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The Dissertation Committee for Katherine Ruth Strout Certifies that this is the approved version of the following dissertation:

The Effects of Diabetic Foot Care Education on Assessments and Behaviors among Adults with Diabetes Mellitus Experiencing Homelessness

Committee:

M. Terese Verklan, Supervisor

Yolanda Davila

Charlotte Wisnewski

Sharon Petronella-Croisant

Angie McInnis

The Effects of Diabetic Foot Care Education on Assessments and Behaviors among Adults with Diabetes Mellitus Experiencing Homelessness

by

Katherine Ruth Strout, MSN, BSN, ADN, RN

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Dedication

The study is dedicated to everyone who participated in the study. I applaud your pioneering spirits to enroll in the study. Your participation lays the foundation for other men and women with diabetes mellitus experiencing homelessness for improvements in the delivery of diabetic foot care education and the prevention of diabetic foot complications. I so enjoyed meeting and working with each of you

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The Effects of Diabetic Foot Care Education on Assessments and Behaviors among Adults with Diabetes Mellitus Experiencing Homelessness

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Adults with diabetes mellitus experiencing homelessness are at risk for preventable diabetic foot complications, including diabetic foot ulcers and non-traumatic lower extremity amputation. Several risk factors such as the lack of routine healthcare, insurance, nutritious meals, and access to diabetic foot self-care education, impact the individual's risk for developing diabetic foot ulcers which may lead to non-traumatic lower extremity amputations. The purpose of the study was to measure the effects of RN-led diabetic foot self-care education on the participants' perceived risks for diabetic foot ulcer or amputation, diabetic foot self-care behaviors, and clinical diabetic foot assessments. The aims of the study were to increase the participant's knowledge and ability to recognize their individual risk factors for developing diabetic foot ulcer (DFU) and amputation and to decrease the participant's risk for diabetic foot ulcer and increase the participant's knowledge of diabetic foot self-care behaviors. A quasi-experimental single group repeated measures design was instituted to meet the aims of the study. The Diabetes Foot: Risk Assessment Education Program was utilized and presented over a period of four-weeks. The educational intervention focused on DFU and/or amputation risk identification and

reduction and promoted five daily diabetic foot self-care behaviors to reduce risk for diabetic foot complications. Thirty individuals meeting inclusion criteria enrolled in the study, and twenty completed the four-week study. The dependent variables consisted of perceived DFU or amputation risk, diabetic foot self-care behaviors, and diabetic foot assessments. Based upon the findings, the participants accurately identified their individual risk factors for DFU or amputation. The risk factors consisted of loss of protective sensation, foot deformity and/or a previous DFU and/or amputation and no difference was noted between the pretest and posttest measures. The educational intervention was effective to increase two diabetic foot self-care behaviors from baseline to the remaining weeks of the intervention. Behavioral change was statistically significant for check feet and look in shoes, as assessed by the diabetic foot self-care behaviors on the Summary of Diabetic Self-Care Activities. The behaviors of wash feet, soak feet, and dry between the toes did not change. The Inlow's 60-Second Diabetic Foot Screen was used for the foot assessments. The educational intervention was not effective to change diabetic foot assessment total scores. The diabetic foot self-care education had a small to moderate effect on two diabetic foot self-care behaviors. Additional studies are needed which focus on the reduction of diabetic foot complications among adults with diabetes mellitus experiencing homelessness.

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List of Abbreviations

ADA	American Diabetes Association
ANA	American Nurses Association
CDC	Centers for Disease Control and Prevention
DFU	Diabetic Foot Ulcer
DM	Diabetes Mellitus
HCH	Health Care for the Homeless
IRB	Institutional Review Board
LOPS	Loss of Protective Sensation
NAEH	National Alliance to End Homelessness
NCH	National Coalition for the Homeless
NHCHC	National Health Care for the Homeless Council
PAD	Peripheral Arterial Disease
RN	Registered Nurse
RNAO	Registered Nurses Association of Ontario
SDSCA	Summary of Diabetes Self-Care Activities
SFSQ	Self-Administered Foot Risk Screening Questionnaire
T1D	Type 1 Diabetes Mellitus
T2D	Type 2 Diabetes Mellitus
UTMB	University of Texas at Medical Branch

Chapter 1 Introduction to the Study

INTRODUCTION

Adults with diabetes mellitus (DM) experiencing homelessness are at-risk for diabetic foot ulcers (DFU) and/or amputation due to chronic hyperglycemia coupled with foot pathologies including: (a) skeletal and pressure related foot deformities, (b) loss of protective sensation (LOPS), and (c) altered pedal circulation (Arnaud, Fagot-Campagna, Reach, Basin, & Laporte, 2009; Baggett, O'Connell, Singer, & Rigotti, 2010; Buck, Brown, Mortensen, Riggs, & Franzini, 2013; Hwang, 2001; Hwang & Bugeja, 2000). The risk factors for DFU and/or amputation include one or more of the following diabetic conditions: (a) diabetic neuropathy, (b) ischemia, (c) foot deformity, and/or (d) a history of DFU or lower-extremity amputation (Schaper, Van Netten, Apelqvist, Lipsky, & Baker, 2015). Identifying the DFU and/or amputation risk factors among adults with DM experiencing homelessness has not been well-studied.

Diabetic foot self-care education is a standard of care according to the ADA (2016), but few studies have included adults with DM experiencing homelessness in diabetic foot self-care educational interventions. Studies are lacking in which adults with DM experiencing homelessness are taught about diabetic foot self-care with a focus on DFU and/or amputation risk identification. Therefore, the purpose of the study was to examine the effects of a Registered Nurse (RN)-led diabetic foot self-care educational intervention on the participant's subjective DFU risk assessment, diabetic self-care behaviors, and clinical diabetic foot assessments among a sample of adults with DM experiencing homelessness.

The diabetic foot self-care educational intervention entitled, *Diabetes Foot: Risk Assessment Education Program,* is an evidenced-base curriculum developed in Ontario, Canada (RNAO, 2004). The curriculum was oriented towards DFU and/or amputation risk

identification and reduction, while teaching diabetic foot self-care behaviors. The educational intervention was implemented over four weeks. The curriculum was divided into three weeks of content so as to provide a specific diabetic foot self-care topic each week. The fourth week was dedicated for the conclusion of the program.

SIGNIFICANCE

Diabetic foot ulcers can have devastating consequences for those affected; non-healing DFU precede approximately 85% of all non-traumatic lower extremity amputations (Murphy, et al., 2012; Rhim & Harkless, 2012; RNAO, 2004). In the domiciled population, survival rates following a non-traumatic lower extremity amputation were 50% at three years, and between 40%-27% at five years (Corbett, 2003; Shapiro, 2016). Survival rates among adults with DM experiencing homelessness who undergo a non-traumatic lower extremity amputation could not be located.

One of the most common diagnoses for hospitalization among persons with diabetes is DFU, with costs for treatment escalating from $27,987 to $70,000 per foot (Rhim & Harkless, 2012). The incidence for recurring DFU was estimated to be 34% within one year of healing the initial DFU; and 70% within five years after the initiation of DFU treatment (Shapiro, 2016). The research documenting DFU treatment costs among adults with DM experiencing homelessness was limited. Studies that measured rates of DFU recurrence among adults with DM experiencing homeless could not be located.

Therefore, experts recommend the best approach for treating diabetic foot disorders is to prevent ulceration from occurring altogether (ADA, 2016; Hwang, 2001; Moy & Sanchez, 1992; Muirhead, Roberson, & Secrest, 2011; Raoult et al., 2001; Wrenn, 1991). Approximately 50% of all DFUs and amputations could be eliminated when the “at-risk foot” is identified and preventive strategies implemented (ADA, 2016). The “at-risk foot” can be identified by providing a diabetic foot assessment and categorizing the individual’s

risk for DFU. One preventive strategy is to provide diabetic foot self-care education for persons with diabetes (ADA, 2016).

Studies have described a relationship between poorly controlled DM and major diabetic complications such as DFUs and non-traumatic lower-extremity amputations, among adults with DM experiencing homelessness (Arnaud et al., 2009; Hwang & Bugeja, 2000; & Martinez-Weber, 1987). However, no studies were located in which the risk factors for DFU and/or amputation were identified, and diabetic foot self-care education was taught to a group of adults with DM experiencing homelessness. The current study was designed to fill the gap in the literature by implementing an educational program focused on DFU and/or amputation risk identification, reduction, and diabetic foot self-care behaviors.

The contribution of the proposed study was significant because of the potential positive impact the education would have on the participant's knowledge and ability to identify his/her individual DFU and/or amputation risk factor/s and to perform diabetic foot self-care to minimize his/her risks. When diabetic foot self-care is implemented, health care providers may see the incidence and prevalence of preventable diabetic foot pathologies leading to DFUs and/or amputations decrease in this population. I anticipated the findings from the study would lead to future studies adding to the science of self-management behaviors among adults with DM experiencing homelessness. Innovations to provide diabetic self-care education were necessary for the uninsured, high-risk individual to benefit from educational interventions. Nursing should challenge the status quo by providing RN-led diabetic foot care education tailored to meet the unique needs of adults with DM experiencing homelessness.

PURPOSE STATEMENT

The purpose of the study was to examine the effects of an RN-led diabetic foot self-care educational intervention on the participant's subjective DFU risk assessment, diabetic

self-care behaviors, and clinical diabetic foot assessment among a sample of adults with DM experiencing homelessness.

SPECIFIC AIMS AND RESEARCH QUESTIONS

The following specific aims and research questions guided the study.

Specific Aim 1

Increase the participant's knowledge and ability to recognize their individual risk factors for developing diabetic foot ulcer (DFU) and amputation.

RESEARCH QUESTION 1.1

What is the difference between pretest and posttest scores on the Self-Administered Foot Risk Screening Questionnaire (SFSQ) among the sample of adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care education?

RESEARCH QUESTION 1.2

What is the risk category for DFU and/or amputation as measured by Inlow's 60-Second Foot Screen tool among participants exposed to the RN-led diabetic foot self-care education?

Specific Aim 2

Decrease the participant's risk for diabetic foot ulcer and increase the participant's knowledge of diabetic foot self-care behaviors.

RESEARCH QUESTION 2.1

What are the effects of RN-led diabetic foot care education on diabetic foot self-care behaviors measured as scores on the foot care subscale items on the Summary of

Diabetes Self-Care Activities (SDSCA) among adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care education?

RESEARCH QUESTION 2.2

What are the effects of RN-led diabetic foot care education on diabetic foot assessments measured by Inlow's 60-Second Diabetic Foot Screen Tool among adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care education?

THEORETICAL FRAMEWORK

The theoretical framework that guided the study was Knowles Adult Learning Theory (1984). Knowles' pedagogy describes the adult learner as one who is oriented to problem solving. The adult learner views learning as a strategy to obtain information to solve the problem. Knowles' assumptions about the adult learner include: (a) a readiness to learn, (b) the need for relevant information, (c) the incorporation of life experiences into learning, and (d) the need for practical information to solve the problem. The diabetic foot self-care curriculum, *Diabetes Foot: Risk Assessment Education Program* (RNAO, 2004), was designed for the adult learner and was based upon Knowles' assumptions. For the purpose of the current study, I presented the risk for DFU and/or amputation as the problem and learning about diabetic foot self-care and DFU and/or amputation risk prevention as the solution to the problem.

Every participant was provided with a *Diabetes Foot: Risk Assessment Education Program* Participant Package (RNAO, 2004) (Appendix A). The workbook provided the participants with opportunities to interact with the curriculum. Numerous self-assessments about diabetic foot self-care, self-foot assessments, and risk factors were presented to reinforce the participants understanding of the content. The self-assessments offered mechanisms for participants to learn how to solve the problem of their risk for DFU and/or

amputation. The curriculum supported readiness to learn and provided relevant information about diabetic foot self-care and DFU risk reduction.

The RNAO (2004) program was pragmatic, focusing on diabetic foot self-care behaviors, risk factors for DFU and/or amputation, and measures the participants can implement into their daily routine to prevent foot injuries (RNAO). As adults with DM experiencing homelessness were less likely to have had any diabetic foot self-care education, the curriculum provided instruction for the participants to be able to perform diabetic foot self-care and how to identify and reduce their risk for diabetic foot complications. The participant's life experiences were incorporated into each lesson. The participants were encouraged to ask questions about the content. The participants shared their life experiences related to issues with their feet. The participants could encourage and support one another, all of which was important for the adult learner.

DELIMITATIONS

The study is limited by time, setting and sample. The study was conducted from November 29, 2017 through February 22, 2019 at five different homeless shelters in East Texas. The sample was limited to only adult's age 25 years and older with DM experiencing homelessness. Data collection took place in a quiet private area of the shelters; clinic, library, or an empty office.

DEFINITION OF TERMS

The section included the conceptual and operational definitions of the relevant terms used in the study.

Diabetic Foot Assessment

Conceptual definition: an assessment of both feet of a person with diabetes for skin integrity, presence and absence of infection, foot deformities, neuropathy, altered pedal circulation, and history of lower-extremity amputation (Schaper et al., 2015).

Operational definition: Inlow's 60-second Diabetic Foot Screen Tool (Inlow, 2004) (Appendix B). The Inlow's screening tool was designed for clinicians to perform a comprehensive diabetic foot assessment for persons with DM to prevent or treat DFUs and/or limb threatening complications. The Inlow's included categories which examined for: (a) foot deformity, (b) ischemia, (c) loss of protective sensation (LOPS), (d) peripheral arterial disease (PAD), (e) presence of DFU and/or history DFU, and (f) history of lower-extremity amputation.

The Inlow's diabetic foot assessment was performed by the investigator at each of the four study visits, immediately before the diabetic foot-care class began. The investigator assessed both feet, first the left and documented the score for each category as the assessment continued. The same procedure was repeated for the right foot.

The diabetic foot assessment included a visual inspection of the skin, nails, and for the presence or absence of deformities on both feet. The participant's footwear was inspected for fit, appropriateness, and for being a source of trauma. The temperature of the feet and range of motion of the great toe were assessed by touch. Then, the sensation of both feet were assessed by performing a ten point Semmes Weinstein Monofilament Test (5.07 10 gm) on both feet. Sensation was also assessed by asking the participant four questions: (a) Were your feet ever numb? (b) Do they ever tingle? (c) Do they ever burn?, and (d) Do they ever feel like insects were crawling on them? The circulation in the feet was assessed by palpating pedal pulses, dependent rubor, and erythema.

The Inlow's total score can range from 0-25 for each foot. A cut-off score of zero, a negative Inlow's test, would indicate that the participant did not have any risk factor for

DFU and/or amputation (Portney and Watkins, 2009). Whereas Inlow's total scores greater than zero demonstrate the presence of risk factors, or a positive Inlow's test. Therefore, higher total Inlow's score indicated the presence of more DFU and/or amputation risk factors.

The Inlow's DFU and/or amputation risk category was determined based upon the findings from the Inlow's categories assessing: (a) sensation, (b) deformity, (c) PAD, and (d) history of DFU and/ or amputation. The cut-off score is zero, indicating a negative test, and no LOPS. The Inlow's risk categories and criteria are presented in (Table 1.1).

Table 1.1: Inlow's DFU and/or Amputation Risk Categories

Risk category	Criteria
0	Normal, no Loss of Protective Sensation (LOPS)
1	LOPS
2a	LOPS and Deformity
2b	Peripheral Artery Disease
3a	Previous history of DFU
3b	Previous history of amputation

Following the assessment, with the participant present, the investigator added the scores from each category and for each foot to obtain the Inlow's total score. The highest total score for either the left or right foot informed the investigator and participant about their risk factors for DFU and/or amputation. I informed each participant about their individual risk factors. Additionally, the highest total Inlow's score is used to guide the frequency of future diabetic foot assessments. The assessment frequency is presented in (Table 1.2). Each participant was also informed about their diabetic foot assessment frequency and their DFU and/or amputation risk category.

Table 1.2: Inlow's Recommend Frequency for Diabetic Foot Assessments

Total Inlow's score	Frequency of Future Foot Assessments
0-6	Annually
7-12	Every six months
13-19	Every three months
20-25	Every one to three months

Diabetic Foot Risk Screening

Conceptual definition: a subjective risk assessment for an individual with diabetes to self-identify their risk factors for DFU or amputation (Valente, Caughy, & Fischbach, 2004).

Operational definition: Self-Administered Foot Risk Screening Questionnaire (SFSQ) (Valente et al., 2004) (Appendix C). The SFSQ is a paper and pencil self-report questionnaire that the participants completed as pretest and posttest assessments of their individual risk factors for DFU or amputation. The screening questionnaire consisted of six statements about risk factors for DFU or amputation. The participants provided a dichotomous (yes or no) response to each of the following statements, (a) I have total feeling in my feet. (b) My feet have some or partial feeling. (c) My feet were normal in shape, (d) My feet were abnormal in shape. (e) In the past, I have had a foot ulcer (deep sore) on the bottom of my foot, and (f) I currently have a foot ulcer (deep sore) on the bottom of my foot, or my toe/foot has been amputated. Each yes and no response was assigned a numerical value related to the degree of risk for DFU or amputation. After each statement was answered, the number of points in the yes and no columns were separately added, then the total points from each column were added together. The total points were then compared with the points in the risk category key to determine if the participant's feet were at-risk for DFU or amputation. The risk category scores ranged from zero to three. The scoring criteria was as follows: (a) six to eight points=grade zero risk, (b) ten points=grade one risk, (c) 12 points=grade two risk, and (d) 13+ points=grade three risk. Higher scores on the SFSQ indicate a higher degree of risk for DFU or amputation (Valente et al., 2004).

Diabetic Foot Self-Care Behaviors

Conceptual definition: self-care behaviors persons with diabetes need to do daily to prevent the development of diabetic foot complications (ADA, 2016).

Operational definition: Summary of Diabetic Self-Care Activities (SDSCA) (Toobert, Hampton, & Glascow, 2000) (Appendix D). The SDSCA is a paper and pencil, self-report tool for participants to record how many times during the past seven days he/she performed any of the five diabetic foot self-care behaviors. The participants were provided with the tool and a pencil at each of the four study visits and completed the SDSCA immediately before the diabetic foot care class began. The SDSCA is the subscale of the five daily diabetic foot self-care behaviors and includes: (a) inspecting the feet, (b) looking inside the shoes, (c) washing the feet, (d), soaking the feet, and (e) drying between the toes. The scores for each item can range from zero, meaning not done on any day; to seven, and meaning done every day. Higher scores indicate that diabetic foot self-care behaviors were performed more frequently, and lower scores indicate the behaviors were performed less frequently. No information was located about an adequate number of days when diabetic foot self-care is performed less than seven days per week. The ADA (2016) recommends that diabetic foot self-care behaviors should be performed daily.

Diabetic Foot Self-Care Education

Conceptual definition: Program of education used to teach persons with diabetes self-care behaviors to reduce their risks for DFU and/or amputation and how to perform diabetic foot self-care behaviors. Diabetic foot self-care education includes: (a) diabetic foot self-care behaviors, (b) risk factors for DFU and/or amputation, (c) risk reduction measures, (d) diabetic foot self-assessment for foot lesions, and (e) when and where to seek treatment for non-healing foot lesions (RNAO, 2004)

Operational definition: RN-led *Diabetes Foot: Risk Assessment Education Program* (RNAO, 2004). The RN-led diabetic foot self-care curriculum was designed for the participants to meet face-to-face in small groups or individually with the RN investigator. The curriculum was divided into four weekly classes. Each participant was given a Participant Package (Appendix A), which is the workbook for the educational

program. The content for each class was guided by the workbook and provided the participants with multiple opportunities to interact with the content. For example, participants could write answers to pretest questions, self-assessment questions, and mark on pictures of feet where the participant had a foot lesion or other type of foot pathology. The curriculum was designed for participants to interact with the PI who demonstrated self-care behaviors and assessments.

The first class consisted of answering questions to the workbook activities; pretest questions and a DFU risk assessment. The teaching included discussion and demonstration of five diabetic foot self-care behaviors. The participants were taught to: (a) check the bottom of the feet, (b) look inside the shoes before putting the shoes on, (c) wash the feet, (d) soak the feet, and (e) dry between the toes. The participants were also taught that diabetic foot self-care behaviors were to be done every day, for DFU and/or amputation risk reduction.

During the second class, two types of foot deformities, pressure related and structural deformities were discussed. Both types of deformity put the participant at-risk for DFU and/or amputation. Pressure related deformities develop when persons with diabetes spend an excessive amount of time on their feet wearing footwear that does not fit properly. Pressure related deformities manifest in the forms of corns, calluses, hot spots and ulcers. Structural deformities manifest in the forms of mallet, hammer and claw toe, and bunions.

The third class consisted of a discussion about risk factors for DFU and/or amputation related to pedal circulation and LOPS. First, I discussed how altered pedal circulation may be a source for intermittent claudication. I asked if the participants had calf-pain when they walked and went away when they rested. I then discussed the location of the pedal pulses and demonstrated how to self-assess their pedal pulses. I circulated among the participants to offer assistance locating and assessing their pulses. The participants recorded their findings in their workbooks. Next I discussed how the insensate

foot is at risk for injury, and DFU and/or amputation. I demonstrated how to perform a ten-point Semmes Weinstein Monofilament Test on my own feet. I discussed the importance of wearing closed toe and heal footwear in order to protect the insensate feet from injury. I then distributed the monofilament to the participants for their self-assessment. I circulated among the participants to provide feedback about their self-assessment technics. The participants recorded the findings from their self-assessment in the workbook.

The fourth class concluded the program and included topics from each previous class. The fourth class was also the last data collection point. I asked the participants to demonstrate diabetic foot care, to verbalize their individual risks for DFU and/or amputation, and to self-assess their feet for neuropathy and circulation. I reinforced their diabetic foot care behaviors and provided guidance when needed. We discussed the participants DFU and/or amputation risk status and the participants documented their answers in their workbook. Next we discussed the post-test questions and answers in the workbook. Lastly, the participants recorded their self-care and knowledge behaviors and that all components of the intervention had been provided.

Throughout the intervention, the PI collected all the data and performed each diabetic foot assessment that were to be included in the analyses. Although each class was anticipated to last for about 30 minutes, some of the classes lasted for an hour or more. Some participants asked about an inconsistency between the SFSQ risk assessment and the risk assessment in the workbook. While others noted an inconsistency between diabetic foot self-care behavior on the SDSCA and the Care Tips in the workbook. The PI clarified the inconsistencies and recommended using lotion rather than soaking the feet for hydration. Additionally, many participants shared their experiences with their healthcare provider and the lack of diabetic foot assessments performed by their providers K. R. Strout (personal communications, May 24, 2018).

Numerous participants asked questions about DM, shared their personal experiences with DM, discussing how DM had impacted their family and consequentially

themselves. For example, some participants had cared for their parent with DM, while others discussed the impact of a parent's lower-extremity amputation and the difficulties the parental diabetic complications imposed on his or her childhood experiences K. R. Strout (personal communication, February 15, 2018).

CONTENTS OF THE DISSERTATION

The dissertation is presented in five chapters followed by appendices and references. Chapter one includes and introduction to the study, significance, purpose statement, specific aims and research questions, theoretical framework, delimitations, and definition of terms. Chapter two includes the review of the literature regarding adults experiencing homelessness, DM and its' impact on the diabetics' feet, and upon adults with DM experiencing homelessness, diabetic self-management education and RN-led diabetic foot care education, Chapter three presents the research design, setting, sample, instruments, procedures, data analyses, and human participants review. Chapter four includes the results of the data analysis. Chapter five presents the findings related to the literature, the limitations and strengths of the study, the conclusions derived from the prior chapter, and ends with recommendations for future research and nursing practice.

Chapter 2 Literature Review

INTRODUCTION

In the U.S., DM has reached epidemic proportions as approximately one in every 11 individuals has been diagnosed with DM. New cases of Type 2 DM (T2D) exceed one million annually (Centers for Disease Control and Prevention [CDC], 2015). In Texas, during the years between 2000 and 2012, the prevalence of DM among adults more than doubled from 7.2 per 100 to 15.2 per 100 adults (CDC, 2014). As the incidence and prevalence of DM rises, so is the likelihood that complications due to DM will also increase. One very common and serious DM complication is DFU and affects approximately 25% of persons with DM (Shapiro, 2016).

Diabetic foot ulcers have severe and disabling effects, leading to non-traumatic lower-extremity amputations, loss of productivity, unemployment, and poor quality of life for those affected. Hospitalizations are more frequent for those with DFUs. DFUs precede about 85% of all non-traumatic lower-extremity amputations. Additionally, the cost of DFU treatment impose an enormous burden on healthcare systems of approximately $38 billion annually (Armstrong, et al., 2013). The ADA (2019) has estimated that the occurrences of DFUs may be reduced by 50% when the "at-risk" foot is identified and diabetic foot self-care education is provided for persons with DM, although no timeframe for DFU reductions was provided.

Armstrong et al. (2013) reported that the National Institutes of Health (NIH) in the years 2000 to 2012, funded just 30 studies about DFU, whereas, 22,532 DM studies were funded. I consulted with a reference librarian at the Moody Medical Library and asked for a search of NIH funded studies to be conducted for the years 2000-2012 using the key terms, DFU and DM. The reference librarian accessed the NIH Research Portfolio Online Reporting Tools database. The search yielded 36 funded DFU studies and 79,625 DM

studies. The findings indicated far fewer DFU studies were funded than those for DM. The lack of DFU research may have serious negative consequences for those at risk for DFU and may lead to preventable diabetic foot complications and non-traumatic lower-extremity amputations.

The research is lacking about DFU and/or amputation among adults with DM experiencing homelessness. No studies were located that measured both subjective DFU risk factors and clinical DFU risk factors among adults with DM experiencing homelessness. Therefore, the current study is urgently needed as it will fill the gap in the literature on a protocol based on identification and reduction of DFU risk factors and diabetic foot self-care education for persons with DM experiencing homelessness (RNAO, 2004; Schaper et al., 2015).

The estimated prevalence of DM among adults experiencing homelessness in the U.S. is higher than in other industrialized countries, contributing to premature morbidity and mortality in this underserved population (Fazel, Geddes, & Kushel, 2014). For an adult with DM experiencing homelessness, managing glycemic control in order to prevent the adverse effects of DM, primarily DFUs, while unstably housed, is further complicated by a lack of insurance, limited access to healthcare, medications, nutritious meals, and diabetic foot self-care education, contributing to the population's premature DM morbidity (Arnaud et al., 2009; Baggett et al., 2010; Buck et al., 2013; Hwang, 2001; Hwang & Bugeja, 2001). In the U.S., DM is the seventh leading cause of death among the general population, whereas DM is the third leading cause of death among adults with DM experiencing homelessness (Bharel et al., 2013).

Due to the paucity of research enrolling adults with DM experiencing homelessness into diabetic foot self-care educational programs with a focus on DFU risk identification and reduction, the current study is timely and urgently needed. The current study was intended to implement an RN-led diabetic foot self-care educational intervention with a

focus on the identification and reduction of DFU risk factors among a group of adults with DM experiencing homelessness. The current study helps fill a gap in the literature.

PURPOSE

The literature review was completed using CINAHL, Ovid MEDLINE and PubMed databases from the years 1980 to 2019. The results demonstrated significant gaps in the literature as only four articles were included in the review about the health of adults experiencing homelessness, two articles pertaining to the unmet health needs of adults experiencing homelessness, only five articles were located about the podiatric health of adults experiencing homelessness, 23 articles were located about DM and adults experiencing homelessness, three articles about DFU risk factors in the general population, two articles about diabetes self-management education and support and among adults with DM experiencing homelessness, and one article about RN-led diabetic foot self-care education among domiciled adults, and one article about managing DFU for adults with DM experiencing homelessness. No studies were located that measured both subjective DFU risk factors and clinical DFU risk factors among adults with DM experiencing homelessness. Furthermore, no studies were located which implemented diabetic foot self-care education and measured the outcome variables of subjective DFU risk factors, diabetic foot self-care behaviors, and provided clinical diabetic foot assessment and categorized the clinical DFU risks factors. Therefore, it is imperative that the paucity of empirical inquiry be addressed at this time. As so little is known about adults with DM experiencing homelessness and their subjective risks for DFU, and/or their diabetic foot self-care behaviors, and clinical diabetic foot assessments, the current study may establish an advantageous approach for health promotion and disease prevention for this population at risk for DFU and/or amputation.

The purpose of this quasi-experimental single group repeated measures study was to address serious gaps in the literature and to contribute to the science of DM self-management of diabetic foot self-care among adults with DM experiencing homelessness.

The literature review was organized into five main topics and addressed Adults Experiencing Homelessness, DM and Sequlae, Adults with DM Experiencing Homelessness, and Diabetic Self-Management Education and Support. A summary and gaps in the literature are presented thereafter.

ADULTS EXPERIENCING HOMELESSNESS

According to the National 2017 Point in Time census of people experiencing homelessness in the U.S., 369,081 were adults, of which 61% were men and 39% were women. African American and Hispanic adults were overrepresented in the census, while Caucasian and Asian adults were underrepresented in the census (NAEHC, 2017). Causal pathways to one becoming homeless are multifaceted (Frankish, Hwang, & Quantz, 2005).

The lack of affordable housing is cited as one of the primary factors leading to homelessness by several national agencies (NAEHC; National Health Care for the Homeless Council [NHCHC], 2017; The National Coalition for the Homeless [NCH], 2017). Predisposing factors such as poverty, catastrophic illness, bankruptcy, mental illness, substance and alcohol abuse are also major factors leading one to become homeless (Fazel, Geddes, & Kushel, 2014; Frankish, et al., 2005). Thus, lacking the financial means to make a house payment or to see a healthcare provider for a physical or mental illness, or having a substance abuse disorder increase the risks for one becoming homeless. Even when sheltered, the individual's risks for becoming homeless persist and are independent risk factors for poor health (Frankish, et al., 2005).

Health of Adults Experiencing Homelessness

Nayamathi, Leak, and Gelberg (2000) aimed to examine the differences between the health of sheltered and non-sheltered homeless women. The sample consisted of 1,051 women who had been experiencing homelessness for at least one year. Seventy-nine percent of the sample were non-sheltered and 44% were residing in homeless shelters. Fifty-nine percent of the non-sheltered women and 33% of the sheltered women reported fair to poor physical health. The strengths of the study were one gender and sample size. The large proportion of non-sheltered women reporting their health status as being fair to poor may be an expected result, because of the women's exposure to weather extremes, and limited access to nutritious meals, hygiene, and healthcare services (Hwang, 2001; Hwang & Bugeja, 2000; Martinez-Weber, 1987).

