27)	-3.27	0.002
	Paired <i>t</i> – test = -0.68 (p=0.49)	Paired <i>t</i> – test = 5.53 (p<0.01)		

In the table 3, the mean of HbA1c level in experimental group decreased from 9.32% ($SD=1.43$) at baseline to 8.47% ($SD=1.27$) at three months later. The results showed that the total mean of HbA1c levels had significant difference ($t=5.53$, $p<0.05$).

Conversely, the mean of HbA1c level in control group increased from 9.33% ($SD=1.44$) at baseline to 9.4% ($SD=1.36$) at 3 months later. The changing in control group was no significant difference ($t=-0.68$, $p>0.05$). After three months, the mean of HbA1c level in experimental group (8.45%, $SD=1.27$) was lower than that in control group (9.41%, $SD=1.36$). When compared the mean of HbA1c level with t test, the results showed that the mean of HbA1c levels was a significant difference after three months ($t=-3.27$, $p=0.002$).

Table 4: Comparison of the number and percentage of the level of diabetes control in the experimental group ($n=41$) and control group ($n=43$) at baseline and 3 months after implementation of the program with Friedman test.

HbA1c control	Baseline	3 months	<i>F</i>	p-value
	n (%)	n (%)		
Experimental group				
Poor (HbA1c >10%)	9 (21.9)	4 (9.7)		
Fair (HbA1c >7%-≤10%)	32 (78.1)	32 (78.1)	8.33	0.04
Good (HbA1c ≤7%)	0 (0)	5 (12.2)		
Control group				
Poor (HbA1c >10%)	30 (69.8)	25 (58.1)		
Fair (HbA1c >7%-≤10%)	13 (30.2)	18 (41.9)	0.2	.65
Good (HbA1c ≤7%)	0 (0)	0 (0)		

In table 4, in experimental group, there were 12.2% of the participants could keep their $HbA1c \leq 7\%$ after 3 months implementation of the program. The proportion

of patients who poorly controlled their HbA1c level decreased from 21.9% at baseline to 9.7% after 3 months. The percentage of participants had good control of HbA1c level was significantly different at baseline and 3 months after ($F=8.33$, $p<.05$). However, in control group, the change was a little bit from 30.2% at baseline to 27.9% after 3 months. The level of diabetes control was no significant difference at pretest and posttest ($F=0.2$, $p>.05$)

Table 5 Comparison the number and percentage of participants in changing the HbA1c level between experimental group (n=41) and control group (n=43).

HbA1c level	Control group (n=43)	Experimental group (n=41)	χ^2	p-value
	n (%)	n (%)		
Stable	15 (34.88)	7 (17.1)	6.5	0.039
Increase	16 (37.21)	7 (17.1)		
Decrease	12 (27.9)	27 (65.8)		

In table 5, approximately the stable in HbA1c level in control group (35%) was higher than that in experimental group (17.1%). The increasing of HbA1c level in control group (37.21%) was higher than that (17.1%) in experimental group. Conversely, the decreasing of HbA1c level in experimental group (65.8%) was higher than that (27.9%) in control group. The changing HbA1c level was statistically different between control and experimental group at posttest ($\chi^2= 6.5$, $p<.05$).

Table 6: Comparison of the number and percentage of the level of diabetes control between the control and the experimental group at 3 months after implementation of the program.

Level of control	Control	Experimental	χ^2	p-value
	Group (n=43)	Group (n=41)		
	n (%)	n (%)		
Uncontrolled (HbA1c >7%)	31 (72.1)	32 (78.1)	12.15	<0.01
Controlled (HbA1c ≤7%)	0 (0)	5 (12.2)		

In table 6, there were a significant difference in the glycemc control between experimental and control group at 3 months after implementation of the program ($\chi^2 = 12.15, p < .05$).

Table 7. The change in self-care agency (SCA) before intervention, 6 weeks and 3 months after implementation in experimental group (n=41) with repeated measurement *F*- test.

Variables	Before	6 weeks	3 months	<i>F</i>	<i>p</i>
	Mean (SD)	Mean (SD)	Mean (SD)		
Total SCA score	41.10 (3.33)	63.46 (2.33)	65.82 (3.63)	623.56	<0.01
Components of SCA					
Having power	16.04 (3.32)	26.51 (2.95)	26.78 (3.34)	253.67	<0.01
Developing power	13.24 (2.19)	22.31 (2.06)	22.90 (2.32)	168.09	<0.01
Lacking power	11.8 (2.37)	14.63 (3.93)	16.14 (2.92)	110.33	<0.01

In table 7 showed that the mean score of SCA was compared during the time conducting the program. The mean score of diabetes self-care agency (DSCA) of the intervention group was higher at 6 weeks and 3 months after implementation the program and they differed significantly ($p < .05$). The mean score of each components of self-care agency was compared at baseline, 6 weeks and 3 months after intervention. The score of all components of self-care agency (having power, developing power and lacking power for self-care) had significant difference at three time points ($p < .05$).

Table 8. Comparison in mean of self-care agency (SCA) before intervention, 6 weeks and 3 months after implementation in experimental group (n=41) with paired t test.

Variables	Difference mean	Paired t test	p-value
Total SCA			
Before – 6 weeks	-22.36	-44.22	<0.01
Before – 3 months	-24.73	-56.33	<0.01
6 weeks – 3 months	-2.36	-5.44	<0.01
Having power			
Before – 6 weeks	-10.46	-19.37	<0.01
Before – 3 months	-10.73	-19.35	<0.01
6 weeks – 3 months	-.26	-.63	<0.01
Developing power			
Before – 6 weeks	- 9.07	-29.53	<0.01
Before – 3 months	- 9.65	-33.63	<0.01
6 weeks – 3 months	-5.8	-1.81	<0.01
Lacking power			
Before – 6 weeks	-2.82	-4.73	<0.01
Before – 3 months	-4.34	-8.5	<0.01
6 weeks – 3 months	-1.51	-2.31	<0.01

In the table 8 showed that the mean of self-care agency was increased in both total score and all dimensions of self-care agency score. For total score, the mean of self-care agency was significantly changed after 3 months implementation program ($p < 0.05$). For dimensions of self-care agency, all dimensions were significantly

increased after 3 months undergoing intervention, except having power and developing power for self-care were not significantly different at 6 weeks and at 3 months ($p < 0.05$).

Table 9. The correlation of self-care agency scores and HbA1c level in experimental group (n=41) at baseline

	Having power	Developing power	Lacking power	Total SCA score	HbA1c
Having power	1				
Developing power	0.48*	1			
Lacking power	-.67*	-.66*	1		
Total SCA score	.84*	.67*	-.39*	1	
HbA1c	-.78*	-.61*	.54*	-.79*	1

* Significance at $p < .05$

In the table 9, the total scores of self-care agency was significantly correlated with HbA1c level at baseline ($p < 0.05$). All components of self-care agency were significantly correlated with total score of self-care agency ($p < 0.05$). In all self-care agency components, the having power and developing power were negatively significant correlation with HbA1c level at baseline ($p < 0.05$). Meanwhile, the lacking

power of self-care was positively significant correlation with HbA1c level at baseline ($p < 0.05$).

Table 10. The correlation of self-care agency scores and HbA1c level in experimental group ($n=41$) at 3 months after implementing of program

	Having power	Developing power	Lacking power	Total SCA score	HbA1c
Having power	1				
Developing power	.90*	1			
Lacking power	-.79*	-.76*	1		
Total SCA score	.85*	.85*	-.41*	1	
HbA1c	-.90*	-.79*	.60*	-.85*	1

* Significance at $p < .05$

The results in table 10 showed that the total score of self-care agency was significantly correlated with HbA1c level at 3 months after intervention ($p < 0.05$). The total of self-care agency were positively significant correlation with having power and developing power for self-care at 3 months ($p < 0.05$). The lacking power for self-care was negatively significant correlation with total self-care agency at 3 months ($p < 0.05$).

In all self-care agency components, all of them was significantly correlated with HbA1c level at 3 months after implementation of the program ($p < 0.05$).

The effect size of this study

The effect size presents the ability to detect an association between a predictor and an outcome variable (Browner, Newman, Cummings, & Hulley, 1988).

The effect size is calculated by the following formula:

$$\begin{aligned} \text{Effect Size} &= \frac{\text{Treatment group mean} - \text{Control group mean}}{\text{Control group standard deviation}} \\ &= \frac{8.4 - 9.4}{1.36} = 0.74 \end{aligned}$$

There are three levels of value of effect size: small = 0.2, medium = 0.5, and large = 0.8 (Cohen, 1988). The effect size of HbA1c at 3 months in this study was medium as 0.74.

In summary, the mean of HbA1c level in experimental group was significantly decreased at 3 months after undergoing the program ($p < 0.05$). Besides that, the mean of HbA1c level in experimental group was significantly lower than that of the control group after 3 months ($p < 0.05$). Moreover, there was a significant difference in comparing each kinds of changing HbA1c level between experimental and control group at 3 months ($p < 0.05$). After 3 months, there was only 12.2% of participants in experimental group could control HbA1c level. This was significant when compared with that of control group ($p < 0.05$). In this study, the HbA1c level was significantly correlated with both total score and components score of self-care agency (SCA) ($p < 0.05$).

CHAPTER V

DISCUSSION

This chapter presented a discussion of the research findings. It examined characteristics of the participants; explored the effects of the supportive educative nursing program on Hb_{A1C} level and self-care agency; and finally, gave recommendations from the results.

