

**EFFECTIVENESS OF A FOOT SELF-MANAGEMENT INTERVENTION THAT  
UTILIZED COMMERCIALLY AVAILABLE INFRARED THERMOMETERS:  
A PATIENT-ORIENTED RESEARCH AND MIXED METHODS RESEARCH STUDY**

By © Laura Kathleen Stevens A dissertation submitted to the school of graduate studies in partial  
fulfillment for the degree of

**Doctor of Philosophy Faculty of Nursing**

Memorial University of Newfoundland

**St. John's, Newfoundland and Labrador**

**May 2020**

## ABSTRACT

**Background:** Patients with diabetes are at high risk for foot issues such as diabetic foot ulcers (DFUs). Given the prevalence, health care costs, and implications of DFUs, it is vital to support effective foot self-management. Education and a commercially available infrared thermometer (CAIT) are promising strategies. As foot self-management is complex, research that develops and tests interventions needs to be patient-oriented to ensure contextual issues are addressed.

**Methods:** A sequential mixed methods research (MMR) study with 3 phases was conducted with an exploratory and explanatory sequence. Phase 1 to the development of the Phase 2 intervention comprised the exploratory sequence (N=24): qualitative interviews were completed with 11 patients, 9 health care providers, and 4 support persons to explore foot self-management. Phase 2 and 3 comprised the explanatory sequence. Phase 2: a randomized control trial (RCT) pilot that tested the intervention was conducted (thermometer and education group, n=34; and an education-only group, n=26). Phase 3: interviews were conducted with RCT participants to gain understanding of the Phase 2 findings (N =9).

**Results:** Phase 1 findings showed that people experienced personal challenges, encountered system barriers, and utilized resources to support foot self-management (presented in Manuscript 1). These findings helped inform the intervention. The RCT found that the thermometer and education group had significantly more days with any assessment completed than the education-only group (150.98/180 vs. 119.84/180,  $p = .02$ ). The study had low power to assess the outcome of DFU. Phase 3 findings offered further explanation that the CAIT engaged participants, prompted action, and offered reassurance about foot health. Phases 2 and 3 are presented in Manuscript 2. This research approach resulted in the testing of a patient-oriented intervention and provided a greater understanding of intervention effectiveness. The benefit and synergy achieved when using this approach is presented in Manuscript 3.

**Conclusion:** The CAIT is an available tool that could support effective foot self-management for people with diabetes. This tool may offer several benefits such as promoting and providing structure for a foot assessment and direction for action.

## ACKNOWLEDGEMENTS

I would like to extend my sincere thank-you to all those who made the completion of this dissertation a reality. Thank-you to my PhD supervisor, Dr. Donna Moralejo, for her immense support, encouragement, and guidance. I would also like to thank my supervisory committee members, Dr. Cathy MacLean and Dr. Steven Ersser, for their support, encouragement, and commitment.

Thank you to all the participants for taking part in this research. I learned so much from you. Thank you to my funding agencies: NL-SUPPORT; Healthcare Foundation; and the College of Registered Nurses of Newfoundland and Labrador. A special thank-you to the patient representatives on my research committee, Ms. Cris Carter and Mr. Richard Murphy. Their input into this study was very valuable in developing and testing an intervention that was meaningful to patients and in reporting the findings. I would like to thank Michelle Swab for answering my many questions and her invaluable assistance in navigating the literature. For assisting with recruitment, I would like to thank the staff at Eastern Health. I would also like to thank the staff at HealthQuest, to the manager, Deanna Skinner, and the pedorthists, Brendan Walsh and Jennifer Fillier, for supporting the study through the completion of orthotic assessments for participants.

Thank you to Dr. Alice Gaudine, Dean of Memorial University Faculty of Nursing, and Dr. Kathy Watkins, Director of the Centre for Nursing Studies, for their encouragement and support. A special thank-you to my classmates, Jill Bruneau and Darlene Ricketts, for their friendship and encouragement.

A very sincere and special thank-you to my family and friends, who have been such amazing support. To my husband Ken, for believing in me, his sacrifices, assistance, and love. To my children, Robbie, Elizabeth, and Daniel, who always help me keep perspective. To my

siblings, who carried on where Mom and Dad left off, for their words of encouragement. To my friends, Pam, Lori, Marlene, Vicki, and Denise, thank you for the encouragement, laughter, many suppers, and trips to Florida!