Frankish et al.'s (2005) focused review about homelessness aimed to provide an overview of homeless research for the purpose of documenting the associations between homelessness and health. Strong associations between homelessness and the negative impact homelessness has on one's health were reported (Frankish et al.). Residing in a homeless shelter was not without risks; conditions may be crowded, increasing the individual's health risk for exposure to parasitic, bacterial, and fungal infectious skin diseases (Frankish et al.). Additionally, sheltered homeless individuals spent an excessive amount of time walking and standing, thus, increasing their podiatric health risk for increased plantar pressure and foot lesions due to repetitive trauma from poorly fitting footwear (Muirhead et al., 2011). Superficial skin infections on the feet may become exacerbated by increased pedal pressure and repetitive trauma and lead to friction blisters, open foot lesions, and cellulitis (Raoult et al., 2001).

Some adults experiencing homelessness obtained health care from a Health Care for the Homeless (HCH) program. Lebrun-Harris et al. (2013) aimed to compare the health status among adults experiencing homelessness and domiciled. The data were collected

from computer-assisted personal interviews from health center patients. A total of 2,683 surveys were obtained from 618 homeless and 2,065 nonhomeless respondents. Fifty two percent of the homeless individuals reported fair to poor health despite having access to routine healthcare services at the HCH centers. While only 36% of the nonhomeless individuals reported fair to poor health and did not have access to healthcare services at the HCH centers. The differences were statistically significant (p=.0001).

Schanzer, Dominguez, Shrout, and Canton (2007) studied the effects of a long-term episode (18 months) of homelessness on the health of adults who became homeless for the first time. The sample consisted of 445 participants comprised of 225 men and 220 women, with 351 individuals completing all follow-up data. Health status data collection occurred at baseline, six months, 12 months, and 18 months via self-reports about physical and subjective health information. Seventeen percent of the sample reported having a chronic illness at baseline. Even though burdened by chronic illness, respondents did not perceive that their physical health impeded their abilities to function physically, socially, or emotionally. It was concluded that homelessness did not have a negative effect on the respondent's health, however, this conclusion is inconsistent with the findings reported by Nayamathi et al. (2000), Frankish et al. (2005), and Lebrun-Harris (2013).

Unmet Health Needs of Adults Experiencing Homelessness

Unmet needs consisted of the inability to obtain medical care and/or the need to delay medical care (Lebrun-Harris et al., 2013). The homeless respondents were twice as likely as the nonhomeless to report having an unmet medical care need in the past year and a higher percentage of having an unmet medical care need than their housed counterparts 43% vs. 29% (p =.0002) respectively. Among the adult HCH patients, homelessness was an independent risk factor for unmet medical needs (Lebrun-Harris et al., 2013). The strength of the study included the nationally representative data from the 2009 HCH Surveys (N = 2,683). Thus, the findings can be generalized for adult HCH patients.

Baggett et al. (2008) analyzed data from 966 adult respondents to the 2003 HCH Survey. The aim of the study was to assess the occurrences and predictor of past-year unmet needs for five types of health care services. The five types of health care services consisted of medical and surgical care, prescription medications, mental health care, eyeglasses, and dental care. The prevalence of having an unmet need was reported by 73% of the respondents, including an inability to obtain medical or surgical care 32%, prescription medications 36%, mental health care 21%, eyeglasses 41%, and dental care 41%. Those experiencing homelessness were four to six times more likely to have an unmet healthcare need when compared to the general population. The primary independent predictor for each unmet need was the lack of health insurance. The findings from the study are important to highlight the impact that the lack of insurance has upon the homeless individual's ability to meet his/her healthcare needs. Access to medical, surgical, and mental health care, prescription medications, nutritious meals, eyeglasses, and health insurance are all necessary in order to self-manage DM. Baggett et al.'s (2008) findings underscore the challenges the population encounter with DM self-management, and factors which contribute to high rates of morbidity among adults with DM experiencing homelessness.

There is a phenomenon called "competing priorities" and/or "competing demands" discussed in the research about the unmet medical needs among adults experiencing homelessness (Gelberg, Gallagher, Andersen, & Keogel, 1997). The phenomenon is consistent with Maslow's hierarchy of needs, with Level 1, the obtainment of food, clothing, and shelter as top priorities in need of fulfillment. The perception among adults experiencing homelessness is to prioritize and meet their subsistence Level 1 needs first, after which lower Level 2 priority needs for safety include environmental, employment, resource, and safety such for health and illness may be addressed. Competing priorities are thought to be a significant nonfinancial barrier to obtaining medical care when it is needed. Thus, competing priorities contributes to the hypothesis which asserts that adults experiencing homelessness are more likely to seek healthcare in a crisis, and less likely to

engage in routine healthcare services or preventative healthcare measures (Bharel et al., 2013; Buck, et al., 2013; Hwang, 2001; Savage et al., 2014). Therefore, it is vitally important for nurse scientists to design, implement, and evaluate educational interventions for health promotion among vulnerable populations, including adults experiencing homelessness.

Podiatric Health and Podiatric Health Needs of Adults Experiencing Homelessness

Foot problems are a major cause of morbidity among adults experiencing homelessness (Hwang, 2001; Muirhead et al., 2011; Moy & Sanchez, 1992; Wrenn, 1991), as approximately 20% of the medical complaints voiced by adults experiencing homelessness are related to foot problems (Raoult et al., 2001; Wrenn). Some of the more prevalent podiatric problems include those resulting from repetitive trauma, such as friction blisters, foot lesions, foot pain, and bunions and callouses. If left untreated, podiatric ulceration and infections may develop (Raoult et al., 2001; Wrenn). When the effects of podiatric pathologies combine in the face of poorly controlled DM, the risk for DFU increases. However, no literature was located that was dedicated to podiatric pathologies among a sample of adults with DM experiencing homelessness. Therefore, a discussion about the five studies located that surveyed the podiatric health and podiatric health needs of adults experiencing homelessness was important to include in the literature review.

Stratigos, et al. (1999) documented podiatric skin conditions among a sample of adult men residing in a homeless shelter. The most prevalent foot infections among the cohort of 142 participants were tinea pedis (n=54, or 38%), pitted keratolysis (n=29, or 20.4%), and toenail fungus (n=22, or 15.5%). The occurrences of superficial fungal and bacterial foot infections may seem inconsequential, however when framed within the contexts of health risks and lifestyle characteristics among adults experiencing homelessness, prompt treatment is recommended. The investigator's recommendations stressed early treatment and measures to prevent foot pathologies in order to prevent limb

threatening complications. Stratigos et al.'s recommendations were instrumental in informing the protocol of the current study as the first steps in the prevention of DFUs are risk factor assessment and the of teaching diabetic foot self-care.

Schanzer et al.'s (2007) longitudinal descriptive survey of newly homeless adults documented unspecified podiatric complaints. The Medical Outcomes Study 36-Item Short Form Health Survey was used to collect self-report data about the participant's general physical and mental health, and the participant's health perceptions. At baseline, 12.4% (n = 351) of the adults experiencing homelessness reported podiatric complaints. When baseline measures were taken, the participants were newly homeless and lacked healthcare. The investigators hypothesized that podiatric complaints decreased over the study period because of the availability of primary health care services within the shelter system at which participants could seek healthcare for their podiatric complaints. By the 18-month data collection point, many participants had been able to obtain health insurance, which could have improved their access to healthcare services. At 18 months, only 5.7% of the participants reported podiatric complaints, a statistically significant decrease (p =.005) (Schanzer et al.). In addition, the shelter system, which served as the study's setting, had case workers on-site who may have encouraged participants with podiatric complaints to seek healthcare at the shelter clinic (Schanzer et al.). The study findings were important to inform the current study due to the participants' reported decrease in the percentages of podiatric complaints. Additionally, the reduction in the percentage of podiatric complaints demonstrated health improvements when primary health care was available and accessible.

Schanzer et al. (2007) raised important considerations for this investigator to be aware of and included in the current study. First, although unspecified, pre-existing podiatric complaints exist among adults experiencing homelessness. The protocol of the current study included diabetic foot assessments that inspected for signs of fungal infection, foot lesions, callouses, and signs of repetitive trauma. Additionally, in the current study, the participant's footwear was also inspected, an extremely important component of a foot

assessment for an adult experiencing homelessness. Finally, the participants in the current study were informed as to when and where to seek treatment for podiatric complaints.

Muirhead et al. (2011) surveyed adults experiencing homelessness to inquire why community-based foot care services were used. A convenience sample of 100 adults who received services at a community kitchen participated. Data were collected on one day during the lunch meal. Most of the respondents valued healthy feet (n = 92), wanted to learn about foot health (n = 74), and felt they needed foot care (n = 52). Sixty-two respondents provided valuable information about self-dignity issues that would deter them from seeking foot care, such as being embarrassed about foot odor, dirty feet, and worn out footwear. Muirhead et al's survey findings were instrumental in informing components of the protocol of the current study. For example, to mitigate potential embarrassment participants were offered wipes to cleanse their feet before the foot assessment was performed and surgical shoe covers when their footwear needed to be removed. Inappropriate and/or worn out footwear was replaced with new and/or gently used sneakers and diabetic socks were provided. The study visits were scheduled at a time that was convenient for the participants.

Chen, Mitchell, and Tran's (2012) review of the literature focused on the podiatric health needs of homeless populations. They could only locate three studies that met inclusion criteria for their review. However, several common findings about the podiatric health among homeless populations were noted. The prevalence of tinea pedis, nail fungus, corns, calluses, bunions, and foot pain were significant among the samples in the studies that were reviewed. Furthermore, it was noted that an unspecified number of participants in one of the studies wore dirty, worn and run-down footwear that imposed additional risks for foot problems. The researchers recommended the need for improved podiatric hygiene, education, and treatment. The extremely limited amount of studies, three that Chen et al. located for their review, is supported by the paucity of studies in the current literature review, underscoring the continued gap in the current literature about the podiatric health

needs of adults experiencing homelessness. In the current study, diabetic foot screenings were performed among a sample of adults with DM experiencing homelessness. The diabetic foot screenings included assessments for tinea pedis, onychomycosis, pressure and skeletal foot deformities, non-traumatic lower-extremity amputation and/or foot ulcer, and will add to the current literature about the podiatric health of adults with DM experiencing homelessness.

Chen, Mitchell, and Tran (2014) aimed to identify podiatric hygiene practices, podiatric lower-extremity status, and related risk factors for poor podiatric health from a sample of sheltered adults (N=299) experiencing homelessness. The majority (73%) changed their footwear every six months and 61% changed their socks daily, which demonstrated appropriate podiatric hygiene practices. Seventy-four percent of the participants reported being on their feet for five or more hours each day. The most common foot conditions included onychomycosis, calluses, and tinea pedis reported by 30%, 26%, and 24% of the sample respectively, consistent with previous findings about the podiatric health of adults experiencing homelessness (Hwang & Bugeja, 2000; Raoult et al., 2001). Over half of the participants experienced foot pain, while 16% experienced numbness, and 21% experienced tingling in the feet. Non-podiatric risk factors related to poor podiatric health consisted of the participant's self-report of the use of alcohol by 43% of the sample. While 38% of the sample reported using marijuana, 24% reported using cocaine and 68% reported tobacco use. Findings are limited by the self-report data on the 37-item survey about foot hygiene practices, foot pathologies, and non-podiatric risk factors for poor podiatric health. An analysis that controlled for the covariates of non-podiatric risks would have been helpful to distinguish the significance of alcohol, illegal substance, and tobacco use and the impact these risks have on podiatric health of the participants. Additionally, foot examinations were not performed, which adds to the gap in the literature about the podiatric health of adults experiencing homelessness and staying in homeless shelters. In the current study, diabetic foot screenings were performed by the RN investigator and the

podiatric health of the participants enrolled was documented. The findings will fill a gap in the literature.

DIABETES MELLITUS AND SEQULAE

Diabetes mellitus is a serious, chronic, and life-long endocrine disorder resulting from pancreatic inefficiencies that impairs insulin production and glycemic control (Wilk, Mora, Chaney, & Shaw, 2002). The hallmark of effective diabetic self-care is one's ability to achieve and maintain glycemic control. Long term ineffective glycemic control is a precursor for diabetic complications which negatively impact human organs, nerves, and limbs (Tan, Magarey, Chee, Lee, & Tan, 2011). Individuals with DM who are unable to achieve and maintain glycemic control are more likely to be at risk for neuropathies, vascular changes, diabetic foot, and non-traumatic lower-extremity amputation. In order to effectively self-manage diabetes, persons with DM need to be knowledgeable about the disease, and have the ability and resources for diabetic self-care (Garcia, & Vaello-Benavides, 2006).

The Incidence and Prevalence of Diabetes Mellitus in the General Population

In 2015, The American Diabetes Association (ADA, 2015) estimated the incidence of DM to be 1.5 million cases in the U.S. The U. S. prevalence of DM was 30.3 million or 9.4% of the U.S. population (ADA). In Texas, during 2015, the median prevalence of DM was 11.2% (Centers for Disease Control and Prevention [CDC], 2015).

The Economics of Diabetes Mellitus

The ADA routinely reports the cost of care for persons with DM in the US. (ADA, 2019). Annual amounts for total direct care have risen from $174 billion in 2007, to $245 billion in 2012, and to $327 billion in 2017, amounting to approximately one in seven healthcare dollars being spent on a person with DM in the U.S. Providing healthcare for a

person with DM now costs an average of $16,752 annually, a 13% increase from the previous year (Riddle & Herman, 2018). The findings highlight the urgent need for the implementation of evidenced-based DM prevention programs in the U.S. Diabetes Mellitus prevention programs and evidenced-base interventions may be viewed as measures to control costs, improve outcomes, and prevent complications such as diabetic foot ulcers.

Diabetic Foot Ulcer

One complication of DM is a DFU, one of the most common, serious, and difficult complications to treat (Schaper et al., 2015). A DFU is a full-thickness wound extending to the dermis layer of the skin on the foot, resulting in an open lesion that heals poorly or not at all (John Hopkins Guide, 2019). DFU's may be preceded by neuropathy, skeletal deformities of the feet, and wearing poorly fitting footwear (Gkogkolou and Bohm, 2014). DFUs are most commonly found on the plantar surfaces of the feet, including the metatarsal heads and mid-foot areas. DFUs are also found on the dorsal aspects of the toes at the joints or distal tips (John Hopkins Guide). An image of a DFU is presented in Illustration a.

Illustration a: DFU Located on the Heel

The precise etiology of diabetic foot ulcers is unclear. However, studies indicate that concomitant risk factors increase a person's likelihood of developing DFUs and when the number of risk factors increase, so does the likelihood of developing a DFU (Abu-

Qamar, 2006; Gkogkolou & Bohm, 2014; Lavery, Armstrong, Vela, Quebedeaux, & Fleischli, 1998; Schaper et al., 2015). No studies were located about risk factors for DFU and adults with DM experiencing homelessness. The current study included measurements of subjective DFU risk factors obtained from the participants' self-reports on the Self-Administered Foot Risk Screening Questionnaire (SFSQ) (Valente et al., 2004). The Inlow's 60-Second Foot Screen tool was used for the clinical diabetic foot assessment of DFU risk factors and will fill the gap in the literature (Inlow 2004).

Significant risk factors predicted diabetic foot ulceration (Lavery et al., 1998). When people with diabetes and a foot ulcer were compared with matched cases without an ulcer, predictive DFU variables included high plantar pressure (>65N/cm2), history of amputation, having DM for greater than 10 years, foot deformities, male gender, poor glycemic control, and one or more subjective symptoms of neuropathy. When common foot specific variables including, neuropathy, foot deformity, and previous non-traumatic lower-extremity amputation were added to the multivariate model, the cumulative DFU risk increased significantly (Lavery, et al.). The risk for DFU was 1.7 times greater for clients with neuropathy who had no other risk factors, and 12.1 times greater for clients with neuropathy and foot deformity (Lavery et al.). The risk for DFU was 36.4 times greater for clients with neuropathy, foot deformity, and previous lower limb amputation (Lavery et al.). Thus, categorizing the level of DFU risk based on podiatric symptoms is extremely important for healthcare providers to understand. The findings inform the practice of healthcare providers to include a thorough assessment of the client's feet.

In between 2011-2015, Rassaneis, Haddad, Mantovani, Marcon, and Pissinati (2017) analyzed DFU risk factors among a sample of 1515 persons with T2D age 40 and older in southern Brazil. One instrument, not named, measured the five independent variables: (a) clinical foot examination to assess DFU risk, (b) socioeconomic status, (c) lifestyle characteristics, (d) co-morbid disorders, and (e) diabetic foot self-care behaviors. Univariate, bivariate, stepwise regression logistics, and hierarchal regressions were used to

analyze the data with a predetermined ($p < .05$) level set. It was found that being male ($p = .020$), having DM for 10 years or more ($p = .011$), insulin use ($p = .012$), retinopathy ($p = .001$), stroke ($p = .018$), and fungal infection of the toes and interdigital spaces ($p = .001$) were predictive for DFU. The findings also reported that a lack of physical activity (p = .013) was also predictive of DFU. The strongest predictors of DFU were retinopathy and fungal infection of the toes and interdigital spaces. Rossaneis et al.'s findings add new empirical information about statistical associations regarding DFU risk factors which have not been reported in other studies. A limitation to the study was that the findings do not imply causality. Rossaneis et al.'s study provides strong support for RN investigators to lead research that examines for associations between the findings from clinical diabetic foot examination and survey data as potential predictors for DFUs. Rossaneis et al., also note that RN's, who traditionally have been the main providers of self-care health education, have made significant contributions for the prevention of diabetic foot complications and should be involved in research that seeks to assess DFU risk factors and teaches diabetic foot self-care.

Predictors for Diabetic Foot Amputation

Sayiner, Can, and Akarsu (2019) aimed to identify clinical characteristics predictive of non-traumatic lower-extremity amputation among 400 participants over the age of 18, diagnosed with T2D and DFUs living in Turkey. Retrospective chart reviews were conducted for the results of diagnostic examinations, demographic data, co-morbid disorders, prior amputation, and Wagner classification of the current DFU. The participants' data were then divided into an amputation or non-amputation group, differentiating between those with a previous amputation and those with no previous amputation. Factors predicting amputation in the group with a history of non-traumatic lower-extremity amputation were: (a) male, (b) coronary artery disease, (c) peripheral arterial disease, (d) hypertension, (e) proteinuria, (f) high grade DFUs, (g) tobacco use, and

(h) previous DFU and/or amputation. The predictors with the strongest significance were the presence of peripheral arterial disease and a previous DFU. One limitation to the findings of the study was the use of retrospective chart reviews, which may have overlooked changes to clients' risk factors for amputation. For example, the degrees of severity of hypertension may improve over time, thus imposing a decreased risk for DFU. Sayiner et al. attributed numerous clinical characteristics predicting future diabetic foot amputations. The findings support the need for the current study, which aimed to implement an diabetic foot self-care educational intervention for the identification and reduction of DFU risk factors and increasing diabetic foot self-care behaviors.

The Cost of Care for Diabetic Foot Ulcers

The ADA's 2007 cost analysis for DM care estimated an annual expense of $116 billion. Approximately 33% of the $116 billion of the 2007 DM expenses, or $38,666 billion was spent to treat DFUs (Driver, Fabbi, Lavery, & Gibbons, 2010). Treatment for DFUs impose a sizeable economic burden on U.S. healthcare systems, however, a limited amount of research was located that assessed the cost-effectiveness of interventions for the prevention of DFUs. The cost for supplies for the participants in the current study was $14.61 per subject for a total cost of $423.69. The supplies included a folder and printing for the Participant Package and a bag and items for the diabetic foot care bags. The diabetic foot care bags included two washcloths, two hand towels, one pump container of antiseptic liquid soap, one pair of diabetic socks, one 13 oz. pump container of diabetic lotion monofilament (5.07), and latex/powder free gloves. Thus, the costs for supplies in the current study provides documentation about the cost effectiveness of an RN driven DFU risk identification and reduction intervention

Tennvall and Apelqvist (2001), aimed to analyze the cost-effectiveness of DFU prevention strategies for patients with various risks for DFUs and non-traumatic lower-extremity amputation. The prevention strategy consisted of patient education, foot care,

and therapeutic footwear for the at-risk participants. The simulation study was conducted over a period of five years and enrolled 10,000 participants who were 24 years and older. The DFU prevention program published by the International Working Group on the Diabetic Foot (IWGDF) was shown to be cost-saving. Non-traumatic lower-extremity amputations were reduced by 25% among the Swedish cohorts with DFUs. The study findings are limited by the simulated model's assumption of patient adherence to a routine diabetic self-foot care protocol. In the current study, the participant's adherence to five diabetic foot self-care behaviors was measured by the SDSCA as the number of times the subject performed the behavior over the past seven days. The repeated SDSCA measurements may provide insight into the participant's adherence to the diabetic foot self-care behaviors.

Foot Screening for the Prevention of Diabetic Foot Ulcers

Tennvall and Apelqvist's (2001) simulated cost analyses study on DFU prevention strategies, routine diabetic foot screening and diabetic foot self-care education demonstrated reductions in costs of care and the occurrences of non-traumatic lower-extremity amputations. The ADA's *Standards of Medical Care in Diab*etes (2019) provide guidelines for healthcare professionals caring for patients with DM. The ADA recommends a diabetic foot assessment at the time of diagnosis and at least annually. When the patient displays DFU risk factors, the diabetic foot assessments need to be performed more frequently in order to prevent the occurrence of DFUs (Abu-Qamar, 2006; ADA, 2019). Yet, the literature indicated that diabetic foot screenings for the prevention of DFU are not being routinely performed (Abu-Qamar, Jadali, Nemati, Jadali, & Jadali, 2018). The current study will fill gaps in the literature pertaining to diabetic foot screening and diabetic foot self-care education. In the current study, the diabetic foot screenings were performed every week for four weeks. The diabetic foot self-care education focused on the daily performance of five diabetic foot self-care behaviors, and measures to identify DFU risks

and reduce the negative effects of DFU risk factors, such as wearing protective footwear, and checking the feet.

Abu-Qamar (2006) documented inconsistencies across several groups of healthcare professionals and their performance of diabetic foot screening with a review of the literature. Primary care providers performed foot screenings for only 18% of a diabetic patient population consisting of 467 adults. Family physicians were more likely to perform diagnostic testing than to perform diabetic foot examinations. Podiatrists also demonstrated inconsistencies with foot screening practices as only 40% of a diabetic patient population of 173 adults had received foot screenings. Abu-Qamar's findings provided support for the need of routine diabetic foot screenings. The ADA guidelines recommend that persons with DM need a diabetic foot screening at least annually and diabetic foot self-care education at the time the DM diagnosis is made (ADA, 2016).

Abu-Qamar (2006) reported various hypotheses to explain why healthcare professionals do not routinely perform foot examinations for patients with DM. The first is that perhaps there is some role confusion among the various providers as to whose responsibility it is to examine the feet of persons with diabetes. Another explanation attributes the variations in foot examinations to fragmented health care systems. Abu-Qamar also offered an alternative theory postulated by others stating that foot examination is the nurse's responsibility while others perceive it as the responsibility of the physician. Rossaneis et al. (2017) advocate for RN's, to be included with the members of the healthcare team to prevent diabetic foot complications. The current study included the performance of diabetic foot screenings performed by the RN investigator. Thus, strong support is presented for the inclusion of a RN to perform diabetic foot screenings.

A foot screening is a non-invasive assessment using inspection and palpation to identify signs of neuropathic changes, altered pedal circulation, structural deformities, signs of plantar pressure, previous ulceration and/or non-traumatic lower-extremity amputation in the early stages so that the prevention of DFU and/or amputation can be

maximized (Abu-Qamar, 2006; Rhim, & Harkless, 2012). Podiatric experts and investigators agree that early identification of DFU risk factors and categorizing the individual's risk for DFU is essential for DFU prevention (Boulton, 2010; Lavery et al., 1998; Schaper et al., 2015; Singh, Armstrong, & Lipsky, 2005; Shapiro, 2016; Rhim, & Harkless). In the current study, Inlow's 60-Second Diabetic Foot Screen (Inlow, 2004) tool was used for the diabetic foot screenings, performed by the PI. The assessment included an inspection of the skin, toenails, presence or absence of pressure related and/or structural deformities, history of DFU and/or amputation, a 10-point Semmes Weinstein Monofilament Test (5.07 10 gm.) for LOPS, and an assessment of pedal circulation and PAD. Performing a 10-point Semmes Weinstein Monofilament test means that 10 spots on the feet are assessed using a monofilament 5.07 mm. in length, and exerting 10 gms. of pressure at each spot. An illustration of the 10-point Semmes Weinstein Monofilament test is presented in Illustration b.

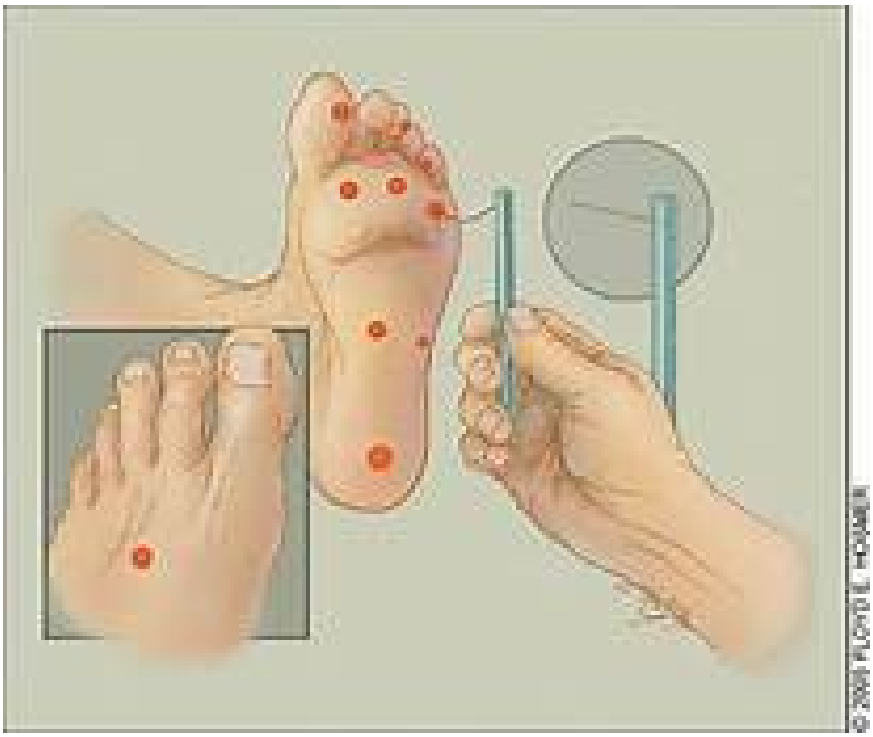

Illustration b: 10-Point Semmes Weinstein Monofilament (5.07 10 gm.) Test

Based upon the Inlow's assessment, the clinical DFU risk can be categorized. In addition, Inlow's tool included an assessment of the participant's footwear, which is very important to assess in adults experiencing homelessness as poorly fitting footwear have been associated with repetitive trauma, friction blisters, calluses, and corns (Hwang & Bugeja, 2000; Martinez-Weber, 1987, Wren 1991).

ADULTS WITH DIABETES MELLITUS EXPERIENCING HOMELESSNESS

Estimating the prevalence of DM among adults experiencing homelessness is difficult because of methodological inconsistencies and variations in the definitions of homelessness (Bernstein et al., 2015; Hwang, 2001; NAEHC, 2017; Savage et al., 2014). Prevalence was estimated to range from 8% (Bernstein, Meurer, Plumb, & Jackson, 2015) to 12% (Fazel et al., 2014) in the U.S., which is higher when compared to other industrialized countries including Canada, France, Portugal, and Ireland with prevalence rates of 4%, 6.2%, 7%, and 8% respectively (Bernstein, et al., 2015). Although the rate of adults with diabetes was 8.2% among the general U.S. population, similar to that of adults experiencing homelessness, adults with DM experiencing homelessness have a higher burden of the disease as exhibited by premature morbidity and mortality (Arnaud et al., 2009; Hwang & Bugeja, 2000). For adults with DM experiencing homelessness, DM is the third leading cause of death, whereas among the general population DM is the seventh leading cause of death (Bharel et al., 2013).

PREMATURE MORBIDITY

Barriers to Diabetic Self-Management Among Adults With DM Experiencing Homelessness

Hwang and Bugeja (2000) identified several barriers to appropriate diabetes management among adults with DM residing in homeless shelters. The participants (N = 50) were Caucasian males between the ages of 40-59, and 86% of the participants had T2D.

Forty-four percent of the participants had the T2D diagnosis for less than five years. Inadequate glycemic control was recorded among 44% of the participants and 62% of the participants took oral antihyperglycemic medication. Difficulties managing DM were reported by 72% of the participants. Greater than half of the participants (64%) reported problems with the meals available at the shelters. The most commonly reported dietary issues were the high amounts of carbohydrates, fats, and sugars, limited availability of fresh fruits and vegetables, and the inability to make food choices consistent with appropriate dietary guidelines for DM. The second most commonly reported barrier to effective DM management for 18% of the participants, was gaining access to medications and supplies, an inability to coordinate their medications with meals, and/or to obtain their diabetic supplies, including insulin and syringes when needed. One limitation to the study was the small sample size. The strength of the study was the mixed-methods design, which afforded the collection and analyses of both quantitative and qualitative data. Even though the setting for the study was homeless shelters in Toronto, Canada, there were similarities with dietary issues at the Toronto shelters and the shelters in East Texas that provided the setting for the current study. Primarily, the participants in both settings could not make food choices considered to be good for someone with DM due to a lack of fresh fruits and vegetables, and an abundance of food high in carbohydrates, sugars, and fats. Many participants at the East Texas shelters commented about the lack of choice being a problem for managing DM K. R. Strout (personal communication, December 6, 2017).

