Effect of Self-Management Support Program on Diabetic Foot Care Behaviors in Patients with Diabetes Mellitus in West Java, Indonesia

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ABSTRACT

Diabetic foot care behaviors are the fundamental component of diabetic foot complications prevention. The objective of this study was to examine the effect of a self-management support (SM) program on diabetic foot care behaviors (DFCB) in patients with diabetes mellitus in West Java, Indonesia. This study was a quasi-experimental study with pretest and posttest control groups. Seventy subjects who could be contacted by phone were recruited from a diabetic unit of a district hospital in West Java, Indonesia. Subjects were assigned into experimental and control groups (35 subjects/group) with the pair-matching technique. The subjects in the experimental group received a five-week foot care self-management support program (SM program) including self-monitoring, self-evaluation, and self-reinforcement for improving DFCB guided by Kanfer and Gaelick-Buys's Self-Management Method (1991). Techniques used in this program consisted of a combination of individual-based foot care education, goal setting and action planning, and brief weekly counseling and follow-up through phone-calls and

face-to-face interview. Diabetic foot care behaviors were evaluated in the first and fifth weeks using the Diabetic Foot Behaviors Questionnaire. The goal achievements were evaluated weekly from the second to the fourth week using phone call follow-ups and in the fifth week using face-to-face interview. The level of goal achievement was determined by counting the number of actions successfully implemented according to the subject's action plans and classified into three levels including completely achieved the goal, partially achieved the goal and no behavioral change (no action) at all.

The results showed that there was a statistically significant difference of DFCB between the experimental ($M = 67.43$, $SD = 5.83$) and the control group ($M = 52.60$, $SD = 8.6$, $t = -8.45$, $p < .001$). In addition, DFCB within the experimental group after participating in the SM program ($M = 67.43$, $SD = 5.83$) was also significantly higher than before ($M = 51.09$, $SD = 9.12$, $t = -10.43$, $p < .001$). Most of the subjects (94.3%) were able to completely achieve the first week goals and approximately two-thirds of the subjects were able to completely achieve the goals in the second to the fourth week. The most improved DFCB component in each week was foot hygiene, footwear, toenail care and a combination of foot hygiene and footwear, respectively. These findings indicate that this SM program effectively improves Indonesian diabetic patients' foot care behaviors. Therefore, nurses can apply this program into practice to enhance diabetic foot care behaviors in order to prevent diabetic foot ulcer or other foot complications.

Keywords: diabetes mellitus, diabetic foot care behaviors, self-management

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CHAPTER 1

INTRODUCTION

Background and Significance of the Problem

Diabetes mellitus (DM) is one of the severe global health issues. Its prevalence worldwide for all age groups is anticipated to increase from 171 million in 2000 to 366 million in 2030 (Wild, Roglic, Green, Sicree, & King, 2004). In South East Asia, it affects nearly 58.7 million people in the ages between 20 and 79 years old (International Diabetes Federation [IDF], 2010). In Indonesia in the year 2000, around 8.4 million people were diagnosed with DM and this might increase to 21.3 million in 2030 (Wild et al., 2004). Additionally, DM became the seventh leading cause of death in Indonesia (Ministry of Health Republic of Indonesia [MOHRI], 2007).

Besides this alarming incidence, DM also leads to serious complications including diabetic neuropathy, foot ulcer, cardiovascular disease, diabetic retinopathy, and nephropathy. Among those complications, diabetic foot ulcer (DFU) is one of the most disabling DM complications. It has affected 15% to 25% of diabetic patients (Singh, Amstrong, & Lipsky, 2005). The prevalence of DFU challenges the health care providers with regard to the effectiveness of treatment and management such as a high consideration of cost, time consumption, high risk for recurrence, poor prognosis and often requires amputation (Canadian Diabetes Association [CDA], 2005; Edmonds, 2006; Ghanassia et al., 2008; Jeffcoate & Hardig 2003; Ragnarson-Tennvall & Apelqvist, 2004). In addition, patients with diabetic related foot amputation are faced with the problems of disability, financial burdens,

depression, poor quality of life, and high mortality (Abdelgadir, Shebeika, Eltom, Berne, & Wikblad, 2008; Stockl, Vanderplas, Tafesse, & Chang, 2004). Diabetic foot ulcer prevention is therefore very important, particularly in developing countries where the healthcare service resources and public health educational programs are limited (World Diabetes Foundation, 2010).

Diabetic foot ulcer can be prevented in several ways. Daily foot care, for instance, is one of the fundamental components of diabetic foot ulcer prevention. Performing daily foot care helps patients in the early detection of foot abnormalities and foot injuries, which can facilitate better treatment outcomes. It was noted that the incidence of DFU among DM patients who adhered to proper foot care was significantly lower than those who did not, 3.1% compared to 31.6%, respectively (Calle-Pascual et al., 2001). Many diabetic patients, however, did not perform foot care properly (Bell, Arcury, Snively, Dohanis, & Quandt, 2005; Gulliford & Mahabir, 2002; Khamseh, Vatankhah, Reza, & Baradaran, 2007). A single center survey study in Indonesia with 92 diabetic patients also noted that around 50% of them lacked knowledge on diabetic foot care and had improper foot care practices (Makmurini, Kosasih, & Rahayu, 2010).

According to the current practice guidelines and standards of care, an educational program has been recommended to be used as one of the most feasible strategies to improve DM patients' foot care behaviors (American Diabetes Association [ADA], 2004; CDA, 2008; Registered Nurses' Association of Ontario [RNAO], 2007). In addition, previous western studies recommended a use of an educational program in combination with other techniques including consultation, booklet/foot care guidance, and/or reminders and follow ups for effectively improving

foot care behaviors (Corbett, 2003; Hazavehei, Sharifirad, &Mohabi, 2007; Lincoln, Radford, Game, & Jeffcoate, 2008; McMurray, Johnson, Davis, & McDougall, 2002; Vatankhah et al., 2009). The validity of these previous studies, however, are still questionable because of the methodological flaws, such as no use of blinded outcome examiners (McMurray et al.; Hazavehei et al.), no baseline data measurement (Lincoln et al.), no control group (Vatankhah et al.), and small sample sizes (Corbett). Also, two systematic reviews reported that most trials conducted in this arena had a low internal validity and a high risk of bias because of three factors: no true randomization of patients, no blinded examiners and an unacceptable drop-out rate (Dorresteijn, Kriegsman, & Valk, 2010; Valk, Kriegsman, & Assendelft, 2005).

Several nursing concepts and theories have been integrated in developing educational programs to enhance patients' behaviors. Among these concepts, self-management has been reported as one of the vital concepts in successfully improving healthy behaviors of chronic patients, including patients with DM. This concept views a patient as the one who is mainly responsible for making day-to-day decisions to manage his/her chronic conditions and to perform healthy behaviors to achieve the best possible health status and quality of life (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Bodenheimer, Lorig, Holman, & Grumbach, 2002; Lorig & Holman, 2003). In addition, it was found that patients who engaged in self-management intervention had better outcomes than those who engaged in the traditional teaching/educational approaches that positioned patients as passive participants who only followed the suggestions of the healthcare providers (Bodenheimer et al. 2002; Funnel & Anderson, 2000). Literature reviews also showed that intervention based on a self-management concept in diabetic patients effectively

facilitated the patients in increasing self-efficacy and quality of life, reducing treatment cost, and improving the patients' knowledge and self-care behaviors on diet, exercise, and foot care (Clark, 2008; Deakin, Cade, Williams, & Greenwood, 2006; Fan &Sidani, 2009; Lorig et al.; McMurray et al., 2002; Warsi, Wang, LaValley, Avorn, & Solomon, 2004).

Self-management has been employed both in single use and in combination with other strategies to enhance patients' behaviors. For instance, goal setting and an action planning strategy combined with certain types of follow up have been widely employed in improving diabetic patients' self-management and achieving healthier behaviors. In comparison with other strategies in terms of achievement of behavioral changes, the goal setting and action planning has an impact in higher patient involvement during the process of a behavioral improvement program. This strategy, therefore, allows patients to intentionally set the most achievable goal and to develop the most effective action plan that finally enlarges the opportunity for goal accomplishments. Several earlier studies found that goal setting and an action planning strategy that were employed as a single intervention strategy or combined with certain types of follow up effectively facilitated patients in improving his/her behaviors (Bodenheimer & Handley, 2009; Clark & Hampson, 2001; Cullen, Baranowski, & Smith, 2001; DeWalt et al., 2009; Handley et al., 2006; MacGregor et al., 2006; Schreurs, Colland, Kuijer, de Ridder, & van Elderen, 2003; Wallace et al., 2009).

The measured outcome parameters from those studies, however, did not represent all of the components of diabetic foot care behaviors (DFCB). For example, the measured diabetic foot care behaviors from the two studies (Deakin et

al., 2006; McMurray et al., 2002) only evaluated the patients' behaviors on selecting proper footwear, inspecting foot condition, inspecting footwear, washing and moisturizing the foot skin. Since each component of DFCB is important and has different challenges for its implementation, the interventions given in those studies left several components unevaluated, such as toenail care, foot hygiene, foot injury prevention, and providing proper foot injury management when it presents.

In the Diabetic Unit of Sumedang District General Hospital West Java, Indonesia, it was found that a health educational program has been included in the standard care of DM patients. This current educational program ordinarily consists of teaching proper diet, exercise, and medication for patients with DM. However, diabetic foot care knowledge was only provided as a general suggestion and only given when patients complained of diabetic neuropathic symptoms or when the physicians/nurses found any foot abnormalities/complications. Therefore, information regarding diabetic foot care was not given to each DM patient. The report from the medical department of this hospital revealed that 22 patients were hospitalized with DFU within a period of three months from January to March 2010 (Medical Record Department of Sumedang District General Hospital, 2010). Therefore, a feasible program to improve diabetic patients' foot care behavior is highly needed. Although several previous western studies as mentioned earlier produced benefits from a self-management program, the generalizability of some previous studies was often limited (Norris, Engelgau, & Narayan, 2001). Thus, it is essential to apply a self-management support program (SM program) in an Indonesian context in order to facilitate improving the DFCB of diabetic patients.

Objectives of the Study

There were three objectives in this study:

1. To compare diabetic foot care behaviors between diabetic patients who received the usual/standard care and those who received the diabetic foot care self-management support program
2. To compare diabetic foot care behaviors of diabetic patients in the experimental group before and after receiving the diabetic foot care self-management support program
3. To identify the levels of goal achievement of diabetic patients who receive the diabetic foot care self-management support program

Research Questions

There were three research questions as follows:

1. Were diabetic foot care behaviors (DFCB) of diabetic patients who received the diabetic foot care self-management support program better than those who received the usual/standard care?
2. Were diabetic foot care behaviors (DFCB) of diabetic patients after receiving the diabetic foot care self-management support program better than before receiving the diabetic foot care self-management support program?
3. What were the levels of goal achievement of diabetic patients who received the diabetic foot care self-management support program?

Conceptual Framework

In order to develop a foot care self-management support program, two concepts including the self-management (SM) method proposed by Kanfer and Gaelick-Buys (1991) and diabetic foot care standards proposed by Indian Health Diabetes Best Practice Foot Care (2009) and RNAO (2007) were integrated to construct the conceptual framework in this study. Self-management is a method that was developed to facilitate an individual in achieving the desired behaviors effectively through three stages: self-monitoring, self-evaluation, and self-reinforcement. In the self-monitoring stage, the individual intentionally monitors and observes his/her particular existing behaviors. In the self-evaluation stage, the individual evaluates the monitored behaviors by comparing his/her current behaviors with the desired behaviors and further judges if his/her existing behaviors meet or do not meet the desired behavioral standards. Then, based on the self-evaluation results, the individual provides self-reinforcement by deciding to take action, modify, or maintain the existing behaviors. The decision making is followed by developing a therapeutic contract that consists of a written statement describing the specific individual's goals and actions required to achieve the desired behaviors (goal setting and action planning). The required action(s) should be written clearly including the frequency, time, duration, accomplishment and non-accomplishment consequences. This therapeutic contract not only facilitates an individual in achieving the goal, but also provides measurable outcomes that assist the facilitator in objectively evaluating the individual's achievements. Since it has been found that a person who has a high level of confidence is more likely to be successful in achieving the goal, it was recommended that the facilitator measure the individual's confidence level in

performing each action plan that each individual develops to achieve the goal (Bodenheimer, Davis, & Holman, 2007; Kanfer et al.).

The content of desired diabetic foot care behaviors (DFCB) was adopted based on Indian Health Diabetes Best Practice Foot Care (2009) and RNAO (2007). The DFCB components were used as desired behaviors for each individual to adjust his/her existing behaviors whether or not those exiting behaviors met the desired behaviors in the stage of self-evaluation of the SM method. Generally, the desired diabetic foot care behaviors consist of daily assessment of foot conditions, maintaining foot hygiene, applying moisturizer, selecting and checking footwear, trimming toenails, preventing foot injuries, attending to a regular foot examination and providing care for an actual foot ulcer/injury when it presents.

In this study, the diabetic foot care self-management support program was a five-week program. In the first week, the researcher assisted each subject in entering the self-management stages and setting DFCB improvement goals and action plans. In the self-monitoring stage, the researcher assisted the subject in conducting individual reflection regarding his/her actual DFCB by using open-ended questions to encourage the subject to intentionally monitor his/her existing DFCB. Then, based on the subject's reflection and prior knowledge of diabetic foot care, the researcher provided an individually-based educational session regarding the desired DFCB. Generally, the topics consisted of a diabetic foot ulcer overview, the significance of DFCB, components of desired DFCB and any additional information required that emerged during the discussion. Technically, the educational session was provided as a combination of a brief lecture, discussion, providing a diabetic foot care booklet, and watching a diabetic foot care video. Next, the researcher moved the subject into a self-

evaluation stage. In this stage, the researcher conducted a discussion and assisted the subject in comparing his/her actual DFCB with the desired activity (what the subject was doing and what ought to be done). Therefore, the subject could identify the DFCB component(s) that needed to be improved and make a decision on whether or not further action be taken for improvement, modification, or just maintain his/her DFCB. Once a decision was made, the researcher aided him/her to set the goals and action plans according to that decision. This session was followed by a short discussion to identify the potential difficulties in implementing the developed action plan(s) and sharing some applicable solutions. Each subject was also measured for his/her confidence level in carrying out the developed action plan(s) by using a self-confidence scale. This scale was a 0 - 10 scale; 0 refers to no confidence at all and 10 refers to total confidence. When the subject reported a confidence level less than 7, the goal and action plan(s) were adjusted to achieve a confidence level score of at least 7 to provide an opportunity for the subject to successfully accomplish the action plan(s) and achieve the goal(s) (Bodenheimer et al., 2007). During the process, the researcher also provided positive reinforcement and shared ideas to facilitate the subject in generating his/her personal reinforcement strategies in order to enhance his/her motivation in performing his/her action plan(s) and achieving the goal(s) developed.

Each subject was followed up and provided brief counseling once a week through a phone call from the second to fourth week of intervention and through a face-to-face interview at the fifth week of intervention. During these follow up periods, the researcher helped the subject to reconduct individual reflection, report the implemented action plan(s), identify weekly goal achievements, identify the barriers

in implementing the action plan(s) and perform his/her self-reinforcement strategies based on the self-evaluation results. Additionally, the researcher provided brief counseling in order to assist the subject in solving those difficulties, reinforce him/her to continuously maintain and improve the achieved behaviors and to help him/her in developing further goals and action plans (Figure 1).

Hypotheses of the Study

The hypotheses of this study were as follows:

1. Diabetic patients who receive the diabetic foot care self-management support program have better diabetic foot care behaviors than those who receive the standard/usual care.
2. Diabetic patients who receive the diabetic foot care self-management support program have better diabetic foot care behaviors than before receiving the diabetic foot care self-management support program.

Definition of Terms

Diabetic foot care self-management support program. The diabetic foot care self-management support program is a five-week program developed by the researcher based on Kanfer and Gaelick-Buys (1991) self-management concept and foot care standards from Indian Health Diabetes Best Practice Foot Care (2009) and RNAO (2007) that aimed to facilitate a diabetic patient to improve his/her DFCB. This self-management support program involves requiring the subject to conduct individual reflection regarding his/her DFCB, providing an individual-based educational session regarding desired DFCB, assisting the subject to evaluate his/her

Foot Care Self-Management Support Program		
Components [a]	**Interventions**	
	Researcher activities	**Patient activities**
	The 1st Week Intervention	
1. Self-monitoring* 2. Self-evaluation** 3. Self-reinforcement*** (Notes: *,**, *** are matched with the contents on the next column)	1. Allocate individual reflection regarding his/her DFCB by using open-ended questions and clarify the subjects' prior knowledge by asking some questions based on prior knowledge assessment results*	1. Individually reflect and monitor DFCB*
	2. Provide an individually-based diabetic foot care educational session** a. Face-to-face discussion and provide information regarding foot ulcer overview, DFU prevention, desired DFCB including its significances and additional information needed (based on the subject's prior knowledge) b. Show the diabetic foot care video and related pictures and provide a diabetic foot care booklet c. Evaluate and clarify the subject's understanding on the given knowledge and allow the subject to ask some questions	2. Actively follow the educational session**
	3. Assist the subject to conduct self-evaluation by comparing his/her actual DFCB with the desired/ideal DFCB and further identify DFCB components that need to be improved**	3. Utilize the knowledge gained to discuss and evaluate DFCB by comparing the current diabetic foot care behaviors with the desired DFCB and then make a judgment whether or not his/her behaviors meet or do not meet the desired DFCB **
	4. Assist the subject in developing self-reinforcement and make a decision for maintaining, modifying, or improving his/her DFCB ***	4. Receive and generate their own reinforcement and make the decision for improving or maintaining DFCB***
	5. Assist the subject in developing the specific, measurable, achievable, and realistic goals and action plans based on self-evaluation results, measure the subjects' confidence level in implementing the developed action plan(s), and further assist the subject to identify the possible barriers and discuss the alternative solutions***	5. Develop specific, measurable, achievable, and realistic goals and action plans based on the self-evaluation results, identify possible barriers and generate alternative solutions***
	The 2nd to 5th Week Intervention	
	6. Conduct weekly follow-up phone calls (2nd , 3rd, and 4th week) and a face-to-face interview follow-up at the 5th week: (a) ask the subject to reflect on his/her current DFCB*, (b) assist the subject in comparing his/her current DFCB with the previous week's goals and action plans**, (c) identify the subject's goal achievements, (d) assist the subject in generating further goals and action plans based on the evaluation results***, (e) provide positive reinforcement*** (f) identify the subject's difficulties while implementing the action plans and provide brief counseling to share some alternative solutions ***	6. (a) Conduct individual reflection regarding current DFCB*, (b) evaluate current DFCB by comparing with the previous week's goals and action plans**, (c) report goals and action plans that were developed in the previous week and the implemented action plans, (d) develop further goals and action plans based on the evaluation results***(e) receive and generate positive reinforcement*** (f) report the difficulties faced during implementing the action plans, received required consultation/counseling and shared some alternative solutions ***

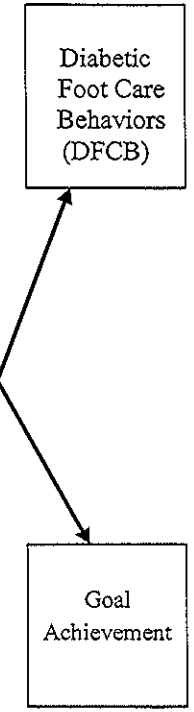

Figure 1. Conceptual framework of the Diabetic Foot Care Self-Management Support Program to enhance diabetic patients' foot care behaviors.