Summary of results of the study

This randomized controlled trial (RCT) study aimed to test the effect of a supportive educative nursing program on HbA1c level in Vietnamese people with uncontrolled type 2 diabetes mellitus. Orem's self-care theory was the theoretical framework for this study.

Data collection was done at a hospital in the North part of Vietnam. The samples were recruited to the study were Vietnamese with uncontrolled type 2 diabetes mellitus aged over 18 years in outpatient clinic of Namdinh General Hospital using the following criteria: had been diagnosed with type 2 diabetes at least 6 weeks; had fasting plasma glucose level over 130 mg/dL at nearly past 6 weeks checking at hospital before entering the program; to be prescribed with one kind diabetes medication and not receive insulin therapy; had no diabetes-related complications (end stage renal disease, heart failure, lower extremity amputation), or other serious illness, or hemoglobinopathies, or alcoholism, or any blood diseases; and able to read Vietnamese.

Ninety participants were randomly assigned to the intervention or the control group by sealed envelope technique. The dropping of participants in this study was low as 8.7% of the participants (eight people): five persons (10.9%) from the intervention group, and three persons (6.5%) from the control group. Finally, eighty four

Vietnamese with uncontrolled type 2 diabetes were left in the intervention group (n=41) and in the control group (n=43).

The proportion of participants got 80% of self-care agency scores (60 points) was dramatically changed after 6 weeks. At baseline, all participants had not enough self-care agency (less than 60 points of self-care agency scores). On the contrary, there were one hundred percent of participants had enough self-care agency (over 60 points of self-care agency scores) after 6 weeks and 3 months intervention. The self-care agency score was significantly correlated with HbA1c level at baseline and 3 months after undergoing intervention (Pearson was - 0.454 ($p=0.003$) and -0.703 ($p<0.001$), respectively).

After the 3 months, the HbA1c level in intervention group was reported a significant decrease after 3 months undergoing intervention ($t=5.53$, $p<0.05$). Moreover, the HbA1c level was significant difference between control and experimental group after 3 months implementation intervention ($t=-3.27$, $p<0.05$). Moreover, the changing of HbA1c level in experimental group was statistically different when comparing with that in control group after 3 months intervention ($p<0.05$). Additionally, the level of diabetes control was significant difference between control group and experimental group at 3 months after implementation program ($p<0.05$). For self-care agency, the mean score of SCA was significant difference at baseline, 6 weeks and 3 months after implementation the program ($p < .05$). The score of all components of self-care agency (having power, developing power and lacking power for self-care) had significant difference at three time points ($p<0.05$).

In summary, data analyzed 41 participants in the intervention group and 43 in the control group. The T-test were used to test the hypotheses. The characteristics of

the samples in the intervention and control group were not significant difference at baseline. The HbA1c level was statistically significant difference between the intervention group and the control group ($p < .05$). The mean of HbA1c level in experimental group was lower at 3 months implementation program than that at baseline ($p < .05$).

Discussion

Characteristics of the participants

Approximately more than a half of the participants in this study (56%) were female and most were married. This is consistent with previous studies which also show a higher ratio of females with type 2 diabetes to males (Bui, 2009; Nguyen & Nguyen, 2014; Trần & Nguyễn, 2009). Trần & Nguyễn. (2009) studied in diabetes type 2 in Ho Chi Minh City found that 110 of 161 of patients were female. Consistency, a research studied males and females aged 19 to 97 found that type 2 diabetes mellitus was more often found in the females (Tran & Tran, 2013). Type 2 diabetes mellitus was more prevalent in older age groups (American Diabetes Association, 2016). Therefore, the mean age of participants chosen for this study was most in elderly ($M = 66.05$, $SD = 10.03$). This result was consistent with the result in previous study which showed the average age of people with type 2 diabetes was late middle age ($M=57.1$, $SD=12.8$) (Bui, 2009; Nguyen & Nguyen, 2014; Trần & Nguyễn, 2009). The results in the studies reflected an actual situation in Vietnam, the type 2 diabetes were popular in people aged over 40 years (Ministry of Health, 2016). Over a third of patients (33.3%) was pensioner this was explained by the age of patients. This results was indicated in the study on 100 people with type 2 diabetes aged from 38 to 68, nearly half of patients was pensioner (Bui, 2009).

Approximately 34.5% of the participants had colleges and undergraduate education. Namdinh General Hospital is province hospital which located on Namdinh City, therefore, this hospital mostly served for residents who may have higher education level than others in difference area. This result was reflected by most of patients living in urban area (70.2%). The evidence of higher proportion of diabetes patients in urban was illustrated in previous studies (Nguyen & Nguyen, 2014; Trần & Nguyễn, 2009). Nguyen & Nguyen. (2014) showed that there were 63.3% of patients living in urban area.

Approximately 76% of the participants got married. Despite the poor economic situation of participants, more than third of the participants (38.1%) were under 50 USD per month. Approximately 35.7% of the patients have family member got the diabetes. The results in this study were consistent with the results in previous studies. There were approximately 32% of patients have family member got type 2 diabetes mellitus (Bui, 2009; Nguyen & Nguyen, 2014). The duration of disease was 0.7 to 9 years ($M=2.37$, $SD=1.61$). This result was different when compared with that in other studies. Bui. (2009) showed that the average duration of disease in type 2 diabetes patients was 7.8 years ($SD=6.48$). It is explained that the time and location of collecting data were different in these studies, therefore, it were illustrated their own characteristics of their population.

Comparison of the characteristics of the participants who participated in the study and those who refused to participate did not show any significant differences. This ensured that the refusal of some participants to participate study would not affect the dependent variables. To control extraneous variables as much as possible, randomization was conducted. Equally all possible distinguishing characteristics of the

participants between the intervention and control groups were compared. Statistical analysis showed no significant difference in demographic characteristics between the intervention and control groups was found because eligible participants were assigned to the groups by randomly. This method secures comparable group. Possible sources of extraneous variables can be controlled (Burns & Grove, 2009).

Withdrawn from the study might be especially high, if data collecting took a long time. A bias may be more than 20% of the participants drop out of the study (Polit & Hungler, 1999). In this study, there was only 8.7% attrition rate (12.2% of experimental group and 6.9% of control group) and the participants who withdrew from the study had reasons which were not to do with dissatisfaction with the program. In addition, participating the program required attendance at the hospital once a week for 5 weeks, consistent with 11 weeks follow-up. Some participants had unforeseen situations in their life during the program time period so they could not complete the whole program as they intended. The unforeseen situations were having the business, moving to another provinces or busy with their life. In addition, the participants who dropped out had similar demographics to the participants who remained in the study. This means that the participants who withdrew from the study did not have significant characteristics that would affect the dependent variables.

Effect of the Supportive Educative Nursing Program (SENP)

Effect of the Supportive Educative Nursing Program (SENP) on dependent variable

The effect of the SENP on the self-care agency and HbA1c level were discussed. In addition, responses of the participants to the SENP were presented.

The program in this study was based on Orem's theory with assumption that, the person had self-care agency, he/she can be good in controlling the glycemic control. Self-care agency is behavior that diabetes patients need have to manage their disease. For changing behavior, people need 4 to 6 weeks to decide whether the behavioral change was taken place (Hongu et al., 2011). Therefore, in this study, the self-care agency was measured from baseline to 6 weeks and 3 months later. Patients got 80% of self-care agency scores were indicated as having self-care agency, otherwise were not. In despite of all participants had inadequate self-care agency at baseline. Under supportive educative nursing system, nurse help participants got adequate self-care agency after 6 weeks and 3 months of undergoing the program. Nurse used helping techniques to teach, guide and to provide the diabetes self-care knowledge and skills during 5 first weeks. The patients had an opportunity to discuss with nurse and other type 2 diabetes patients to explore the knowledge and skills. Nurse supported patients the help and experiences from other type 2 diabetes patients that help patients deeply understand, be confident and ability in caring themselves at home.

Moreover, patients were supported by telephone call follow up every week from nurse to help them overcome their problem regarding to perform self-care. Patients had an opportunity to share their actions to let others know their difficulties and their psychological issues when performing self-care. Patients were reduced their anxiety and stress, then, they can be easy to accept and uphold their activity. Moreover, nurse deeply explored patient's obstacles that help nurse got into patient's self-care deficits and self-care demands. From that, nurse gave the best solution to motivate patients enhance their self-care agency. The result in this study was consistent with the results of previous studies. The self-care behaviors in the experiment group before the

educational intervention was low (29.06 ± 10) and it significantly improved (39.69 ± 4.74) after 3 months educational intervention ($p < 0001$) (Zareban, Karimy, Niknami, Haidarnia, & Rakhshani, 2014).

In the findings, we found that there was significant correlation between self-care agency and HbA1c level both at baseline and 3 months after implementation program ($p < .001$). All components of self-care agency was significant correlation with HbA1c level both at baseline and 3 months after implementation program ($p < .05$). Under Orem's theory, when the patients had therapeutic self-care demands that came from their health deviation self-care requisites, in order to improve their wellbeing, patients need help from nursing system. In all nursing system, educative supportive nursing system is the most applicable. Using helping technique, nurse became a key person to teach, guide, provide, support and motivate patients to improve their ability in performing self-care and maintaining their action in their daily life. From that, patients can control their HbA1c level and prevent onset of diabetes complications.

In this study, the participants in experimental group had lower mean of HbA1c level after 3 months entering the supportive educative nursing program than before ($t = 5.53$, $p < .05$). This result was explained by the way nurse helping the patients. Nurse not only provided the knowledge, skills and deeply understanding patients' self-care agency, but also run along with patients in performing their activities at home. Moreover, nurse also let patient become the most important person in performing self-care activities that help patients recognize their role and responsibility in changing and maintaining their self-care. That mean patients enhanced their self-care agency to meet their therapeutic self-care demands in order to reduce their HbA1c level.