## TABLE OF CONTENTS

<b>CHAPTER 1 LITERATURE REVIEW AND OVERVIEW OF STUDY .....</b>	<b>1</b>
Introduction.....	1
Methods of the Literature Search.....	3
Background.....	4
Burden of Disease.....	4
Incidence and prevalence.....	4
Mortality.....	6
Cost.....	6
Implications of DFUs for the Patient and Support Person.....	7
Physical.....	7
Psychological.....	8
Social.....	9
Pathophysiology and Factors that Contribute to DFU.....	10
Pressure that results in trauma.....	10
Repetitive pressure injury.....	11
Excess pressure injury.....	11
Excess pressure and repetitive stress injury.....	12
Peripheral neuropathy.....	12
Vascular disease.....	13
Other sources of trauma.....	13
Other contributing factors.....	14
Process of Inflammation.....	14
Foot Self-Management Prevention Measures.....	16
Regular care of feet.....	16
Appropriate footwear.....	18
Regular assessment by a health care provider.....	18
Interventions for Foot Self-Management.....	19
Education interventions.....	20
Comprehensive diabetes education that included foot care education compared with usual care.....	21
Individualized foot care education compared with no intervention.....	21
Intensive education compared to a short education intervention.....	22
Summary.....	25
Complex education interventions.....	27
Education centred complex interventions compared to usual or less intensive programs.....	27
Intensive and comprehensive complex interventions compared to usual care.....	29
Summary.....	31
Overall summary.....	33
Complexity of Self-Management.....	33
Factors that impact foot self-management.....	34
Physical barriers.....	35

Knowledge and education.....	35
Risk perception.....	36
Social Support networks.....	36
Interactions with health care providers.....	37
Self-efficacy.....	37
Readiness to change.....	38
Summary.....	39
Infrared Thermometry as an Assessment Tool.....	40
Intervention research that utilized an infrared thermometer.....	43
Overview of CAIT validation study.....	46
Research Problem.....	47
Research Questions.....	50
Intervention.....	50
Methodology.....	51
Mixed Methods.....	51
Interpretive Description.....	52
Methods.....	54
Phase 1 (Qualitative).....	54
Sampling.....	54
Recruitment.....	54
Data collection.....	55
Data analysis.....	55
Rigor.....	55
Phase 2 (Quantitative).....	56
Recruitment.....	56
Sample size.....	57
Intervention.....	58
Revision to temperature measurement and the intervention.....	58
Data collection.....	60
Measurement.....	61
Rigor.....	63
Phase 3 (Qualitative).....	63
Rigor.....	64
Ethical Considerations.....	65
Funding.....	65
Outline of Dissertation.....	65
References.....	66

**CHAPTER 2 ..... 79**  
**Patient, Support Person and Health Care Provider Perspectives on Foot Self-Management for Patients with Type 1 and Type 2 Diabetes: Personal Challenges**

Introductory Statement..... 79  
 Authorship Statement..... 79  
 Key Words ..... 79  
 Funding ..... 79  
 Abstract ..... 80  
 Introduction..... 81  
 Objective ..... 82  
 Methods..... 82  
   Setting and participants..... 82  
   Procedures..... 83  
   Data Analysis..... 85  
   Ethics..... 85  
 Results..... 85  
   Participants’ characteristics..... 85  
   Interview results..... 86  
     Readiness to self-manage foot health ..... 88  
     Communicating with HCPs ..... 91  
 Discussion..... 93  
 Conclusion ..... 96  
 References..... 97

**CHAPTER 3 ..... 100**  
**Effectiveness of a Foot Self-Management Intervention that Utilized Commercially Available Infrared Thermometers: Mixed Methods Research Incorporating a Pilot RCT**

Introductory Statement..... 100  
 Authorship Statement..... 100  
 Key Words ..... 100  
 Funding ..... 100  
 Abstract ..... 101  
 Introduction..... 102  
 Research Questions ..... 104  
 Primary and Secondary Outcomes..... 105  
 Research Design and Methods..... 105  
 Phase 2 Setting and Sample ..... 108