Note: [a] = each component was integrated throughout a 5-week intervention

DFCB, providing self-reinforcement, assisting the subject to develop his/her goal and action plan for improving DFCB, evaluating the subjects' self-confidence level, and conducting brief weekly counseling and phone call follow ups.

Standard/usual care program. Standard/usual care program refers to the usual care services support system provided by the staff of the Diabetic Unit of Sumedang District General Hospital for every diabetic patient who attends this service unit. The care services support system includes the monthly regular check-up, physical/foot examination, medication, actual problem treatment, blood glucose/laboratory examination, exercise, and educational program. This educational program was a group-based lecture using a traditional approach that covers certain topics including diabetic diet, exercise, insulin injection, medication, and blood glucose control, but only on rare occasions covered specific topics on diabetic foot care. Generally, the diabetic foot care topic would be provided individually when foot problems/complications were presented by the patients or when those were found by the physician/nurses during the patients' regular hospital check-up.

Diabetic foot care behaviors (DFCB). Diabetic foot care behaviors refers to the frequency of diabetic patients' activities over the past week to inspect their foot conditions, to maintain foot hygiene, to check, select, and wear proper footwear, to maintain foot skin moisture, to trim toenails properly, to avoid any potential foot-damaging activities, to attend regular foot care examination and to determine appropriate action to take care of any foot injury, wound, or ulcer. These behaviors were measured twice in the first and fifth week of the intervention by using a questionnaire that was modified from the Nottingham Assessment of Functional Foot Care (NAFF) developed by Lincoln and colleagues (2007).

Goal achievement. The goal achievement level refers to the frequency of completion, partial completion, and non-completion of goals and action plans that the subjects attempted to accomplish. It was evaluated during weekly follow-ups by asking the subjects to indicate whether or not they accomplished their weekly goal(s). The goal achievement level was categorized into completely achieved (all action plans successfully accomplished), not completely achieved (some action plans successfully executed), and no behavioral change (no action plan was successfully performed).

Scope of the Study

This study was conducted to measure the effect of the diabetic foot care self-management support program on diabetic foot care behaviors in patients with DM in West Java, Indonesia. The subjects were recruited from the Diabetic Unit of Sumedang District General Hospital, one of the secondary hospitals in West Java Province, Indonesia from October 2010 to January 2011.

Significance of the Study

The outcomes derived from this study provided evidence regarding the utilization of a diabetic foot care self-management support program in improving diabetic foot care behaviors among patients with diabetes mellitus. Additionally, the program provided advantages for the diabetic patients in achieving healthier behaviors, particularly in diabetic foot care behaviors. Furthermore, the findings of this present study provided valuable information for future studies, especially, the studies related to self-management and diabetic foot care behaviors in Indonesia.

This thesis contributes to the following published manuscripts:

1. Kurniawan, T., & Petpichetchian, W. (2011). Evidence-based interventions enhancing diabetic foot care behaviors among hospitalized DM patients: A case study. *Nurse Media Journal of Nursing, 1,* 43-59.
2. Kurniawan, T., Sae-Sia, W., Maneewat, K., & Petpichetchian, W. (2011). Effect of self-management support program on goal achievement of diabetic foot care behaviors in Indonesian diabetic patients. A paper presented at The 2nd International Conference on Prevention & Management of Chronic Condition & The 11th World Congress of Self-care Deficit Nursing Theory in Bangkok, Thailand, March 23-25, 2011 (manuscript in press).
3. Kurniawan, T., Sae-Sia, W., & Maneewat, K. (2011). Effect of self-management support program on diabetic foot care behaviors in patients with diabetes mellitus in West Java, Indonesia (manuscript in process).

CHAPTER 2

LITERATURE REVIEW

This quasi-experimental study aimed to develop a diabetic foot care self-management support program for diabetes mellitus (DM) patients, the details of knowledge underpinning this study was intensely reviewed and is discussed in this chapter as follows:

1. Diabetic foot ulcer
    1.1 Diagnosis, classification, and management of diabetic foot ulcer
    1.2 Risk factors of diabetic foot ulcer
    1.3 Pathogenesis of diabetic foot ulcer
2. Prevention of diabetic foot ulcer
    2.1 Identification of diabetic foot ulcer risks
    2.2 Management of modifiable risk factors
    2.3 Improvement of diabetic foot care knowledge and behaviors
    2.4 Diabetic foot care program in Indonesia
3. Self-management
    3.1 Self-management processes
    3.2 Contributing factors of diabetes self-management
    3.3 Self management support program in patients with diabetes mellitus
    3.4 The preliminary study of a self-management (SM) support program

Diabetic Foot Ulcer

Diabetes mellitus (DM) has become one of the global health problems affecting more than 150 million people (Wild et al., 2004). In South-East Asia, for example, 58.7 million people were diagnosed with DM (International Diabetes Federation [IDF], 2010). From this, 8.4 million people with DM were found in Indonesia (Wild et al.).

The associated long-term complications of DM cause problems with cardiovascular, cerebrovascular, neurological, and nephrology systems. For example, reports from the United States in 2004 and 2005 documented the causes of death of DM patients as heart disease 68%, stroke 16%, mild to severe forms of nervous system damage 60% to 70%, and end-stage kidney disease 44%, in each year (Centers for Disease Control and Prevention [CDC], 2008).

Diabetic foot ulcer (DFU) is one of the most common foot injuries which lead to lower extremity amputation (Edmonds, 2006; Jeffcoate & Hardig 2003; Singh et al., 2005), increased health care cost, and decreased quality of life in long term survival. Consequently, a DM amputee patient can develop psychological problems (Peters et al., 2001) which result in having a low quality of life and high mortality rate (Abdelgadir et al., 2008). The high hospital fees and treatment costs also become another negative impact from DFU. For instance, diabetic patients who develop ulcers spent nearly USD 18,000/person/year and it increased to almost double the cost when he/she had an amputated extremity (Ragnarson-Tennvall, & Apelqvist, 2004). When also considering the limitation of healthcare services, particularly the number of diabetic experts and other resources in developing countries, these negative

impacts may be more devastating (World Diabetes Foundation, 2010). The issue of DM complications, in particular DFC, is therefore a high concern and awareness from all health care providers is needed in allocating the resources and care to decrease all negative impacts.

Diagnosis, Classification, and Management of Diabetic Foot Ulcer

According to the International Working Group on Diabetic Foot [IWGDF] (2007), DFU was defined as a full thickness wound below the ankle in a DM patient. The diagnoses of DFU was mainly based on the information derived from symptoms and physical/comprehensive foot examinations and further investigations regarding causes, infection, severity, or other data needed for treatment gathered from other diagnostic tests, such as x-ray, laboratory tests, or ultrasound tests (Ferry, 2008; Lipsky et al., 2004). For symptoms, patients may complain about visible wounds with or without pain, walking difficulties, new or lasting numbness, or a history of foot injury. For a comprehensive foot examination, the healthcare providers may find an actual wound with/without pus or drainage, skin redness, swelling tissue, localized warmth, and/or hard skin. The laboratory tests may include blood tests, particularly an increased white blood cell count that indicates infection and perform drainage and/or pus culture to identify the cause of the infection. For diagnostic tests, an X-ray at the ulcer area, for instant, may provide information to identify the development of ulcer gangrene and a Doppler ultrasound test provides information regarding blood flow and peripheral vascular disease (Ferry).

Among the various approaches of diabetic foot ulcer classification systems, the Wagner classification system is one of the most commonly used. The Wagner classification system assesses diabetic ulcer based on the wound depth and the extent of necrotic tissue by using a wound classification grading system, grades 0 - 5: grade 0 (pre- or post-ulcerative lesion), grade 1 (partial/full thickness ulcer), grade 2 (the ulcer penetrating to the tendon or joint capsule), grade 3 (deep ulcer with abscess or osteomyelitis), grade 4 (partial foot gangrene), and grade 5 (whole foot gangrene) (Fard, Esmaelzadeh, & Larijani, 2007; Oyibo et al., 2001). The Wagner classification system is broadly used and tested as a valid and reliable DFU classification system (Abbas, Lutale, Game, & Jeffcoate, 2008; Oyibo et al.). This system however, does not include the compulsory information needed for ulcer treatment because it does not address the presence of wound infection. The Wagner classification system, therefore, should be used in combination with other strategies such as an infection test in order to effectively classify DFU conditions.

Regarding the diabetic foot ulcer management, some standards and evidence-based practices recommend essential DFU management including assessment, wound bed preparation, and management of co-morbidities (Canadian Diabetes Association [CDA], 2008; Delmas, 2006; Registered Nurses' Association of Ontario [RNAO], 2005). The assessment investigation must include three parts: (1) the causes, such as foot neuropathy, pain loss sensation, or foot injury, (2) ulcer characteristics including location and grade and (3) identifying the infection including the inflammation signs and symptoms, laboratory tests, and wound culture. When wound culture and sensitivity results are positive, broad spectrum systemic antibiotics are applied as soon as possible according to the results. Wound bed preparation

involves debridement of necrotic tissue and maintenance of an adequate moist wound environment by applying an appropriate wound dressing. Management co-morbidities include controlling hyperglycemia (optimizing diet, exercise and medication), improving peripheral vascular disease, and managing foot abnormalities.

Risk Factors of Diabetic Foot Ulcer

There were some significant risk factors for diabetic foot ulcerations, which can be drawn from previous studies including diabetic peripheral neuropathy (DPN), peripheral arterial disease (PAD), foot injury, peak plantar pressure and foot deformity, previous foot ulceration, and inadequate diabetic foot care knowledge and practice as detailed in the following.

Diabetic Peripheral Neuropathy

Diabetic peripheral neuropathy (DPN) was the most common problem in long-standing DM patients and was reported as the strongest predictor of foot ulcerations (Al-Mahroos & Al-Roomi, 2007; Reiber et al., 1999). The prevalence of DPN was more than 40% in patients with DM type 2 (Kumar et al., 1994) and almost 30% in European patients with DM type 1 (Tesfaye et al., 1996). Based on the current meta-analysis study, the incidence of ulceration was significantly higher in people with neuropathy that indicated the feet were insensate to ≤ 5.07 monofilaments (≤ 10g pressure) and have higher vibration perception thresholds (VPT) than those who did not have these signs (Crawford, Inkster, Kleijnen, & Fahey, 2007).

Foot Injury

Foot injury was reported as the second topmost risk factor of foot ulceration (Reiber et al., 1999). Walking barefoot, wearing improper footwear and using a razor blade to cut a callus or toenails were reported as common habits related to foot injury that were also commonly found in diabetic patients in the developing countries (Abbas & Morbach, 2005), with no exception in Indonesia, particularly in the rural areas. Accordingly, a study conducted in Indonesia showed that improper footwear was the most common cause of foot injury in diabetic patients that further developed foot ulcerations (Hastuti, 2007).

Peripheral Arterial Disease (PAD)

Atherosclerotic peripheral arterial diseases (PADs) were another prolonged DM macro-vascular complication which worked in combination with DPN and foot injury in developing ulceration (Boulton et al., 2008). The previous meta-analysis and cohort study revealed that diabetic patients with PAD in conjunction with a transcutaneous oxygen tension (TcPO2) less than 30 mmHg were highly associated with ulcer development in comparison to those who had a higher TcPO2 (31 to 60 mmHg). Also, a study reported from one cohort study and another case study showed that DM patients with advanced stage of vascular problems indicated by a history of lower limb bypass or amputation could predict the incidence of ulceration (Crawford et al., 2007).

Plantar Pressure and Foot Deformity

High plantar pressure in diabetic patients is a basic cause in developing peripheral neuropathy, which leads to the development of foot deformities. Consequently, foot posture changes, combined with excessive pressure and over-stimulation on certain parts of the foot, which eventually provokes ischemia, injury, calluses, or hemorrhages, results in developing a foot ulcer (Calhoun, Overgaard, Stevens, Dowling, & Mader, 2002). In addition, a study conducted by Ledoux and colleagues (2005) noted that foot deformities, particularly fixed hammer and hallux limitus were significantly associated with an increased risk of ulceration. Also, high foot pressures ($\geq$ 6 kg/cm^2) were independently associated with foot ulcerations (Frykberg et al., 1998). The effect of high plantar pressure on foot ulceration was also found in a meta-analysis study conducted by Crawford and colleagues (2007) who suggested that higher plantar pressures could represent a risk for foot ulceration.

Previous Foot Ulceration

Patients who had previous foot ulcer history mostly developed prolonged DPN, PAD, or had improper foot ulceration prevention behaviors (Mezra & Tesfaye, 2003). In addition, it was found that foot ulcer recurrence occurred in more than 60% of previously healed ulcers within 6.5 years (Ghanassia et al., 2006). A systematic review and meta-analysis study also revealed that foot ulceration was found more often in diabetic patients who had a previous foot ulceration history (Crawford et al. 2007; Mezra et al.).

Diabetic Foot Care Knowledge and Practice

An inadequate knowledge of diabetic foot care was linked to improper diabetic foot care practice (Chandalia, Singh, Kapoor, Chandalia, & Lamba, 2008; Khamseh, Vatankhah, & Baradaran, 2007; Olson et al., 2009). Diabetic patients with proper foot care practices can detect early on any foot abnormalities that trigger them to take early action to prevent foot ulceration or at least minimize further negative impacts. Accordingly, it was noted that patients who performed proper foot care and other prevention programs had a significantly lower risk of suffering from foot ulceration than those who did not perform proper foot care (Calle-Pascual et al., 2001; Hokkam, 2009).

Pathogenesis of Diabetic Foot Ulcer

Diabetic peripheral neuropathy (DPN), foot deformities, and foot injuries were congruently linked in developing diabetic foot ulcer (Reiber et al. 1999). Diabetic neuropathy affects multiple nerve fiber subtypes including sensory, motor, and autonomic (Calhoun et al., 2002). The sensory neuropathy causes pain-loss sensation where the DM patient loses sensation and is unable to feel pain, even from repeated injury. The motor nerve neuropathy causes an anatomic foot deformity which changes the foot posture followed by excessive pressure on certain parts of the foot. Consequently, repeated over-stimulation on the pressure point eventually provokes ischemia, injury, calluses, or hemorrhages that finally produce a foot ulcer. Additionally, autonomic neuropathy causes the alteration of normal temperature and secretion regulation that leads to the development of dry skin, cracking, and fissures

that results in diminishing the effectiveness of foot skin barriers (Sing et al., 2005; Williams & Pickup, 2004).

Once an ulcer has formed, the other diabetic complications, such as hyperglycemia, plantar pressure abnormality, and peripheral vascular problems together worsen the ulcer along with the process of ulcer healing. Hyperglycemia and ischemia cause an alteration of the immune function response at the injured tissue and results in inhibiting new cell growth, developing an imbalance of matrix metalloproteases (MMP) and tissue inhibitors of metalloproteases (TIMPs) regulation. Consequently, prolonged inflammation, delayed healing process, and increased infection risk were developed (Black, 2005; Fitzgerald, 2009; Stotts, 2003; Stotts & Wipkie-Tevis, 2001). Therefore managing these risk conditions and minimizing the process of foot injury are effective strategies to promote ulcer healing.

Prevention of Diabetic Foot Ulcer

According to standard care and practice guidelines, foot ulcer prevention consists of foot ulcer risk identification, high risk evaluation and/or management, and a foot care educational program (ADA, 2004; CDA, 2008; Indian Health Diabetes Best Practice Foot Care, 2009; RNAO, 2007; McIntosh et al., 2003). The details of these components are discussed in the following:

Identification of Diabetic Foot Ulcer Risks

Diabetic foot ulcer risk identification aims to detect at an early stage the risk factors of DFU. Data derived from this activity provide a basis in determining further treatments to minimize or eliminate those risk factors effectively. Many DM patients however, failed to detect foot ulcer occurrence as nearly 40% of foot ulcers were found by healthcare providers (Macfarlane & Jeffcoate, 1997). The risk factors and identification of DFU consists of identifying all parameters related to DFU.

The first identification is on the dermatological condition including skin color, sweating, dryness, cracking, fissures, evidence of infection, nail condition, calluses, and ulcer. Other identifications are the detection of a foot deformity and a neurological assessment using 10-g monofilament, vibration test using 128-Hz tuning fork, pinprick sensation, ankle reflexes, and vibration perception threshold (VPT) testing. Also, vascular status assessment on foot pulses (dorsalis pedis and tibialis posterior) and ankle brachial index (ABI), and retinopathy (visual acuity) are done to identify the risks (CDA, 2008; Indian Health Diabetes Best Practice Foot Care, 2009; RNAO, 2007). Besides these risk factor assessments, three randomized controlled trial (RCT) studies further recommended assessment of foot skin temperatures as one of the important risk identification factors of foot ulceration (Amstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). The RNAO (2007) emphasized the importance of assessing patients' foot care knowledge and behaviors.

The frequency of foot screening and examination by healthcare providers was suggested to be performed at least once a year and is recommended more frequently for high risk patients (ADA, 2004; RNAO, 2007). The frequency of

comprehensive foot examinations was also suggested according to the risk category proposed by Boulton and colleagues (2008) as showed in Table 1.

Table 1

Risk Classification Based on the Comprehensive Foot Examination

Risk category	Definition	Recommended Treatment	Suggested follow-up
0	No LOPS, no PAD, no deformity	Patient education including advice on appropriate footwear	Annually (by generalist and/or specialist)
1	LOPS± deformity	☑ Consider prescriptive or accommodative footwear ☑ Consider prophylactic surgery if the deformity cannot be safely accommodated in shoes. ☑ Continue patient education	Every 3-6 months (by generalist and/or specialist)
2	PAD ± LOPS	☑ Consider prescriptive or accommodative footwear. ☑ Consider vascular consultation for a combined follow-up.	Every 2–3 months (by specialist)
3	History of ulcer or amputation	☑ Same as category 1. ☑ Consider vascular consultation for a combined follow-up if PAD is present.	Every 1–2 months (by specialist)

Note: PAD = peripheral artery diseases and LOPS = loss of protective sensation. Adopted from "Comprehensive Foot Examination and Risk Assessment," by A. J. M., Boulton et al., 2008, *Diabetes Care, 31,* p. 1679 -1685.