Characteristics of Adults With DM Experiencing Homelessness

Arnaud et al. (2009) sought to describe the characteristics of DM among sheltered adults experiencing homelessness and then compared the characteristics to a group of non-diabetic adults experiencing homelessness residing in the same shelters in Paris, France. Thirty-five participants with DM and 433 participants without DM participated. Among those with DM, 73% were on their feet most of the day, 41% had difficulties with

ambulation and 43% of those with difficulties had permanently reduced mobility. Among those without DM only 25% had difficulties ambulating, which was a statistically significant difference (p =.033) compared to those with DM. Additionally, major diabetic complications were found among the individuals with DM despite their young age (M = 45 years) at diagnosis, having had DM for only five years or less and moderate glycemic control as measured as a glycosylated hemoglobin A1c of greater than 8%. Arnaud et al. (2009) reported major diabetic complications including retinal disorders among 32% of the participants with DM, 42% of the participants had loss of protective sensation in the feet, and 17% of the participants had a previous non-traumatic lower-extremity amputation of a toe and/or foot. It was estimated that one in three participants needed regular foot care due to a high podiatric risk of loss of protective sensation or a very high podiatric risk due to previous non-traumatic lower-extremity amputation (Arnaud et al., 2009). Arnaud et al.'s, (2009) finding were important to support the need for the DFU risk assessment and diabetic foot assessments provided in the current study as very little is known about DFU risk factors and diabetic foot assessment findings among a sample of adults with DM experiencing homelessness in East Texas.

Diabetic Foot Ulcer Management

Matteoli et al. (2019) aimed to examine the effectiveness of a mobile voluntary health service intervention on diabetic foot ulcer treatment for adults with DM experiencing homelessness in Rome, Italy. The sample size consisted of 21 participants of whom 85% were males and females 15% with an average age of 43 years. All of the 21 participants presented with a DFU, thus meeting inclusion for the DFU treatment intervention. Prior to the implementation of the treatment intervention, diabetic foot examinations were provided to assess for podiatric circulation, neuropathy, and for signs and symptoms of DFU infection. The depth of the DFU was graded according to the Wagner classification. The DFU treatment was provided under sterile conditions in the

ambulance and consisted of wound debridement, incision and drainage of abscesses, and antibiotic administration. The DFUs were then disinfected and dressed. All the participants in the treatment arm were given protective footwear. Following the initial treatment, each DFU was treated every week for 12 months. The effectiveness of the intervention was measured as the number of successfully cured DFUs based on a reduction of the initial Wagner classification score for each DFU. Following three years of treatment, the DFUs among 86% of the participants were fully healed. One subject died due to septic shock and two participants required non-traumatic lower-extremity amputation due to a clinical worsening of the DFUs.

The findings are limited by the small sample size. Matteoli et al. (2015) demonstrated that with regular and consistent treatment, DFUs can be cured. However, the study also demonstrates the length of time it takes to cure a DFU and the incredible amount of voluntary professional man-hours that were dedicated to the treatment of DFU among a group of adults with DM experiencing homelessness in Rome, Italy. Matteoli et al. (2015) underscores the importance of DFU prevention for adults with DM experiencing homelessness.

DIABETIC SELF-MANAGEMENT EDUCATION AND SUPPORT

Diabetic self-management education and support (DSMES) programs are the gold standard for anyone diagnosed with DM (ADA, 2016). Learning how to self-manage DM is imperative to maintain glycemic control and prevent the development of complications, such as hyperglycemia and diabetic foot problems. The aim of DSMES programs are to improve preventive practices for people with DM. Diabetic Self-Management Education and Support classes are usually taught by specially trained Certified Diabetic Educators (CDEs) or Advanced Practice Nurses (APNs) who can adjust medication regimes, order diagnostic tests, and perform specialized assessments in the clients' milieu (Hunt, 2013). Diabetic Self-Management Education and Support classes taught by CDEs or APNs have

shown efficacy for lowering blood glucose levels and increasing the number and frequency of diabetic foot self-care behaviors among domiciled adults with DM (Hunt). Only two studies were located in which adults with DM experiencing homelessness were enrolled into a DSMES program, indicating a serious and significant gap in the literature.

Savage et al.'s (2014) quasi-experimental pilot study sought to assess the viability of implementing a 12-week DSMES intervention based upon the chronic disease self-management and nursing case management models for adults with T2D experiencing homelessness. The study also aimed to assess the ability to retain participants. The target sample size for the pilot study was 12 participants. Once enrolled, the subject was asked if he/she wanted to be in the intervention group or the control group. The sample size was (*N* = 9), three participants volunteered for the intervention group and six participants volunteered for the control group. By the twelfth week, two participants remained in the intervention group and three participants remained in the control group. All participants were scheduled for the six research visits over the 12-week time period. The intervention group received DSMES at each visit, and the control had contact only visits. Contact only was not defined by the investigator. The participants from both groups participated in data collection scheduled at the first and sixth research visits. Outcome variables included self-efficacy to manage disease, utilization of health resources, health behaviors, and health related quality of life. The participants in both groups had similar health behavior and health related quality of life scores at the first and sixth research visits. Scores increased from the first and the sixth research visit for health behaviors among participants in the intervention group (Savage et al.) As the investigator notes, due to the small sample size power could not be detected between groups, therefore no statistical report was provided about the results of the outcome variables. A process evaluation was also conducted to assess the viability of the intervention by determining the fidelity of the program. Additionally, retention of participants was calculated as the proportion of participants who enrolled and attended all research visits. The study lacks any discussion about its

limitations. Although one limitation with the sample should be noted which may have affected retention, because Savage et al.'s sample included both adults with DM staying in homeless shelters, and those not staying in shelters. An analyses of the participant's shelter status, group assignment, and retention should have been provided, as very little is known about retaining adults with DM experiencing homelessness in intervention studies. However, the discussion of the implementation of the intervention provided valuable recommendations for future intervention studies for adults with DM experiencing homelessness. Savage et al. recommended to recruit participants from multiple sites, include the shelter staff for assistance with recruitment, anticipate attrition, implement a pertinent DSMES curriculum, and to avoid a long period of time for the research visit and between research visits. Savage et al.'s recommendations were implemented in the procedures for the current study, which are discussed at length in chapter three of this manuscript. In the current study, recruitment occurred at five different homeless shelters and with the assistance of lay case managers, the sample size projected for 25% attrition, and only one component of DSMES, diabetic foot self-care was taught, and the research visits were weekly and estimated to last 30 minutes.

Sage, Keep, Edie, Couzens, and Perira (2016) aimed to improve diabetes knowledge and empowerment in a sample of previously homeless low-income adults (n = 25) and currently homeless (n = 7) with T2D. The DSMES was implemented at a community center by three peer-leaders. The peer-leaders had a diagnosis of T2D and a history of homelessness. A registered nurse (RN) provided the peer-leaders with education pertaining to the DSMES content and an orientation to the overall program. The peer-leaders' knowledge of the educational material was assessed and confirmed prior to the implementation of the DSMES intervention. The DSMES curriculum, based upon focus group feedback included, (a) DM complications, (b) DM diet, (c) self-monitoring blood glucose, and (d) management of medications. The main outcome measures assessed the participants' pretest and posttest knowledge of diabetic self-care behaviors, and

empowerment to manage DM, at each research visit. Only one domain of pretest and posttest DM knowledge about symptoms of DM complications reached statistical significance (p = .030) at the first research visit. At the fourth research visit pretest and posttest knowledge about DM medications was also statistically significant (p = .045). Empowerment scores remained constant throughout the program. Limitations included that the peer leaders expressed concerns about their understanding of the educational material, stating, "It was too difficult," (Sage et al., 2016, 78), despite having passed a knowledge test prior to implementing the intervention. As the peer leaders who did the actual teaching of the DM content and had similar characteristics of the participants, the participants may have also had issues with the complexity of the DM content that was not captured in the data analyses. Secondly, the retention rate was only 33% of the sample size (N = 32). There is a lack of substantial information about when participants left the study and no explanation was provided about why participants left the study. Due to the lack of statistical information about the number of participants that completed data collected for each research visit, a Type 1 error cannot be ruled out. The peer leaders' feedback did provide valuable recommendation for future DSMES intervention studies for adults with DM experiencing homelessness. The peer leaders recommended that the health literacy, time constraints, and unique barriers to DM management need to be considered when preparing DSMES interventions for adults with DM experiencing homelessness. Several of the peer-leaders' recommendations were included in the procedures of the current study. As the health literacy of the participants in the current study was not known, the instruments chosen to measure the outcome variables had been written using lay terminology by the original investigators. The level of measurement of the outcome variables were dichotomous or required a number. The research visits were estimated to last about 30 minutes. The curriculum for the diabetic foot self-care education was also written in lay terminology. Additionally, because diabetic foot self-care education is considered a

standard of care by the ADA (2016), no physician approval was necessary for subject participation.

RN-Led Diabetic Foot Care Education

Very little is known about the role of the RN in diabetic foot self-care education as only one RN-led study was located. Corbett's (2003) study enrolled 40 home health clients with DM who had no current foot ulceration or history of amputation. The participants were randomized into either the intervention group or the control group. The controls received the same RN-led diabetic foot care education which was administered in the same manner after data collection at week 12. The intervention group received RN-led diabetic foot care education immediately after the data was collected at week six. The one-on-one, face-to-face foot care education was administered one time in the participant's home and lasted between 10-20 minutes. Diabetic foot care topics included, (a) individual risk factors, (b) washing and drying feet, (c) toenail care, (d) footwear, (e) moisturizing the feet, and (f) reportable foot problems. The RN individualized the foot care education based upon the participants DFU risks. For example, if the subject had neuropathy, the RN reinforced the importance of wearing appropriate footwear and not going barefoot. Data collection occurred at three points in time, baseline, and six weeks and 12 weeks after enrollment. At each data collection point, diabetic foot risk, diabetic foot care knowledge, foot care self-efficacy, and foot care behaviors were measured in both groups by the participant's self-report on the questionnaires. The baseline data reported high percentages of DFU risk factors among participants in both groups. Seventy percent of the participants had loss of protective sensation, 67% had impaired pedal circulation, and 50% had structural deformities. Inappropriate footwear was worn by 49% of the participants and 61% had inappropriate toenail length. The intervention group analyses reported the greatest statistically significant increases in knowledge, self-efficacy, and foot care behaviors between the six- and 12-week data collection points. The control group showed very little

change in the outcome variables during the course of data collection. The findings do support the efficacy of RN-led diabetic foot self-care educational intervention among a group of participants at risk for DFU who are receiving home health care. A limitation of the study was the small sample size, so generalizations about the findings cannot be made. Corbett's study provides support for the current RN-led diabetic foot self-care educational intervention by demonstrating that the content is appropriate for a RN to teach.

Summary and Gaps in the Literature

Based upon the findings from studies that reported poor health, unmet health needs, and several podiatric risks, among adults experiencing homelessness, very few studies were found that presented interventions aimed to minimize the effects of the risk factors while unstably housed. The review of the literature exposed more research about DM and adults experiencing homelessness using descriptive, epidemiological, unspecified review, and retrospective methodologies than research in which an intervention for DSMES was instituted. The research in which a DSMES intervention was provided lacked any findings about the DFU risks or diabetic foot self-care behaviors among adults with DM experiencing homelessness. Therefore, due to the paucity of research enrolling adults with DM experiencing homelessness into diabetic foot self-care educational programs with DFU risk identification and reduction, the current study is timely and urgently needed.

Chapter 3 Research Design and Methods

INTRODUCTION

Chapter three provides an overview of the problem, research design, and the setting and sample for the study. The instruments, procedures, and the plan for the data analyses are presented. The specific aims of the study and research questions posited to address the aims were also presented. A quasi-experimental single group repeated measures design was used to meet the specific aims. The study investigated the effects of a four-week program of RN-led diabetic foot self-care education on subjective risk for DFU, diabetic foot self-care behaviors, and diabetic foot assessments among a group of adults with DM experiencing homelessness.

OVERVIEW OF THE PROBLEM

Adults with Diabetes Mellitus (DM) experiencing homelessness are at risk for developing preventable diabetic foot complications due to lifestyle characteristics, decreased access to a health care provider, medications, nutritious meals, and diabetic foot self-care education (Hwang, 2001; Hwang & Bugeja, 2000; Martinez-Weber, 1987). Studies show that DM is poorly controlled in the homeless population as evidenced by chronic hyperglycemia and major diabetic complications, such as DFUs and amputations (Arnaud, Fagot-Campagna, Reach, Basin, & Laporte, 2009; Hwang & Bugeja; Martinez-Weber). When poor glycemic control is coupled with foot problems such as deformities (hammer toe), plantar pressure (callus formation), LOPS due to neuropathy, and altered pedal circulation resulting from peripheral vascular disease, the risk for developing a DFU and/or amputation is extremely high (ADA, 2016; IWGDF, 2015). Without proper treatment and diabetic foot self-care education aimed at reducing the risk for DFU, ulcers can lead to gangrene, amputation, and death (Frykberg, 1998; Raoult et al, 2001; RNAO, 2004).

Lifestyle characteristics such as walking, sitting, and/or standing for long periods of time in ill-fitting foot wear can easily lead to the development of foot lesions, such as calluses, corns, pressure sores, stasis dermatitis, and friction blisters (Hwang & Bugeja, 2000; Martinez-Weber, 1987; Wren, 1991). The loss of sensation in the lower extremity and foot caused by diabetic neuropathy may impede early detection of foot lesions increasing the likelihood for the development of DFUs and amputation (Frykberg, 1998; Martinez-Weber; Raoult et al., 2001). Numerous studies indicate that a DFU is predictive for amputation, therefore, best practice guidelines to reduce the risk for developing DFU should be instituted (Armstrong et al., 2013; Boulton, 2010; Murphy et al., 2012; Sing, Armstrong, & Lipsky, 2005). However, no studies could be located in which adults with DM experiencing homelessness were taught only about diabetic foot self-care, or how to identify and reduce their risk for DFU, and/or when or where to seek treatment for diabetic foot complications. Furthermore, the best way in which to provide culturally tailored education about diabetic foot self-care has not been established for adults with DM experiencing homelessness.

The majority of adults experiencing homelessness in the U.S. do not have health insurance (Hwang, 2000). While studies indicate that some adults experiencing homelessness may have Medicare, Medicaid, or Veteran's benefits, most do not (Baggett et al., 2010; Buck et al., 2013). Adults experiencing homelessness may not be able to provide documentation of eligibility or be able to negotiate the complex process of applying for public insurance (Buck et al.). Therefore, access to healthcare and education promoting self-care behaviors is limited for adults experiencing homelessness; making the ability to manage chronic illness nearly impossible.

Diabetic self-management education is the gold standard for anyone diagnosed with DM (ADA, 2016). Learning how to self-manage diabetes is imperative to maintain glycemic control and prevent the development of complications such as hyperglycemia and diabetic foot problems. Diabetic self-management classes are usually taught by specially

trained Certified Diabetic Educators (CDEs) or Advanced Practice Nurses (APNs) who can adjust medication regimes, order laboratory tests, and perform specialized assessments in the clients' milieu (Hunt, 2013). Diabetic self-management classes taught by CDEs or APNs have been shown to lower blood glucose levels and increase diabetic foot care behaviors among domiciled adults with DM (Hunt). Yet, adults with DM experiencing homelessness are less likely to have access to the education without having health insurance or a source of payment. An alternative model in which a RN teaches only diabetic foot self-care has shown positive results by increasing diabetic foot care knowledge, self-efficacy, and foot self-care behaviors among home health care patients (Corbett, 2013). However, the efficacy of the alternative model of RN-led diabetic foot self-care education has not been established among a sample of adults with DM experiencing homelessness.

RESEARCH DESIGN

A quasi-experimental approach using a single group repeated measures design was used to address the research questions. In quasi-experimental studies, participants are not randomized into intervention or control groups and each subject receives the same intervention. A quasi-experimental approach was appropriate for this study because the study population lacked access to diabetic foot self-care education and were at high risk to develop DFUs and amputation based upon the review of the literature. Therefore, in the PI's judgment the use of a control group in this study was considered inappropriate and would have been unfair and unethical to exclude eligible subject from participating in the study. The benefits of repeated measures within-subjects design are that the subjects serve as their own controls, and intervention effects are associated with differences observed with a subject across intervention conditions, rather than between subjects across randomized groups (Portney & Watkins, 2009). Portney and Watkins perceive the current study a longitudinal study as a group of subjects were followed over a period of time and data was collected at every visit during the study period. A longitudinal approach was

therefore necessary for the documentation of changes in the diabetic foot self-care behaviors and diabetic foot assessments (Portney & Watkins). Threats to the internal validity of longitudinal studies include testing effects, attrition, and confounding variables. Measures to minimize the threat of testing effect were handled by scheduling research visits at one week intervals. In order to minimize the threat of attrition, the sample size of 45 subjects included 9 subjects or 25% more participants to offset the effect of attrition. The threat of confounding variables can be handled in the data analysis by controlling for covariates (Portney & Watkins).

SETTING

Five homeless shelters in East Texas provided the setting for the study. East Texas is divided into three geographical sections; Upper, Deep, and South East Texas. The homeless shelters that provided the setting for the study were in Upper East Texas. The shelters were located in Bowie, Gregg, and Smith counties, in which there are a few cities with populations of 100,000 or more, but most of the surrounding areas are rural. One shelter housed only men, two housed only women, and two accommodated both men and women. Quiet private areas within the facilities reserved for the implementation of the intervention were the shelter clinic, library, and day room.

SAMPLE

The target population included male, female, and/or transgendered adults with either T1D or T2D experiencing homelessness. The National Alliance to End Homelessness (NAEHC) defines an adult experiencing homelessness as being age 25 or older. The main characteristic of homelessness is housing instability, which affects the individual's ability to reside in his/her own private residence. For the purpose of the study an adult experiencing homelessness did not have permanent housing and stayed at the homeless shelters that provided the setting for the study (NAEHC, 2017).

Sample Size

The sample size was calculated for the Repeated Measures Analysis of Variance (RM ANOVA) for the four times the data were collected and for within-subjects. Based on the power analysis with an alpha=.05, power=.80, f =.025 the estimated sample size was 36 participants. To offset the effects of a 25% rate of attrition, nine participants were added for a total sample size of 45 participants.

Inclusion and Exclusion Criteria

To be included in the study, participants must have been experiencing homelessness, be over the age of 25 and diagnosed with either T1D or T2D. Additionally, the subject needed to read and speak English. The participant's motor skills needed to be intact in order to perform diabetic foot care. Finally, the subject must have agreed to the study procedures and provided informed consent. Exclusion criteria included individuals, who were not homeless, less than the age of 25 years and did not have T1D or T2D. Additionally those not speaking or reading English, who lacked the motor skills to perform foot care, and would not agree to the study procedures or provide informed consent were excluded. Furthermore, it was not known if the participant had a current DFU at the time of enrollment.

INSTRUMENTS

Demographic Data Sheet

The demographic data sheet was developed specifically for this study (Appendix E). The demographic data included date of birth from which age was calculated, gender (male, female, or transgender), marital status (married, single, widowed divorced, separated, or common law marriage), U.S. Veteran status, race (Asian, Native Hawaiian or other Pacific Islander, Black/African American, White, non-Hispanic white, and American Indian/Alaska Native or other. Additionally, the highest level of education was recorded

(less than high school, high school graduate or GED, trade/technical school, some college no degree, associate degree, bachelor's degree, Master's degree or Doctorate). The participant's insurance status was recorded as either uninsured or insured. If insured, the type of insurance was obtained (private employer paid, private self-paid, Medicaid, Medicare, Tricare, or other). Employment status was recorded (full-time, part-time, retired, student, not currently employed, disabled, or other). Five questions addressed the participant's diabetic history and included: (a) type of DM either T1D, T2D, or don't know, (b) type of DM medications either Insulin, pills, or both, (c) the length of time with DM in years, and, (d) diabetic foot examination in the past year, answered as yes or no, and (e) diabetic foot care education in the past year, answered as yes or no. Lastly, participants were asked to document in years, their length of time without their own home or own place to live.

The Self-Administered Foot Risk Screening Questionnaire (SFSQ)

The SFSQ is a paper and pencil self-report questionnaire that the participants completed as pretest and posttest assessments of their individual risk factors for DFU or amputation (Valente et al., 2004) (Appendix C). The screening questionnaire consisted of six statements about risk factors for DFU or amputation. The participants provided a dichotomous (yes or no) response to each of the following statements: (a) I have total feeling in my feet., (b) My feet have some or partial feeling., (c) My feet are normal in shape., (d) My feet abnormal in shape., (e) In the past I have had a foot ulcer (deep sore) on the bottom of my foot., and (f) I currently have a foot ulcer (deep sore) on the bottom of my foot, or my toe/foot has been amputated. Each yes and no response was assigned a numerical value related to the degree of risk for DFU or amputation. After each statement was answered, the number of points in the yes and no columns were added, then the total points from each column were added together. The total points were then compared with the points in the risk category key to determine if the participant's feet were at-risk for

DFU or amputation. The risk category scores ranged from zero to three. The scoring criteria was as follows, (a) six to eight points=grade zero risk, (b) ten points=grade one risk, (c) 12 points=grade two risk, and (d) 13+ points=grade three risk. Higher scores on the SFSQ indicate a higher degree of risk for DFU or amputation (Valente et al., 2004).

Valente et al. (2004) validated the SFSQ subjective risk category and the clinical foot risk category by assessing the sensitivity, specificity, positive and negative predictive values. The items with the highest sensitivity and specificity were items one, two, and five for identifying foot risk in the sample. Items 3, 4, correctly identified people with normal foot shape, but not for abnormal foot shape, and item 6 classified patients without an ulcer or foot amputation, but did not identify those with an ulcer or amputation at the time the questionnaire was completed (Valente et al., 2004). The SFSQ was found to be valid for identifying patients at the highest risk for ulceration or amputation; the sensitivity, specificity, and positive and negative predictive values were 83.3%, 100%, 100%, and 96% respectively (Valente et al., 2004).

In the current study, the SFSQ was obtained as pretest and posttest measures to assess the effectiveness of the educational intervention. A paired *t*-test was planned to measure the difference between pretest and posttest scores. The sensitivity, specificity, positive and negative predictive values of SFSQ scores were also analyzed.

Summary of Diabetic Self-Care Activities (SDSCA)

The SDSCA is a paper and pencil, self-report tool for participants to record how many times during the past seven days he/she performed any of the five diabetic foot self-care behaviors (Toobert et al., 2000) (Appendix D). The participants were provided with the tool and a pencil at each of the four study visits, and they completed the SDSCA immediately before the diabetic foot care class began. The SDSCA is the subscale of the five daily diabetic foot self-care behaviors and includes (a) inspecting the feet, (b) looking inside the shoes, (c) washing the feet, (d) drying between the toes, and (d) soaking the feet.

The scores for each item can range from zero, meaning not done on any day; to seven, and meaning done every day. Higher scores indicate that diabetic foot self-care behaviors were performed more frequently (Toobert, et al., 2000). The diabetic foot care items on the SDSCA were consistent with the diabetic foot care behaviors taught in the diabetic foot care curriculum, with the exception of one behavior. Since the SDSCA was developed, soaking the feet is not recommended for dry skin. The RNAO (2004) recommends applying lotion to the feet to aid with the suppleness and hydration of the skin. There was a dearth of information about the psychometric properties of the SDSCA diabetic foot care items. Despite the lack of reliability measures, the SDSCA foot care subscale items was used because the tool was easy to read and was specific regarding a length of to recall their performance. In the current study, the SDSCA was obtained at each of the four study visits to assess the effectiveness of the educational intervention and to assess for changes in diabetic foot self-care behaviors over the course of the study. The data were analyzed using RM ANOVA with a predetermined alpha level or 0.5 (Portney & Watkins, 2009).

Inlow's 60-Second Diabetic Foot Screen Tool (Inlow's)

Inlow's 60-second Diabetic Foot Screen Tool was designed for clinicians to perform a thorough diabetic foot assessment for persons with diabetes in order to prevent diabetic foot complications and/or to detect for signs of limb-threatening complications (Inlow, 2004) (Appendix B). The Inlow's diabetic foot assessment was performed by the PI at each of the four study visits, immediately before the diabetic foot-care class began. The investigator assessed both feet, first the left and documented the score for each parameter as the assessment continued. The same procedure was repeated for the right foot.

The Inlow's diabetic foot assessment was performed by the investigator at each of the four study visits, immediately before the diabetic foot-care class began. The investigator assessed both feet, first the left and documented the score for each category as the assessment continued. The same procedure was repeated for the right foot.

The diabetic foot assessment included a visual inspection of the skin, nails, and for the presence or absence of deformities on both feet. The participant's footwear was inspected for fit, appropriateness, and for being a source of trauma. The temperature of the feet and range of motion of the great toe were assessed by touch. Then, the sensation of both feet were assessed by performing a ten point Semmes Weinstein Monofilament Test (5.07 10 gm) on both feet. Sensation was also assessed by asking the participant four questions, (a) Were your feet ever numb?, (b) Do they ever tingle?, (c) Do they ever burn?, and (d) Do they ever feel like insects were crawling on them? The circulation in the feet was assessed by palpating pedal pulses, dependent rubor, and erythema.

The Inlow's total score can range from 0-25 for each foot. A cut-off score of zero, a negative Inlow's test, would indicate that the participant did not have any risk factors for DFU and/or amputation (Portney and Watkins, 2009). Whereas Inlow's total scores greater than zero demonstrate the presence of risk factors, or a positive Inlow's test. Therefore, higher total Inlow's score indicated the presence of more DFU and/or amputation risk factors.

The Inlow's DFU and/or amputation risk category was determined based upon the findings from the Inlow's categories assessing: (a) sensation, (b) deformity, (c) PAD, and (d) history of DFU and/ or amputation. The cut-off score is zero, indicating a negative test, and no LOPS. The Inlow's risk categories and criteria are presented in (Table 1.1).

Following the assessment, with the participant present, the investigator added the scores from each category and for each foot to obtain the Inlow's total score. The highest total score for either the left or right foot informed the investigator and participant about their risk factors for DFU and/or amputation. I informed each participant about their individual risk factors. Additionally, the highest total Inlow's score is used to guide the frequency of future diabetic foot assessments. Each participant was also informed about their diabetic foot assessment frequency and their DFU and/or amputation risk category.

Inlow's 60-second Diabetic Foot Screen Tool has been assessed for inter- and intra-rater reliability, and predictive validity by Murphy, Laforet, Da Rosa, Tabamo, and Woodbury (2012). "Reliability is reported using the interclass correlation coefficient and 95% confidence intervals. Intra-rater reliability ranged from 0.96 to 1.00 right foot and 0.97 to 1.00 left foot. Inter-rater reliability ranged from 0.92 to 0.83 right foot and 0.93-0.83 left foot. Preliminary information about the predictive validity of Inlow's screening tool was very positive for predicting DFU. Two participants had events, one ulcer and one amputations, that were associated with high Inlow screening scores" (Murphy et al., 2012 p, 261). Because the current study included only one rater, inter-rater, intra-rated, and predictive validity could not be determined.

In the current study, the Inlow's assessment was performed at each of the four study visits. A RM ANOVA with a predetermined alpha of .05 was used to analyze the Inlow's scores for changes during the four-week intervention. The DFU and/or amputation risk was categorized from the assessment obtained at each study visit. Non-parametric testing was performed because the level of measurement of the risk category is ordinal. As there was only one rater in the current study neither intra-rater nor inter-rater reliability could be determined.

PROCEDURES

Recruitment

Following approval of the study protocol from the University of Texas at Medical Branch Institutional Review Board (UTMB IRB, study #17-0180) recruitment commenced (Appendix F). To recruit participants to the study, convenience and snowball sampling was used. Convenience sampling is a method by which anyone meeting inclusion criteria can participate in the study (Portney & Watkins, 2009). Snowball sampling occurs when one participant tells another potential participant about the study (Streubert & Carpenter, 2011). Recruitment flyers were posted in common areas at the homeless shelters, such as the day

room and dining room (Appendix G). However, the director of shelter #1 would not allow the posting of flyers at either the men's or women's shelters under his directorship. The director had provided written permission for the shelter's support as a setting for the study and for the recruitment of participants (Appendix H). The director of shelter #1 verbally renewed the written agreement prior to data collection which commenced on November 29, 2017 at shelter #1.

Lay case managers assisted with recruitment by identifying potential participants who met the inclusion criteria to participate in the study. Following the participant's enrollment into the study, the lay case manager was to include the participant's participation in the diabetic foot self-care education on the participant's care plan. The lay case manager's adherence to documentation of a participant's participation on his/her care plan was not assessed.

I spoke with the lay case manager at shelter #1 to inform him of my study and the inclusion criteria of the study. I gave the lay case manager at shelter #1 flyers to give to potential participants. The flyer included a cell phone number and email address for potential participants to call or write me to express their interest in participating in the study. Since after a few days I had not receive any calls from potential participants, I talked with the lay case manager at shelter #1, and he gathered a group of potential participants and made arrangements for me to meet with the potential participants to discuss the study and obtain informed consent on November 29, 2017 at 1830 hours. I met with the potential participants on the day and at the time suggested.

I had also made arrangements to meet face-to-face to discuss the study and obtain written permission for recruitment and participation in the study from the director of shelter #2. The director at shelter #2 provided written consent for recruitment and participation in the study (Appendix I). During our meeting, the director at shelter #2 telephoned the lay case manager and informed her of the study. I left recruitment flyers with the director at shelter #2 to give to the lay case manager. The director recommended that I return on

February 1, 2018 at 1830 hours to meet with potential participants and obtain informed consent, which I did.

I had also made arrangements to meet face-to-face to discuss the study and obtain written permission for recruitment and participation in the study from the director of shelter #3. The director at shelter #3 provided written consent for recruitment and participation in the study (Appendix J). During our meeting, the director at shelter #3 spoke with the lay case manager and informed her of the study. I left recruitment flyers with the director at shelter #3 to give to the lay case manager. The director recommended that I return on May 24, 2018 at 1830 hours to meet with potential participants and obtain informed consent, which I did.

As the recruitment procedure had deviated from what had been initially approved by the IRB at shelters #1, #2, and #3, documents were submitted to the IRB that explained the deviations in the recruitment procedure. Documentation of the modifications of the recruitment procedure made by this investigator were submitted per IRB request (Appendix K). The investigator's response to the IRB stipulations were submitted (Appendix L). Subsequently, the revised procedure for recruitment was approved by the IRB and all the data collected from shelters #1, #2, and #3 were permitted to remain in the study (Appendix M). The recruitment procedure continued as approved at shelters #4 and #5.

