Examining the Feasibility, Acceptability and Effects
of a Foot Self-Care Educational Intervention
in Adult Patients with Diabetes at Low Risk for Foot Ulceration

by

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Graduate Department of Nursing Science
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Abstract

Background: Foot ulceration and subsequent lower extremity amputation are common, serious, and expensive chronic complications for patients with diabetes. Foot-care education, provided to patients with diabetes at low-risk for ulcers, prevents minor foot problems that may lead to ulceration. Little evidence is available to support the effectiveness of educational intervention in low-risk diabetic patients.

Objectives: The objectives of the pilot study were to examine the feasibility and acceptability of the foot care educational intervention, and to explore its effects on patients’ foot self-care knowledge, efficacy, and behaviors, and the occurrence of minor foot problems in adult patients with diabetes at low risk for foot ulceration.

Methods: A one group repeated measures design was used. The intervention was given over a 3-week period. The first intervention session consisted of a 1-hour one-on-one, provider-patient interaction to discuss foot self-care strategies; the second session involved a 1-hour hands-on practice training. The third and fourth sessions entailed two 10-minute telephone contact booster sessions. Seventy eligible participants with type 2 diabetes at low risk for foot ulcerations were enrolled in the study, and 56 participants (30 women and 26 men; mean age: 55.8±13.2 years) completed the study. The outcomes of foot self-care knowledge, efficacy, behavior, and foot and footwear conditions were
assessed at pre-test, following the first two sessions, and 3-month follow-up. Repeated measures analysis of variance, and paired-t test were used to examine changes in outcomes over time.

**Results:** The findings provided initial evidence suggesting the foot self-care educational intervention is feasible and acceptable to adult patients with type 2 diabetes. It was effective in improving patients’ foot self-care knowledge ($F(2, 54) = 230.444, p < 0.01$), self-efficacy ($F(2, 54) = 94.668, p < 0.01$), and foot self-care behaviors ($t(55)=117.228, p < 0.01$), in reducing the occurrence of minor foot skin and toenails problems (all $p<0.05$), and in improving wearing proper shoes and proper socks (all $p<0.05$) at 3-month follow-up.

**Conclusions:** The findings from this pilot study support the effects of the intervention. Future research should evaluate its efficacy using a randomized clinical trial design, and a large sample of patients with diabetes at low risk for foot ulcerations.
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Patients with diabetes are vulnerable to nerve and vascular damage that can result in loss of protective sensation in the foot, poor circulation, altered biomechanics of the foot and skin trauma. Insufficient knowledge and improper self-care behavior related to foot care can increase the risk of foot ulceration and lower-extremity amputations (American Diabetes Association, 2004 & 2010; Canadian Diabetes Association, 2008; Litzelman, Marriott, & Vinicor, 1997). Foot ulceration and subsequent lower extremity amputation are common, serious, and expensive chronic complications for patients with diabetes (Singh, Armstrong, & Lipsky, 2005; Valk, Kriegsman, & Assendelft, 2007). Thus, several provincial and national (ADA, 2004; CDA, 2008; Registered Nurses Association of Ontario, 2004 & 2005), as well as international organizations (International Diabetes Federation, 2005, World Health Organization, 1990) have set a goal to decrease the incidence of foot ulceration and lower-extremity amputation by 50% among patients with diabetes because of the high incidence of disabilities, death and health care cost for foot ulceration.

Lower extremity amputation (LEA) among patients with diabetes is associated with high personal, family, social, and economic burden (Boulton, Vileikyte, Ragnarsson-Tennvall, & Apelqvist, 2005; Driver, Goodman, Fabbi, French, & Andersen 2010; Vileikyte et al., 2006). Empirical evidence suggests that the devastating consequences of foot complications could be prevented in most cases (Apelqvist & Larsson, 2000;
Boulton, Meneses, & Ennis, 1999). Educational interventions aimed at reinforcing appropriate foot care play an important role in preventing foot ulcerations (CDA, 2008, RNAO, 2004 & 2005; Mayfield, Reiber, Sanders, Janisse, & Pogach, 1998; Singh et al., 2005). However, during the past two decades, most studies have focused primarily on patient education to prevent foot complications among patients with diabetes, who, for the most part, were at high risk for foot ulceration. Results of a systematic review suggests that patients’ knowledge and performance of foot self-care were improved following educational interventions, and that foot ulceration and amputation in high risk patients were reduced on a long term basis (Valk et al., 2007). Little is known about the effects of educational interventions for patients who are at low risk for foot ulceration. Therefore, it is important to examine the feasibility, acceptability and effects of the educational intervention in adult patients with diabetes at low risk for foot ulceration.

Background of the Study

Diabetes is a serious, life-long condition. Worldwide, the prevalence of diabetes is increasing annually. It affects more than 2 million Canadians. Diabetes and its complications are the leading cause of death (RNAO, 2004 & 2005; CDA, 2008). Foot ulceration and subsequent amputation of the lower extremity is one of the common, serious, and expensive chronic complications for patients with diabetes. It represents a major medical, social and economic problem all over the world (Singh et al., 2005; Valk et al., 2007).

The prevalence of foot ulceration ranges from 4% to 10% among patients with diabetes based on results of recent studies (Abbott, Vileikyte, & Williamson, 1998; IWGDF, 1999 & 2003; Lavery, Armstrong, Wunderlich, Tredwell, & Boulton, 2003;
Reiber, 2001). The lifetime risk of developing a foot ulcer could be as high as 25% in a patient with diabetes (Boulton et al., 2005; Singh et al., 2005). If not treated appropriately, the foot ulceration contributes to a high rate, up to 85%, of lower extremity amputation (Mayfield et al., 1998; Pecoraro, Reiber, & Burgess, 1990; Ragnarson-Tennvall & Apelqvist, 2000). Foot ulcerations and subsequent amputation are associated with high diabetes-related hospitalizations, emotional reactions, physical suffering, as well as loss of productivity and quality of life, and huge financial losses both in developed countries and in developing countries. (ADA, 2004; Boulton et al., 2005; CDA, 2008; Meijer, Trip, & Jaegerset, 2001; Driver et al., 2010; Ragnarson & Apelqvist, 2000; Vileikyte, 2001; Vileikyte & Boulton, 2000).

Foot problems have become an enormous, global disease burden in terms of epidemiology and economic consequences. The International Diabetes Federation has chosen to focus on the global burden of diabetic foot disease in 2005 (Wild, Roglic, Green Sicree, & King, 2004; IDF, 2005). The International Diabetes Federation has therefore declared that now is the time to increase awareness of foot problems in persons with diabetes (Jeffcoate & Bakker, 2005) in view of the vast personal, social, medical, and economic costs of what should be one of the most preventable long-term complications of diabetes (Boulton, 2004; Driver, et al., 2010; Vileikyte et al., 2006).

The high prevalence and serious complications of foot ulceration demand the development of an educational intervention to raise awareness among patients with diabetes of the risk factors for foot ulcerations that include decreased sensation, poor circulation, altered biomechanics, a history of previous foot ulceration, and poor foot self-care behavior and limited self-care knowledge (RNAO Nursing Best Practice
Guideline, 2004; Mayfield et al., 1998). The goal of educational interventions is to assist patients with diabetes to address modifiable risk factors that are amenable to change and prevent the occurrence of foot ulceration (Halpin-Landry & Goldsmith, 1999).

**Need for Education about Foot Ulceration Prevention**

Despite the high incidence of foot ulceration and lower extremity amputation, patients with diabetes lack adequate foot self-care knowledge. Fewer than 40% of patients with diabetes have received formal education about their condition and its management (RNAO, 2004 & 2005). Several national and international organizations have emphasized the importance of enhancing patients’ knowledge of foot self-care. The organizations set a goal to decrease the incidence of foot ulceration and lower-extremity amputation by 50% among patients with diabetes (IDF, 2005; RNAO, 2004 & 2005; WHO, 1990). Studies have identified that patient education on foot self-care plays a significant role in preventing foot complications in patients with diabetes (Mayfield et al., 1998; Singh et al., 2005). Empirical evidence showed that the risk of diabetes-related foot complications can be reduced by an estimated 49 to 85% by proper preventive measures, disseminated through foot self-care education (Apelqvist, Bakker, & van Houtum, 2000).

Researchers have designed and implemented educational interventions to prevent foot complications among patients with diabetes for years. Results of studies that evaluated such interventions showed that educational interventions focusing on foot self-care improved patients’ foot self-care knowledge and behavior, and reduced foot ulceration and lower extremity amputation in patients with diabetes at high risk for ulceration, on a long-term basis (Valk et al., 2007). However, studies that evaluated educational interventions had some limitations including: no study examined the effects
of educational interventions in patients with diabetes at low-risk for foot ulceration; and the intervention was not designed to specifically promote self-efficacy related to foot self-care. Self-efficacy is required to initiate and maintain adequate foot self-care.

RNAO Nursing Best Practice Guideline has proposed that all individuals with diabetes should receive ongoing basic foot care education and regular foot examinations to assess and address risk factors for foot ulceration/amputation, if the incidence of foot complications is to be reduced (RNAO, 2004 & 2005). Studies indicated that most patients with diabetes do not pay attention to protecting their feet, are not aware of the risk factors for foot ulceration, have limited knowledge of strategies to prevent foot ulceration and its complications, resulting in high hospitalization rate for treatment of foot ulcerations (Boulton et al., 1999; RNAO, 2004 & 2005; Ucciol, Aldeghi, & Faglia, 1995). Inappropriate knowledge and improper self-care in patients with diabetes still lead to unnecessary foot ulcerations, amputation of lower extremities, compromised quality of life, and substantial health care cost (Bielby, 2006; Mayfield et al., 1998; Wraith, Lawrence, Campbell, & Colman, 2005).

Much effort and research have been directed towards patient education to prevent foot complications among patients with diabetes during the past two decades. A total of 10 experimental studies evaluated the effectiveness of patient education in preventing foot ulceration targeting patients with diabetes. The outcomes examined in the 10 experimental studies on foot-care educational interventions are presented in Table 1.
Of the seven studies that examined knowledge of foot care, five studies showed positive outcomes where patients who received the educational intervention reported improvement in knowledge of foot care. Seven studies investigated the effects of education on foot self-care behavior performance, and the results of five studies indicated positive outcomes. Four studies showed decreased occurrence of foot problems following education. In addition, of the four studies that focused on minor foot problems, the results of two studies demonstrated no significant changes in the minor foot problems at the study endpoints. Further, only two of the 10 foot-care educational intervention studies examined self-efficacy of foot-care and the results were inconsistent.
Overall, the results suggest that patients’ knowledge and performance of foot care were improved following educational interventions, and that foot ulceration and amputation, particularly in high-risk patients, were reduced in the long-term (at one year follow up). However, it is uncertain whether development of minor foot problems (i.e., calluses, skin dryness and cracking, infection, and trauma) that could contribute to ulceration could be significantly reduced in patients with diabetes at low-risk for foot complications. Minor foot problems are common in individuals with diabetes and can lead to foot ulcers and amputation if delayed or inappropriate treatment is given (Hamalainen, Ronnemaa, Toikka, & Liukkonen, 1998). Eighty-six percent of the eventual amputation cases resulted from a pivotal triggering event that is, a preventable minor foot trauma such as wearing improper shoes and improper cutting of toenails (Halpin-Landry & Goldsmith, 1999). Therefore, it is necessary to conduct further research to determine the effects of educational interventions in preventing minor foot problems that can lead to ulceration and subsequent amputation in patients with diabetes (Valk et al., 2007).

Of the 10 experimental studies on foot-care educational interventions mentioned earlier, only one study targeted participants at high risk for foot ulceration (Malone et al., 1989); and one study assessed participants’ risk for foot ulceration before random assignment, but the investigators mixed participants at high and low risk for ulceration together in the experimental and comparison groups (Litzelman et al., 1993). Participants either at low (i.e., have normal protective sensation, normal circulation of lower extremities, no foot deformity, no history of previous foot ulceration or amputation, and absence of present foot problems) or high risk (i.e., have any or a combination of the following: history of peripheral neuropathy, peripheral vascular disease, foot deformity,
previous foot ulceration or amputation, and present ulceration) for foot complications had not been separated to examine the effectiveness of interventions in these two groups (International Working Group on the Diabetic Foot, 1999 & 2011; Mayfield et al., 1998; RNAO, 2004 & 2005). No study focused on the effects of the educational intervention in patients with diabetes at low-risk for foot ulceration. The latter group of patients may receive little, if any, information about foot complications and how to prevent them (McInnes et al., 2011). Yet, prevention of foot ulceration is better than its treatment. The potential consequences of poor foot care in diabetes are grave. The importance of foot health and foot-care must be communicated at an early stage of the disease (McInnes et al., 2011). To be more effective in reducing foot ulceration and amputation, educational interventions to prevent foot problems of any type, even if minor, must start as early as possible; that is, patient education should be initiated in patients with diabetes at low-risk of developing foot ulcers, so that primary prevention of foot ulceration can be successfully achieved (Apelqvist & Larsson, 2000; Halpin-Landry & Goldsmith, 1999).

There are no specific evidence-based guidelines regarding the content or provision of foot care advice for diabetes patients at low risk for foot ulceration (McInnes et al., 2011), although several guidelines currently exist for the general diabetes population (ADA, 2010; CDA, 2008; Interventional Working Group (IWG) on the diabetic foot, 2004; National Institute for Clinical Excellence (NICEG) Guideline, 2004; RNAO, 2004). The best practice guideline, Reducing Foot Complications for People with Diabetes (RNAO, 2004) proposes that nurses in all practice settings should provide and reinforce basic foot care information to prevent foot complications in patients with diabetes. The basic foot care educational intervention should include the following
content: awareness of personal risk factors; value of thorough annual examination of feet by a healthcare professional; daily self-care and self-monitoring of foot including daily washing and drying, moisturizing, inspecting foot for problems, massaging foot, and foot gymnastics; footwear; nail care; prevention of foot trauma; and when to seek advice from a healthcare professional (ADA, 2009; CDA, 2008; Fan, et al., 2005; NICE Guideline, 2004; RNAO, 2004).

Recognition of risk factors, increasing foot self-care knowledge and improving foot self-care behavior are identified in related literature as essential in preventing foot ulceration in patients with diabetes (Lavery et al., 2005; Mensing, Boucher, & Cypress, 2006; RNAO, 2004 & 2005). Increasingly, evidence suggests that a greater emphasis on supporting self-care behaviors is essential to effective disease management. One theory that may be applied to assist in understanding how to promote changes in health behaviors is the social cognitive theory by Bandura (1989 & 1997).

Bandura states “what people need is knowledge about how to regulate their behavior and firm belief in their personal efficacy to turn concerns into effective preventive actions” (Bandura, 1997). The social cognitive theory uses the concept of self-efficacy as predictive of a particular behavior. Self-efficacy is the amount of confidence a person believes he or she has to perform a set of specific activities or behaviors (Bandura, 1997). Bandura states that self-efficacy is the most predictive factor in the development and maintenance of a new behavior. He also states that people who are persuaded that they can succeed are more likely to expend the effort needed to perform the behavior. Bandura (1989) presumes that successful self-care is dependent on supporting a person’s knowledge and skills, while also ensuring ongoing confidence in being able to put this
knowledge and skill into practice. Based on social cognitive theory, bolstering confidence in the ability to effectively implement self care strategies is an important component of interventions for promoting active patient participation in diabetes self-care (Ellison & Rayman, 1998). Empirical evidence indicates that self-efficacy is independently associated with self-management behaviors in patients with diabetes (Sarkar, Fisher, & Schillinger, 2006). Patients with diabetes who display a higher degree of self-efficacy or confidence in self care implemented better self-care practices than those with a low level of self-efficacy (Hurley & Shea, 1992). Educational interventions enhanced self-efficacy for self-management among patients with low levels of self-efficacy (Glasgow, Toobert, & Gilette, 2001). Study results support the following actions to improve the education outcomes for adults with diabetes: involve people with diabetes in their own care, guide them in actively learning about the disease, and teach them the skills necessary to adjust their self-care behavior to control their own health outcomes. These actions are related to improvement in their individual self-efficacy and, accordingly, their self-management ability (Krichbaum, 2003).

According to social cognitive theory (Bandura, 1997), it is essential to focus on behavior to enhance self-efficacy and hence performance of self-care behavior in everyday life. While knowledge and behavior of foot self-care are frequently linked, most interventions aimed at foot self-care in patients with diabetes were not explicitly designed to promote self-efficacy. Only two studies examined the self-efficacy of foot-care following foot-care educational interventions, with inconsistent findings (Borges & Ostwald, 2008; Corbett, 2003). Thus, it is necessary to further investigate the effects of interventions designed to provide ample opportunity to practice foot self-care activities,
on the initiation and maintenance of adequate foot self-care, and the reduction of foot problems.

Of the 10 experimental studies reviewed earlier, seven were conducted in the United States of America; the others were conducted in Australia, Finland and China. The target population involved primarily white patients with diabetes. Two studies consisted of 75% African-Americans; and one study focused on the Chinese population.

Canada’s population continues to increase due to immigration (Statistics Canada, 2006). With a population of 5.6 million in 2006, the Greater Toronto Area (GTA) is Canada’s largest metropolitan area and accounts for 43.2% of Ontario’s population. Its population is a mixture of numerous cultural groups (Statistics Canada, 2006). According to the Canadian Diabetes Association (2008), 2 million Canadians (5.5 % of adult population) had been diagnosed with diabetes in 2005, and the prevalence of diabetes is growing rapidly. It is estimated that over 308,000 of the population in the GTA have diabetes based on relevant figures (Statistics Canada 2006; CDA, 2008). Patients with diabetes are vulnerable to nerve and vascular damage due to high blood glucose level that may result in loss of protective sensation in their feet, and poor circulation of lower-extremity that increase the risk for foot problems (ADA, 2004; CDA, 2008; RNAO, 2004 & 2005). Advocating protection of patients’ feet, and prevention and management of foot problems at an early stage will reduce occurrence of foot complications. This is accomplished by providing effective foot-care educational interventions that are consistent with the proposition of social cognitive theory and core principles of clinical practice guidelines (CDA, 2008; RNAO, 2004 & 2005). However, there is no study that
examined foot-care educational interventions for preventing foot problems in patients with diabetes at low risk for foot ulceration.

**Statement of the Problem**

There is increasing emphasis on reducing foot ulceration and amputation in patients with diabetes. Educational interventions addressing the prevention of foot problems must be initiated as early as possible. Prevention of foot ulceration is far more important than its treatment. Foot-care education should be started at an early stage of the disease and before the development of minor foot problems (McInnes et al., 2011), that is, in patients with diabetes at low-risk for foot ulceration, so that prevention of foot ulceration and subsequent amputations can be achieved (Apelqvist & Larsson, 2000; CDA, 2008; Halpin-Landry & Goldsmith, 1999; Hamalainen et al., 1998).

Among the 10 experimental studies reviewed earlier, nine studies included participants with diabetes with no clear evaluation of their risk for foot ulceration. Therefore, participants included those at low or high risk for foot complications; however, no subgroup analysis was done to examine the effectiveness of interventions in these two groups (Mayfield et al., 1998). Only one of 10 studies focused on participants with diabetes at high risk for foot ulceration, and no study examined the effects of a foot-care educational intervention on knowledge, behavior, and self-efficacy of foot self-care targeting the diabetic population at low risk for foot problems. The researcher had designed and evaluated a foot care educational intervention for Chinese patients with diabetes. The intervention is intensive and focuses on the practice of foot self-care activities with the ultimate goals of improving performance of foot self-care strategies, and reducing the development of foot problems (i.e., calluses, skin dryness and cracking,
infection, and trauma) that could contribute to ulceration (Fan, Li, Zheng, & Lu, 2006). Although the foot self-care educational intervention showed effectiveness in achieving the expected outcomes, it has the following limitations. Firstly, the intervention was not designed to increase foot self-care self-efficacy which is the most predictive factor in the development and maintenance of a new health behavior (Bandura, 1997). Secondly, the study targeted adult Chinese patients with diabetes having a mix of high and low risk for foot ulceration in the experimental and comparison groups, which may have affected the magnitude of its effects on the ultimate outcomes. Furthermore, although the educational intervention was effective, its applicability in the Canadian population is questionable due to differences in culture, social and health contexts between the two countries, Canada and China. Therefore, the intervention should be adapted to the needs and preferences of the Canadian population and examined for its feasibility and acceptability, prior to testing its efficacy (Whittemore & Grey, 2002). Feasible interventions will be successfully implemented as designed, and interventions perceived by participants as acceptable tend to be adhered to resulting in the achievement of intended outcomes (Sidani, Epstein, & Miranda, 2006).

Thus, the present study focused on examining the feasibility, acceptability, and effects of an educational intervention for the prevention of foot problems in patients with diabetes at low-risk for foot ulceration. The intervention was based on social cognitive theory, and aimed at promoting foot self-care self-efficacy. It targeted adult Canadians with type 2 diabetes at low risk for foot ulceration living in the GTA.

Cole and Dendukuri (2004) defined the feasibility of the intervention as the degree to which the participants enroll in, complete, and comply with the intervention.
Based on Cole and Dendukuri’s definition (2004), the feasibility of the foot self-care educational intervention in this study was evaluated in terms of participants’ enrolment in, withdrawal from, and compliance with the intervention. The specific indicators of feasibility included: number of eligible persons who took part in the study; number of persons who declined enrollment, and reasons for non-participation; number of persons who withdrew before completing all intervention sessions; and reasons for attrition; and number of eligible persons who attended the intervention sessions; and reasons for non-attendance.

According to Kazdin (1980), Witt and Elliott (1985), and Sidani et al. (2009), acceptability of an intervention is defined as patients’ appraisal of the intervention’s appropriateness, fairness, reasonableness, benefits, unintrusiveness, intensity, and satisfaction. Acceptability of the intervention was assessed at the completion of the intervention using a self-report measure.

**Purpose of the Study**

The specific objectives of this pilot study were: 1) to examine the feasibility and acceptability of the foot care educational intervention, operationalized in terms of (a) enrolment rate of participants in the study and the reasons for non-enrolment; (b) the intervention completion rate by participants and the reasons for attrition; (c) the compliance rate of participants with the intervention, that is, participants’ attendance at the intervention sessions, and reasons for non-compliance, and (d) participants’ acceptability of the foot self-care educational intervention represented by perception of its appropriateness, fairness, reasonableness, benefits, effectiveness, intensity, and satisfaction; and 2) to explore the effects of the foot self-care educational intervention on
(a) patients’ foot self-care knowledge, (b) foot self-care efficacy, (c) foot self-care behaviors, (d) the occurrence of minor foot problems (i.e., calluses, skin dryness and cracking, infection, and lesions), and wearing improper shoes and socks in adult Canadian patients with diabetes at low risk for foot ulceration living in the GTA.

**Significance**

Although a foot self-care educational intervention targeting patients with diabetes living in China has been developed (Fan et al., 2006), its applicability in the Canadian population with diabetes is unknown. According to Whittemore and Grey (2002), it is very important to test the feasibility and acceptability of a newly designed intervention or an intervention being used in a new population. It is therefore necessary to test the feasibility and acceptability of the adapted foot self-care educational intervention in the new target population, that is, the Canadian adult patients with type 2 diabetes at low risk for foot ulceration.

Interventions that are feasible and acceptable contribute to achievement of intended outcomes. It is assumed that if participants perceive the foot self-care education intervention as acceptable, they may actively engage in the learning and training activities comprising the intervention, and consequently may gain knowledge and skills, and develop self-efficacy that bolsters confidence in the ability to effectively implement and maintain performance of foot self-care strategies. Based on the social cognitive theory, self-efficacy is the most predictive factor in the development and maintenance of a new behavior (Bandura, 1997). Therefore, implementing a well-designed, feasible and acceptable foot care educational intervention should increase patients’ attendance at intervention sessions, and compliance with the intervention, reduce attrition rate, and
improve satisfaction with the intervention (Macias et al., 2005). This in turn, will assist patients to achieve the intended intervention outcomes that include gaining and retaining knowledge related to foot self-care, building up high self-efficacy related to foot self-care, and initiating and maintaining foot self-care performance, and subsequently preventing foot complications.
Chapter 2 Literature Review and Conceptual Framework

The review of literature is organized in three sections. The first section synthesizes the prevalence of foot ulceration and lower-extremity amputation, risk factors for, and consequences of foot ulceration and lower-extremity amputation. The second section consists of a critical review of studies that evaluated the effects of foot self-care educational interventions on foot self-care knowledge, foot self-care efficacy, foot self-care behaviors, and occurrence of foot problems in patients with diabetes. The chapter concludes with the presentation of the conceptual framework that guided the design of the intervention and the study. The main elements of the intervention theory operationalizing the framework are described.

Prevalence of Foot Ulceration and Lower-Extremity Amputation (LEA)

Ulceration of the foot and subsequent amputation of the lower extremity are common, serious, and expensive chronic complications for patients with diabetes. They have become major medical, social and economic problems all over the world (CDA, 2008; Singh et al., 2005; Valk et al., 2007; Vileikyte et al., 2006). The most common single precursor to lower extremity amputations is foot ulceration (Locking-Cusolito et al., 2005; Pecoraro et al., 1990). Approximately 40-60% of all lower extremity amputations (LEA) are related to diabetes and in some instances, rates of amputation as high as 70-90% have been reported (Adler, Boyko, & Ahroni, 1999; Boulton et al., 2005). The risk of a LEA in people with diabetes is 20 to 46 times higher than in people without diabetes (Armstrong, Lavery, & Harkles, 1998; Halpin-Landry & Goldsmith, 1999; Lavery et al., 1998; Singh et al., 2005; Valk et al., 2007). According to recent studies, the
prevalence of foot ulceration ranges from 4% to 10% among patients with diabetes (Abbott et al., 1998; IWGDF, 1999 & 2003; Lavery et al., 2003; Reiber, 2001).