Management of Modifiable Risk Factors

Evaluation and Management of Diabetic Peripheral Neuropathy

The most often recommended clinically based evaluation of DPN was the 10-g Semmes-Weinstein monofilament (SWF) (ADA, 2010; Howard, 2009; Singh et al., 2005). Similarly, one study also suggested that clinical examination and the SWF test were the two most sensitive tests for identifying patients at risk for foot ulceration, especially when the tests were used in conjunction with each other. In addition, using A Biothesiometer to test Vibration Perception Threshold (VPT) was also helpful and could be used as an alternative neuropathy evaluation (Pham et al., 2000).

Management of DPN still remains a challenge for healthcare providers because DPN treatments are time consuming, costly, and damaged nerves seem to be irreversible. The DPN management was divided into two purposes: 1) treatment that targeted relief of symptoms and 2) treatments that focused on a cure or a decrease of the underlying pathogenic mechanisms. Pharmacological therapy using pain killers and antidepressants effectively improved neuropathic pain (Dworkin et al., 2007). In addition, pharmacological therapy using oral alpha-lipoid acid or sequential intravenous and oral actovegin were identified to effectively improve neuropathic symptoms, pain, vibration perception threshold (VPT), sensory function, and quality of life patients with symptomatic DPN (Ziegler et al., 2006; Ziegler et al., 2009).

In addition, complementary therapy using topical oil "Neuragen PN®", high frequency external muscle stimulation, fifteen-day acupuncture treatment, and monochromatic infrared photo-energy (MIRE) demonstrated significant improvement

of neuropathic pain relief and the last two complementary therapies identified improved function of foot sensation (Harkless, DeLellis, Carnegie, & Burke, 2006; Li, 2010; Reichstein, Labrenz, Ziegler, & Martin, 2005; Yanqing, Hongyang, & Bing, 2010).

Apart from those recommended treatments, preventing and/or slowing the progress or complications of diabetic neuropathy by controlling the glycemic level was the best way to deal with a diabetic neuropathy problem (Tesfaye et al., 2005; Booya et al., 2005; Sorensen, Molyneaux, & Yue, 2002). Since the incidence of neuropathy was also associated with vascular problems, controlling modifiable cardiovascular risk factors including triglyceride level, body-mass index, smoking, and hypertension were also strongly recommended as part of diabetic neuropathy management (Gundogdu, 2006; Tesfaye et al.).

Evaluation and Management of Plantar Pressure

Previously, evaluation of the plantar pressure was conducted by applying a discrete sensor or a matrix of multiple sensors to measure plantar pressure and was used to measure the force of action on each sensor while the foot was contacting a supporting surface. The magnitude of pressure was then determined by dividing the measured force by the known area of the sensor or sensors evoked while the foot was in contact with the supporting surface. Pressure values could be reported in newtons per square centimeter, kilograms per square inch, or kilopascals or megapascals (Orlin, McPoil, Selby-Silverstein, Pierrynowski, & Effgan, 2000). Nowadays, plantar pressure can be measured using a variety of instruments, such as force-sensing resistors (FSRs), Hydrocells, microcapsules, projection devices,

pedoscopes, capacitance transducers and critical light deflection. Among those, hydrocell technology permits the quantification of pressure that allows the examiner to estimate the pressure more accurately (Orlin et al).

The common treatments for patients who were identified as having high plantar pressure consisted of specialized footwear (custom insole) and surgical treatment. One systematic review conducted by Spencer (2000) indicated that in-shoe orthotics seemed to be a beneficial prevention strategy resulting in fewer calluses and ulcerations. Maciejewski and colleagues (2004) also identified an association between protective foot-wear and the incidence of foot ulceration, particularly among the group of patients with severe foot deformities. In accordance with Amstrong and others (1999), since peak pressures on the plantar area of the forefoot were significantly reduced after per-cutaneous lengthening of the Achilles tendon in high risk diabetic patients, the surgical procedure might be a benefit as an adjunctive therapeutic or prophylactic measure to reduce the risk of neuropathic ulceration.

Improvement of Diabetic Foot Care Knowledge and Behaviors

As mentioned previously, a lack of diabetic foot care knowledge and practice of diabetic patients were significant risk factors for diabetic foot ulceration. The vital diabetic foot care knowledge and skills have been studied and addressed. According to RNAO (2007), the vital knowledge and skills/practice of foot care education includes awareness of personal risk factors, knowing the significance of getting an annual foot examination by a healthcare provider, daily foot self-inspection, proper footwear, proper nail and skin care, foot injury prevention and

management and seeking help or specialized referral when a foot problem occurs. As observed, most of the foot care knowledge and skills can be learned by diabetic patients. Therefore, educating the patients on the required knowledge and skills, particularly daily foot care practices, is very important and can be done through an educational program.

According to Indian Health Diabetes Best Practice Foot Care (2009) and RNAO (2007), the recommended activities of daily foot care practices performed by the diabetic patients, consisted of performing foot self-examination, maintaining foot hygiene, wearing proper footwear, toenail care, preventing foot injury, and managing the presence of any foot injury. In performing self-foot examination, the diabetic patients were encouraged to independently inspect his/her foot conditions including the posture, skin color, dryness, toenail infection, foot injury signs, or other foot abnormalities. Maintaining the foot hygiene component includes washing under plain water, no brushing or using abrasive equipment, no soaking of the foot, drying the foot properly after washing and keeping it moist. Proper footwear activities consist of selecting proper footwear size and type (e.g. no high-heel, no pointed shoes, and made from smooth and elastic materials), checking inside the footwear before wearing, and always wear the footwear both inside and outside the house. Proper trimming of toenails consists of selecting the correct nail cutter and cutting the toenails in a straight direction. Preventing foot injury includes avoiding improper footwear, checking water temperature before using, never go barefoot, and using proper toenail cutters. Finally, providing proper management for actual injury or ulceration consists of cleaning the injury site and closing it using clean gauze or

another wound dressing (Indian Health Diabetes Best Practice Foot Care, 2009; RNAO, 2007).

Contributing Factors of Diabetic Foot Care Behaviors

Patients' diabetic foot care behaviors were influenced by several factors as discussed in the following topics.

Patients' knowledge and diabetic foot care education. Lack of knowledge related to proper diabetic foot care practices/behaviors was identified as one of the barriers for diabetic patients in properly performing diabetic foot care (Gondal et al., 2007; Khamseh, et al., 2007; Shaya et al., 2007). From this, an educational program was crucial in improving patients' knowledge and foot self-care behaviors (Bazian ltd., 2005; Corbett, 2003, McMurray et al., 2002; Schmidt, Mayer, & Panfil, 2008; Vatankhah et al., 2009).

The significance of an educational program on DFCB has been studied and found a positive correlation. For instance, a study conducted by Schmidt and colleagues (2009) revealed that diabetic patients who participated in more than three educational/training programs had significantly better DFCB than patients who participated in only one training program. Furthermore, patients who had received foot care education and those whose feet had been examined by their physician were more likely to check their feet regularly (Bell et al., 2005; De-Berardis et al., 2004). Adequate information together with regular physician-foot examinations provided a better chance and motivation for diabetic patients to develop proper DFCB.

Patients' characteristics. A study conducted by Johnston and others (2006) revealed that a younger age, higher educational level and an African-American

background were found to be vital characteristics that were significantly associated with greater foot care practice. The other characteristics associated with foot care behaviors were gender (Bell et al., 2005; Salmani & Hosseini, 2010), educational level (Khamseh et al., 2007) and self-efficacy (Perrin, Swerisse, & Payne, 2009).

Complications of diabetes mellitus. Complications of diabetes mellitus can cause physical disabilities that result in reducing patients' capacity in performing foot care. For instance, vision problems were identified as the barriers in performing self-foot care practice (Olson et al., 2009). On the other hand, diabetic complications may increase patients' awareness regarding the risk of foot ulceration and trigger them to perform better diabetic foot care behaviors. For example, DM complications such as previous foot ulcer during the prior 12 months, perceived neuropathy, and prior amputation were documented as predictors for greater diabetic patients' adherence to the foot care practice (Johnston et al., 2006; Pollock, Unwin, & Connolly, 2004; Salmani & Hosseini, 2010).

Resources availability. For diabetic patients who suffer from retinopathy or other complications or conditions that further affect his/her ability such as the inability to assess, reach, or perform foot self-care properly, they need assistance from a caregiver in performing diabetic foot care. Also, a lack of foot care equipment, such as a mirror, foot-stool, and nail cutter, can inhibit patients in performing foot care properly (Bell et al., 2007).

Diabetic Foot Care Knowledge and Behaviors Improvement Program

There were 9 studies (4 RCTs, 3 quasi-experimental studies, and 2 systematic reviews) that evaluated the effectiveness of a diabetic foot care program in

improving foot care behaviors and preventing foot ulcers. From this, some studies evaluated foot care behaviors as secondary outcomes under self-care behaviors (Deakin et al., 2006; McMurray et al., 2002). The general information regarding the RCTs and quasi-experimental studies are outlined in Table 2. As seen from Table 2, methods and follow-up strategies used in those studies were telephone call, card reminder, home visit, and follow-up as scheduled at the clinic/outpatient department. Besides this, the other studies also reported that phone call intervention for giving health education and/or follow-up effectively improved the patients' behaviors (DeWalt, et al., 2009; Eakin, Lawler, Vandelanotte, & Owen, 2007; Lorig, Ritter, Villa, & Piette, 2008).

According to Table 2, the duration or scope of the studies varied from 1 month (Hazavehei et al., 2007) to 14 months (Deakin et al., 2007). The outcomes of the studies were measured at different periods of time, such as at 4 or 6 months and 12 or 14 months after implementing the program (Deakin et al.; Lincoln et al., 2008). Time spent implementing a diabetic foot care program also varied from 20 minutes (Vatankhah et al, 2009) to 120 minutes (Hazavehei et al.; Lincoln et al.). One systematic review suggested that the intensive diabetic foot care program which increased the interaction between the patient and healthcare provider seemed to be more effective than a single/one-off brief session of a diabetic foot care program (Bazian ltd., 2005).

Methodologically, there were a number of issues that might be a threat to the validity of those studies, such as small sample size (Corbett, 2003), did not measure base line data of foot care behaviors (Lincoln et al. 2008), did not explain evaluated diabetic foot care components and/or did not evaluate foot care components

Table 2

General Information of Studies Reviewed

No	First Author (Year)	Country	Study Design		Setting/ Location			Mode		Methods						Follow-up Strategies			Educator		Durations		Materials		
			RCT	Quasi-Experiment	Inpatient	Outpatient	Home care/Community	Group	Individual	Education	Demonstration	Counseling	Reminder card	Motivational	Leaflet/booklet	Telephone	Home visit/face-to-face	When patients check up	Clinician/Trained	Multidiscipline	< 24 weeks	24 weeks and more	Guideline	Other	Unexplained
1.	Lincoln, et al. (2008)	UK	√				√		√	√				√		√			√			√	√		
2.	McMurray, et al. (2002)	USA	√		√				√	√		√	√	√				√	√	√		√	√		
3.	Corbett (2003)	USA	√				√		√	√	√			√			√		√		√		√		
4.	Vatankhah, et al., (2009)	Iran		√		√			√	√					√			√				√		√	
5.	Viswanathan, et al., (2005)	India		√		√			√		√	√			√			√	√		√				√
6.	Hazavehei, et al. (2007)	Iran		√		√		√		√	√								√		√			√	
7.	Deakin, et al. (2006)	UK	√				√	√		√	√			√	√		√		√	√		√	√		

comprehensively (McMurray et al., 2002), did not perform randomization (Viswanathan, Madhavan, Rajasekar, Chamukuttan, & Ambady, 2005), did not explain the control group, sampling, and randomization procedure, and did not explain the evaluated diabetic foot care components (Hazavehei et al., 2007). Accordingly, the systematic reviews reported that even though trials in this arena significantly improved patients' foot care knowledge and behaviors, most of those studies had lower internal validity and a high risk of bias. Some of those limitations did not include true randomization, no blinded examiners, incompletely described the confounding factors, incompletely reported the drop-out rate, and some studies had unacceptable drop-out rates (Bazian ltd., 2005; Valk et al., 2005).

Most of the previous studies provided diabetic foot care programs as an individual (face-to-face) or a group approach that was combined with demonstrations of some foot care activities, showing related pictures, having discussions, providing a leaflet/booklet and providing other motivational sessions or counseling. In comparison, the effectiveness of both an individual and group approach (4-8 patient/group) in improving the outcomes was equal and may even provide other benefits regarding time and cost (Deakin et al., 2006; Rickheim, Flader, Weaver, & Kendall, 2002).

There were only three studies that clearly mentioned they had developed the educational material based on foot care standards or guidelines launched by the International Consensus on the Diabetic Foot (Lincoln, et al., 2008), the American College for Foot and Ankle Surgeon (Vatankhah et al., 2009) and the National Standards for Self-Management Program (McMurray, 2002). The key contents consisted mostly of individual risk factors (signs and symptoms), foot

hygiene, proper footwear, regular foot examinations, foot moisturizing, toenail trimming, reporting and managing foot abnormalities.

The measured outcomes were the patients' foot care knowledge, patients' foot care behaviors, and clinical outcomes including foot ulcer, foot problems and foot problems leading to amputation. Those studies revealed that diabetic foot care programs improved the patients' foot care knowledge, behaviors, and self-efficacy (Corbett, 2003), improved patients' perceptions of barriers, benefits, severity, threat, and susceptibility of foot care (Hazavehei et al., 2007), and reduced the incidence of foot complications or new foot problems (Viswanathan et al., 2005). However, there was no significant reduction of foot ulcer incidents, particularly in high risk patients (Lincoln et al., 2008).

In the previous studies, the patients' self-report questionnaire on perceived foot care behaviors were generally used to measure the outcome of patients' foot care behaviors. Observational methods were also used in combination with the patients' self-report in evaluating foot care behaviors. Unfortunately there were no clear details on the evidence of this assessment method (Hazavehei et al., 2007). The launched questionnaires developed to evaluate foot care behaviors included the Nottingham Assessment of Functional Foot-care Questionnaire (NAFF), DisFoKa-32, and Summery of Diabetes Self-Care Activity (SDSCA).

Nottingham Assessment of Functional Foot-care Questionnaire (NAFF). This instrument was developed by Lincoln and colleagues in 2007 and primarily consisted of a 51-item questionnaire. It was implemented with 100 diabetic patients and 61 healthy volunteers in an outpatient department. The internal consistency was 0.46 and 0.39 in people with diabetes and in healthy volunteers,

respectively. From this, 28 items were found to have significant differences between each group. The instrument was then revised from 51 items to 29 items. The revised questionnaire consisted of questions on foot assessment (2 questions), footwear (13 questions), foot hygiene (3 questions), foot injury prevention (7 questions), toenail, callus/corn care (2 questions), and wound/ulcer care (2 questions). The internal consistency was 0.53 and there was a significant correlation ($\gamma = 0.83$; $p < 0.001$) and no significant differences ($p = 0.85$) between the scores of the test and a retest study. However, since this questionnaire was developed and utilized in European countries, utilization in other regions is therefore needed to be modified to fit each particular context and culture.

DisFoKaPS-32 Questionnaire. This questionnaire was developed by Khamseh and colleagues (2007) based on foot care principles, their direct experiences as healthcare providers and the recommendations from the American College of Foot and Ankle Surgeons and the British Diabetic Association. It was originally developed in a Persian-language version and consisted of 16 items on knowledge and 16 items on foot care behaviors. A foot care practice section comprised of foot self-examination (4 questions), footwear (3 questions), toenail care (2 questions), and foot hygiene (7 questions). The content validity was approved by five physicians and one nurse and tried out on Iranian diabetic patients. However, there was no report regarding a reliability test of this questionnaire.

Summary of Diabetes Self-Care Activities (SDSCA) Questionnaire. The SDSCA is a brief self-report questionnaire to assess diabetes self-management including: general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking (Toobert, Hampson, & Glasgow, 2000). The internal consistency-reliability

of the 5 categories of this questionnaire ($\gamma = 0.47$) was reported at a high level with the exception of the specific diet test-retest correlation which was at a moderate level ($\gamma = 0.40$). Furthermore, the SDSCA questionnaire was a brief, reliable, and valid self-report measure of diabetes self-management which included foot care practice and it was suggested for use in both research and clinical practice (Toobert et al., 2000). However, it might not represent the whole picture of diabetic foot care behavior components since few items asked about foot care practice.

In comparison, regarding the components measured, NAFF and DisFoKaPS-32 included and covered more on diabetic foot care aspects than SDSCA. In addition, NAFF and DisFoKaPS-32 have some similarities including foot inspection, foot hygiene, footwear, prevention of foot injury, toenail/callus/corn care and moisturizing foot skin to measure foot care behaviors. However, since the NAFF was developed in a European country, some of the measured items may not fit the measurement of foot care behaviors in non-European countries. Therefore, it should be used with care and in consideration of each local context.

During the last decade, as discussed through this chapter, most of the studies regarding diabetic foot care were conducted in Western countries and there are still no new published studies and reports evaluating interventions/programs to improve foot care behaviors or prevent foot ulceration in developing countries, particularly in Asia. In Western studies, the programs were found to effectively improve patients' foot care knowledge and behaviors. The evidence from many cross-cultural studies has shown that successful implementation of new interventions in one country need to be modified for effective use in other countries. It may be possible to improve foot care behaviors in Indonesian diabetic patients by modifying the well-

known Western diabetic foot care programs. However, some Western concepts do not fit the demands of nursing care and patients in the context of some special cultures (Ekintumas, 1999). For instance, Muslims wash/clean the feet before praying at least five times per day. The implementation of foot-care programs, therefore, needs to be congruent with health care and cultural differences.

Diabetic Foot Care Program in Indonesia

There were no published and accessible studies evaluating diabetic foot care programs in Indonesia. However, one head nurse who is working at the Diabetic Unit of Sumedang District General Hospital shared the information on the treatment program and standardized care for diabetic patients in this unit. This program consists of diagnostic procedures, medication, regular (monthly) laboratory check-ups, physical examinations, consultation, and an educational program. In addition, patients are encouraged to join the Diabetes Club (PERSADIA) of the hospital. This club conducts weekly activities focusing on an exercise program. Diabetic treatment regiments are prescribed by a physician, while nurses take more responsibility for initial screening including vital sign recording, asking about the chief complaint and allocating an educational program. Knowledge on diet and exercise are regularly provided in an educational program, whereas knowledge on foot care is only given by a physician when patients complain about the symptoms of diabetic neuropathy or the nurses/physician find evidence of foot abnormalities. The specific foot care examination tools, however, are not used in this unit (Head Nurse of

Diabetic Unit at Sumedang District General Hospital, personal communication, March 16, 2010).