The decrease HbA1c level in this study was similar with the result in Zareban et al (2014) study in which mean HbA1c (9.7%) of the test group reached (8.30%) 3 months after, paired *t*-test with 95% confidence showed significant difference between them ($p < .05$). However, the results in this study was higher than that in the meta-analysis study of Norris et al. (2002) in which SENP education decreased HbA1c by approximately 0.26% at 1 and 3 months of follow-up. Similar to Norris et al.'s study a meta-analysis by Ellis et al. (2004) showed that HbA1c change in the intervention group was 0.294% at 3 months after intervention. In contrast, the average HbA1c decrease in this study was lower than that in Keeratiyutawong et al (2005). In Keeratiyutawong's study, the mean decrease HbA1c level was 2.04 ($SD = 2.13$) at 3 month compared with baseline. The reason for the difference between two studies may be explained by the difference of average of HbA1c level at baseline. In Keeratiyutawong's study, the average of HbA1c level of patients was 8.93 ($SD=2.38$) which was lower than that in this study ($M=9.32, SD=1.34$).

The mean of HbA1c level in experimental group was significant difference from that in control group after 3 months undergoing the program ($t= -3.27, p<.05$). When comparing the interventions which each group of participants received, we found some benefits of supportive educative nursing program from patient's participation. Firstly, the participants in control group was only received the general knowledge in disease and diabetes care tasks. Conversely, the participants in experimental were not only received the specific diabetes self-care knowledge and skills but also received the supports from nurse through telephone call every week to help patient know how to perform diabetes self-care activities. Secondly, in routine care, the nurse did not spend much time with patient because the overload of patients

and the environment was noisy. Therefore, there was limit time in interaction between healthcare providers and patients. Conversely, in intervention group, the nurse and participant met in private room to discuss on the patient's own situation, from that the patient's own self-care deficit and self-care demands were explored. Each participants had at least 30 minutes to discuss therefore nurse and patients could deeply understand each other. This action increased the nurse-patient interaction and patient participation in their own work. Lastly, in routine care, patient had no other supports to help them maintain their self-care actions when they stay at home. They did activities if they though it useful otherwise they did not.

Conversely, the patients in experimental group were received 11 telephone calls follow-up from nurse. Through those telephones, nurse help patients find their own problems and find their own solutions to overcome those problems. Patients received formal information that was appropriate with their situation. From that, they did in the accurate way to make their self-care activities effectively act on their HbA1c level control. Moreover, talking with nurse help patient feel better and reduce stress to follow diabetes regimen. Meanwhile, only receiving the routine care, the patient did their self-care by their own way. They explained that they did not force them to do sometimes because they thought in their mind that it was not necessary to do, they must enjoy their life to taste and do everything that they want before they die. It is essential confirmation that using the patient participation in self-care behavior change was very important. This help patients individual realization their own responsibility, ability and mission in controlling their HbA1c level. The results in this study were consistent with the findings in previous studies. There was statistically

significant improvement of HbA1c level in intervention groups compared with control groups (Hunt, 2013; Loveman et al., 2008; Minet et al., 2010; Zareban et al., 2014).

In this study, there were statistically different between control and experimental group after 3 months intervention in changing HbA1c level as stable, increase or decrease status ($p < .05$). In the control group, there were 27 of participants had decreased HbA1c levels at 3 months compared with baseline. This could be explained by the fact that the participants in the control group received diabetes education from a diabetes health care team of the hospital on the date of the physician's visit. The participants received the general knowledge in diabetes care and also the information from videos. Moreover, in some participants, they can found the information from such a resources: the internet, magazine, or bulletin etc. Those patients could apply the information to their situation in order to control their HbA1c level. Those things may have encouraged the people in the control group to be more concerned about their disease and take care of themselves.

However, there was smaller number of participants of HbA1c decrease than the SENP group. In addition, there were some patients were stable in their HbA1c level both in control (34.88%) and experimental group (17.1%). Additionally, there were 37.2% of participants in control group and 17.1% of participants in experimental group increased their HbA1c level after 3 months. The reason may occur when patients could not overcome their thinking that they could not keep their HbA1c level as acceptable range even though they want. Therefore, they skipped their old behavior or change a litter bit. The other reason may have, in some cases, the patients had sudden stress in their life, and they had been looking the food to reduce the stress as they explained. Meanwhile, the weakness point in this program was explored that the stress

management was little mentioned in this study. Therefore, the researcher could not help patients overcome their situation if they got serious stress.

Moreover, the other reason for stable and increasing HbA1c level in experimental group might be explained by the fact that when the patients had other problems in their life such as health problems, economic problems or family problems, these factors may have influenced their life satisfaction. Consequently, the motivation to maintain diabetes SENP may be affected. However, process of self-care agency development in patient with diabetes requires time, energy, effort, motivation, self-discovering of appropriate actions, and reinforcement from significant person and health care provider (Keeratiyutawong, 1994). After self-care activities declined, this may have affected HbA1c levels.

Other possible reason for the decline of outcome score after 3 months is that the strategies to encourage self-motivation of the participants to maintain their self-care agency were not intensive enough. The SENP gave telephone calls to the patients every week. Although the participants could call the researcher whenever they had any problems to discuss, some patients may not have called even when they did have problems. Thus, perhaps the researcher received SENP problems from the patients too late to help them solve their problem before the date of data collection. This may be why outcome measured increase in some cases at 3 months.

The SENP in this study was designed to improve skill abilities. The SENP was based on a supportive-educative nursing system comprised of teaching, supporting, guiding, motivating and providing a suitable environment to help patients control their HbA1c level. In addition, providing telephone calls was beneficial for helping the participants cope with diabetes and for encouraging internal motivation to

take care of themselves. Holistic care for patients with diabetes was an important concern.

The findings in this study showed that the level of diabetes control was significant difference at 3 months after implementation program ($F= 8.33, p<.05$), in despite of no significant difference at baseline ($p>.05$). The number of participants could control their HbA1c level in experimental group was 12.2% at 3 months. Keeratiyutawong et al. (2003) explored self-care experiences of Thai patients with type 2 diabetes who were not successfully controlling their blood glucose levels and reported that when these patients believed their blood glucose level was “in control”; they did not follow strictly their self-care regimens. In addition, there were several factors related to blood glucose levels such as the progression of disease in each individual, change in life patterns, interference from other illnesses, and energy expenditure change. The patients must cope with new situations which they became involved in and balance their SENP with these new situations. These processes require time for management until the patients can regain of control the situation. The researcher helped patients pass through this process by giving information, encouraging and motivating patients to solve their problems in a proper way.

For example, during the telephone call we found that in some patients after finishing session five of the SENP, this patient had hypoglycemic symptoms very often then she took off medications. Consequently, she became anxious and felt burden. She told that she could not remain her self-care activities, she would returned her old lifestyle. Researcher had to take a long time to discuss with her about what did she thing that would help her can improve her situation. She told only one sentence that “I will be better if I live like before”. By convince her, the nurse told her about the family,

the future and did not forget to add the consequences of uncontrolled diabetes. The researcher tried to find the person who had to face with serious situation with diabetes complications was known by this patient. At the end of discussing on that person's situation, the patients said "oh I know my point". Then next telephone, she told that she separated her food in 6 times per day and made a schedule for it. Parallel with that took medicine and wrote the self-report to evaluate the blood glucose level. From that, the patient reduced HbA1c level from 10.1 at baseline to 8.5 at 3 months later.

However, in this study, the number of participants could control their HbA1c level ($\leq 7\%$) was very low (12.2%). This could be explained by the HbA1c level at baseline of experimental group was very high at 9.32% ($SD=1.43$). In Vietnamese culture, the patients believed that all conditions of disease would be disappeared by only using the medicines. Therefore, they were strictly adhered with medicine, otherwise, they did not adhere with other all diabetes self-care. The person with type 2 diabetes was not helped with medication adherence only. They need adhere all diabetes self-care regimes. In some cases, they felt hard to adhere with diet sometimes and they ignored it as they explained. The other reason for their ignoring was that the participants lived with their children or grandchildren, they prepared the food for them, and therefore, they did not want to bother their children. That why they eat same things that were prepared for them. The program should be run with specific solution on helping participants adhere with diet regime. Additionally, the intervention need more time to explore patients' nonadherence to diabetes self-care, from that can help them overcome it.

Furthermore, this intervention need more strategies to improve strengthen such as improving family supports and control the environment effect to

patients. This result was higher than that in previous study. The percentage of participants in the intervention group who had decreased HbA1c level compared with baseline was 55% at 3 months; these were higher percentages than in the control group (Keeratiyutawong et al, 2005). Those results continuously confirmed the evidence in the meta-analysis study of Norris et al. (2002) in which HbA1c decreased more with additional contact time between participant and educator; a decrease of 1% was noted for every additional 23.6 hours (13.3-105.4) of contact.

In summary, the SENP was more effective in improving mean score of diabetes self-care agency in persons with uncontrolled type 2 diabetes mellitus. From that, the mean HbA1c levels in the SENP group were lower than those both in group before and after intervention and in comparing with control group at 3 months. The effect size of HbA1c at 3 months in this study (0.71) was a little bit higher than that in Fan & Sidani. (2009) meta-analysis (0.63).