Foot ulceration and infections are among the most serious complications of diabetes, and a leading cause of diabetes-related hospitalizations both in developed and in developing countries. For example, in the United States of America, approximately 20% of hospitalized diabetic patients are admitted because of foot complications (Litzelman et al., 1993); further, 46% of all ulcer hospitalizations were in people with diabetes (Mayfield et al., 1998). Diabetic foot problems were responsible for 23% of the hospital days over a period of two years (Smith, Weinberger, & Katz, 1987). In India, more than 10% of all admissions for diabetes are primarily for the management of foot problems. Also, more than 70% of patients required surgical intervention and more than 40% of those interventions were either a toe or lower extremity amputation (Sathe, 1993). In China, 12.8% of diabetic patients’ hospitalizations are related to foot ulceration, leading to significantly prolonged hospital stays (Fan, Zhang, & Lu, 2005; Fan et al., 2006). In Australia, approximately 25% of inpatients have diabetes and of these, 20% have foot pathology that requires acute care and management upon discharge (Wraight et al., 2005). In the United Kingdom, more than 50% of the bed occupancy of patients with diabetes is due to foot problems (Waugh, 1988). A large survey in the U.K. showed that of 6,000 patients attending diabetes clinics, more than 2% had an active foot ulcer and 2.5% were amputees (MacLeod, Williams, Sonksen, & Boulton, 1991). In Canada, it is estimated that 15% of the 2 million Canadians with diabetes develop foot ulcers. In Ontario, 70% of all amputations of a lower extremity occur in patients with diabetes (Diabetes Task Force: Report to the Ministry of Health and Long-Term Care, 2004).
The lifetime risk of developing a foot ulcer could be as high as 25% in patients with diabetes (Boulton et al., 2005; Singh et al., 2005). If not treated appropriately, the foot ulceration contributes to a high rate, up to 85%, of LEA. Once an individual has undergone an amputation there is a 50% risk of an amputation of the remaining extremity within 5 years (Mayfield et al., 1998; Ragnarson-Tennvall & Apelqvist, 2005; Reiber et al., 1998; Reiber, Vileikyte, & Boyko, 1999). Amputation is associated with emotional reactions, physical suffering, as well as loss of productivity and reduced quality of life, and subsequent financial losses (Boulton et al., 2005; Meijer, Trip, & Jaegerset, 2001; Ragnarson & Apelqvist, 2000; Vileikyte, 2001; Vileikyte & Boulton, 2000).

**Impact of Foot Ulceration and Lower-Extremity Amputation on Quality of Life**

Foot ulceration is not only a serious complication of diabetes that is associated with adverse consequence such as LEA and high health care costs, but it also has a significant impact on quality of life (QOL). Research evidence shows that the presence of a diabetic foot and its complications has a serious deleterious effect on QOL. QOL refers to physical, social, economic and psychological functions. The degree of disruption in QOL is proportional to the severity of the complications experienced as a result of foot ulceration by both patients with diabetes and their care-givers (Price, 2004; Ribu, Hanestad, Moum, Birkeland, Rustoen, & Vileikyte, 2001).

Ragnarson Tennvall and Apelqvist (2000) compared QOL between three groups of patients: those with current diabetic foot ulcers, those with healed ulcers, and those who have undergone minor and major amputations. The authors reported that QOL was significantly lower in patients with current diabetic foot ulcers than in patients with...
healed ulcers. Not surprisingly, QOL was also found to be reduced following major amputations.

A qualitative study by Brod (1998) demonstrated that not just the patients with foot ulcerations but also their caregivers are affected. The participants reported that the condition had an adverse impact on all QOL domains, primarily as a result of the reduction in mobility experienced following ulceration/amputation, and the consequent need to adapt their lifestyles. In terms of the social domains encompassing leisure activities, social life and family life, patients found that their loss of mobility greatly affected their ability to perform their usual roles and visitation with family and friends, and to engage in hobbies and leisure time activities. In addition, perceived over dependence of patients on immediate family members and emotional tension were sources of friction in family life (Brod, 1998; Price, 2004; Vileikyte, 2001).

The lives of patients with foot ulcerations were also adversely affected economically. About 50% of patients with foot ulcerations were no longer working because of their ulcer and their productivity and career advancement were limited by their condition. Although ulcer treatment may be free, there were costs associated with traveling to hospital appointments, and buying proper footwear. Patients often tried to hide their condition from the employers for fear of losing their jobs; however, it eventually became unfeasible to remain in the job without seriously jeopardizing the physical condition of their feet. For most of the younger patients, loss of employment opportunity resulted in diminished self-esteem (Price, 2004; Vileikyte, 2001).

In the psychological domain, individuals with foot ulcerations reported feelings of frustration, anger and guilt, as well as anxiety about the possible development of new
ulcers and the threat of amputations. Carrington, Mawdsley and Morley (1996) compared the QOL of patients with diabetes and chronic foot ulceration or unilateral lower limb amputation with the QOL of patients who had diabetes without a history of foot complications. Both amputees and patients with ulcers were found to have a significantly poorer psychosocial adjustment to illness than those without a history of foot complications. Those with ulcers were more depressed and less satisfied with their personal lives than the patients without ulceration. Finally, patients with foot ulcers expressed the most negative attitudes, indicating that, of all three groups, they had the lowest psychological functions. In a sample of 134 persons who had amputations (Thompson & Haran, 1984), 61 of whom had been wearing prostheses for up to 2 years, almost half were found to be at risk of psychiatric illness, and 13% stated that amputation contributed to depression.

The results of these studies confirm that the development of a diabetic foot ulcer has specific negative effects on health-related QOL. The overriding concern of affected patients and their care-givers is the lack of mobility, which impacts upon all aspects of their lives. A diminished social life and increased sense of social isolation are common and have very damaging consequences on their well-being. The requirement for time off work impacts job prospects and is a cause of anxiety for young patients (Vileikyte, 2001).

**Economic Consequences of Foot Ulceration and Lower-Extremity Amputation**

In addition to influencing QOL, foot problems result in substantial economic consequences for patients with diabetes, their families, and society. It was estimated that for patients with diabetes who had a foot ulceration or amputation in the US, the total costs of care corrected to 1998 currency were US$16,437 for a non-ischemic ulceration,
$27,203 for an ischemic ulceration, $43,892 for a minor amputation, and $64,265 for a major amputation (Apelqvist, Ragnarson-Tennvall, & Larsson, 1995; Ragnarson-Tennvall & Apelqvist, 2004). Foot ulcerations and amputations were estimated to cost US healthcare payers $10.9 billion in 2001 (Gordois, Scuffham, Shearer, Oglesby, & Tobian, 2003a; Shearer, Scuffham, Gordois, & Oglesby, 2003). In Canada, the estimated direct and indirect costs of an amputation were between $35,000 and $50,000 per patient per year. By 2010, it was estimated that treatment for diabetes and diabetes-related complications such as foot ulcerations would cost the Canadian healthcare system $15.6 billion a year and that number would rise to $19.2 billion by 2020 (CDA, 2005-2009). UK estimates based on the same methodology were 5% of the total national health services expenditure in 2001 (£3 billion). The total annual cost of diabetes-related foot complications was estimated at £252 million (Gordois, Scuffham, Shearer, & Oglesby, 2003b).

Based on recent studies in North America and Europe, up to 20% of total expenditure on diabetes care might be attributable to the management of foot ulcerations (Girod et al., 2003; Gordois et al., 2003 a, b; Shearer et al., 2003; Van Acker, Oleen-Burkey, & De Decker, 2000). Foot problems have become an enormous, global disease burden in terms of epidemiology and economic consequences. Several national and international organizations have therefore set goals, objectives and declarations aimed at reducing amputation rates by 50% (World Health Organization [WHO, Europe] and International Diabetes Federation [IDF, Europe], 1990; Halpin-Landry & Goldsmith, 1999). The International Diabetes Federation has chosen to focus on the global burden of diabetic foot disease in 2005 (Wild, Roglic, Green, Sicree, & King, 2004; IDF, 2005).
The International Diabetes Foundation has therefore declared that now is the time to increase awareness of foot problems in persons with diabetes (Jeffcoate & Bakker, 2005) in view of the vast personal, social, medical, and economic costs of what should be one of the most preventable long-term complications of diabetes (Boulton, 2004; Vileikyte et al., 2006).

**Risk Factors of Foot Ulceration and Lower-Extremity Amputation**

Risk factors identification is fundamental for effective prevention of the foot problems leading to ulceration in patients with diabetes (ADA, 2010; CDA, 2008; RNAO, 2004 & 2005). Halpin-Landry and Goldsmith (1999) proposed that a foot ulceration risk profile includes both modifiable and non-modifiable factors. Modifiable factors include poor glucose control, smoking, minor foot trauma, inappropriate foot care behaviors and inadequate knowledge of foot care. Patients can control or modify these factors. Non-modifiable factors include advanced age, male sex, long duration of diabetes, impaired visual acuity, microvascular disease (i.e., neuropathy, retinopathy and nephropathy), and macrovascular disease (i.e., peripheral vascular diseases, and cardiovascular disease), altered biomechanics (i.e., foot deformity and limited joint mobility), and previous foot ulcers or amputation, over which the patient has no control (Halpin-Landry & Goldsmith, 1999). Although it is nearly impossible to change these non-modifiable risk factors, patient educational intervention focusing on preventing foot ulceration can alter modifiable risk factors (Halpin-Landry & Goldsmith, 1999; Levin, 1995).

Of the modifiable and non-modifiable risk factors for foot ulceration and amputation, five principal factors increase significantly the risk of foot ulcerations and lower-extremity amputations. These include: sensation (peripheral neuropathy),
circulation (peripheral vascular disease), altered biomechanics, a history of previous foot ulceration or amputation, and inappropriate foot self-care behavior and knowledge (ADA, 2010; RNAO, 2004 & 2005; Mayfield et al., 1998).

**Sensation**

The most common symptom of peripheral neuropathy in patients with diabetes is changes in sensation in the feet (ADA, 2010; CDA, 2008; Mayfield et al., 1998). The prevalence of neuropathy increases with age, duration of diabetes, and poor blood glucose control (ADA, 2004 & 2010; Mayfield et al., 1998). Peripheral neuropathy can result in loss of protective sensation in the foot that is associated with an 8-to 18-fold higher risk of ulceration and a 2-to 15-fold higher risk of amputation (Lavery et al., 2007; Patak, Herrmann, Regat, & Vuagnat, 2008; Valk, Kriegsman, & Assendelft, 2007).

Diabetic neuropathy involves varying degrees of sensory neuropathy, motor neuropathy and autonomic neuropathy (Melbourne Health, 2004). Sensory neuropathy is the most common form of clinical neuropathy, affecting up to 50% of patients who have had diabetes for more than 15 years (Kumar, Ashe, & Fernando et al., 1994). It results in the loss of protective sensation, and is probably the greatest independent risk factor for lower-extremity ulceration (Boulton, 1994; Kumar, Ashe, & Parnell, 1994). Protective sensation is defined as the level of feeling necessary to protect the lower extremity from injury (Umeh, Wallhagen, & Nicoloff, 1999).

Sensory neuropathy causes loss of the sensory network's protective functions (Halpin-Landry & Goldsmith, 1999). Both small and large nerve fibers are affected in diabetes-associated peripheral sensory neuropathy. Damage to small nerve fibers of the feet causes numbness, burning, tingling, itching, and pain. Large nerve fiber damage
causes changes in vibratory perception, proprioception, and deep tendon reflexes (Sieggreen, 2005). Twenty to 50% of people with diabetes who have had diabetes for more than 10 years will experience distal sensory neuropathy, resulting in progressive distal-to-proximal loss of sensation in both lower extremities. After the toes have been affected, neuropathy spreads to the rest of the foot; in severe cases, it may progress to knee level. A major concern with sensory neuropathy is loss of protective sensation in patients with diabetes: they will not be able to feel pain or discomfort while walking and therefore will not compensate for plantar pressures by changing gait pattern to avoid injury (Halpin-Landry & Goldsmith, 1999). A 10g (5.07 cm in length) Semmes-Weinstein monofilament is recommended as the screening test of choice for detecting loss of protective sensation in patients with diabetes (ADA, 1020; CDA, 2008; Kumar, 1991; RNAO, 2004 & 2005). The monofilament is calibrated to buckle when a 10g force is applied and the foot is considered insensate if a patient cannot feel the applied pressure. The monofilament examination has the advantages of being cheap, easy to perform, reproducible, and practical across a spectrum of practice settings.

Motor neuropathy impairs functioning of the intrinsic muscles of the affected body part. When the foot is initially affected, the metatarsals flex and the toes draw up into a "claw" position. This creates pressure points beneath the metatarsal heads and over the dorsum and tips of the toes. At the same time, the sensory component of neuropathy diminishes awareness of these pressure points (Halpin-Landry & Goldsmith, 1999). Foot deformities may include mallet, hammer, and claw-toes, bunions (hallux varus or valgus), and bony prominences. Motor neuropathy weakens foot muscles, leading to deformities
and gait changes. Increased pressure or shear stress over deformed bony prominences sets the stage for ulceration (Sieggreen, 2005). These changes increase the risk for ulceration.

Autonomic neuropathy in the skin results in atrophic skin changes, nail loss, and failure of the foot to perspire that affects the sweat glands, reducing or eliminating perspiration and leading to dry, flaky, and cracked, atrophic skin and encouraging callus formation (Halpin-Landry & Goldsmith, 1999; Sieggreen, 2005).

**Circulation**

The abnormal metabolic state accompanying diabetes results in changes in the state of arterial structure and function (ADA, 2011) leading to peripheral vascular disease. Peripheral vascular disease, defined as atherosclerosis of the peripheral arteries and characterized by atherosclerotic occlusive disease of the lower extremities, is 4 to 20 times more likely to develop in people with diabetes than in the general population. As such, it is a major risk factor for lower-extremity amputation (ADA, 2011; Ahroni & Scheffler, 2006; Kannel & McGee, 1979; Sieggreen, 2005). Peripheral vascular disease reduces blood flow to the legs and feet which contributes to ulcer formation and compromises healing (ADA, 2010 & 2011; Sieggreen, 2005). Peripheral vascular disease plays a major role in delayed wound healing and in the development of gangrene, thereby contributing to almost half of the amputations among persons with diabetes (ADA, 2004 & 2010; Fletcher, 2006; Gregg, Sorlie, & Paulose-Ram, 2004; Tapp, Zimmet, & Harper, 2004; Valk et al., 2007).

Peripheral vascular disease leads to the poor circulation in lower extremities, manifested in absence of pulse. It is clinically identified by intermittent claudication (calf pain), rest pain, and / or absence of peripheral pulses in the lower legs and feet. These
clinical manifestations reflect decreased arterial perfusion of the lower extremity (ADA, 2010 & 2011; Palumbo & Joseph Melton, 1995). It was noted in 15% of patients at 10 years and 45% of patients at 20 years after diagnosis of diabetes (Sieggreen, 2005). Peripheral vascular disease affects the femoral and iliac arteries in a similar rate in people with and without diabetes; however, those with diabetes are much more likely to have involvement of the peroneal and tibial artery vessels (Melbourne Health, 2004). Peripheral vascular disease related to poor circulation plays a major role in delayed wound healing and development of gangrene and is a contributing factor to almost half of the amputations (Pecoraro et al., 1990).

The presence of peripheral pedal pulses represents a minimum systolic pressure of 80 mmHg (Lavery & Gazewood, 2000). The National Evidence Based Guidelines for the Management of Type 2 Diabetes (Australian Centre for Diabetes Strategies, 2005) states that the absence of peripheral pulses has prognostic significance for future amputation in people with or without foot ulceration.

Claudication is defined as pain in the calf, cramping, or aching in the calf or thigh that develops upon walking exercise and is relieved by rest (ADA, 2011; Mayfield, et al., 1998). Rest pain, is a continuous burning pain due to ischemia of the lower extremities that often awaken patients at night when sleeping and is relieved by sitting or standing (Mayfield, et al., 1998). There has been report of diagnostic benefits in combining the results of clinical history and examination findings when attempting to initially identify individuals with peripheral vascular disease by health care professionals (ADA, 2010; CDA, 2008; McGee & Boyko, 1998). Although a number of non-invasive, and more accurate investigative modalities, such as use of Doppler testing and ankle-brachial index
(ABI), have been used to identify individuals with poor distal blood flow, implementing these tests needs availability of medical devices, and special training for health care professionals. Two commonly used tests for initial screening of peripheral vascular disease are the absence of peripheral pulses and the presence of claudication or rest pain (ADA, 2011). RNAO best practice guidelines (2004 & 2005) suggest that nurses may conduct the initial assessment of circulation in lower extremity by assessing the pedal pulses and taking clinical history such as claudication or rest pain (McGee & Boyko, 1998).

Palpation of pedal pulses is the most common means for initially assessing circulation condition of the lower extremities. Palpation is an easy, simple, convenient, non-invasive, inexpensive initial clinical screening for distal blood flow status. One study showed that pulse palpation in 458 volunteers with diabetes had a sensitivity/specificity of 67 to 69%, using a gold standard of blood pressures, treadmills, and Doppler studies (Marinelli, Beach, Glass, Primozich, & Strandness, 1979). Therefore, the initial clinical screening for peripheral artery disease contains assessment for history of claudication and rest pain, and examination of signs of clinical compromise by palpating lower extremities’ dorsalis pedis and posterior tibial artery pulses (ADA, 2010 & 2011; RNAO, 2004 & 2005).

**Altered Structure and Biomechanics of the Feet**

Altered biomechanics can cause excessive plantar pressure. Foot deformity such as mallet, hammer or claw toes, flat feet, bunions, and limited joint mobility also are related to excessive plantar pressure that cause the development of calluses and corns (Abu-Qamar, 2006; McGuire, 2006; Mueller, Hastings, & Commean, 2003; Zimny,
Calluses may function as a foreign body at the skin surface and further increase localized pressure by up to 29%. Calluses were associated with an 11-fold higher risk of ulcers. Abnormal foot skin conditions increase the risk of foot ulcers. The site of ulceration is highly related to the associated foot pathology and pivotal event. One recent study found that the particular triad of minor trauma, foot ulceration, and wound healing failure preceded 72% of amputations, often in combination with gangrene and infection (Halpin-Landry & Goldsmith, 1999). Minor foot trauma, especially when repetitive such as rubbing from unfitting footwear, improper cutting of toenails, dryness or cracking of the skin, edema, fungal infection, and ingrown toenails can lead to skin disruption and subsequent ulcerations (Altman & Altman, 2000; Anarella, Toth, & DeBello, 2001; Boike & Hall, 2002; Chincholikar & Pal, 2002; Fletcher, 2006; Gupta & Humke, 2000; Mayser, Hensel, & Thoma, 2004).

**Previous History of Foot Ulceration or Lower Extremity Amputation**

Foot ulcerations are open sores that occur on the feet (Apelqvist, Larsson, & Agardh, 1990). There are three common types of foot ulcerations: venous stasis ulcers, arterial (ischemic) ulcers, and neurotrophic (diabetic) ulcers. Arterial and neurotrophic ulcers are frequently experienced by patients with diabetes (ADA, 2004 & 2010).

Previous history of foot ulceration or low-extremity amputation (related problems in peripheral neuropathy, peripheral artery disease, trauma or other factors) is one of the key risk factors for recurrence of foot ulceration and subsequent lower extremity amputation (ADA, 2010; CDA, 2008). Recurrence rates for foot ulcers may be as high as 50-70% over 3-5 years (ADA, 1999; Apelqvist et al., 1990; Bloomgarden, 2008). Empirical evidence showed that previous foot ulceration or amputation increases the risk
of a new ulceration 13-fold and the risk of amputation 2 to 10.5 fold (Abu-Qamar, 2006; Lee, Lu, & Lee, 1993; Maluf & Mueller, 2003; Mayfield, et al., 1996). A foot ulceration history is described as preceding approximately 85% of lower extremity amputations (Pecoraro et al., 1990).

**Knowledge and performance of Foot Self-Care**

Patients’ knowledge of and performance of foot self-care behavior are significant factors in foot ulcer development (ADA, 2010; CDA, 2008; Reiber, Vileikyte, & Boyko, 1999). Poor knowledge and performance of foot self-care have been considered risk factors for foot ulceration in patients with diabetes. Lack of patient education on foot care is associated with inadequate knowledge of foot self-care strategies that are useful for addressing foot problems and preventing ulceration (RNAO, 2004 & 2005). Foot care education is significantly linked with increased knowledge and performance of foot self-care (CDA, 2008; Hutchinson et al., 2000; Valk et al., 2007) and reduced amputation risk (Reiber, Pecoraro & Koepsell, 1992). Evidence showed that the lack of foot-care education has been associated with a 1 to 3.2 fold increased risk of ulceration and amputation (Fan et al., 2006; Mason et al., 1999).

**Other Risk Factors**

In addition to the above-mentioned five principal risk factors for foot ulceration and amputation, evidence shows that other factors are related to foot complications including advanced age, increased duration of diabetes, male sex, ethnicity, lower socioeconomic status, living alone, poor blood glucose control, impaired vision acuity, smoking, presence of other complications including microvascular diseases (retinopathy, nephropathy) and macrovascular diseases (coronary artery disease).
The risk of ulcers and amputation increases two to four fold with increasing age and duration of diabetes (Levin, 1995; Moss, Klein, & Klein, 1992 & 1999; Nelson et al., 1988; Rith-Najarian & Reiber, 2000). In the U.S., between 1989 and 1993, the prevalence of amputations was 1.6% for diabetic people aged 18-44 years, 2.4% for people aged 45-64 years, and 3.6% for people aged ≥ 65 years. In Wisconsin, the prevalence of amputation was 2.4% for people with diabetes onset before age 30 years, and 4.4% for people with older onset diabetes (Moss, Klein, & Klein, 1992 & 1999). Duration of diabetes is a predominant predictor of ulcer and amputation (Moss et al., 1992 & 1999; Mayfield, et al., 1996). Long duration of diabetes (>10 years) increased in 3 fold the risk of ulcers and amputation (ADA, 2004; Lavery et al., 1998).

Male sex has been associated with 1.6 increased risk of ulcers (Moss et al., 1992 & 1999) and 2.8- to 6.5-fold higher risk of amputation (Mayfield, Reiber, Nelson, & Greene, 1996; Moss et al., 1992 & 1999; Rith-Najarian & Reiber, 2000; Selby & Zhang, 1995) in people with type 2 diabetes. The mechanism of the increased risk for men is not clear and requires further investigation. A two fold higher risk of amputation has been described for Hispanics and African-Americans as compared to Whites (Lavery et al., 1996) and up to a four fold higher rate was reported for Pima Indians (Nelson et al., 1988). The reason may be related to diet high in carbohydrates and lack of exercise. However, an analysis of a California health maintenance organization database found no difference by race (Selby & Zhang, 1995).

The prevalence of foot ulcer increased with smoking, from 10.3% among nonsmokers to 11.9% among former smokers to 15.8% among current smokers (CDC, 2002). Cigarette smoking is associated, in a dose response manner, with an increased rate
of major lower-extremity amputation. There was a strongly significant association between smoking more than 10 cigarettes per day and amputation compared with those who smoked less than 10 cigarettes per day (Adam, Mahmoud, & Mohamed E Ahmed, 2009).

The lack of "social connectedness", which is defined as living alone, no visits from a friend or relative in the past month, non-attendance at social or religious gatherings, and personal life dissatisfaction, is associated with a 2.1 to 3.8-fold higher risk of amputation (Reiber, Pecoraro, & Koepsell, 1992). People presenting with a foot ulcer were more likely to live alone or be from a lower socio-economic class (Masson et al., 1989).

Poor blood glucose control increases the risk of neuropathy and amputation (ADA, 2004 & 2010; CDA, 2008; Lee et al., 1993; Lehto, Ronnemaa, Pyorala, & Laakso et al., 1996; Moss, Klein, & Klein, 1992; Selby & Zhang, 1995). A glycosylated hemoglobin (HbA1c) level > 13.4% was associated with a 2.2 relative risk of amputation in Finnish people with type 2 diabetes (Lehto et al., 1996). Similarly, a 50 mg/dl increase in the mean random glucose in the Pima Indians was associated with a 1.6 odds ratio (OR) for amputation (Mayfield et al., 1996). A 1.4-1.5 increased risk of self reported ulcers was associated with a 2% increase in HbA1c in people with both type 1 and type 2 diabetes in Wisconsin (Moss et al., 1992). Poor blood glucose control (HbA1c > 9%) was associated with a 3.2 Odds for ulceration in patients with diabetes (Lavery et al., 1998). Impaired vision (acuity <20/40) associated with diabetes may also limit self-care, and had a 1.9 relative risk for foot ulceration (Boyko et al., 1999).
The high prevalence and serious complications of foot ulceration demand prompt intervention. Educational interventions are necessary to raise awareness of patients with diabetes of the risk factors for foot ulcerations and to assist them address modifiable risk factors and prevent the occurrence of foot ulceration (CDA, 2008; Halpin-Landry & Goldsmith, 1999; RNAO, 2004 & 2005).

**Effects of Foot Self-Care Educational Interventions**

Much effort and research have been directed towards primary patient education to prevent foot complications among patients with diabetes during the past two decades. In this section, a critical review of studies that evaluated the effects of educational interventions focusing on the foot self-care knowledge, foot self-care self-efficacy, foot self-care behaviors, and foot problems in patients with diabetes is presented below.

1) **Foot Self-Care Knowledge**

Foot self-care knowledge refers to specific information about the risk factors and different aspects of foot self-care. Foot self-care knowledge is identified as essential for understanding the importance of performing foot self-care, and preventing foot ulceration in patients with diabetes (Clinical Practice Guidelines Expert Committee, 2003; RNAO, 2004 & 2005). Seven studies were found in which foot self-care knowledge was evaluated as an outcome of educational interventions targeting patients with diabetes. Foot self-care knowledge was measured using a variety of instruments before and after the implementation of the intervention (Barth, Campbell, Allen, Jupp, & Chisholm, 1991; Borges & Ostwald, 2008; Corbett, 2003; Fan, et al., 2006; Hamalainen et al., 1998; Kruger & Guthrie, 1992; Rettig, Shrauger, Recker, Gallagher, & Wiltse, 1986; Ronnemaa, Hamalainen, Toikka, & Liukkonen, 1997).
The educational interventions evaluated in the seven studies varied in terms of content, format, and dose. The interventions covered content related to daily feet hygiene such as washing feet, drying feet, inspecting feet, moisturizing feet, and foot exercise, foot problems evaluation, toenails care, and wearing suitable shoes and socks (Barth et al., 1991; Corbett, 2003; Fan et al., 2006; Hamalainan et al., 1997 & 1998; Kruger & Guthrie, 1992) and risk factors for foot ulceration (Borges & Ostwald, 2008; Corbett, 2003; Fan et al., 2006; Hamalainan et al., 1997 & 1998; Rettig et al., 1986). The educational interventions were individualized in five studies (Borges & Ostwald, 2008; Corbett, 2003; Fan et al., 2006; Hamalainan et al., 1997 &1998; Rettig et al., 1986). One study applied hands-on teaching strategies to enhance the effectiveness of educational intervention (Kruger & Guthrie, 1992). The dose of the interventions varied from 20-minute to 90-minute sessions, given over a 6-month period.