The recruitment procedure was approved for homeless shelters, transitional housing units, and safe havens. I was provided with a list of contacts for 13 transitional housing units in East Texas from a nursing student at my place of employment. I telephoned the directors of all 13 transitional housing units, with an invitation to participate in the study. All 13 directors declined to participate. I also sent email invitations to participate in the study to two Salvation Army location in East Texas, three additional homeless shelters in East Texas, and one community-based organization that provided transitional housing units for their clients. Despite repeated emails followed up by telephone calls, there wasn't any interest from the two Salvation Army agencies, the three homeless shelters, or the

community-based organization. As recruitment had stalled by early May 2018, I invited two community clinics who serve the target population to participate in the study. The directors showed a high degree of interest in the study. I kept in close contact with my committee chair and apprised her of my recruitment efforts.

As recruitment had stalled on May 11, 2018, I submitted an amendment with two requests to amend the study protocol to IRB. The first request asked for permission to recruit potential participants from East Texas community health clinics where adults with DM experiencing homelessness go for healthcare. The second request was to reduce the incentive from $20 Walmart gift card to a $10 Walmart gift card to be distributed at each study visit the participants attended. The request to reduce the amount of the incentive was made because the study was self-funded and distributing a $20 gift care was not sustainable. On May 31, 2018, the amendment and miscellaneous requests were approved by the IRB (Appendix M). I then obtained written permission from the clinic signatory to conduct the research at the clinic #1. The signed permission to conduct research was submitted to IRB and approved. I notified the clinic signatory that IRB approval was obtained and asked her to post recruitment flyers at clinic #1. I called the clinic director to post recruitment flyers at the clinic. Despite the additional measures and changes to the study protocol, I did not receive any telephone calls or emails from potential participants at clinic #1. Consequently, the director at clinic #2 did not provide written permission to conduct the research.

Approval was due to expire on September 7, 2018 even though data collection was still in progress. Prior to the expiration of the study approval, the IRB reviewed the procedures for the current study. IRB granted continuing approval to conduct the study from September 7, 2018 through September 7, 2019 (Appendix N).

I continued to recruit and enroll new participants to the study, with the assistance of the lay case managers at shelters #1, #2, #3, #4, and #5. By the end of October 2018, recruitment had stalled for the second time. I informed my chair about the recruitment issue

and was informed to reach out to my dissertation committee members to inform them of the problem and for their suggestions for additional recruitment sites, such as soup kitchens or other shelters. I searched for soup kitchens and other shelters that served the target population and did not find any and informed my committee members. I asked the committee for permission to expand the geographical area beyond East Texas to include North West Louisiana, and to Central, South, and Southeast Texas. On December 13, 2018, I submitted an amendment to IRB requesting to expand the geographical area for recruitment to North West Louisiana, and to Central, South, and Southeast Texas which have more metropolitan cities and services for the target population.

The IRB approved the amendment (Appendix O). I then called two homeless shelters in North West Louisiana to invite the shelters to participate in the study. The invitation was declined and I informed my committee members. As the metropolitan areas in Central, South, and Southeast Texas were approximately a four- to six-hour one-way distance from where I am located in East Texas, it was agreed upon that traveling such a distance was not pragmatic. Additionally, to meet the sample size, 13 participants were needed to enroll and remain in the study for all four weeks, which was highly unlikely. Recruitment ended on February 22, 2019.

RN-Led Diabetic Foot Self-Care Education

Diabetes Foot: Risk Assessment Education Program (RNAO, 2004) was developed by the working group of the Diabetes Nursing Interest Group of the Registered Nurses Association of Ontario Canada (RNAO). The educational program is based upon the RNAO best practice guidelines for the reduction of diabetic foot complications among people with DM. The curriculum was designed as a train the trainer workshop for RN's to teach other RN's and Licensed Vocational Nurses (LVN) the core components of diabetic foot self-care education focusing on DFU risk identification and risk reduction. *Diabetes Foot: Risk Assessment Education Program* was chosen as the educational intervention for

the current study as the curriculum was designed for RNs who were not necessarily APN's or CDE's and because the curriculum was consistent with the specific aims of the current study (RNAO). In the current study, the educational materials were divided into four separate classes that were thought to last approximately 30 minutes each and held for four weeks. I thought that by providing one topic of the curriculum, and having a class that lasted less than one hour, the participant's time constraints were being considered. The scheduling of the classes was consistent at each shelter. For example, once I met with a cohort on a Wednesday at 1830, the remaining classes were held every Wednesday at 1830 for the next three weeks. At shelters #1, #2, and #3 the classes were held after the evening meal, at 1830 hours. At shelter #4 the classes were held at 1000 hours, after the morning meal. At shelter #5 the classes were held at 1300 hours, after the noon meal.

In order to ensure the fidelity of the educational intervention, I created a Point List (Appendix P) of talking points for the topics that were presented each week of the educational intervention. The Point List was obtained from the facilitator's guide for *Diabetes Foot: Risk Assessment Education Program* (RNAO, 2004). The following narrative provides a discussion about the risk assessment education that was presented each week during the four-week diabetic foot self-care educational intervention.

WEEK 1

I instructed the participants to turn to the Diabetic Foot Risk Assessment pretest in the Participant Package. I utilized the pretest items as talking points for the first session to assess the participants' learning needs, and to generate discussion and group participation. I encouraged participants to record their answers on the pages designated for the pretest.

The first week educational component consisted of teaching diabetic foot self-care behaviors, including washing the feet using soap and warm water, drying the feet and between the toes, applying lotion to the feet, inspecting the feet and inside the shoes daily, appropriate footwear, and nail care. I instructed the participants to turn to Care Tips for the

Feet in the Participant Package. The Care Tips for the Feet provided four guidelines with rationales for each behavior to be performed every day. I demonstrated how to perform the diabetic foot self-care behaviors by following the guidelines from the Care Tips for the Feet and used items from my diabetic foot care bag. I simulated washing the feet with warm water and antiseptic soap, drying the feet and in between the toes and applying lotion to the feet. I asked each participant to perform diabetic foot care with me. I provided the participants with feedback about their techniques and the completion of the process. I encouraged the participants to ask questions and answered their questions immediately. Before the class dismissed, I distributed an example of the Diabetic Foot Care Log and explained how to use the document (Appendix Q). Then I collected the example of the Diabetic Foot Care Log. The participants were given a blank copy of the Diabetic Foot Care Log to document their diabetic foot care behaviors for the next seven days (Appendix R). The participants were instructed to bring his/her workbook and Diabetic Foot Care Log to the next class. Before the class dismissed, the date and time for the next class was scheduled.

WEEK 2

The topics for Week 2 education included a discussion and identification of risk factors for DFUs. I discussed the five key risk factors for developing DFU, with a focus on pressure related and structural abnormalities of the feet. I showed pictures of DFUs and had the participants locate the DFU pictures in their Participant Package. I explained how pressure on the soles of the feet and/or toes can very easily lead to ulcers, especially in the presence of the insensate foot. I reinforced the importance of daily foot inspection to observe for foot pathologies that may otherwise go unnoticed. I instructed the participants to remove their shoes and socks and inspect their own feet for any skin problems and to document their findings on Presence/History of Foot Ulcers page in their Participant Package.

Next, I instructed the participants to turn to the pages of pictures of structural abnormalities on the toes in their Participant Package. I discussed the various types of structural abnormalities that may cause pressure to build up on the foot/toes by wearing improperly fitting footwear. I instructed the participant to examine both of their feet without shoes and socks for structural abnormalities and to document their findings on the Structural Abnormality page in their Participant Package. I circulated among the group to help identify hammertoe, claw toes, calluses, blisters, fungal infections, and bunions. I demonstrated an assessment of footwear by comparing a closed toe shoe in good condition with a closed toe shoe in poor condition. Problems with shoes that can cause pressure on the feet and toes include uneven soles, pointed toes, and shoes that are too small for the feet. The participants will inspect their shoes. I replaced any poorly fitting footwear with a pair of properly fitting footwear. A blank copy of the Diabetic Foot Care Log was given to the participants before the class dismissed. The participants were instructed to bring his/her workbook and Diabetic Foot Care Log to the next class.

WEEK 3

The topic for Week 3 included DFU risks related to poor circulation and peripheral neuropathy. I instructed the participants to remove their shoes and socks, and assisted the participants to locate their pedal pulses by palpating the dorsalis pedis and posterior tibial pulses. I followed the instructions in the Participant Package (Appendix A) to explain and demonstrate the assessment of pedal pulses. I assessed the participants' pedal pulses in both feet and graded the pulses either as strong, weak, or absent. I instructed the participants how to perform an assessment of their own pedal pulses and to record their findings on the page labeled Circulation in their Participant Package. I circulated among the participants to provide assistance and to validate their technique.

Next, I discussed how loss of protective sensation in the feet affects the development of DFUs. I asked a volunteer to participate in the demonstration of how to

perform a Semmes Weinstein Monofilament (10 Gm, 5.07) test. I gave each participant the monofilament so they could perform their own Semmes Weinstein test. I followed the instructions on the Protective Sensation page of the Participant Package, and discussed and demonstrated how to assess for protective sensation. I circulated and assisted the participants with the assessment. I instructed the participants to document their findings on the Protective Sensation page of the Participant Package. Before the class dismissed, I gave the participants a blank copy of the Diabetic Foot Care Log.

WEEK 4

The diabetic foot risk assessment and performing diabetic foot care were the topics for the last class. I asked the participants remove their shoes and socks and pair with another participant in order to perform the diabetic foot assessment on each other. The Participant Package was used to guide the instruction and demonstration of the diabetic foot risk assessment. I then instructed the participants to perform diabetic foot care on their own feet. I circulated among the participants to check techniques and to validate appropriate diabetic foot care behaviors.

DATA ANALYSES

Preliminary Analyses

Prior to analysis, the data were entered into International Business Machines Statistical Package for the Social Sciences (SPSS) Version 26 on the investigator's computer. The data entered into SPSS 25 was compared visually to the data on the hard copies of the Demographic Data Form, SFSQ, SDSCA, and Inlow's to examine the accuracy of data variables and assessing for violations in logic (B. Bannon, personal communication, July 4, 2019). Descriptive statistics were calculated to assess for errors in data entry, outliers, and missing data by comparing the frequencies, and minimum and

maximum scores for each variable on the output data with the values in the SPSS codebook. All errors were corrected before any analyses were performed.

Demographic Data

Descriptive statistics were used to describe the characteristics of the sample of adults with DM experiencing homelessness who participated in the current study. Measures of central tendency including mean, median, mode, standard deviations, range, percentile rank, and interquartile range were obtained to examine the sample's characteristics and variability. An examination of the sample's homogeneity utilized descriptive statistics and histograms.

Specific Aim 1

Increase the participant's knowledge and ability to recognize their individual risk factors for developing diabetic foot ulcer (DFU) and amputation.

RESEARCH QUESTION 1.1

What is the difference between pretest and posttest scores on the Self-Administered Foot Risk Screening Questionnaire (SFSQ) among the sample of adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care education? To examine this research question a *paired t-test* with a predetermined alpha of .05 was performed. A *paired t-test* is a parametric test for comparing two means for correlated samples. Therefore, with a *paired t-test* changes between pretest and posttest SFSQ scores are compared within the subject (Portney & Watkins, 2009).

RESEARCH QUESTION 1.2

What is the risk category for diabetic foot ulcers for adults with DM experiencing homelessness who participated in the RN-led diabetic foot self-care education, measured by the Inlow's 60-Second Foot Screen tool? To examine this research question, non-

parametric statistics were used because the variable has an ordinal level of measurement. The Wilcoxin's was used to examine the pairs of risk categories between Week 1(T1) versus Week 2 (T2), Week 2 (T2) versus Week 3 (T3), Week 3 (T3) versus Week 4 (T4), and Week 1(T1) versus Week 4 (T4) (Portney & Watkins, 2009).

Specific Aim 2

Decrease the participant's risk for diabetic foot ulcer and increase the participant's knowledge of diabetic foot self-care behaviors.

RESEARCH QUESTION 2.1

What are the effects of RN-led diabetic foot care education on diabetic foot self-care behaviors measured as scores on the foot care subscale items on the Summary of Diabetes Self-Care Activities (SDSCA) among adults with DM experiencing homelessness? To examine this research question a RM ANOVA with a predetermined alpha 0.05 was used. A RM ANOVA examined for changes in the mean SDSCA scores for each of five diabetic foot self-care behaviors for Week 1 (T1) and Week 2 (T2), Week 2 (T2) and Week 3 (T3), and Week 3 (T3) and Week 4 (T4), and between Week 1 (T1) and Week 4 (W4).

RESEARCH QUESTION 2.2

What are the effects of RN-led diabetic foot care education on diabetic foot assessments measured by Inlow's 60-Second Diabetic Foot Screen Tool among adults with DM experiencing homelessness? To examine this research question a RM ANOVA with a predetermined alpha 0.05 was used. A RM ANOVA examined for changes in the mean Inlow's scores between Week 1 (T1) and Week 2 (T2), Week 2 (T2) and Week 3 (T3), and Week 3 (T3) and Week 4 (T4), and between Week 1 (T1) and Week 4 (W4).

HUMAN SUBJECTS REVIEW

Before the study was initiated, permission to conduct the research was obtained from the University of Texas at Medical Branch, Institutional Review Board (UTMB IRB study #17-0180). Prior to obtaining informed consent, I explained the study protocol in a way the participant could understand using lay terminology (Appendix S). I read the consent form to the participants as necessary to enhance his/her understanding of the study procedures. Furthermore, when the procedures were amended regarding recruitment procedures, recruiting at community-based clinics, and reducing the amount of the incentive, these changes were also included in the informed consent document (Appendix T). I informed the potential participants that the lay case managers at the shelters may know of his/her participation in the study because the lay case managers wanted to record his/her participation in the diabetic foot self-care education on the participant's plan of care. Additionally, if the results of any diabetic foot assessments revealed open sores on the feet, signs of podiatric infection, bleeding or any finding that in this investigator's opinion required medical treatment, I would notify the participant's physician, lay case manager, and/or a healthcare provider at the clinic.

The risks for choosing to participate in the study were explained to the potential participants. The study posed a potential risk for emotional harm related to the participant's embarrassment regarding foot odor, and/or the condition of his/her socks and shoes. The investigator minimized the participant's risk of embarrassment by providing wipes to cleanse his/her feet and surgical shoe covers to minimize the amount of time his/her feet were exposed. Participation in the study posed minimal risk for physical harm because the intervention was educational and no invasive procedures were performed during data collection. I exerted every effort to prevent any risk of physical harm from occurring.

Prior to the start of participation in the study, the privacy and confidentiality risks were fully disclosed to the participants. I assured each participant that no information

collected prior, during, or following the study would be shared with any person living in the homeless shelter. Confidentiality was assured by assigning a code to each participant as well as removing any identifying information from the instruments that were used for data analysis. The signed consent forms were stored in a separate, secured location from all other study related materials. Data was stored on the investigator's password protected desktop computer as well a password protected external hard drive. The external hard drive was stored in a locked cabinet within the personal home office of the researcher. At the conclusion of the study and the final data analyses the data was destroyed.

The potential participant was assured that consent was voluntary and that he/she could withdraw from the study at any time without repercussions. The potential participant was encouraged to ask questions about any area of the informed consent that was not clear and I answered questions at that time. As long as the potential participant met the inclusion criteria for the study and agreed to participate in the study protocol, the participant was asked to sign the consent form. After providing informed consent, the participant could contact me by cell phone or email if questions arose.

SUMMARY

There is a limited amount of studies that included adults with DM experiencing homelessness in a diabetic self-management and support educational intervention (Savage et al., 2014; Sage et al., 2016). Furthermore, diabetic foot self-care educational studies that focused on DFU and/or amputation risk identification and reduction among adults with DM experiencing homelessness were lacking. Therefore, a quasi-experimental single group repeated measures design was implemented. The diabetic foot self-care educational intervention focused on DFU and/or amputation risk identification and reduction by teaching diabetic foot self-care behaviors (RNAO, 2004).

The potential participants were recruited from homeless shelters, transitional housing units, and other safe havens in East Texas. Lay case managers at the shelters

assisted with recruitment and identified potential participants for the study. A total of 30 participants enrolled into the study and 20 participants completed all four-weeks of the intervention. Participants left the study for two reasons that included a move to permanent housing or he/she was asked to leave the shelter.

Chapter 4 Results

INTRODUCTION

Chapter four presents the results of the data analyses of the current study, which examined the effects of diabetic foot self-care education on subjective DFU or amputation risk, diabetic foot self-care behaviors, and clinical diabetic foot assessment scores and clinical DFU or amputation risk categories among a sample of adults with DM experiencing homelessness. The specific aims of the study were to, (a) increase the subject's knowledge and ability to recognize their individual risk factors for developing DFU or amputation, and, (b) decrease the subject's risk for DFU and increase the subject's knowledge of diabetic foot self-care behaviors. Chapter four is organized by an examination of the sample's characteristics and an examination of the results for each of the research questions to meet the Specific Aims 1 and 2.

SAMPLE CHARACTERISTICS

The convenience sample consisted of (N = 30) individuals who met the inclusion criteria and provided informed consent (Table 4.1). The average age of the subjects was 53.47 years. The average length of time homelessness was 2.17 years. The subjects were primarily (66.7%) female. The majority were single (33.3%), had not served in the military (90%), and were Caucasian not Hispanic (96.7%). A small percentage (20%) of the sample had not finished high school, however, the majority (80%) of the sample had completed high school or the equivalency, or had some technical training, and/or higher education. The majority (43.3%) were unemployed, and (56.7%) uninsured. When compared to the samples in studies of adults with DM experiencing homelessness residing in homeless shelters, Hwang and Bugeja's (2000) and Arnaud et al.'s. (2009) samples were primarily male, (82%) and (80%) respectively, whereas, the sample in the current study was primarily female (66.7%) and males (33.3%).

Table 4.1: Sample Characteristics

Characteristic	*n*	%
Gender		
Male	10	33.3
Female	20	66.7
Marital status		
Married	3	10.0
Single	10	33.3
Widowed	3	10.0
Divorced	7	23.3
Separated	7	23.3
Military service		
No	27	90.0
Yes	3	10.0
Hispanic		
No	29	96.7
Yes	1	3.3
Level of education finished		
Less than high school	6	20.0
Graduated HS/GED	9	30.0
Trade/Technical school	1	3.3
Some college no degree	9	30.0
Associate's degree	3	10.0
Bachelor's degree	1	3.3
Master's or doctorate degree	1	3.3
Employment status		
Full-time	1	3.3
Part-time	2	6.7
Retired	2	6.70
Student	1	3.30
Unemployed	13	43.3
Disabled		10.0
Other	1	3.30
Health insurance		
No insurance	17	56.7
Medicaid	8	26.7
Medicare	5	16.7
Mean age	53.47	
Mean years homeless	2.17	

Note. $N = 30$.

DIABETIC HISTORY

The sample's ($N = 30$) diabetic history was obtained and is presented in (Table 4.2). The majority (83.3%) had a T2D diagnosis and eight subjects (26.7%) had DM for one to

five years, while (20%) reported having DM for over 20 years. Most of the subjects (53.3%) were prescribed oral anti-hyperglycemic medications while 23.3% were prescribed both oral medication and insulin. Nearly all (93.3%) of the subjects had not received diabetic foot care education during the last year and 86.7% had not received a diabetic foot examination in the past year.

Table 4.2: Sample Diabetic History

Diabetic history	*n*	%
Type DM		
T1D	2	6.7
T2D	25	83.3
Don't know	3	10.0
Length of time with DM (years)		
1–5	8	26.7
5–10	6	20.0
10–15	5	16.7
15–20	4	13.3
>20	6	20.0
Don't know	1	3.3
Type of medication		
None	3	10.0
Insulin	4	13.3
Pills	16	53.3
Insulin and pills	7	23.3
Diabetic foot care education past year		
No	28	93.3
Yes	2	6.7
Diabetic foot assessment past year	26	
No	4	86.7
Yes		13.3

Note. $N = 30$.

SAMPLE ATTRITION AND RETENTION

Ten subjects withdrew their participation in the study. Subjects withdrew their participation for two reasons; either he/she left the shelter and moved to permanent housing and were no longer experiencing homelessness, or he/she was dismissed from the shelter and lost to follow-up. The sample size at baseline was 30 subjects, at Week 2 25 subjects

remained, at Week 3 22 subjects remained, and at Week 4 20 subjects remained. The rate of attrition was 33.3%, while the rate of retention was 66.7%. The retention rate in the current study was much higher than in Sage et al's. (2016) study that reported a 33% rate of retention.

The descriptive statistics of the demographic data and diabetic history were examined for the 20 subjects who completed the four-week study. The sample was statistically similar when compared to the 30 subjects at baseline. Sixty-five percent were female, with an average age of 53 years. A small percentage (20%) of the sample had not finished high school, however, the majority (80%) of the sample had completed high school or the equivalency, or had some technical training, and/or higher education. The majority were unemployed (60%) and uninsured (65%). Type 2 DM was predominant (80%), and (55%) were prescribed oral anti-hyperglycemic medication. One hundred percent of the subjects had not had diabetic foot education in the past year and 90% had not had a diabetic foot examination in the past year.

RESULTS OF THE RESEARCH QUESTIONS FOR THE SPECIFIC AIMS

Specific Aim 1

The first specific aim was to increase the subject's knowledge and ability to recognize his/her individual risk factors for developing DFU and amputation. Two research questions were posited to meet Specific Aim 1.

RESEARCH QUESTION 1.1

What is the difference between pretest and posttest scores on the SFSQ among the sample of adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care education? A *paired t-test* was planned to analyze the interval level data for the 20 subjects who completed the pretest and posttest SFSQ. The difference between pretest and posttest scores were calculated using SPSS 26. The difference scores were tested for

normality using the Shapiro-Wilk test. When the result of the Shapiro-Wilk test is $p > .05$ normality can be assumed and if the result is $p < .05$ normality cannot be assumed. The Shapiro-Wilk test result was $p = .003$ and normality could not be assumed. Therefore, the non-parametric Sign test for related samples was used. There was no statistically significant difference ($p = .58$) between the SFSQ pretest and posttest scores for the 20 subjects. The null findings of the Sign test were anticipated because the DFU risk factors, including loss of protective sensation, foot deformity, and previous DFU and previous amputation measured by the SFSQ are unlikely to change.

The validity of the SFSQ as a screening tool, was examined by calculating the sensitivity, specificity, and positive and negative predictive values utilizing the pretest subjective SFSQ DFU or amputation risk categories, and the clinical Inlow's DFU or amputation risk categories obtained at week 1, guided by Valente et al.'s, (2004) approach for validation of the SFSQ. The subjective data was obtained from SFSQ pretest risk categories, and the clinical data was obtained from the Inlow's Week 1 risk categories for 29 subjects.

The sensitivity indicates a test's ability to obtain a true positive value when the condition is really present (Portney and Watkins, 2009). The sensitivity of the SFSQ was 86%; the proportion of subjects with foot risk among all subjects with clinical signs of foot risk. Therefore, the SFSQ was an appropriate screening tool to rule in foot risk among those who have foot risk factors. According to (Portney and Watkins), "the sensitivity of a test increases as the number of persons with the condition who are correctly classified increases, that is, fewer persons with the disorder are missed" (p. 620).

The specificity indicates the ability of the test to obtain a true negative result when the condition is really absent. The specificity of the SFSQ was 69%; the proportion of subjects without foot risk among those who did not have clinical signs of foot risk. Therefore, the SFSQ was an appropriate screening tool to rule out foot risk.

In order to determine the practicality of a screening tool, the tool should produce a sufficient number of accurate responses to be clinically useful as indicated by the test's predictive value (Portney and Watkins, 2009). "The positive predictive value estimates the likelihood of a person who tests positive actually has the condition" (p, 622). The positive predictive value of the SFSQ was 73%. Therefore, the SFSQ predicted DFU and amputation foot risk in 73% of the subjects who truly had foot risk. The negative predictive value indicates the likelihood that a person who tests negative for a condition, truly does not have the condition (Portney and Watkins, 2009). The negative predictive value of the SFSQ was 83%. Therefore, the SFSQ predicted DFU and amputation foot risk in 83% of the subjects who truly did not have any foot risk.

RESEARCH QUESTION 1.2

What is the risk category for diabetic foot ulcers for adults with DM experiencing homelessness who participated in the RN-led diabetic foot self-care education, as measured by the Inlow's 60-Second Foot Screen tool? To examine this research question, the non-parametric Sign test for related samples was used, because the variable has an ordinal level of measurement. The Sign test examined the median scores for the pairs of risk categories between Week 1(T1) versus Week 2 (T2), Week 2 (T2) versus Week 3 (T3), Week 3 (T3) versus Week 4 (T4), and Week 1(T1) versus Week 4 (T4) for the 20 subjects (Portney & Watkins, 2009). There was no difference in the subjects' median scores of risk category between Week 1(T1) versus Week 2 (T2), Week 2 (T2) versus Week 3 (T3), Week 3 (T3) versus Week 4 (T4), or Week 1(T1) versus Week 4 (T4) (Table 4.3).

Table 4.3: Sign Test for Related-Samples of Inlow's Risk Categories

Null hypothesis	Test	Sig.	Decision
The median of differences between RISKCATW1 and RISKCATW2 equals 0.	Related-samples Sign	1.000	Retain the null hypothesis.
The median of differences between RISKCATW2 and RISKCATW3 equals 0.	Related-samples Sign	1.000	Retain the null hypothesis.

Null hypothesis	Test	Sig.	Decision
The median of differences between RISKCATW3 and RISKCATW4 equals 0.	Related-samples Sign	1.000	Retain the null hypothesis.
The median of differences between RISKCATW1 and RISKCATW4 equals 0.	Related-samples Sign	1.000	Retain the null hypothesis.

Specific Aim 2

The second specific aim of the study was to decrease the subject's risk for DFU and increase the subject's knowledge of diabetic foot self-care behaviors. Two research questions were posited to meet Specific Aim 2. The findings of the research questions are presented next.

RESEARCH QUESTION 2.1

What are the effects of RN-led diabetic foot care education on diabetic foot self-care behaviors measured as scores on the foot care subscale items on the Summary of Diabetes Self-Care Activities (SDSCA) among adults with DM experiencing homelessness? To examine this research question a one-way RM ANOVA with a predetermined alpha of 0.05 was used for the with-in subjects design. Only the data for the 20 subjects were used because the one-way RM ANOVA examines the mean scores for the same participants. The one-way RM ANOVA examined for changes in the mean SDSCA scores for each of five diabetic foot self-care behaviors for Week 1 (T1), Week 2 (T2), Week 3 (T3), and Week 4 (T4), for the 20 subjects who completed all four weeks of the intervention. All SDSCA data was collected before any diabetic foot self-care education was presented for the study visit. The results of the one-way RM ANOVAs are presented for each of the five diabetic foot self-care behaviors.

SDSCA Behavior One: Check Feet

A one-way RM ANOVA was performed to determine if there was a statistically significant difference in SDSCA behavior one, check feet, mean scores over the four-week diabetic foot self-care educational intervention. The assumption of sphericity was not met as assessed by Mauchly's test of sphericity χ^2 (12.299) = df 5, p = .031. The Epsilon (ε) was (p = .667) according to the Greenhouse-Geisser test, which adjusts for the value of the level of significance and for violations of sphericity. The Greenhouse-Geisser test of within-subjects effects are displayed in Table 4.4. There was a statistically significant difference in SDSCA behavior one, check feet, among the 20 subjects during the four-week intervention, F (2.001, 38.015) = 5.942, p = .006, partial η^2 = .238. The check feet behavior increased from Week 1 (T1) (M = 4.35, SD = 2.925) to Week 2 (M = 6.05, SD = 1.504) to Week 3 (M = 6.25, SD = 1.293) to Week 4 (M = 6.45, SD = 1.91).

Table 4.4: One-way RM ANOVA for SDSCA Behavior 1 Check Feet

Source		Type III sum of squares	*df*	Mean square	*F*	Sig.	Partial eta squared
SDSCA 1 Check feet	Sphericity assumed	55.750	3.000	18.583	5.942	.001	.238
	Greenhouse-Geisser	55.750	2.001	27.864	5.942	.006	.238
Error (SDSCA1)	Sphericity assumed	178.250	57.000	31.27			
	Greenhouse-Geisser	178.250	38.015	4.689			

The data from the RM ANOVA was then examined by the Bonferroni post hoc analysis. The Bonferroni post hoc analyses is the test of choice to determine when changes in mean scores occurred (Portney and Watkins, 2009). The Bonferroni post hoc analyses compares one week of data to all of the other weeks of data. For example, Week 1 data was compared to the data obtained at Weeks 2, 3, and 4. Conversely, Week 2 data was compared

to the data obtained at Weeks 1, 3, and 4. Week 3 data was compared to the data obtained at Weeks 1, 2, and 4 and Week 4 data was compared to the data obtained at Weeks 1, 2, and 3. The Bonferroni post hoc pairwise analyses demonstrated a statistically significant difference (p = .029) between Weeks 1 and 2 and Weeks 2 and 1 (p = .029) for the mean scores of SDSCA behavior one, check feet. No other statistically significance differences were noted from the Bonferroni post hoc analyses. The diabetic foot self-care educational intervention was effective in increasing the number of times the subjects checked their feet. At baseline, the subjects checked their feet an average of four times per week. Whereas at Weeks 2, 3, and 4, the subjects checked their feet an average of six times per week.

SDSCA Behavior Two: Look in Shoes

A one-way RM ANOVA was performed to determine if there was a statistically significant difference in SDSCA behavior two, look in shoes, mean scores over the four-week diabetic foot self-care educational intervention. The assumption of sphericity was met as assessed by Mauchly's test of sphericity χ^2 (6.642) = df 5.0, p = .249. The Greenhouse-Geisser tests of within-subjects effects with sphericity assumed are displayed in (Table 4.5). There was a statistically significant difference in SDSCA behavior two, look in shoes, among the 20 subjects during the four-week intervention, F (2.473, 46.985) = 15.560, p = .000, partial η^2 = .450. The look in shoes behavior increased from Week 1 (M = 2.20, SD = 2.353) to Week 2 (M = 4.55, SD = 2.892) to Week 3 (M = 5.35, SD = 2.455) to Week 4 (M = 5.65, SD = 2.601).