Phase 2 Intervention, Data Collection and Analyses .....	109
Phase 3 Methods .....	113
Results.....	114
Sample characteristics.....	114
Diabetic Foot Ulcers .....	116
Improved foot assessment.....	116
Improved actions based on foot assessment .....	118
Use of the thermometer.....	119
Issues using the thermometer.....	121
Lack of clarity regarding thermometer purpose.....	121
Interpreting the findings and taking action .....	121
Logistics of using the CAIT.....	123
Knowledge of foot self-management.....	124
Discussion .....	125
Conclusion .....	131
References.....	132
<b>CHAPTER 4 .....</b>	<b>138</b>
<b>Research into Prevention of Foot Problems Related to Diabetes:</b>	
<b>The Synergy of Patient-Oriented Research and Mixed Methods Research</b>	
Introductory Statement.....	138
Authorship Statement.....	138
Key Words .....	138
Funding .....	138
Abstract .....	139
Background and Purpose .....	140
Overview of the Study .....	141
Results.....	145
Examples from the exploratory sequence.....	145
Addition of a comprehensive education component.....	146
Addition of a mirror .....	146
Critical role of support person .....	146
Measure of readiness.....	146
Examples from the explanatory sequence.....	147
Thermometer and foot assessment.....	149
Understanding a foot concern and taking action.....	149
Readiness to manage foot health.....	150
Discussion .....	150
Conclusion .....	152

References.....	153
<b>CHAPTER 5 SUMMARY.....</b>	<b>156</b>
Introduction.....	156
Synopsis of Key Results .....	158
Results from the exploratory sequence .....	158
Results from the explanatory sequence.....	159
Synergy of POR and MMR. ....	160
Strengths and Limitations .....	160
Recommendations.....	161
Diabetes foot self-management program .....	161
Practice.....	163
Policy .....	164
Education .....	165
Research.....	165
Conclusion .....	166
References.....	167

**List of Tables**

Table 1.1 Measures and Schedule of Data Collection .....	62
Table 2.1 Interview Guides for Patients, Support Persons, and Health Care Providers .....	84
Table 2.2 Patient Characteristics (N=11).....	86
Table 3.1 Measures and Schedule of Data Collection .....	112
Table 3.2 Patient Characteristics.....	115
Table 3.3 Logbook Data .....	117
Table 3.4 Exit Interview Results for Thermometer Group .....	119
Table 4.1 Exploratory Model and the Impact on the Intervention and RCT Method (Phase 2).....	145
Table 4.2 Explanatory Model Examples of Integration Across the Three Phases.....	147

**List of Figures**

Figure 1.1 Process of Plantar Inflammation for the Diabetic Foot. ....	15
Figure 1.2 Logic Model. ....	49
Figure 3.1: Mixed Methods Exploratory and Explanatory model .....	106
Figure 3.2: Consort Flow Diagram .....	107
Figure 4.1 Prevention of Plantar Skin Breakdown and the Infrared Thermometer. ....	143

## List of Appendices

Appendix A Literature Summary Table .....	168
Appendix B Summary of Topics Covered in Education Module .....	173
Appendix C Teaching Points Used for Participants in the Thermometer Group .....	174
Appendix D Letter to Healthcare Provider .....	176
Appendix E Recruitment Script for Phase 1 .....	177
Appendix F Phase 1 Information Sheet Provided to Potential Participants.....	178
Appendix G Locations for Recruitment.....	180
Appendix H Inclusion and Exclusion Criteria .....	182
Appendix I Informed Consent Form Phase 1 .....	183
Appendix J Phase 1 Interview Guides .....	188
Appendix K Poster and Pamphlet for Phase 2 Recruitment .....	191
Appendix L Script for Screening for Phase 2 .....	195
Appendix M Consent to Take Part in a Clinical Trial .....	197
Appendix N Letters with New Information .....	206
Appendix O Individual and Group Tracking Forms.....	211
Appendix P Description of Measures .....	214
Appendix Q Phase 2 Measures .....	221
Appendix R Phase 3 Telephone Consent and Script .....	242
Appendix S Phase 3 Interview Guide .....	243
Appendix T Ethics Approval Letter.....	246

## CHAPTER 1

### Introduction

Diabetes is a global health emergency, which is estimated to increase throughout the 21<sup>st</sup> century (Guariguata et al., 2014). Approximately 2.3 million people in Canada have diabetes (Statistics Canada, 2017) and in Newfoundland and Labrador (NL) there are over 70,000 people with diabetes (NL Centre for Health Information, 2017). This disease impacts the circulation and nerves in the feet and the increasing number of people with diabetes will result in a rise in foot complications such as diabetic foot ulcers (DFUs) and amputations (Botros et al., 2019).