Despite variability in the specific content of the intervention, results of five (of seven) studies demonstrated that the foot self-care knowledge increased significantly after implementation of the intervention focusing on foot care (Barth et al., 1991; Corbett, 2003; Fan et al., 2006; Hamalainan et al., 1997 & 1998; Rettig et al., 1986). Three studies showed sustained increase in foot self-care knowledge following educational interventions within one month (Barth et al., 1991), three months (Corbett, 2003), and nine months post intervention (Fan, et al., 2006). One study showed maintenance in knowledge gains for up to seven years (Hamalainan et al., 1998). However, the increase in knowledge was of a small-moderate magnitude.

The validity and reliability of the instruments measuring foot self-care knowledge were not reported in most studies. Measurement error presents a threat to construct
validity and reduces statistical power to detect significant effects (Shadish, Cook & Campbell, 2002). None of the studies examined the foot self-care knowledge in patients with diabetes at low risk for foot ulceration.

2) Foot Self-Care Efficacy

Bandura’s social cognitive theory (1989) states that successful self-care is dependent on supporting a person’s knowledge and skills, and enhancing a sense of self-efficacy, that is ongoing confidence in personal ability to put knowledge and skills into practice (Bandura, 1989). Two studies investigated the effects of educational interventions on self-efficacy related to foot self-care in patients with diabetes. Other studies examined the relationship between self-efficacy and adherence to general self-care behaviors in patients with diabetes.

Corbett (2003) examined a brief individualized foot self-care educational intervention provided by home care nurses to 40 patients with diabetes. Participants in the intervention group showed a significant overall improvement in self-efficacy (p=0.014).

Borges and Ostwald (2008) examined the effects of two interventions aimed at promoting Mexican American patients’ engagement in foot self-care behaviors. The interventions included risk assessment and brief education. In the risk assessment intervention, participants received a 5-minute foot examination to assess the risk for lower extremity amputation. In the brief educational intervention, participants received a foot examination of their risk for lower extremity amputation and were asked to demonstrate the use of the monofilament. Participants also received a 15-minute brief foot self-care educational intervention. Diabetes self-efficacy scores were high at baseline and remained high at follow-up for all groups resulting in a ceiling effect. Therefore, no
statistically significant difference in self-efficacy scores between groups was noted at follow-up (p=0.11).

Self-efficacy, a key construct in social cognitive theory, acts as the mediating link between cognitive preparation (knowledge and skills) and actual task performance (Bernal, Woolley, & Schensul, 1997). Bandura (1986) and others (Strecher, DeVellis, & Becker, 1986) have shown that self-efficacy is a powerful predictor of one’s approach to tasks, perseverance at tasks, and task success in a variety of settings.

Several correlational studies examined self-efficacy in adult patients with diabetes and found that self-efficacy was successful in predicting levels of adherence to self-care. Grossman, Brink, and Hauser (1987) found a positive association between self-efficacy and metabolic control in young women. Crabtree (1986) found that self-efficacy was a predictor of diet, exercise, and general self-care. Hurly and Shea (1992) found that self-efficacy accounts for one third of the variance in diabetes self-care management. Sousa et al. (2004) reported that individuals with greater diabetes knowledge had greater self-efficacy and those with greater self-efficacy had better diabetes self-care management. In summary, the predictive ability of self-efficacy to explain adherence to diabetes general self-management behaviors such as diet, exercise, and home blood testing, was supported in several studies (Homko, Silvan, & Reece, 2002; Rapley & Fruin, 1999; Via & Salyer, 1999; Rose, Fliege, Hildebrandt, Schirop, & Klapp, 2002; Senecal, Nouwen, & White, 2000; Skelly, Marshall, Haughey, Davis, & Dunford, 1995).

Despite the association of self-efficacy with general self-care behavior performance, only two studies examined the effects of educational interventions on self-efficacy related to foot-care among patients with diabetes. The results of the two studies
were inconsistent which may be explained by the nature of the interventions, which may not have specifically targeted self-efficacy. Therefore, the extent to which educational interventions improve self-efficacy of foot self-care, specifically in patients with diabetes at low risk for ulceration, is unknown, and was examined in this study.

3) Foot Self-Care Behaviors

Foot self-care behaviors are actions in which patients with diabetes engage to prevent or manage foot problems. These foot self-care behaviors are derived from practice guidelines (Clinical Practice Guidelines Expert Committee, 2003; RNAO, 2004 & 2005). They fall within the following commonly reported categories: washing feet; inspecting feet every day for abnormal conditions such as swelling, redness, tenderness, cut, blisters, and ulcers; applying lotion to moisturize feet skin every day after bath; massaging the feet and lower legs to keep the blood flowing to the feet; performing exercise of lower extremity; selecting and using appropriate shoes and socks; and correct cutting of toenails (Fan et al., 2005 & 2006; Halpin-Landry & Goldsmith, 1999; Kiely, 2006; LeMone & Burke, 2006; RNAO, 2004; US National Institutes of Health, 2008; Zhang, Fan, & Yu, 2006).

Seven studies examined performance of foot self-care behaviors following educational interventions (Borges & Ostwald, 2008; Corbett, 2003; Fan et al., 2006; Hamlainen et al., 1998; Kruger & Guthrie, 1992; Litzelman et al., 1993; Rettig et al., 1986). The findings are summarized in Appendix 1. The results of one study indicated that there were no significant differences on foot-care behavior between two groups at one month follow-up (Borges & Ostwald, 2008). Six studies’ results showed that educational interventions increased performance of foot self-care behaviors in patients
with diabetes post intervention. Performance of foot self-care behaviors was assessed with different instruments that demonstrated reliability and validity. No study examined the foot self-care behaviors in patients with diabetes at low risk for foot ulceration.

4) Foot Problems

The results of eight studies that examined the effects of educational interventions on foot problems are presented in Appendix 1. The studies’ results were inconsistent. Three studies demonstrated that minor foot problems were reduced between nine months and one year following the interventions (Fan, et al., 2006; Litzelmean et al., 1993; Ronnemaa, et al.,1997), and one study showed that the major foot problems such as ulcerations and lower extremities amputations were reduced significantly one year post intervention (Malone et al., 1989). Four studies did not show significant reduction in the occurrence of foot problems after the educational interventions (Barth et al., 1991; Bloomgarden et al., 1987; Hamlainen et al., 1998; Rettig et al., 1986). Of the eight studies, one targeted patients with diabetes at high risk for foot ulcerations, whereas seven studies did not identify patients’ risk for foot ulcerations. The possible reasons for the inconsistent results may primarily be associated with the inclusion of participants at low and high risk for foot problems, and the time for follow-up assessment. There is a need to separate patients at low and high risk for foot ulcers and to observe the effects of educational interventions on changes in foot problems at short (1-3 months) and intermediate (3-6 months), and long term (6-12 months or longer). The present study pilot tested the short-term (3 months) effects of a foot self-care educational intervention on foot problems in patients with diabetes at low risk for foot ulceration.

5) Wearing Shoes and Socks Condition
The most common cause of self-injury in persons with diabetes was ill-fitting new shoes (Isakov, Susak, Budoragin, & Mendelevich, 1992). Improper fitting shoes and socks are major contributors to diabetes foot ulcerations (Pedorthic Association of Canada, 2009). Use of proper footwear plays a positive role in protection of foot from injury, and the prevention of foot lesions by reducing ulceration associated with peripheral neuropathy (Levin, 1993; Reddy, Vaid, & Child, 1989; Soulier, Godsey, Asay, & Perrotta, 1987). Most studies that focused on assessment of shoes and socks in patients with diabetes were descriptive studies. These findings indicated that nearly a third of participants wore improper fitting shoes and socks (Burns, Leese, & McMurdo, 2002; Fan et al., 2006; Reddy et al., 1989).

Two experimental studies that examined the effects of educational interventions on shoe and sock practices showed inconsistent results. Fan et al. (2006) found that the percentage of patients with diabetes wearing improper shoes and socks significantly decreased at 9-month post-intervention. Litzelman et al. (1997) conducted a prospective evaluation of footwear characteristics as predictors of diabetic foot wounds. Their study found no difference in the types and quality of footwear worn between intervention and control groups at one year follow-up (Litzelman, Marriot, & Vinicor, 1997).

Summary

The results of the previously reviewed studies provided some evidence suggesting that educational interventions result in an increase in foot self-care knowledge and performance of foot self-care behaviors, and in a reduction of foot problems in patients with diabetes. Research on self-efficacy of foot-care is rare and the results of the only two studies are inconsistent. Of the studies reviewed, only one targeted patients with diabetes.
at high risk for foot ulceration, whereas the rest of the studies did not identify patients’ risk for foot ulceration. Including a mix of participants at high and low risk for foot ulcers could have contributed to inconsistent results for foot problems.

The present foot self-care educational intervention is adapted from a previous study, and targets adult Canadians with type 2 diabetes at low risk for foot ulceration. The adaptation involved incorporating strategies to enhance self-efficacy and performance of recommended foot self-care behaviors. The intervention mode of delivery included one-on-one, interactive teaching and discussion, hands-on practice training, and telephone contact booster sessions.

**Conceptual Framework**

The social cognitive theory gave direction to the adaptation of the intervention and its evaluation (Bandura, 1989 & 1997). In this section, the social cognitive theory is briefly reviewed and the intervention theory that guided the evaluation of the intervention is presented.

**Social Cognitive Theory**

Self-efficacy is the main concept in the Social Cognitive Theory. Self-efficacy is the amount of confidence a person believes he or she has to perform a set of specific activities or behaviors. It is “the exercise of human agency through people’s beliefs in their capabilities to produce desired effects by their action” (Bandura, 1997).

The social cognitive theory presumes that self-efficacy is the most predictive factor in the development and maintenance of a new behavior. Bandura (1997) proposes that people who are persuaded that they can succeed are more likely to expend the effort needed to perform the behavior. Accordingly, interventions aimed at changing health
behaviors should strengthen the patients’ efficacy beliefs. People with high self-efficacy are more likely to invest their personal resources to sustain the level of effort needed to adopt, adhere, and maintain health-promoting behaviors. Performance of these behaviors can improve health-related quality of life and reduce the need for medical services.

Successful self-management is dependent on supporting a person’s knowledge and skill, while also ensuring ongoing confidence in being able to put this knowledge and skill into practice. Bandura (1997)’s principal sources of efficacy information which were applied in the intervention under investigation to enhance self-efficacy included mastery experience or performance attainments, vicarious experiences, and verbal persuasion. Mastery experience or performance attainment is the most influential source of self-efficacy information and requires that individuals have the opportunity to master a task. Human beings grow from their successes and failures; they manage failures to learn from their mistakes. Bandura notes that mastery is the most successful form of building self-efficacy. The implication for the design of the educational intervention is that researcher should assist patients with diabetes to learn knowledge and skills of foot self-care through training, and provide patients opportunities to apply the skills learned.

The second way of creating and strengthening self-efficacy used in the intervention under evaluation relates to “vicarious experiences” (Bandura, 1997, p.86). Vicarious experience refers to learning through observing others. It requires that individuals have a role model with whom they can compare their own behavior. Seeing people similar to oneself succeed by sustained effort raises the observers' confidence that they too possess the capabilities to master comparable skills. They persuade themselves that if others can do it, they should be able to achieve at least some improvement in
performance. For example, if person A views person B as successful and competent, then person A is likely to model the same behavior exhibited by person B. Thus, an intervention aimed at enhancing self-efficacy should arrange opportunities for observing other people’s practice of foot self-care behaviors, and sharing of successful experience in foot self-care. In the foot self-care educational intervention under study, vicarious experiences were promoted through observation of foot self-care practices shown in slide presentation and demonstrated by the researcher.

Verbal persuasion is the third way used in the intervention under evaluation to strengthen people’s self-efficacy through discussion that they have what it takes to succeed (Bandura, 1997, p.101). Verbal persuasion refers to the process of giving praise and coaching, and is probably dependent on who is giving it. To the extent that persuasive boosts in self-efficacy lead people to try hard enough to succeed, they promote development of skills and a sense of self-efficacy. Accordingly, in this proposed foot self-care educational intervention, presentation and provision of feedback by the educator were used to enhance self-efficacy in foot self-care.

The physiological state, which refers to the level of arousal (related to stress and anxiety) present during task attainment may affect performance of a particular task. (Bandura, 1997; Bernal, Woolley, Schensul, & Dickinson, 2000). Helping persons to reduce their level of arousal prior to task performance is one strategy to enhance self-efficacy. This strategy was not incorporated in the foot self-care educational intervention under evaluation.

It is assumed that manipulating sources of self-efficacy can result in the adoption and enhancement of health behaviors. Several studies found that self-efficacy of persons
with diabetes predicted their levels of adherence to self-care and improved diabetes self-management. Self-efficacy is both an outcome of interventions and a predictor of functional status and performance of self-care behaviors in patients with diabetes (Allen, 2004; Homko, Silvan, & Reece, 2002; Rapley & Fruin, 1999; Rose et al., 2002; Senecal, Nouwen, & White, 2000; Skelly, Marshall, Haughey, Davis, & Dunford, 1995; Sousa, Zauszniewski, Musil, McDonald, & Milligan, 2004; Via & Salyer, 1999).

In light of Bandura’ self-efficacy theory (1997), bolstering confidence in the patients’ ability to effectively implement self-care strategies is an important aspect of interventions for promoting active patients’ involvement in diabetes self-care (Ellison & Rayman, 1998). The theory guided the development of the intervention theory. An intervention theory usually explains how the intervention works, and specifies the components and outcomes of the intervention. The components of the intervention under investigation that enhance foot self-care knowledge, skills, and self-efficacy consisted of a lecture presentation and discussion, foot self-care hands-on training, and telephone contact booster sessions. The lecture presentation primarily provides relevant information to strengthen patient's self-efficacy of foot self-care through verbal persuasion. The hands-on training session, which assists patients to master the related foot self-care skills and successfully implement foot self-care behaviors, enhances self-efficacy through performance attainment. Additionally, the hands-on training session enhances self-efficacy through vicarious experiences of observing the performance of the foot self-care behaviors. Also, telephone contact booster sessions, which address patients’ concerns, and remind their performance of foot self-care in daily life, enhance self-efficacy through verbal persuasion.
**Intervention Theory**

Theories are important to intervention evaluation research because they guide the development of the intervention and the design and conduct of the evaluation study (Cooper Brathwaite, 2003). An intervention theory specifies the nature of the intervention, the nature of the ultimate outcomes expected of the intervention, the processes mediating the intervention effects on the ultimate outcomes, and the conditions affecting the intervention delivery and effectiveness (Sidani & Braden, 1998).

An intervention theory includes the following elements: problem definition, the critical inputs, and the expected outcomes. Problem definition refers to the condition amenable to treatment by the intervention in a particular patient population. Critical inputs define the components, mode of delivery and dosage of the intervention required for the achievement of the intended outcomes. The expected outcomes refer to the changes expected after the intervention delivery (Sidani & Braden, 1998). Elements of the theory underlying the foot care educational intervention are described next.

**Problem Definition**

As identified previously, the problem is the lack of knowledge related to appropriate foot self-care. Empirical evidence indicates that most patients with diabetes do not pay attention to protecting their foot, are not aware of the risk factors for foot ulceration, and have limited knowledge of strategies to prevent foot ulceration and its complications (Boulton et al., 1999; Reiber et al., 1998; Uccioli, Aldeghi, & Faglia, 1995). Plummer and Albert (1995) reported that up to 40% of patients with diabetes reported insufficient foot care knowledge, basic errors in foot care, and poor foot condition on a daily basis. Lack of foot self-care knowledge is manifested in patient’s
lack of awareness of personal risk factors for foot ulceration, and foot self-care. Fan, Zhang, and Hao (2005) surveyed 352 adult Chinese patients with diabetes and found that nearly 50% of patients with diabetes could not recognize diabetic foot problems and related risk factors; also over 50% of patients had limited knowledge of daily foot self-care behaviors related to washing and inspecting feet, cutting toenails, and selecting and using proper shoes and socks. Inappropriate knowledge and improper self-care in patients with diabetes lead to unnecessary foot ulceration, amputation of lower extremities, and substantial health care costs (Bielby, 2006; Mayfield et al., 1998; Wraight et al., 2005).

**Critical Inputs**

The critical inputs are described in relation to the components and key activities comprising the educational intervention for foot care, its dose and mode of delivery. The intervention components are based on relevant sources of self-efficacy as proposed by the social cognitive theory, national best practice guidelines, and empirical evidence related to foot care interventions found effective in patients with diabetes (ADA, 2004 & 2010; CDA, 2008; Fan et al., 2005; National Institute for Clinical Excellence Guideline, 2004; RNAO, 2004 & 2005). The overall goals of the educational intervention are to raise patients’ awareness of risk factors for foot ulceration; and improve patients’ knowledge, self-efficacy, and behavior performance of foot self-care. The foot self-care educational intervention covers the following content: awareness of risk factors; importance of thorough annual examination of feet by a healthcare professional; daily self-care and self-monitoring of foot including daily washing and drying, moisturizing, inspecting foot for problems, massaging foot, and foot exercise; footwear; nail care; and when to seek advice

The foot-care educational intervention consisted of 4 sessions including: 2 sessions comprised of interactive presentation and discussion and hands-on training, and 2 telephone contact booster sessions. The two interactive sessions were of one-hour duration each, and given over a one-week period. The telephone booster sessions took 10-15 minutes each and were offered once a week over a two-week period.

**Expected Outcomes**

Outcomes describe the changes that take place in patients with diabetes as a result of the intervention (Sidani & Sechrest, 1999). Four outcomes were expected of the foot-self-care educational intervention. Foot self-care knowledge is the first outcome and is defined as acquisition of and understanding of specific information about prevention of foot ulcerations in patients with diabetes (Fan et al., 2005). The second outcome was perceived foot self-care efficacy which refers to the extent to which patients with diabetes have confidence to perform foot self-care strategies by themselves (Corbett, 2003).

Foot self-care behaviors represent the third outcome and encompass the foot-care strategies that patients with diabetes apply to prevent foot problems. The strategies are: washing and drying feet daily, inspecting feet for injury, applying lotion to feet daily, massaging feet, and exercising lower extremities; trimming toenail appropriately; and selecting and wearing proper shoes and socks. Minor foot problems, the fourth outcome, refer to foot skin and toenails problems, that include dry and cracked skin, fissures, calluses, blisters, fungal infection, and trauma. The conceptual framework underlying the
design of the foot self-care educational intervention and its evaluation is illustrated in Figure 1.

The researcher, a RN and Certified Diabetes Educator (CDE) in Canada, delivered the intervention and conducted outcomes assessment. She received the special training on foot assessment and care for patients with diabetes at Hong Kong University Mary Hospital, and completed the Lower Extremity Amputation Prevention and Treatment of the Neuropathic Foot in US National Hansen’s Disease Program, and the Train-the-Trainer course in Project HOPE’ China Diabetes Education Program given by the American World Health Foundation in Beijing.

Assessment of Feasibility and Acceptability

The feasibility and acceptability of the foot self-care educational intervention were evaluated in this pilot study. Cole and Dendukuri (2004) defined the feasibility of the intervention as the degree to which eligible persons enroll in, complete, and comply with the intervention. The feasibility of foot self-care educational intervention was assessed with the following: 1) enrolment: patients’ rate of enrolment in the intervention and reasons for non-participation; 2) compliance: rate of intervention attendance and reasons for non-attendance; 3) completion: rate of intervention completion and reasons for attrition; and 4) the length of time for recruitment, data collection, and delivery of the foot care educational intervention sessions. Patients’ acceptability of the foot self-care educational intervention referred to their appraisal of its appropriateness, fairness, reasonableness, benefits, unintrusiveness, intensity, and satisfaction (Witt & Elliott, 1985).
Summary

The social cognitive theory guided the design of the foot self-care educational intervention and the specification of its expected outcomes. The intervention was delivered over a period of three weeks. The first two sessions, which involved presentation and discussion, and hands-on practice training, covered all content of the intervention. Two telephone contact booster sessions were offered to enhance the information gained at the first two sessions. Knowledge, self-efficacy, and performance of foot self-care behaviors and non-occurrence of minor foot problems were the outcomes expected of the foot self-care educational intervention.
Figure 1. Conceptual Framework for the Foot Self-Care Educational Intervention in Adult Patients with Diabetes at Low Risk for Foot Ulceration

<table>
<thead>
<tr>
<th>Intervention Contents</th>
<th>Expected Outcomes</th>
</tr>
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<tbody>
<tr>
<td>● Awareness of personal risk factors</td>
<td>● ↑ Foot-care knowledge</td>
</tr>
<tr>
<td>● Importance of annual feet inspection</td>
<td>● ↑ Foot-care self-efficacy</td>
</tr>
<tr>
<td>● Knowledge and behavior of daily self foot-care</td>
<td>● ↑ Foot-care behavior performance</td>
</tr>
<tr>
<td>● Proper nail care</td>
<td>● ↓ Occurrence of minor foot problems</td>
</tr>
<tr>
<td>● Proper footwear</td>
<td>● ↑ Wearing proper shoes and socks</td>
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<tr>
<td>● Prevention of foot trauma</td>
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<tr>
<td>● When to seek help</td>
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Chapter 3  Methodology

The specific objectives of this pilot study were: 1) to examine the feasibility and acceptability of the foot self-care educational intervention, and 2) to explore the effects of the foot self-care educational intervention on patients’ foot self-care knowledge, self-efficacy, and behaviors, and the occurrence of minor foot problems in adult patients with diabetes at low risk for foot ulceration. In this chapter, the research methods applied in the study are described.

Research Design

A one group repeated measures design was used to address the study objectives. This design is appropriate given that this study represents a Phase I trial to test feasibility and acceptability of the intervention with the target population of adult Canadian patients with diabetes at low risk for foot ulceration. Phase I trial is a pilot study that generally includes a small number of participants assigned to the intervention under evaluation. A control group is not necessary when the purpose is to examine the delivery of the intervention (Fletcher, Fletcher, & Wagner, 1996). The repeated measure design has several advantages. First, a within-subject design has more power to detect significant intervention effects than a between-subject design. According to Keselman et al. (2001), variability due to individual differences is eliminated from the estimate of error variance, making it easier to detect intervention effects. Second, the patterns of change in the outcomes over time can be determined, which allows examination of the changes in outcomes within individuals following the delivery of the intervention (Burns & Grove, 2005). Third, a smaller sample size is required in a within-subject design than a between-subject design and offers the same accuracy in
statistical conclusions as achieved with a large sample in a between-subject design (Fletcher et al., 1996; Keselman, Algina, & Kowalchuk, 2001).

The intervention consisted of four sessions. The first session was an individual, face-to-face presentation and discussion session, and the second one was a foot self-care hands-on practice training session. The first two sessions covered all content of the intervention. The third and fourth sessions were two telephone contact booster sessions to reinforce what participants gained at the first two sessions.

The outcomes expected of the foot self-care educational intervention were assessed at baseline (T1), right after completion of the first two sessions of the intervention (T2), and at 3-month follow-up after completion of all intervention sessions (T3) as illustrated in Figure 2. Foot self-care behaviors and foot problems were not assessed at T2 as no meaningful changes in these outcomes could be achieved at this point in time. The design involved only one group, and after collection of the baseline data, all eligible patients with diabetes received the foot self-care educational intervention.

The potential threat of testing produced through repeated administration of same instruments over times was minimized by having adequate and meaningful time intervals between occasions of measurement. Incentives, in the form of TTC tokens for transportation, were given to participants to reduce attrition. Additional participants were selected to account for possible withdrawal of participants and to accrue the required sample size.

- **T1** (Pre-test) → Intervention → **T2** → Telephone contact → **T3** (3-month Follow-up)

(Figure 2  Repeated measure design)
Setting

The setting for this pilot study was a Family Health Team in the Greater Toronto Area (GTA). The setting was selected based on the following considerations. First, there are 17 family physicians located in eight different medical centers, serving over 32,000 patients residing in the catchment area. There are approximately over 2,000 patients with diabetes attending the centre, which increased the pool of potentially eligible participants and the accrual of the required sample size. Second, the center provided an examination room with comfortable chairs, and relevant medical devices (i.e., weight scale, mercury sphygmomanometer, monofilament) and teaching equipments and tools (i.e., computer, Common Foot Problems Display Kit, suitable shoes and socks model), which facilitated the delivery of the intervention. Third, the setting is easily accessible by public transportation, which promoted participation in the study.

Sample

A convenience sampling technique was used to select study participants. The target population consisted of adult patients with type 2 diabetes, who lived in the catchment area served by the family health centre in the GTA. Participants who met the following eligibility criteria were included:

1. Persons who had a diagnosis of type 2 diabetes;
2. Persons who have not received formal diabetes education;
3. Persons who were at low risk for foot ulceration, ascertained by the researcher, using a 10-g monofilament and assessing for relevant signs and symptoms. Low risk was indicated by:
a) Normal protective sensation tested by monofilament, and patients’ report of no numbness, burning, tingling, itching, and pain in lower extremities;
b) Normal circulation of lower extremities identified by presence of pedal pulses (assessed by the researcher following the procedure described in Appendix 8), and patients’ self-report of no claudication or rest pain.
c) Absence of foot deformity (i.e., bunions, mallet toe, hammer toe, claw toe) on observation by the researcher;
d) Patients’ self-report of no history of previous foot ulceration or amputation, and absence current ulceration as observed by the researcher;

4. Persons who resided in the centre’s catchment area and were not planning to be away for at least 3 months;
5. Able to participate in the on-site education sessions;
6. 18 years of age or older;
7. Able to speak, read and understand English;
8. Had access to a working telephone at home to participate in the phone booster sessions.