Responses of the participants to the supportive educative nursing program

The participants in the SENP group showed a positive response to the diabetes SENP. In general, the participants were enthusiastic about joining the program as evidenced by the attendant rate during the program. Most of them had participated in the program regularly and punctually. The participants suggested that diabetes SENP should be performed more often at the hospital. They said that participants may not be interested in joining the group at first when they heard about it. If the participants had an opportunity to attend the program, they would know about the benefits that they would come and frequently join. One person said "I feel comfortable and friendly, so I can ask any questions that I want. The program has taught me everything about diabetes care and has time for discussion that made me understand how to care for myself."

Every participants in the program said that they felt happy to join the program. They agreed that it was a good way to share their experiences about diabetes care together. Some people shared that they shared the knowledge and skills which they learnt from the program with their friends or their relatives. The participants suggested that the program should have more content about showing the way to teach other people because they felt that it was a difficult task to convince other people to believe what they were saying about diabetes care. After the program finished, the participants would like to continue meeting together to share their experiences about diabetes care and encourage each other to maintain their diabetes self-care behaviors.

These reflections illustrated that all the participants were satisfied with the SENP. The program enhanced a process of learning for diabetes self-care and increased their ability to take care of themselves. Moreover, the program provided an environment for sharing knowledge of self-care experiences and group cohesion was established.

Limitations

The design of this study was more concerned about threats to internal validity by the selection of a heterogeneous sample; therefore, generalizability was decreased. In this study, homogeneous samples were obtained by balancing between sufficient controls and real clinical practice situations. Thus, the results of this study were generalizable only to uncontrolled adult and older people with type 2 diabetes mellitus at the level of a province hospital in Vietnam. A province hospital in Vietnam is likely to share characteristics such as geographies, size, health care services, characteristics of patients with diabetes, and treatments. However, there are some points to be aware of when implementing this SENP in other settings. This SENP would have limited

application for patients who have limits on their functional ability, patients took more medicines and patients with serious diabetes related complications.

This program was not strong on reducing the stress for participants when they had. During the implementing the program, some cases expressed their stresses on adherence to diabetes self-care, therefore, it should be better if the researcher did well on stress reduction plan.

In reality, not only nurse was the person that patients contacted, they may have others such as family, colleagues, friends or others. Those people were also important. However, the role of those people was not mentioned and got them into the program in this study. Therefore, the point of social support was not strong in this study.

Recommendations and Implications

The findings of this study can implicate in nursing practice, nursing education, and national health policy. In addition, recommendations for future research were presented.

1. Implications for nursing practice

The diabetes SENP should be implemented at the province hospital level in Vietnam. The current province hospital diabetes education services were given to the control group; the new self-care education program was conducted in the experimental group. The results showed that the outcomes were better for the experimental groups. Therefore, supportive educative nursing program should be a part of diabetes educational services. Diabetes education in a province hospital was normally run in the morning on the day of the physician's visit while the patients wait for laboratory results and a lecture given at the clinic. This kind of service

may not be effective because the environment was not conducive for learning. It can be noisy, crowded, and interrupted. Also, the characteristics of patients are different, therefore, they may have different problems of self-care and need different nursing interventions. Diabetes education services should set up a new model and may be provided on the day when the physician was not present.

Currently, nurses in some hospitals had responsibility to educate for diabetes patients but some did not. The reasons may be they did not have enough time and lack of consider about that. This needs to be resolved; all hospitals should train the nurses in diabetes self-care education and force them to educate for patients. This model was only conducted 3 hours per week within 5 weeks and 20 minutes per pay within 11 weeks but help patients with diabetes learn to manage their disease effectively. The self-care education program responds to the National Chronic diseases Management which aims to provide quality services to all people equally, responding to people's needs, and encouraging people to participate in taking care of themselves.

However, this program is better if the nurse focus more in the part to help patient develop their power and reduce lacking of power for self-care. The strategy for this concern may be supporting a good environment such as family support, peer supports, and social support. Additionally, the time to expand the patient's ability to perform their self-care should be one of part for future study.

2. Implications for nursing education

Curriculum of diabetes self-care should be developed for training advanced nurse practitioners. The nurse practitioner should focus on how to make a network to share information in caring diabetes patients. The program on promote self-care and behavioral change, Orem's self-care theory and the concept of patient

empowerment; medical knowledge about diabetes mellitus, pathology of diabetes, diabetes care, diabetes medications; goal setting, problem solving skills, communication skills; practical skills, foot care, exercise, food management, and self-monitoring skill should be conducted very three month for update the information for nurse. The effect of this program on glycemic control and other health indicators in type 2 diabetes patients should be explored in further study.

3. Implications for national health policy in Vietnam

The health care reform proposes to develop the health care system to provide quality services within the same health expenditure or at a lower cost (Ministry of Health, 2012). The National Healthcare Policy is the major vehicle health financing and health service delivery reform. To decentralize health resources to a community level, primary medical care levels need to be strengthened to provide good quality of care as well as improve the capacity of health care providers. The results of this study showed the effectiveness of the diabetes self-care program at the province level. From those findings, there were some following points should be concerned in the national health policy:

1. Promoting models of health care delivery which focus on patient self-care should be emphasized. Should have a strategy to help diabetes patients participate in diabetes self-care education as such volunteer program. And this program should no conduct only in the hospital also in community. The materials of diabetes self-care program should be free distributed for all people.
2. The nurse educator should be trained in this supportive educative nursing program to be able to train for nurse students to make a strong system in caring for diabetes patients.

3. A network of diabetes care should be set up for sharing of resources among provincial hospitals, community hospitals, and health centers of each region. This network should be supported by government or Ministry of Health.

4. The principle of the supportive educative nursing program on type 2 diabetes may apply to other chronic illnesses such as type 1 diabetes, hypertension, and ischemic heart disease. However, those programs should be developed and tested the effectiveness.

4. Recommendations for future research

In this study showed that the supportive educative nursing program was effectiveness on reducing HbA1c level in person with type 2 diabetes. However, the maintaining diabetes self-care for longer periods of time was a challenging issue for nurse practitioner. In some previous studies illustrated that the HbA1c level reduced at three months but increased at longer time. In the meta-analysis study of Norris et al. (2002) demonstrated that on average, the intervention decreased HbA1c by 0.76% (95% CI 0.34-1.18) more than the control group at immediate follow-up; by 0.26% (0.21% increase - 0.73% decrease) at 1-3 months of follow-up; and by 0.26% (0.05-0.48) at \geq 4 months of follow-up. Therefore, the further study on long term effect of the SENP should be conducted.

The limitation of this study was only focused on HbA1c level in order to assess glycemic control of patients. However, other health indicators and other sensitive outcomes of patients should be assessed in future study to demonstrate more effectiveness of the SENP.

The major problem of diabetes self-care was relapse from self-care activities over a longer period of time. The factors related to self-care relapse in Vietnamese diabetes patients should be explored. Moreover, strategies to prevent relapse or to maintain diabetes self-care should be studied.

This study was not explored the psychological issues of people with type 2 diabetes. However, during implementation program, some of psychological issues were engaged. Therefore, the adding of more psychological strategy in content of the SENP should be studied in future.

The research on implementation of the diabetes self-care program in province hospitals throughout the entire health care system should be performed. Additionally, a diabetes care network among provincial hospitals, community hospitals, and health centers of each region, which focuses on how to share resources and what a referral system should be, should be further studied.

The intervention with stronger in stress management and social support should be assessed the effectiveness in persons with uncontrolled type 2 diabetes mellitus.

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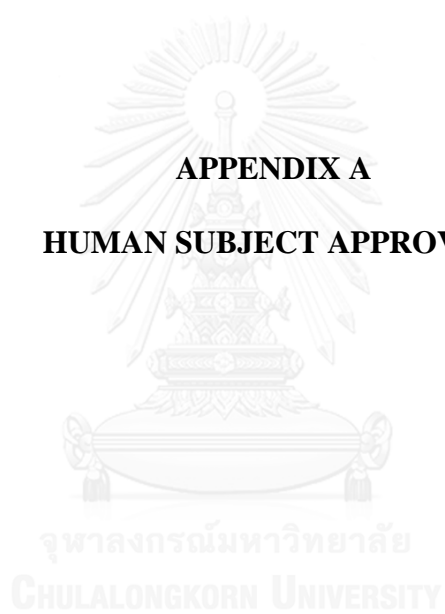
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APPENDIX A
HUMAN SUBJECT APPROVAL



MINISTRY OF HEALTH
HANOI SCHOOL OF PUBLIC HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom - Happiness

No.: 290/2014/YTCC-HD3
Subject: Ethical Approval

Ha Noi, November 19, 2014

DECISION

On Ethical approval for research involving human subject participation

THE CHAIR OF THE ETHICAL REVIEW BOARD FOR BIOMEDICAL RESEARCH
HANOI SCHOOL OF PUBLIC HEALTH

- Based on Decision No. 201/QĐ-YTCC by the Dean of Hanoi School of Public Health on Establishment of The Institutional Ethical Review Board of Hanoi School of Public Health; 12 April 2012 ;
- Based on decision No. 202/QĐ-YTCC by the Dean of Hanoi School of Public Health on the Issuing Regulation of the Institutional Ethical Review Board of Hanoi School of Public Health; 12 April 2012;
- After reviewing research ethics application No. **014-290/DD-YTCC** submitted by Nguyen Thi Minh Chinh, PhD Candidate- Faculty of Nursing, Chulalongkorn University, Thailand, on 09 November, 2014.