The International Diabetes Federation in their *2017 Clinical Practice Recommendations for the Diabetic Foot* argue that more focus needs to be on the prevention of DFUs as the disability, suffering, and cost implications are high (International Diabetes Federation, 2017). Therefore, it is important to develop strategies to maintain foot health and prevent DFUs and amputations. An important aspect of maintaining foot health is self-management (Boulton et al., 2008; Chang, Peng, Chang, & Chen, 2013). This is a complex activity that involves several prevention measures such as: regular care of feet; wearing appropriate footwear; not smoking; and seeking regular assessment from a health care provider (World Diabetes Foundation, 2014). Many studies have explored the experiences people with diabetes have caring for their feet (Coffey, Mahon, & Gallagher, 2019). However, what is needed to develop effective foot self-management strategies for a given population and region is increased understanding of these experiences in the local context.

Diabetes Canada's position statement on amputation prevention calls for affordable and timely access to devices, education, and care for individuals with diabetes (Diabetes Canada, 2019b). Infrared thermometry is a promising self-management device that could be incorporated into interventions to help people detect early inflammation in their feet so they can take action to

prevent skin breakdown that leads to ulceration. A commercially available infrared thermometer (CAIT) can be used to detect the temperature increase associated with inflammation before skin breakdown occurs (Mufti, Coutts, & Sibbald, 2015). Once the increase is identified, the individual can address the underlying source of inflammation by relieving pressure, for example by resting, until the temperature normalizes and inflammation decreases (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). If the temperature does not normalize in two days then a physician should be consulted. Multi-modal self-management strategies that focus on identifying and addressing early signs of inflammation, such as a temperature increase, may be effective in preventing skin breakdown and potential DFUs and amputation.

This dissertation research was a patient-oriented and mixed methods sequential exploratory and explanatory study that explored foot self-management of people with diabetes and tested a multi-modal intervention to prevent DFUs. Chapter 1 provides context for the study by summarizing the relevant literature and overview of the mixed methods study. This literature review identifies what is known about foot self-management and diabetes and the important contributing factors related to foot inflammation and DFUs. As well, the review identifies a gap in the evidence that led to the formulation of the research problem and supports the need for an intervention study that examines the use of a CAIT as part of a self-management strategy. Additionally, the review helps identify key factors that need to be assessed to best evaluate important outcomes and potential confounders. As the studies directly related to thermometry and foot self-management were deemed to be key studies, the details of these publications are presented in a literature summary table in Appendix A. Chapters 2-4 consist of manuscripts related to this research, and Chapter 5 presents a discussion of the implications of this research. Further details of the manuscripts and chapters are summarized at the end of Chapter 1.

## **Methods of the Literature Search**

For this review, the databases searched were CINAHL, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL) Scopus, PsychINFO, Web of Science, and Epistemonikos since inception, when these topics appeared in the literature, until 2019. This timeframe was chosen as issues experienced by adults with diabetes in relation to foot self-management were not expected to vary greatly over time. Multiple systematic searches were conducted to address incidence, prevalence, risk factors, and foot self-management interventions and using the appropriate combinations of the following key words with MeSH terms: diabetes, self-management, infrared thermometry, feet, foot, incidence, prevalence, diabetic amputation, foot ulcer, patient education, diabetes education, and training program. Studies published in English and French were considered for inclusion in this review. The reference lists of articles were searched for additional articles. Grey literature sources were also searched using the following websites: OpenGrey: Proquest Dissertations and Thesis; Google; websites for various diabetes associations, and MedNar.

Quantitative studies and systematic reviews included in the background were critically appraised using the Public Health Agency of Canada (PHAC) Critical Appraisal Toolkit (2014). Qualitative studies included in the review were critically appraised using the Critical Appraisal Skills Program (CASP) (CASP, 2018). Qualitative systematic reviews were appraised using the Joanna Briggs Institute Critical Appraisal tool (Joanna Briggs Institute, 2017). All quantitative studies included in the literature review were critically appraised to be of medium or high quality which indicates that the limitations were not sufficient to compromise the internal validity and the ability to draw a conclusion about the association of interest. The systematic reviews and meta-analyses included in the review were also determined to be medium or high quality based on an appraisal of the methodology and the quality of the research included in the publication

(PHAC, 2014). The qualitative studies included were appraised to have strong methodological quality which indicates that bias was addressed in the design, conduct, and analysis (Joanna Briggs Institute, 2017).

## **Background**

Before exploring self-management and CAITs it is important to understand the problem of DFU in relation to: burden of disease; implications of DFUs for the patient, family, and health care system; and pathophysiology. These topics will be summarized in the next few sections. The literature related to diabetes and foot self-management will then be presented.