**Exclusion Criteria:**

Patients with diabetes at high risk for foot ulceration were excluded if they had any one of the following:

1. Self-reported history of peripheral neuropathy (complaint of numbness, burning, tingling, itching, and pain), and absence of protective sensation ascertained with the monofilament;
2. Self-reported history of peripheral vascular disease (complaint of claudication or rest pain), and weakness or absence of pedal pulses examined by researcher;
3. Foot deformity (bunions, mallet toe, hammer toe, claw toe) observed by the researcher; and
4. Self-reported history of previous foot ulceration or amputation, and present ulceration observed by the researcher (RNAO, 2004 & 2005).

Recruitment and Screening

The researcher submitted the research proposal for approval by the Research Ethics Board at the University of Toronto and the Family Health Team. Once approval was obtained, recruitment began. The family physicians at the Family Health Team were provided with a letter introducing the purposes of the study, a list of participants’ eligibility criteria (Appendix 1), and recruitment flyers (Appendix 2). Family physicians informed their patients with diabetes of the study at a regularly scheduled visit, and provided recruitment flyers to those potential participants who were interested in the study. Recruitment flyers were also placed in easily visible and accessible places in family physicians’ offices and waiting rooms. Interested patients were instructed to call the researcher at the study research office, University of Toronto. The researcher made an initial telephone contact (Appendix 3), and arranged to meet with interested participants. At the meeting, the researcher explained the study (Appendix 4). Participants showing interest in taking part in the study were assessed for eligibility after obtaining verbal agreement. The researcher conducted a foot examination to identify their level of risk for foot ulceration. Participants who met all eligibility criteria received further verbal and written information about the study, and provided written
consent (Appendix 5). Participants who were deemed ineligible for the study continued to receive usual care and were provided a free of charge pamphlet on foot self-care for patients with diabetes for future reference. After providing written consent, eligible participants were requested to complete the baseline measures, and attend the intervention sessions.

**Sample Size**

A one group repeated measures design was used to address the research questions. Data were collected once before (T1), once during (T2), once after delivery of the intervention (T3). For a one-group repeated measure design, calculation of effect size is based on intra-class correlation (ICC) coefficient. However, no previous studies have reported this coefficient for any of the outcome variables of interest. Therefore, the sample size was estimated using guidelines presented by Hertzog (2008) for sample size calculation in pilot studies. A sample size of 50 was considered more than adequate to detect changes of moderate magnitude in the outcomes from pre- to post-implementation of the intervention, setting p-value at 0.05 and power at 0.80.

In previous studies that evaluated foot-care educational interventions, dropout rates between 12% and 23% have been reported (Barth et al., 1991; Bloomgarden et al., 1987; Corbett, 2003; Fan et al., 2006). In anticipation of potential dropouts in the proposed study, an additional 7 to 14 participants were included to account for an attrition rate of 12% and 23% respectively. Thus, a total of 64 participants were recruited for this study.
Variables and Measures

The variables of interest are summarized in table 3 and categorized into screening criteria, demographic characteristics, clinical characteristics, indicators of feasibility of the intervention, acceptability of the intervention, and outcomes.

Screening Criteria

Risk for foot ulceration was assessed in terms of foot sensation, circulation, deformities, and previous history of foot ulcerations. Foot sensation was assessed with subjective and objective measures. The subjective measure included asking patients to report on presence of numbness, burning, tingling, itching, and pain in the lower extremities. The objective measure consisted of testing for normal protective sensation with a monofilament. The procedure for using the monofilament entails eight steps (RNAO, 2004 & 2005).

Similarly, assessment of foot circulation was done with participants’ self-report of no claudication or rest pain and with an objective assessment. The latter encompassed examination of pedal pulses. To assess the dorsalis pedis artery pulse, the researcher gently placed the tips of the 2nd, 3rd and 4th fingers adjacent just lateral to the extensor tendon of the great toe and felt the pulse. To test for the posterior tibial artery, the researcher placed the three fingers behind and slightly below the medial malleolus of the ankle. It was palpated by wrapping the fingers around so that the tips come to rest on the appropriate area (Goldberg, 2008; Jarvis, 2005).

Foot deformities were assessed by the researcher. They were indicated by observation of: 1) Bunions: manifested by joint at the base of the big toe being pushed to the side (mild / moderate) or the big toe being under the second toe (severe); 2)
Mallet toe: bent joint nearest the tip of the toe; 3) Hammer toe: bent middle joint; and 4) Claw toe: joint at base of toe is bent up and middle joint is bent down (RNAO, 2004 & 2005). In addition, patients were asked about history of previous foot ulceration or amputation. The researcher also observed for foot ulcers.

**Demographic Characteristics**

The demographic characteristics entailed age, gender, education level, marital status, ethnicity background, and living arrangement. They were assessed with standard questions.

**Clinical Characteristics**

(1) Body Mass Index (BMI) is a continuous variable and is calculated by measuring participants’ weight (kg) and height (m) and applying the formula \( \frac{\text{weight (kg)}}{\text{height (m)}^2} \) to compute BMI. Weight and height were assessed by the researcher. The weight was measured with a standard standing scale available in the medical examination room at the Family Health Team. The investigator calibrated a standard platform weighting scale to zero by adjusting the calibrating knob. Participants were asked to stand on the scale and remain still, and the researcher read weight to the nearest 0.5 kilogram. Standing height was measured without shoes. A measuring tape was attached vertically to the wall. The researcher asked participants to stand erect exercising good posture, and read to the nearest 0.5 cm.

(2) Duration of Diabetes is a continuous variable and participants were requested to provide the actual number of years they have been diagnosed with diabetes.
(3) Fasting Blood Glucose (FBG), and HbA1c indicate the patients’ average blood glucose level over the past three months. The researcher obtained latest FBG and HbA1c reported in the participants’ medical record after they signed consent.

**Feasibility**

The feasibility of the intervention relates to the degree to which the participants enroll in, complete, and comply with the intervention (Cole & Dendukuri, 2004). Feasibility was monitored with the research activity log. The log documented: (1) the number of persons who inquired about and showed interest in the study; number of persons who were screened and found eligible or ineligible, and the reported reasons for ineligibility; (2) the number of eligible participants who enrolled in the study; the number of eligible participants who declined enrollment in the study, and the reported reasons for non-participation; (3) the number of sessions attended, and reasons for non-attendance; (4) the number of participants who completed all intervention sessions, and the number of participants who withdrew before completing the sessions, and the reported reasons for attrition; and (5) length of time to implement the intervention sessions.

**Acceptability**

Acceptability of the intervention was measured with the Intervention Rating Profile-15 (IRP-15) developed by Witt and Marterns (1983). The IRP-15 is an adapted version of the Treatment Evaluation Inventory (TEI), which is a global measure for the evaluation of the acceptability of psychological interventions (Hunsley, 1992; Kazdin, 1980; Kelley, Heffer, Frank, Gresham, & Elliott, 1989; Witt & Elliott, 1985). The IRP-15 is a 15-item Likert-type scale that assesses general acceptability of interventions.
The 15-item IRP assesses the acceptability of an intervention in terms of patients’ perception of the intervention’s appropriateness, fairness, reasonableness, benefits, unintrusiveness, timing, dosage/intensity, and satisfaction (Kazdin, 1980; Witt & Elliott, 1985). Participants were asked to indicate their response to each item on a 6-point Likert scale that ranged from ‘strongly disagree’ to ‘strongly agree’. Scores generated by the IRP-15 range from 15 to 90. Higher scores indicated higher levels of acceptance (Von Brock & Elliott, 1987). The IRP-15 has demonstrated acceptable reliability and validity. The Cronbach’s alpha was reported at 0.98 in a study of behavioral interventions (Elliott, Witt, & Kratochwill, 1991). Martens et al. (1985) found the IRP-15 to differentiate the degree to which teachers found two different interventions acceptable. Results of these studies support the validity of the IRP-15 (Witt & Elliott, 1985). The IRP-15 was adapted to reflect the foot self-care educational intervention under evaluation in this study. Acceptability of the intervention was assessed at time 3 only.

**Foot Self-Care Knowledge**

Knowledge of foot self-care was measured with the Foot Self-Care Knowledge Questionnaire (Fan, Li, Lu, & Zheng, 2006). The Foot Self-Care Knowledge Questionnaire was comprised of 11 questions with a “true”, “false”, or “don’t know” response options. A score of zero was assigned to an incorrect or don’t know response, and a score of 1 was assigned to a correct response. The total scale scores ranged from zero to 11, with higher scores indicating greater foot self-care knowledge. The questions addressed knowledge regarding the following foot self-care strategies: wash and dry feet daily, inspect feet daily, use cream daily, massage feet daily, and do lower
extremity exercises daily, trim toenails correctly, wear proper shoes and socks, wear socks and shoes all the time except in bed, and what needs to be done if foot problems such as a blisters develop. The content validity of the instrument was evaluated with five experts including health care professionals with specialization in endocrinology and diabetes education. The content validity index was 0.84. The internal consistency reliability was assessed in a sample of participants (n=30) with diabetes. The Cronbach’s alpha coefficient was 0.85 indicating that the items were internally consistent (Fan et al., 2006).

**The Foot Self-Care Efficacy**

Self-efficacy related to the performance of foot self-care behaviors was assessed by the Foot Self-Care Self-Efficacy Questionnaire developed by Corbett (2003). The adapted Foot-Care Self-Efficacy Questionnaire asked participants to rate their confidence in performing nine aspects of foot self-care that corresponded to the content of the 5-step daily foot self-care strategies covered in the foot self-care educational intervention. The 9 items related to the ability to safely wash and dry feet; inspect feet on daily basis; use cream daily; massage feet daily; do lower extremity exercises daily, trim toenails correctly; wear the correct type of shoes and socks; wear shoes and socks as needed; and seek help from doctor if getting a blister or foot sore. A 6-point Likert scale, ranging from ‘strongly agree’ (6) to ‘strongly disagree’ (1) was used. The range of possible total scale scores was from 9 to 54 with high scores indicating high levels of self-efficacy. Content validity was established by a panel of diabetes clinicians, and the instrument was pilot tested for clarity and readability with patients with diabetes.
Internal consistency reliability of the tool was demonstrated with Cronbach’s alpha coefficients >0.70.

**Foot Self-Care Behavior**

Performance of foot self-care behaviors was measured with the Foot Self-Care Behavior Questionnaire (Fan et al., 2006). The Foot Self-Care Behavior Questionnaire was comprised of 11 items with two response options: “yes” (1) and “no” (0). The total scale scores ranged from 0 to 11; higher scores indicated performance of most foot self-care behaviors. The items covered the following foot self-care behaviors: wash and dry your feet daily, inspect feet daily, use cream daily if the foot skin is dry or rough, massage feet daily, do lower extremity exercises daily, trim toenails correctly, select and wear proper shoes and socks, wear sock and shoes all the time when not in bed, do not walk with bare feet, and see doctor if getting a blister. The content validity index of the instrument was 0.84. The Cronbach’s alpha coefficient was 0.85 indicating that the items were internally consistent (Fan et al., 2006).

**Foot Conditions**

Foot conditions were evaluated with the Foot Assessment Form, which covered foot skin, toenails, and wearing shoes and shocks condition. The form is an established tool that was used in previous research (Barth et al., 1991; Corbett, 2003; Fan et al., 2006; Hamalainan et al., 1998; Litzelman et al., 1993; Rettig et al., 1986). Foot conditions were assessed by the researcher, by thoroughly inspecting the participants’ feet skin, toenails, and wearing shoes and socks conditions.

Foot skin condition in the Foot Assessment Form included the following items: 1) Dry and cracked skin. 2) Fissure, which is a long, narrow opening or gap that can
extend into the dermis, dry or moist. 3) Corns: manifested by a conical, horny induration and thickening of the skin caused by friction or pressure. Hard corns may develop on the tops or tips of the toes. 4) Calluses: manifested by a horny layer of skin caused by pressure or friction. It may spread across the ball of the foot or along the outer edge of the heel or big toe. 5) Blisters, which are vesicles of fluid under the outer layer of skin. The fluid may be clear or filled with blood or pus. 6) Skin lesion/ulcer, which involves loss of the upper portion of the skin (epidermis) and part of the lower portion (dermis). 7) Skin fungal infection manifested with itchy, scratchy foot skin with small blisters (Ahroni & Scheffler, 2006; CDA 2008; Litzelman, Marriott, Vinicor, 1997; NIDDK, 2009; RNAO, 2004 & 2005; Zhang et al., 2006).

Toenails assessment included the following items in the Foot Assessment Form: 1) Hygiene: toenails should be kept clean. 2) Length: the appropriate length for a toenail should be even with the tip of the toe. 3) Thickness: normal toenails should be of appropriate thickness. 4) Ingrown toenail: a condition in which the edge of the toenail grows into the skin surrounding the nail. It is manifested by redness, drainage, and swelling usually of the big toe, which is where most infections occur. 5) Toenails fungal infection indicated by cracked, yellow, discolored, streaked, thickened, or spotted toenails (Ahroni & Scheffler, 2006; CDA, 2008; RNAO, 2004 & 2005).

Shoe assessment entailed the following items in the Foot Assessment Form: 1) Inside shoe: the inside of each shoe having no ridge, wrinkles, or rough areas, smooth and seamless linings are considered proper. 2) Shoe styles: proper shoes should have a thick, flexible rubber sole, fitting with closed, rounded or square toes and closed in heels, with low, strong heels. The toe box should be wide and deep enough to
accommodate the toes. Shoe styles are considered as improper if shoes have tight, pointed toes, or high heels (higher than 1 inch), and if sandals have thongs in between the toes. 3) Adjustment: Shoes with laces, a strap, velcro, buckles or elastics that can provide more support, allowing adjustment on the side and top of the foot, and hold shoes firmly on, are considered as proper. 4) Shoe materials: soft, and breathable uppers made of leather, and textile such as canvas, cloth fabric that allow air to flow through the shoe, keeping the foot dry and odor free are considered suitable. Synthetic materials that do not cause the feet to sweat, are appropriate. Wearing shoes made of vinyl or plastic is improper as they do not stretch or "breathe". 5) Shoe fitting: Toe area: allow (thumbnail's length, half-inch) space between top of longest toe on largest foot and the end of the toe box. Width area: foot should fit comfortably into the shoe without stretching the upper part. Heel area: heel can move but is not supposed to slip (Ahroni & Scheffler, 2006; Barron & Basson, 2010; CDA, 2008; Litzelman et al., 1997; RNAO, 2004 & 2005).

Sock assessment consisted of the following items in the Foot Assessment Form: 1) Fit: socks are of appropriate size for the feet, fit comfortably, without being tight at the cuff, with smooth seams, no wrinkle, and no hold (if a toe tightly lodges in a hole of the sock that can affect the circulation of the toe). Material: sock material usually consists of breathable fibers such as a cotton or a cotton / wool blend so the feet can breathe and sweat. 3) Non-binding top: the tops are non-binding so blood circulation is not constricted from the foot. 4) Color: white or light colored socks quickly alert the wearer to a bleeding or oozing from wounds. These characteristics were consider proper to prevent foot problems. (Ahroni & Scheffler, 2006; Barron & Basson, 2010;
Litzelman et al., 1997; RNAO, 2004 & 2005). Information on the variables, measures, and data collection time is summarized in Table 2.

**Table 2  Variables, Measures, and Data Collection Overview**

<table>
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<td>Foot Assessment From</td>
<td>T1</td>
</tr>
<tr>
<td>Demographic data</td>
<td>Age, Gender, Educational level, marital Status, Ethnicity background, Living arrangement</td>
<td>Demographic Characteristics</td>
<td>T1</td>
</tr>
<tr>
<td>Health-related data</td>
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<td>Clinical Characteristics</td>
<td>T1</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Enrollment rate, Completion rate, Compliance rate</td>
<td>Research Activity Log</td>
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<tr>
<td>Acceptability</td>
<td>Intervention Rating Profile-15 (IRP-15)</td>
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<td>Knowledge</td>
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**Intervention**

**Components of the Intervention**

The intervention components were based on the proposition of Social Cognitive Theory, the national best practice guidelines and empirical evidence related to foot care for patients with diabetes (ADA, 2010; Fan et al., 2005; National Institute for Clinical...
Excellence Guideline, 2004; RNAO, 2004 & 2005). The content covered and the activities performed as part of the intervention are detailed below.

1. Awareness of Risk Factors for Foot Ulceration

The first topic covered consisted of an introduction to the five principal risk factors for ulceration and lower extremity amputation among patients with diabetes. They were: 1) sensation, 2) circulation, 3) altered structure and biomechanics of the foot, 4) history of previous ulcerations, and 5) knowledge and behavior of foot self-care (Halpin-Landry & Goldsmith, 1999; RNAO, 2004 & 2005). For each risk factor the following content was covered.

Sensation

The goal of this part of the educational intervention was to raise patients’ awareness of loss of protective sensation, which was one of the major risk factors for foot ulceration. The most common symptom of peripheral neuropathy in patients with diabetes is a change in sensation in the feet, which includes numbness, burning, tingling, itching, and pain in the feet (Mayfield et al., 1998). Neuropathy increases with age, duration of diabetes, and poor blood glucose control (ADA, 2010; Mayfield et al., 1998).

The following points related to peripheral neuropathy were presented: 1) Peripheral neuropathy frequently causes loss of protective sensation, which is a key risk factor for foot ulceration in patients with diabetes. 2) The most common symptoms and signs of peripheral neuropathy include numbness, burning, tingling, itching, and pain. 3) The harm of loss of protective sensation: when sensory nerves are damaged, patients are unable to detect heat and cold, which increases the risk for burn or frostbite; and
patient are not able to feel pain or discomfort while walking with inappropriate shoes, and stepping on a sharp tack with the bare foot. The injury can result in an ulcer if untreated, which can become infected, leading to gangrene and amputation.

Activities performed to relay this information included presentation by the researcher. PowerPoint slides with photo pictures complemented the presentation, illustrating clinical incidents that occurred in patients with diabetes due to loss of protective sensation. In addition, the discussion addressed the importance of protective sensation, the harm of loss of protective sensation, and the common symptoms and signs of peripheral neuropathy in patients with diabetes. Lastly, participants were provided with a written material (pamphlet) about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan, et al., 2005 & 2006; NIDDK, NIH, 2009).

Circulation

Peripheral vascular disease is 4 to 20 times more likely to develop in people with diabetes than in the general population, and is a major risk factor for lower-extremity amputation (ADA, 2011; Ahroni & Scheffler, 2006; Kannel & McGee, 1979; Sieggreen, 2005). Peripheral artery disease reduces blood flow to the legs and feet which contributes to ulcer formation and compromises healing (Sieggreen, 2005). The goals of this part of educational intervention were to: 1) raise awareness of the harm of peripheral artery disease that can result in poor circulation in the lower extremities and may be a key risk factor for foot ulceration, and 2) learn common symptoms and signs of poor circulation in lower extremities.
The content of the educational intervention with regard to peripheral vascular disease included: 1) peripheral vascular disease related to poor circulation of lower extremities is one risk factor for foot ulcer in patients with diabetes. 2) The harm of poor circulation of lower extremities is associated with non-healing ulceration, gangrene, and amputations. 3) The common symptoms and signs of poor circulation of lower extremities include absence or weakness of pedal pulses, and intermittent claudication (calf pain) or rest pain. Claudication is defined as pain in the calf that develops upon walking and is relieved within 10 minutes of rest. Rest pain is a continuous burning pain due to ischemia of the lower extremities that often awaken patients at night when sleeping and is relieved by sitting or standing (Mayfield et al., 1998). Initial examination of signs of clinical compromise by palpating lower extremities’ dorsalis pedis and posterior tibial artery pulse, is done by health care professionals.

Activities performed to relay this information consisted of presentation and discussion. PowerPoint slides with pictures were prepared by the researcher. The researcher gave the presentation, illustrating clinical features that occurred in patients with diabetes due to poor circulation in the low extremities, and examination of pedal pulses. The discussion emphasized the importance of good circulation, the harm of poor blood supply in lower extremities, and the common symptoms and signs of peripheral vascular disease in patients with diabetes. Lastly, participants were provided with a pamphlet about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on
RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).

**Altered Structure and Biomechanics of the Feet**

The goal of this part of the educational intervention was to increase awareness of the altered structure and biomechanics of the foot that can be important risk factors for foot ulceration. The content of the educational intervention with regard to altered biomechanics of the foot included: 1) Knowing that altered structure and biomechanics of the foot is one risk factor for ulceration in patients with diabetes. Structural and biomechanical abnormalities, which are often noted to be associated with soft and bony tissue deformities, impaired joint mobility, and pressure, have consistently been identified as risk factors for lower extremity ulceration and amputation (Boyko et al., 1999; Cavanagh, Simoneau, & Ulbrecht, 1993 & 1996; Lavery & Gazewood, 2000; Mayfield & Sugarman, 2000; Pham, Armstrong, & Harvey, 2000; Reiber, Vileikyte, & Boyko, 1999) particularly when peripheral neuropathy is present in patients with diabetes (Mayfield & Sugarman, 2000). Although some foot deformities are congenital, the majority result from motor neuropathy (e.g., claw / hammer toes), or improper footwear leading to the formation of callus, corns and bunions (Borssen, Bergenheim, & Lithner, 1990; Lavery, Lavery, & Quebedeax-Famham, 1995; Mayfield et al., 1998). Observable structural and biomechanical abnormalities result in weight redistribution, increased plantar pressure, and shearing stress to soft tissue (RNAO, 2004 & 2005). 2) Recognizing common abnormalities of the feet such as mallet toes, clawed toes, hammer toes, and bunions.
Two activities were performed to relay this content. First, the researcher gave the presentation using PowerPoint slides for illustration of common foot abnormalities such as clawed toes, hammer toes, and bunions. Second, patients were provided with a pamphlet about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).

**History of Previous Foot Ulcerations**

The goals of this part of the educational intervention were to raise awareness that previous history of foot ulceration or amputation is one key risk factor for recurrence of foot ulceration, and to increase knowledge of the clinical manifestations of foot ulcerations. The lecture presentation emphasized the points that previous history of foot ulceration is a risk factor for recurrence of foot ulceration and subsequent lower extremity amputation in patients with diabetes. Ulcerations are defined as a deep open sore or break in the epidermis. It can become infected and lead to serious problems such as gangrene and amputation (Apelqvist, Larsson, & Agardh, 1990). The clinical manifestations of foot ulcerations were reviewed.

The lecture presentation was supplemented with pictures of foot ulcerations. In addition, participants were provided with a written material (pamphlet) about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).
2. Importance of Annual Inspection of Feet by a Health Care Professional:

The goal of this component of the educational intervention was to promote patients’ understanding of the importance of annual inspection of feet by health care professionals, and of the general content of annual thorough examination of feet. The content covered two points. First, the importance of an annual feet examination by a health care professional in detecting risk for foot ulcerations was highlighted. Second, the annual foot examination was described as consisting of assessment of foot complications, and of risk factors for foot ulcerations including sensation, circulation, structural and biomechanical abnormalities, and history of previous foot ulcers (ADA, 2010; Apelqvist & Larsson, 2000; CDA, 1998; Fan, Zhang, & Lu, 2005; Institute for Clinical Systems Improvement, 2000; New Zealand Guidelines Group, 2000; Pinzur, Slovenkai, & Trepman, 1999; RNAO, 2004 & 2005). The two points were discussed by the researcher with participants.

3. Knowledge and Behavior Performance of Daily Foot Self-Care (5-Step Strategies)

The goals of this component of the educational intervention were to increase knowledge of foot self-care, build up self-efficacy or confidence in daily foot self-care, and enhance performance of foot self-care behaviors on a daily basis. Increasing knowledge and self-efficacy of foot care is the foundation of improving behavior performance of foot care. The content covered the 5-step daily foot self-care strategies. The first topic relates to washing feet daily, with lukewarm water and mild soap. Participants were instructed to check that the water is not too hot before putting the feet in it, check by elbow or a thermometer (32-35 °C / 90-95° F is safe); do not soak the feet (wash feet within 5 minutes); dry carefully with a soft towel, especially the skin
between the toes. Second, participants were told to inspect feet daily between and under all toes as well as top and bottom of both feet; look for red areas, cuts, sores, blisters, or any open areas; and if they are unable, to have someone else check or use a mirror to help them perform a self-assessment. The third topic focused on the daily application of cream. Participants were informed to use cream daily: apply a moisturizing emollient daily to prevent dryness and cracking after washing, avoid putting cream between toes. The fourth topic was about massaging the feet and lower legs daily to keep the blood flowing to the feet. The fifth topic emphasized exercise of lower extremities daily. Specifically, participants were instructed in the performance of toes, ankles and knees exercise (RNAO, 2004 & 2005; US National Institutes of Health, 2008; Zhang, Fan, & Yu, 2006). The purposes of performing the 5-step daily foot self-care strategies were to keep the feet clean; maintain foot softness and smoothness; prevent foot dryness, cracking, and trauma; identify / detect minor foot problems in a timely manner and deal with them as soon as possible; promote blood circulation to the feet; and increase muscle strength of feet and legs, which may reduce the occurrence of foot problems (Zhang et al., 2006).

Teaching activities performed to relay the 5-step daily foot self-care strategies consisted of presentation and discussion, and hands-on training to enhance patients’ self-efficacy of daily foot self-care. Items to demonstrate foot-care included a basin, a towel, a bottle of cream or lotion, and a small mirror.

The specific protocol for this component of the intervention encompassed four steps. First, the researcher presented the 5-step strategies for daily foot self-care using power point slides. Second, the researcher reviewed with the patient the key points
related to daily foot self-care. Third, the hands-on training in the performance of the 5-step daily foot self-care strategies were conducted as follows: 1) The researcher showed the PowerPoint slides, and foot model to demonstrate the foot self-care strategies step by step, including washing and inspecting feet, applying cream, massaging feet and legs, and performing exercise of lower extremities. 2) The participant performed the foot self-care strategies while the investigator provided feedback on correct application of the strategies. The researcher gave praise if the participant performed these strategies correctly or further coached if the patient performed them incorrectly until the participant performed the foot self-care strategies appropriately. 3) The researcher reviewed the 5-step foot self-care again; this offered the participants additional opportunity to review the strategies. 4) The researcher encouraged participants to perform the 5-step foot self-care strategies on a daily basis at home following the hands-on practice training instruction. Results of Zhang et al. (2006)' study indicated that “the 5-step daily foot self-care strategies” represent a simple, practical, and effective approach to the prevention of foot complications among Chinese patients with diabetes. Lastly, participants were provided with a pamphlet about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).