DECIDED

Article 1. Grant ethical approval for ethnographic study project:

- Project Title: **The effect of supportive-education nursing program on HbA1C level in Vietnamese type 2 Diabetes patients.**
- Principle Investigator: Nguyen Thi Minh Chinh-PhD Candidate- Faculty of Nursing, Chulalongkorn University, Thailand
- Supervisors: Assoc. Prof. Sureeporn Thanasilp and Dr. Sunida Preechawong- Faculty of Nursing, Chulalongkorn University, Thailand
- Research site in Vietnam: Nam Dinh General Hospital, Nam Dinh province, Vietnam.
- Project time: from 01/05/2014 to 31/12/2015
- Data collection time: from 25/11/2014 to 28/02/2015
- Review process: exempt review

Article 2. This decision is effective from **19/11/2014**.

Article 3. Principle Investigator should notify the Institutional Ethical Review Board of Hanoi School of Public Health (IRB of HSPH) immediately of any adverse effects arising from this study (e.g. unexpected adverse outcomes, unexpected community/subject risk factors or complaints, etc.). Active research projects are subject to random audit by the IRB of HSPH.

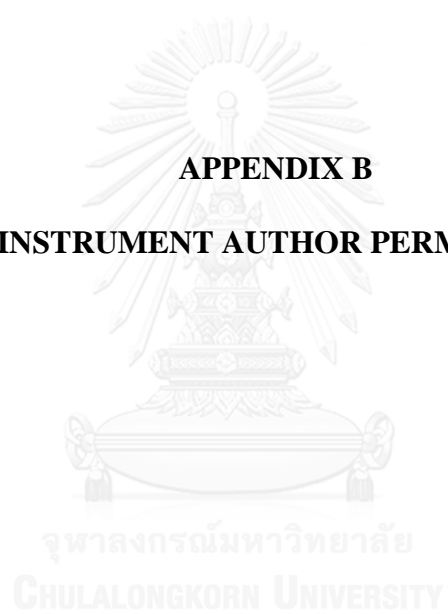
CHAIR OF
INSTITUTIONAL ETHICAL REVIEW BOARD
(Signature and full name)

Do Mai Hoa

SECRETARY
(Signature and full name)

Nguyen Thi Minh Thanh

APPENDIX B
INSTRUMENT AUTHOR PERMISSION



Trả lời: The letter for helping the getting permission of using instrument

00:10 Ngày 06 tháng 11 năm 2014

Dear Nguyen Thi Minh Chinh,

On behalf of Dr. Valmi Sousa, the University of Kansas School of Nursing grants you permission to use the Diabetes Appraisal of Self-care Agency scale in your dissertation work as outline below. Attached is a copy of the scale. Please note that four of the items needed to be reverse scored before creating a total scale score as indicated in the document. You are being granted this approval on the condition you get the appropriate Institutional Review Board (IRB) approval to conduct your study. I will look forward to hearing the results of your study.

Please do not hesitate to contact me if you need further information.

Sincerely,

Marge J. Bott, RN, PhD
Associate Professor and Associate
Dean, Research
University of Kansas School of Nursing
[3901 Rainbow Blvd. MSN 4043](#)
[Kansas City, KS 66160](#)
[913-588-1692](#)
[913-588-4531](#) (FAX)



APPENDIX C

CONSENT FORM AND PARTICIPATION INFORMATION SHEET

จุฬาลงกรณ์มหาวิทยาลัย
CHULALONGKORN UNIVERSITY

Informed consent for participation in research

Title: The effect of supportive educative nursing program on HbA1c level in Vietnamese with uncontrolled type 2 diabetes patients

Code:

I were informed by the researcher about the research objective, procedures, as well as benefits, risk/harm that may occur in this study.

I have read and understood the Participant Information Sheet.

I understood that I will complete the questionnaires and take the blood test for HbA1c.

I understood that I will participate in education session in 3 hours per week within 5 weeks. In this session, I will be asked to share my ideal. I also understood that I will receive 11 telephone call within 11 weeks. Each telephone call will be 10 or 15 minutes every week to describe my daily activity focus on diabetes self-care.

I am aware that participation in this study involves completion of blood tests which is routinely used as preliminary screens for clinical conditions of which I might not be aware. I understand that this assessment needs for disease management purposes, it will be used in this study.

I am taking part in this research study voluntarily.

Namdinh, datemonthyear 20....

Participant's signature

Participation information sheet

Title: The effect of supportive educative nursing program on HbA1c level in Vietnamese with uncontrolled type 2 diabetes patients

Researcher's name: Nguyen Thi Minh Chinh

Position: PhD. student, Doctoral of Philosophy in Nursing Science Program, Faculty of Nursing, Chulalongkorn University, Thailand

Address: Fundamental of Nursing Department, Namdinh University of Nursing, 257 Han Thuyen stress, Namdinh City, Vietnam

Mobile phone: (+84) 945347695

E-mail: minhchinh_ndd@yahoo.com

I am doing a doctoral dissertation which aims to determine the effect of supportive – educative nursing program on glycemic control in type 2 diabetes patients. This study had permission of the Faculty of nursing of Chulalongkorn University as well as approval from the Ethics Review Committee for Research Involving Human Research Subjects of the Hanoi School of Public Health (N0.290/2014/YTCC-HD3) and consent letter of chairman of Namdinh General Hospital.

Participating in this study, you will be taught, provided, guided and supported to perform your self-care activities that will help you improve your ability to prevent the disease's complications and control your disease. Moreover, you will participate in program with other people with same your disease, it is useful to share and promote your experiences. However, it will be uncomfortable with taking blood test and spending time to travel and attend in the program.

Therefore, the purpose of this document is to inform you about the researcher and the data collection procedure in this study, and to allow you to make a decision about whether you would like to participate or not.

In this study, firstly, you will be asked to take an a sealed envelope which is placed you will participate either in supportive educative nursing program group (experimental group) or control group.

After that, you will be asked and guided to complete three questionnaires and to take blood test for HbA1c as baseline tests. It takes to 10 – 15 minutes to complete the questionnaires and 5 – 10 minutes to take blood test.

If you participate into experimental group, you will take a role in following actions:

You will be assigned to participate in the supportive – educative nursing intervention at Outpatient unit in Namdinh General Hospital. Your group will be given time in a meeting room in the Outpatient unit for answering the Michigan Diabetes Research and training center's brief Diabetes Knowledge Test, the summary of diabetes self-care activities and the appraisal of self-care Agency Scale – Revised questionnaire. Each questionnaire will be took around 10 to 15 minutes. Based on your answering, a self-care deficit and self-care demands will be emerged. From that, the researcher will discuss with you about the contents of learning diabetes self-care. You will be distributed a set of written diabetes material, a notebook and a pencil at the beginnings of the first session. The objectives of each session, materials, strategies, questions for guiding a discussion, content, handout assignments, activities, skills training, and time for each activity will be explained in the Manual of the Type 2 Diabetes Supportive Educative Nursing Program.

The supportive –educative nursing program consists of 5 training sessions will be weekly conducted within 5 weeks and 11 weekly telephone calls follow-up. The training sessions consists of five sessions: (1): What is diabetes? The pathology of diabetes and its complications; (2): Diabetes diet, build a diabetes menu for Vietnamese people and how to manage stress from adhere diet regimen; (3): diabetes exercise and how to deal with overlaps of self-care activities; (4): Diabetes self-monitoring and how to examine foot and how to monitor hyperglycemia and hypoglycemia; and (5): Using medication in diabetes and how to deal with relapse. Each session will be conducted in 3 hours. During 11 weeks, researcher will conduct a telephone call you every week to discuss on your self-care problems and your health problems. Reminding you for treatment regimens and providing consultation for manage your self-care tasks will be performed. Researcher will encourage and motivate you overcome the stress and difficulties to maintain your self-care activities. Each telephone call time is around 15 to 20 minutes.

You will be asked to take an assignment about diabetes care problems and then, the researcher will answer your questions and help you find the solution for your problems

Ten minutes break for refreshment can be taken after the program run for one hour in every session. Lunch will be given free for you on training day.

After that, you will be asked to complete questionnaire (ASCAS-R) at week 6th.

If you participate into control group, you will take a role in following actions:

You will receive a set of written materials on the date of data collection at baseline.

You will have appointments with the physician every month after data collected at baseline. The time of the appointments will depend on your health status. On the day of the physician's visit, you will be watched five videotapes about diabetes care (one or two videotapes per visit).

You will contact with your physician via telephone call at 11th week to remind you of dates of appointments.

You will be given appointments to visit the outpatient unit on different dates for the intervention group to prevent participants contamination.

After that, you will be asked to have a blood test for HbA1c at month 3th.

You will not be required to pay any money when participate in this study.

You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed.

You have the right to omit or refuse to answer or respond to any question that is asked of you if it is sensitive for you.

You have the right to have your questions about the procedures answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

Your information will be ensured secret. Your information only serves for purpose research and don't serve for any other purpose

I, researcher, will be glad to answer your questions about this study at any time. You may contact me at my email: minhchinh_ndd@yahoo.com or my phone number: 0945347695.



APPENDIX D

MAMNUAL OF THE SUPPORTIVE EDUCATIVE NURSING PROGRAM

จุฬาลงกรณ์มหาวิทยาลัย
CHULALONGKORN UNIVERSITY

Manual of supportive educative nursing program

The Purpose of this Manual

This manual provides a theoretical framework for a diabetes education program that is based on the Orem's theory. The objectives of this manual are:

- 1) To provide a general orientation to the philosophy and preparation of nurses dedicated to providing diabetes education.
- 2) To explore specific aspects of diabetes self-care such as diet, exercise, medication-taking and self-monitoring.
- 3) To provide programs with practical strategies, tools, and suggestions that will assist nurses in working effectively with their patients.