## **Burden of Disease**

Lower limb complications related to diabetes have been identified as a large and preventable cause of the global burden of disease (Lazzarini, Pacella, Armstrong, & van Netten, 2018). The incidence, prevalence, mortality, and cost of DFUs and amputations are indicators of this considerable burden.

**Incidence and prevalence.** Incidence and prevalence are important indicators to assess when considering the impact of diabetes and to provide direction for policy and interventions. Incidence refers to the new cases in a select period of time. Incidence is particularly important in understanding contributing factors as it allows comparisons of rates between subgroups with varying exposure to risk factors (Ward, 2013). Increased understanding of the contributing factors is important for identifying who is at risk and for developing primary and secondary prevention strategies and interventions. In comparison, prevalence refers to the total number of people in the population who have the disease at a given point in time. Prevalence numbers provide direction for program planning in relation to staffing and facilities (Ward, 2013) as well as the development of secondary and tertiary prevention interventions.

Over a decade ago the estimated lifetime incidence of a DFU for people with diabetes was estimated to be 25% (Singh, Armstrong, & Lipsky, 2005). In Canada in 2011 it was reported that the incidence of foot ulcers was 14,449 cases (Hopkins, Burke, Harlock, Jegathisawaran, & Goeree, 2015). Hopkins et al. (2015) pointed out in Canada the incidence may be underestimated due to the coding of DFU and follow-up care in the national health administrative databases for hospital admissions. It is not just the first ulcer that is a concern as ulcer reoccurrence estimates are high; 40% of DFUs reoccurred one year after healing and 60% reoccurred three years after healing (Armstrong, Boulton, & Bus, 2017). It was also reported that an estimated 75-85% of amputations were the result of a DFU (Boulton, Vileikyte, Ragnarson-Tennvall, & Apelqvist, 2005). However, there were no recent incidence studies that considered lifetime incidence of DFUs and amputations.

Compared to incidence, more information is known about global prevalence of DFU. In a 2017 systematic review and meta-analysis that included 67 publications from 33 countries with a date range from 1991 to 2015, the global prevalence for DFUs was reported to be 6.3% [95% CI: 5.4-7.3]. North America had the highest prevalence (13%, 95% CI: 10-15.9); Canada was the country that had the second highest prevalence rate (14.8%, 95% CI: 9.4-20.1) (Zhang et al., 2017). The Canadian prevalence rate was based on one study that was conducted in 2006 that focused on a northern Indigenous community.

A more recent study conducted by Hopkins et al. (2015) reported that in 2011 the national prevalence of DFU in Canada was 25,597 cases. These authors noted that this number was based on acute care facilities and did not take into account patients in the community with a DFU and the actual number of DFUs may have been much higher. In the last five years Diabetes Canada released provincial reports and infographics that provided prevalence estimates. The number of cases ranged from 180-300 DFUs and 31 amputations in Prince Edward Island (PEI) (Diabetes

Canada, 2015b) to 16,600-27,600 DFUs and nearly 2,000 amputations in Ontario (Diabetes Canada, 2015a). For NL in 2018 the prevalence estimates were 760-1,260 cases for DFUs and 160 for amputations (Diabetes Canada, 2018). The limited findings highlight the gap in population research and the tracking of incidence and prevalence of lower limb complications related to diabetes in Canada. Even so, these numbers reflect that foot health complications related to diabetes are a problem that needs to be addressed with prevention strategies.

**Mortality.** Mortality information also reflected the burden of disease for lower limb complications. Authors of a well-conducted systematic review which included 12 cohort studies conducted from 1980 to 2013, considered the impact of DFU and amputation on mortality rate. They reported that the mortality rate after a DFU was 40% after five years; the rate increased to 63% for diabetic patients who had a DFU followed by an amputation (Jupiter, Thorud, Buckley, & Shibuya, 2016).

**Cost.** DFUs and amputation present a significant cost to the health care system. A recent well-conducted systematic review that included nine studies compared the cost of diabetic foot in France, Germany, Spain, Italy, and the United Kingdom. These authors reported these countries sustained a large cost related to diabetic foot and related complications such as ulcers, infections, and amputations and that care associated with these complications cost more than major cardiac diseases. The costs were reported in 2016 United States Dollar values with the care for an uninfected ulcer being \$6,174 in 2002 to \$14,441 in 2005 and costs of amputation ranged from \$15,046 in 2001 to \$38,621 in 2005 (Tchero et al., 2018). Even with the variation with different patient populations and healthcare systems the costs are substantial. Furthermore, these numbers reflect costs during the period between 2001 to 2005 and it is unknown if costs have increased or decreased since then. For example, much has changed in relation to revascularization interventions and options for dressings that would impact these costs.