4. Proper Toenails Care

The goals of this part of the educational intervention were to raise participants’ awareness of the importance of toenail care, and to recognize common types, symptoms / signs of toenail problems including cuts, infected toenails, and ingrown toenails.
The content included the importance of proper toenails care in preventing foot trauma that could lead to foot ulcerations. Minor toenail problems are common in patients with diabetes, such as cuts and infections of the skin around or under the nails, ingrown nails, and fungal nail infections. If these minor foot problems are not dealt with appropriately, they can cause severe foot problems that may develop into foot ulceration and subsequent lower extremity amputation (Apelqvist et al., 1990; Neil, Thompson, Thorogood, Fowler, & Mann, 1989). One study showed that the first three leading causes of foot lesions were wearing unsuitable shoes (58%), cutting toenails in the wrong way (47%), and dealing with minor foot problems inappropriately (44%) by patients with diabetes (Zhang et al., 2006). In addition, common types, symptoms and signs of toenail problems were discussed. Participants were informed that incorrect cutting of toenails was one of the common conditions leading to foot trauma, and subsequent foot infection and ulceration (Litzelman, Marriott, & Vinicor, 1997; Mayfield et al., 1996). Signs of infection of the skin around or under the nails include pain, swelling, redness, tenderness, or heat; discharge of pus; a green, white, or yellow color under the nail; even fever, and swollen lymph nodes in the groin. Patients were informed about ingrown toenails, which are often caused by improper trimming, tight shoes, or heredity. The toenails may grow into the surrounding skin, causing pain, swelling, and infection (Zhang et al., 2006; Litzelman et al., 1997). Fungal nail infections (onychomycosis, or ringworm of the nail) occur when fungi invade a toenail and the skin underneath the nail (nail bed). Toenails are more commonly affected than fingernails, and symptoms include cracked, yellow, discolored, streaked, thickened, or spotted nails. Foot skin fungal infections result in blisters and foot lesions that may lead
to foot ulcerations in patients with diabetes (Litzelman et al., 1997; Zhang et al., 2006). The principles of proper toenails care were discussed. Instructions were given on correct cutting of toenails which included: trim toenails with toenail clippers after washing feet; avoid the use of scissors to trim toenails; trim the toenails following the shape of the toes, cut straight across and not too short, and smooth toenails with a nail file until no sharp edges present; get help to cut the toenails if needed; and if toenails are not soft and easy to cut, or have toenail problems, patients need to see a podiatrist trained in diabetes care in a timely way (Halpin-Landry & Goldsmith, 1999; Kiely, 2006; LeMone & Burke, 2006; RNAO, 2004 & 2005; Zhang et al., 2006). The content is detailed in the pamphlet.

Teaching activities preformed to relay the proper toenails care included lecture presentation and discussion, and hands-on training. The session contained three steps to enhance participants’ self-efficacy of proper toenails care as described earlier. First, the researcher gave a presentation on proper toenails care using PowerPoint slides. Second, discussion focused on reviewing the key points on proper toenails care. Third, the hands-on training in proper cutting of toenails was initiated, where the researcher requested patients to assess if their toenails were appropriately trimmed off, invited participants to demonstrate the proper cutting toenails, and provided feedback for the participants about correct toenails care behavior performance. Lastly, participants were provided with a written material (pamphlet) about this content of the educational intervention for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005; 2006; NIDDK, NIH, 2009).
5. Proper Shoes and Socks

The fifth content of the educational intervention addressed the importance of proper shoes and socks in preventing foot ulceration. The goal was to increase the patients’ knowledge of selecting and using proper shoes and socks in daily life.

Content of the educational intervention highlighted the importance of selecting and using proper shoes and socks for patients with diabetes; the harm of improper shoes and socks in patients with diabetes; and the principles of selecting and using proper shoes and socks.

Shoes come in a variety of styles and shapes. Persons with normal sensation in their feet can wear almost any shoe style with little risk of injury. However, since persons with diabetes are vulnerable to nerve and vascular damage that can result in loss of protective sensation in the feet, poor circulation, and altered biomechanics of the feet, poorly designed or improperly fitting shoes can cause serious foot injuries and ulceration. Clinical research evidence shows that wearing unsuitable footwear is the first leading cause of foot lesions (Zhang et al., 2006). Patients need to recognize that almost all foot traumas can be prevented by wearing properly fitting, appropriately styled shoes and socks. In one study of persons with diabetes, peak pressures on the sole were highest when walking barefoot and were significantly lowered when measured in properly selected and fitted shoes (Samow et al., 1996). Athletic running shoes decreased plantar callus formation in a group of patients with diabetes by threefold, and reduced the number of patients complaining of painful callus by 70% (Soulier, 1986).
Tovey (1984) summarized the principles of proper shoes selection. Footwear should relieve areas of excessive plantar pressure, reduce shock and shear, and accommodate, stabilize, and support deformities. Shoes should fit both the foot shape and size. The first metatarsophalangeal joint should be accommodated in the widest part of the shoe and the length should allow 1/2 inch between the end of the shoe and the longest toe. The shoe should have sufficient room in the toe area and over the instep. Shoes with laces or Velcro are used to accommodate for edema and deformities. The heel should fit snugly without undue motion. People with balance problems may benefit from footwear with wide, low heels to improve stability, and assistive devices such as canes.

Most people with diabetes, and specifically neuropathy, should avoid thongs and open-toe, pointed-toe, and open-back shoes, and can wear commercial shoes such as walking shoes and athletic shoes, insoles, and extra depth or larger toe-box shoes, that meet Tovey's principles mentioned above. People with hammer toes, bunions, or evidence of high plantar pressure need extra depth, depth-inlay, or custom shoes that provide a slightly wider and deeper toe box (Kiely, 2006; Mayfield et al., 1998).

Instructions for selecting and using proper socks included: wear soft socks made of breathable fibers such as a cotton or a cotton / wool blend so the feet can breathe and sweat; avoid nylon knee-high stockings and constrictive socks, avoid mended socks with seams; socks should be white or light color to enable to tell if there is any drainage from the feet; wear clean and dry socks; change socks daily; and avoid bare feet, wearing socks and shoes except to sleep (Halpin-Landry & Goldsmith, 1999; Kiely, 2006; LeMone & Burke, 2006; RNAO, 2004; Zhang et al., 2006).
Teaching activities performed to relay relevant information were presentation, observation of the proper shoes and socks, and identification of shoes and socks that were appropriate. The researcher gave a presentation on selecting and using proper shoes and socks using PowerPoint slides. The researcher exposed participants to samples/models of shoes and socks that were appropriate for participants with diabetes. The participants then performed a self-examination to determine if his or her shoes and socks were appropriate based on the principles of selecting proper shoes and socks discussed by the researcher. Also, the participant was provided with a pamphlet about this content for review after the educational session. The pamphlet was developed by the researcher based on RNAO guidelines (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).

6. Prevention of Foot Trauma

The sixth topic of the educational intervention focused on prevention of foot trauma. The goal of this component was to protect the feet, prevent foot trauma, and reduce the development of minor foot problems. In almost all ulceration and subsequent amputations, an event can be identified that set off the cascade of consequences, culminating in amputation. The pivotal event may be an acute traumatic event, such as stepping on a tack, cuts, puncture wounds, thermal injury, or repetitive minor trauma, such as wearing new shoes that cause a blister. Almost half of the pivotal events are potentially preventable: cuts and puncture wounds from walking barefoot, burn and shoe trauma from new or ill-fitting shoes. Participants were given tips for preventing foot trauma including: inspect the feet and toes daily for injuries such as blisters, lacerations, abrasions, and cuts; check bath water temperatures before stepping in; see a
podiatrist for treating and removing corns and calluses; do not attempt to cut these away; do not use over-the-counter commercially prepared corn medicines, plaster, or chemicals such as iodine or boric acid on the feet; avoid using antiseptics on the feet; do not go barefoot, especially on hot surfaces such as sidewalks, driveways, and beaches, or around swimming pools; avoid exposure to cold temperatures; if the feet feel cold, put on cotton socks; do not use heating pads, electric blankets, hot water bottles, or ice packs on the feet; do not wear socks that become thin or worn out; wear protective shoes and check shoes for foreign objects and rough spots; change socks and shoes every three to four hours during waking hours since all shoes begin to allow the foot to slide parallel to the sole of the shoe after three to four hours of continuous use; use this opportunity of changing socks and shoes to check the feet for unsuspected injuries, obtain prompt treatment, check if tiny stones or sands are in shoes (Halpin-Landry & Goldsmith, 1999; Kiely, 2006; LeMone & Burke, 2006; RNAO, 2004 & 2005; Zhang et al., 2006). The detailed content is presented in the pamphlet.

Teaching activities performed to relay information on preventing foot trauma included presentation and discussion. During the presentation, the researcher discussed key points related to preventing foot trauma. Participants were provided with a written material (pamphlet) about this content for their review after the educational session. The pamphlet was developed by the researcher based on RNAO guideline (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).
7. When to Seek Help for Foot Problems

When to seek help for foot problems was the last component of the foot care educational intervention. The goal was to know about when and from whom to seek help for foot problems. The researcher taught patients to contact the healthcare professional if they feel their foot condition has changed, such as presence of redness, swelling, skin breaks, pain, or foot ulceration. It is necessary for patients with diabetes to have the relevant knowledge and information to seek help to deal with their foot problems in a timely and appropriate way so that minor foot problems can be addressed and effectively treated (CDA, 2008; 2011; National Institute for Clinical Excellence, 2004; NIDDK, 2009; RNAO 2004 & 2005). Teaching activities included presentation and discussion. In addition, participants were provided with a pamphlet about this content for future reference. The pamphlet was developed by the researcher based on RNAO guideline (2004 & 2005) and relevant literature (Fan et al., 2005 & 2006; NIDDK, NIH, 2009).

Content of Telephone Contact Booster Sessions

The purpose of the two telephone contact booster sessions was to reinforce what participants gained at the first two sessions in terms of foot self-care knowledge. The telephone exchanges with participants with diabetes were guided by an assessment / intervention protocol. The researcher reviewed the key points related to daily self foot-care strategies (5-steps strategies), proper toenail care, wearing proper shoes and socks, and preventing foot trauma described earlier. The protocol served as a basis for identifying foot self-care concerns that participants may still have following the first two sessions, reviewing the key points with regard to the foot self-care practices on a
daily basis, and checking for or reminding patients to perform foot self-care strategies on a daily basis. An overview of the foot-care educational intervention is outlined in table 3.

<table>
<thead>
<tr>
<th>Content</th>
<th>Week1</th>
<th>Week2</th>
<th>Week3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Session 1</td>
<td>Session 2</td>
<td>Session 3</td>
</tr>
<tr>
<td></td>
<td>Presentation</td>
<td>Hands-on</td>
<td>Phone contact</td>
</tr>
<tr>
<td></td>
<td>/discussion</td>
<td>practice</td>
<td>booster</td>
</tr>
<tr>
<td></td>
<td>session</td>
<td>training</td>
<td>session</td>
</tr>
</tbody>
</table>

| Overview of the foot-care education intervention |
| Awareness of risk factors for foot ulceration |
| Importance of annual inspection of feet by a health care professional |
| Knowledge and performance of daily self foot-care strategies (5-steps strategies) | ✓ ✓ ✓ ✓ |
| Proper toenail care | ✓ ✓ ✓ ✓ |
| Selecting and using proper shoes | ✓ ✓ ✓ ✓ |
| Selecting and using proper socks | ✓ ✓ ✓ ✓ |
| Preventing foot trauma | ✓ ✓ ✓ ✓ |
| When to seek help about foot problems | ✓ |

**Dosage of the Intervention**

It is important to decide the dosage of the intervention after the goal, the content, and teaching strategies for each component were specified. According to Sidani and Braden (1998), the dosage of the intervention is the strength or intensity of the intervention that includes amount, frequency, and duration required to produce the desired outcomes. The foot self-care educational intervention was given over a period
of three weeks. The first session consisted of a one-hour lecture presentation and discussion and the second session involved a one-hour foot self-care hands-on practice training. The first two sessions were given within the first week and covered all (seven) topics discussed earlier. The third and fourth sessions entailed telephone contact booster sessions of 10-15 minute duration; in these sessions, the researcher reviewed key points covered in the first two sessions; the sessions were offered once a week over two weeks.

**Mode of Delivering the Intervention**

Mode of delivery relates to the educational techniques used to provide the intervention. The results of a meta-analysis of diabetes self-management education intervention (Fan & Sidani, 2009) indicated that an interactive teaching method mixed with face-to-face and telephone contact delivery strategies, and both one-on-one and group mode of delivery are effective in enhancing knowledge, self-efficacy, and behavior performance. To achieve best outcomes, the foot-care educational intervention was delivered by the researcher using one-on-one, face-to-face format in a comfortable room setting. The educational techniques were also consistent with those found to enhance self-efficacy (Bandura, 1997; Lorig, Lubeck, Kraines, Seleznick, & Holman, 1985; Lorig, et al., 1989).

Lecture presentation and discussion covered the intervention content using visual aids such as slides to raise participants’ awareness of the importance of foot self-care, and relay information on foot self-care in a meaningful way. The researcher maximized discussion with participants by reviewing key points, sharing information,
and experiences and by addressing personal concerns related to the performance of foot self-care strategies.

The hands-on practice training was done in a one-on-one format to enhance self-efficacy and performance of the 5-step daily foot self-care strategies, cutting toenails, and selecting and using proper shoes and socks. Teaching activities included demonstrating, instructing, coaching, praising, and modeling. The researcher encouraged participants to maximize hands-on practice while performing the foot self-care strategies, by facilitated support of active engagement in foot self-care.

Written material in the form of pamphlet were given to participants. The pamphlet presents, in simple terms, the key content covered in the educational intervention related to risk factors for foot ulceration, daily 5-steps strategies for foot-care, proper toenail care, and selecting and using proper shoes and socks. The pamphlet served as a reference to be used by participants when carrying out the foot self-care behaviors in daily life.

**Procedure for Data Collection**

*Pre-Intervention*

Baseline data collection (T1) occurred right after participants’ eligibility was determined and consent signed, in the examination room. Data were gathered on demographic characteristics, clinical characteristics, foot condition, and foot-self care knowledge, self-efficacy, and behaviors. The Demographic Characteristics, Clinical Characteristics and Foot Assessment Form were completed in 15-20 minutes by the researcher. Foot Self-Care Knowledge Questionnaire, the Foot Self-Care Behavior Questionnaire, and Foot Self-Care Self-Efficacy Questionnaire were completed by the
participants; this took about 15-20 minutes. The researcher obtained the participants’ phone number to inform them of the date and time at which the foot self-care educational intervention sessions were to be given.

**Following Face-to-Face Sessions**

After delivering the two face-to-face sessions (T2), participants completed the outcome measures including the Foot-Care Knowledge Questionnaire and Foot-Care Self-Efficacy Questionnaire in the examination room. At this time (T2), no changes in participants’ foot self-care behaviors and feet condition were anticipated; therefore, the Foot Self-Care Behaviors Questionnaires and Feet Assessment Form were not administered at this time. Within the two weeks after the face-to-face sessions, participants received two telephone contact booster sessions to reinforce the information on foot self-care that they learned. One week prior to 3-month follow-up (T3) the researcher telephoned each participant to confirm the date and time for completing the T3 measures at the center. Participants completed the Foot Self-Care Knowledge Questionnaire, Foot Self-Care Behavior Questionnaire, Foot Self-Care Self-Efficacy Questionnaire, and the Intervention Rating Profile-15 measuring intervention acceptability. Completion of the questionnaires took about 20 minutes. The researcher completed the Foot Assessment in 15 minutes.

The researcher telephoned participants one week prior to, to arrange for and remind them of, the scheduled intervention and data collection sessions. Participants were provided TTC tokens to cover transportation costs associated with attendance at the intervention and data collection sessions.
Plan for Data Analysis

Descriptive statistics, including frequency distributions, measures of central tendency and dispersion, were used to describe the sample in terms of demographics and clinical characteristics, intervention acceptability, and the outcomes measured at each data collection time. The indicators of feasibility were quantified as follows:

*Enrollment rate* was the percentage of eligible participants who accepted and consented to participate in the study, out of the number of participants who met the study eligibility criteria.

*Attrition rate* was the percentage of participants who withdrew from the study at any point in time out of the number of eligible consenting participants.

*Compliance rate* was operationalized as the percentage of participants who attended the four intervention sessions out of the total number of eligible consenting participants.

In addition, the reasons for ineligibility, refusal / withdrawal, and non-compliance as given by participants were content analyzed. The frequency with which a reason was given was examined.

Repeated Measures Analysis of Variance (RM-ANOVA) was used to examine changes in foot self-care knowledge and self-efficacy, across the three points of measurement (i.e., T1, T2, and T3). A statistically significant F-test was followed with post hoc analysis to determine the occasion at which changes in the mean scores occurred. Paired t-test was used to examine differences in the group’s mean scores on the outcomes between T1 – T2 and T2 - T3.

Since foot self-care behaviors and minor foot problems were measured on two occasions (i.e., T1 and T3) only, paired t-test was used to examine differences in the
mean scores for behavior. Chi-square test was used to examine differences in the frequency of the performance of foot self-care behaviors, occurrence of minor foot problems, and wearing improper shoes and socks respectively, between T1 and T3. Fisher's exact test was used when one or more of the cells had an expected count of less than 5 (Weaver, 2008). For all analyses, the level of significance was set at p<0.05.

The outline of variables, data collection, and statistical analysis plan is presented in Table 4.

Table 4  Variables, data collection, and statistical analysis plan overview

<table>
<thead>
<tr>
<th>Items</th>
<th>Variables</th>
<th>Data Collection</th>
<th>Statistical analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening criteria</td>
<td>Sensation Circulation Foot deformity History of foot ulceration</td>
<td>T1</td>
<td>Frequency distribution Measures of central tendency and dispersion</td>
</tr>
<tr>
<td>Demographic data</td>
<td>Age Gender Educational level Marital Status Ethnicity background Living arrangement</td>
<td>T1</td>
<td>Frequency distribution Measures of central tendency and dispersion</td>
</tr>
<tr>
<td>Clinical data</td>
<td>Body Mass Index (BMI) Duration of diabetes Fasting blood glucose (FBG) HbA1c</td>
<td>T1</td>
<td>Frequency distribution Measures of central tendency and dispersion</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Enrollment rate Completion rate Compliance rate</td>
<td>T3</td>
<td>Frequency distribution Measures of central tendency and dispersion</td>
</tr>
<tr>
<td>Acceptability</td>
<td>IRP-15</td>
<td>T3</td>
<td>Frequency distribution Measures of central tendency and dispersion</td>
</tr>
<tr>
<td>Knowledge</td>
<td>Foot self-care knowledge</td>
<td>T1, T2, and T3</td>
<td>RM-ANOVA, Post hoc analysis, Paired-t test</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>Foot self-care self-efficacy</td>
<td>T1, T2, and T3</td>
<td>RM-ANOVA, Post hoc analysis, Paired-t test</td>
</tr>
<tr>
<td>Behaviors</td>
<td>Foot self-care behaviors</td>
<td>T1, and T3</td>
<td>Paired t-test, and Chi-square test</td>
</tr>
<tr>
<td>Foot conditions</td>
<td>Foot minor problems Wearing proper shoes &amp; socks</td>
<td>T1, and T3</td>
<td>Chi-square test or Fisher's exact test</td>
</tr>
</tbody>
</table>
Data Management

The database was developed and maintained using SPSS 17 for windows. Coded data collection forms were stored in a locked filing cabinet at all times. Coded data were entered into the database. Data entry errors were detected through double entry and corrected (Burns & Grove, 2005). Range checks were preformed to ensure the accuracy of data entry.

Ethical Conduct and Considerations

Informed Consent

Informed consent was obtained at baseline. The researcher explained the study verbally based on the information in the consent form. The researcher addressed any questions they may have had prior to obtaining the written consent (Appendix 5). One copy of the consent was kept on file and one copy was given to the patient.

Freedom to Withdraw

Participants were made aware that they can withdraw from the study at anytime and if they choose to withdraw from the study or refuse to answer any questions, the care they were receiving or will receive in the future would not be affected.

Confidentiality

Confidentiality was honored throughout the study. All information would remain confidential. All questionnaires, logs, and computerized databases were assigned code numbers. The researcher kept a master list of names and code numbers in a sealed envelope within in a locked cabinet in the research office at the Faculty of Nursing, University of Toronto to which only the researcher had access. Data were saved on a password-protected computer. All data were kept in a locked cabinet for a
period of seven years at which time all hard copies will be shredded and all computer files will be deleted.

The information obtained was used only for research purposes. Participants’ responses were reported as group data. Participants’ name and other identification were not used nor shared with anyone outside of the study personnel.

**Benefits and Risks**

There were no known risks for participating in this study. Although there were no direct benefits to participants the study results could inform health care providers about the effectiveness of the early foot-care educational intervention in preventing foot problems in people with diabetes.

**Compensation**

There was no cost to participants for taking part in this research study beyond the time they spent attending the educational intervention and completing the questionnaires. All participants received a free package on foot self-care after the first two sessions. They also received Toronto Transit Commission (TTC) tokens to cover expenses related to the transportation to the study site.
Chapter 4 Results

This chapter presents the results of the pilot study in relation to: 1) feasibility of the intervention, 2) acceptability of the intervention, 3) demographic profile of participants, 4) clinical characteristics of participants, and 5) effects of the intervention on foot self-care knowledge, efficacy, behavior, and foot problems.

Feasibility of the Intervention

Feasibility of the intervention was examined in relation to initial interest in the study expressed by persons with diabetes, enrollment rate, length of time to recruit and collect data, length of time to implement the intervention sessions, intervention attendance rate, and attrition rate. As well, results of comparison between completers and dropouts are summarized.

Initial Interest Rate

A total of 94 persons with diabetes from the Family Health Team inquired about the study in response to information about the study given by family physicians or available on the flyers. Ninety persons showed an interest in the study, and 4 persons did not. Most (n=3) gave no specific reason for their expressed non-interest, and one person explained that she does not experience any foot problems. All 90 persons showing an interest in the study gave verbal agreement to and underwent screening. Eleven persons did not meet the study eligibility criteria, including non-type 2 diabetes (n=1), less than 18 years of age (n=1), received formal diabetes education in the past years (n=2), planning to be away for at least 3 months (n=2), and feet at high risk for foot ulceration (n=5). Of the five persons at high risk for foot ulceration, three had abnormal protective sensation and two had abnormal foot shape including bunions and hammer toes. In total,
79 persons with diabetes met the study eligibility criteria representing 87.7% of screened persons. Figure 3 illustrates the study flow diagram.

**Figure 3  Study Flow Diagram**

**Enrollment Rate**

Nine of the 79 eligible persons declined further enrollment in the study. Three persons did not provide a specific reason for refusal. The remaining six persons offered the following reasons for declining participation: family issue such as taking care of husband who had stroke at home (n=1); time issue such as inability to take days off from work to attend the intervention sessions (n=3); and lack of interest in this study (n=2). A total of 70 eligible participants provided written consent to participate in the study. The enrollment rate, defined as the percentage of eligible participants who enrolled in this study, was 88.6%.
Length of Time to Recruitment and Data Collection

It took about 12 months to recruit the study sample (n=70) from the Family Health Team, which consists of 17 family physicians in multi-centers across the GTA. Delivery of the intervention and collection of outcome data occurred over a 15-month period.

Length of Time to Implement the Intervention Sessions

The foot self-care educational intervention consisted of a total of four sessions given over a three week period. The first two sessions involved face-to-face contact with participants, which lasted an average of one hour (60-70 minutes) for each session. These sessions were given on the same day rather than on two separate days within one week (as originally planned) because participants did not want to travel twice within one week to attend the intervention sessions. The third and fourth sessions, consisting of telephone contact booster sessions, were on average of 10 minute duration (8-13 minutes). They were given once a week over two weeks.

Intervention Attendance Rate

Intervention attendance log was kept to track the number of the intervention sessions attended by participants. Of the 70 eligible and consenting participants, 67 (95.7%) participants attended all four intervention sessions, and 3 (4.3%) participants did not complete all sessions. Specifically, two participants attended the first three sessions, and one participant attended the first two sessions only. Reasons for non-completion of all intervention sessions included: traveling to another country (n=1); on a business trip (n=1); and moving to another province due to family issue (n=1).
**Attrition Rate**

Of the 70 eligible consenting participants, 56 (80.0%) participants successfully completed the 3 months follow-up visit. The number of participants who completed data at the three time points is presented in Table 5. A total of 14 participants withdrew from the study yielding an attrition rate of 20%. The reasons for withdrawal included moving to other cities (n=2), attending a diabetes program at another hospital (n=1); changes in health condition such as broken ankle (n=1) and pregnancy (n=1); and can’t take days off from work (n=3). Six participants did not provide any reason and were considered to have been lost to follow up.