In the context of Indonesia, the daily religious practices, such as praying, might influence foot care practice behaviors. Generally, since most Indonesian people are Muslim, they regularly wash their feet ("wudhu"/purifying) five times a day before praying. Based on the researcher's experience, although a study conducted in Iran revealed no influence of 'wudhu' on patients' foot care behaviors (Khamseh et al., 2007), this activity might have both positive and negative impacts on diabetic foot care practice. For instance, 'wudhu' provides an opportunity for Muslim DM patients to clean and inspect his/her feet frequently. Irritation between the toe areas, however, can be developed if they do not dry the foot properly after washing. A number of factors, particularly on the cultural and religious issues, therefore need to be highly considered and integrated prior to development of a culturally sensitive DFC program that fits the Indonesian diabetic patients and context.

Self-Management

Similar to other chronic diseases, diabetes mellitus needs lifelong management since it is incurable with a high potential to develop serious DM related complications. In order to harmoniously live with DM, diabetic patients need to have the capability of being "self-managed". From this, they will be able to conduct day-to-day decision making, tasks and skills in controlling, minimizing, and improving the chronic conditions (Barlow et al., 2002; Lorig & Holman, 2003).

Self-management was defined as the individuals' ability in managing the symptoms, treatments, physical and/or psychological consequences, and lifestyle changes that are caused by chronic conditions. This individual management aimed to achieve the required responses including the cognitive, behavioral, and emotional responses in maintaining and/or improving the desired quality of life (Barlow, 2001). The effort, intervention, strategy, or method that aims to improve patients' self-management status is the so called self-management support program/method/ intervention. According to Ryan and Sawin (2009), a self-management program is a set of activities that propose to prepare/train the patients to accept the responsibilities for managing their chronic conditions and/or engaging in health promotion activities. The components of the program consist of performing goal setting, action planning, decision making, and managing the physical, psychological, and cognitive responses. Consequently, more adequate knowledge, behaviors, clinical status, and desired heath status would be achieved (Ryan & Sawin).

Accordingly, Kanfer and Gaelick-Buys (1991) defined a self-management method as a set of treatments in providing a therapeutic environment to encourage chronic patients' acceptance of his/her responsibilities on his/her own behaviors to engage in a behavioral change process in order to deal with their chronic conditions. Similarly, self-management could be achieved through the process of activating self-monitoring, establishing specific rules to conduct behaviors, performing self-evaluation, and generating self-reinforcement. Furthermore, Kanfer and Gaelick-Buys described a self-management method that may cause three outcomes including (a) help the patient obtain more effective interpersonal, cognitive, and emotional behaviors; (b) alter the patient's perceptions and evaluate the attitudes

of problematic situations; and (c) help the patient learn to cope with stress-inducing change or an intimidating environment by accepting that it is unavoidable.

Self-Management Processes

Basically, the self-management method proposed by Kanfer and Gaelick-Buys (1991) was derived from self-regulation theory. It consists of three main cyclical stages/processes including self-monitoring, self-evaluation and self-reinforcement. The self-monitoring stage is the phase in which the individual intentionally monitors/observes his/her own certain behaviors. In the self-evaluation stage, the individual compares his/her existing behaviors (result of self-monitoring process) with the desired behaviors and judges whether the actual behaviors meet or do not meet the desired standard behaviors. Based on those results, a person performs self-reinforcement by providing emotional or cognitive responses either as feedback or feed-forward and makes further decisions to improve, modify or just maintain the current behaviors properly. The next cycle of the self-management's process will simultaneously occur until the desired behaviors are achieved.

According to Kanfer and Galick-Buys (1991), in order to facilitate the effectiveness of those self-management processes, the patient and facilitator should develop a therapeutic contract once a patient has decided to improve his/her particular behaviors. A therapeutic contract is a statement of agreement between the patient and facilitator regarding certain behaviors that a person wishes to improve and the consequences of the accomplishment and non-accomplishment (Kanfer & Gaelick-Buys.). This contract is very useful for both parties, particularly in providing

measurable outcomes that facilitate the objective evaluation of the patient's achievements while implementing the program.

While building the contract, there are seven points that should be included: (1) a written detailed and clear description of the required behaviors, (2) tentative time or frequency to perform the behaviors (3) positive and negative consequences as the indicators of accomplishment, (4) provisions for some aversive consequences, contingent on nonfulfillment of the contract within a specified time period or with a specified frequency, (5) positive sentences as additional positive reinforcement for the achievement(s), (6) statement of observable, measurable, and recordable behaviors, and (7) providing reinforcement as soon as possible. The term 'therapeutic contract' was widely used in other studies as 'goal setting' and 'action-planning' (DeWalt et al., 2009; Bodenheimer & Handley, 2009; Clark & Hampson, 2001; MacGregor et al., 2006; Wallace et al., 2009).

In addition, since a patient's confidence level is closely related to his/her goal achievement(s), it is recommended that the facilitator assess the patient's confidence level in performing each action plan and achieving the goal that he/she developed while implementing the self-management program (Bodenheimer et al., 2007; Bodenheimer & Handley, 2009; Kanfer & Gaelick-Buys, 1991). According to Bodenheimer and others (2007), a self-confidence scale was used by a facilitator to measure a patient's self-confidence level. The facilitator asked the patient to range his/her self-confidence by using a self-confidence scale from 0 (totally not confident) to 10 (totally confident). A score of 7 or higher means the goals and action plans that the patient developed would most likely be accomplished. Conversely, a score less

than 7 means that the goal/action plan should be adjusted to make it more achievable (Bodenheimer et al., 2007).

Contributing Factors of Self-Management

There are some contributing factors influencing self-management of patients with diabetes mellitus. These include individual-related factors, social factors, and healthcare provider-related factors as explained in the following.

Individual-Related Factors

These factors consist of the level of knowledge regarding disease and its treatments, gender, self-efficacy, long duration of DM, perception about treatment effectiveness, and depression. The most commonly reported barriers for performing self-management was a lack of knowledge on the disease and treatments (Bayliss, Ellis, & Steiner, 2007; Nagelkerk, Reick, & Meengs, 2005). Regarding gender, one study conducted by Whittemore, Melkus, and Grey (2005) revealed that women with DM type 2 reported higher difficulty than men in managing diet behaviors and physical activity. Women also had greater depressive symptomatology which is one of the significant self-management barriers (Ponzo et al., 2006).

As mentioned previously, since self-management is closely related to a patient's self-efficacy, patients with higher self-efficacy were more likely to perform better self-management (Lanting et al., 2008; Savoca & Miller, 2001; Whittemore et al.). Furthermore, patients with a longer duration of DM and persistent depressive symptoms were significantly associated with lower diabetes self-management,

whereas patients with greater treatment effectiveness were significantly associated with higher diabetes self-management (Bayliss et al.; Ponzo et al.).

Social Related Factors

Social factors that potentially influenced self-management were cultural and ethnic background and social support. Several studies concluded that self-management was highly related to patients' ethnic and sociocultural backgrounds (Chiu-Chu, Anderson, Hagerty, & Bih-O, 2007; Lanting et al., 2008; Ponzo et al., 2006). Regarding social/family support, diabetic patients with greater social/family support were associated with better diabetes self-management (Chiu-Chu et al.; Nagelkerk et al., 2005; Whittemore et al., 2005).

Healthcare Providers-Related Factor

Since social support and self-efficacy were identified as the important components of effective diabetes self-management, the quality of healthcare services and therapeutic relationships with the patients become very essential components in improving patients' ability in performing effective diabetes self-management. It was identified that developing a collaborative relationship between healthcare providers and patients, maintaining a positive attitude that prompts patients' proactive learning, and providing a support person who provides encouragement and promotes patients' confidence living with diabetes were the effective strategies of improving patients' diabetes self management (Nagelkerk et al., 2005; Whittemore et al., 2005).

The current systematic reviews and meta-analysis related to self-management intervention in diabetic patients suggested that self-management interventions in diabetic patients effectively improved patients' blood glucose level, knowledge, body weight, systolic blood pressure, self-management behaviors, and self-efficacy (Barlow et al., 2002; Clark, 2008; Ellis et al., 2004; Fan & Sidani, 2009; Minet, Møller, Vach, Wagner & Henriksen, (2010); Norris et al., 2001; Warsi, Wang, LaValley, Avorn, & Solomon, 2004). The other positive effects of self-management intervention also noted in some primary studies included improved patients' quality of life and reduced risks of coronary heart disease (Wattana, Srisuphan, Pothiban, & Upchurch, 2007), improved patients' diabetes related distress (Wallace et al., 2009), reduced diabetes medication, improved body mass index, total cholesterol, physical activity levels, foot care practice, and diet behaviors (Deakin, Cade, & Greenwood, 2006), as well as exercise behaviors (DeWalt et al., 2009).

A meta-analysis study conducted by Ellis and colleagues (2004) found several strategies to implement a self-management program including didactic strategy, goal setting and action planning, situational problem solving, and cognitive reframing. According to Ellis and colleagues (2004), didactic strategy consisted of giving lectures or printed materials to convey information or instruction. Goal setting and an action planning strategy can be done by the facilitator and patients to develop goals of treatment/behavioral improvement and action plans concurrently. The facilitator and patients jointly develop strategies to overcome treatment barriers during situational problem solving sessions. While in cognitive reframing, the

facilitator suggests alternative self-perceptions to assist the patients in improving their self-management.

The Preliminary Study of a Self-Management Support Program

Before conducting this current study, the researcher applied the preliminary study of a self-management support program with four hospitalized diabetic patients that met the inclusion criteria. In this preliminary study, the intervention was developed and adjusted from a goal setting and action planning protocol proposed by DeWalt and colleagues (2009). Initially, the researchers assessed patients' demographic data and relevant clinical information, foot conditions, and the patients' foot care knowledge and behaviors. Based on the assessment findings, the researchers provided individual-based (face-to-face) education related to proper diabetic foot care, gave a booklet of desired DFCB as an additional guide, and clarified the participants' understanding on the information given. Each patient then was assisted in setting his/her own goal(s) and action plan(s) in order to improve his/her diabetic foot care behaviors. Next, the researchers discussed with each patient the possible difficulties while implementing the action plan(s) and to further identify effective solutions. Furthermore, the patient's family members were involved in each step of intervention and were asked to act as the patient's reminder, support provider, assistant, or other roles to facilitate the effectiveness of action plan implementation.

The evaluation outcomes included the patient's understanding regarding proper foot care, patient's foot care goal(s) and their action plan(s), and potential foot care behaviors. The evaluations were done on the third day after the

first meeting and with follow-up phone calls one week after the patients were discharged. During the phone call sessions, the researcher discussed with the patients their action plans implemented, goals achieved, identified difficulties faced during action plan implementation, and provided brief consultation to assist each patient in finding possible solutions or to develop further goals and action plans.

Based on the baseline data derived from the four hospitalized diabetic patients, it was shown that all patients needed improvement either on the diabetic foot care knowledge or diabetic foot care behaviors. No patients were totally correct on 10 simple questions related to desired diabetic foot care. The diabetic foot care behaviors score ranged from 28.42% to 74.2%. Although, none of them had experience in diabetic foot ulcer, all of them were at high risk to develop diabetic foot ulcer.

At the end of this pilot study, it was identified that the applied program effectively improved hospitalized diabetic patients' foot care knowledge and their perceived foot care behaviors. All four patients in this pilot study could establish diabetic foot care improvement incorporated with other goals to improve their health-related behaviors including exercise, regular check up, diet program, and smoking cessation. In addition, three of four patients did not report any possible barriers while implementing those plans. The evaluation session suggested that every patient was able to restate the goal(s) and action plan(s) that they set in the previous meeting step. Also, members of the entire family, included during the first meeting, stated that they would like to do their best to assist the patient in implementing the identified action plan to achieve the goal(s). However, during follow-up phone calls, only two patients were accessible. Both patients reported that the action plans were performed and the foot care behaviors improvement goal including inspecting the feet 3 times per week,

wearing footwear outdoors and not wearing shoes without socks were achieved. The other two patients could not be contacted because in one case the researchers incorrectly recorded his phone number and in the other case the patient did not answer the phone call. The details of this pilot study report was presented at Java International Nursing Conference and published in Nurse Media Journal of Nursing (Kurniawan & Petpichetchian, 2011).

In general, the SM support program using a combination of some strategies applied in this preliminary study seemed to be feasible and provide effective intervention to assist diabetic patients in improving their diabetic foot care knowledge and behaviors. However, there were some essential points that should be improved for further study. Firstly, in this preliminary study, the diabetic patients' DFCB, while they were being hospitalized, could not be evaluated since they faced some barriers including physical, environmental, and hospital facilities to conduct daily foot care. Therefore, if diabetic foot care behaviors were measured as outcomes, the outpatient setting was strongly recommended. Secondly, to improve the effectiveness of follow-up phone calls, setting the appointment for the follow -up should be conducted properly. The appointment information should cover the patients' preferred time available, valid contact/phone number, the activities to be performed during the phone call, the purposes, significances, and time duration of the phone call. Thirdly, the patients' cultural background might contribute to the DFCB; therefore cultural sensitivity issues should be attached in the measurement development and any modifications.

In summary, knowledge derived from a literature review provides basic knowledge to develop a foot-care program for DM patients in Indonesia. There are some important factors regarding foot care behaviors and foot ulcer prevention in diabetic patients that need to be considered. Diabetic foot ulcer is one of the serious complications of diabetes mellitus that is influenced by tremendous risk factors, including the patients' clinical factors and behaviors. Fortunately, the evidence has suggested that diabetic foot ulcer is preventable by improving the patients' behaviors, particularly in performing daily foot care practice. The standard foot care practice consisted of foot assessment, improving foot hygiene, moisturizing foot skin, attending to a regular foot examination, avoiding foot injury, and providing care to manage actual foot ulcer/injury when it presents.

Based on a literature review, a self-management program has been reported on the positive effects on chronic patients' behaviors and health outcomes. Using a self-management support program as a strategy to assist patients as active learners and to perform interaction between the patients and healthcare providers can effectively improve desired behaviors and health outcomes including patients' adherence, self-care behaviors, quality of life, and cost of treatments. However, some methodological flaws were found in previous studies such as capturing only some components of foot care behaviors and conducting the studies primarily in Western countries. From this, the available measurements developed within a western context may not fit the people in Eastern countries. In Muslim countries, for instance, people have unique habits on foot care/hygiene. Hence, it is important to conduct a study to implement diabetic foot care practice that fits the local population, particularly in

Indonesia in order to improve diabetic patients' foot care behaviors and foot ulcer prevention.

CHAPTER 3

RESEARCH METHODOLOGY

This chapter describes the research design, setting, population and sample, instrumentation, intervention, ethical considerations, data collection procedures, and data analysis of the study.

Research Design

This study was a quasi-experimental design using a two-group pre-test and post-test design with a single blind method to examine the effect of the diabetic foot care self-management support program on diabetic foot care behaviors and goal achievements among patients with diabetes mellitus in West Java, Indonesia. The control group received standard/usual care for diabetic patients given by the staff of the Diabetic Unit of Sumedang District General Hospital. The experimental group received both the standard/usual care and the diabetic foot care self-management support program.

Setting

This study was conducted at the Diabetic Unit of Sumedang District General Hospital, West Java, Indonesia. This hospital is a secondary hospital that has an independent diabetic unit. The staff at this unit consists of an administrative staff, two physicians, and two nurses. The routine standard care includes monthly check-

ups or two-week follow-ups for patients with poor blood glucose control and/or with complications, prescribed medication, prescribed laboratory examinations, vital sign examinations, and monthly health education by nurses and/or nursing students. Patients attend a lecture session with one way communication without evaluating the outcomes, such as the patient's understanding or knowledge gained. The contents in the current educational program mostly address the diabetic diet, hypo/hyperglycemia symptom management, medication, exercise, but rarely address diabetic foot care. Generally, information regarding diabetic foot care is only given when foot problems/complications are presented by the patients and/or when those problems/complications are identified by physician/nurses.

Population and Sample

The population of this study consisted of all diabetic patients who attend the Diabetic Unit of Sumedang District General Hospital. The inclusion criteria of the sample included (1) ages 18 - 65 years (2) can be contacted by phone, (3) able to read and speak, (4) no severe vision problem, (5) no hearing problem, and (6) able to perform daily living activities independently. The selected group of ages less than 65 years aimed to minimize the common impacts of the aging process on subjects' physical/psychological functional status that would potentially inhibit them in performing their daily life activities independently. Subjects were excluded if they developed severe complications or became unable to perform diabetic foot care independently due to severe diabetic retinopathy, joint problems, and/or being

hospitalized during the study period. In the actual study period, there were no subjects who met the exclusion criteria.

Sample Size

The sample size in this study was determined based on the meta-analysis study of Fan and Sidani (2009). These authors identified the effect size of several strategies commonly employed in the self-management education intervention. The effect sizes of those strategies ranged from 0.29 to 0.95. Since this present study also employed several strategies to enhance diabetic foot care behaviors including individual-based education combined with printed material (booklet), brief counseling and follow-up, either through phone calls or face-to-face, the moderate effect size ($d = 0.6$) was used to calculate the sample size. According to Cohen (1988) (Table 2.4.1, page 54), the minimum sample size for a significance level of $\alpha = .05$, power = .80, and an effect size ($d = 0.6$) was 35 subjects per group or 70 subjects in total. During the study, 70 subjects who met the inclusion criteria were recruited and none of them withdrew from the study.

Sampling Procedures

Initially, the subjects who met the inclusion criteria were approached by the first research assistant (RA) and introduced to the researcher thereafter. The researcher then explained the details of the study purposes, benefits, rights to participate and withdraw from the study, and confidentiality issues (Appendix A) to ascertain the subjects' interest and decision to participate in this study. Subjects' who decided to join in this study and provided verbal or written consent were matched

based on the subjects' foot ulcer history, complaints of diabetic foot neuropathy symptoms and/or other foot problems, and the subjects' experience in receiving diabetic foot care information.

In order to minimize the interaction threat between the subjects in the experimental and control groups, the sample recruitment in both groups were conducted separately. An interaction threat in this study occurred because the diabetic foot self-management support program was conducted in the waiting room of the diabetic unit where patients who came in the same day could easily access the interventions and/or interact with each other between the control and experimental groups. The eligible subjects who came in the first day of data collection were assigned either into the experimental or control group by tossing a coin. Then, the matched subjects who came in the next day were assigned into the opposite group. This recruitment procedure continued sequentially until the researcher obtained the total number of 35 subjects in each group.

Instrumentation

The instruments used in this study were divided into two parts; Part I: Diabetic Foot Care Self-Management Support Program and Part II: Data Collection Instruments.

Part I: Diabetic Foot Care Self-Management Support Program.