In Canada more recent data from 2011 showed that DFUs and related care cost the health care system \$547 million. Related care referred to: acute care admissions; emergency room and clinic visits; long term care for current and new patients; interventions such as amputation and bypass surgery; and home care (Hopkins et al., 2015). Recent provincial reports released by Diabetes Canada between 2015 and 2018 indicated direct health care costs for DFUs and amputations were very high with a range from \$3.4 million in PEI (Diabetes Canada, 2015b) up to \$400 million in Ontario (Diabetes Canada, 2015a). In NL, it was reported that the yearly direct cost was estimated as \$16-18 million with the indirect cost being \$2-3 million and the specific cost of care for each ulcer was \$13,132-\$22,904 (Diabetes Canada, 2018). In spite of limited data and variation across provinces and settings, these studies indicate that cost of DFUs and amputations are a significant burden to the Canadian healthcare system.

### **Implications of DFUs for the Patient and Support Person**

A DFU represents a significant crisis for a person with diabetes and for his/her family. A large body of literature supports that DFUs have physical, psychological, and social impacts on the patient and support persons (Coffey et al., 2019; Hoban et al., 2015; Khunkaew, Fernandez, & Sim, 2018).

**Physical.** Findings from quantitative studies and qualitative studies that were medium and high quality showed the negative physical impact of having a DFU (Coffey et al., 2019; Khunkaew et al., 2018). Authors of a well conducted meta-analysis that included two cohort and ten cross-sectional studies used the Medical Outcome Short Form (SF 36) to assess health related quality of life (QoL). A lower score on this scale indicated more disability with a 100 being the maximum possible score. Results showed that health related QoL was low for: physical functioning (mean score 42.75, (Standard Estimates (SE) 1.5, 4 studies); general health (mean score 39.52, (SE 1.7), 5 studies); body pain (mean score 45.75, SE , 5.7, 5 studies); and role

physical (Ware, Snow, Kosinski, & Gandek, 1993) (mean score 20.61, (SE 1.7), 5 studies). In the Medical Outcome Short Form (SF 36), role physical measures problems with employment or activities of daily living that are a result of physical health (Khunkaew et al., 2018). These findings were also in keeping with a meta-synthesis that included 42 publications that reported on 35 qualitative studies. In spite of the variability in designs, participants, and research questions, these authors identified common physical implications as: pain; difficulty sleeping; difficulty healing; recurring ulceration; and difficulty dealing with other areas of self-management as a result of reduced mobility (Coffey et al., 2019).

**Psychological.** Dealing with a DFU also resulted in negative psychological impacts for the patient and support persons (Coffey et al., 2019; Hoban et al., 2015; Khunkaew et al., 2018). As discussed above, Khunkaew et al. (2018) conducted a systematic review and meta-analysis that included ten studies and used the SF (36) to assess health related QoL. The domains related to psychological functioning were low in five studies for: role emotional which measures problems with employment or activities of daily living because of emotional health (Ware et al., 1993) (mean score 46.67, SE 11.1); mental health (mean score 55.26, SE 2.2); and vitality (mean score 45.73, SE 2.8) (Khunkaew et al., 2018). Similar findings were reported by Hoban et al. (2015) who conducted a medium quality cross-sectional study and compared the mental health of patients with diabetes who had a foot complication (n = 47) with patients who did not (n = 49). Patients who experienced foot problems were found to have: more diabetes symptoms (15 vs. 8, p = .001); more depression symptoms (6 vs. 3, p = .001); lower QoL scores, lower scores on six of the SF (36) subscales ( p = .001-.003); and more reported suicidal symptoms (4 vs. 3, p =.03). As well, the caregivers of patients that had a diabetes foot complication (n=21) scored high on the Montgomery Caregiver Burden Assessment with a mean score of 36 (Hoban et al., 2015).

As discussed previously, Coffey et al. (2019) conducted a meta-synthesis of 42 qualitative publications with variable designs and participants. These authors identified that psychological impacts were also experienced by participants who had a DFU. Participants reported anxiety, fear, guilt, and a loss of independence related to having a DFU. They worried about further harm happening to their foot and the ulcer reoccurring and leading to amputation. Participants expressed regret regarding their lack of attention to foot health that resulted in a DFU. Other common emotions were frustration, anger, and powerlessness. However, some participants viewed the DFU in a positive light believing it made them stronger and more patient as well as further increasing their understanding of diabetes (Coffey et al., 2019).