<table>
<thead>
<tr>
<th>Data collection completed</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1 (Pretest)</td>
<td>70 (100.0%)</td>
</tr>
<tr>
<td>T2 (Post face-to-face sessions)</td>
<td>70 (100.0%)</td>
</tr>
<tr>
<td>T3 (3-month follow-up)</td>
<td>56 (80.0%)</td>
</tr>
</tbody>
</table>

**Comparison Between Dropouts and Completers**

Results of comparisons between completers and dropouts indicate the extent of selection bias that may be associated with attrition. Participants who completed the study (n=56) were compared to those who withdrew (n=14) on characteristics measured at baseline, including demographic profile, clinical characteristics, foot skin and toenails condition, wearing proper shoes and socks, foot self-care knowledge, behavior, and self-efficacy. The comparisons were done using the Chi-square test for categorical variables, and independent sample t-test for continuous variables. The results indicated
that patients with diabetes who completed and those who withdrew from the study were similar (all \( p > 0.05 \)) on demographic profile and clinical characteristics (Tables 6 and 7), foot skin condition (Table 8), toenails condition (Table 9), wearing proper shoes and socks (Table 11), and levels of foot self-care knowledge, behavior and self-efficacy (Table 7).
<table>
<thead>
<tr>
<th>Variable</th>
<th>Completers (n=56)</th>
<th>Dropouts (n=14)</th>
<th>$x^2$(df),p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>26 (46.2%)</td>
<td>5 (35.7%)</td>
<td>$x^2(1)=0.521$, p&gt;0.05</td>
</tr>
<tr>
<td>Female</td>
<td>30 (53.8%)</td>
<td>9 (64.3%)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>7 (12.5%)</td>
<td>0 (0.0%)</td>
<td>$x^2(2)=5.786$, p&gt;0.05</td>
</tr>
<tr>
<td>Married/partnered</td>
<td>49 (87.5%)</td>
<td>13 (92.9%)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>0 (0.0%)</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>Widowed status</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Educational level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade school or less</td>
<td>2 (3.6%)</td>
<td>1 (7.2%)</td>
<td></td>
</tr>
<tr>
<td>High school graduate</td>
<td>19 (33.9%)</td>
<td>5 (35.7%)</td>
<td></td>
</tr>
<tr>
<td>College/university or higher</td>
<td>35 (62.5%)</td>
<td>8 (57.1%)</td>
<td>$x^2(2)=0.396$, p&gt;0.05</td>
</tr>
<tr>
<td><strong>Ethnicity/cultural background</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South East Asians: Filipino</td>
<td>17 (30.4%)</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>South Asians: Indian</td>
<td>6 (10.7%)</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>Srilankaise</td>
<td>2 (3.6%)</td>
<td>3 (21.5%)</td>
<td></td>
</tr>
<tr>
<td>Pakistani</td>
<td>2 (3.6%)</td>
<td>2 (14.3%)</td>
<td></td>
</tr>
<tr>
<td>East Asians: Chinese</td>
<td>2 (3.6%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Canadians</td>
<td>11 (19.6%)</td>
<td>4 (28.6%)</td>
<td></td>
</tr>
<tr>
<td>South Americans: Guyana</td>
<td>3 (5.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Caribbean: Jamaican</td>
<td>1 (1.7%)</td>
<td>2 (14.3%)</td>
<td></td>
</tr>
<tr>
<td>European: Scottish</td>
<td>2 (3.6%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Greek</td>
<td>3 (5.4%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Italian</td>
<td>4 (7.1%)</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>Ukrainian</td>
<td>1 (1.7%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Africans</td>
<td>2 (3.6%)</td>
<td>0 (0.0%)</td>
<td>$x^2(11)=17.052$, &gt;0.05</td>
</tr>
<tr>
<td><strong>Living arrangement</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with family</td>
<td>51 (91.1%)</td>
<td>14 (100.0%)</td>
<td>$x^2(1)=1.346$, p&gt;0.05</td>
</tr>
<tr>
<td>Living alone</td>
<td>5 (8.9%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI &gt;24.9 (kg/m²)</td>
<td>49 (87.50%)</td>
<td>12 (85.71%)</td>
<td>$x^2(1)=0.032$, p&gt;0.05</td>
</tr>
<tr>
<td>Duration of diabetes (≤1 year)</td>
<td>28 (50.00%)</td>
<td>5 (35.7%)</td>
<td>$x^2(1)=0.213$, p&gt;0.05</td>
</tr>
<tr>
<td>FBG&gt;7.0 (mmol/L)</td>
<td>45 (80.35%)</td>
<td>9 (64.28%)</td>
<td>$x^2(1)=1.641$, p&gt;0.05</td>
</tr>
<tr>
<td>HbA1c ≥7.0 (%)</td>
<td>45 (80.35%)</td>
<td>12 (85.71%)</td>
<td>$x^2(1)=0.213$, p&gt;0.05</td>
</tr>
</tbody>
</table>
### Table 7  Comparison between completers and dropouts on continuous variables at baseline

<table>
<thead>
<tr>
<th>Variables</th>
<th>Completers(n=56)</th>
<th>Dropouts(n=14)</th>
<th>t (df), p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>55.8 ±13.2</td>
<td>51.9±9.8</td>
<td>t(68)=1.049, p&gt;0.05</td>
</tr>
<tr>
<td>BMI(kg/m²)</td>
<td>30.1 ±6.0</td>
<td>30.9±6.0</td>
<td>t(68)=0.493, p&gt;0.05</td>
</tr>
<tr>
<td>Duration of diabetes (years)</td>
<td>5.9±7.1</td>
<td>6.2±5.7</td>
<td>t(68)=0.130, p&gt;0.05</td>
</tr>
<tr>
<td>FBG (mmol/L)</td>
<td>9.96±3.58</td>
<td>9.82±4.23</td>
<td>t(68)=0.119, P&gt;0.05</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8.11±1.58</td>
<td>8.72±1.61</td>
<td>t(61)=1.271, P&gt;0.05</td>
</tr>
<tr>
<td>Foot self-care knowledge</td>
<td>5.80±2.48</td>
<td>5.35±2.61</td>
<td>t(68)=0.594, p&gt;0.05</td>
</tr>
<tr>
<td>Foot self-care behavior</td>
<td>4.30±2.08</td>
<td>4.21±2.77</td>
<td>t(68)=0.134, p&gt;0.05</td>
</tr>
<tr>
<td>Foot self-care self-efficacy</td>
<td>33.66 ±10.70</td>
<td>32.57±12.70</td>
<td>t(68)=0.334, p&gt;0.05</td>
</tr>
</tbody>
</table>

### Table 8  Comparison between completers and dropouts on foot skin condition at baseline

<table>
<thead>
<tr>
<th>Skin condition</th>
<th>Completers (n=56)</th>
<th>Dropouts (n=14)</th>
<th>x²(df), p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calluses /corns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (57.1%)</td>
<td>8 (57.1%)</td>
<td>x²(1)=0.00, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>24 (42.9%)</td>
<td>6 (42.9%)</td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (85.7%)</td>
<td>11 (78.6%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8 (14.3%)</td>
<td>3 (21.4%)</td>
<td>x²(1)=0.574, p&gt;0.05</td>
</tr>
<tr>
<td>Crackness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (28.6%)</td>
<td>3 (21.4%)</td>
<td>x²(1)=0.289, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>40 (71.4%)</td>
<td>11 (78.6%)</td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (17.9%)</td>
<td>2 (14.3%)</td>
<td>x²(1)=0.101, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>46 (82.1%)</td>
<td>12 (85.7%)</td>
<td></td>
</tr>
<tr>
<td>Fissures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (8.9%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>51 (91.1%)</td>
<td>14 (100.0%)</td>
<td>x²(1)=1.346, p&gt;0.05</td>
</tr>
<tr>
<td>Moist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>14 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Fungal infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (3.6%)</td>
<td>0 (0.0%)</td>
<td>x²(1)=0.515, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>54 (96.4%)</td>
<td>14(100.0%)</td>
<td></td>
</tr>
<tr>
<td>Blister</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (1.8%)</td>
<td>0(0.0%)</td>
<td>x²(1)=0.254, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>55 (98.2%)</td>
<td>14 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>14 (100.0%)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 9: Comparison between completers and dropouts on toenails condition at baseline

<table>
<thead>
<tr>
<th>Toenails</th>
<th>Completers(n=56)</th>
<th>Dropouts(n=14)</th>
<th>$\chi^2$(df), p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Hygiene</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>45 (81.4%)</td>
<td>12 (85.7%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>11 (19.6%)</td>
<td>2 (14.3%)</td>
<td>$\chi^2(1)=0.213$, p&gt;0.05</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>43 (76.8%)</td>
<td>9 (64.3%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>13 (23.2%)</td>
<td>5 (35.7%)</td>
<td>$\chi^2(1)=0.916$, p&gt;0.05</td>
</tr>
<tr>
<td><strong>Thickness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>45 (80.4%)</td>
<td>11 (78.6%)</td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>11 (19.6%)</td>
<td>3 (21.4%)</td>
<td>$\chi^2(1)=0.022$, p&gt;0.05</td>
</tr>
<tr>
<td><strong>Ingrown</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>14 (100.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Fungal infection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (8.9%)</td>
<td>1 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>51 (91.1%)</td>
<td>13 (92.9%)</td>
<td>$\chi^2(1)=0.046$, p&gt;0.05</td>
</tr>
</tbody>
</table>

### Table 10: Comparison between completers and dropouts on wearing proper shoes and socks at baseline

<table>
<thead>
<tr>
<th>Variables</th>
<th>Completers(n=56)</th>
<th>Dropouts(n=14)</th>
<th>$\chi^2$(df), p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Shoes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inside shoe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>56 (100.0 %)</td>
<td>14 (100.0 %)</td>
<td>n/a</td>
</tr>
<tr>
<td>Improper</td>
<td>0 (0.0 %)</td>
<td>0 (0.0 %)</td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>45 (80.4 %)</td>
<td>12 (85.7 %)</td>
<td>$\chi^2(1)=0.213$, p&gt;0.05</td>
</tr>
<tr>
<td>No</td>
<td>11 (19.6 %)</td>
<td>2 (14.3 %)</td>
<td></td>
</tr>
<tr>
<td>Style</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>48 (85.7 %)</td>
<td>12 (85.7 %)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>8 (14.3 %)</td>
<td>2 (14.3 %)</td>
<td>$\chi^2(1)=0.000$, p&gt;0.05</td>
</tr>
<tr>
<td>Adjustable with laces</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (85.7 %)</td>
<td>13 (92.9 %)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8 (14.3 %)</td>
<td>1 (7.1 %)</td>
<td>$\chi^2(1)=0.510$, p&gt;0.05</td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>45 (88.4 %)</td>
<td>12 (85.7 %)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>11 (11.6 %)</td>
<td>2 (14.3 %)</td>
<td>$\chi^2(1)=0.213$, p&gt;0.05</td>
</tr>
<tr>
<td><strong>Socks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25 (44.4 %)</td>
<td>7 (50.0 %)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>31 (55.6 %)</td>
<td>7 (50.0 %)</td>
<td>$\chi^2(1)=0.130$, p&gt;0.05</td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>30 (53.6 %)</td>
<td>7 (50.0 %)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>26 (46.4 %)</td>
<td>7 (50.0 %)</td>
<td>$\chi^2(1)=0.570$, p&gt;0.05</td>
</tr>
<tr>
<td>Binding legs &amp; feet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18 (32.1 %)</td>
<td>6 (42.9 %)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>38 (67.9 %)</td>
<td>8 (57.1 %)</td>
<td>$\chi^2(1)=0.571$, p&gt;0.05</td>
</tr>
<tr>
<td>Color</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>16 (28.6 %)</td>
<td>5 (35.7 %)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>40 (71.4 %)</td>
<td>9 (64.3 %)</td>
<td>$\chi^2(1)=0.272$, p&gt;0.05</td>
</tr>
</tbody>
</table>
Acceptability of the Intervention

Acceptability of the foot-care educational intervention was measured with the Intervention Rating Profile-15 (IRP-15) (Martens, Witt, Elliott, & Darveaux, 1985) at 3 months after the foot-care educational intervention (T3). As shown in Table 11, overall participants viewed the intervention favorably. Specifically, they rated the intervention as highly acceptable, appropriate, effective, safe, reasonable, and suitable for participants with diabetes. Participants judged the intensity of the intervention as suitable. They liked the 5-step foot self-care approach used in the intervention. They stated they were willing to use the intervention, and perceived it as a fair and good way to prevent foot problems. Overall, they felt benefits from and were satisfied with the intervention. The mean total scale score was 88.30 (SD=2.65) which indicates that participants considered the foot self-care educational intervention highly acceptable.

Table 11 The mean score on the intervention acceptability

<table>
<thead>
<tr>
<th>Acceptability of the intervention (IRP-15)</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acceptability</td>
<td>5.96</td>
<td>0.18</td>
</tr>
<tr>
<td>2. Appropriateness</td>
<td>5.91</td>
<td>0.28</td>
</tr>
<tr>
<td>3. Effectiveness</td>
<td>5.89</td>
<td>0.31</td>
</tr>
<tr>
<td>4. Use of this intervention to other patients</td>
<td>5.89</td>
<td>0.31</td>
</tr>
<tr>
<td>5. Need to use the intervention to prevent foot problem</td>
<td>5.58</td>
<td>1.09</td>
</tr>
<tr>
<td>6. Suitableness of the intervention intensity</td>
<td>5.80</td>
<td>0.40</td>
</tr>
<tr>
<td>7. Willingness to use this intervention</td>
<td>5.78</td>
<td>0.41</td>
</tr>
<tr>
<td>8. Safety</td>
<td>5.91</td>
<td>0.28</td>
</tr>
<tr>
<td>9. Suitability for variety of patients with diabetes</td>
<td>5.91</td>
<td>0.28</td>
</tr>
<tr>
<td>10. Fairness</td>
<td>5.89</td>
<td>0.31</td>
</tr>
<tr>
<td>11. Reasonableness</td>
<td>5.91</td>
<td>0.28</td>
</tr>
<tr>
<td>12. Like the procedures used in the intervention</td>
<td>5.94</td>
<td>0.22</td>
</tr>
<tr>
<td>13. Good way to prevent foot problems</td>
<td>5.94</td>
<td>0.22</td>
</tr>
<tr>
<td>14. Overall benefits</td>
<td>5.96</td>
<td>0.18</td>
</tr>
<tr>
<td>15. Overall satisfaction</td>
<td>5.98</td>
<td>0.13</td>
</tr>
</tbody>
</table>
Demographic Profile

The demographic profile of participants with type 2 diabetes who completed the study (n=56) is described in Table 6. Participants had an average age of 55.8 years (SD=13.2). They were mostly married (87.5%) women (53.8%) living with family (91.1%). About two-thirds (63%) of participants were college/university graduates, 33.9% were high school graduates, and 3.6% were grade school graduates.

Due to wide diversity of ethnicity reported by participants, the responses were categorized based on their country of origin. Nearly one-third of participants (17, 30.3%) were Filipinos; ten (17.8%) participants were from other South Asian countries including India, Sri Lanka, and Pakistan. Eleven (19.6%) participants indicated they were Canadians, and ten (17.8%) were from European origin which consisted of Scottish, Greek, Italian or Ukrainian background.

Diabetes-Related Clinical Characteristics

Clinical characteristics included duration of diabetes, body mass index (BMI), and glycemic control. The indicators of glycemic control consisted of fasting blood glucose (FBG) and HbA1c. According to the clinical practice guidelines from Canadian Diabetes Association (CDA, 2008), FBG target level is within a range of 4.0-7.0 mmol/L; HbA1c target is \( \leq 7.0 \% \); the healthy BMI range is 18.5-24.9(kg/m\(^2\)), whereas BMI between 25-29.9 kg/m\(^2\) is considered overweight; and BMI over 29.9 kg/m\(^2\) is classified as obesity. As showed in Table 7, participants had diabetes for an average of 5.9 years (SD=7.1); 28 participants (50.0%) were newly diagnosed (< 1 year) with diabetes. They had an average BMI of 30.1 kg/m\(^2\) (SD=6.0); and 49 participants (87.5%) were overweight or obese. The average fasting blood glucose was 9.96 mmol/L.
(SD=3.58), and HbA1c was 8.11 % (SD=1.58). Overall, 80.35% participants did not reach the glycemic control targets for FBG and HbA1c.

**Results Pertaining to Outcome Variables**

The objectives of the pilot study related to examining the effects of the intervention on foot self-care knowledge, behavior, and self-efficacy, and foot problems including skin and toenail conditions, and wearing proper shoes and socks in persons with diabetes at low risk for foot ulceration. The results pertaining to each outcome are presented in terms of mean scores at each point of measurement, change scores between T1 and T2 or T3 and findings of statistical analysis to determine differences in the mean scores over time.

**Effects of Intervention on Foot Self-Care Knowledge**

**Mean scores over time**

The total mean scores (SD) for foot self-care knowledge at the three points of measurement are presented in Table 12. On average, participants had moderate levels of foot self-care knowledge at baseline (T1). The total mean scores for foot self-care knowledge increased at T2, and kept nearly the same level at 3-month follow-up (T3).

**Table 12  Mean scores on foot self-care knowledge over time**

<table>
<thead>
<tr>
<th>Variables</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot self-care knowledge</td>
<td>5.80±2.48</td>
<td>10.96±0.18</td>
<td>10.87±0.57</td>
</tr>
</tbody>
</table>

Score range: 0-11
Change scores over time

The mean change scores on foot self-care knowledge over time are shown in Table 13. The change score quantifies the magnitude of the difference on the outcome from T1 to T2, and from T2 to T3.

The mean change score on foot self-care knowledge was positive (implying improvement) between T1 and T2, and almost zero between T2 and T3. As shown in table 14, the overwhelming majority of participants (54, 96.4%) reported improvement in foot self-care knowledge from T1 to T2, and no change from T2 to T3. Only 4 (7.1%) participants displayed worsening foot self-care knowledge from T2 to T3. The results indicate that the level of foot self-care knowledge increased following the face-to-face educational sessions and was maintained at the 3 months follow-up.

<table>
<thead>
<tr>
<th>Time</th>
<th>Variables</th>
<th>Mean±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T2</td>
<td>Foot self-care knowledge</td>
<td>5.16±2.47</td>
<td>-11.0 to 0</td>
</tr>
<tr>
<td>T2-T3</td>
<td>Foot self-care knowledge</td>
<td>-0.08±0.61</td>
<td>-1 to 4</td>
</tr>
</tbody>
</table>

Table 14 Distribution of change scores on foot self-care knowledge over time

<table>
<thead>
<tr>
<th>Changes scores on foot self-care knowledge</th>
<th>T1-T2</th>
<th>T2-T3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Improvement</td>
<td>54</td>
<td>96.4%</td>
</tr>
<tr>
<td>No change</td>
<td>2</td>
<td>3.6%</td>
</tr>
<tr>
<td>Worsening</td>
<td>0</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Results of the RM-ANOVA

The results of the Repeated Measures Analysis of Variance (RM-ANOVA) indicated a statistically significant time effect for foot self-care knowledge (F (2, 54) = 230.444, p < 0.01). To determine the point in time at which changes in this outcome occurred, post-hoc analysis using dependent sample or paired t-test was conducted. The results (Table 15) showed a statistically significant difference in the mean knowledge score from T1 to T2, and no significant difference in this outcome from T2 to T3. In general, the findings imply that participants gained knowledge right after receiving the educational intervention and retained it at 3 months post-intervention.

Table 15 Results of paired t-test for foot self-care knowledge

<table>
<thead>
<tr>
<th>Pairs</th>
<th>Mean ± SD Difference</th>
<th>Paired t values</th>
<th>Df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T2</td>
<td>-5.16 ± 2.47</td>
<td>-15.58</td>
<td>55</td>
<td>0.000</td>
</tr>
<tr>
<td>T2-T3</td>
<td>0.08 ± 0.61</td>
<td>1.093</td>
<td>55</td>
<td>0.279</td>
</tr>
</tbody>
</table>

Effects of Intervention on Foot Self-Care Efficacy

Mean scores over time

The total mean scores (SD) for foot self-care efficacy at the three points of measurement are presented in Table 16 (score range: 9-54). On average, participants had moderate levels of foot self-care efficacy at T1. The foot self-care efficacy level increased after the 2 face-to-face sessions, and remained at nearly the same level at 3-month follow-up.
Table 16  Mean scores on foot self-care efficacy over time

<table>
<thead>
<tr>
<th>Variables</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot self-care efficacy</td>
<td>33.66±10.70</td>
<td>53.00±1.88</td>
<td>52.28±2.35</td>
</tr>
</tbody>
</table>

Change scores over time

The mean change score on foot self-care efficacy (in Table 17) between T1 and T2 was 19.33, and close to zero between T2 and T3. Specifically, all participants showed improvement in foot self-care efficacy level from T1 to T2 (in Table 18). A quarter (25.0 %) of participants reported improvement and 26.8% had no change in mean scores in foot self-care efficacy level between T2 to T3, indicating that more than half of participants maintained foot self-care efficacy level at 3-months follow-up. About 48.3% of participants displayed a slight decrease (mean score 0.71) in foot self-care efficacy level from T2 to T3; but no statistically significant difference was found on the mean score on foot self-care efficacy level between T2 to T3 (P>0.05).

Table 17  Mean change scores on foot self-care efficacy

<table>
<thead>
<tr>
<th>Time</th>
<th>Variables</th>
<th>Mean±SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T2</td>
<td>Foot self-care efficacy</td>
<td>19.33±10.52</td>
<td>-42 to -4</td>
</tr>
<tr>
<td>T2-T3</td>
<td>Foot self-care efficacy</td>
<td>-0.71±3.13</td>
<td>-8 to 10</td>
</tr>
</tbody>
</table>

Table 18  Distribution of change scores on foot self-care efficacy over time

<table>
<thead>
<tr>
<th>Change scores on foot self-care efficacy</th>
<th>T1-T2</th>
<th>T2-T3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Improvement</td>
<td>56</td>
<td>100.0</td>
</tr>
<tr>
<td>No change</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Worsening</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Results of the RM-ANOVA

The results of the RM-ANOVA indicated a statistically significant time effect for foot self-care efficacy (F(2, 54) = 94.668, p = 0.000). The results of post-hoc analysis (Table 19) demonstrated a statistically significant difference in the mean score on foot self-care efficacy from T1 to T2. A small but non-significant decrease in mean score on foot self-care efficacy was found between T2 and 3-month follow-up (T3).

<table>
<thead>
<tr>
<th>Pairs</th>
<th>Mean ±SD difference</th>
<th>Paired t values</th>
<th>Df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T2</td>
<td>-19.33±10.52</td>
<td>-13.755</td>
<td>55</td>
<td>0.000</td>
</tr>
<tr>
<td>T2-T3</td>
<td>0.714±3.13</td>
<td>1.707</td>
<td>55</td>
<td>0.094</td>
</tr>
</tbody>
</table>

Effects of Intervention on Foot Self-Care Behavior

T2 data collection occurred immediately after the completion of the first two face-to-face sessions, participants had no opportunity to make any change in the foot self-care behavior (on the same day). Thus, foot self-care behavior was not measured at T2, but was assessed at pre-test (T1) and 3-month follow-up (T3). On average, the participants had lower levels of foot self-care behavior at pre-test (mean=4.30, SD=2.08, range: 0-11) than 3-month follow-up (mean=10.03, SD=1.11, range: 0-11). The mean difference was 5.73 (SD=2.48). The mean scores significantly increased between T1 and T3 (t(55)=117.228, p<0.01). Almost all (98.2%) participants showed improvement in foot self-care behavior at 3-month follow-up (Table 20). As shown in Table 21, a larger percentage of participants reported performing the specific foot self-care behavior at 3-month follow-up than at pre-test (all individual items p<0.01). Overall,
the results indicated that the intervention was effective in enhancing participants’ performance of daily foot self-care behaviors.

Table 20  Distribution of change scores on foot self-care behavior across time

<table>
<thead>
<tr>
<th>Changes in mean scores on foot self-care behavior</th>
<th>T1-T3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td>Improvement</td>
<td>55</td>
</tr>
<tr>
<td>No change</td>
<td>1</td>
</tr>
<tr>
<td>Worsening</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 21  Comparison of the number of participants performing foot self-care behavior over time

<table>
<thead>
<tr>
<th>Foot self-care behavior</th>
<th>Pre-test (T1) n (%)</th>
<th>3-month F/U(T3) n (%)</th>
<th>$x^2$(df, p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I wash my feet every day in warm water.</td>
<td>39 (69.6%)</td>
<td>54 (96.4%)</td>
<td>$x^2$(1)=14.261, p=0.000</td>
</tr>
<tr>
<td>I dry my feet thoroughly, with a towel.</td>
<td>24 (42.9%)</td>
<td>54 (96.4%)</td>
<td>$x^2$(1)=38.009, p=0.000</td>
</tr>
<tr>
<td>I look at my feet carefully every day.</td>
<td>18 (32.1%)</td>
<td>50 (89.3%)</td>
<td>$x^2$(1)=38.332, p=0.000</td>
</tr>
<tr>
<td>I use a lotion to moisten my feet every day.</td>
<td>12 (21.4%)</td>
<td>44 (78.6%)</td>
<td>$x^2$(1)=36.571, p=0.000</td>
</tr>
<tr>
<td>I massage my feet and legs every day.</td>
<td>5 (8.9%)</td>
<td>40 (71.4%)</td>
<td>$x^2$(1)=45.506, p=0.000</td>
</tr>
<tr>
<td>I do feet and legs exercise every day.</td>
<td>3 (5.4%)</td>
<td>44 (78.6%)</td>
<td>$x^2$(1)=61.627, p=0.000</td>
</tr>
<tr>
<td>I trim my toenails straight across.</td>
<td>19 (33.9%)</td>
<td>55 (98.2%)</td>
<td>$x^2$(1)=51.619, p=0.000</td>
</tr>
<tr>
<td>I wear extra wide, extra big shoes.</td>
<td>34 (67.7%)</td>
<td>56 (100.0%)</td>
<td>$x^2$(1)=27.378, p=0.000</td>
</tr>
<tr>
<td>I wear cotton, and loose socks</td>
<td>27 (48.2%)</td>
<td>54 (96.4%)</td>
<td>$x^2$(1)=32.516, p=0.000</td>
</tr>
<tr>
<td>I wear socks and shoes all the time, except in bed</td>
<td>30 (53.6%)</td>
<td>55 (98.2%)</td>
<td>$x^2$(1)=30.501, p=0.000</td>
</tr>
<tr>
<td>If I get a blister or foot sore, I let my doctor know right away</td>
<td>30 (53.6%)</td>
<td>56 (100.0%)</td>
<td>$x^2$(1)=33.860, p=0.000</td>
</tr>
</tbody>
</table>

Effects of The Intervention on Foot Skin Condition

The researcher assessed participants’ skin condition at pre-test and 3-month follow-up. At pre-test, more than half of the participants had skin dryness and calluses,
and over a quarter had cracks. No moisture between toes, lesions or skin ulcers were found. The results of Chi-square test showed that the percentage of participants who had minor skin problems such as dryness, crackness, and redness significantly decreased from pretest to 3-month follow up (Table 22) (all p<0.001). Since the expected frequencies on fissures, blister, fungal infection, and lesions were less than 5, the Fisher’s exact test was used to analyze these items. The results of Fisher’s exact test indicated that these items had no significant decrease from pretest to 3-month follow-up (all p>0.05).