Table 4.5: One-Way RM ANOVA for SDSCA Behavior 2 Look in Shoes

Source		Type III sum of squares	*df*	Mean square	*F*	Sig.	Partial eta squared
SDSCA 2 Look in shoes	Sphericity assumed	146.438	3.000	48.813	15.560	.000	.450
	Greenhouse-	146.438	2.473	59.217	15.560	.000	.450

Source		Type III sum of squares	*df*	Mean square	*F*	Sig.	Partial eta squared
	Geisser						
Error (SDSCA2)	Sphericity assumed	178.813	57.000	3.137			
	Greenhouse-Geisser	178.813	54.559	3.806			

A Bonferroni post hoc analysis was performed and demonstrated statistically significant differences between Week 1 and Week 2 (p = .005), Week 1 and Week 3 (p = .001) and Week 1 and Week 4 (p = .000) mean scores of SDSCA behavior two, look in shoes. At baseline, the subjects looked in their shoes an average of two times per week. Whereas at Week 2, the subjects looked in their shoes an average of four times, and in Weeks 3 and 4 the subjects looked in their shoes an average of five times per week. The diabetic foot self-care educational intervention was effective to increase the number of times the subjects looked in their shoes.

SDSCA Behavior Three: Wash Feet

A one-way RM ANOVA was performed to determine if there was a statistically significant difference in SDSCA behavior three, wash feet, mean scores over the four-week diabetic foot self-care educational intervention. The assumption of sphericity was not met as assessed by Mauchly's test of sphericity χ^2 (31.318) = df 5.0, p = .000. The Epsilon (ε) was p = .501 according to the Greenhouse-Geisser test, which adjusts for the value of the level of significance and for violations of sphericity. The Greenhouse-Geisser test of within-subjects effects are displayed in (Table 4.6). There was no statistically significant difference in SDSCA behavior three, wash feet, among the 20 subjects during the four-week intervention, F (1.502, 28.538) = .920, p = .437, partial η^2 = .238. The wash feet behavior remained consistent from Week 1 (T1) (M = 6.00, SD = 1.777) to Week 2 (M = 6.00, SD = 1.747) to Week 3 (M = 6.20, SD = 1.152) to Week 4 (M = 6.45, SD = .945). The

diabetic foot self-care education intervention had no effect on the amount of times per week the subjects washed their feet. The subjects washed their feet an average of six times per week.

Table 4.6: One-way RM ANOVA SDSCA Behavior Three: Wash Feet

Source		Type III sum of squares	*df*	Mean square	*F*	Sig.	Partial eta squared
SDSCA 3 Wash feet	Sphericity assumed	2.737	3.000	0.912	.920	.437	.046
	Greenhouse-Geisser	2.737	1.502	1.823	.920	.384	.046
Error (SDSCA3)	Sphericity assumed	56.512	57.000	0.991			
	Greenhouse-Geisser	56.512	28.538	1.980			

SDSCA Behavior Four: Soak Feet

A one-way RM ANOVA was performed to determine if there was a statistically significant difference in SDSCA behavior four, soak feet, mean scores over the four-week diabetic foot self-care educational intervention. The assumption of sphericity was met as assessed by Mauchly's test of sphericity χ^2 (2.861) = df 5.0, p = .772. The difference barely reached significance for SDSCA behavior four, soak feet, among the 20 subjects during the four-week intervention, F (2.696, 51.216) = 3.013, p = .043, partial η^2 = .137. The check feet behavior increased from Week 1 (T1) (M = .06, SD = 1.569) to Week 2 (M = 1.15, SD = 2.254) to Week 3 (M = 1.70, SD = 2.736) to Week 4 (M = 2.25, SD = 2.989). The diabetic foot self-care intervention had a small effect on behavior four, soak feet. Current ADA (2016) guidelines recommend applying diabetic foot lotion to the feet instead of soaking the feet for hydration.

SDSCA Behavior Five: Dry Between the Toes

A one-way RM ANOVA was performed to determine if there was a statistically significant difference in SDSCA behavior five, dry between the toes, mean scores over the four-week diabetic foot self-care educational intervention. The assumption of sphericity was not met as assessed by Mauchly's test of sphericity χ^2 (20.292) = df 5.0, p = .001. The Epsilon (ε) was p = .613 according to the Greenhouse-Geisser test, which adjusts for the value of the level of significance and for violations of sphericity There was no statistically significant difference in SDSCA behavior five, dry between the toes, among the 20 subjects during the four-week intervention, F (1.838, 34.926) = 1.633, p = .211, partial η^2 = .079. The dry between the toes behavior was consistent throughout the four-week study intervention. There was very little change from Week 1 (T1) (M = 5.25, SD = 2.807) to Week 2 (M = 5.75, SD = 2.197) to Week 3 (M = 5.75, SD = 1.888) to Week 4 (M = 6.15, SD = 1.694). The diabetic foot self-care education intervention had no effect on the mean scores for drying between the toes.

RESEARCH QUESTION 2.2

What are the effects of RN-led diabetic foot care education on diabetic foot assessments measured by Inlow's 60-Second Diabetic Foot Screen Tool among adults with DM experiencing homelessness? First, the descriptive statistics are presented for the Inlow's parameters assessing the skin, nails, deformity, and footwear are presented. The findings are presented for the (n=20) participants that completed the four week intervention and displayed in (Table 4.7).

Table 4.7: Inlow's Descriptive Statistics

Parameter	*n*	%
Skin		
Intact and healthy	3	15
Dry with fungus or light callus	14	70
Heavy callus	2	10

Parameter	*n*	%
Open ulcer or previous ulcer	0	0
Nails		
Well kept	11	55
Unkempt/ragged	6	30
Thick, damaged, or infected	3	15
Deformity		
None	9	45
Mild	7	35
Major	4	20
Footwear		
Appropriate	17	75
Inappropriate	3	25

The findings for the skin on the feet ranged from 0 indicating intact and healthy skin (*n* = 3, 15%), to 1 for dry skin with fungus or light callus (*n* = 14, 70%), to heavy callus build up (*n* = 2, 10%), to skin with current or previous ulcer (n = 1, 5%). No participants had an open DFU during his/her participation in the study. The majority of participants had well-kept toe nails (*n* = 11, 55%), while others had toe nails that were unkempt or ragged (*n* = 6, 30%), and a small percentage had nails that were thick, damaged, and/or infected (*n* = 3, 15%). Bony deformities of the foot was assessed as no deformity (*n* = 9, 45%), to mild deformity including bunions (*n* = 7, 35%) to major deformity including amputation (*n* = 4, 20%). The participant's footwear was assessed as appropriate (75%), inappropriate such as opened toed shoes (25%), and footwear causing trauma (0%).To examine this research question a one-way RM ANOVA with a predetermined alpha 0.05 was used. A RM ANOVA examined for changes in the mean Inlow's total assessment scores for the left and right foot between Week 1 (T1), Week 2 (T2), Week 3 (T3),) and Week 4 (T4). The findings for the left and right feet are presented individually.

Inlow's Total Score: Left Foot

A one-way RM ANOVA was conducted to determine if there was a statistically significant difference in the total Inlow's assessment scores for the left foot over the course of the four-week diabetic foot self-care educational intervention among the 20 subjects. Sphericity was assumed as assessed by Mauchly's test of sphericity χ^2 = (3.789), df = 5, *p* = .581. The results of the within-subjects effects are displayed in (Table 4.8).

Table 4.8: One-way RM ANOVA Inlow's Total Scores Left Foot Multivariate Tests[a]

Source		Value	*F*	Hypothesis *df*	Error *df*	Sig.	Partial eta squared
Inlow's total score left foot	Pillai's trace	.183	1.268[b]	3.000	17.000	.317	.183
	Wilk's lambda	.817	1.268[b]	3.000	17.000	.317	.183
	Hotelling's trace	.224	1.268[b]	3.000	17.000	.317	.183
	Roy's largest root	.224	1.268[b]	3.000	17.000	.317	.183

a. Within subjects design: INLOWTOTLF
b. Exact Statistic

There was no statistically significant difference in the Inlow's totals assessment scores for the left foot, among the 20 subjects during the four-week intervention, F (3.000, 17.000) = 1.268, *p* = .317, partial η^2 = .183. The total Inlow's scores were consistent throughout the four-week study intervention. There was very little change from Week 1 (T1) (*M* = 7.70, *SD* = 3.481) to Week 2 (*M* = 6.80, *SD* = 4.200) to Week 3 (*M* = 7.50, *S*D = 4.968) to Week 4 (*M* = 7.10, *SD* = 4.217). The diabetic foot self-care education intervention had no effect on the mean scores for Inlow's total assessment scores during the four-week intervention among the 20 subjects.

Inlow's Total Score: Right Foot

A one-way RM ANOVA was conducted to determine if there was a statistically significant difference in the total Inlow's assessment scores for the right foot over the course of the four-week diabetic foot self-care educational intervention among the 20 subjects. Sphericity was assumed as assessed by Mauchly's test of sphericity $\chi^2 = (2.003)$, df = 5, $p = .845$. The results of the within-subjects effects are displayed in (Table 4.9).

Table 4.9: One-way RM ANOVA Inlow's Total Scores Right Foot Multivariate Tests[a]

Source		Value	*F*	Hypothesis *df*	Error *df*	Sig.	Partial eta squared
Inlow's total score right foot	Pillai's trace	.114	.732[b]	3.000	17.000	.547	.114
	Wilk's lambda	.868	.732[b]	3.000	17.000	.547	.114
	Hotelling's trace						
	Roy's largest root	.129	.732[b]	3.000	17.000	.547	.114

a. Within subjects design: INLOWTOTRF
b. Exact Statistic

There was no statistically significant difference in the Inlow's total assessment scores for the right foot, among the subjects during the four-week intervention, F (3.000, 17.000) = .732, $p = .547$, partial $\eta^2 = .114$. The total Inlow's scores were consistent throughout the four-week study intervention. There was very little change from Week 1 (T1) ($M = 7.95$, $SD = 4.501$) to Week 2 ($M = 7.25$, $SD = 4.471$) to Week 3 ($M = 7.60$, $SD = 4.695$) to Week 4 ($M = 7.35$, $SD = 4.671$). The diabetic foot self-care education intervention had no effect on the mean scores for Inlow's total assessment scores during the four-week intervention among the 20 subjects.

SUMMARY

The purpose of the study was to examine the effects of an RN-led diabetic foot self-care educational intervention on the subject's subjective DFU risk assessment, diabetic self-care behaviors, and clinical diabetic foot assessment. No statistically significant

difference was found between pretest and posttest SFSQ scores. It is thought that the subjects in the current study made accurate self-assessments of his/her DFU or amputation risks. The intervention was effective for increasing the two diabetic foot self-care behaviors of check feet and look in shoes. Both of these daily diabetic foot self-care behaviors are extremely important in order to self-assess and/or prevent risk for foot injury. The intervention did not significantly change the mean scores for washing, soaking, or drying between the toes in the current sample. It was thought that because the subjects were staying in homeless shelters access to showering was readily available. However, not every subject showered every day, or washed their feet and/or dried between their toes daily. The intervention did not have any effect upon the diabetic foot assessments or DFU risk categories in this sample. The finding may represent the stability of the examiner, as diabetic foot assessment scores would reflect a clinical change in the subject's assessment. Furthermore, it was an expected outcome that DFU risk categories remained unchanged because the presence of neuropathy, peripheral arterial disease, previous ulcer and/or amputation were unlikely to change at all.

Chapter five will present the results of the study in relation to previous works. The limitations to the study findings will also be presented. The implications for nursing practice will be discussed. Recommendations for future research and conclusions from the study will also be presented.

Chapter 5 Discussion, Recommendations, and Conclusion

INTRODUCTION

Chapter five presents a summary of the study including the purpose, aims, research questions, an overview of the methodology and the major findings. The findings are further discussed in relation to previous research that guided the study. The relevance of the theoretical framework that also guided the study are presented. The implications for nursing practice and recommendations for future research are presented. The chapter ends with closing remarks in the conclusion.

SUMMARY OF THE STUDY

Due to the paucity of research enrolling adults with DM experiencing homelessness into diabetic foot self-care educational interventions that focused of DFU and/or amputation risk identification and reduction the study was timely and urgently needed. The current study implemented RN-led diabetic foot self-care educational intervention over a period of four-weeks. In order to assess the efficacy of the intervention, the dependent variables consisted of subjective assessment for DFU or amputation risk factors, diabetic foot care behaviors, and clinical diabetic foot assessments.

PURPOSE STATEMENT, AIMS AND RESEARCH QUESTIONS

The purpose of the study was to examine the effects of an RN-led diabetic foot self-care education intervention on the participant's subjective DFU risk assessment, diabetic foot self-care behaviors, and clinical diabetic foot assessment with the DFU risk categorized.

Aim 1

Increase the participant's knowledge and ability to recognize their individual risk for developing DFU and/or amputation.

Research Question 1.1: What is the difference between pretest and posttest scores on the SFSQ among the sample of adults with DM experiencing homelessness who were exposed to the RN-led diabetic foot self-care educational intervention?

Research question 1.2: What is the risk category for DFU and/or amputation as measured by Inlow's 60-Second Foot Screening Tool among the sample of adults with DM experiencing homelessness exposed to the RN-led diabetic foot self-care educational intervention?

Aim 2

Decrease the participants risk for DFU and increase the participant's knowledge of diabetic foot self-care behaviors

Research Question 2.1: What are the effects of RN-led diabetic foot self-care education on diabetic foot self-care behaviors as measured by the SDSCA subscale of diabetic foot self-care behaviors?

Research Question 2.2: What are the effects of RN-led diabetic foot self-care education on diabetic foot assessments as measured by Inlow's 60-Second Diabetic Foot Screening Tool among the sample of adults with DM experiencing homelessness?

Review of the Methodology

A quasi-experimental approach using a single group repeated measure design was used to address the research questions. A convenience sample of 30 adults with DM experiencing homelessness were enrolled into the study. However, 20 participants completed the four-week study. Five homeless shelters in East Texas provided the setting for the study.

The *Diabetes Foot: Risk Assessment Education Program* (RNAO, 2004) was chosen as the educational intervention for the study. The core components of the curriculum focused on DFU and/or amputation risk reduction and identification while teaching diabetic foot self-care behaviors to reduce diabetic foot risks. The intervention was also consistent with the purpose and aims of the study.

In addition to obtaining the participant's demographic information and diabetic history, three instruments were used to measure the dependent variables of the study the; SFSQ, SDSCA, and the Inlow's. The SFSQ measured the participant's subjective risk factors for DFU or amputation and was collected at the pretest and posttest data collection points. Diabetic foot self-care behaviors were assessed by the SDSCA foot self-care subscale items. The SDSCA was collected at each of the four data collection points of the protocol in order to assess for changes in the participant's diabetic foot self-care behaviors. The Inlow's was used for the diabetic foot assessments and categorization of DFU risk. The diabetic foot assessments were performed at each of the four data collection points of the protocol, in order to assess for any clinical changes of the participant's feet or DFU risk category.

DISCUSSION

The participants in the current study were predominantly female, unemployed, and uninsured. The participants in the current study were unique regarding gender as previous studies enrolling adults with DM experiencing homelessness were predominantly male (Arnaud et al., 2009; Hwang and Bugeja, 2000). The majority of the participants had T2D, however, in the past year, had not received diabetic foot self-care education nor had they received a diabetic foot assessment. The ADA recommends that any person diagnosed with DM need to receive DSMES at the time the disease is diagnosed. DSMES includes diabetic foot self-care education. According to the ADA's (2019) standards of care, a diabetic foot assessment should be performed by a healthcare provider at least annually. Abu-Qamar

(2006) found that healthcare providers do not perform diabetic foot assessments consistently, and is supported by the lack of an annual diabetic foot assessment among the study participants.

The findings of the study indicated that the adults with DM experiencing homelessness in the current study, accurately identified their foot risks for DFU or amputation on the SFSQ. The SFSQ provided a self-assessment for LOPS, foot deformity, and for a history of DFU and/or lower extremity amputation. The mean SFSQ pretest scores were 12.25 and posttest scores 12.50. No statistically significant difference ($p = .58$) was found between the pretest and posttest SFSQ scores. The intervention did not Increase the participant's knowledge and ability to recognize their individual risk for developing DFU or amputation. The participants in the current study had a very good understanding of their individual risk factors for DFU or amputation. The findings cannot however be generalized to all adults with DM experiencing homelessness. No studies were located which measured the participant's subjective DFU or amputation risk factors in a sample of adults with DM experiencing homelessness.

The findings from the Inlow's assessments examining the skin, nails, and deformities of the feet, and footwear revealed the participant's podiatric health and podiatric risks for DFU or amputation. The majority (70% of the sample) had dry skin with fungus or light callus, while (90%) had LOPS. Stratigos et al.'s (1999) study of adults experiencing homelessness and residing in a shelter reported (38%) with fungus but did not report the occurrences of callus. The findings of the current study, showed a much higher percentage of participants with dry skin with fungus or light callus. Participants with LOPS is important to note although no studies were located which assessed LOPS in a similar sample. Twenty-five percent of the sample exhibited Charcot changes, as evidenced by high scores in the Inlow's parameters of deformity and sensation. Charcot changes reflect severe diabetic foot pathologies in the nerves and boney structures of the foot. No

studies were located for comparison. The findings from the current study add important information about the podiatric health and podiatric health risks for DFU or amputation.

The study findings which assessed the DFU and/or amputation risk category was assessed from the Inlow's diabetic foot assessment categories measuring LOPS, foot deformity, and previous DFU and/or amputation. The findings of the Inlow's DFU and/or amputation risk categories varied from zero (10% of the sample) with no LOPS, to one (70% of the sample) with LOPS, to two (5% of the sample) with LOPS and deformity, to three (15% of the sample) with previous DFU and/or amputation. No statistically significant difference was found for the participant's DFU and/or amputation risk category (p = 1.00) for the four data collection points. Although no studies were located that specifically categorized the DFU and/or amputation risks, Arnaud et al.'s, (2009) study of adults with DM experiencing homelessness and staying in shelters (n = 35); found major diabetic foot complications including (42%) with LOPS and (17%) with a previous toe or foot amputation, based upon the clinical diabetic foot assessment. The findings from both the current and Arnaud et al.'s (2009) studies indicated the participants were at risk for DFU and/or amputation, although there was a higher percentage of participants with LOPS in the current study and a higher percentage of participants with previous amputation in Arnaud et al.'s study. The findings from both studies revealed the need for routine diabetic foot assessments and daily diabetic foot self-care.

The RN-led diabetic foot self-care educational intervention decreased the participant's risk for DFU by increasing the participant's knowledge of and performance of two of the five daily diabetic foot self-care behaviors. The findings of the repeated measures of the SDSCA foot subscale items were used to address the efficacy of the intervention. The diabetic foot self-care behaviors included: (a) check feet, (b) look in shoes, (c) wash feet, (d) soak feet, and (e) dry between the toes. There were statistically significant differences for the check feet and look in shoes behaviors. No statistically significant difference was found for wash feet, soak feet or dry between the toes behaviors.

At Week 1 the participants checked their feet an average of four times per week. Whereas for Weeks 2, 3, and 4 the participants checked their feet an average of six times per week. The findings were statistically significant F (2.001, 38.015) = 5.942, p = .006 with a small effect size of .238. Based upon the post hoc analyses the greatest change occurred between Week 1 and Week 2 (p = .029). No studies were found that measured daily diabetic foot self-care behaviors over a four-week period among a sample of adults with DM experiencing homelessness.

At Week 1 the participants looked in their shoes an average of two times per week. Whereas the behavior increased to an average of four times a week at Week 2. At Weeks 3 and 4 the participants looked in their shoes an average of five times per week. The findings were statistically significant F (2.473, 46.985) = 15.5, p = .000 with a moderate effect size of .450. Based upon the post hoc analyses the greatest changes occurred between Weeks 1 and 2 (p = .005), Weeks 1 and 3(p = .001) and Weeks 1 and 4 (p = .000). No studies were found that measured daily diabetic foot self-care behaviors among a sample of adults with DM experiencing homelessness.

The RN-led diabetic foot self-care educational intervention had no effect on the participant's Inlow's diabetic foot assessment total scores. The Inlow's was performed every week during the four-week study. No statistically significant differences were found for either the left or right feet at any of the data collection points. No studies were found that used the Inlow's diabetic foot screening tool to assess the feet of participant's with DM.

Theoretical Framework

The theoretical framework that guided the study was Knowles Adult Learning Theory (1984). Knowles' pedagogy describes the adult learner as one who is oriented to problem solving. The adult learner views learning as a strategy to obtain information to solve the problem The diabetic foot self-care curriculum, *Diabetes Foot: Risk Assessment*

Education Program (RNAO, 2004), was designed for the adult learner and was based upon Knowles' assumptions. For the purpose of the current study, I presented the risk for DFU and/or amputation as the problem and learning about diabetic foot self-care and DFU and/or amputation risk prevention as the solution to the problem.

Knowles' Adult Learning Theory includes several assumptions about the adult learner, all of which were evident among the participants of adults with DM experiencing homelessness in the current study. The participants were self-directed learners with responsibility for own learning and demonstrated this assumption by arriving on time to the foot care classes, bringing their workbooks, and showing interest in learning how to prevent diabetic foot complications. The participants asked relevant questions about content that was unclear. Further, adults learn best when they have a need and readiness to learn which was demonstrated the majority (86.7%) of the participants had not had received diabetic foot care education in the last year, and some participants stated they had never been taught how to prevent foot complications by performing diabetic foot self-care behaviors. Adult learners also incorporate and use their own knowledge and life experiences into their learning. Many of the participants shared their DM knowledge and past experiences with each other in the class, as noted in Chapter three. Many were motivated to learn how to care for their feet based upon their life experience with a family member with DM. The participants were taught diabetic foot self-care behaviors within the context of DFU and/or amputation risk identification and reduction.

As the educational intervention was based on Knowles' Adult Learning Theory, several strategies reflecting the principles were integrated throughout the program. For instance, the tasks of diabetic foot self-care reflected the participants' interest and encouraged the use of the items in their diabetic foot care bags. I seized upon every opportunity to provide positive feedback, and frequently commented about what great shape their feet were in, now is the perfect time to learn about diabetic foot self-care in order to prevent DFU and/or amputation. The participants applied previous knowledge and

experiences to increase their awareness of need for information and skills, thus motivating learning and problem-solving (Teal, 2011). The use of Knowles' Adult Learning Theory was appropriate to use among adults with DM experiencing homelessness. The participants recognized the need to prevent complications such as amputation and therefore ready and motivated to learn self-care skills, especially if they have already experienced diabetic foot complications (Knowles, 1990).

The use of self-report SFSQ subjective DFU or amputation risk assessment reflect Knowles' assumptions for self-directed learning and using their own knowledge because the participants were able to self-assess their individual risk factors. In turn, learning about their DFU or amputation risk factors helped the participants to understand that the information in the program was relevant to them. The use of the self-report SDSCA diabetic foot self-care behaviors was beneficial because the participants were able to track their progress of diabetic foot care over the four-week intervention. The SDSCA data provided an avenue for positive feedback from the PI and also results that were used to improve the participant's confidence and a belief in their own ability to manage the diabetic foot self-care (Knowles, 1990).

Limitations

The limitations of the current study consisted of a small sample, attrition, and self-report data. The sample size consisted of 30 subjects at baseline. However, all subjects were staying in homeless shelters. Throughout the course of the study, ten subjects left the study. Subjects left the study for two reasons; either they obtained permanent housing or were dismissed from the shelter. Self-report data can be affected by the Hawthorne effect. The Hawthorne effect occurs when data is collected in the presence of the investigator and subjects respond to questions based upon what they think will please the investigator (Portney and Watkins, 2009). However, Gelberg and Seicke (1997) found that adults experiencing homelessness were accurate reporters of their health information.

Strengths of the Study

The current study had several strengths. First, the quasi-experimental repeated measures within-subjects design was a strength because each participant serves as their own control and intervention effects are associated with differences observed with a participant across the intervention, rather than between participants across randomized groups. Furthermore, all participants meeting the inclusion criteria received the diabetic foot self-care education, and diabetic foot assessments. The participants accurately identified the DFU or amputation risk factors before and education was presented. The participants also demonstrated adherence related to diabetic foot self-care behaviors throughout the four-week study. Another strength was the theory based diabetic foot care curriculum and the use of two self-report instruments. No study enrolling adults with DM experiencing homelessness was theoretically framed by Knowle's Adult Learning Theory. Savage et al. (2014) DSMES intervention was framed by the Chronic Disease Model. Despite a small sample, all of the participants were staying in homeless shelters, which was also a strength.

Implications for Nursing Practice

Registered Nurses need to be included as members of the interprofessional healthcare team caring for patients with DM. Rossaneis et al. (2017) noted that RN's, who traditionally have been the main providers of self-care health education, have made significant contributions for the prevention of diabetic foot complications. The American Nurses Association (ANA) (2109) empowers professional nurses to be able to practice to their full potential guided by ANA's *The Nursing Scope and Standards of Practice. The Nursing Scope and Standards* state "The profession exists to achieve the most positive patient outcomes in keeping with nursing's social contact and obligation to society" (ANA, 2109, p. 1). Furthermore, "nursing is defined as the protection, promotion, and optimization of health and abilities, prevention of illness and injury…and advocacy in the care of

individuals, families, groups, communities, and populations" (ANA, 2019, p. 1). Yet, the role of the RN is poorly understood or articulated in the literature with respect to diabetic foot self-care education and DFU risk reduction.

Recommendations for Future Research

In 2015, the publication "Summary Guidance for Daily Practice" "provided evidenced-base guidelines for the prevention of diabetic foot complications among persons with diabetes mellitus" (DM) (Schaper, Van Netten, Apelqvist, Lipsky, & Bakker, 2015, 7). The guide directs healthcare providers to identify the "at-risk" foot and to provide diabetic foot self-care education to the client, family, and healthcare providers (Schaper et al., 2015). Studies are lacking, not only for adults with DM experiencing homelessness, but also in the general population, that measure and categorize DFU or amputation risk factors.

Rossaneis et al. (2017) also provided strong support for RN investigators to lead research that examines for associations between the findings from clinical diabetic foot examination and survey data as potential predictors for DFUs. Nursing would benefit from research that seeks to assess DFU risk factors, categorize the risks, measure diabetic foot self-care behaviors and teach diabetic foot self-care, especially to individuals with DM who are underserved and vulnerable.

CONCLUSION

The purpose and aims of the current study were met and the research questions answered. A small sample of adults with DM experiencing homelessness enrolled in the study which aimed to provide empirical support about DFU and/or amputation risk factors, diabetic foot self-care behaviors, and the clinical diabetic foot assessments. The diabetic foot self-care was led by the RN investigator and focused on identifying and reducing the participant's risks for DFU and/or amputation. Throughout the four-week study, the

participant's risk factors did change nor did their clinical diabetic foot assessments. The participants in the current study performed diabetic foot self-care behaviors routinely and two behaviors showed a significant increase from baseline. The participants demonstrated a great deal of interest, readiness to learn, and appreciation for the education.

SUMMARY

Chapter five has presented an overview of the study and the findings related to the literature. The limitations and the strengths of the study findings have also been presented. The implications for nursing practice have been discussed. Recommendations for future research and the conclusions from the study were also presented.

Appendix A Participant Package

Diabetes Foot: Risk Assessment
Objectives and Critical Behaviours

At the end of this skills workshop, you will be able to:

Objectives

1. Conduct a foot assessment for clients with known diabetes in order to:
    a. Identify the presence of foot ulceration or history of previous foot ulcers.
    b. Assess sensation in the foot using a Semmes-Weinstein monofilament.
    c. Observe the client's feet and assess for physical/structural abnormalities.
    d. Assess recent history of intermittent claudication and palpate pedal pulses bilaterally.
    e. Assess previous foot care education.
2. Provide basic education for the prevention of foot ulcers for all clients with diabetes.
3. Implement appropriate actions when clients are assessed at higher risk for foot ulcers and/or amputation.
4. Document a foot risk assessment and classify the level of risk.

Critical Behaviours

1. Identify the five key risk factors for foot ulceration and amputation in clients with diabetes.
2. Assess the client's foot for loss of sensation.
3. Assess the client's foot for structural abnormalities.
4. Palpate the dorsalis pedis and posterior tibial pulses.
5. Assess self-care ability to perform foot care.
6. Assess the appropriateness of foot wear.
7. Verbalize the key elements of appropriate foot care.
8. Verbalize instructions to the client on the importance of regular foot examination by a health care professional, based on level of risk.
9. Accurately record a foot assessment.

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Diabetes Foot: Risk Assessment
Pre-Test / Post-Test

1. Diabetes mellitus increases the risk of foot amputation by 20 fold.

D True D False

2. Trauma is one of the most common causes of skin ulceration in persons with diabetes.

D True D False

3. List the five key risk factors for foot ulcers in persons with diabetes.

_____

_____

_____

_____

_____

4. Identify the most effective way to measure sensation in the foot of a person with diabetes.

_____

_____

_____

5. Describe where you can palpate a pulse in your foot.

_____

_____

_____

_____

_____

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6. How often should a health provider reinforce the importance of diabetes foot care for persons at lower risk for the development of foot ulcers?

_____

_____

_____

7. How frequently should a person with diabetes inspect his/her feet?

_____

_____

_____

8. Identify two factors that might make it difficult for a person with diabetes to complete proper foot care.

_____

_____

_____

9. What additional information is required to complete the following advice to a person with diabetes: "Wash feet daily, dry thoroughly and apply cream to dry areas."

_____

_____

_____

10. A person with diabetes who develops a foot ulcer should be advised to see a doctor if it does not heal in three days.

D True D False

Assessment of Five Key Risk Factors
Foot Risk Assessment Form

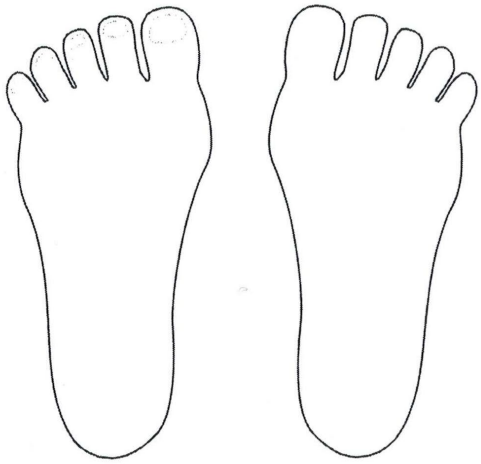
◆ Presence/History of Foot Ulcers

Examine both feet, without shoes.