As discussed in Chapter 1, the diabetic foot care self-management support program consisted of several strategies constructed to facilitate the subjects in

conducting individual reflection, providing an individual-based diabetic foot care educational session based on the subjects' diabetic foot care prior knowledge in combination with the DFCB booklet, discussion, and diabetic foot care video. Then, the subjects were assisted in performing self-evaluation, goal setting and action planning, self-reinforcement, and received brief counseling by a weekly phone call (Appendix B). In total, the duration of this program was 5 weeks. The protocol of each week comprised of the following activities:

The first week interventions. In the first meeting, subjects were assisted individually to perform self-monitoring by reflecting and monitoring his/her current diabetic foot care behaviors (DFCB) within a 3-minute duration. Then, the researcher gave an individual-based diabetic foot care education for 30 minutes using a lecture format with discussion, giving the DFCB booklet, and having him/her watch a diabetic foot care video. During the educational session, the researcher initially clarified the subjects' understanding on the desired diabetic foot care based on his/her prior knowledge assessment and subjects' reflection. Then, the researcher provided a brief explanation of diabetic foot care contents in the booklet and added more information if needed. After finishing the discussion with the subject, he/she watched a diabetic foot care video provided by the researcher. At the end of this session, the researcher and the subjects discussed further some important topics to help him/her clearly understand the given information/materials (Appendix C).

The materials given consisted of general and specific information regarding desired diabetic foot care, the significance, and diabetic foot care components including foot examination, foot hygiene, toenail care, proper footwear, foot injury prevention and management, and regular comprehensive foot

examinations. All of these diabetic foot care components were documented in the booklet and could be used as a simple guide in performing proper diabetic foot care on a daily basis (Appendix D).

Then, the researcher helped the subjects conduct a self-evaluation by comparing his/her current foot care behaviors with the desired diabetic foot care behaviors and further determined whether or not his/her diabetic foot care behaviors met the desired diabetic foot care behaviors standard that he/she learned from the educational session. Based on the subjects' self-evaluation results, the researcher helped the subjects identify the diabetic foot care components that needed to be improved, and further helped them to make decisions to develop realistic goals and action plans in order to improve their DFCB. In this step, each subject was provided the Goal Achievement Form (Appendix E) that was attached to the booklet and advised them to record his/her daily foot care activities. Then the researcher also measured the subjects' confidence level in performing the actions planned by using the Self-Confidence Scale adopted from Bodenheimer and colleagues (2007). At the end of this session, the researcher asked for an available time from each subject for a phone call session to encourage the subjects to follow his/her action plans and/or to provide brief counseling.

The second, third, and fourth week interventions. The follow-up counseling phone call was conducted during these weeks. The researcher talked to the subjects following the structured interview guidance (Appendix B) to aid the subjects in performing reflection on his/her current diabetic foot care behaviors, to identify the implemented action plans during the evaluation week, to assess the goal achievements, and to facilitate the subjects in developing his/her own reinforcement

based on the goal achievements. At the end of each phone call session, the researcher reminded the subjects regarding the time for the next follow-up.

The fifth week interventions. In this week, each subject was followed up and counseled with a face-to-face interview by the researcher at the diabetic unit on the day of the regular hospital check-up. The interview questions aimed to explore the subjects' current DFCB, implemented action plans, goal achievements, identified difficulties of action implementation, and any further plans in maintaining and improving his/her DFCB (Appendix B).

Part II: Data Collection Instruments.

The data collection instruments consisted of the Demographic Data Questionnaire, Diabetic Foot Care Prior Knowledge Questionnaire, Goal Achievement Form, Self-Confidence Scale, and Diabetic Foot Care Behaviors Questionnaire as detailed in the following sections.

Demographic Data Questionnaire (DDQ). The DDQ was developed by the researcher to collect subjects' demographic data and general clinical information. It consisted of 7 items of demographic data (age, gender, religion, marital status, occupation, income, and level of education) and 8 items of general clinical information (foot conditions, body weight and height, diabetes mellitus duration, co-morbid diseases, latest fasting blood glucose, check-up history, experience of getting diabetic foot care information, and smoking history) (Appendix F).

Diabetic Foot Care Prior Knowledge Questionnaire. This questionnaire consisted of 10 true/false simple questions that were used to screen the

subjects' prior knowledge on diabetic foot care (Appendix G). These prior knowledge questions were used to guide the researcher in designing the individual-based educational intervention.

Goal Achievement Form. This form was used to record the subject's goal(s) and action plan(s) that he/she developed each week and the action plans that he/she implemented during the evaluation week. Both components were then compared to analyze the goal achievements. If every action plan was implemented, the subject was categorized as having completely achieved the goal. If only some actions were done, the subject was categorized as having partially achieved the goal, and if there was no action plan done the subject was categorized as having no behavioral change at all. Any difficulties faced during the action plan implementation were also recorded in the form (Appendix E).

Self-Confidence Scale. This instrument was used to estimate the subjects' confidence level to carry out their action plan. It was measured by using a 0 – 10 numeric rating scale in which 0 referred to no confidence at all and 10 referred to total confidence. When the subjects' confidence level was less than 7, the goal and action plans were adjusted to attain a confidence level of at least 7 that indicated a better chance for them to successfully execute the action plan(s) and achieve the goal(s) that he/she developed previously (Bodenheimer et al., 2007).

Diabetic Foot Care Behaviors Questionnaire. The subjects' DFCB were measured by using the modified version of the Nottingham Assessment of Functional Foot-care Questionnaire (NAFF) originally developed by Lincoln and colleagues in 2007. The original version of this tool consisted of 29 items: checking foot conditions (2 items), foot hygiene (2 items), footwear (13 items), preventing foot

injuries (10 items), and foot injuries treatment (2 items). Originally, each item was measured using a four point (0 – 3) Likert scale in which the positive statement "0" referred to never practice and "3" referred to always practice, and conversely the opposite scoring was applied for the negative statement. The higher scores in total and subscale score indicated better diabetic foot care behaviors. Statistically, this tool proved to be a reliable and valid measurement to assess diabetic patients' foot care behaviors. The test and retest reliability measured by using the Spearman rank correlation coefficient was .83 and the internal consistency reliability of this same questionnaire was .53 (Lincoln et al.). However there were some items in the original tool that do not fit Indonesian culture such as using a thermometer to measure bath water temperature, putting the foot near a fire or radiator or the use of corn remedies. In addition, there were some important components that were not included in the original instrument including the way of washing the feet, toenail trimming, a foot inspection component and the equipment for toenail trimming. Therefore, the researcher modified this instrument to achieve a best fit with cultural sensitivity.

For the modification process, the researcher firstly discussed the appropriateness of the tool with the nurse working at the study setting and one diabetic expertise from the Faculty of Nursing, Padjadjaran University, Indonesia, to identify unmatched items. Secondly, the researcher and the expert explored unmatched items and further discussed how to figure out the most suitable behaviors/actions. The modified NAFF (Appendix H) was developed in an English version, validated by three experts and translated into the Indonesian language by using the back translation method and tested for the reliability prior for use in data collection.

Validity and Reliability of the Instruments

Validity of the Instruments. The content validity of the intervention program/protocol, teaching plan and materials, DDQ, prior knowledge questionnaire, and the NAFF modified version were validated by three experts from the Faculty of Nursing, Prince of Songkla University, Faculty of Nursing, Padjadjaran University, and Sumedang District General Hospital. All experts came to a general agreement in using the data collection instruments following corrections in the wording of some items and suggestions for use with cultural concerns. For the intervention instruments, the experts suggested to provide clearer explanations on the activities of the nurse/the researcher while performing the self-management support program.

Translation of the Questionnaires. All questionnaires were initially developed and modified in English by the researcher. For developing the Indonesian version of all tools, the researcher then used the back-translation technique for making conceptual equivalence across the languages of these questionnaires. In this study, the back-translation employed three translators since the preferred back-translation approach requires at least two independent translators (Hilton & Skrutkowski, 2002). The first bilingual expert translator translated the original English version of questionnaires into the Indonesian language. Then, the second bilingual translator translated the Indonesian version back into English (second version). After that, the third translator compared both English versions, identified the discrepancies and discussed those discrepancies with the researcher, the first translator and the second translator. The discrepancies found between these two versions included the translation of "between the toes area", "washing", "lace up shoes", "pointed shoes", "razor blade", and "scrub". Based on this discussion and previous suggestions from

the three experts, the researcher revised the Indonesian version and the discrepancies were resolved.

Reliability of the Questionnaires. The Indonesian version of the Diabetic Foot Care Prior Knowledge Questionnaire and the Indonesian NAFF modified version were tried out with 20 diabetic patients who had the same inclusion criteria with the samples. The results showed that the internal reliability of the Indonesian NAFF modified version was at Cronbach's alpha of .64. The reliability got better at Cronbach's alpha of .72 after removing items 10 and 12. For the prior knowledge questionnaire, the reliability test using the KR-20 technique was lower at .63. Since the questionnaire was developed using the "true" and "false" question type, it might cause a low variance that reduced the KR-20 value (Haladyna, 2004). Even though it was considered a low reliability, the prior knowledge in this study was not the main outcome and it was measured as "screening" and used as basic information for the researcher in providing the educational session. However, for further improvement, it was recommended to use another response format of questionnaire, such as a multiple choice format.

Ethical Consideration

The subjects who agreed to participate in this study were informed that they would be assigned into either the experimental or the control group. Informed consent was sought and obtained from all subjects. The researcher talked with each subject prior to their participation to explain the purpose and details of the study and assured them that all data were kept confidential and would be destroyed after

completion of the study (Appendix A). They were allowed to make a free and independent decision to participate or refuse to take part, without coercion. Also, the subjects were allowed to ask any questions related to this study and had the right to withdraw from the study at anytime without penalties. In addition, the phone number, email, and mailing address of the researcher were provided in the booklet and reassured them that they could contact the researcher any time as needed. In addition, all subjects in the control group received a free diabetic foot care booklet at the end of the study. For those who preferred to receive more information, they could receive a short course foot care self-management support program without follow-up phone call intervention at the end of the study.

Pilot Study

A pilot study was conducted to evaluate the feasibility of the data collection procedure, protocol design, and measurement reliability tests in order to improve the quality and efficacy of the real study (Altman et al., 2006). In this pilot study, a diabetic foot care self-management support program with a one-week follow-up phone call was implemented with three diabetic patients who met the inclusion criteria.

Generally, the program described previously in Part I (the diabetic foot care self-management support program and data collection procedure) was applicable in this present study. However, since the diabetic unit waiting room was the only possible place for implementing the program and collecting the data, the anticipated environmental constraints of a waiting room were overcrowding and noise. In

addition, there was only one of the three included subjects who reported that he recorded his daily foot care practices in the available form as advised in the first meeting. It indicated that the log book might not be applicable in this present study. The researcher also found that the subject came for the hospital regular check-up in the fifth week after the first meeting. Based on this pattern, the researcher added one follow-up phone call in the fourth week of intervention. Therefore, each subject received in total a five-week diabetic foot care self-management support program with three follow-up phone calls.

Data Collection Procedures

Data collection was conducted at the Diabetes Unit in the Outpatient Department of Sumedang District General Hospital in West Java, Indonesia. It was divided into two phases; preparation phase and implementation phase.

Preparation Phase

Preparation phase consisted of: (1) obtaining the ethical approval from the Faculty of Nursing, Prince of Songkla University, (2) acquiring permission for data collection from the Director of Sumedang District General Hospital, (3) preparing the educational session materials, (4) preparing the package of measurements including the informed consent form, (5) recruiting and conducting research assistant training, and (6) conducting the pilot study.

In this study, two research assistants (RA) were employed. The first RA, working at the setting, took responsibility for initially approaching the eligible

subjects, explaining how to properly fill in the pretest and posttest questionnaires, and introduced the eligible subjects to the researcher. She did not know and was not involved in the process of assigning the subjects into groups. Then the researcher approached each subject and obtained informed consent. The second RA was a nurse working in another unit of the hospital and took responsibility for documenting the non-routine diabetic unit activities that were provided to the diabetic patients during the study period.

Prior to the data collection, the researcher trained the RAs. The training was conducted at the diabetic unit. Firstly, the researcher explained the purposes, intervention protocol, measurements used in this study, and data collection procedures including how to complete the questionnaires. Secondly, for the first RA, the researcher explained each item of the questionnaires and how to complete each questionnaire properly. Any discrepancies between the researcher and the RA regarding the items of the questionnaires were discussed. For the second RA, the researcher explained and provided some examples of non-routine diabetes unit activities that she must record.

Implementation Phase

The researcher and two RAs collaboratively collected the data in a certain manner. The first RA performed her responsibility as explained above. Each subject completed the pretest questionnaires that took around 10 minutes prior to the diabetic self-management support program. Next, subjects in the experimental group attended an educational session that lasted around 45 minutes. At the end of this session, the appointment for the following week follow-up phone call was made.

During the follow-up phone calls in the second through the fourth weeks, the subjects were interviewed regarding his/her current diabetic foot care behaviors, implemented action plan(s), goal achievement(s), and difficulties they had been facing during the evaluating week. The researcher assisted each subject in developing self-reinforcement, creating the next week's goal and action plan(s), and provided brief counseling. In the fifth week of intervention, the researcher met each subject at the diabetic unit and repeated similar activities conducted during the follow-up phone calls. At each data collection point, the researcher recorded the subjects' weekly goals and action plans, the subjects' self-confidence scale, the implemented action plans, the subjects' goal achievements, and any reported difficulties.

For data collection of the pretest questionnaires in the control group, data were collected similarly to the experimental group. However, after completing the pretest questionnaires, the researcher immediately made an appointment for the next meeting during their regular check-up schedule one month later and informed them that they could continue their usual care/treatment in the diabetic unit. A change in the check-up schedule was anticipated. Therefore, each subject was informed that he/she would be contacted by a phone call one week before the date of the regular check-up. For those who changed the schedule before the phone call appointment, they were advised to inform the researcher at least one day before the scheduled date.

At the end of the program implementation (second meeting), the first RA asked each subject to fill in the posttest diabetic foot care behaviors questionnaire. After returning the questionnaire, each subject received brief counseling in order to provide suggestions, alternative solutions of difficulties that they faced during the program and they were provided reinforcement to continuously maintain and/improve

their diabetic foot care behaviors. All subjects in the control group received the diabetic foot care booklet and 29 (82.86%) subjects who indicated their interest received a short course in the diabetic foot care self-management support program without a follow-up phone call (Figure 2). Whereas, the rest of the subjects reported that they preferred to receive only the diabetic foot care booklet.

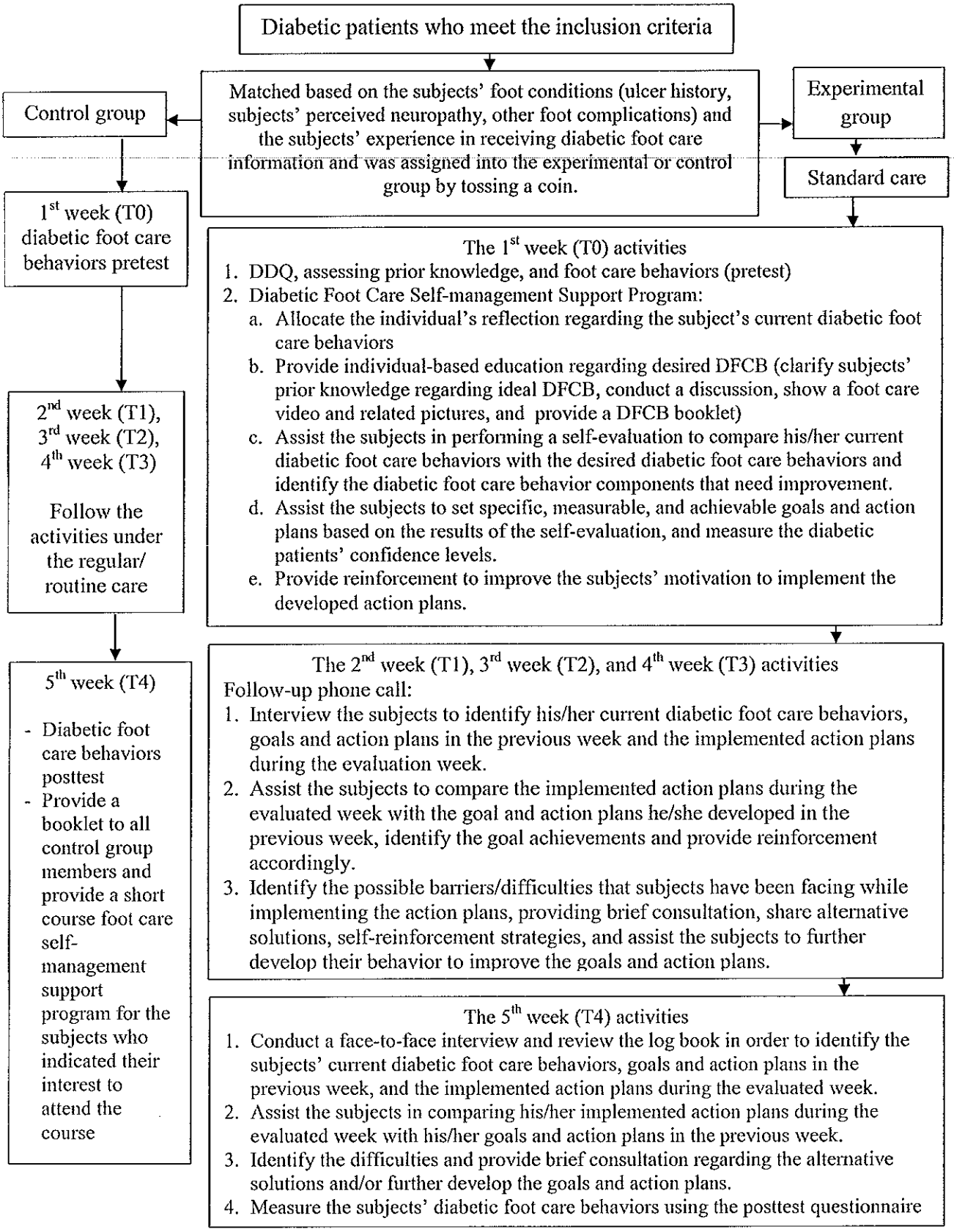

Figure 2. The implementation phase of the data collection procedures.

Data Analysis

Descriptive statistics including frequencies, percentages, means, and standard deviations were used to analyze and describe the demographic data, relevant clinical characteristics, prior knowledge, and foot care behaviors. A Chi-square test and an independent t-test were used to compare the equivalence of the demographic and clinical characteristics between the experimental and the control group. In addition, for an alternative statistical analysis the Fisher's exact test was used for a two-by-two contingency table when expected frequencies were too small.

Before analyzing the data, the assumption of parametric statistics including normality and homogeneity of variance were checked. The diabetic foot care behaviors (DFCB) and the prior knowledge variables of both the experimental and control groups met these assumptions. The independent t-test was used to test the differences of DFCB between the experimental and control groups. The dependent t-test was used to test the differences of DFCB within the experimental group, before and after receiving the self-management support program.

For hypothesis testing, the level of significance was set at $p < .05$. Furthermore, to answer the third research question, descriptive statistics including frequencies and percentage were applied to describe the level of goal achievement of subjects in the experimental group while receiving the diabetic self-management support program.