In Table 23 the changes in percentage of foot problems from pretest to 3-month follow-up are presented. The results showed that most participants having foot problems such as dryness, crackness, redness, fissures, blister, and fungal infection at pretest experienced improvement in the respective problem conditions at 3-month follow-up. However, the number of the participant who had fissure (n=3), blister (n=1) and fungal infection (n=2) was small. In contrast, most participants who had calluses/corns at pretest demonstrated no changes in these foot problems at 3-month follow-up. Overall, The results indicated that the intervention was effective in preventing the development or worsening of minor foot skin problems.
<table>
<thead>
<tr>
<th>Foot skin condition</th>
<th>Pre-test (T1)</th>
<th>3-month follow-up (T3)</th>
<th>Chi-square test: $x^2$ (df), p / Fisher’s exact test: p (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Calluses/corns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (57.1%)</td>
<td>23 (44.1%)</td>
<td>$x^2(1)=2.89, p=0.089$</td>
</tr>
<tr>
<td>No</td>
<td>24 (42.9%)</td>
<td>33 (58.9%)</td>
<td></td>
</tr>
<tr>
<td>Dryness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (85.7%)</td>
<td>5 (8.9%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8 (14.3%)</td>
<td>51 (91.1%)</td>
<td>$x^2(1)=66.23, p=0.000$</td>
</tr>
<tr>
<td>Crackness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16 (28.6%)</td>
<td>0 (0.0%)</td>
<td>$x^2(1)=18.67, p=0.000$</td>
</tr>
<tr>
<td>No</td>
<td>40 (71.4%)</td>
<td>56 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (17.9%)</td>
<td>0 (0.0%)</td>
<td>$x^2(1)=10.98, p=0.001$</td>
</tr>
<tr>
<td>No</td>
<td>46 (82.1%)</td>
<td>56 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Fissures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (8.9%)</td>
<td>2 (3.6%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>51 (91.1%)</td>
<td>54 (96.4%)</td>
<td>p=0.219</td>
</tr>
<tr>
<td>Blister</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (1.8%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>55 (98.2%)</td>
<td>56 (100.0%)</td>
<td>p=0.500</td>
</tr>
<tr>
<td>Moist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>56 (100.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>Fungal infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 (3.6%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>54 (96.4%)</td>
<td>56 (100.0%)</td>
<td>p=0.248</td>
</tr>
<tr>
<td>Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>2 (3.6%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>54 (96.4%)</td>
<td>p=0.248</td>
</tr>
</tbody>
</table>
**Table 23 Changes in percentage of foot problems over time**

<table>
<thead>
<tr>
<th>Skin condition</th>
<th>Improvement</th>
<th>No change</th>
<th>Worsening</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Calluses/corns</td>
<td>9</td>
<td>28.2</td>
<td>23</td>
</tr>
<tr>
<td>Dryness</td>
<td>43</td>
<td>89.5</td>
<td>5</td>
</tr>
<tr>
<td>Crackness</td>
<td>16</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Redness</td>
<td>10</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Fissures</td>
<td>3</td>
<td>60.0</td>
<td>2</td>
</tr>
<tr>
<td>Blister</td>
<td>1</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Moist</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
</tr>
<tr>
<td>Fungal infection</td>
<td>2</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Lesions</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Effects of The Intervention on Toenails Condition**

As shown in Table 24, less than a quarter of the participants experienced minor toenail problems including improper toenail in length, poor hygiene, abnormal thickness, and fungal infection at pre-test. No ingrown or other toenail problems were found. The results of Chi-square analysis showed that the percentage of participants who had minor toenail problems significantly decreased from pretest to 3-month follow up (p<0.05).

Since the expected frequencies on fungal infection was less than 5, the Fisher’s exact test was used to analyze the item. The result of Fisher’s exact test indicated that fungal infection had no significant decrease from pretest to 3-month follow-up (p>0.05).

As presented in Table 25, the majority (>70%) of participants showing a poor hygiene, improper length, improper thickness, and fungal infection of toenails at pretest demonstrated improvement in the respective problem conditions at 3-month follow-up.
Table 24  Results of statistical analysis for toenails condition

<table>
<thead>
<tr>
<th>Toenails</th>
<th>Pre-test (T1) n (%)</th>
<th>3-month follow-up (T3) n(%)</th>
<th>Chi-square test: $x^2$(df), p</th>
<th>Fisher’s exact test: p (1-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hygiene</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>45 (80.4%)</td>
<td>56 (100.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>11 (19.6%)</td>
<td>0 (0.0%)</td>
<td>$x^2$(1)=12.198, p=0.000</td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>43 (76.8%)</td>
<td>53 (94.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>13 (23.2%)</td>
<td>3 (5.4%)</td>
<td>$x^2$(1)=7.292, p=0.007</td>
<td></td>
</tr>
<tr>
<td>Thickness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>45 (80.4%)</td>
<td>53 (94.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abnormal</td>
<td>11 (19.6%)</td>
<td>3 (5.4%)</td>
<td>$x^2$(1)=5.224, p=0.022</td>
<td></td>
</tr>
<tr>
<td>Ingrown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>56 (100.0%)</td>
<td>56 (100.0%)</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Fungal infection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (8.9%)</td>
<td>1 (5.8%)</td>
<td></td>
<td>p=0.103</td>
</tr>
<tr>
<td>No</td>
<td>51 (91.1%)</td>
<td>55 (94.2%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 25 Changes in toenails condition over time

<table>
<thead>
<tr>
<th>Toenails</th>
<th>Improvement n</th>
<th>No change n</th>
<th>Worsening n</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Hygiene</td>
<td>11 100.0%</td>
<td>0 0.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Improper length</td>
<td>10 76.9%</td>
<td>3 23.1%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Thickness</td>
<td>8 72.7%</td>
<td>3 27.3%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Ingrown</td>
<td>0 0.0%</td>
<td>0 0.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>Fungal infection</td>
<td>4 80.0%</td>
<td>1 20.0%</td>
<td>0 0.0%</td>
</tr>
</tbody>
</table>

Effects of The Intervention on Wearing Proper Shoes and Socks

As shown in Table 26, nearly one-fifth of the participants wore improper shoes, and more than one-third of the participants wore improper socks at baseline.
Since the expected frequencies on shoe style and adjustable with laces/velcro were less than 5, the Fisher’s exact test was used to analyze this two items, and Chi-square test was used to analyze the rest of items on wearing proper shoes and socks. The results of Chi-square test and Fisher’s exact test showed that the percentage of participants who wore improper shoes in terms of shoe style, materials, and shoes with adjustable laces/velcro significantly decreased from T1 to T3. Similarly, the percentage of participants who wore improper socks in terms of sock fit, materials, color, and sock loose in legs significantly decreased from T1 to T3 (all variables p<0.05). The majority of participants (over 64%) demonstrated improvement in wearing proper shoes and socks conditions at 3-month follow-up (Table 27). The findings indicated that the intervention was effective in assisting participants in selecting and wearing proper shoes and socks.
Table 26  Results of statistical analysis for wearing proper shoes and socks

<table>
<thead>
<tr>
<th>Shoes and socks</th>
<th>Pre-test (T1)</th>
<th>3-month F/U (T3)</th>
<th>Chi-square test: ( \chi^2(\text{df}) ), ( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shoes</strong></td>
<td></td>
<td></td>
<td>Fisher’s exact test: ( p(\text{1-sided}) )</td>
</tr>
<tr>
<td>Inside shoe</td>
<td>56 (100.0%)</td>
<td>56 (100.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>Improper</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>n/a</td>
</tr>
<tr>
<td>Fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>45 (80.4%)</td>
<td>52 (92.9%)</td>
<td>( \chi^2(1)=3.772, p=0.052 )</td>
</tr>
<tr>
<td>No</td>
<td>11 (19.6%)</td>
<td>4 (7.1%)</td>
<td></td>
</tr>
<tr>
<td>Style</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>48 (85.7%)</td>
<td>56 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>8 (14.3%)</td>
<td>0 (0.0%)</td>
<td>( p=0.003 )</td>
</tr>
<tr>
<td>Adjustable with laces</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (85.7%)</td>
<td>56 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8 (14.3%)</td>
<td>0 (0.0%)</td>
<td>( p=0.003 )</td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>45 (80.4%)</td>
<td>56 (100.0%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>11 (19.6%)</td>
<td>0 (0.0%)</td>
<td>( \chi^2(1)=12.198, p=0.000 )</td>
</tr>
<tr>
<td><strong>Socks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25 (44.6%)</td>
<td>55 (98.2%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>31 (55.4%)</td>
<td>1 (1.8%)</td>
<td>( \chi^2(1)=39.375, p=0.000 )</td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>30 (53.6%)</td>
<td>53 (94.6%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>26 (46.4%)</td>
<td>3 (5.4%)</td>
<td>( \chi^2(1)=24.615, p=0.000 )</td>
</tr>
<tr>
<td>Binding legs and feet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>38 (67.9%)</td>
<td>51 (91.1%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>18 (32.1%)</td>
<td>5 (8.9%)</td>
<td>( \chi^2(1)=9.247, p=0.002 )</td>
</tr>
<tr>
<td>Color</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper</td>
<td>16 (28.6%)</td>
<td>47 (83.9%)</td>
<td></td>
</tr>
<tr>
<td>Improper</td>
<td>40 (71.4%)</td>
<td>9 (16.1%)</td>
<td>( \chi^2(1)=34.866, p=0.000 )</td>
</tr>
</tbody>
</table>
Table 27  Changes in wearing proper shoes and socks over time

<table>
<thead>
<tr>
<th>Shoes and socks</th>
<th>Improvement</th>
<th>No change</th>
<th>Worsening</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>Shoes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inside shoe</td>
<td>0</td>
<td>0.0</td>
<td>0</td>
</tr>
<tr>
<td>Fit</td>
<td>7</td>
<td>63.6</td>
<td>4</td>
</tr>
<tr>
<td>Style</td>
<td>8</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Adjustable with laces /Velcro</td>
<td>8</td>
<td>100.0</td>
<td>0</td>
</tr>
<tr>
<td>Material</td>
<td>11</td>
<td>100.0</td>
<td>0</td>
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<tr>
<td>Socks</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td>30</td>
<td>96.7</td>
<td>1</td>
</tr>
<tr>
<td>Material</td>
<td>23</td>
<td>86.4</td>
<td>3</td>
</tr>
<tr>
<td>Binding legs and feet</td>
<td>13</td>
<td>72.2</td>
<td>5</td>
</tr>
<tr>
<td>Color</td>
<td>31</td>
<td>77.5</td>
<td>9</td>
</tr>
</tbody>
</table>

Summary

The results of the pilot study provided initial evidence suggesting the foot self-care educational intervention was feasible and judged as acceptable by adult patients with type 2 diabetes. It was effective in improving patients’ foot self-care knowledge, foot self-care efficacy, and foot self-care behaviors performance, in reducing the occurrence of minor foot skin and toenails problems, and improving wearing proper shoes and socks.
Chapter 5 Discussion and Implications

The specific objectives of this pilot study were to examine the feasibility, acceptability, and effects of the foot care educational intervention on foot self-care knowledge, behaviors, self-efficacy, and foot problems in adults with type 2 diabetes at low risk for foot ulcerations living in the GTA. In this chapter, the feasibility and acceptability of the intervention, and sample characteristics are discussed first. Then findings pertaining to the research objectives, and contribution of the study to preventive foot-care education are discussed in relation to relevant literature. Lastly, the study strengths and limitations are highlighted, and implications for future research are presented.

Discussion

Feasibility of the Intervention

Several indicators have been used to assess the feasibility of an intervention. The most frequent indicators include participants’ enrollment, attendance at the intervention sessions, adherence to intervention, and dropout or withdrawal (Cole & Dendukuri, 2004; Hinkkal et al., 2007; King, Sanchez-Johnsen, Van Orman, Cao, & Matthews, 2008; Van Haastregt et al., 2007). Attendance at the intervention sessions also was used to reflect intervention acceptability in a diabetes self-management support intervention (Tang et al., 2005). The present study used Cole and Dendukuri’s (2004) definition of feasibility, that is, the feasibility of the intervention relates to the degree to which participants enroll in, complete, and comply with the intervention.

The enrollment rate was high (88.6 %). This rate is comparable to the enrollment rate (89.4%) reported by Malone et al. (1989) who evaluated an educational
intervention to assist patients with diabetes manage foot problems. These rates are higher than those reported in other studies (74.1%-54.2%) for the prevention of foot problems in patients with diabetes (Borges & Ostwald, 2008; Litzelman et al., 1997). The differences in enrolment rates across studies may be related to the nature of the intervention or the target population. Specifically, participants in the pilot study had no previous diabetes education and therefore were interested in learning more about foot self-care to prevent complications. A total of nine persons (11.4%) declined enrollment in the pilot study. The reasons were lack of interest in the study and logistics associated with travel to the clinic where the intervention was delivered. The reasons for non-participation were not related to the nature of the intervention.

The high enrollment rate in this pilot study may be related to the implementation of complementary recruitment strategies. The strategies encompassed recruiting participants at multiple medical centers, having family physicians inform potential participants of the study at a regularly scheduled visit, and placing recruitment flyers in easily visible and accessible places in family physicians’ offices and waiting rooms.

The majority (80%) of participants completed the intervention, and 20% withdrew. This attrition rate is comparable to that reported in other studies (12% - 23%) examining the effectiveness of foot care educational interventions in patients with diabetes (Barth et al., 1991; Bloomgarden et al., 1987; Corbett, 2003; Fan et al., 2006). The reasons for withdrawal were also not directly related to the nature of the intervention; they consisted of moving to other cities, changes in health condition such as broken ankle and pregnancy, inability to take time off from work to attend the
intervention sessions, and loss to follow up. The reported inability to take days off from work to attend the intervention sessions requires consideration of alternative modes for delivering the intervention. Internet-based delivery of educational interventions may be explored in future research.

Attrition has been recognized as a factor that threatens the internal validity and reduces statistical power in a study (Brown et al., 2006). To minimize attrition, three strategies were adopted in this pilot study: 1) Giving the first two intervention sessions on the same day rather than on two separate days within one week based on participants’ preferences; 2) Calling participants to remind them of the upcoming intervention and data collection session; 3) Offering written materials on foot self-care for future reference, and incentives in the form of a toenail clipper and TTC tokens to cover expenses related to transportation to the study site to attend the intervention sessions.

Providing the educational intervention on one day followed with telephone calls to reinforce foot care recommendations were convenient for participants, and facilitated attendance at the intervention sessions. Thus, convenience in delivery of the intervention may have minimized attrition; also, it may have enhanced feasibility of the intervention.

Attrition may contribute to self-selection bias when individuals who withdraw from the study differ from those who complete the study on baseline characteristics (Chatfield, Brayne, & Matthews, 2005). To examine the extent of self-selection bias, the baseline characteristics of completers and dropouts were compared. The results of comparisons indicated that completers and dropouts were similar in demographic
profile, clinical characteristics, foot condition, foot self-care knowledge, behavior and self-efficacy measured at pre-test. Therefore, attrition did not result in self-selection bias.

Compliance with the intervention was operationalized as the percentage of participants who completed the four intervention sessions out of the number of eligible participants who consented and provided baseline data. The high level (95.7%) of attendance found in this pilot study was comparable to that reported (90-95%) for other diabetes self-management education interventions (Corbett, 2003; D’Eramo Melkus et al., 2004). The high intervention attendance and compliance rate in the pilot study may be related to the nature of the intervention, its delivery, and the incentives provided to participants. The focus of the intervention on foot self-care raised awareness of the importance of avoiding foot problems such as foot ulcers and lower-extremity amputations, which may have motivated participants and increased their interest in the prevention of foot problems. The intervention sessions were offered in face-to-face format on one day and in follow-up phone calls. This format was convenient to participants and may have facilitated attendance. In addition, the incentives (TTC tokens) assisted participants with the cost of transportation and may have promoted attendance.

The high enrollment, completion, and compliance rates observed in this pilot study support the feasibility of the intervention. A feasible intervention is successfully implemented as designed and adhered to, resulting in the achievement of intended outcomes. This was consistent with results of Corbett (2003) study. In Corbett’s study and in this pilot study, the diabetes self-management education intervention was
provided in an individual face-to-face session, covered a range of topics that are of relevance to patients, aimed at increasing foot self-care knowledge, practice, and self-care efficacy, and practical recommendations that are of utmost importance to patients with diabetes. Although the dose of the intervention in the present study differed from Corbett’s study, which applied a 20-minute brief verbal teaching, the attendance rate was high in both studies, indicating that the dose of the intervention did not interfere with its feasibility.

**Acceptability of the Intervention**

Acceptability was defined as participants’ perception of the intervention’s effectiveness, appropriateness, fairness, and benefits, as well as willingness to use the intervention. Overall, participants viewed the foot care educational intervention as highly acceptable. Specifically, they rated the intervention as very appropriate, effective, and suitable for patients with diabetes. Participants liked the 5-step foot self-care approach used in the intervention, considered it beneficial, and were willing to use it daily; they were satisfied with the intervention. The findings are consistent with the results of a previous study that evaluated the effects of a self-management intervention in patients with type 2 diabetes (Tang et al., 2005).

In this pilot study, participants of different ethnic backgrounds rated the newly designed foot care educational intervention as highly acceptable. They perceived it as beneficial, and were willing to apply it on a daily basis. Accordingly, it was well received by diverse ethnic groups.

It is possible that the acceptability of the intervention may have contributed to high attendance and compliance. According to Sidani et al. (2009b), participants who
judge an intervention as acceptable are usually willing to use it in daily life, and to comply with it; therefore, they are likely to achieve the intended outcomes.

**Characteristics of Participants**

Participants in the present study had an average age of 55.8 years, were mostly married (87.5%) women (53.8%) living with family (91.1%). About two-thirds of participants were college/university graduates, and one-third were high school graduates. This finding was consistent with data from Statistics Canada (2006), indicating that highly educated individuals reside in the GTA. As well, there is a tendency for diabetes to occur in higher stress jobs (such as those involving management and sales), and sedentary jobs (such as business and retail), which are often held by individuals with higher levels of education (Bindon, 1997; Aldana, 2001). In contrast, diabetes tends to happen in low-income people because of unhealthy eating habits (Yannakoulia, 2006).

Participants in the present study identified with different ethnic groups reflective of the ethnic-cultural diversity of Canada, and in particular the GTA (Statistics Canada, 2001). People of Asian, South Asian, and African descent, Aboriginal, and Hispanic are genetically more susceptible to develop diabetes (CDA, 2011). Individuals of South Asian descent represent Canada’s fastest-growing immigrant population. Of all expatriate ethnic groups, they have the highest rates of morbidity and mortality from diabetes related complications (CDA, 2008). In the present study nearly half of the participants were Southeast (30%) and South (17.8%) Asians. In Ontario, South Asians and or Southeast Asians comprise 12% of the population with diabetes, yet they account for less than 4% of the overall population (Glazier et al., 2007). In summary,
the ethnic distribution of the sample in the present study is comparable to that of the GTA, which support its representativeness.

In terms of diabetes related clinical characteristics, 87% of participants were overweight or obese and 50% of them had not well controlled diabetes (i.e., FBG and HbA1C were not at targets). This observed clinical profile is anticipated because 50% of participants were newly diagnosed, and the remaining had diabetes for a rather short duration. However, this finding highlight the importance of referring patients to diabetes self-management education program as early as possible following diagnosis in order to assist them in successfully carrying out self-management recommendations and maintaining an acceptable levels of glycemic control. Such control is necessary to reduce the risk of foot problems. Patients are encouraged to attend the diabetes self-management education program either before or concurrently with the foot self-care educational intervention to maximize the benefits.

Overall, the sample was representative of the target ethnically diverse population with type 2 diabetes residing in the GTA. As such, the results of this pilot study are applicable to patients with diabetes at low risk for foot ulceration.

Effects of Intervention on Outcomes

Effects of Intervention on Foot Self-Care Knowledge

The foot self-care educational intervention demonstrated effectiveness in increasing foot self-care knowledge. Participants’ level of foot self-care knowledge significantly increased immediately at the completion of the face-to-face intervention sessions, and was maintained at 3 months follow-up. This pattern of change in foot self-
care knowledge indicated that the intervention was successful in achieving this outcome in the short term.

This finding is consistent with the results of four previous studies that evaluated foot-care education interventions given in individual face-to-face sessions (Corbett, 2003; Fan et al., 2006; Hamalainen et al., 1997 & 1998; Rettig et al., 1986). The four studies targeted diabetic patients with mixed (i.e., low and high) risk for foot ulcerations. The results indicated significant improvement in foot-care knowledge at six weeks (Corbett, 2003), six months (Rettig et al., 1986), at nine months post intervention (Fan et al., 2006). One study showed maintenance in knowledge gains at one year and at a seven-year follow-up (Hamalainen et al., 1997 & 1998). In contrast, Kruger et al.’s (1992) findings were inconsistent showing no significant improvement in foot-care knowledge at 6 months post-intervention. The high attrition rate and the small sample size in Kruger et al.’s study may explain the observed difference in findings.

Results of the present study suggest that patients at low-risk for foot ulceration appear to benefit from an educational intervention. The format for delivering the intervention may have contributed to its effectiveness in enhancing knowledge. The format entailed individual face-to-face contacts, which allowed the interventionist to relay information in a way that is relevant and meaningful to each participant and to clarify, on the spot, any misunderstanding (Weinger & Carver, 2009). The use of slides highlighting key points and showing illustrative pictures complemented the presentation and discussion, and may have facilitated knowledge retention (Touro & Joglekar, 2011). In addition, the hands-on practice of foot self-care strategies offered an opportunity for participants to apply the foot self-care knowledge they learned, and to
receive constructive feedback on their performance, which are in keeping with the Bandura’s Social Cognitive Theory (1989). As well, participants were provided with a booklet that reinforced the information discussed and served as a reference when applying foot self-care strategies in day-to-day life. Participants stated that they liked the pamphlet since it was well-designed, abundant in content, practical, and easy to read. They also reported having read the booklet a few times, wrote notes, and followed the instructions.

The interventionist employed teaching aids such as slides, tools (i.e., model of healthy foot, model of common foot problems, mirror with long-handle, soft towel, toenails clippers, models of proper shoes and socks, 10g-monofilaments), and color printed booklets. Teaching aids are important components of training interaction during a learning event. They are useful as a means of adding concreteness to an otherwise abstract or complicated content, thereby facilitating the learning process, and increasing the effectiveness of teaching and knowledge retention (Kitao & Kitao, 1997; McKimm & Jollie, 2007; Touro & Joglekar, 2011). Furthermore, the telephone booster sessions may have reinforced the knowledge of foot self-care that participants learned in the first two intervention sessions, contributing to the 3-month sustainability of the knowledge gain (Centers et al., 2007). The integration of different educational formats and teaching strategies that target self-efficacy: 1) was innovative, as it had not been done previously, and 2) may have contributed to knowledge retention.

As compared to previously described interventions, the content of the educational intervention in the pilot study was comprehensive, covering topics of relevance to foot self-care including awareness of risk factors for foot ulceration,
importance of annual inspection of feet by a health care professional, knowledge and behavior performance of daily foot self-care, proper toenails care, wearing proper shoes and socks, prevention of foot trauma, and when to seek help for foot problems (Fan et al., 2005; RNAO, 2004 & 2005). The intervention content raised participants’ awareness of the importance of preventing foot problems, and the mode of its delivery enhanced teaching effectiveness which may have motivated participants to learn strategies to care for their feet, and to retain the knowledge gain at 3-month follow-up.

**Effects of Intervention on Foot Self-Care Efficacy**

The foot self-care educational intervention demonstrated effectiveness in increasing foot self-care efficacy immediately after completion of the face-to-face sessions, which was maintained at 3-month follow-up. Only two studies examined the effects of educational interventions on self-efficacy of foot-care, and their results were inconsistent.

The present study findings were consistent with those of Corbett’s study (2003) in which the intervention was brief, involving one-on-one discussion for 10 to 20 minutes; it incorporated verbal and written instructions. However, Borges and Ostwald (2008) reported non-significant change in Mexican American patients who received a 5-minute foot examination to assess the risk for lower extremity amputation and a 15-minutes brief foot self-care educational intervention. The possible reasons for the non-significant change in self-efficacy include participants’ social-cultural characteristics (lower income, lack of insurance, and cultural beliefs and values), the low dose of the educational intervention and high (50 %) attrition rate at one-month follow-up.
The observed effectiveness of the present foot self-care educational intervention can be attributed to its components that were consistent with the proposition of the Social Cognitive Theory. The presentation and discussion component of the intervention operationlized verbal persuasion, and the hands-on practice component of the intervention were consistent with mastery and vicarious experiences, which are principal sources of self-efficacy as proposed in the Social Cognitive Theory (Bandura, 1989 & 1997). During the hands-on practice, participants engaged in the 5-step foot self-care approach, toenails care, and wearing proper shoes and socks. This training opportunity for observing and performing foot self-care behaviors created experiential learning and reinforced theoretical knowledge. Additionally, the telephone contact booster sessions enhanced self-efficacy through verbal persuasion.

The findings demonstrated that more than half of participants enhanced and maintained foot self-care efficacy level at 3-months follow-up; whereas 48 % of participants displayed some decrease in the self-efficacy level at 3-months follow-up. The application of combined strategies (presentation, discussion, and hands-on practice) as proposed in the Social Cognitive Theory, contributed to increased levels of self-efficacy related to foot self-care immediately after the face-to-face session. However, the reason for the observed decline at 3-month follow up is not clear and requires further investigation. It suggests the need for a booster session within the 3-month period after completion of the intervention.

**Effects of Intervention on Foot Self-Care Behaviors**

Present findings indicated that foot self-care behavior can be significantly improved at 3-months following the intervention. Most participants showed significant
improvement in performance of washing feet and drying the feet thoroughly with a
towel after washing, inspecting the feet every day, using a lotion to moisten the feet
every day, massaging the feet every day, doing feet exercise every day, trimming
toenails straight across, wearing cotton and loose socks, and wearing socks and shoes
all the time. The findings are consistent with those of previous studies supporting the
effectiveness of foot self-care interventions in enhancing performance of foot self-care
behaviors (Corbett, 2003; Fan et al., 2006; Hamalainan et al.,1997 & 1998; Litzelman
et al., 1997; Kruger & Guthrie, 1992; Rettig et al., 1986), despite variability in the
formats of delivering intervention, the content covered, and participants’ risk for foot
ulcerations.