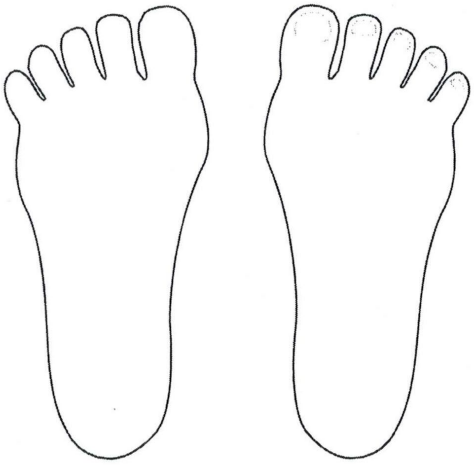
Sore(s) present? Yes / No

Ask: Have you ever had a sore on your foot that took more than two weeks to heal? Yes / No

Chart any sores on the diagrams below.



Left Foot Top *Left Foot Bottom*



Right Foot Bottom *Right Foot Top*

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Diabetes Foot Assessment/Risk Screening Summary

Use this guide to assess and/or document the presence of potential risk factors for foot ulceration and amputation. Examine both feet and inquire about client self-care practices. Tick the "yes" or "no" box next to an assessment element for each potential risk factor. Summarize the findings by circling the level of risk, and/or if a self-care knowledge deficit is identified.

Risk Factors	Yes	No
1. Foot ulcer (a wound that took > 2 weeks to heal) now or in the past		
2. Loss of sensation at any one site (determined after testing the 4 sites: great toe, first, third, and fifth metatarsal heads using the 10 gram/5.07 monofilament)		
3. Callus present on soles of feet or toes or abnormal foot shape (e.g., claw or hammer toes, bunion, obvious bony prominence, Charcot's foot or joint)		
4. Pedal pulses (dorsalis pedis or posterior tibial) not palpable by nurse and positive history of lower limb pain on exertion that is relieved with rest.		
5. Client unable to see the bottom of feet and/or unable to reach the bottom of feet and does not have someone who has been taught to perform appropriate foot care/inspection.		
6. Poor fitting footwear (shoes too narrow or short, no toe protection, rough or worn interior, uneven wear on sole or heel).		
7. Client has not received foot care education before.		
8. Client does not check condition of feet most days. *Ask* "How do you know if you have a reddened area or other problem with your feet?" or "How often do you check your feet?"		
9. Client does not report foot problems to health care provider. *Ask* "What would you do if you found a blister on your foot?"		
10. Client does not take steps to reduce risk of injury. Ask if client walks bare foot out or indoors, checks for foreign objects in shoes before wearing them, checks water temperature before entering a bath, etc.		
If the answer is NO to all items 1 – 4, the client is at		LOWER RISK
If the answer is YES to any items 1-4, the client is at		HIGHER RISK

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If the answer is YES to any items 5 – 10, this indicates an opportunity to enhance self-care knowledge and behaviour.

SELF-CARE KNOWLEDGE DEFICIT

Adapted from: Sharon Brez, RN, BScN, MA(Ed), CDE, Advanced Practice Nurse, Endocrinology and Metabolism, The Ottawa Hospital, Ottawa, Ontario.

Care Tips for the Feet

Did you know that having diabetes puts you at risk of developing complications such as foot ulcers?

Managing your blood sugar is important for healthy feet.
See your healthcare provider –
Get complete diabetes education!

YEARLY EXAM NEEDED!

Have a health professional examine your feet at least once a year.

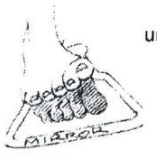
Find out if you have lower or higher risk feet.

RISK FACTORS

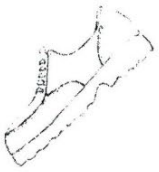
- A previous foot ulcer
- Loss of normal feeling in your feet
- Abnormal shaped foot, including

Protect your feet! Follow these simple guidelines:

If you c urself, have someone else check for you.



1. **Check your feet daily**
   - Look for red areas, blisters or any open area.
   - See your doctor or foot specialist right away if you find a problem!
2. **Protect your feet - always wear shoes!**
   - Wear shoes that fit well, support your foot and are not too tight. Do not wear shoes that cause reddened or sore areas.
   - See a specialist for footwear advice if you have a higher risk foot.



3. **Keep your skin clean and soft**
   - Wash your feet regularly, but do not soak them.
   - Dry well between your toes. Check that the water is not too hot before putting your feet in it.
   - Use unscented creams. Do not put cream between the toes.
4. **Don't hurt yourself with nail clippers or razors**
   - Cut your nails straight across. Get help to cut your nails, if needed.
   - Don't cut calluses. See a local foot care clinic. Many are covered by the Ontario Health Insurance Plan (OHIP).

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◆ Referral

Refer as appropriate, depending on risk status.

Diabetes Education/Care Resources

Diabetes education may be available in a variety of settings, depending upon your local resources.

Local Diabetes Education Resources

_____

_____

_____

_____

_____

Local Diabetic Foot Care Specialists

_____

_____

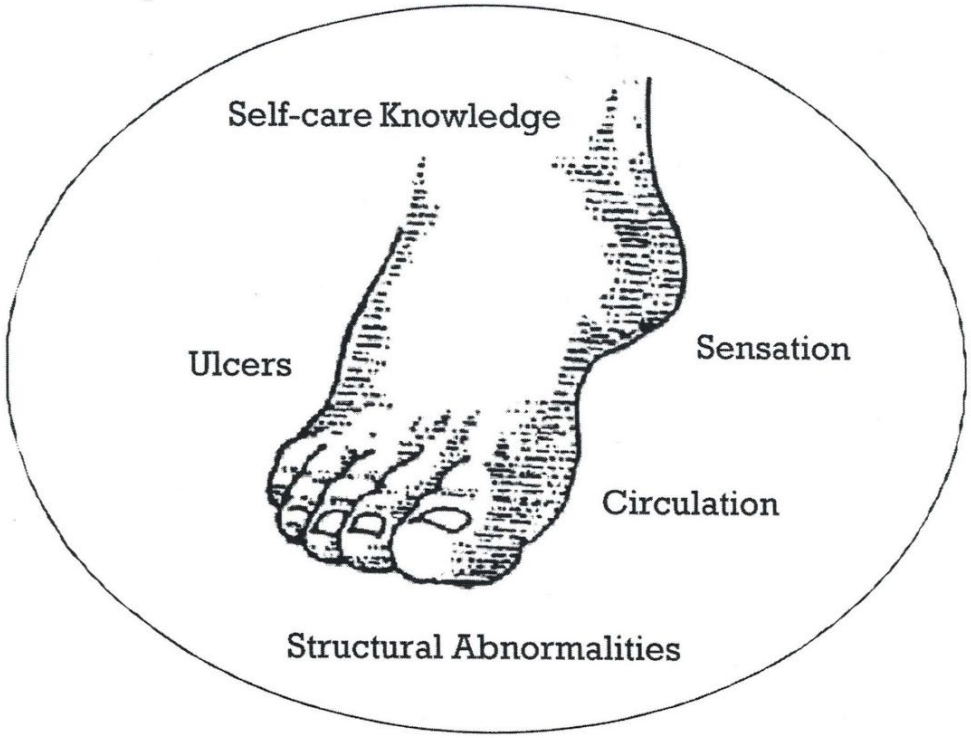
_____

Week

2

Deformities

Five Key Risk Factors



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Find out if you have lower or higher risk feet.

RISK FACTORS

- A previous foot ulcer
- Loss of normal feeling in your feet
- Abnormal shaped foot, including calluses and bunions

Protect your feet! Follow these simple guidelines:

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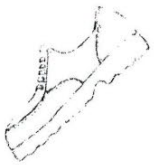
1. **Check your feet daily**
   - Look for red areas, blisters or any open area.
   - See your doctor or foot specialist right away if you find a problem!



2. **Protect your feet - always wear shoes!**
   - Wear shoes that fit well, support your foot and are not too tight. Do not wear shoes that cause reddened or sore areas.
   - See a specialist for footwear advice if you have a higher risk foot.

3. **Keep your skin clean and soft**
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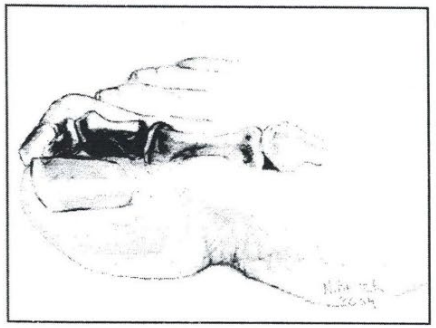
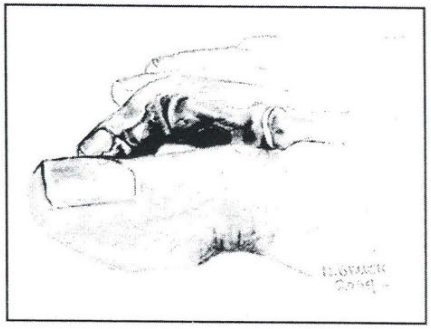
Deformities



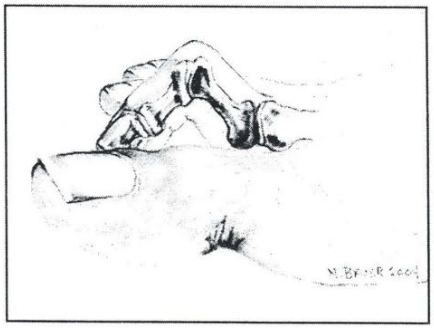
Mallet Toe

With a mallet toe, the joint nearest the tip of the toe is bent.



Hammer Toe

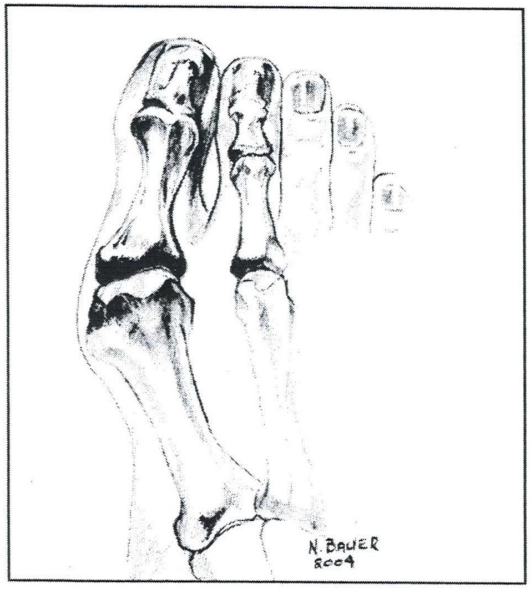
With a hammer toe, the middle joint is bent.



Claw Toe

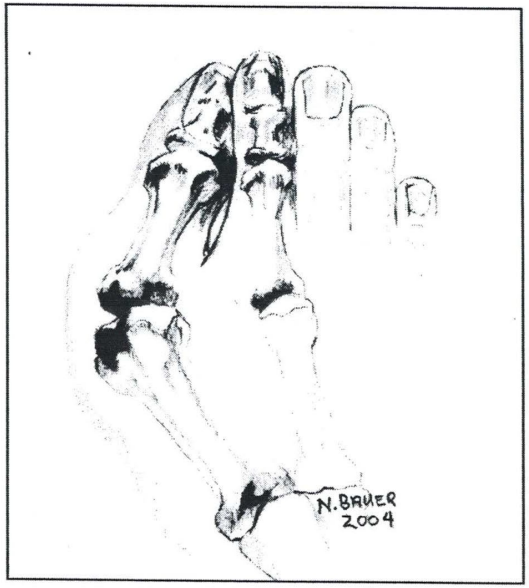
With a claw toe, the joint at the base of the toe is bent up. The middle joint is bent down.

Deformities



Hallux Valgus (Mild/Moderate)

A small bump (sometimes called a bunion) forms when the big toe turns in toward the second toe. The joint at the



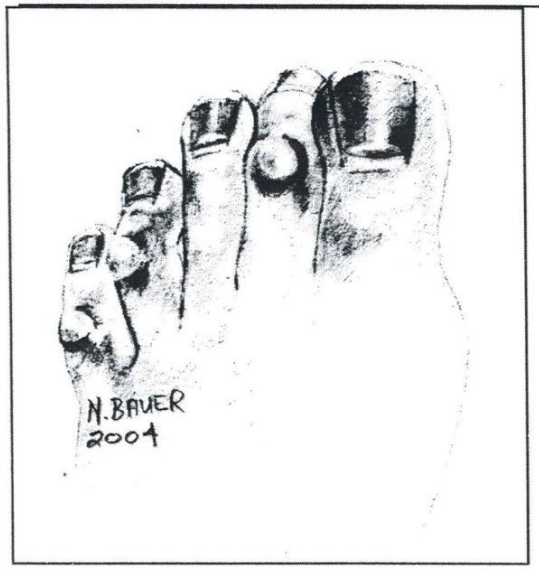
Hallus Valgus (Severe)

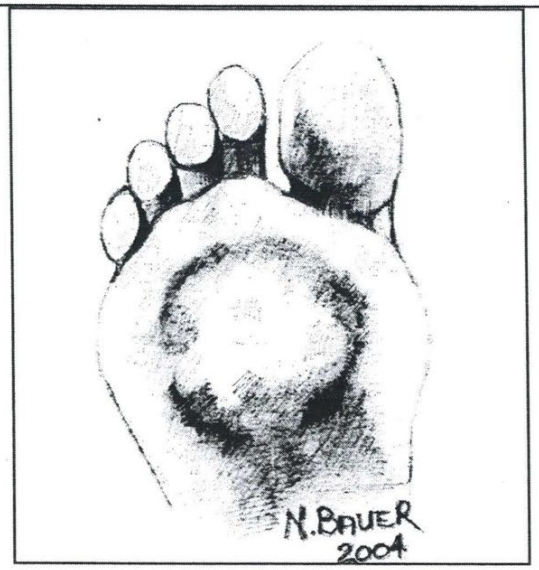
base of the big toe is pushed to the side. The angulation of the big toe is marked, forming a large bunion. The big toe may move under the second toe.

Deformities

~~A callus is 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. A callus may develop a central core or plug of tissue where the pressure is greatest.

Pressure Related





Corns

A corn is 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. Soft corns

Calluses

develop between the toes. A callus is 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. A callus may develop a central core or plug of tissue where the pressure is greatest.

Pressure Related

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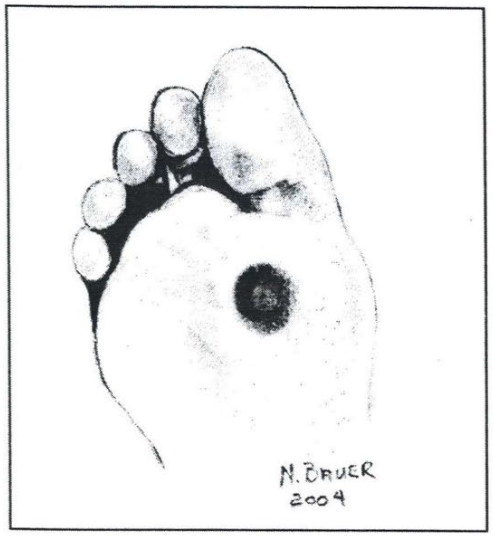
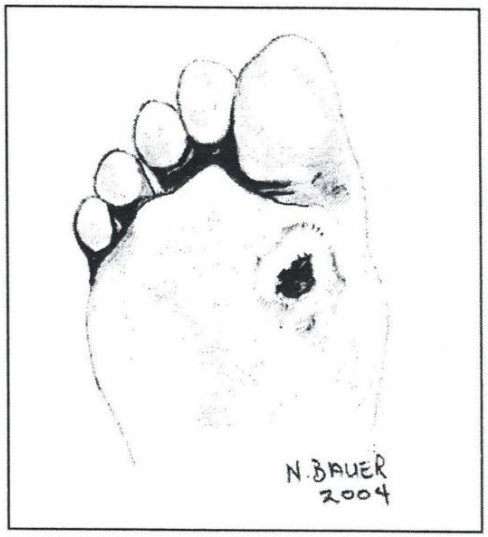
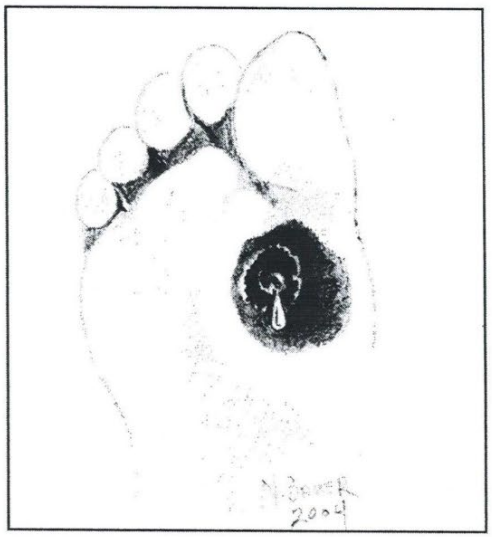






Hot Spots

Red "hot spots" on the feet are signs of pressure or friction. If pressure is not relieved, a hot spot may develop into a blister. Left untreated, a blister may turn into an open wound or a corn or callus.

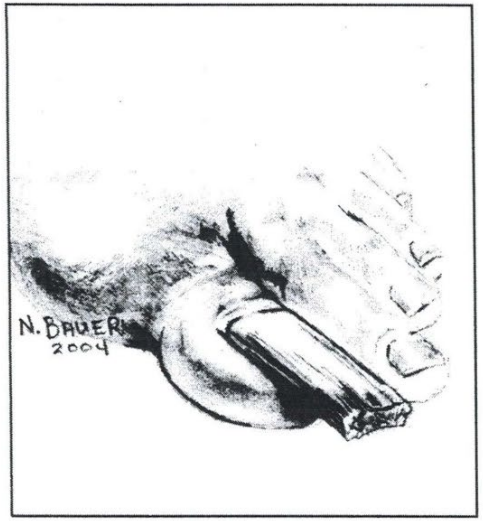
Ulcer

If corns or calluses press into the foot, they destroy underlying skin layers, and an ulcer results. Ulcers may lead to infection. In some cases, skin from a callus or corn

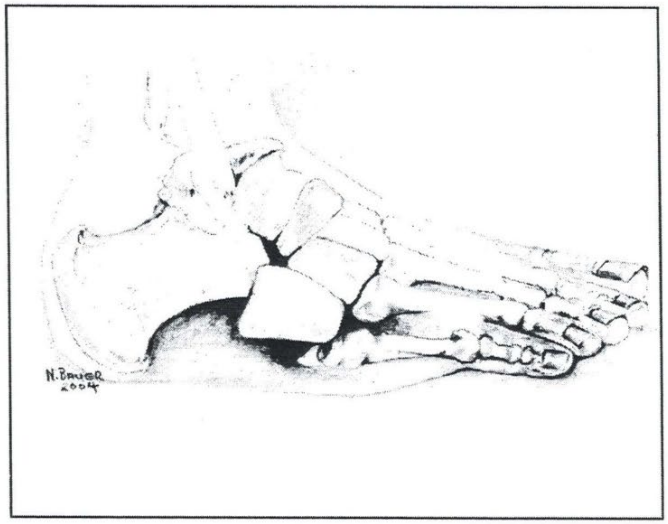
may cover an open wound, making it difficult to assess.

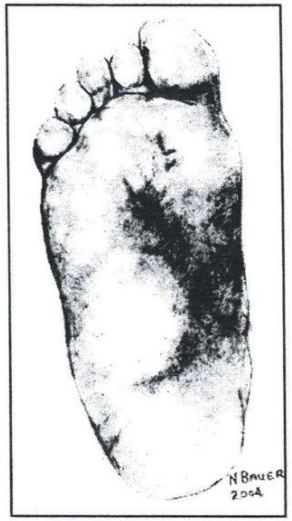
Infected Ulcer

Infected ulcers may result in the death of healthy tissue.
Symptoms of infection include white, yellow or green discharge, bleeding or odor.



Fungal Nails





Charcot Joint

Fungal nails may be the result of fungal infections such as Athlete's Foot, the use of artificial nails
or nail polish, or injury to the nail. Fungal nails may become
thickened, inflamed, and sensitive and may turn unnatural colors.

Charcot joint is a form of neuroarthropathy that occurs most often in the foot. Nerve damage from diabetes causes decreased sensation, muscle atrophy and subsequent joint instability. Walking on an insensitive
joint makes it worse. In the acute stage there is inflammation and bone reabsorption which weakens the bone. In later stages, the arch falls and the foot may develop a "rocker bottom" appearance. Early treatment can stop bone destruction and help healing.

◆ Structural Abnormalities

Examine both feet without socks and shoes, standing and sitting or lying down. Check all that apply.

Structural Abnormality	Yes
Toe deformities (e.g., claw or hammer toes)	
Blisters, Calluses, Fungal Infection (Please circle all that apply)	
Hallux valgus (Bunion)	
Amputation (Please specify: Right / Left Level:_____Year:_____)	
Charcot's joint (foot warm, swollen, red, and painless)	
Footwear	
Uneven wear on soles of shoes	
A wide toe box (1/2" between the tip of the toe and the end of the shoe)	
Sufficient depth	
Good arch support	
Shoe fits without rubbing along any area of the foot	

See Images – The Diabetic Foot *for illustrations*

Week

3

◆ Circulation

a) Assess for Intermittent Claudication

Ask: Do you have pain in the calf when walking or on exertion that is relieved by rest within 10 minutes?
Yes / No

b) Assess Pedal Pulses

Pedal Pulse	Present	Absent
Right posterior tibial		
Left posterior tibial		
Right dorsalis pedis		
Left dorsalis pedis		

Instructions for locating and palpating Pedal Pulses

Dorsalis Pedis
Place fingers just lateral to the extensor tendon of the great toe. (If you cannot feel a pulse, move fingers more laterally.)

Posterior Tibial
Place fingers behind and slightly below the medial malleolus of the ankle. (In an obese or edematous ankle, the pulse may be more difficult to feel.)

To enhance technique, assume a comfortable position for you and the client. Place hand in position and linger on the site. Varying pressure may assist in picking up a weak pulsation. Do not confuse client's pulse with your own pulsating fingertips. Use your carotid pulse for comparison, if needed.

◆ Protective Sensation

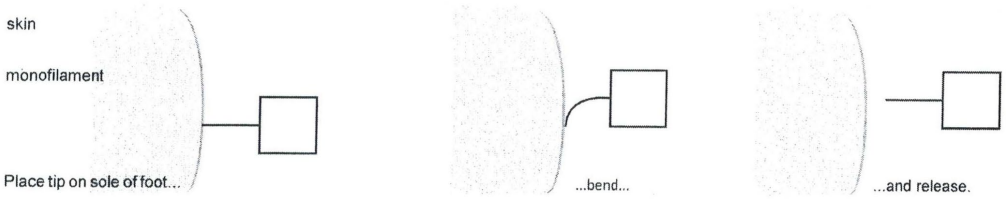
Assess using the Semmes-Weinstein Monofilament (10 gram, 5.07).

Instructions for use of Semmes-Weinstein Monofilament

1. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.

2. Ask the patient to turn his/her head and close his/her eyes or look at the ceiling.

3. Hold the monofilament perpendicular to the skin.



4. Place the tip of the monofilament on the sole of the foot. Ask the patient to say 'yes' when he/she feels you touching his/her foot with the monofilament.

DO NOT ASK THE PATIENT 'did you feel that'?

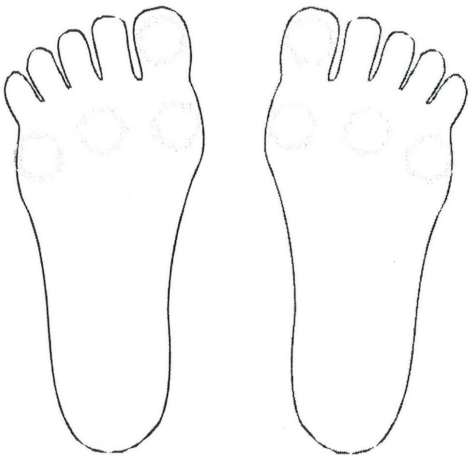
If the patient does not say 'yes' when you touch a given testing site, continue on to another site. When you have completed the sequence, RETEST the area(s) where the patient did not feel the monofilament.

5. Push the monofilament until it bends, then hold for 1-3 seconds.

6. Lift the monofilament from the skin (Do not brush or slide along the skin).

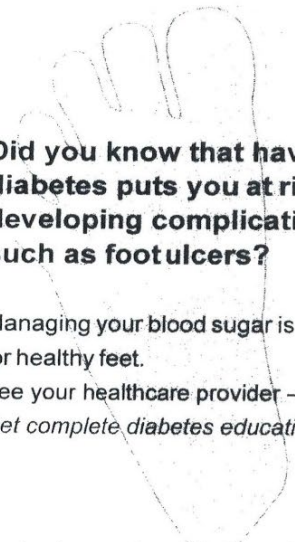
7. Repeat the sequence randomly at each of the testing sites on each foot (see figure at right).

8. Clean the monofilament according to agency infection control protocols and store according to the manufacturer's instructions.



Mark the four, circled areas of the foot. Use a plus sign (+) if they can feel the monofilament and a minus sign (–) if they cannot.

Care Tips for the Feet



Did you know that having diabetes puts you at risk of developing complications such as foot ulcers?

Managing your blood sugar is important for healthy feet.
See your healthcare provider –
Get complete diabetes education!

YEARLY EXAM NEEDED!

Have a health professional examine your feet at least once a year.

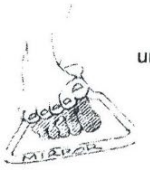
Find out if you have lower or higher risk feet.

RISK FACTORS

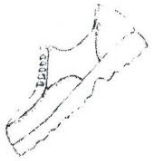
- D A previous foot ulcer
- D Loss of normal feeling in your feet
- D Abnormal shaped foot, including

Protect your feet! Follow these simple guidelines:

If you c urself, have someone else check for you.



1. **Check your feet daily**
   - Look for red areas, blisters or any open area.
   - See your doctor or foot specialist right away if you find a problem!
2. **Protect your feet - always wear shoes!**
   - Wear shoes that fit well, support your foot and are not too tight. Do not wear shoes that cause reddened or sore areas.
   - See a specialist for footwear advice if you have a higher risk foot.



3. **Keep your skin clean and soft**
   - Wash your feet regularly, but do not soak them.
   - Dry well between your toes. Check that the water is not too hot before putting your feet in it.
   - Use unscented creams. Do not put cream between the toes.
4. **Don't hurt yourself with nail clippers or razors**
   - Cut your nails straight across. Get help to cut your nails, if needed.
   - Don't cut calluses. See a local foot care clinic. Many are covered by the Ontario Health Insurance Plan (OHIP).

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Week

4

Wrap-up

1 Pre-Test/Post-Test Answers
2 Tips for Client Education: Adult Learning Principles
3 Workshop Evaluation

◆ Pre-Test / Post-Test Answers

1. Diabetes mellitus increases the risk of foot amputation by 20 fold.

True. Up to 15% of patients with diabetes may develop foot ulcers in their lifetime (ADA, 1999; Palumbo & Melton, 1985; Pham et al., 2000).

In one study, a non-healing foot ulcer preceded 84% of diabetic lower limb amputations (Pecoraro, Reiber, & Burgess, 1990; Reiber et al., 1999).

In Ontario, the evidence suggests that effective outpatient care for diabetic foot ulcers and infections is reducing minor amputation rates (Hux, Jacka, Fung, & Rothwell, 2002).

Three important actions to prevent peripheral vascular disease include:

- Stop smoking
- Improve blood glucose control
- Get regular foot care (Hux et al., 2002)

2. Trauma is one of the most common causes of skin ulceration in persons with diabetes

True. The most frequent component causes for lower extremity ulcers are trauma, neuropathy and deformity. Traumatic event can be the result of 1) low pressure and continuing stress, or 2) high pressure of short duration that results in a break in the skin or tissue damage (Reiber et al., 1999).

3. List the five key risk factors for foot ulcers in persons with diabetes.

Foot ulcer, now or in the past
Diminished sensation Structural abnormalities
Impaired circulation
Lack of foot care education (self-care knowledge deficit)

4. Identify the most effective way to measure sensation in the foot of a person with diabetes.

Semmes Weinstein monofilament (10 gram, 5.07).

5. Describe where you can palpate a pulse in the foot.

Dorsalis Pedis: dorsal aspect of foot, lateral to extensor tendon of big toe
Posterior Tibial: ankle, behind medial malleolus
A positive history of lower limb intermittent claudication combined with non-palpable pedal pulses bilaterally increases the likelihood of identifying PVD in diabetes (Boyko et al., 1997).

6. How often should a health provider reinforce the importance of diabetes foot care for persons at lower risk for the development of foot ulcers?

Each visit

7. How frequently should a person with diabetes inspect his/her feet?

Daily

8. Identify two factors that might make it difficult for a person with diabetes to complete proper foot care.

Poor vision Decreased mobility

Lack of energy
(Reinforce importance of getting support)

9. What additional information is required to complete the following advice to a person with diabetes: "Wash feet daily, dry thoroughly and apply cream to dry areas."

... but do not apply cream between the toes because it will predispose to maceration and skin breakdown.

10. A person with diabetes who develops a foot ulcer should be advised to see a doctor if it does not heal in three days.

False. Should be advised to consult a doctor immediately.

Interventions

1. Communicate Risk Status
2. Teach/Reinforce Diabetes Self-care Knowledge and Behaviour
3. Refer to Diabetes Education/Care Resources
4. Documentation

◆ Communicate Risk Status

Explain the level of risk and provide information on how to reduce the risk through self-care and regular foot examination, paying particular attention to the gaps in self-care knowledge.

Risk Classification and Nursing Intervention Guide	
LOWER RISK	HIGHER RISK
Explain risk for foot complications related to diabetes.	Explain risk for foot complications related to diabetes. Inform client of personal risk factors identified in this nursing assessment.
Teach or reinforce basic foot care practices and strategies for foot injury prevention.	Teach or reinforce basic foot care practices and strategies for foot injury prevention.
Reinforce benefits of annual foot examination.	Reinforce benefits of regular professional foot exam and risk assessment (every 3-6 months). Refer patient to primary care provider or diabetes care/ education program for further assessment and follow-up.

◆ Teach or Reinforce Self-care Knowledge and Behaviour

Please refer to the resource "Care Tips for the Feet" on the next page.

Care Tips for the Feet

Did you know that having diabetes puts you at risk of developing complications such as foot ulcers?

Managing your blood sugar is important for healthy feet.
See your healthcare provider –
Get complete diabetes education!

YEARLY EXAM NEEDED!

Have a health professional examine your feet at least once a year.

Find out if you have lower or higher risk feet.