CHAPTER 4

RESULTS AND DISCUSSION

This chapter presents and discusses the findings of this study. The study findings were derived from 70 diabetic patients at the diabetic unit of Sumedang District General Hospital, West Java, Indonesia. It is presented in five parts: (1) demographic data and clinical characteristics, (2) diabetic foot care prior knowledge and behaviors, (3) self-confidence levels, (4) effect of the diabetic foot care self-management support program on DFCB and (5) discussion.

Results

Demographic Data

More than half of the subjects in the experimental group (57.14%) and the control group (62.86%) were female. All subjects in both groups were Muslim. Most of them, 80% in the experimental group and 88.57% in the control group, were married. Half of the subjects in the experimental and control groups had a university education (51.43% and 48.57%, respectively). The majority of the subjects in the experimental group (97.14%) and the control group (94.29%) worked as non-healthcare related staff. The mean ages of the subjects in the experimental and the control group were 53.54 years (SD = 7.33) and 52.20 years (SD = 6.13), respectively. In addition, the average monthly income in the experimental group was USD 265.53 (SD = 92.40) and USD 290.18 (SD = 105.38) in the control group.

Statistically, there were no significant differences of the demographic characteristics between both groups (Table 3 and 4).

Table 3

Frequencies and Percentages of Demographic Data of the Experimental and Control Groups (N = 70)

Characteristics	Experimental Group (n = 35) n (%)	Control Group (n = 35) n (%)	χ^2	*p*
Gender				
Male	15 (42.86)	13 (37.14)	0.24[a]	.63
Female	20 (57.14)	22 (62.86)		
Marital Status				
Married	28 (80.00)	31 (88.57)	0.97[a]	.32
Widower	7 (20.00)	4 (11.43)		
Religion				
Islam	35 (100.00)	35 (100.00)	0.00	1.00
Level of Education				
Basic education level	6 (17.14)	8 (22.86)	.36[a]	.83
Senior high school	11 (31.43)	10 (28.57)		
University	18 (51.43)	17 (48.57)		
Occupation				
Healthcare related worker	1 (2.86)	2 (5.71)	0.35[b]	.50
Non-healthcare related worker	34 (97.14)	33 (94.29)		

Note: [a] = Chi-square test, [b] = Fisher exact test

Table 4

Means (M) and Standard Deviations (SD) of Age and Income of the Experimental and Control Groups (N = 70)

Variable	Experimental Group (n = 35)	Control Group (n = 35)	t	*p*
	M (SD)	M (SD)		
Age (years)	53.54 (7.34)	52.20 (6.13)	-.83[c]	.41
Monthly Income (USD)	265.53 (92.40)	290.18 (105.38)	.86	.39

Note: [c] = equal variance not assumed (df = 65.91), t = Independent t-test

Clinical Characteristics

Seven clinical characteristics were examined and no statistically significant differences were found between the experimental and the control groups, except co-morbid diseases and the latest blood glucose level. The mean duration of being diagnosed with DM in the experimental group was not significantly longer than in the control group (z = - 1.96, p = .05). Although most of the subjects were not new cases and almost all subjects in both groups attended check-ups regularly (94.29%), most of them (80%) had never received any information regarding diabetic foot care. Additionally, the latest blood glucose level in the experimental group was significantly higher than in the control group (t = -2.03, p = .046). Most of the subjects in both groups did not have a smoking history (74.29% in the experimental group and 80% in the control group) and only a few of them had a body mass index (BMI) more than 30 or an obesity problem (8.57% in the experimental group and 11.43% in the control group). Additionally, 42.86% of the subjects in both groups complained about foot neuropathic symptoms such as numbness or foot pain. The

means of the latest blood glucose levels in the experimental and control groups were 179.60 mg% (SD = 67.57) and 150.69 mg% (SD = 50.39), respectively. Some subjects (42.86% in the experimental group and 68.57% in the control group) noted that they had at least one co-morbid disease. Statistically, the number of subjects without co-morbid diseases in the experimental group was significantly higher than those in the control group ($\chi^2 = 4.69$, $p = .03$) (Table 5 and 6).

Table 5

Frequencies and Percentages of Clinical Characteristics of the Experimental and Control Groups (N = 70)

Characteristics	Experimental Group (n = 35) n (%)	Control Group (n = 35) n (%)	χ^2	*p*
Check up				
Regularly	33 (94.29)	33 (94.29)	0.00[b]	1.00
Irregularly	2 (5.71)	2 (5.71)		
Body weight				
Normal weight	22 (62.86)	14 (40.00)	3.10[a]	.08
Overweight	10 (28.57)	17 (48.57)		
Obese	3 (8.57)	4 (11.43)		
DM foot care information				
Never got information	28 (80.00)	28 (80.00)	0.00[a]	1.00
Received information	7 (20.00)	7 (20.00)		
Smoking history				
No smoking history	26 (74.29)	28 (80.00)	0.32[a]	.57
Had smoking/history	9 (25.71)	7 (20.00)		

Note: [a] = Chi-square, [b] = Fisher exact test

Table 5 (Continued)

Characteristics	Experimental Group (n = 35) n (%)	Control Group (n = 35) n (%)	χ^2	*p*
Foot conditions				
No foot problem complaints	10 (28.57)	10 (28.57)	0.00 [a]	1.00
Had complaints of neuropathy symptoms and/or other foot problems	25 (71.43)	25 (71.43)		
Co-morbid diseases				
No co-morbid disease	20 (57.14)	11 (31.43)	4.69 [a]	.03
Had at least one co-morbid disease	15 (42.86)	24 (68.57)		

Note: [a] = Chi-square, [b] = Fisher exact test

Table 6

Means, Standard Deviations, Medians, Minimums, and Maximums of Diabetes Mellitus Duration and Blood Glucose Level in the Experimental and Control Groups (N = 70)

Variable	Experimental Group (n = 35) M (SD)		Control Group (n = 35) M (SD)		t	*p*
Latest BG (mg%)	179.60 (67.57)		150.69 (50.39)		-2.03	.046
	Median	Min-Max	Median	Min-Max	z	*p*
DM duration (years)	4.00	1 - 23	3.00	0.1 – 18	-1.96	.05

Note: BG = Blood glucose, Min = Minimum, Max = Maximum, t = Independent t-test, z = Mann-Whitney U test

Diabetic Foot Care Prior Knowledge and Behaviors

The mean scores of prior knowledge of diabetic foot care behaviors in the experimental and the control groups were 7.00 (SD = 1.00) and 7.03 (SD = 1.56), respectively. The pretest scores of DFCB in the experimental and control groups were 51.09 (SD = 9.12) and 51.43 (SD = 8.98), respectively. There were no significant differences of both variables between the experimental and control groups (Table 7). The two lowest percentages of the correct answers were found in item 2 when asked about walking barefoot indoors (25.7% of the subjects in the experimental group and 40% of the subjects in the control group) and item 7 when asked about the best recommended sandals for diabetic patients (40% of the subjects in both groups) (Appendix I).

Table 7

Means and Standard Deviations of Diabetic Foot Care Knowledge and Behaviors at Baseline (N=70)

Variable	Experimental Group (n = 35)	Control Group (n = 35)	t	*p*
	M (SD)	M (SD)		
Diabetic foot care knowledge	7.00 (1.00)	7.03 (1.56)	.09	.93
Diabetic foot care behaviors	51.09 (9.12)	51.43 (8.98)	.16	.88

Note: df = 68, t = Independent t-test

Self-Confidence Levels

The levels of self-confidence in the experimental group were measured while assisting the subjects to conduct weekly goal setting and action planning. The

mean scores of the self-confidence levels from the first week through the fourth week of intervention were 8.69 (SD = 0.83), 8.17 (SD = 0.67), 8.29 (SD = 0.79), and 8.29 (SD = 0.71), respectively. A repeated measure of analysis of variance (ANOVA) demonstrated that there was a statistically significant difference of self-confidence levels across the four weeks of intervention (F = 3.35, p = .02) (Table 8 and Figure 3). Additionally, the pairwise comparisons (Benferroni) only showed a significant difference between the first and the second week of intervention (p = .04) (Table 8).

Table 8

The Differences of Self-Confidence in the Experimental Group Over Time (n =35)

Intervention time	M (SD)	*df*	F	*p*
First week of intervention*	8.69 (0.83)			
Second week of intervention *	8.17 (0.67)	3	3.35	.02
Third week of intervention	8.29 (0.79)			
Fourth week of intervention	8.29 (0.71)			

Note: * = First week of intervention > Second week of intervention, F = Repeated Measures ANOVA.

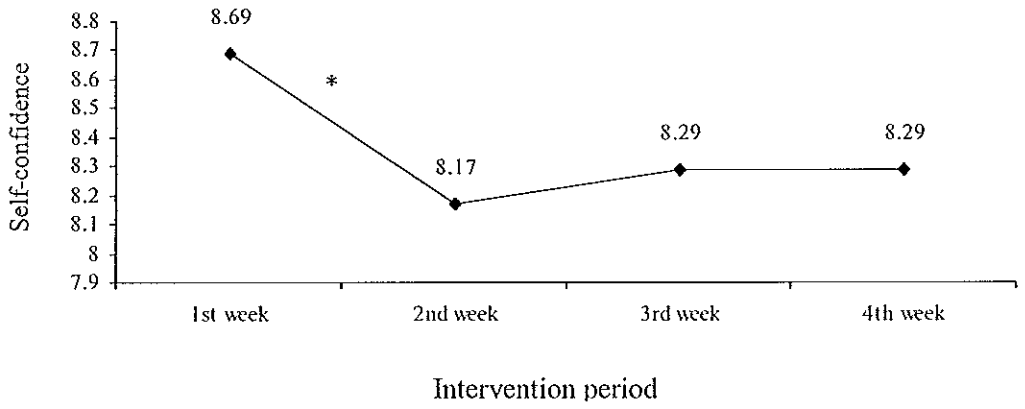

Figure 3. Self-confidence levels in the experimental group over time (* = self-confidence level in the 1st week > 2nd week).

Effect of Diabetic Foot Care Self-Management (SM) Support Program

Diabetic foot care behaviors (DFCB) between groups. In order to examine the effect of the Diabetic Foot Care Self-Management Support Program on DFCB in this study, the DFCB before (pretest) and after (posttest) implementation of SM support program in the experimental and the control groups were examined. The mean of the pretest DFCB score (M = 51.09, SD = 9.12) in the experimental group was not significantly different from that in the control group (M = 51.43, SD = 8.99). When considering the DFCB after (posttest) implementation of the SM program between the experimental and control groups, the mean of the DFCB posttest score in the experimental group (M = 67.43, SD = 5.83) was significantly higher than in the control group (M = 52.60, SD = 8.60) (p = .00) (Table 9).

Table 9

Means and Standard Deviations of Diabetic Foot Care Behaviors Pretest and Posttest Scores in the Experimental and Control Groups (N = 70)

Variable	Experimental Group (n = 35)	Control Group (n = 35)	t	*p*
	M (SD)	M (SD)		
Pretest DFCB	51.09 (9.12)	51.43 (8.99)	0.16	.88
Posttest DFCB	67.43(5.83)	52.60 (8.60)	-8.45[c]	.00

Note: [c] = equal variance was not assumed (df = 59.80), t = Independent t-test

Diabetic foot care behaviors within the experimental group. To further clarify the effect of the Diabetic Foot Care Self-Management Support Program provided in this study, the DFCB in the experimental group before and after receiving

the program were examined and compared. The mean of DFCB pretest and posttest scores in the experimental group were 51.09 (SD = 9.12) and 67.43 (SD = 5.83), respectively. The mean of the DFCB score after receiving the SM support program was significantly higher than before receiving the SM support program (p = .00) (Table 10).

Table 10

Means and Standard Deviations of the Diabetic Foot Care Behaviors Pretest and Posttest Scores in the Experimental Group (N = 35)

Variable	Experimental Group M (SD)	t	p
Pretest DFCB score	51.09 (9.12)	-10.43	.00
Posttest DFCB score	67.43 (5.83)		

Note: df = 34, t = Dependent t-test

The level of goal achievement. During implementation of the diabetic foot care self-management support program, the researcher recorded the subjects' level of goal achievement in each week. In the first follow-up phone call, almost all subjects completely achieved the goals (n = 33, 94.30%). Approximately 60% to 70% of the subjects completely achieved the goals in the second (n = 22, 62.90%), third (n = 21, 60%), and last follow-up phone calls (n = 24, 68.6%). A comparison of completely achieved goals in each follow-up using the McNemar test revealed that there were significant differences in the frequency of completely achieved goals between the first and the other follow-up phone calls (p =.001, p = .00, and p = 0.01, respectively) (Figure 4).

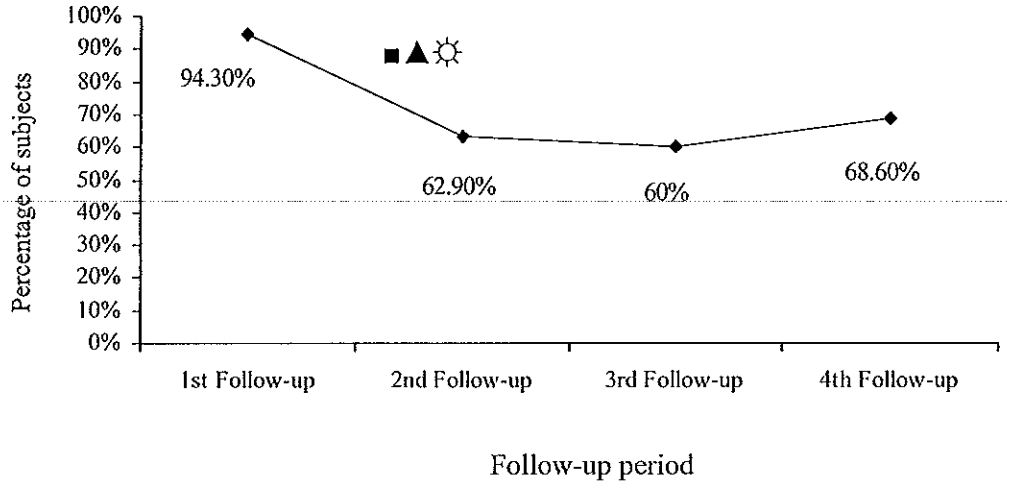

Figure 4. Percentages of subjects who completely achieved the weekly goals in the experimental group (n = 35); Mc Nemar test showed ■ = first follow-up > second follow up (p =.001), ▲= first follow-up > third follow-up (p = .00), ☼ = first follow-up > fourth follow-up (p =.001).

In total, each subject had four weekly goals throughout the implementation period. Less than half of subjects (42.86%) demonstrated the capability to completely achieve the four weekly goals with only one subject (2.86%) who never completely achieved the four weekly goals (Figure 5).

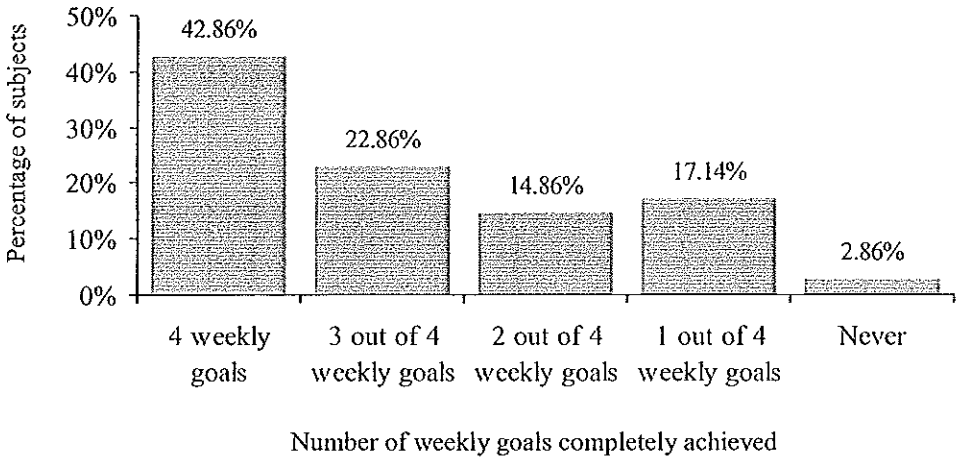

Figure 5. Total weekly goals that were completely achieved in the experimental group (n = 35).

The improved diabetic foot care components. During the intervention period (from the 1st to the 4th week), the topmost selected DFCB component as a weekly goal was foot hygiene (n = 16, 45.7%), followed by footwear (n = 22, 62.9%), toenail care (n = 12, 34.3%), and a combination of foot hygiene and footwear (n = 13, 37.1%). Compared with the DFCB components that were planned to be improved in the other weeks, the highest percentage of completely achieved component was foot hygiene (n = 14, 87.50%) (Table 11).

Table 11

The Frequencies and Percentages of the Top DFCB Components Planned for Improvement and the Complete Achievement of Those in Each Week

Week of Intervention	Top DFCB Components Set as weekly goal (n)		Completely achieved goal n (%)
First week	Foot hygiene and skin care	16	14 (87.50)
Second week	Footwear	22	10 (45.45)
Third week	Toenail care	12	8 (66.67)
Fourth week	Foot hygiene & footwear	13	10 (76.92)

Discussion

The First and Second Hypothesis

The effectiveness of the five-week diabetic foot care SM support program was evident when applied to a group of patients with DM in West Java, Indonesia. The results of this study support both hypotheses. Firstly, the results showed that at the end of the study, the DFCB of subjects who received the diabetic

foot care SM support program (experimental group) was significantly better than the subjects who received standard care (control group) (Table 9). Secondly, the results also showed that after receiving the diabetic foot care SM support program, subjects in the experimental group had significantly better DFCB than before intervention (Table 10).

The findings of this study were consistent with previous studies that a SM support program effectively improved patients' DFCB (Corbett, 2003; Deakin et al., 2006; Lincoln et al., 2008; McMurray et al., 2002; Vatankhah et al., 2009). Those previous studies reported the improvement of DFCB at 6 and 12 weeks (Corbett), 6 months (Vatankhah et al.), 12 months (Lincoln et al.; McMurray et al.), and at 14 months (Deakin et al.) after intervention began. However, this present study evaluated the improved DFCB only at four weeks after intervention began.

Regarding the components of the DFCB evaluated, this present study added some components to the DFCB including toenail care, preventing foot injuries, proper footwear, and foot injury management when it presents that were not evaluated in previous studies. Some previous studies examined foot care behaviors as secondary outcomes under the diabetic patients' self-care behaviors domain. It was found that only some components of DFCB were evaluated that included the checking of foot conditions, washing and drying the feet after washing, checking the inside of shoes, and whether the patient soaked their feet or not (Deakin et al., 2006; McMurray et al. 2002, Tobert et al., 2000).

There were some reasons underpinning the effectiveness of this five-week SM support program that applied in this study. The reasons included the SM support program employed, the partnership between researcher and subjects, the

combined strategies being used and the outcomes measured. The following sections will explain in detail each reason.