The contents of this Manual

1. Part 1: Education session

Session 1: Diabetes and diabetic complications

Session 2: Diabetes diet

Session 3: Diabetes physical exercise

Session 4: Diabetes medications

Session 5: Self-monitoring

2. Part 2: Supportive session

Session 1: Patient's story (based on daily diabetes record)

Session 2: Discussion on problems and appropriate solutions

Group Format: 9-10 participants/group

The group discussion was guided by 6 questions to test participants understanding on the relevance topic

Content of telephone call conversation was followed 6 questions to explore participants' performance, problems and solutions in self-care

Materials: Poster board, markers, computer, notebook, pencil, handouts, exercise assignments, videos and telephone.

Schedule

1. Part 1: Education session

Week 1st:

8.00-8.30: What is diabetes? The pathology of diabetes mellitus

8.30 – 9.00: Diabetes complications

9.00 – 9.10: Time break

9.10 – 10.10: Group discussion

10.10 – 10.40: Summary on the content and give assignment

10.40 – 11.10: Watching video with title “What diabetes is”

11.10: Closing

Second week:

8.00-8.30: Diet in type 2 diabetes

8.30 – 9.00: Build a diabetes menu for Vietnamese people and how to manage stress from adhere diet regimen

9.00 – 9.10: Time break

9.10 – 10.10: Group discussion

10.10 – 10.40: Summary on the content and give assignment

10.40 – 11.10: Watching video with title “Diabetes foods”

11.10: Closing

Third week:

8.00- 8.30: Diabetes exercise

8.30 – 9.00: Practice stretching exercises

9.00 – 9.10: Time break

9.10 – 10.10: Group discussion

10.10 – 10.40: Summary on the content and give assignment

10.40 – 11.10: Watching video with title “Exercise”

11.10: Closing

Forth week:

8.00- 8.30: Diabetes medication

8.30 – 9.00: Using medication in diabetes and how to deal with overlaps

9.00 – 9.10: Time break

9.10 – 10.10: Group discussion

10.10 – 10.40: Summary on the content and give assignment

10.40 – 11.10: Watching video with title “Living with diabetes with a good quality of life”

11.10: Closing

Fifth week:

8.00- 8.10: Diabetes self-monitoring

8.10 – 9.10: Practice blood glucose test and foot care

9.10 – 9.20: Time break

9.20 – 10.20: Group discussion

10.20 – 10.50: Summary on the content and give assignment

10.50 – 11.00: Watching video with title “Food care” and “Blood sugar testing”

11.00: Closing

2. Part 2: Supportive session (day/week)

Morning session: 4 person

Afternoon session: 3 person



APPENDIX E
OVERVIEW OF THE INTERVENTION PROCEDURE

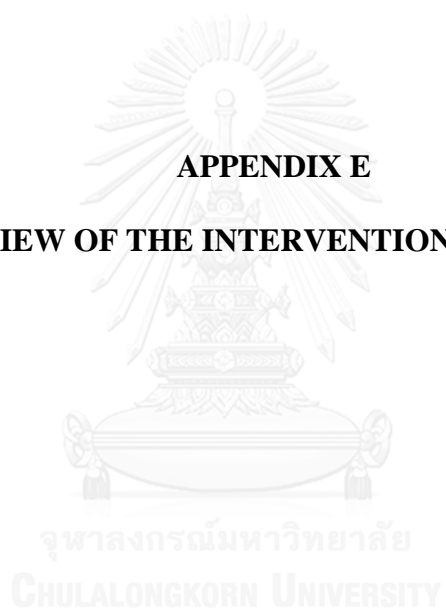


Table Overview of the intervention procedure in this study

Week	Session (minute)	Theme	Tools & Homework	Instrument
0	1 (60)	Pre-Test		Blood sample Test (HbA1c) DASCA-R Scale
1	1 (180)	Diabetes and its complications	Written booklet and video	
	Telephone Call (15-20)	What's experience on it	Self-report	
2	2 (180)	Diabetes diet	Written booklet and video	
	Telephone Call (15-20)	What's experience on it	Self-report	
3	3 (180)	Diabetes exercise	Written booklet and video	
	Telephone Call (15-20)	What's experience on it	Self-report	
	4 (180)	Diabetes medication	Written booklet and video	

4	Telephone Call (20) (1x/week)	What's experience on it	Self-report	
5	5 (180)	Diabetes self- monitoring and how to examine foot and how to monitor hyperglycemia and hypoglycemia	Written booklet and video	
	Telephone Call (20) (1x/week)	What's experience on it	Self-report	
6	1 (15)	Monitor intervention		ASCAS-R scale
7 to 11	Telephone Call (20) (1x/week)	What's experience on it	Self-report	
12	1(60)	Post-Test		Blood Test (HbA1c) ASCAS-R scale



APPENDIX F
INSTRUMENTS

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Session 1 : Personal Information Sheet

Date interview:/...../20.....

Code:.....

A1. How old are you?

A2. What is your gender?

1. Male

2. Female

.
.
.
.

A9. Are there any family member having same your disease?

1. Yes

2. No

Session 2: Measure HbA1c level

Table 1: Advantages and disadvantages of various HbA1c assay methods

Assay	Principle	Advantages	Disadvantages
Ion Exchange Chromatography	HbA1c has lower isoelectric point and migrates faster than other Hb components.	Can inspect chromatograms for Hb variants. Measurements with great precision.	Variable interference from hemoglobinopathies, HbF and carbamylated Hb but the current ion exchange assays correct for HbF and carbamylated Hb does not interfere.
Boronate Affinity	Glucose binds to m-aminophenylboronic acid.	Minimal interference from haemoglobinopathies, HbF and carbamylated Hb.	Measures not only glycation of N-terminal valine on β chain, but also β chains glycated at other sites and glycated α chains.
Immunoassays	Antibody binds to glucose and between 4-10 N-terminal amino acids on β chain.	Not affected by HbE, HbD or carbamylated Hb. Relatively easy to implement under many different formats	May be affected by haemoglobinopathies with altered amino acids on binding sites. Some interference with HbF.

Session 3: The Diabetes Appraisal of Self-Care Agency Scale - Revised

Please circle the best answer for each statement listed below using the following scale:

1 = Totally disagree

4 = Agree

2 = Disagree

5 = Totally agree

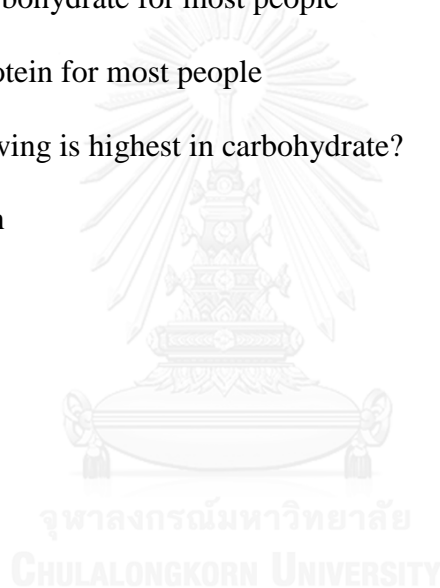
3 = Neither disagree or agree

Statement	1	2	3	4	5
1. As circumstances change, I make the needed adjustments to stay healthy...					
2. If my mobility is decreased, I make the needed adjustments...					
.					
.					
.					
.					
15. I am not always able to care for myself in a way I would like...					

Session 5. The Michigan Diabetes Research and Training Center's Brief Diabetes**Knowledge Test**

The questions below ask you about your knowledge. Please circle in your answer.

1. The diabetes diet is:
 - a. the way most American people eat
 - b. a healthy diet for most people
 - c. too high in carbohydrate for most people
 - d. too high in protein for most people
2. Which of the following is highest in carbohydrate?
 - a. Baked chicken
 - b. Swiss cheese
 - c. Baked potato
 - d. Peanut butter
23. Which one of the following will most likely cause an insulin reaction:
 - a. heavy exercise
 - b. infection
 - c. overeating
 - d. not taking your insulin



APPENDIX G
VALIDITY CHECK

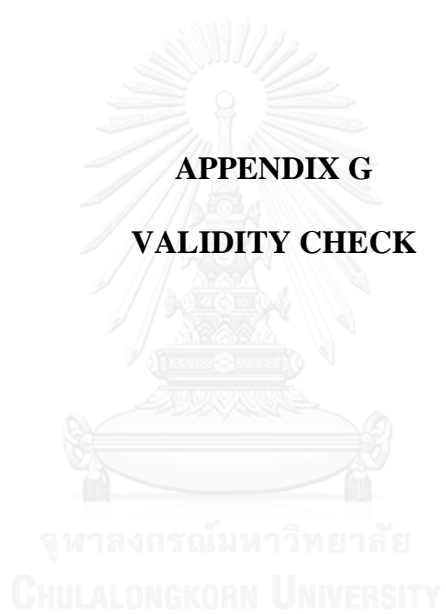


Table 1. Report of self-care agency score in experimental group (n=41) at before, 6 weeks and 3 months