RISK FACTORS

- D A previous foot ulcer
- D Loss of normal feeling in your feet
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Protect your feet! Follow these simple guidelines:

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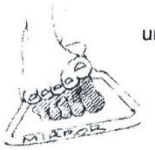
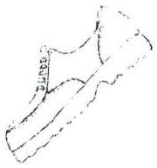
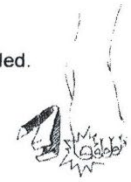


1. **Check your feet daily**
   - Look for red areas, blisters or any open area.
   - See your doctor or foot specialist right away if you find a problem!



2. **Protect your feet - always wear shoes!**
   - Wear shoes that fit well, support your foot and are not too tight. Do not wear shoes that cause reddened or sore areas.
   - See a specialist for footwear advice if you have a higher risk foot.

3. **Keep your skin clean and soft**
   - Wash your feet regularly, but do not soak them.
   - Dry well between your toes. Check that the water is not too hot before putting your feet in it.
   - Use unscented creams. Do not put cream between the toes.



4. **Don't hurt yourself with nail clippers or razors**
   - Cut your nails straight across. Get help to cut your nails, if needed.
   - Don't cut calluses. See a local foot care clinic. Many are covered by the Ontario Health Insurance Plan (OHIP).

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Observe and/or question the client to complete the assessment

Self-care Knowledge and Behaviour	Yes	No
Able to see and/or reach the bottom of feet or, has help from someone who has been taught to do daily foot care		
Able to do own skin and nail care		
Has received foot care education in the past year		
Has annual foot examination by a professional		
Checks condition of feet most days		
Knows to report foot problems to a health provider (e.g., would seek advice from health provider for a blister on foot)		
Wears well-fitting footwear		
Takes steps to reduce risk of injury:		
• Avoids going barefoot outside or indoors		
• Checks for foreign objects in shoes before wearing them;		
• Checks water temperature before entering a bath, etc. (using thermometer or wrist, not feet)		
Knows that having diabetes increases risk for foot problems		
Knows personal risk factors for foot complications		

◆ Documentation

Intervention	Yes	No
Explained risk for diabetes foot complications due to history of foot ulcers, impaired sensation, structural abnormalities or impaired circulation. (Tailor to individual risk and need.)		
Provided/reinforced diabetes foot self-care and injury prevention as outlined in handout *Care Tips for the Feet.*		
Gave handout to client/caregiver.		
Provided information and handout on local diabetes resources.		
Referred for further assessment and follow-up:		
Primary health care provider		
Diabetes education program		
Other (Please specify)		

Appendix B Inlow's 60-Second Diabetic Foot Screen Tool

ID number: **Date:**

Look – 20 seconds	Score Left Foot	Score Right Foot	Care Recommendations
1. Skin 0 = intact and healthy 1 = dry with fungus or light callus 2 = heavy callus build up 3 = open ulceration or history of previous ulcer			
2. Nails 0 = well-kept 1 = unkempt and ragged 2 = thick, damaged, or infected			
3. Deformity 0 = no deformity 2 = mild deformity 4 = major deformity			
4. Footwear 0 = appropriate 1 = inappropriate 2 = causing trauma			

Touch – 10 seconds	Left Foot	Right Foot	Care Recommendations
5. Temperature – Cold 0 = foot is warm 1 = foot is cold			
6. Temperature – Hot 0 = foot is warm 1 = foot is hot			
7. Range of Motion 0 = full range to hallux 1 = hallux limitus 2 = hallux rigidus 3 = hallux amputation			

Assess – 30 seconds	Left Foot	Right Foot	Care Recommendations
8. Sensation – Monofilament Testing 0 = 10 sites detected 2 = 7 to 9 sites detected 4 = 0 to 6 sites detected			

9. Sensation – Ask 4 Questions:

i. Are your feet ever numb?
ii. Do they ever tingle?
iii. Do they ever burn?
iv. Do they ever feel like insects are crawling on them?

0 = no to all questions
2 = yes to any of the questions

10. Pedal Pulses

0 = present
1 = absent

11. Dependent Rubor

0 = no
1 = yes

12. Erythema

0 = no
1 = yes

Score Totals =

Screening for foot ulcers and/or limb-threatening complications. Use the highest score from left or right foot.

Score = 0 to 6 □ recommend screening yearly
Score = 7 to 12 □ recommend screening every 6 months
Score = 13 to 19 □ recommend screening every 3 months
Score = 20 to 25 □ recommend screening every 1 to 3 months

Comments:

Instructions for Use

General Guidelines:

This tool is designed to assist in screening persons with diabetes to prevent or treat diabetes-related foot ulcers and/or limbthreatening complications. The screen should be completed on admission of any person with diabetes and then repeated as directed by risk and clinical judgment. **Do not confuse patient visits with patient screening.** Your patient may require frequent and regular visits for routine care but complete the screening as indicated or as relevant based on clinical judgment.

Specific Instructions:

Step 1: Explain screening to the patient and have them remove their shoes, socks from both feet.

Step 2: Remove any dressings or devices that impair the screening.

Step 3: Review each of the parameters for each foot as listed in the Inlow's 60-second Diabetic Foot Screen and select the appropriate score based on patient's status. (An amputation may affect the score on the affected limb.)

Step 4: Once the screen is completed determine care recommendations based on patient need, available resources and clinical judgement.

Step 5: Use the highest score from either the left or right foot to determine recommended screening intervals.

Step 6: Set up an appointment for the next screening based on screening score and clinical judgement.

PARAMETER REVIEW

1. SKIN

Assess the skin on the foot: top, bottom and sides including between the toes.

0 = skin is intact and has no signs of trauma. No signs of fungus or callus formation
1 = skin is dry, fungus such as a moccasin foot or interdigital yeast may be present. Some callus build-up may be noted
2 = heavy callus build-up
3 = open skin ulceration present

2. NAILS

Assess toenails to determine how well they are being managed either by the patient or professionally.

0 = nails well-kept
1 = nails unkempt and ragged
2 = nails thick, damaged or infected

3. DEFORMITY

Look for any bony changes that can put the patient at significant risk and prevent the wearing of off-the-shelf footwear

0 = no deformity detected
2 = may have some mild deformities such as dropped metatarsal heads (MTHs) (the bones under the fat pads on the ball of the foot). Each MTH corresponds to the toe distal to it, so there is a 1st MTH at the base of the first toe etc. Bunions/Charcot may also be considered a deformity as well as deformities related to trauma.
4 = Amputation

4. FOOTWEAR

Look at the shoes that the patient is wearing and discuss what he or she normally wears.

0 = shoes provide protection, support and fit the foot. On removal of the footwear there are no reddened areas on the foot
1 = shoes are inappropriate do not provide protection or support for the foot.
2 = shoes are causing trauma (redness or ulceration) to the foot either through a poor fit or a poor style (e.g., cowboy boots).

5. TEMPERATURE – COLD

Does the foot feel colder than the other foot or is it colder than it should be considering the environment? This can be indicative or arterial disease.

0 = foot is of "normal" temperature for environment.
1 = foot is cold – compared to other foot or compared to the environment

6. TEMPERATURE – HOT

Does the foot feel hotter than the other foot or is it hotter than it should be considering the environment? This can be indicative of an infection or Charcot changes.

0 = foot is of "normal" temperature for environment
1 = foot is hot – compared to other foot or compared to the environment

7. Range of Motion

Move the first toe back and forth – plantar flex and dorsiflex.

0 = first toe (hallux) is easily moved
1 = hallux has some restricted movement
2 = hallux is rigid and cannot be moved
3 = hallux amputated

8. Sensation – Monofilament testing

Using the 5.07 monofilament, test the sites listed. Do not test over heavy callus.

- digits: 1st, 3rd, 5th
- MTH: 1st, 3rd, 5th
- midfoot: Medial, Lateral
- heel
- top (dorsum) of foot And then score out of 10:

0 = 10 out of 10 sites detected
2 = 7 to 9 out of 10 sites detected
4 = 0 to 6 out of 10 sites detected

9. Sensation – Questions

Ask the following four questions:

i. Are your feet ever numb?

ii. Do they ever tingle?

iii. Do they ever burn? iv. Do they ever feel like insects are crawling on them?

0 = answered No to all four questions
2 = answered Yes to one or more of the four questions

10. Pedal pulses

Palpate (feel) the dorsalis pedis pulse located on the top of the foot. If unable to feel the pedal pulse feel for the posterior tibial pulse beneath the medial malleolus.

0 = pulse present
1 = pulse absent

11. Dependent rubor

Pronounced redness of the feet when the feet are down and pallor when the feet are elevated. This can be indicative of arterial disease.

0 = no dependent rubor
1 = dependent rubor present

12. Erythema

Look for redness of the skin that does not change when the foot is elevated. This can be indicative of infection or Charcot changes.

0 = no redness of the skin
1 = redness noted

Reminder: Strategies for the prevention and management of diabetic foot ulcers need to consider more than just the results from a foot screen. It is important that the health-care professional completes a holistic assessment that also monitors lipids, hypertension, glucose and patient activity and exercise. **Persons with diabetes who are cognitively impaired or have diseases such as end-stage renal disease are at higher risk and may need more frequent screening than indicated.**

Interpreting Results

Inlow's 60-second Diabetic Foot Screen has been designed to allow the clinician to screen persons with diabetes to prevent or treat diabetes-related foot ulcers and/or limb-threatening complications. By combining the results from different parameters identified with Inlow's 60-second Diabetic Foot Screen, the clinician can identify pathologies and/or care deficits.

Parameters												Indications
1	2	3	4	5	6	7	8	9	10	11	12	
												Self Care Parameters:
■	■		■									High scores in parameters 1, 2 and 4 ➔ indicative of self care deficit.
												Integument Parameters:
			■			■						Moderate scores in parameters 4 and 7 ➔ indicative of callous formation.
■					■						■	High scores in parameters 1, 6 and 12 ➔ indicative of infected ulcer.
	■				■						■	High scores in parameters 2, 6 and 12 ➔ indicative of infected nails.
												Arterial Flow Parameters:
				■					■	■		High scores in parameters 5, 10 and 11 ➔ indicative of peripheral arterial disease.
												Sensation Parameters:
							■	■				High scores in parameters 8 and 9 ➔ indicative of loss of protective sensation or neuropathy.
												Boney Changes Parameters:
		■					■	■				High scores in parameters 3, 8 and 9 ➔ indicative of Charcot changes.

Determining Risk

Inlow's 60-second Diabetic Foot Screen can also assist in determining patient risk. By reviewing the results from Inlow's 60-second Diabetic Foot Screen, the clinician can use the International Working Group on the Diabetic Foot (IWGDF) – Risk Classification System to identify a risk category for their patients.

Step 1: Complete Inlow's 60-second Diabetic Foot Screen by assessing both feet on every patient with diabetes.

Step 2: Using the IWGDF Risk Classification System, identify which category your patients falls into.

International Working Group on the Diabetic Foot (IWGDF) – Risk Classification System (Modified[1])

Risk category	Criteria
0	Normal – no neuropathy
1	Loss of protective sensation
2a	LOPS and deformity
2b	Peripheral arterial disease
3a	Previous hx of ulceration
3b	Previous hx of amputation

1. Lavery LA, Peters EJG, Williams JR, Murdoch JR, Hudson A, Lavery DC. Reevaluating the Way We Classify the Diabetic Foot. Restructuring the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care* 31:154–156, 2008.

Considerations Based on Clinical Settings

1. **Acute Care:** Due to the high turnover of patients in acute care, clinicians needs to ensure that the initial assessment goes with the patient to their next level of care.

2. **Long Term or Residential Care:** Patients with diabetes may have mobility issues and are in bed or wheelchairs. Feet still may become traumatized by the use of inappropriate footwear even if they are non-weight bearing.

3. **Dialysis Unit:** Some dialysis units may wish to augment this tool with toe pressures and blood work, depending of their clinical support.

4. **Home or Community Care:** Clinicians can use this tool for communication with their patients, each other or other departments, such as specialized clinics.

5. **Foot Clinic:** Foot clinic standards of assessment will be at a higher standard. However, this document is a good communication tool with other clinicians that may be caring for the person with diabetes.

More Information

For more information on the assessment and management of the diabetic foot, refer to:

1. *Best Practice Recommendations for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers*: Update 2010 at www.cawc.net

2. RNAO Best Practice Guideline *Reducing Foot Complications for Persons with Diabetes* at www.rnao.org

3. RNAO Best Practice Guideline *Assessment and Management of Foot Ulcers for People with Diabetes* at www.rnao.org

4. *The International Working Group on the Diabetic Foot* at www.iwgdf.org

5. *Diabetes, Healthy Feet and You* at www.cawc.net/index.php/public/feet/

Appendix C Self-Administered Foot Risk Screening Questionnaire

Name: _____ ID#:_____ Date: _____

Take this test to see if you are at risk for foot ulcers or amputation.

1. Carefully read each statement that *best describes your feet.*
2. If the entire statement is true, check yes.
3. If the entire statement is false, check no.
4. Now, add the number of points and compare your total with the points in the key (listed below) to determine if your feet are at risk.

Please answer all statements.

Statements	Yes	No
I have total feeling in my feet. (This means my feet are not numb)	_____(1)	_____(3)
My feet have some or no feeling. (This means my feet are partially or totally numb)	_____(3)	_____(1)
My feet are *normal* in shape. (I do not have a high or low arch. I have no hammertoe or abnormal shape to my toes or foot).	_____(1)	_____(2)
My feet are abnormal in shape. (I have a high or low arch. I have a hammertoe or abnormal shape to my toes or foot, or was told I had a Charcot foot).	_____(2)	_____(1)
In the **past** *I have had* a foot ulcer (deep sore) on the bottom of my foot,	_____(8)	_____(1)
I **currently** have a foot ulcer (deep sore) on the bottom of my foot, or my toe/foot has been amputated.	_____(8)	_____(1)
Total Points		
Key: 6 to 8 points = grade 0 risk 10 points = grade 1 risk 12 points = grade 2 risk 13+ points = grade 3 risk		

Appendix D Summary of Diabetes Self-Care Activities

Name: _____ ID #:_____ Date: _____

Instructions

The questions below ask you about your diabetic self-care foot care activities performed during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Please read each question carefully. To answer each question, please circle the number under each question that corresponds to the number of times you did what the question is asking.

On how many of the last SEVEN DAYS did you check your feet? 0 1 2 3 4 5 6 7
On how many of the last SEVEN DAYS did you inspect the inside of you shoes? 0 1 2 3 4 5 6 7
On how many of the last SEVEN DAYS did you wash your feet? 0 1 2 3 4 5 6 7
On how many of the last SEVEN DAYS did you soak your feet? 0 1 2 3 4 5 6 7
On how many of the last SEVEN DAYS did you dry between your toes after washing? 0 1 2 3 4 5 6 7

Appendix E Demographic Data Sheet

Full Name _____ Identification Number _____ Facility Number _____

Date of Birth_____ Male_____ Female_____ Transgender_____

1. Place an X on the line to indicate your marital status?

Married_____

Single_____

Widowed_____

Divorced_____

Separated _____

Common law marriage _____

2. Are you a U.S. Veteran?

Yes____

No_____

3. Are you Hispanic?
Yes _____
No_____

4. Place an X one the line next to the name of the race, which you consider yourself to be.
Asian____
Native Hawaiian or other Pacific Islander ___
Black/African American____
White____
American Indian/Alaska Native_____
Other (write on the line) _____

5. Place an X on the line next to the highest level of education you did finish.
Less than High School_____
Graduated High School/GED_____
Trade/Technical School_____
Some College No Degree_____
Associate Degree_____
Bachelor Degree_____
Advanced Degree (Masters' or Ph. D.)_____

6. At this time, do you have Health Insurance? (Place an X on the line)
Yes _____
No_____

7. If you answered Yes to # 6, place an X on the line to indicate what kind of Health Insurance you do have.
Private employer paid_____
Private self-paid_____
Medicaid_____
Medicare_____
Tricare_____
Other (Write in) _____

8 Place an X next to the choice that best describes your current work status?
Full-time_____
Part-time_____
Retired_____
Student_____
Not currently employed_____
Other (write in) _____

9. Place an X next to the type of Diabetes you have
Diabetes Type 1_____
Diabetes Type 2_____
Don't know _____

10. What type of medicine do you take for your Diabetes?
Insulin _____
Pills _____

11. How many years have you had Diabetes?

Years_____

12. Have you had anyone teach you about Diabetic Foot Care in the past year?
Yes. _____
No_____

13. Have you had a Diabetic Foot Assessment during the past year?
Yes _____
No _____

14. How long have you been without a home or your own place to live?
Write in the number of years_____

Appendix F IRB Initial Approval

utmb Health

Working together to work wonders.

Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158

26-Oct-2017

MEMORANDUM

TO: Katherine Strout
SON Nursing PhD Program 152200

[redacted]

FROM: Elena Sbrana, MS, PhD
Vice-Chairman, IRB #2

RE: Initial Study Approval

IRB #: IRB # 17-0180

TITLE: The Effects of Diabetic Foot Care Education on Assessments and Self-Care among Adults with Diabetes Mellitus Experiencing Homelessness

DOCUMENTS: Research Protocol Version 2 9.10.17
Consent Form Version 3 10.23.17
Diabetic Risk Assess Package Version 2
Recruitment Flyer
Educational Checklist
Foot Risk Screening Questionnaire Version 1 4/26/2017

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **13-Oct-2017**. Having met all applicable requirements, the research protocol is approved for a period of 12 months. The approval period for this research protocol begins on **26-Oct-2017** and lasts until **13-Oct-2018**.

The research protocol cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to the expiration date.

The approved number of subjects to be enrolled is **45.00**. The IRB considers a subject to be enrolled once s/he signs a Consent Form. If, additional subjects are needed, you first must obtain permission from the IRB to increase the approved sample size.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

1. The research will be conducted in homeless shelters, transitional housing units, and safe havens for adults experiencing homelessness in East Texas

Appendix G Recruitment Flyer

Do you have Diabetes Type 1 or Diabetes Type 2

Do you have problems with your feet?

Would you like to learn how to better care for your feet?

Would you like to learn how to reduce your risk for diabetic foot complications?

Are you experiencing homelessness?

Please contact Katherine Strout MSN, RN

[redacted]

[redacted]

You may qualify to participate in her study about teaching diabetic foot care, performing diabetic foot assessments, risk assessments, and reducing risk for diabetic foot ulcers and amputations

Appendix H Site #1 Permission

Mr. Eric Burger
Executive Director
HiWay 80 Rescue Mission
P.O. Box 3223
Longview, TX 75606

March 29, 2017

I, Eric Burger, Executive Director Hi Way 80 Rescue Mission, grant Ms. Katherine Strout MSN, RN nursing doctoral student at the University of Texas at Medical Branch permission to conduct her dissertation research at the Hi Way 80 Rescue Mission Men's and Women's Shelters in Longview, TX. Ms. Strout may also has my permission conduct her dissertation at HiWay men's and women's shelters and at the Gateway to Hope in Tyler, TX.

Ms. Strout's' dissertation is entitled "The Effects of Diabetic Foot Education on Assessment and Self-Care among Adults with Diabetes Experiencing Homelessness".

With kindest regards,

[redacted]

Eric Burger
Executive Director

Appendix I Site #2 Permission

Katherine Strout, MSN, RN PhD.
Student UTMB GSBS
[redacted]

Jennifer Laurent
Executive Director
Randy Sams' Outreach Shelter
Be the Blessing Bakery
402 Oak Street Texarkana, TX 75501

January 31, 2018

I, Jennifer Laurent, Executive Director Randy Sams' Outreach Shelter, grant Ms. Katherine Strout MSN, RN, nursing doctoral student at the University of Texas at Medical Branch (UTMB), permission to conduct her dissertation research at Randy Sams' Outreach Shelter.

The title of the dissertation is "The Effects of Diabetic Foot Education on Assessments and Self- Care among Adults with Diabetes Mellitus Experiencing Homelessness." Permission to conduct the study has been granted by the Institutional Review Board at UTMB. The IRB study number is 17-0180.

Sincerely,

Jennifer Laurent, Executive Director [redacted] Date 1-31-18

Appendix J Site #3 Permission

Sister Helen Johnson
Director House of Hope
Women's Shelter
Longview, TX

May 21, 2018

I. Sister Helen Johnson, Director, House of Hope Women's Shelter, grant Ms. Katherine Strout MSN, RN, nursing doctoral student at The University of Texas at Medical Branch (UTMB), permission to conduct her dissertation research at the House of Hope Women's' Shelter, Longview, TX.

The dissertation is entitled *"The Effects of Diabetic Foot Education on Assessments and Self-Care among Adults with Diabetes Mellitus Experiencing Homelessness."* The Institutional Review Board at UTMB has assigned study number 17-0180 to the dissertation research, thus granting permission for the study to be conducted.

M. Terese Verklan, PhD, CCNS, RNC, FAAN, chairs my dissertation committee and oversees my research activities. Dr. Verklan is available to answer any question that may arise during the study period. Dr. Verklan's email address is mtverkla@utmb.edu.

Thank you very much for agreeing to participate in my dissertation research.

Sincerely,
Katherine Strout MSN, RN
Nursing doctoral student, UTMB
Galveston TX
krstrout@utmb.edu
903.407.6000

Signature: Sister Helen Johnson Date: May 21, 2018

Investigator Signature: Kathie Strout Date: 5-21-2018

Appendix K IRB Amendment Request Approval

utmb Health

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Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158
Submission Page

31-May-2018

MEMORANDUM

TO: Katherine Strout
SON Nursing PhD Program 152200

[redacted], CIP

FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Contingent Amendment/Miscellaneous Request Approval

IRB Number: IRB # 17-0180

TITLE: The Effects of Diabetic Foot Care Education on Assessments and Self-Care among Adults with Diabetes
Mellitus Experiencing Homelessness

The **Amendment** request to the above referenced study has been reviewed via an expedited review procedure on .

The IRB found the modifications to your research project to be approvable, **contingent** upon your satisfactory response to the following stipulations:

GENERAL CHANGES:

* Please upload all recruitment site approval letters received to date.

* Please confirm that the approval letter from each community health clinic will be submitted via infoEd to the IRB prior to enrolling subjects at that facility.

Please do not revise the originally reviewed study documents to include changes other than those requested by the IRB and outlined above.

In order for your response to be reviewed, please submit your response via InfoEd by selecting the blue respond link within the submission package. Select the appropriate response type from the drop-down

menu. Select the "edit" button next to the document needing revision (documents appear in the light blue fields at the top).

Please be advised if you do not respond to these stipulations **within 60 days**, this request may be withdrawn from further IRB consideration.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

Appendix L Response to Stipulations

31-May 2018

TO: Dwight Wolf, MD Chairman, IRB #2

RE: Response to Contingent Amendment/Miscellaneous Request Approval

FROM: Katherine Strout Study #17-0180

1. I have uploaded all recruitment site approvals received to date. I have approval from three sites, Burger, Laurent, and Johnson.

2. I confirm that the approval letter from each community health clinic will be submitted via InfoEd to the IRB prior to enrolling subjects at that facility.

3. I will not revise the originally reviewed study documents to include changes other than those requested by the IRB and outlined above.

Respectfully,

Katherine Strout

Appendix M IRB Approval

utmb Health

Working together to work wonders.™

Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158
Submission Page

31-May-2018

MEMORANDUM

TO: Katherine Strout
SON Nursing PhD Program 152200

[redacted], CIP

FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Amendment/Miscellaneous Request Approval

IRB #: IRB # 17-0180

TITLE: The Effects of Diabetic Foot Care Education on Assessments and Self-Care among Adults with Diabetes
Mellitus Experiencing Homelessness

DOCUMENTS: Protocol Version 2, dated 05/11/2018
Research Consent Form Version 5, dated 05/11/2018

The **Protocol/Consent Form Changes Response** request to the above referenced study has been reviewed via an expedited review procedure on **31-May-2018** and approved by the UTMB Institutional Review Board (IRB) in accordance with 45 CFR 46.110(a)-(b)(2).

The approval period for this modified research protocol begins on **31-May-2018**. Amendment approvals do not change the approval period of the protocol. Therefore, the expiration date will remain the same as was determined for the protocol at the time of initial or continuing review.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

Description of Changes/Submission

Modifications to the protocol include: 1. Expand recruitment sites to include East Texas community healthcare clinics; 2. Reduce gift card amount from $20 to $10; 3. Letters for approved recruitment sites: 1) Randy Sams' Outreach Shelter [Jennifer Laurent]; House of Hope Women's Shelter [Sister Helen Johnson] and Hi Way 80 Rescue Mission [Eric Burger]; and 4. Revised consent.

Appendix N IRB Continuation Approval

utmb Health

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Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158
Submission Page

07-Sep-2018

MEMORANDUM

TO: Katherine Strout
SON Nursing PhD Program 152200

[redacted]

FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Final Approval of Continuing Review

IRB #: IRB # 17-0180

TITLE: The Effects of Diabetic Foot Care Education on Assessments and Self-Care among Adults with Diabetes
Mellitus Experiencing Homelessness

DOCUMENTS: Research Protocol Version 3 5/15/18
Research Consent Version # 5 Date 5/11/18

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **07-Sep-2018** in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research protocol is approved for continuation for a period of 12 months. The approval period for this research protocol begins on **07-Sep-2018** and lasts until **07-Sep-2019**.

The research protocol cannot continue beyond the approval period without continuing review and approval by the IRB. In order to avoid a lapse in IRB approval, the Principal Investigator must apply for continuing review of the protocol and related documents before the expiration date. A reminder will be sent to you approximately 90 days prior to the expiration date.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

General Instructions

To maintain IRB approval in good standing, please observe the following requirements:

1. All subjects must sign the consent form before undergoing any research study procedures, including screening procedures. A photocopy of the signed consent form(s) should be given to each participant. The copy of the consent form(s) bearing original signature(s) should be kept with other records of this research for at least six years past the completion of the research study. The IRB considers a subject to be enrolled once s/he signs a Consent Form.
2. Obtain prior IRB approval for any modifications including addition of new recruiting materials, changes in research personnel or site location, sponsor amendments or other changes to the protocol or associated documents. Only those changes that are necessary to avoid an immediate apparent hazard to a subject may be implemented without prior IRB approval.
3. Report all adverse events, protocol violations, DSMB reports, external reports and study closures promptly to the IRB.
4. Make study records available for inspection. All research-related records and documentation may be inspected by the IRB for the purpose of ensuring compliance with UTMB policies and procedures and federal regulations governing the protection of human subjects. The IRB has authority to suspend or terminate its approval if applicable requirements are not strictly adhered to by all research study personnel.
5. When enrolling subjects who do not speak or read English, a bilingual translator must be available to facilitate communications between research personnel and a subject.

Appendix O IRB Approval

utmb Health

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Institutional Review Board
301 University Blvd.
Galveston, TX 77555-0158
Submission Page

23-Apr-2019

MEMORANDUM

TO: Katherine Strout
SON Nursing PhD Program 152200

[redacted]

FROM: Dwight Wolf, MD
Chairman, IRB #2

RE: Amendment/Miscellaneous Request Approval

IRB #: IRB # 17-0180

TITLE: The Effects of Diabetic Foot Care Education on Assessments and Self-Care among Adults with Diabetes
Mellitus Experiencing Homelessness

DOCUMENTS: Research Protocol Version 5 date 2/01/2019
Consent Form Version 7 Date 12/13/2018

The **Miscellaneous Response** request to the above referenced study has been reviewed via an expedited review procedure on **18-Apr-2019** and approved by the UTMB Institutional Review Board (IRB) in accordance with 45 CFR 46.110(a)-(b)(2).

The approval period for this modified research protocol begins on **18-Apr-2019**. Amendment approvals do not change the approval period of the protocol. Therefore, the expiration date will remain the same as was determined for the protocol at the time of initial or continuing review.

If you have any questions, please do not hesitate to contact the IRB office via email at IRB@utmb.edu.

Description of Changes/Submission

Protocol:

Adding additional geographical location for the recruitment of subjects from East Texas only and add to my East Texas area, the geographical locations of Northwest Louisianna, North Texas, South East Texas, Central Texas. The rationale for my request is that my data collection has stalled. My last cohort participated during October, 2018. I believe there are a couple of reasons for this occurrence, 1.) East Texas has few recruitment sites, and 2.) East Texas lacks heavily populated cities simlar to those in other areas of Texas and Northwest Louisianna. For example, Dallas/Ft.Worth, Houston, and in Louisianna Shreveport/Bossier City I believe that by expanding my geographical areas for recruitment sites, the change will allow for greater access to potential participants, and solve the problem I'm experiencing with data collection. I will need to revise the informed consent document to include all areas for recruitment, North, Central, South, and East Texas as well as Northwest Louisianna. I do not know if the change is administrative and/or editorial.
Consent:
The proposed change consists of adding Southeast, Central, North, and/or East Texas as well as and/or Northwest Louisiana.

Appendix P Point List

Week 1: Point List Has anyone taught you how to take care of your feet?

A. Talking Points from the Pretest/Posttest in the Participant Package
While we are getting situated here, I'd like to ask you a few questions about diabetes and foot problems.

1. Do you think diabetes mellitus increases a person's risk of foot amputation by a lot or a little?
2. Do you think that a foot injury is one of the most common causes for skin ulcers on the foot?
3. What are some risk factors for foot ulcers in people with diabetes?
4. If you have a health provider, do they let you know how often to have your feet examined?
5. How often should a person with diabetes check their feet?
6. If a person with diabetes has a foot ulcer that has not healed within a few days when should that person see a doctor?

That's great! Now I'd like to talk about how to take care of your feet to prevent problems like open wounds that can lead to infections, gangrene, and amputations.
If you'll turn to the page **"Care Tips for the Feet"** I'll be discussing and demonstrating from the information on this page. Please feel free to ask any questions you may have during the class.

B. Diabetic Foot Care

1. Anyone with diabetes needs to have a foot examination at least every year. It is also important to find out if your feet are either low or high risk for developing diabetic foot ulcer and/or amputation. Your participation in this study ensures that you have had a foot examination for this year and that your foot risk has been evaluated.
2. Risk factors for developing a foot ulcer and/or amputation are:
    a. Previous or current foot ulcer.
    b. Loss of normal feeling in one or both feet
    c. c. Abnormally shaped foot, including calluses on the bottom of the feet, bunions, and/or curled toes, and/or high or low foot arches.
    d. Previous lower limb amputation.
3. The best way to prevent foot ulcers is to take care of your feet every day by following these simple guidelines. You have been provided with the supplies that you will need to do diabetic foot care in your diabetic foot care bag. I'll demonstrate how to do diabetic foot care, then I'll have you all show me how to diabetic foot care.

a. Check the top and bottom of your feet every day. Also check your toes and in between your toes. If you cannot see the bottom of your feet use a mirror or ask someone else to look at the bottom of your feet. These are the things you will be looking for.