The Self-Management Support Program applied. This SM program facilitated the effectiveness of DFCB improvement in several ways. A SM support program that valued subjects as active participants provided a lot of benefits and was reported as the most effective approach for patients with chronic diseases (Bodenheimer et al., 2002; Fan & Sidani, 2009). Individual reflection activity assisted subjects to intentionally monitor their DFCB and be aware of those behaviors. In the self-evaluation stage, subjects were assisted in evaluating their DFCB and further identifying which component of their DFCB needed to be improved. Then, through self-reinforcement activities, subjects were assisted to decide whether they would like to maintain, modify, or improve their DFCB and were further assisted to develop goals and action plans according to the decision made. Therefore, subjects knew what activities should be done, why these activities should be conducted, and how to perform the activities properly. In other words, subjects were prepared and enabled to be involved actively in the improvement processes, responsible, and be motivated to achieve the goals/conditions expected (Kanfer & Gaelick-Buys, 1991).

Partnership between researcher and subjects. This partnership also provided a positive environment that greatly facilitated subjects to effectively improve their behaviors. At least, during the actual SM support program, subjects had a facilitator who regularly evaluated their progress and provided additional information needed. Some studies reported the significance of feedback and encouragement in facilitating behavioral improvement (Bodenheimer et al., 2007; Bodenheimer & Handley, 2009). The relationship developed between subjects and facilitator

potentially improved effective communication and trust that were identified as essential components that significantly improved the subjects' adherence to perform the expected behaviors (Fox et al., 2009; Martin, Williams, Haskard, & DiMatteo, 2005; O'Malley, Sheppard, Schwartz, & Mandelblatt, 2004). Culturally, Asian patients highly respect professional healthcare providers (physicians/nurses). This condition improved the subjects' motivation to perform the required actions and achieve the goals that the healthcare provider expected.

The combined strategy employed. The combined strategy employed in this study facilitated the DFCB improvement for some reasons. Firstly, the individual-based educational session that was provided not only aided the subjects to achieve sufficient required knowledge, but also allowed them to intensively discuss additional information they personally needed and/or share any problem for effective problem solving. Although a previous study reported that both individual and group-based educational sessions were beneficial (Barlow et al., 2002), some individual learning related to DFCB was more achievable in the individual educational session. The strategy of providing the booklet in this present study allowed subjects to re-read, remind and/or even strengthen the information gained during the educational/ discussion session. This booklet also functioned as a simple guide for the subjects in performing the expected DFCB. One previous study reported that the individual-based educational session combined with a booklet effectively improved a patients' diabetic foot care knowledge and behaviors after 6 months (Vatankhah et al., 2009). Furthermore, discussions regarding the subjects' difficulties in implementing a DFCB improvement program strengthened the subjects' problem solving skills that fundamentally needed for behavioral improvement.

Secondly, the goal setting and action planning strategy could assist each subject to intentionally take responsibility and engage in improving DFCB with his/her own achievable goals and feasible action plans. Additionally, the specific, measurable, clear, and short period (weekly) goals and action plans provided clear guidance for the subjects regarding what activities should be done, how, and how many times to achieve the recommended behaviors (Bodenheimer et al., 2007). The clearly formulated goals stimulated the subjects to examine any possible strategies toward the desired goals and anticipate any possible barriers that potentially violate the goal achievements (Kanfer & Guilick-Buys, 1991). The short duration of goal evaluations applied in this study also allowed subjects to breakdown a big goal into several smaller goals that were more achievable. The main purpose of goal setting and an action planning activity is to improve the patients' self-efficacy (belief in self-confidence) and self-confidence resulting in a higher likelihood that the subjects would be able to achieve the healthier behaviors (Bodenheimer et al., 2002; Bodenheimer & Handley, 2009).

Accordingly, a previous study using a goal setting and action planning strategy reported that this strategy effectively improved the patients' self-efficacy (Wallace et al., 2009). This strategy also reported that the strategy effectively facilitated patients to achieve healthier behaviors (Bodenheimer & Handley, 2009; Cullen, Baranowski, & Smith, 2001; Wallace et al.; Handley et al., 2006). Unfortunately, the findings of this present study could not explain whether or not the intervention improved the subjects' self-confidence level that would further facilitate the subjects to improve their behaviors as reported in the study conducted by Wallace and colleagues. In this present study, the researcher only evaluated the subjects' self-

confidence scores after the subjects received the diabetic foot care SM support program. In addition, the subjects' self-confidence scores were adjusted during the self-confidence evaluation. When the subjects reported a self-confidence score of less than 7, the goals and action plans would be adjusted until the subjects' self-confidence scale increased to at least 7 out of 10. Thus, the mean scores of the self-confidence level throughout the program were always higher than 7.

In this present study, the first week self-confidence level of subjects in the experimental group was significantly higher than in the other weeks (Figure 3). One explanation underpinning this result was the intervention given. During the goal setting session, subjects were encouraged to start with the most achievable goal and progress to the most difficult one. Since, the subjects started with the easiest goal, not surprisingly, the means of the self-confidence levels in the first week appeared as the highest ones. However, this does not explain the means of the self-confidence levels in the other weeks. One reason underneath this finding was the components of DFCB that were selected to be improved each week. Lower self-confidence levels in the second to fourth week indicated that the components selected to be weekly goals were perceived as more difficult. The footwear component that was selected to be improved in the second week was perceived as the most difficult one. It was evident that the percentage of completely achieved goal of footwear was also the lowest one. In the last week, most of the subjects selected foot hygiene and footwear to be maintained and/or improved where basically they had been improved in the first and second week of intervention. By improving similar components, subjects had better experience which allowed them to report higher levels of self-confidence that indicated the goal in the last week was more achievable than in the second or third

week. It was confirmed that the percentage of completely achieved goal in the last follow-up was higher than in the third and fourth follow-ups.

Thirdly, weekly follow-ups and brief counseling provided regular empowerment that facilitated subjects to continuously enhance their knowledge, responsibility, skill, and motivation to improve their behaviors. Previous studies revealed that patients who set behavior change goals and received follow-ups, (phone calls , e-mails, or repeat visits) which provided feedback and encouragement on their progress, performed better expected behaviors than those who set only behavior change goals without follow-ups or feedback (Bodenheimer et al., 2007; Bodenheimer & Handley, 2009). Additionally, Kimman and colleagues (2010) reported that phone call follow-ups revealed high patient satisfaction, which substantially reduced clinic visits, and was an acceptable alternative to the traditional hospital follow-up.

Goal Achievement Level

The results of this study showed that almost all subjects (94.30%) were able to completely achieve the goal(s) in the first week and decreased to approximately 60% to 70% in the following weeks. Throughout the program, only 42.60% of the subjects always completely achieved the four weekly goals and only one subject was never able to completely achieve the weekly goal. These findings indicated that the applied SM support program not only effectively facilitated subjects to set the goals and develop action plans to improve their DFCB, but also effectively assisted and enabled subjects to implement the developed action plans and achieve the targeted goals.

These findings were consistent with the findings of previous studies that also employed a SM support program with a goal setting and action planning strategy. The study conducted by DeWalt and colleagues (2009) revealed that this combined strategy effectively facilitated diabetic patients in setting the goals, developing action plans, and achieving goals of dietary and exercise behavior improvement. As well as in the study conducted by Handley and colleagues (2006), this strategy effectively facilitated patients in achieving the healthier behaviors to improve cardiovascular health outcomes. Both of these previous studies allowed the subjects to select broader behavioral change areas, whereas in this present study, the subjects were assisted to achieve healthier DFCB only.

Besides the SM support program and combined strategies in facilitating the results of this study that were mentioned earlier, there were other reasons identified that supported the goal achievement level outcomes in this study. Those reasons included the goal achievement evaluation method, the subjects' prior knowledge, the DFCB component that was selected as the weekly goal, the self-confidence level, and the religious and cultural background.

The method of goal achievement categorization potentially affected the percentage of goal achievement levels in this study. As mentioned earlier, subjects would be categorized into completely achieved the goal only when he/she successfully performed all developed action plans and would be categorized in the no behavioral change at all only when none of the developed action plans were properly implemented. Consequently, more than half of the subjects (57.14%) were categorized into not always achieved the four weekly goals or they failed to completely achieve at least one out of four weekly goals. Since there were no subjects

categorized into no behavioral change at all, the results indicated that all subjects in this study were able to improve some components of their DFCB, but only less than half of the subjects (42.86%) were always able to successfully execute all of the developed weekly action plans. Therefore more effective/intensive combined strategies are recommended to be utilized in increasing the number of subjects to achieve the weekly goals.

The subjects' prior knowledge on diabetic foot care also potentially contributed to the goal achievement outcomes in this study. Based on each item prior knowledge assessment, identification of the questions related to footwear were the two lowest correctly answered questions, i.e. not walking barefoot inside the house and not wearing flip-flop sandals only 25.70% and 40%, respectively (Appendix I). One previous study reported that diabetic patients who lacked foot care knowledge were more likely to have poor proper foot care practice (Khamseh, et al., 2007; Shaya et al., 2007). Although each subject received information regarding proper footwear, changing footwear behaviors was also culturally challenging. Wearing footwear inside the house is an uncommon habit for Indonesian people and sometimes considered as impolite. In addition, Indonesian people commonly use flip-flop sandals as their daily footwear. Therefore, subjects not only face cultural challenges, but also need to expend more effort when buying new and more appropriate sandals.

Regarding the DFCB components, toenail care was also challenging and needed improvement because of some reasons. The first reason was the subjects' habit of toenail trimming. Most subjects usually cut their toenails in a curved line and cut both corner sides of the toenails. Thus, they should wait until both corner sides of the toenails grow longer so as to trim the toenails in a straight line as advised.

Unfortunately, both corner sides of the toenails often caused pain or developed ingrown toenails. Therefore, the subjects usually cut their toenails as they did before. The second reason was the toenail problem. Some subjects in this study reported that they actually had ingrown toenails. For these subjects, the toenail conditions made it more difficult to trim the toenails in the way as recommended since the toenail edges grew abnormally (too deep). As well as the first reason, these problems lead the subjects to trim the toenails improperly. Even worst, some subjects reported that sometimes they removed the toenail edges using a razor blade or other harmful sharp equipment.

Besides the types of foot care components, the self-confidence levels also potentially influenced the goal achievement levels. As seen in Figure 3 and 4, the higher self-confidence levels were in the same direction as the higher goal achievements. This finding supports previous evidence suggesting that higher self-confidence was significantly related to better achievement (Bodenheimer et al., 2007; Bodenheimer & Handley, 2009; Kanfer & Gaelick-Buys, 1991; Perrin et al., 2009). However, there were interesting findings in the third and last follow-up weeks. Although subjects had similar mean scores of self-confidence levels, goal achievement levels were better than the third follow-up. The reason underneath this finding was that most of the DFCB components selected as a goal in the last week had actually been selected as a goal in the first and second weeks. Therefore, they had better experience in performing the developed action plans and had a better chance of achieving the expected goal.

Based on religious background, all of the subjects in this study were Muslim. Being Muslim, they must wash their feet at least five times a day before

praying. Thus, they only need to attach the additional foot hygiene activities from the desired DFCB into their religious foot hygiene practices. Consequently, compared with improving other components, improving foot hygiene was easier and more achievable. It was proved that the completely achieved goal percentage of foot hygiene component was the highest one.

In short, the five-week diabetic foot care self-management support program given by using a combination of strategies effectively improved the DFCB in the targeted group. Additionally, at the end of the program, all subjects in the experimental group reflected their satisfaction and benefits derived from this program and none of the subjects withdrew from the program. This indicated that the program implemented in this study was not only effective but was also appropriate in the Indonesian context. The importance of utilizing this program to cover all patients with DM in Indonesia is therefore indicated.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

Conclusion

This quasi-experimental study was conducted to examine the effects of a five-week diabetic foot care self-management support program on diabetic foot care behaviors in Indonesian patients with diabetes mellitus. Seventy subjects were recruited from the Diabetic Unit of Sumedang District Hospital in West Java, Indonesia, based on the inclusion criteria and the pair-matching technique. The data collection was conducted from October 2010 to January 2011. The subjects in the control group received the regular care, whereas the patients in the experimental group received the five-week diabetic foot care self-management support program. The baseline data were collected before implementing the program. Each recruited subject was asked to fill out the demographic and clinical information questionnaire as well as being evaluated on prior diabetic foot care knowledge and behaviors. Then, the frequency, percentage, mean, and standard deviation were used to describe the participants' characteristics. The Chi-square and Fisher exact tests were used to test the equivalence of the characteristics between the experimental and the control groups. In addition, the independent and dependent t-tests were employed to test the first and second research questions, while a descriptive statistic was used to answer the third research question.

The study findings revealed that the subjects who received the Diabetic Foot Care SM Support Program had significantly better DFCB than those who received the regular care. In comparison, the patients in the experimental group also

had significantly better DFCB than before receiving the Diabetic Foot Care SM Support Program. Additionally, almost all subjects in the experimental group completely achieved the goals in the first follow-up and approximately 60 – 70% of them completely achieved their weekly goals in the second through fourth follow-up. From this, foot hygiene, footwear, toenail care, and a combination of foot hygiene and footwear were sequentially selected as the topmost goals of the DFCB components from the first to the fourth week of intervention.

Strength and Limitation of the Study

The strength of this study can be derived from the study design and the methodologies used in data collection. Since this study used a quasi-experimental study with a single blinded examiner, a control group, and complied with using the pretest and posttest design, the design to examine the effect of intervention with minimum conclusion bias was appropriate. Additionally, by using the toss of a coin and pair-matching technique in assigning patients either into the experimental or the control group minimized the selection bias. Also, since the process of subject recruitment into each group was conducted on different days, the interaction and contamination threats between subjects in both groups were further reduced.

The combination of strategies used as seen in the program also facilitated the diabetic patients in achieving healthier behaviors. In addition, with a focus only on DFCB improvement and using a short duration of evaluation, behavioral goal achievement allowed the subjects to easily achieve the targeted goal(s) and increase the possibility of behavioral improvement. The combination of strategies employed in this study, including individual-based education combined

with a booklet, goal setting and an action planning strategy and weekly phone call counseling and follow–ups, showed a higher effect size than the study conducted by Vatankhah and colleagues (2009) that only applied an individual-based educational session combined with a booklet ($d = 2.02$ vs. $d = 0.20$) (Appendix K). The effect size of this present study was also higher than the average effect sizes of previous studies using a SM support program which were 0.29 to 0.95 (Fan & Sidani, 2009). Furthermore, the diabetic foot care behaviors questionnaire used in this study was validated by three experts on diabetes mellitus management, used the back translation method and statistically had acceptable internal consistency.

In spite of these strengths, there were some limitations including single setting, sample characteristics, period of study, and measurements used. The generalizability of the study findings might be limited since the subjects were recruited from one setting with a limited age of less than 65 years old, and all of them were Muslim. In general, since elderly DM patients may have other barriers related to impacts of aging processes (e.g. physical/psychological deficiency), applying a SM support program in this group would be more challenging and might give different findings than from this present study. Similarly, non-Muslim subjects and/or subjects with other cultural backgrounds may produce different challenges and results in implementing the program. Furthermore, the short study duration of only 5 weeks is not enough to predict or evaluate the sustainability of the achieved DFCB.

Regarding the measurements used, besides the prior knowledge questionnaire that had low internal consistency, A DFCB questionnaire that measures mainly the subjects' self-report on their foot care activities may produce scores/results that are higher than actual foot care behaviors. In addition, the self-confidence scale

was adopted directly from a previous study without re-testing the validity and reliability. This, therefore, potentially produced inconsistent self-confidence findings.

Implications and Recommendations

The positive outcomes of this diabetic foot care SM support program in enhancing DFCB among Indonesian diabetic patients lead to a strong recommendation to utilize this program, particularly in an outpatient setting. Furthermore, this program can be used in a nursing curriculum as well as in a clinical guideline for nurses and nursing students in providing care for patients in this group. Future research should be done with a larger sample size, including an older age (> 65 years old) population, a longer duration of study, and using established (valid and reliable) measurements in order to further clarify, strengthen the evidence, and maximize the benefits for patients with DM across the Indonesian nation and on a global basis.

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APPENDICES

Appendix A

Research Information Sheet

My name is Titis Kurniawan, I am a lecturer of the Nursing Faculty of Padjadjaran University – Indonesia, doing my Master's Degree of Nursing at Faculty of Nursing, Prince of Songkla University, Thailand. I am conducting a research the effect of self-management support program on diabetic foot care behaviors in patients with diabetes mellitus in West Java, Indonesia. It is therefore expected that the research findings will contribute to improve the effectiveness and health care quality for patients with diabetes mellitus. This study has been approved by the Institutional Review Board (IRB) of Prince of Songkla University, Thailand, and also has been granted permission by the IRB of Sumedang District General Hospital, Indonesia. I would like to ask you to participate as the subject in this research project. When you decide to participate in this project voluntarily, I will initiate the following procedures:

Explanation Procedures

a. Grouping
    1. You will be assigned either to the experimental group or the control group by using coin draw.
    2. When you are in the experimental group, in addition to what you usually receive regular treatment and care that this hospital provides for diabetic patients, you will receive diabetic foot care self-management support program during the study period of five weeks. This program consists of individual reflection, individual-based educational session, diabetic foot care behaviors self-evaluation, self-reinforcement, goal setting and action planning, and weekly brief counseling and follow-up through telephone call.
    3. When you are in the control group, you will continually receive regular treatment that this hospital provides to every diabetic patient who is attended at this diabetic unit and if you want you will receive the similar program and diabetic foot care booklet after the completion of the study.

b. Evaluation and Forms

You will be asked to fill the forms about your personal data, general health information, and your prior knowledge regarding the diabetic foot care. This will take time around 10 minutes. You also will be asked to fill diabetic foot care behaviors questionnaire in the first week and five week of intervention. This activity will take time another 15 minutes.

Risk and Comfort

There is no known risk or harm for you joining in this study. However, the program may make you spend more time with us. In addition, there is neither cost nor payment to you for your participation in this project.

Benefits

For you, this study will help you to learn how to improve your behaviors, particularly in improving diabetic foot care behaviors. The knowledge and experiences you gained may valuable for your future life. In addition, the finding of this study will help nurses and other healthcare providers to provide better quality of diabetic foot ulcer prevention by improving patients' diabetic foot care behaviors. It also will be useful information for the future research related to this topic.

Confidentiality

All information and your responses in the present study will remain confidential and anonymous. In addition, only the researcher, research advisors, and research committee in this project are eligible to access the data. Neither your name nor any identifying information will be used in the report of the study.

Participation and Withdrawal from Participation

Your participation in this project is voluntary, you have the right to choose, either participate or not participate. You also have right to withdraw from your participation in this study at any time without any consequences, penalty, influence on your receiving service, or influence in any medical treatment.

participation in this study at any time without any consequences, penalty, influence on your receiving service, or influence in any medical treatment.