**Social.** Findings from primarily medium and high quality quantitative studies and qualitative studies also showed the social impacts of having a DFU (Coffey et al., 2019; Khunkaew et al., 2018). In the systematic review and meta-analysis discussed earlier, pooled data for five studies using the SF (36) in the domain of social functioning showed a low mean score of 54.08 (SE 3.2) (Khunkaew et al., 2018). Social impacts were identified by Coffey et al. (2019) and referred to the difficulty with maintaining lifestyle as some activities such as bathing, driving, shopping, and vacations were difficult to accomplish and often required assistance. Participants also had difficulty maintaining social roles such as parenting and grandparenting. In relation to work some participants reported less productivity and loss of employment as a result of having a DFU and this in turn caused financial difficulties. Time was needed for appointments and treatments which left less time for other obligations. People had concerns about smell related to the ulcer and reported feelings of embarrassment in social situations (Coffey et al., 2019).

Although some people thought the experience made them closer to their partner some people also shared their concern about being a burden and had difficulty talking to their family and friends about their ulcer. The change in roles in a family as a result of the DFU also

negatively impacted family relationships. Some felt that the seriousness of their ulcer was not understood by those closest to them and reported not receiving enough support (Coffey et al., 2019).

### **Pathophysiology and Factors that Contribute to DFU**

Given the prevalence, costs to the health care system, and implications of DFUs it is vital to prevent this complication. In order to develop effective interventions, it is important to understand the pathophysiology and the factors that contribute to the development of DFUs. DFUs are defined as a deep wound on the foot as the result of diabetes (Schaper, 2004). The pathophysiology that leads to ulceration is very similar for most patients (International Working Group on the Diabetic Foot, (IWGDF), 2015). Hyperglycemia is the key underlying factor that precipitates and hastens nerve and vascular changes that lead to ulceration (Alavi et al., 2014). With consistently high sugar levels in the blood stream, the sugar molecules adhere to the sides of the blood vessel and the blood vessels are damaged and narrowed. As a result of the reduction in blood flow, the nerves no longer receive the oxygen and nutrients that are needed for the nerve to function well and the patient experiences nerve damage, also called neuropathy (World Diabetes Foundation, 2014). Several factors contribute to the development of a DFU and, along with pressure that results in trauma, these lesions most often occur when the patient has two or more risk factors such as peripheral neuropathy and vascular disease (Alavi et al., 2014; Boulton, 2013; IWGDF, 2015; van Schie & Slim, 2012). These factors are discussed in the next sections.

**Pressure that results in trauma.** Trauma caused by pressure is a factor required for skin breakdown to occur. The three types of pressure that can result in tissue damage that can lead to skin breakdown are repetitive pressure, excess pressure, or pressure that is both repetitive and excessive. These amounts of pressure would cause pain in the foot that has not lost sensation and cause the person to respond by relieving the pressure. However, if the person has neuropathy with

loss of protective sensation, they do not feel the pain and if the pressure continues the result is tissue damage that can lead to skin breakdown and ulceration (van Schie & Slim, 2012). It is important to note that a person may experience one or more of these types of pressure which lead to skin breakdown and that the strength and duration of the pressure are also factors to consider when analyzing pressure. The types of pressure injuries will be described below.

***Repetitive pressure injury.*** A repetitive pressure foot injury results from repeated movement of the foot that results in an injury. For the person with diabetes walking can result in a repetitive stress injury that causes injury to the skin and subcutaneous tissue of the diabetic foot. Van Schie and Slim (2012) compare this to mechanical fatigue as the tissue in the foot is unable to maintain its integrity due to the repeated pressure. As a result of these pressures the foot forms a callus for protection. However, if the callus is too large it increases pressure on healthy soft tissue resulting in a subcutaneous injury and ulceration (van Schie & Slim, 2012).

***Excess pressure injury.*** Both low and high pressure can result in a break in the skin that can lead to ulceration. Trauma can occur from excess high pressure that occurs at one point in time that breaks the skin in that moment. For example, stepping on a nail would be the example of a high pressure injury. Low pressure over a period of time can also cause trauma (van Schie & Slim, 2012). One of the main causes of excess low pressure to the foot is foot deformity which results in abnormal loading of pressure to parts of the foot which causes tissue damage that can lead to ulceration (Shaw & Boulton, 1997). For example, overlapping toes can cause low pressure; this deformity is a frequent site of foot ulceration in people with diabetes (Boulton et al., 2008). Another deformity that results in increased pressure is Charcot's foot. This is considered the most severe deformity as this condition results in microfractures and collapse of the foot (Plummer & Albert, 2008), which can lead to increased pressure on the plantar surface of the foot and a DFU.