1. Look for red spots, blisters or any open areas.
2. Look inside your shoes for any areas that are discolored. Also look for stones or pebbles that could cause pressure on the bottom of your feet.

b. Protect your feet-always wear shoes

1. Wear shoes that fit well and that support your feet and are not too tight. We can replace your shoes today if your shoes don't fit properly. Avoid going barefoot or wearing sandals or other types of open toed shoes.
2. Do not wear shoes that cause reddened or sore areas on your feet or toes. Red and sore spots on your feet and/or toes can lead to blisters, hot spots, calluses, bunions, which increases your risk for developing a foot ulcer. We need to replace your shoes today if they are making your feet sore or causing red spots.

c. Keep the skin on your feet and toes clean and soft. Do the following everyday:

1. Wash your feet every day using warm water.
2. Dry your feet well and dry in between your toes.

d. Don't hurt your feet with nail clippers or razors.

1. Cut your nails straight across. Get help cutting your nails if needed.
2. Don't cut calluses, instead go to the clinic to have calluses assessed.

C. Point List to explain how to use the Diabetic Foot Care Log

1. I need you to use the diabetic foot care log to record how many times you do any part of diabetic foot care during the next 7 days. Day 1 is today and Day 7 is when we will meet for the next class. You need to bring your diabetic foot care log with you to the next class.
2. On the left side of the form are the list of things you need to do every day to take care of your feet every day. These are the same things we talked about today, to care for your feet. What I'd like for you to do is to put an x in the box next to what you did that day to care for your feet. For example if you checked your feet, looked inside your shoes, washed your feet, put lotion on your feet, and dried between your toes.
3. Then bring the diabetic foot care log with you to the next class.

D. How to use the items in the Diabetic Foot Care Bag

1. The items in your diabetic foot care bag are for you to have what you need to take care of your feet every day. You will take the bag with you and bring it back with you to the next class.

E. Distribute $20 Walmart gift cards

Week 2 Point List

A. This week we will focus two risk factors for developing diabetic foot ulcers; pressure on the feet and abnormalities of the toes. Plus we will talk about how to decrease your risk and prevent injuries to your feet.

1. Please turn to the pages in your Participant package that has **pictures the diabetic foot**. I have extra packets if you need one. Please feel free to ask questions at any time during the class.
2. If pressure builds up on the bottom of your feet or the tops of your toes, you can develop a foot ulcer, open sore. If you don't have feeling in your feet open sores can develop without you knowing about it. This is why it so very important to check your feet every day and take care of your feet every day.
3. If your shoes don't fit properly and cause blisters, red spots, or thick skin to develop, your shoes need to be replaced, and we can do that today.
4. PI demonstrates on her own feet how to check the feet. Now, I'd like for you to take off your shoes and socks and look at your feet for any red spots, blisters, or thick skin. Have you ever had a sore on your foot that too more than two weeks to heal? Sores on the feet need immediate attention. You can write what you found on the page in your packet **"Presence/History of Foot Ulcers."** Good job! Do you have any questions? We are going to examine the toes next, and I have shoe covers you can put on for now.
5. Now let's turn to the page in your packet that describes problems with the toes. Notice, how the toes are curled, some worse than others. Having curled toes can happen by wearing shoes that do not fit properly. The reason having curled toes is a problem is that pressure can build up on the tip of the toe and also on the top of the toe where it is curled.
6. PI demonstrates on her own toes how to check the toes. Now, I'd like for you to look at your own toes and I'll help you identify any abnormalities. Toe abnormalities can be recorded on the page entitled **"Structural Abnormalities**"

B. Ways to decrease your risk for foot ulcers and prevent injuries to your feet

1. The best way to lessen your risk for foot ulcers and to prevent injuries to your feet is to take care of your feet every day by following these simple guidelines. You have been provided with the supplies that you will need to do diabetic foot care in your diabetic foot care bag. I'll demonstrate how to do diabetic foot care, then I'll have you all show me how to take care of your feet.

a. Check the top and bottom of your feet every day. Also check your toes and in between your toes. If you cannot see the bottom of your feet use a mirror or ask someone else to look at the bottom of your feet. These are the things you will be looking for.

1. Look for red spots, blisters or any open areas.
2. Look inside your shoes for any areas that are discolored. Also look for stones or pebbles that could cause pressure on the bottom of your feet.

b. Protect your feet-always wear shoes

1. Wear shoes that fit well and that support your feet and are not too tight. We can replace your shoes today if your shoes don't fit properly.

2. Avoid going barefoot or wearing sandals or other types of open toed shoes.
3. Do not wear shoes that cause reddened or sore areas on your feet or toes. Red and sore spots on your feet and/or toes can lead to blisters, hot spots, calluses, bunions, which increases your risk for developing a foot ulcer. We need to replace your shoes today if they are making your feet sore or causing red spots.

c. Keep the skin on your feet and toes clean and soft. Do the following everyday:

1. Wash your feet every day using warm water.
2. Dry your feet well and dry in between your toes.

d. Don't hurt your feet with nail clippers or razors.

1. Cut your nails straight across. Get help cutting your nails if needed.
2. Don't cut calluses, instead go to the clinic to have calluses assessed.

C. Point List to explain how to use the Diabetic Foot Care Log

1. I need you to use the diabetic foot care log to record how many times you do any part of diabetic foot care during the next 7 days. Day 1 is today and Day 7 is when we will meet for the next class. You need to bring your diabetic foot care log with you to the next class.
2. On the left side of the form are the list of things you need to do every day to take care of your feet every day. These are the same things we talked about today, to care for your feet. What I'd like for you to do is to put an x in the box next to what you did that day to care for your feet. For example if you checked your feet, looked inside your shoes, washed your feet, put lotion on your feet, and dried between your toes.
3. Then bring the diabetic foot care log with you to the next class.

D. How to use the items in the Diabetic Foot Care Bag

1. The items in your diabetic foot care bag are for you to have what you need to take care of your feet every day. You will take the bag with you and bring it back with you to the next class.

E. Distribute $20 Walmart gift cards

Week 3 Point List

This week we will focus two more risk factors for developing diabetic foot ulcers; poor circulation in the feet, and numbness if the feet. I'd like to teach you how to check the pulses in your feet and how to check for numbness in your feet. We will also discuss the importance of taking care of your feet by doing diabetic foot care every day.

A. Poor circulation in the feet is a risk factor for developing foot ulcers. Many people with diabetes experience discomfort in their legs and feet, with symptoms such as cramping, numbness, tingling, and pain. The cause may be poor circulation, nerve

damage, or both. High blood sugar may be the cause of both conditions. Please feel free to ask any questions during the class.

First I'd like to ask:

1. Do you have pain in the calf when walking or on exertion that goes away with resting for 10 minutes or so?
2. This is called intermittent claudication and is a symptom of poor blood flow in the arteries in the feet and/or legs. You may experience these symptoms of poor blood flow, such as; numbness, coldness, or tingling of the legs and feet; and slow healing of cuts and sores on the affected extremities. If you have a cut or sore on your feet that does not heal within three days you need to have it assessed by a doctor or advanced practice nurse. Cuts and sores that do not heal can easily become infected or lead to a foot ulcer,
3. Next I'd like to teach you how to check the pulses in your feet. PI demonstrates checking pedal pulses, both posterior tibial and the dorsalis pedis on both feet. You'll need to remove your shoes and socks, and I have shoe covers if you need a pair.
4. There are two pulses in each foot. One is one the top of the foot and the other is near the ankle bone on the inner part of the foot. First place your first two fingers on the top of the right foot near the tendon of the big toe. Then feel for a pulse, you may need to move your fingers around a bit, I'll help you to find your pulse on the top of your foot. I may need to mark the spot with a pen if that is alright with you. Great what did you feel? Strong, weak, absent? Now, turn to the page entitled **Circulation** in your participant package. I have extras if you need one. Now, you'll mark either present or absent for the pulse on the top of the right foot. Next we will do the same for the left foot. I'll help you. Now, mark either present or absent for the pulse on the top of the left foot. Super! Now let's check the pulses near the ankle. Place your first two fingers near the right ankle bone. I can help you all find this one, sometimes this pulse is hard to find. Great! What did you feel? Strong, weak, or absent? You can make either present or absent for the pulse near the ankle bone. Super, now we'll do the same thing to check for the pulse near the left ankle bone. Good job! What did you feel? Strong, weak, absent? Go ahead and mark either present or absent for the pulse near the left ankle.
5. Damage to the nerves in the feet can be common for a person with diabetes and cause numbness, tingling in the feet. These types of changes in the feet can change the way you walk, and impair your balance and coordination. In turn, the changes related to nerve damage can cause foot deformities, a loss of sensation in the feet, leading to blisters and sores that you don't feel.
6. I'd like to teach you how to check for numbness in your feet. Turn to the page **"Protective Sensation"** in your participant package. I have extras if you need one. First, to do this we will use a piece of fishing line to test the feet for numbness. This is what we will use and if you need fishing line I have extra. There is fishing line in you diabetic foot care bag. First I'll show you on my feet. I'll take the fishing line and touch the tip of my big toe with it. Then I'll say if I

felt it or not. Then I'll repeat the same procedure on three spots of the bottom of my feet. Now, if you are comfortable you can do this with someone else in the group. If not, that's o.k. you can assess your own feet.

B. Ways to decrease your risk for foot ulcers and prevent injuries to your feet

1. If you have poor circulation in your feet and/or numb feet, the best way to lessen your risk for foot ulcers and to prevent injuries to your feet is to take care of your feet every day by following these simple guidelines. You have been provided with the supplies that you will need to do diabetic foot care in your diabetic foot care bag. I'll demonstrate how to do diabetic foot care, then I'll have you all show me how to take care of your feet.

a. Check the top and bottom of your feet every day. Also check your toes and in between your toes. If you cannot see the bottom of your feet use a mirror or ask someone else to look at the bottom of your feet. These are the things you will be looking for.

1. Look for red spots, blisters or any open areas.
2. Look inside your shoes for any areas that are discolored. Also look for stones or pebbles that could cause pressure on the bottom of your feet.

b. Always protect your feet-by wearing shoes and socks

1. Wear shoes that fit well and that support your feet and are not too tight. We can replace your shoes today if your shoes don't fit properly.
2. Avoid going barefoot or wearing sandals or other types of open toed shoes.
3. Do not wear shoes that cause reddened or sore areas on your feet or toes. Red and sore spots on your feet and/or toes can lead to blisters, hot spots, calluses, bunions, which increases your risk for developing a foot ulcer. We need to replace your shoes today if they are making your feet sore or causing red spots.

c. Keep the skin on your feet and toes clean and soft. Do the following everyday:

1. Wash your feet every day using warm water.
2. Dry your feet well and dry in between your toes.

d. Don't hurt your feet with nail clippers or razors.

1. Cut your nails straight across. Get help cutting your nails if needed.
2. Don't cut calluses, instead go to the clinic to have calluses assessed.

C. Point List to explain how to use the Diabetic Foot Care Log

1. I need you to use the diabetic foot care log to record how many times you do any part of diabetic foot care during the next 7 days. Day 1 is today and Day 7 is when we will meet for the next class. You need to bring your diabetic foot care log with you to the next class.
2. On the left side of the form are the list of things you need to do every day to take care of your feet every day. These are the same things we talked about today, to care for your feet. What I'd like for you to do is to put an x in the box next to what you did that day to care for your feet. For example if you checked your feet, looked inside your shoes, washed your feet, put lotion on your feet, and dried between your toes.
3. Then bring the diabetic foot care log with you to the next class.

D. How to use the items in the Diabetic Foot Care Bag

1. The items in your diabetic foot care bag are for you to have what you need to take care of your feet every day. You will take the bag with you and bring it back with you to the next class.

E. Distribute $20 Walmart gift cards

Week 4 Point List

Since this is our last week of classes, we will put it altogether. We will focus on the diabetic foot assessment and diabetic foot care. Please feel free to ask any questions during the class.

A. First let's go through the diabetic foot assessment. I'll demonstrate one first including, assessing the skin on the feet and toes, and checking toes for curling. Then I'll check for circulation and numbness in my feet.

1. Please turn to the pages in your Participant package that has **pictures the diabetic foot**. I have extra packets if you need one. Please feel free to ask questions at any time during the class.
2. If pressure builds up on the bottom of your feet or the tops of your toes, you can develop a foot ulcer, open sore. If you don't have feeling in your feet open sores can develop without you knowing about it. This is why it so very important to check your feet every day and take care of your feet every day.
3. If your shoes don't fit properly and cause blisters, red spots, or thick skin to develop, your shoes need to be replaced, and we can do that today.
4. PI demonstrates on her own feet how to check the feet. Now, I'd like for you to take off your shoes and socks and look at your feet for any red spots, blisters, or thick skin. Have you ever had a sore on your foot that too more than two weeks to heal? Sores on the feet need immediate attention. You can write what you found on the page in your packet **"Presence/History of Foot Ulcers."** Good job! Do you have any questions? We are going to examine the toes next, and I have shoe covers you can put on for now.
5. Now let's turn to the page in your packet that describes problems with the toes. Notice, how the toes are curled, some worse than others. Having curled toes can happen by wearing shoes that do not fit properly. The reason having curled toes is a problem is that pressure can build up on the tip of the toe and also on the top of the toe where it is curled.
6. PI demonstrates on her own toes how to check the toes. Now, I'd like for you to look at your own toes and I'll help you identify any abnormalities. Toe abnormalities can be recorded on the page entitled **"Structural Abnormalities**"
7. There are two pulses in each foot. One is one the top of the foot and the other is near the ankle bone on the inner part of the foot. First place your first two fingers on the top of the right foot near the tendon of the big toe. Then feel for a pulse, you may need to move your fingers around a bit, I'll help you to find your pulse on the top of your foot. I may need to mark the spot with a pen if that is alright with you. Great what did you feel? Strong, weak, absent? Now, turn to the page entitled **Circulation** in your participant package. I have extras if you need one. Now, you'll mark either present or absent for the pulse on the top of the right foot.

Next we will do the same for the left foot. I'll help you. Now, mark either present or absent for the pulse on the top of the left foot. Super! Now let's check the pulses near the ankle. Place your first two fingers near the right ankle bone. I can help you all find this one, sometimes this pulse is hard to find. Great! What did you feel? Strong, weak, or absent? You can make either present or absent for the pulse near the ankle bone. Super, now we'll do the same thing to check for the pulse near the left ankle bone. Good job! What did you feel? Strong, weak, absent? Go ahead and mark either present or absent for the pulse near the left ankle.

8. Damage to the nerves in the feet can be common for a person with diabetes and cause numbness, tingling in the feet. These types of changes in the feet can change the way you walk, and impair your balance and coordination. In turn, the changes related to nerve damage can cause foot deformities, a loss of sensation in the feet, leading to blisters and sores that you don't feel.
9. I'd like to teach you how to check for numbness in your feet. Turn to the page **"Protective Sensation"** in your participant package. I have extras if you need one. First, to do this we will use a piece of fishing line to test the feet for numbness. This is what we will use and if you need fishing line I have extra. There is fishing line in you diabetic foot care bag. First I'll show you on my feet. I'll take the fishing line and touch the tip of my big toe with it. Then I'll say if I felt it or not. Then I'll repeat the same procedure on three spots of the bottom of my feet. Now, if you are comfortable you can do this with someone else in the group. If not, that's o.k. you can assess your own feet.

B. Diabetic Foot Care

1. Anyone with diabetes needs to have a foot examination at least every year. It is also important to find out if your feet are either low or high risk for developing diabetic foot ulcer and/or amputation. Your participation in this study ensures that you have had a foot examination for this year and that your foot risk has been evaluated.
2. Risk factors for developing a foot ulcer and/or amputation are:
    a. Previous or current foot ulcer.
    b. Loss of normal feeling in one or both feet
    c. Abnormally shaped foot, including calluses on the bottom of the feet, bunions, and/or curled toes, and/or high or low foot arches.
    d. Previous lower limb amputation.
3. The best way to prevent foot ulcers is to take care of your feet every day by following these simple guidelines. You have been provided with the supplies that you will need to do diabetic foot care in your diabetic foot care bag. I'll demonstrate how to do diabetic foot care, then I'll have you all show me how to diabetic foot care. .

a. Check the top and bottom of your feet every day. Also check your toes and in between your toes. If you cannot see the bottom of your feet use a mirror or ask someone else to look at the bottom of your feet. These are the things you will be looking for.

1. Look for red spots, blisters or any open areas.

2. Look inside your shoes for any areas that are discolored. Also look for stones or pebbles that could cause pressure on the bottom of your feet.

b. Protect your feet-always wear shoes

1. Wear shoes that fit well and that support your feet and are not too tight. We can replace your shoes today if your shoes don't fit properly.
2. Avoid going barefoot or wearing sandals or other types of open toed shoes.
3. Do not wear shoes that cause reddened or sore areas on your feet or toes. Red and sore spots on your feet and/or toes can lead to blisters, hot spots, calluses, bunions, which increases your risk for developing a foot ulcer. We need to replace your shoes today if they are making your feet sore or causing red spots.

c. Keep the skin on your feet and toes clean and soft. Do the following everyday:

1. Wash your feet every day using warm water.
2. Dry your feet well and dry in between your toes.

d. Don't hurt your feet with nail clippers or razors.

1. Cut your nails straight across. Get help cutting your nails if needed.
2. Don't cut calluses, instead go to the clinic to have calluses assessed.

C. Now I'd like you to turn to the page entitled "Self-Care Knowledge and Behavior."

Please check either yes or no to each question as I read the questions aloud. If you need a participant package I have extras. After you answer each question we can talk about your answers.

1. The PI will read aloud each question on the Self-Care Knowledge and Behavior page. There are ten items pertaining to diabetic foot assessment and care. The response is either yes or no.

Following the discussion the PI will distribute the $20 Walmart gift card and the extra incentive to those who attended all 4 classes. And thank each participant.

Appendix Q Diabetic Foot Care Log Example

Use this log to record how many time you performed any part of diabetic foot care during the week.

Put a checkmark in the box next to the behavior for each day you performed the foot care activity.

For example, if you checked your feet every day, put an X in each box for Day 1 to Day 7 next to "Check your feet."

If you soaked your feet three days, then put a check mark in the boxes next to "Soak the feet" on the day you performed the activity.

Diabetic foot care behavior	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	TOTAL
Check your feet	×	×	×	×	×	×	×	7
Look inside the shoes								
Wash the Feet								
Soak the feet	×			×	×			3
Dry between the toes								

Appendix R Diabetic Foot Care Log

Use this log to record how many time you performed any part of diabetic foot care during the week

Put a checkmark in the box next to the behavior for each day you performed the foot care activity.

For example, if you checked your feet every day, put an X in each box for Day 1 to Day 7 next to "Check your feet."

If you soaked your feet three days, then put a check mark in the boxes next to "Soak the feet" on the day you performed the activity.

Diabetic foot care behavior	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	TOTAL
Check your feet								
Look inside the shoes								
Wash the Feet								
Soak the feet								
Dry between the toes								

Appendix S Informed Consent Form #1

IRB Approved
26-Oct-2017-
13-Oct-2018

The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

Protocol Title: The effects of diabetic foot education on assessments and self-care among adults with diabetes mellitus experiencing homelessness

IRB Number: 17-0180

Principal Investigator: Katherine R. Strout MSN, RN

301 University Blvd. Galveston, TX 77555

(903) 503-8113

Why am I being asked to take part in this research study?

You are being asked to take part in this study because adults with diabetes mellitus (DM) experiencing homelessness often lack access to diabetic foot care education Diabetic foot care education has been shown to decrease a person's risk for developing diabetic foot ulcers and lower limb amputation. Adults with DM experiencing homelessness are at high risk for developing diabetic foot ulcers and lower limb amputations.

What is the purpose of this research study?

The purpose of the study is to investigate the effects of RN-led diabetic foot education have on (a.) your ability to assess your own risk for diabetic foot ulcer and/or lower limb amputation, (b) your ability to do diabetic foot self-care every day, (c) your clinical diabetic foot assessments and (d) your clinical diabetic ulcer and amputation risk scores.

How many people will take part in this study?

About 45 people who are adults with diabetes mellitus experiencing homelessness in East Texas will take part in this study.

What procedures are involved as part of this research study?

If you agree to take part, you will be asked to sign this consent form and complete the following procedures.

1. To fill out a form to answer questions about yourself, your diabetes, previous diabetic foot care education and diabetic foot assessment, and how long you have been without your own home. You will be asked to fill out this form one time after signing the consent form.

2. To fill out a form to answer questions about how you would rate your risk for developing diabetic foot ulcer and/or lower limb amputation. You will fill out this form two times. Once at the first study visit, ad once at the fourth study visit.

3. To fill out a form to answer questions about how many times during the week you do diabetic foot care. You will fill out this form four times. Once at the first study visit and then at each of the three remaining study visits.

4. To allow the PI, Katherine Strout, MSN, RN, to perform four diabetic foot assessments, including a risk assessment for diabetic foot ulcer and/or lower limb amputation. The first assessment will be done at the first study visit, and then at each of the three remaining study visits

5. To come to four study visits in which the PI will teach you about diabetic foot care, diabetic foot assessment, and how to reduce your risk for developing a diabetic foot ulcer and/or lower limb amputation. There are four study visits in this protocol; each lasting approximately one hour.

What are the possible risks for choosing to participate in this research study?

The known psychological risk, such as embarrassment about the condition of your feet, and/or potential discomfort may be experienced by subjects when they need to take off their shoes and socks for the PI to perform the diabetic foot assessment. In order to minimize embarrassment and discomfort, you will be given a wipe, such as a baby wipe to cleanse our feet and a pair of shoe covers so that one foot can be covered while the other is examined.

The same procedure will be observed at each study visit. The chance that a given physical harm may occur is unlikely because the intervention is educational and the methods for data collection are not invasive.

Any time information is collected; there is a potential risk for loss of confidentiality.

In order to minimize the loss of confidentiality your name and any other identifying information will be scrubbed (removed) from study documents and replaced by a study identification number. I will give each subject their own study identification number.

The PI will secure the information obtained in this research study by observing the following procedure. Your information will be kept on my office computer at my place of employment The University of Texas at Tyler Longview University Center 3201 N. Eastman Rd. Longview, TX 75605. My office is locked when not in use by myself and the computer is password protected. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What are the potential benefits for participating in this research study?

There are several potential benefits for participating in this research study. One potential benefit for participating in this research study is that you will have access to diabetic foot care education provided by a Registered Nurse (RN). Another potential benefit for participating in this research study is that you will have access to the information and skills that are needed to perform diabetic foot self-care so that you can decrease your risk for developing diabetic foot ulcers and/or lower limb amputation.

Additional potential benefits of participating in the research project are to decrease your risk for developing a diabetic foot ulcer and increase your knowledge about diabetic foot care and foot complications. By learning about diabetic foot care and foot complications, you may be able to recognize your risk factors for diabetic foot ulcer better than you were before learning about diabetic foot care. You may also be able to recognize foot sores (lesions) before the skin opens and ulceration develops, and to know when and where to seek treatment for diabetic foot sores.

The benefits of participating in this study are that you will have the opportunity to learn:

- How and when to perform diabetic foot care.
- How to assess your risk for diabetic foot ulcer and/or lower limb amputation.
- What to do to lessen your risk for developing diabetic foot ulcer and/or lower limb amputation.
- You will learn when and where to seek treatment for diabetic foot complications before foot ulcers (deep sores) develop on your foot/feet.
- You will also receive all supplies for the classes including a diabetic foot care bag, and shoes that fit your feet properly.

Will I be reimbursed for participating in this research study?

Yes. You will receive a $20 Wal Mart gift card at each study visit you attend.

Is there an alternative treatment/procedure?

The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?

- Yes, if you come to a study visit impaired by alcohol and/or other mind altering substance.
- Yes, you can be removed for not keeping appointments and/or following the researcher's instructions.

How will my information be protected?

All results obtained in this study will be kept confidential and only available to myself and my professors who are providing supervision during the study.

How will my privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The PI, Katherine Strout, MSN, RN will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, date of birth, education, income, and type of insurance.

The PI, Katherine Strout, MSN, RN will know your identity and that you are in the research study. Other people, particularly your doctor, lay case manager, or the healthcare providers at the shelter may also see your information. For example, results of your diabetic foot assessments, such as open sores, signs of infection, bleeding, or findings that require treatment, would be shared to aid in your treatment, health care, and for your safety.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization

Who can I contact with questions about this research study?

If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact Katherine Strout MSN, RN at 903. 503-8113 or the chairperson of my dissertation committee Dr. Verklan 409-772-8373.

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, at (409) 266-9475 or irb@utmb.edu.

Do I have to participate?

No. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without anything bad happening to you or loss of benefits, such as being asked to leave the shelter, safe haven, or housing unit, to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

_____ _____
Signature of Subject Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

_____ _____
Signature of Person Obtaining Consent Date and Time of Consent Obtained

_____
Printed Name of Person Obtaining Consent

Version # 3 Date: 10/23/2017
Page 5 of 5

IRB Approved
31-May-2018-
13-Oct-2018

The University of Texas Medical Branch at Galveston Minimal Risk Consent Form

Protocol Title: The effects of diabetic foot education on assessments and self-care among adults with diabetes mellitus experiencing homelessness

IRB Number: 17-0180

Principal Investigator: Katherine R. Strout MSN, RN
301 University Blvd. Galveston, TX 77555
[redacted]

Why am I being asked to take part in this research study?

You are being asked to take part in this study because adults with diabetes mellitus (DM) experiencing homelessness often lack access to diabetic foot care education Diabetic foot care education has been shown to decrease a person's risk for developing diabetic foot ulcers and lower limb amputation. Adults with DM experiencing homelessness are at high risk for developing diabetic foot ulcers and lower limb amputations.

What is the purpose of this research study?

The purpose of the study is to investigate the effects of RN-led diabetic foot education have on (a.) your ability to assess your own risk for diabetic foot ulcer and/or lower limb amputation, (b) your ability to do diabetic foot self-care every day, (c) your clinical diabetic foot assessments and (d) your clinical diabetic ulcer and amputation risk scores.

How many people will take part in this study?

About 45 people who are adults with diabetes mellitus experiencing homelessness in East Texas will take part in this study.

What procedures are involved as part of this research study?

If you agree to take part, you will be asked to sign this consent form and complete the following procedures.

1. To fill out a form to answer questions about yourself, your diabetes, previous diabetic foot care education and diabetic foot assessment, and how long you have been without your own home. You will be asked to fill out this form one time after signing the consent form.

2. To fill out a form to answer questions about how you would rate your risk for developing diabetic foot ulcer and/or lower limb amputation. You will fill out this form two times. Once at the first study visit, ad once at the fourth study visit.

3. To fill out a form to answer questions about how many times during the week you do diabetic foot care. You will fill out this form four times. Once at the first study visit and then at each of the three remaining study visits.

4. To allow the PI, Katherine Strout, MSN, RN, to perform four diabetic foot assessments, including a risk assessment for diabetic foot ulcer and/or lower limb amputation. The first assessment will be done at the first study visit, and then at each of the three remaining study visits

5. To come to four study visits in which the PI will teach you about diabetic foot care, diabetic foot assessment, and how to reduce your risk for developing a diabetic foot ulcer and/or lower limb amputation. There are four study visits in this protocol; each lasting approximately one hour.

What are the possible risks for choosing to participate in this research study?

The known psychological risk, such as embarrassment about the condition of your feet, and/or potential discomfort may be experienced by subjects when they need to take off their shoes and socks for the PI to perform the diabetic foot assessment. In order to minimize embarrassment and discomfort, you will be given a wipe, such as a baby wipe to cleanse our feet and a pair of shoe covers so that one foot can be covered while the other is examined.

The same procedure will be observed at each study visit. The chance that a given physical harm may occur is unlikely because the intervention is educational and the methods for data collection are not invasive.

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What are the potential benefits for participating in this research study?

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Additional potential benefits of participating in the research project are to decrease your risk for developing a diabetic foot ulcer and increase your knowledge about diabetic foot care and foot complications. By learning about diabetic foot care and foot complications, you may be able to recognize your risk factors for diabetic foot ulcer better than you were before learning about diabetic foot care. You may also be able to recognize foot sores (lesions) before the skin opens and ulceration develops, and to know when and where to seek treatment for diabetic foot sores.

The benefits of participating in this study are that you will have the opportunity to learn:

How and when to perform diabetic foot care.

How to assess your risk for diabetic foot ulcer and/or lower limb amputation. What to do to lessen your risk for developing diabetic foot ulcer and/or lower limb amputation.

You will learn when and where to seek treatment for diabetic foot complications before foot ulcers (deep sores) develop on your foot/feet.

You will also receive all supplies for the classes including a diabetic foot care bag, and shoes that fit your feet properly.

Will I be reimbursed for participating in this research study?

Yes. You will receive a $10 Walmart gift card at each study visit you attend.

Is there an alternative treatment/procedure?

The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?

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The PI, Katherine Strout, MSN, RN will know your identity and that you are in the research study. Other people, particularly your doctor, lay case manager, or the healthcare providers at the shelter may also see your information. For example, results of your diabetic foot assessments, such as open sores, signs of infection, bleeding, or findings that require treatment, would be shared to aid in your treatment, health care, and for your safety.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?

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CONSENT TO PARTICIPATE:

The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

_____ _____

Signature of Subject Date

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

_____ _____

Signature of Person Obtaining Consent Date and Time of Consent Obtained

_____

Printed Name of Person Obtaining Consent

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Vita

I was born in Chicago, Illinois on June 9, 1955 to my parents, Briard and Elaine Strout. I have been a RN since 1979 and have had a lifetime of wonderful experiences as a nurse. I have been teaching in the School of Nursing at the University of Texas at Tyler since 2005. Prior to teaching, I obtained my Master's of Science in Nursing in 2005, and bechelor's of Nursing in Science in 2002, both from the University of Texas at Tyler. I received my Associates Degree in Nursing from the Indian River Community College in Ft. Pierce, Florida.

My permanent address is 313 Crestwood Dr. Marshall, TX 75672.

This dissertation was typed by its author, Katherine R. Strout