Pt. ID	Total self-care agency scores			Having power for self-care			Developing power for self-care			Lacking power for self-care		
	W1	W6	W12	W1	W6	W12	W1	W6	W12	W1	W6	W12
14	18	22	25	11	20	22	12	18	16	41	60	63
15	12	22	23	12	20	20	15	19	18	39	61	61
17	13	25	26	12	22	21	15	17	16	40	64	63
18	15	24	25	10	20	20	15	19	18	40	63	63
19	17	26	30	13	22	25	11	16	15	41	64	70
30	22	28	30	14	23	25	8	15	13	44	66	68
31	22	29	30	16	25	25	8	15	18	46	69	73
34	16	25	22	12	20	20	12	17	20	40	62	62
36	20	24	28	13	22	25	11	18	15	44	64	68
37	12	23	25	12	20	20	14	19	18	38	62	63
48	20	26	30	16	20	25	9	18	13	45	64	68
49	14	27	28	12	22	25	15	18	14	41	67	67
50	15	25	27	13	23	23	12	16	15	40	64	65
54	16	26	25	13	20	20	12	17	18	41	63	63
79	13	25	30	14	20	25	8	18	9	35	63	64
81	16	24	30	15	20	25	12	17	10	43	61	65
83	13	21	21	10	20	20	15	20	20	38	61	61
84	11	23	22	12	20	23	14	19	18	37	62	63

85	12	30	30	12	24	25	15	12	13	39	66	68
86	14	30	30	16	25	25	14	10	14	44	65	69
93	18	28	23	12	24	22	9	8	18	39	60	63
94	16	30	30	14	25	25	13	9	12	43	64	67
96	13	30	30	15	25	25	9	10	15	37	65	70
99	11	23	23	15	22	20	11	18	19	37	63	62
100	15	30	30	13	25	25	13	10	12	41	65	67
110	20	30	30	16	25	25	10	10	15	46	65	70
115	18	30	26	15	25	23	13	9	17	46	64	66
116	19	30	22	11	22	20	13	10	20	43	62	62
117	14	28	25	12	20	20	15	15	18	41	63	63
121	12	23	22	10	20	20	15	18	20	37	61	62
133	18	30	30	16	25	25	10	15	18	44	70	73
134	20	30	30	16	25	25	9	12	15	45	67	70
137	17	25	24	13	20	20	11	19	19	41	64	63
138	18	30	30	13	23	25	12	12	13	43	65	68
139	10	23	20	8	20	20	15	20	20	33	63	60
141	13	30	30	15	24	25	10	7	12	38	61	67
144	19	25	28	13	22	25	10	14	17	42	61	70
145	20	27	30	18	23	25	9	10	15	47	60	70
146	22	30	30	17	25	25	8	10	18	47	65	73
147	16	27	25	13	25	20	11	10	18	40	62	63
155	18	23	23	10	22	20	11	16	20	39	61	63

Table 2. Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.862	.862	15

Table 3. Item- total statistics of Diabetes Appraisal self-care agency scale-Revised

Item-Total Statistics					
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
agency1	21.1000	26.783	.481	.845	.855
agency2	21.1000	27.334	.393	.584	.859
agency3	21.0667	26.409	.544	.484	.852
agency4	21.1000	26.783	.481	.901	.855
agency5	21.1000	27.610	.349	.232	.862
agency6	21.0667	26.409	.544	.884	.852
agency7	21.0667	26.409	.544	.797	.852
agency8	21.0667	25.651	.671	.818	.845
agency9	21.0667	27.168	.420	.354	.858
agency10	21.0667	25.651	.671	.822	.845
agency11	21.0667	25.926	.624	.693	.848
agency12	21.0667	26.409	.544	.484	.852
agency13	21.2000	28.028	.289	.786	.864
agency14	21.2000	27.338	.399	.409	.859
agency15	21.0667	26.133	.589	.726	.849

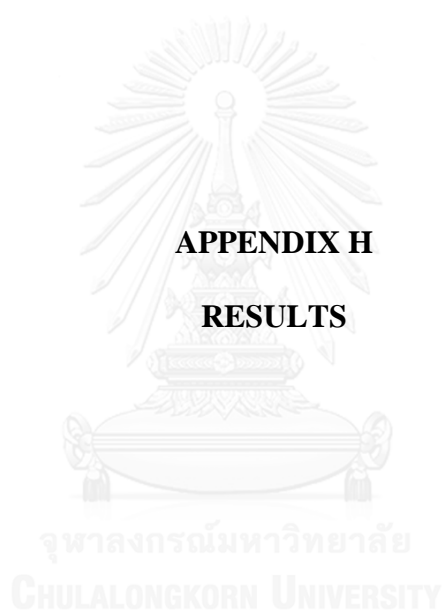


Table 1 Report of HbA1c level in control group (n=43) and in experimental group (n=41)

Patient ID	HbA1c level (%) in control group (n=43)			Patient ID	HbA1c level (%) in experimental group (n=41)		
	At baseline	At 3 months	HbA1c change		At baseline	At 3 months	HbA1c change
2	8.3	8.3	0	14	9.2	8.2	1
7	10.6	10.7	-0.1	15	11.3	9.3	2
11	7.6	8.1	-0.5	17	10.1	8.5	1.6
12	8.5	9.7	-1.2	18	10.9	9.2	1.7
13	9.2	9.2	0	19	9.7	7.7	2
20	11.4	11.4	0	30	7.6	7.8	-0.2
21	9.8	9.8	0	31	7.3	6.8	0.5
24	9	9	0	34	9.4	10.2	-0.8
25	7.6	9.1	-1.5	36	8.8	7.8	1
29	10	10.2	-0.2	37	11.3	9.8	1.5
38	8.3	8.3	0	48	8.2	7.8	0.4
39	9.5	9.5	0	49	12.4	8.4	4
40	8.3	8.3	0	50	8.9	8.9	0
43	10.3	11.3	-1	54	9.3	9.3	0
45	12.5	11.5	1	79	12.2	8.1	4.1
68	10.8	9.8	1	81	9	8	1
71	7.3	7.2	0.1	83	12	10.5	1.5

Patient ID	HbA1c level (%) in control group (n=43)			Patient ID	HbA1c level (%) in experimental group (n=41)		
	At baseline	At 3 months	HbA1c change		At baseline	At 3 months	HbA1c change
74	9.3	9.8	-0.5	84	9.7	9.7	0
75	11.9	10.9	1	85	9.5	7.5	2
77	8.8	8	0.8	86	8.3	7.3	1
160	10.9	11	-0.1	93	9.7	9.7	0
87	10.4	9.4	1	94	8.6	7.6	1
88	7.9	7.3	0.6	96	9.9	6.9	3
89	7.8	7.7	0.1	99	9.9	9.9	0
90	8.6	8.6	0	100	9.1	7.4	1.7
91	7.9	8.9	-1	110	7.6	7	0.6
102	13.1	12.1	1	115	8.4	8.6	-0.2
104	10.5	9.5	1	116	8.5	9.1	-0.6
105	11.1	12	-0.9	117	9.5	8.5	1
107	7.6	7.2	0.4	121	10.1	10.1	0
108	9.4	9.8	-0.4	133	7.6	6.6	1
65	11.4	11.4	0	134	7.7	7.2	0.5
131	9.7	9.7	0	137	9.1	9.1	0
122	10.1	11.1	-1	138	8.2	7.2	1
124	9.1	9.1	0	139	12.9	12.7	0.2
128	8	8	0	141	9.7	7.7	2

Patient ID	HbA1c level (%) in control group (n=43)			Patient ID	HbA1c level (%) in experimental group (n=41)		
	At baseline	At 3 months	HbA1c change		At baseline	At 3 months	HbA1c change
130	8.4	8.9	-0.5	144	8	8.3	-0.3
166	7.8	7.8	0	145	7.6	7.8	-0.2
148	8	7.8	0.2	146	7.8	6.8	1
149	7.8	7.8	0	147	9.3	8.3	1
151	8.8	9	-0.2	155	7.9	9.9	-2
153	9.1	10	-0.9				
176	9.2	10.3	-1.1				

Table 2 The Change in HbA1c level between control group (n=43) and in experimental group (n=41)

HbA1c Level	Experimental		Control Group	
	(n=41)		(n = 43)	
	n	%	n	%
Decrease in HbA1c				
> 0 – 1	15	36.6	12	27.9
1.1 – 2	9	21.9	0	0.0
> 2	2	4.9	0	0.0
Total	26	63.4	12	27.9
Mean	1.46 (SD=0.97)		0.68 (SD=0.38)	
Max change	4.1		1	
Increase in HbA1c				
> 0 – 1	5	12.19	13	30.23
1.1 – 2	0	0.0	3	6.98
> 2	0	0.0	0	0.0
Total	5	12.19	16	37.21
Mean	-0.61 (SD=0.65)		-0.69 (SD=0.43)	
Max change	0.3		1.5	
No Change in HbA1c	10	24.39	15	34.88
Total Mean HbA1c Change (N = 84)	0.85 (SD=1.19)		- 0.067 (SD = 0.65)	

APPENDIX I
DATA COMPUTER OUT PUT



จุฬาลงกรณ์มหาวิทยาลัย
CHULALONGKORN UNIVERSITY

Session 1: Report on SCA score**The mean of self-care agency at baseline, 6 weeks and 3 months****Descriptive Statistics**

	N	Minimum	Maximum	Mean	Std. Deviation
HP1	41	10.00	22.00	16.0488	3.32379
DP1	41	8.00	18.00	13.2439	2.19978
LP1	41	8.00	15.00	11.8049	2.37928
Total of scacs_baseline	41	33	47	41.10	3.330
HP2	41	21.00	30.00	26.5122	2.95907
DP2	41	20.00	25.00	22.3171	2.06687
LP2	41	7.00	20.00	14.6341	3.93545
Total of scacs_6 week	41	60	70	63.46	2.336
HP3	41	20.00	30.00	26.7805	3.34299
DP3	41	20.00	25.00	22.9024	2.32169
LP3	41	9.00	20.00	16.1463	2.92883
total of SCACS_3months	41	60.00	73.00	65.8293	3.63938
Valid N (listwise)	41				