Lastly, if you have any questions or suggestions you can directly contact me by phone +62227303876. If you agree to participate in this study, please kindly sign your name on the consent form.

Thank you very much for your kind cooperation.

Titis Kurniawan
Researcher

Research Information Sheet

(The Diabetic Foot Care Self-Management Support Program Group)

During this program you will receive following procedures:

1. The first week of intervention
   a. Initially, you will be asked to fill some forms including the demographic data, general clinical information, prior knowledge, and foot care behaviors questionnaire. Totally this activity will take time around 25 minutes. In this step, the research assistant will help you to complete the forms.
   b. You will be facilitated to conduct individual reflection that followed by individual-based foot care educational session with regard to your prior knowledge on desired diabetic foot care. Based on your gained knowledge and reflection, you and the researcher will collaboratively evaluate your current diabetic foot care behaviors, determine whether the diabetic foot care behaviors meet or unmeet the desired behaviors standard, and further discuss to help you develop your own goal and action plans to improve your diabetic foot care behaviors.
   c. At the end of session you will receive the diabetic foot care booklet to facilitate your further learning and will be asked regarding the time for follow-up phone call that you available for.
2. The second to fourth week of intervention

   In these periods, the researcher will make three follow-up phone calls to evaluate your current progress in implementing the action plan that you set before. During this activity, you will be asked to report your progress regarding your activities being implemented according to your own action plan. In this session you will also be allowed to share any difficulties during implementation of your action plan or ask questions or suggestions from the researcher to improve the effectiveness of action plan implementation and goal achievement. In addition, if necessary, the researcher will provide brief consultation in order to assist you develop further goal and action plans.

3. The fifth week of intervention.

   In the last week of the study, you will be followed-up by the researcher in the Diabetic Unit of Sumedang District General hospital during your regular visit in order to review your weekly diabetic foot care behaviors progress. You and the researcher collaboratively review your weekly goal and action plans, the action plan that you implemented each week, and your goal achievement. Similar with follow-up phone call, in this session you are allowed sharing your difficulties that you face during implementing the action plan and discussing the possible solutions with the researcher. In addition, if necessary the researcher will provide brief consultation to assist you setting the further goal and action plan. The process will take time approximately 15 minutes depending on your needs. In this meeting, you will be asked to fill the diabetic foot care behavior questionnaire. This will take time around 15 minutes. Research assistant will help you to complete the form.

Informed Consent Form

Title : Effect of Self-Management Support Program on Diabetic Foot Care Behaviors in Patients With Diabetes Mellitus in West Java, Indonesia

Researcher : Titis Kurniawan (Master Student Faculty of Nursing, Prince of Songkla University Hatyai, Thailand)

Patient's Name: .....Age:.....

Patient's Consent

I,....., was informed of the detail of the research entitled "The effect of self-management support program on diabetic foot care behaviors in patients with diabetes mellitus in West Java, Indonesia" and was assured that no part of my personal information and research result shall be individually revealed to the public. If any problem or issues arise, I can discuss with the researcher. I reserve the right to withdraw from this project at any time without any effects on any nursing/medical service and treatment. I am willing to participate in this research project voluntarily and hereby endorse my signature.

Given by :.....(Consentee) Date: .....

Researcher Note:

I had given the detailed information of the research entitled "entitled "The effect of self-management support program on foot care behaviors in patient with diabetes mellitus in West Java, Indonesia" to the patient. The signature on the form, indicate that you understand what is involved and that you consent to participate in this study voluntarily. You have been given the opportunity to ask question and were satisfied with the answer.

Signature ..... (Researcher)

Date : .....

Appendix B

The Diabetic Foot Care Self-Management Support Program Guideline

No	Activity	Method	Duration	Action	
				Facilitator/The researcher	Patient
1.	Allocating individual reflection	Asking patient an open ended questions	5 minutes	a. The researcher ask questions related to patients' current diabetic foot care behaviors: a. What you perceive the ulceration risk on your feet? b. Please tell me the way you usually take care of your foot? c. Please tell me the good things you have done in taking care of your foot? What the benefit/limitation in solving foot problem? d. Why you think that it was adequate/not adequate?	Answer the researcher question by describing his/her current activities in maintaining and improving foot condition in order to prevent diabetic foot ulcer or minimize the foot ulcer risks.
2.	Individual-based educational session	Lecture Discussion Booklet	30 minutes	Teaching plan (Appendix C)	Teaching plan (Appendix C)
3.	Assisting diabetic patients conduct self-evaluation and self-reinforcement	Discussion	7 minutes	The researcher ask questions to facilitate discussion in evaluating diabetic patients' foot care behaviors: a. "Based on the information given during educational session, what do you think about your diabetic foot care behaviors?" b. ..... c.	Patients answer and actively involved in the discussion, such as: a. Give opinions regarding his/her current foot care behaviors compared with the desired diabetic foot care behaviors. b. ..... c. .....

Appendix C

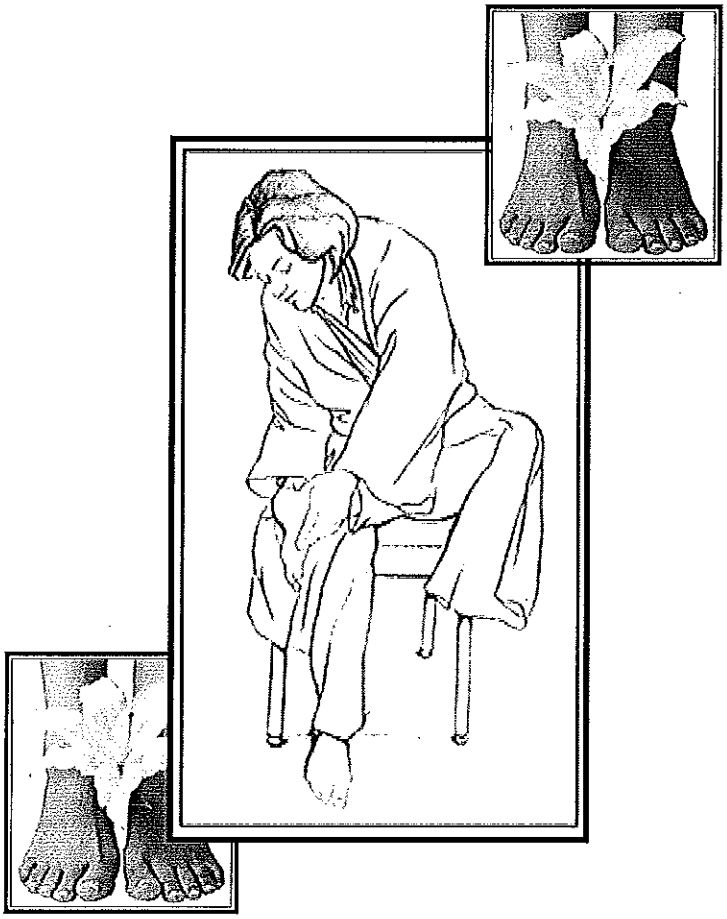
Teaching Plan (Guideline) for Individual-based Educational Session

No	Topic	Objectives	Content	Method & time	Activities	
					The Researcher	Patients
1	Introduction	To prepare the patient to follow the individual-based educational session	In this session the researcher will provide some explanation regarding the objective, duration, the activities will be conducted, and expected contribution from the patients during individual-based session. "This 30 minutes individual-based educational session is aimed to help you improve your knowledge regarding the desired diabetic foot care and help you to evaluate whether your current diabetic foot care behaviors meet or unmeet the desired ones. During this session the researcher will clarify and briefly discuss regarding your prior knowledge on desired diabetic foot care behaviors and further explain the required topics that generally consist of diabetic foot ulcer overview, diabetic foot care significances, and desired diabetic foot care components. In addition, to strengthen the information given, the researcher will show diabetic foot care video, related pictures, and provide diabetic foot care booklet. Furthermore, please feel free to actively involve either by asking any question, give comment, clarifying unclear information, or sharing your experiences".	- Lecture - 2 minutes	a. Explain the objectives, duration, contents of the individual-based educational session and the expected contribution from the patients during the session b. Ask some question based on patients' prior knowledge on desired diabetic foot care behaviors and their self-monitoring results	a. Answer the questions b. Pay attention c. Provide comment d. Clarify the unclear information/ ask further explanation
2.	.....	.....	.....	.....	.....	.....
3.	.....	.....	.....	.....	.....	.....

Appendix D

Diabetic Foot Care Booklet

Diabetic Foot Care



Master Nursing International Program

Faculty of Nursing

Prince of Songkla University

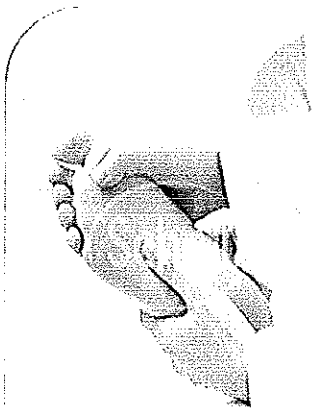
2010

Diabetic Foot Care Procedures

1. Take care your DM

Continue and consult to healthcare providers to manage your glucose level, manage diet, practice appropriate exercise, and regularly check-up and medication.

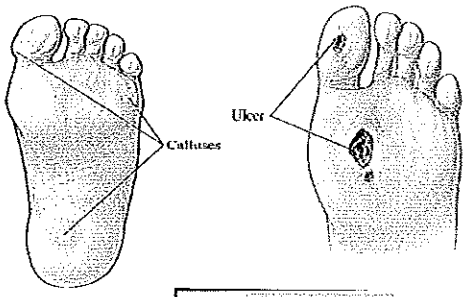
2. Inspect all part of foot



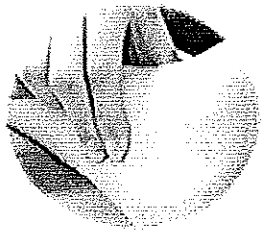
Inspect and identify:

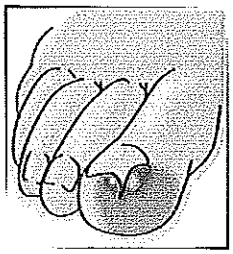
a) Foot postural changes
b) Swelling, pain, blister, ulcer (size, site, and exudates)
c) Change in foot skin color: redness pale, bruised or purple skin
d) Loss of pain sensation
e) Between toes area (irritation/laceration)

Inspecting foot conditions



f) Dry skin, calluses, cracking, fissure, or wound
g) Toenails infection or ingrown
h) When you able check the pulse





3. .....

4. .....

Appendix E

Goal Achievement Form

No
.....

Structured interview guidance

1. What is/are your last week goal and action plan?
2. What is/are action(s) you have implemented throughout this past week?
3. Do you think that you achieve the goal that you develop in the previous week? Why?
4. What is/are your barriers during implementation of your action plans?
5. What is/are the possible solution(s) to deal with those barriers effectively?
6. What is/are your goal and action plan(s) for the next week?

Planning	Implementation	Goal Achievement
Week 1 **Goal:** ..... **Action plan** 1. ..... 2. ..... 3. ..... **Possible barriers:** .... **Possible problem solution:** .... (SE scale: ...)	What: .... When: .... Frequency: .... How:	☐ Totally achieve the goal ☐ Not achieve the goal but some behaviors change ☐ No behaviors change et all
Week.....	.....	☐ ..... ☐ ..... ☐ .....
Week.....		☐

Appendix F

Demographic Data Questionnaire (DDQ)

Instruction:

Below is the form to acquire information about your current demographic data and health information.

Demographic Data

1. No subject :.....
2. Age :..... years
3. Phone number :.....
4. Gender : ☐ Male ☐ Female
5. Marital status : ☐ Single ☐ Married ☐ Widowed
6. Religion : ☐ Muslim ☐ Christian ☐ Catholic
   ☐ Buddhist ☐ Hinduism
7. Educational level : ☐ Elementary school ☐ Junior high school ☐ Others
   ☐ High school ☐ University
8. Occupation :.....
9. Income :.....Rupiah
10. Regular check up : ☐ No ☐ Yes
11. Experience of receiving foot care educational program: ☐ No ☐ Yes
12. Comorbid disease : ☐ No ☐ Yes, what is/are the co-morbid disease(s):
    .....
13. Smoking history : ☐ No ☐ Yes, how long:..... year(s)..... piece/day
14. .....
15. .....
16. .....

Appendix G

ID:

Diabetic Foot Care Prior Knowledge Questionnaire

Instruction:

Please fill the column true or false by marking (√) for each statement based on your knowledge.

	Statements	TRUE	FALSE
1.	Diabetes patients must check the temperature of water that they will use to wash his/her feet.		
2.	It is better for diabetes patients to walk barefoot in the house.		
3.	It is recommended for DM patients to check their foot conditions every day.		
4.	……..		
5.	……		
6.	……		
7.	……		
8.	……..		
9.	……		
10.	It is suggested for DM patients to check the inside part of shoes (footwear) before and after wearing it.		

Appendix H

Foot Care Behavior Questionnaire (NAFF Modified version)

ID:

We would like to know what you do to look after your feet during this past week. Please tick the category which best reflects what you actually do. Please answer every question. Thank you.

1. How many times you inspect your foot conditions?
   More than once/day(…) Once/day(…) 4-6 times a week (…) Once/week or less (…)

2. When you inspect your foot, you inspect all parts of your foot?
   Often (…) Sometimes (…) Rarely (….) Never (….)

3. When you examine your foot, you check pulse of your foot?
   Often (…) Sometimes (…) Rarely (…) Never (…)

4. Do you attend in regular foot examination schedule in the healthcare service?
   Always (…) Often (….) Sometimes (….) Rarely/Never (….)

5. How many times you wash your foot?
   More than once a day (…) Daily (…) 3-4 times a week (….) 1-2 times a week (…)

6. ……

7. ……

…. ……

30. Do you report the ingrown toenails when you get one?
    Always (…) Sometimes (….) Rarely (….) Never (…)

…… …., 201..

Examiner

Appendix I

Diabetic Foot Care Prior Knowledge of the Experimental and the Control Group

Table 12

Frequencies and Percentages of Correct Answer to Each Item of Diabetic Foot Care Prior Knowledge in the Experimental and the Control Group (N =70)

Prior Knowledge	Experimental Group (n = 35)	Control Group (n = 35)
	n (%)	n (%)
1. Diabetes patients must check the temperature of water that they will use to wash his/her feet.	21 (62.90)	25 (71.40)
2. It is better for diabetes patients to walk barefoot in the house.	9 (25.70)	14 (40.00)
3. It is recommended for DM patients to check their foot conditions every day.	31 (88.60)	28 (80.00)
4. Numbness in the diabetic patients' foot is normal.	23 (65.70)	23 (65.70)
5. No need to dry between toes area in every time after washing the feet.	26 (74.30)	24 (68.60)
6. It is suggested for diabetic patient to soak his/her foot every day.	27 (77.10)	25 (71.40)
7. Sandal/flip-flop is the most recommended footwear for DM patients.	14 (40.00)	14 (40.00)
8. Diabetic patients are not allowed to trim the toenails by using razor blade or scissor.	27 (77.10)	27 (77.10)
9. Diabetic patients are suggested to scrub their feet strongly when he/she wash his/her feet.	31 (88.60)	33 (94.30)
10. It is suggested for DM patients to check the inside part of shoes (footwear) before and after wearing it.	35 (100.00)	33 (94.30)

Appendix J

Means and Standard Deviations of Each Dimension of the Diabetic Foot Care Behaviors

Table 13

Pretest and Posttest Means and Standard Deviations of Each Dimension of Diabetic Foot Care Behaviors in the Experimental and Control Group (N =70)

Dimension of DFCB	Experimental Group (N = 35)		Control Group (N = 35)	
	Pretest M (SD)	Posttest M (SD)	Pretest M (SD)	Posttest M (SD)
Foot Examination	5.80 (2.44)	7.57 (2.25)	5.49 (2.25)	5.83 (2.16)
Foot Hygiene	9.40 (2.95)	12.71 (1.86)	10.03 (2.84)	9.80 (2.72)
Footwear	19.06 (3.51)	23.66 (2.99)	18.97 (3.22)	20.11 (3.09)
Toenails Care	8.80 (1.49)	11.37 (1.06)	8.83 (1.87)	8.46 (1.72)
Preventing foot Injuries	4.86 (2.34)	6.89 (2.01)	5.17 (2.51)	5.00 (2.68)
Foot Injuries Management	3.17 (2.13)	5.23 (1.29)	2.94 (2.14)	3.40 (1.94)

Appendix K

Effect Size Calculation

$$ES = \frac{M2 - M1}{PooledSD}$$

Where ES = Effect size

M1 = Mean of DFCB posttest score of the control group

M2 = Mean of DFCB posttest score of the experimental group

SD = Standard Deviation

SD1 = Standard Deviation of DFCB posttest score in the control group

SD2 = Standard Deviation of DFCB posttest score in the experimental group

$$\text{Pooled SD} = \sqrt{\frac{(SD1)^2 + (SD2)^2}{2}}$$

$$= \sqrt{\frac{(8.60)^2 + (5.83)^2}{2}}$$

$$= \sqrt{\frac{(73.96) + (33.989)}{2}} = \sqrt{\frac{107.949}{2}} = \sqrt{53.975} = 7.35$$

$$\text{ES} = \frac{M2 - M1}{PooledSD}$$

$$= \frac{67.43 - 52.60}{7.3467} = \frac{14.83}{7.3467} = 2.02$$

Appendix L

List of Experts

Three experts examined the construct and cultural applicability for the Diabetic Foot Care Self-Management Support Program and NAFF modified version, they were:

1. Hartiah Haroen, S.Kp. M.Kes. MNg.

   Nursing Lecturer, Universitas Padjadjaran, Indonesia

2. dr. Bambang Haribowo, Sp.PD

   Internist, Sumedang District General Hospital Sumedang, West Java, Indonesia

3. Assist. Prof. Dr. Sang-arun Isaramalai

   Nursing Lecturer, Prince of Songkla University, Thailand

VITAE

Name Mr. Titis Kurniawan

Student ID 5210420045

Educational Attainment

Degree	Name of Institution	Year of Graduation
Bachelor of Nursing	Padjadjaran University	2005

Scholarship Awards during Enrollment

Directorate of Higher Education, Ministry of National Education, Republic of Indonesia

Work Position and Address

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Phone/Fax.: +62 22 7795596. E-Mail: titiz_kazep@yahoo.com

List of Publications

Kurniawan, T., & Petpichetchian, W. (2011). Evidence-based interventions enhancing diabetic foot care behaviors among hospitalized DM patients: A case study. *Nurse Media Journal of Nursing, 1,* 43 – 59.

Kurniawan, T., Sae-Sia, W., Maneewat, K., & Petpichetchian, W. (2011). Effect of self-management support program on goal achievement of diabetic foot care behaviors in Indonesian diabetic patients. *Nurse Media Journal of Nursing*, (in press).