In contrast to previously evaluated interventions, the educational intervention
pilot-tested in this study was carefully designed. It covered a range of topics including
the 5-step daily self foot-care strategies which were consistent with the latest published
national diabetes best practice guidelines and empirical evidence related to foot self-
care. It also provided participants the opportunity for foot self-care hands-on practice
given in individual format, to low risk diabetic patients. The hands-on practice is a
source of self-efficacy as proposed by the Social Cognitive Theory. These foot self-care
behaviors were comprehensive, practical, and easy to use in daily life which could have
facilitated their implementation in daily life. The findings demonstrated that patients’
perceived self-efficacy and consequently performance of foot self-care behaviors were
significantly improved following the intervention.

In summary, the individual format of delivering the foot self-care educational
intervention, its comprehensive content, and the opportunity for self foot-care hands-on
practice may be unique factors that could have contributed to improvement in the performance of foot self-care behaviors in adult diabetic patients at low risk for foot ulceration.

**Effects of Intervention on Foot Skin Condition**

The foot self-care educational intervention demonstrated effectiveness in preventing occurrence of and enhancing management of minor foot problems. The percentage of participants who had no minor skin problems such as dryness, crackness, and redness significantly increased from pretest to 3-month follow up. For participants with a minor foot problems, most showed improvement in dryness, crackness, redness, fissure, blister, and fungal infection post intervention delivery.

The present findings were consistent with results of studies targeting people with diabetes who have not been identified at risk for foot ulcerations (Fan et al., 2006; Hamalainen et al., 1998), and participants with high risk for foot ulceration (Malone et al., 1989). The results of the present study suggest that development of minor foot problems (i.e., calluses, skin dryness and cracking) that could contribute to ulceration could be significantly reduced in patients with diabetes at low-risk for foot complications. To be effective in reducing foot ulceration and amputation, educational interventions must start as early as possible, and must target patients with diabetes at low-risk for developing foot complications, so that prevention of foot problems can be achieved (Apelqvist & Larsson, 2000; Halpin-Landry & Goldsmith, 1999; Hamalainen et al., 1998).

Participants in the pilot study performed and practiced the 5-step daily foot self-care strategies, and wore proper shoes and socks which may have contributed most to
non-occurrence of minor foot problems. Along with regular foot examinations, a daily foot-care routine is vital to help maintain the health of the feet and protect against foot problems that could lead to amputation (Pedorthic Association of Canada, 2009).

**Effects of Intervention on Toenails Condition**

The effects of the intervention on toenail conditions were also examined. There was a significant decrease in the percentage of participants who had minor toenail problems such as improper toenail length, poor hygiene, and abnormal thickness from pre-test to 3-month follow up. Also, most participants having a toenail problem at pretest demonstrated improvement in the problem condition at 3-month follow-up.

Although a limited number of studies reported toenail conditions in detail, the available findings were similar to those of this study. Corbett (2003) found that 61% of patients with diabetes had inappropriate toenail length at pre-test, and significantly improved at 3-month follow-up. Kruger and Guthrie (1992) and Borges and Ostwald (2008) reported an increase in the percentage of participants trimming toenails appropriately and regularly from pre-test to post-test. Bloomgarden and colleagues (1987) found that participants’ nail dystrophy and fungal infection significantly decreased at 18 month follow-up. Similarly, Hamalainen and colleagues (1998) reported that fungal infection of toenails and ingrown toenails were significantly decreased at 12 month-post intervention.

Minor toenail conditions, such as improper toenail care, ingrown toenails, and fungal infection, can injure foot, and cause foot skin non-integrity, and minor injuries to the foot, which may increase the risk of an open foot ulceration (Apelqvist et al., 1990; Neil et al., 1989). Performance of five-step daily foot self-care strategies, and proper
toenail care may have contributed to this outcome. Other investigators (Borges & Ostwald, 2008; Corbett, 2003; Hamalainen et al., 1998) have substantiated that foot self-care educational interventions were effective in decreasing the occurrence of toenail problems in patients with diabetes. Present findings support that a foot self-care educational intervention addressing proper toenail care plays a role in reducing the development of toenail problems in participants with diabetes at low risk for foot ulcerations.

**Effects of Intervention on Wearing Proper Shoes and Socks**

The study findings show that the percentage of participants who wore proper shoes (i.e., shoe style, materials, and shoes with adjustable laces/Velcro) and socks (i.e., sock fit, materials, color, and sock loose in legs) significantly increased at 3-month follow-up. Most descriptive studies that focused on assessment of shoes and socks in patients with diabetes reported similar findings. Nearly one third of patients with diabetes wore improper fitting shoes and fitting socks (Burns et al., 2002; Fan et al., 2006; Litzelman et al., 1997; Reddy et al., 1989).

On the other hand, experimental studies examining the effects of educational interventions on shoe and sock practices reported inconsistent results in patients with diabetes at mixed risk for foot ulcerations. Fan et al. (2006) found that the percentage of patients with diabetes wearing improper shoes and socks significantly decreased at 9-month post-intervention. Litzelman et al. (1997) observed no difference in the types and quality of footwear worn between intervention and control patients at either baseline or one year follow-up. The inconsistency in results may be related to differences in the measurement of outcomes, which was done by self-report, over a 1-
year interval. It was possible that patients wore a variety of types and styles of shoes over such a long time period.

Improper or poorly fitting shoes are major contributors to diabetes foot ulcerations (Pedorthic Association of Canada, 2009). Empirical evidence indicates that the most common cause of self-injury was ill-fitting new shoes, and the second most common cause was cutting toenails improperly (Isakov et al., 1992). Use of proper footwear protects the foot from injury, and prevents foot lesions, thereby reducing ulceration associated with peripheral neuropathy (Levin, 1993; Reddy, Vaid, & Child, 1989; Soulier et al., 1987). It also is vital in maintenance of an intact foot once an ulcer has healed (Coleman, 1993; Miller, 1993). Patients at low risk for foot ulcerations should be encouraged to pay attention to their footwear, and to wear properly fitted shoes and socks to protect their feet at the early stage of the disease, as was done in the pilot study.

**Contribution of the Study to Foot Self-Care Education**

Diabetes is a silent disease until the onset of overt complications; thus, there is no symptom-driven motivation for patients to change behaviors, especially in the early stages of the condition (Johnson, Newton, & Jiwa, 2005). Foot ulceration and subsequent lower extremity amputation are common, serious, and expensive chronic complications for persons with diabetes (Valk et al., 2007). As presented earlier, the prevalence of foot ulcerations ranges from 4% to 10% among patients with type 2 diabetes (Lavery et al., 2003), with a lifetime risk of developing a foot ulcer as high as 25% (Boulton et al., 2005). If not treated appropriately, the foot ulceration contributes up to 85% of lower extremity amputations (Ragnarson-Tennvall & Apelqvist, 2000).
Studies in Ontario indicate that less than 40% of patients with diabetes have received formal diabetes education. Most patients may self-manage their conditions but may not pay enough attention to the protection of their feet. This may be related to lack of awareness of the risk factors for foot ulceration, and limited knowledge to prevent foot complications, resulting in high admission rate for treatment of foot problems (RNAO, 2004). Empirical evidence suggests minor foot problems are common in patients with diabetes and can lead to foot ulcers and amputation if delayed or inappropriate treatment is given (Hamalainen, et al., 1998). Therefore, the importance of foot health and foot self-care must be communicated to patients at an early stage of their diseases (Connor, 1999; Kneepkens, et al., 2006), as recommended in a newly published consensus statement on foot care education in patients with diabetes at low risk of complications (McInnes, 2010).

This foot self-care educational intervention was developed in response to the urgent need to instruct patients at low risk for foot ulceration in knowledge and behavioral skills for protecting their feet and preventing complications. The intervention design was guided by the Social Cognitive Theory and aimed at enhancing patients’ self-efficacy and consequently performance of appropriate foot self-care behaviors.

Evidence from this pilot study indicates that the foot self-care educational intervention was feasible, acceptable, and effective in improving foot self-care knowledge, self-efficacy and behaviors, and in reducing occurrence of minor foot problems in adult patients with type 2 diabetes at low risk for foot ulcerations at 3-month follow-up. As such, the present foot self-care educational intervention addresses
an identified gap in the prevention of foot ulceration among low risk diabetes population. The extent to which the foot self-care educational intervention is acceptable to and effective in patients at high risk for ulceration should be investigated in future research.

The unique design of the foot self-care educational intervention may have contributed to its effectiveness in improving the intended outcomes, and should be adapted in future research and in clinical practice. The design involved a combination of presentation of practical recommendations and hands-on practice of foot care strategies, as well as provision of feedback on performance of foot self-care.

Giving the two face-to-face sessions on one day rather than on two separate days based on participants’ preferences made convenient and facilitated intervention attendance, minimized attrition, and enhanced feasibility and acceptability of the intervention, which in turn may also have contributed to the achievement of intended outcomes.

Participants did not reach the glycemic control targets for HbA1c and FBG. Participants’ profile indicates the need for providing patients diabetes self-management and foot self-care education at an early stage of the disease. Improving patients’ knowledge and skills related to healthy eating, weight management, physical activity, taking medications, and regular monitoring of metabolic indicators (i.e. blood glucose, blood pressure, lipids profile, and body weight, et al.) is necessary to reach acceptable blood glucose control. Blood glucose level is a modifiable risk factor for foot ulceration. Achieving adequate blood glucose control reduces this risk in patients with diabetes.
Strengths of the Study

The strengths of this pilot study were mainly related to the research design, instruments measuring the outcomes, and fidelity of intervention implementation. First, the one group repeated measures design was appropriate to pilot test the feasibility, acceptability and effects of the foot self-care educational intervention on expected outcomes. The repeated measure design, which is a within-subject design, offers greater statistical power relative to sample size to detect significant intervention effects than a between-subject design (Burns & Grove, 2005). This pilot study was adequately powered to examine changes in the outcomes.

Second, instruments used to measure intervention acceptability (IRP-15), and outcomes of foot self-care knowledge, self-efficacy, and behavior were reliable and valid. They demonstrated acceptable internal consistency reliability, thereby reducing error of measurement and enhancing the power to detect changes in outcomes.

Third, fidelity of the intervention implementation was maximized using a delineated intervention protocol. Implementing the intervention with fidelity maintained validity of study conclusions.

Limitations of the Study

The limitations of this study were related to testing effects (repeated administration of the instruments), experimenter’s expectation and subjective bias or social desirability. The potential threat of testing is due to the short time interval (about 3 hours) between T1 and T2 assessment of foot self-care knowledge and self-efficacy. The time interval from T1 to T2 was reduced since participants expressed preference to have the first two intervention sessions on one day instead of having them on two
different days within one week. With repeated administrations of the same measures at
the short time interval, participants may identify or remember the correct answers
which results in score gains that may bias the results and pose a potential threat to
internal validity (Kubinski, Rudy, & Boston, 1991).

The second limitation was related to the potential of experimenter’s expectation
or detection bias since the investigator assessed the outcomes on foot conditions at pre-
test (T1) and 3-month follow-up (T3) and provided the intervention. To minimize this
potential threat, the investigator used standard and reliable measures, with strictly
defined criteria on the assessment of foot conditions.

The potential for subjective bias or social desirability could have been
introduced when responding to self-report questionnaires measuring outcomes (Burns
& Grove, 2005). It is likely that subjective bias may have influenced the results since
the study participants were asked by the investigator who provided the educational
intervention to complete the questionnaires. Participants could have altered their
responses to please the interventionist. Strategies that were used to reduce the influence
of social desirability included explanation for participants that there were no right or
wrong answers, and that all information remained confidential by assigning code
numbers to the questionnaires, and that the information obtained was used only for
research purposes.

Most participants (63 %) had a high level of education, which may affect
the generalizability of the findings to people with lower level of education. The
feasibility, acceptability, and effects of the intervention should be explored in the
latter subgroup of the target population in future research.
Implications for Research

The results of this pilot study provided preliminary evidence of the feasibility, acceptability, and effectiveness of the foot self-care educational intervention, which warrants future testing of its efficacy. Implications for future efficacy testing relate to the use of: 1) the RCT design; 2) a large sample of patients with diabetes at low risk for foot ulcerations; 3) multiple interventionists involved in the study; and 4) long-term evaluation of the foot self-care educational intervention effects over a one year period.

The future study design could be randomized controlled trial to examine the efficacy of the foot self care educational intervention on foot self-care knowledge, self-efficacy, behaviors, and foot problems over time. Participants will be randomly assigned to the intervention group and usual care group, which will minimize selection bias. As well, the future efficacy study could use a large sample of patients with diabetes at low risk for foot ulcerations. The sample size should have adequate power to detect significant group differences in the outcome variables.

A single Registered Nurse interventionist with a strong commitment to this study delivered the foot self-care educational intervention, and followed a clearly delineated intervention protocol. This assisted in maintaining the fidelity of intervention delivery. The future efficacy trial can involve multiple interventionists who receive training in the implementation of the intervention. Having multiple interventionists would facilitate analysis to determine the potential influence of their interactional style. As well, the assessment of foot condition in this pilot study was conducted by the researcher. Although the experimenter’s expectation were minimized via use of standard and reliable outcome variables measures, additional strategies should be used
to avoid this bias in future efficacy test. To avoid the threat of experimenter’s
effect expectation, multiple research assistants blinded to participants’ assignment should be
ascribed the responsibility of outcome assessment.

To assess / examine social desirability bias the future efficacy study could
administer the Marlowe-Crowne Social Desirability Scale (MCSDS) (Crowne &
Marlowe, 1960), which is one of the most commonly used measures of socially-
desirable responding. Scores on this scale are computed, and the potential association
of desirability with responses to outcome measures is controlled for statistically when
examining the intervention effects.

Evaluation of the long-term effects (i.e., one year follow-up) of the foot self-
care educational intervention is warranted. It would help to determine the sustained
effectiveness of the educational intervention in reducing the occurrence of foot
problems.

Future applications of the foot self-care educational intervention should
incorporate relevant elements that are consistent with its components which contributed
to its preliminary effectiveness. 1) The foot self-care educational intervention was
provided in two intervention sessions, using one-on-one, provider-patient interactive
teaching methods and hands-on practice, followed by two telephone contact booster
sessions, given once a week for two weeks. To meet participants’ preferences, and
minimize attrition, the adjustment was made in the frequency of delivering the face-to
face sessions; the first two intervention sessions were given on the same day rather than
on two separate days within one week based on participants’ feedback indicating
logistical problems in attending the sessions on two different days. The higher
intervention completion rate (80%) reflected the appropriateness of the adjustment in delivering the educational intervention. Future research could also explore internet-based delivery of the educational intervention to enhance attendance by working patients who may not be able to attend face-to-face sessions. 2) The intervention dose which consisted of 2 hours in length for the first two intervention sessions, and two 10 minute-telephone contact booster sessions, was suitable based on participants’ rating on the IRP-15. However, the ability of incorporating additional booster sessions in maintaining high levels of self-efficacy needs to be investigated. 3) The intervention educational and behavioral components covered seven topics that were comprehensive, consistent with the most recently published diabetes best practice guidelines and empirical evidence related to foot self-care for patients with diabetes, and addressed practical recommendations of relevance to patients. The content was rated as acceptable and relevant to patients with low-risk for ulceration. Whether the intervention would be acceptable and effective in patients with high-risk should be studied. 4) The format for delivering the educational intervention, which included individual face to face contact, interactive teaching and discussion, and hands-on practice of foot self-care behaviors, followed by the telephone contact booster sessions, was viewed as suitable to participants; also it may have enhanced foot care knowledge retention, behavior performance, and self-efficacy gained at post-intervention and maintained at 3 month follow-up. 5) Teaching aids and teaching tools, which included slides, models of healthy and unhealthy foot, proper shoes and socks, mirror with long-handle, soft towel, toenails clippers, and monofilaments, and color printed booklets, may have facilitated learning and contributed to the observed effects of the intervention on the outcomes.
Conclusions

The primary focus of the study was to examine the feasibility, acceptability, and effects of the foot care educational intervention on foot self-care knowledge, self-efficacy, behaviors, and foot condition in adult patients with type 2 diabetes at low risk for foot ulcerations. The intervention was provided in two sessions, using one-on-one, provider-patient interactive teaching methods and hands-on practice, and two telephone contact booster sessions. The intervention was found feasible, acceptable, and effective in improving patients’ foot self-care knowledge, foot self-care efficacy, and performance of foot self-care behaviors, in reducing the occurrence of minor foot skin and toenails problems, and improving wearing proper shoes and socks at 3-month follow-up. Further evaluation of its efficacy is warranted.
References


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Appendix 1

Recruitment Letter for Family Physicians

Dear Physicians,

This is to inform you of a pilot study aimed at examining the feasibility and acceptability of a foot self-care educational intervention for adult patients with diabetes. The study is currently being conducted at the Family Health Team Centre. The pilot study is conducted by Lifeng Fan, a doctoral student under the supervision of Dr. S. Sidani at the Faculty of Nursing University of Toronto.

Foot ulceration and subsequent amputation of the lower extremity is one of the common, serious, and expensive chronic complications for patients with diabetes. Empirical evidence suggests that the devastating consequences of foot complications could be prevented in most cases. Educational interventions aimed at reinforcing appropriate foot care play an important role in preventing foot ulcerations. Little is known about the effects of educational interventions for patients who are at low risk for foot problems. Therefore, this study will examine the feasibility, acceptability and effects on foot self-care knowledge and practice, and foot problems of the educational intervention in adult patients with diabetes at low risk for foot ulceration.

We are requesting you support in referring patients with diabetes to the study. The following are eligibility criteria: 1) a diagnosis of type 2 diabetes, 2) 18 years of age or older; 3) Able to speak, read and understand English, and 4) Living in the Greater Toronto Area, and able to participate in the on-site education sessions.

We kindly request your assistance in making eligible patients aware of the study and in giving patients the information to contact the investigator. The contact information to hand to patients is enclosed.

If you have any questions or concern, please don’t hesitate to contact the investigator.

Sincerely,

Lifeng Fan
Lifeng.fan@utoronto.ca
Telephone: (416)978-6969
Appendix 2

Research Study Information for participants

The Study Title:
Examining the Feasibility, Acceptability and Effects of a Foot Self-Care Educational Intervention in Adult Patients with Diabetes at Low Risk for Foot Ulceration

Eligibility Criteria:
1) A diagnosis of type 2 diabetes;
2) 18 years of age or older;
3) Able to speak, read and understand English;
4) Living in the Greater Toronto Area;
5) Able to participate in the on-site education sessions.

Investigator Contact Information:
Lifeng Fan

Faculty of Nursing, University of Toronto.
footcare-study@utoronto.ca
Telephone: 416-978-6969
Appendix 3

Telephone Script

Hello Mr. /Ms.____________________,

This is Lifeng Fan speaking. I am the investigator on the foot-care study. I am returning your call. Thank you very much for your interest in the study. Is this a good time to give you more information about the study? If yes, then explain; and if no, then arrange for a convenient time.

Person with diabetes may develop problems in the feet like dry skin and calluses. This study involves giving you information and teaching you what you can do to prevent problems in the feet. They may also injure their feet. If these problems are not well treated, they may lead to ulcers in the feet. Prevention of foot ulcers is more important than their treatment. Prevention is done by taking care of the feet. You are being asked to take part in a research study that will examine if education about how person with diabetes can take care of their feet is feasible, acceptable, and effective.

You are being asked to volunteer for this study because you are an adult with diabetes, 18 years or older, and living in the Greater Toronto Area. If you are interested in participating in the study, the researcher will arrange to meet with you in a study room at a Family Health Team. The researcher will ask you questions and examine your feet to see if you are eligible to take part in this study. If you are not eligible, the researcher will give you a pamphlet on how to take care of your feet.

If you are eligible, your participation in this study will involve: (1) attending two sessions in which you will be shown how to take care of your feet, and (2) answering two telephone calls from the researcher, once a week for two weeks; (3) and completing a questionnaire before and after the first two sessions, and 3 months after completion of the telephone calls.

Do you have any question about the foot-care study?
Are you still interested in the foot-care study?

If the answer is yes: If you are interested in this study, and then I will arrange to meet with you in the study room at the Family Health Team Centre. Let’s set a date and time for your visit. What is the good date and time for you? (booking the time/date).

Thank you very much once again for being interested in taking part in the study. Looking forward to seeing you on the time / month / day. Take care and have a good day.

If the answer is no, Thank you very much once again for your telephone call! Take care and have a good day.
Appendix 4

Participant Letter of Explanation

Title of Project: Examining the Feasibility, Acceptability and Effects of a Foot Self-Care Educational Intervention in Adult Patients with Diabetes at Low Risk for Foot Ulceration

Investigator: Lifeng Fan, PhD student at Faculty of Nursing, University of Toronto

Introduction

Person with diabetes may develop problems in the feet like dry skin and calluses. They may also injure their feet. If these problems are not well treated, they may lead to ulcers in the feet. Prevention of foot ulcers is more important than their treatment. Prevention is done by taking care of the feet. You are being asked to take part in a research study that will examine if education about how person with diabetes can take care of their feet is feasible, acceptable, and effective.

You are being asked to voluntarily participate in this study because you are an adult with diabetes (that is, you have high sugar level in the blood), 18 years or older, and living in the Greater Toronto Area. The researcher will ask you questions and examine your feet to see if you are eligible to take part in this study. If you are not eligible, the researcher will give you a pamphlet on how to take care of your feet.

If you are eligible, your participation in this study will involve: (1) attending two sessions in which you will be shown how to take care of your feet, and (2) answering two telephone calls from the researcher, once a week for two weeks; (3) completing questionnaires before and after the first two sessions, and 3 months after completion of the telephone calls.

Procedure

There are three steps involved in becoming a participant in the study. The steps are presented below and then each step is described in detail.

Step 1: Interview and examination of your feet to determine eligibility for the study, and completion of questionnaires.

Step 2: Attendance at the sessions and subsequent telephone calls, reminding you what you have learnt in the first two sessions.
Step 3: Completion of questionnaires 3 months after the last telephone call.

Explanation of the 3 steps

Step 1:
The first step is an interview and examination of your feet by the researcher to determine if you are eligible for the study. If you are eligible and agree to participate in this study, the researcher will require that you come to the office at Family Health Team centre to meet the researcher. At that meeting, the researcher will examine your feet to see if your foot sensation is normal; to check for the pulses in your feet and to see if you have any foot deformity. The researcher will ask if you have any numbness, burning, tingling, itching, and pain in the legs. This is done to determine if you are eligible for the study. If you are not eligible for the study, you will not continue to participate in the study. You will continue to receive usual care and the researcher will give you a pamphlet on how to take care of your feet. If you are eligible in this study, then the researcher will ask you to complete a questionnaire that relate to your knowledge and practice about how you take care of your feet. Completing the questionnaires will take 15-20 minutes. The questionnaire contains questions about how to take care of your feet.

Step 2:
The second step includes attendance at the two sessions and two telephone calls. The researcher will invite you to two sessions. In the first session, the researcher will present and discuss information on how to take care of your feet. In the second session, the research will give you opportunities to practice how to take care of your feet. Each of these sessions is about 1-hour long. Then, you will be asked to complete the questionnaire, and the researcher will give you a pamphlet on how to take care of your feet. The questionnaire is also about how to take care of your feet.

After that, the researcher will call you twice, once a week for two weeks. During the telephone call, the researcher will review key points what you have learned in the first two sessions, answer any question you may have, and check with you whether you have practiced at home what you have learned. Each phone call will take about 10 to 15 minutes.

Step 3:
The third step involves the completion of a questionnaire 3 months after the last telephone call. Three months after completion of the education sessions, you will come to our office at Scarborough Academic Family Health Team again. The researcher will examine your feet, and you will be asked to complete the same questionnaire about how to take care of your feet. It will take about 20 minutes to complete it.
**Potential Benefits and Risks**
There are no known risks for participating in this study. You may gain some knowledge about taking care of your feet. The results will help us understand how to provide assistance to persons with diabetes take care of their feet.

**Compensation**
There is no cost to you to participate in this research study. You will be provided with Toronto Transit Commission (TTC) tokens to cover all the transportation cost to the center. There is no other fee paid to you.

**Voluntary Participation**
Your participation in this study is entirely voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer any question if you so desire, and to withdraw from the study at any time, for any reason. You may stop being in the study without affecting the care you might be receiving or loss of benefits to which you are entitled.

**Confidentiality**
Your anonymity and confidentiality are of utmost importance and will be protected at all times. All information would remain confidential. Your name will not appear on the questionnaires, or any other forms used in this study. Code numbers will be assigned. The investigator will keep all information you provide in a sealed envelope within in a locked cabinet in the research office at the Faculty of Nursing, University of Toronto to which only the investigators have access. In addition, your name is not recorded on any form completed nor is your name identified in any report that may be published.

If you agree to participate in this research study, please sign the form on the next page. Your signature indicates your consent and that you have understood the information regarding the research study.

If you have any questions about your right as a research participant, please call the Ethics Review Unit at 416-946-3389. This person is not involved with the research project in any way and calling him/her will not affect your participation in the study.
Appendix 5
Participant Consent Form

Title of Project: Examining the Feasibility, Acceptability and Effects of a Foot Self-Care Educational Intervention in Adult Patients with Diabetes

Investigator: Lifeng Fan, MScN, RN

I, ____________________________________________, the undersigned, agree to my participation in the research study described above.

Any questions have been answered and I understand what is involved in the study. If I have any questions about any aspect of the research study or about this consent form, I can contact the investigator at the address given below.

I realize that participation is voluntary, that there is no guarantee that I will benefit from my involvement in the study, and that I will receive TTC tokens to cover expenses related to my transportation to the centre upon completing the questionnaires at 3 months follow-up.

I acknowledge that a copy of this form has been given to me.

_______________________________________________________________________
Participant Name                                     Signature                                       Date

________________________________________________________________________
Witness Name                                          Signature                                       Date

To the best of my ability I have fully explained the nature of this research study. I have invited questions and provided answers. I believe that the participant fully understand the implications and voluntary nature of the study.

________________________________________________________________________
Investigator Name                                     Signature                                       Date

Investigator: Lifeng Fan
PhD student
Faculty of Nursing, University of Toronto
Phone: 416-978-6969