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
						Lower	Upper		
Pair 1	HP1 - HP2	-10.46	3.45758	.53998	-11.55	-9.37	-19.37	40	.000
Pair 2	HP1 - HP3	-10.73	3.54982	.55439	-11.85	-9.61	-19.35	40	.000
Pair 3	HP2 - HP3	-.26	2.69281	.42055	-1.11	.58	-.63	40	.527
Pair 4	DP1 - DP2	-9.07	1.96711	.30721	-9.69	-8.45	-29.53	40	.000
Pair 5	DP1 - DP3	-9.65	1.83861	.28714	-10.23	-9.07	-33.63	40	.000
Pair 6	DP2 - DP3	-.58	2.06126	.32191	-1.23	.06	-1.81	40	.076
Pair 7	LP1 - LP2	-2.82	3.82689	.59766	-4.03	-1.62	-4.73	40	.000
Pair 8	LP1 - LP3	-4.34	3.26810	.51039	-5.37	-3.30	-8.50	40	.000
Pair 9	LP2 - LP3	-1.51	4.18403	.65344	-2.83	-.19	-2.31	40	.026

Pair 10	Total of scacs_baseli ne - Total of scacs_6 week	-22.36	3.238	.506	-23.38	-21.34	-44.22	40	.000
Pair 11	Total of scacs_baseli ne - total of SCACS_3m onths	-24.73	2.81091	.43899	-25.61	-23.84	-56.33	40	.000
Pair 12	Total of scacs_6 week - total of SCACS_3m onths	-2.36	2.78169	.43443	-3.243	-1.487	-5.446	40	.000

ANOVA

		Sum of Squares	df	Mean Square
HP1	Between Groups	2137.285	2	1068.642
	Within Groups	505.512	120	4.213
	Total	2642.797	122	
DP1	Between Groups	1317.122	2	658.561
	Within Groups	470.146	120	3.918
	Total	1787.268	122	
LP1	Between Groups	764.537	2	382.268
	Within Groups	415.756	120	3.465
	Total	1180.293	122	
Total of scacs_baseline	Between Groups	12061.577	2	6030.789
	Within Groups	1160.585	120	9.672
	Total	13222.163	122	

ANOVA

		F	Sig.
HP1	Between Groups	253.678	.000
DP1	Between Groups	168.091	.000
LP1	Between Groups	110.334	.000
Total of scacs_baseline	Between Groups	623.560	.000

Correlations

		Having power	Developi ng power	Lacking power	Total of scacs_ baseline	HbA1c_ baseline
having power	Pearson Correlation	1	.487**	-.672**	.840**	-.778**
	Sig. (2-tailed)		.001	.000	.000	.000
	N	41	41	41	41	41
Developing power	Pearson Correlation	.487**	1	-.664**	.672**	-.615**
	Sig. (2-tailed)	.001		.000	.000	.000
	N	41	41	41	41	41
lacking power	Pearson Correlation	-.672**	-.664**	1	-.395*	.548**
	Sig. (2-tailed)	.000	.000		.011	.000
	N	41	41	41	41	41
Total of scacs_ baseli ne	Pearson Correlation	.840**	.672**	-.395*	1	-.791**
	Sig. (2-tailed)	.000	.000	.011		.000
	N	41	41	41	41	41
HbA1c_ baseline	Pearson Correlation	-.778**	-.615**	.548**	-.791**	1
	Sig. (2-tailed)	.000	.000	.000	.000	
	N		41	41	41	41

** . Correlation is significant at the 0.01 level (2-tailed).

Correlations

		Having power	Developing power	Lacking power	Total of scacs_baseline	HbA1c_baseline
Having power	Pearson Correlation	1	.902**	-.793**	.856**	-.906**
	Sig. (2-tailed)		.000	.000	.000	.000
	N	41	41	41	41	41
Developing power	Pearson Correlation	.902**	1	-.763**	.853**	-.794**
	Sig. (2-tailed)	.000		.000	.000	.000
	N	41	41	41	41	41
Lacking power	Pearson Correlation	-.793**	-.763**	1	-.410**	.607**
	Sig. (2-tailed)	.000	.000		.008	.000
	N	41	41	41	41	41
Total of scacs_baseline	Pearson Correlation	.856**	.853**	-.410**	1	-.850**
	Sig. (2-tailed)	.000	.000	.008		.000
	N	41	41	41	41	41
HbA1c_baseline	Pearson Correlation	-.906**	-.794**	.607**	-.850**	1
	Sig. (2-tailed)	.000	.000	.000	.000	
	N	41	41	41	41	41

** . Correlation is significant at the 0.01 level (2-tailed).

Session 2: Report on HbA1c level

In control group

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HbA1c _baseline	9.3395	43	1.44356	.22014
	HbA1c _3month	9.4070	43	1.36004	.20740

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	HbA1c _baseline & HbA1C _3month	43	.895	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2- tailed)
		Mean	Std. Deviation	Std. Error	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	HbA1c _baseline - HbA1C _3month	-.06744	.64650	.09859	-.2664	.13152	-.684	42	.498

In experimental group**Paired Samples Statistics**

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	HbA1c _baseline	9.3220	41	1.42750	.22294
	HbA1c _3month	8.4683	41	1.26559	.19765

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	HbA1c _baseline & HbA1c _3month	41	.613	.000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 HbA1c _baseline - HbA1c _3month	.85366	1.19417	.18650	.47673	1.23059	4.577	40	.000

Compare HbA1c level between two groups

Group Statistics

Group		N	Mean	Std. Deviation	Std. Error Mean
HbA1c _baseline	Control	41	9.3220	1.42750	.22294
	Experimental	43	9.3395	1.44356	.22014
HbA1c _3month	Control	41	8.4683	1.26559	.19765
	Experimental	43	9.4070	1.36004	.20740

Independent Samples Test

	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
HbA1c	.197	.658	-.056	82	.955	-.01758	.31340	-	.605
_baseline								.64103	
			-.056	81.88	.955	-.01758	.31331	-	.605
Equal variances not assumed								.64087	
HbA1c	.448	.505	-3.271	82	.002	-.93868	.28700	-	.367
_3month								1.5096	
			-3.276	81.954	.002	-.93868	.28650	-	.368
Equal variances not assumed								1.50863	

Compare in changing HbA1c level between two groups

Ranks

		N	Mean Rank	Sum of Ranks
group - HbA1c change	Negative Ranks	0 ^a	.00	.00
	Positive Ranks	22 ^b	11.50	253.00
	Ties	1 ^c		
	Total	23		

a. group < HbA1c change

b. group > HbA1c change

c. group = HbA1c change

Test Statistics^b

	group - HbA1c change
Z	-4.284 ^a
Asymp. Sig. (2- tailed)	.000

a. Based on negative ranks.

b. Wilcoxon Signed Ranks Test

Ranks

		N	Mean Rank	Sum of Ranks
group - HbA1c change	Negative Ranks	12 ^a	6.50	78.00
	Positive Ranks	0 ^b	.00	.00
	Ties	27 ^c		
	Total	39		

a. group < HbA1c change

b. group > HbA1c change

c. group = HbA1c change

Test Statistics^b

	group - HbA1c change
Z	-3.464 ^a
Asymp. Sig. (2- tailed)	.001

a. Based on positive ranks.

b. Wilcoxon Signed Ranks Test

Ranks

		N	Mean Rank	Sum of Ranks
HbA1c change - group	Negative Ranks	7 ^a	4.00	28.00
	Positive Ranks	0 ^b	.00	.00
	Ties	16 ^c		
	Total	23		

a. HbA1c change < group

b. HbA1c change > group

c. HbA1c change = group

Test Statistics^b

	HbA1c change - group
Z	-2.646 ^a
Asymp. Sig. (2- tailed)	.008

a. Based on positive ranks.

b. Wilcoxon Signed Ranks Test

Compare in proportion of control of HbA1c level between two groups

Friedman Test_control group

Ranks

	Mean Rank
baseline	1.51
3 months	1.49

Test Statistics^a

N	43
Chi-Square	.200
df	1
Asymp. Sig.	.655

a. Friedman Test



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Friedman Test_experimental group

Ranks

	Mean Rank
baseline	1.62
3months	1.38

Test Statistics^a

N	41
Chi-Square	8.333
df	1
Asymp. Sig.	.004

a. Friedman Test



Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 Total of scacs_baseli ne - Total of scacs_6 week	-20.317	4.00	.626	-21.58	-19.05	-32.45	40	.000
Pair 2 Total of scacs_baseli ne - total of SCACS_3m onths	-2.16E1	4.133	.64558	-22.938	-20.32	-33.51	40	.000
Pair 3 Total of scacs_6 week - total of SCACS_3m onths	-1.31	2.534	.39577	-2.116	-.51719	-3.328	40	.002

VITA

Nguyen Thi Minh Chinh was born in 1981 at Namdinh province. She received a Bachelor of Nursing Science from Hanoi Medical University in 2003. She got a Master of Nursing Science (Adult Nursing), Saxion Universities of Applies and Sciences, The Netherlands in 2010. She was a nursing instructor at Namdinh University of Nursing, Vietnam since 2003 to present. She had received scholarship from Ph.D. study from the Chulalongkorn University, Thailand. She had studied Philosophy Program in Nursing Science, Faculty of Nursing, Chulalongkorn University from 2011.