***Excess pressure and repetitive stress injury.*** Trauma can also occur from excessive low pressure that is repetitive over an extended period of time. For example, when shoes or orthotics do not fit well the result is low excessive repetitive pressure on a part of the foot (van Schie & Slim, 2012). Wounds Canada has identified footwear that does not fit well as a factor that puts a person with diabetes at increased risk for ulceration (Botros et al., 2019). As well, if a person's gait is impacted this can result in excess pressure and repetitive stress to the foot. For example, if a person had a previous amputation his/her gait and biomechanics can be negatively impacted resulting in areas of increased pressure and therefore potential for compromised skin integrity (Botros et al., 2019). With this low pressure there is a decrease in blood flow to the cells which leads to ischemia, inflammation, necrosis and a subsequent wound; this process may take several days (van Schie & Slim, 2012).

**Peripheral neuropathy.** Peripheral neuropathy is a key factor in the development of DFUs. For the individual with type 1 diabetes it may take five years from the time of diagnosis for the symptoms of neuropathy to develop (Sibbald, Mufti, & Armstrong, 2015). However, there is evidence that neuropathy can occur before the diagnosis of type 2 diabetes is made (Singleton, Smith, & Bromberg, 2001; Tabak, Herder, Rathmann, Brunner, & Kivimaki, 2012).

Neuropathy contributes to foot complications by impacting the sensory, motor, and autonomic nerves. Specifically, motor neuropathy results in foot deformity, joint immobility, and structural changes that cause loading of pressure to different parts of the foot and an abnormal gait (Alavi et al., 2014; Armstrong et al., 2017). As discussed in the section on trauma, high pressure to an area can result in thick skin or callus formation which further increases the pressure to healthy skin. Sensory neuropathy causes loss of protective sensation which puts the foot at high risk for injury. People experience a continuum of symptoms related to sensory neuropathy ranging from burning, intermittent pain, or constant pain, with some people not

having any symptoms (Boulton, Vinik et al., 2005). Sometimes people are unaware that they have lost sensation which further increases their risk for injury. Autonomic neuropathy causes decreased sweating which leads to dry skin which can result in cracks and fissures on the plantar surface of the feet (Armstrong et al., 2017). These breaks in the skin provide a portal of entry for bacteria and increase the risk of infection (World Diabetes Foundation, 2014).

**Vascular disease.** Peripheral vascular disease (PVD) is a common factor that contributes to DFUs (Botros et al., 2019; Boulton, 2013) and 50% of individuals who have a DFU have PVD (IWGDF, 2015). As with neuropathy, PVD is often a cause of a DFU in combination with other factors. A possible scenario is a foot injury that becomes infected and is not noticed because of neuropathy. The infection results in an increasing need for blood supply which is beyond the vascular capacity due to PVD and a neuro-ischemic or ischemic ulcer is the result (Boulton, 2013). PVD is a risk factor for poor wound healing and amputation (IWGDF, 2015). The combination of smoking and diabetes puts people at high risk of amputation. Smoking negatively impacts circulation and is one of the leading causes of PVD. Smoking cessation decreases risk of intermittent claudication associated with PVD and lowers the risk of amputation (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

**Other sources of trauma.** There are also other sources of trauma that can lead to a DFU. In a qualitative meta-synthesis of 35 studies, Coffey et al. (2019) reported trauma such as burns, scratching or peeling skin off the foot, or attempts to care for a trauma at home preceded a DFU. Another source of trauma was use of chemicals such as corn plasters to treat corns (Laing, 1998). Additionally, having a previous wound placed the person at risk for skin breakdown as a healed wound is less resilient and elastic (Botros et al., 2019).

**Other contributing factors.** Age related changes in the structure and function of the skin also placed skin at risk for trauma. The normal changes of aging coupled with the impact of diabetes on their feet makes it difficult, and for some individuals impossible, to care for their feet. By the age of 50 people have lost approximately half of the fatty padding on their feet. Skin also has less moisture and as a result, skin on the feet may develop cracks and fissures that are painful and provide a portal of entry for microorganisms that can lead to infection. Women are at greater risk of stress fractures in any of the bones in their feet during this phase of their lives due to the impact of aging (Harvard Medical School, 2018).

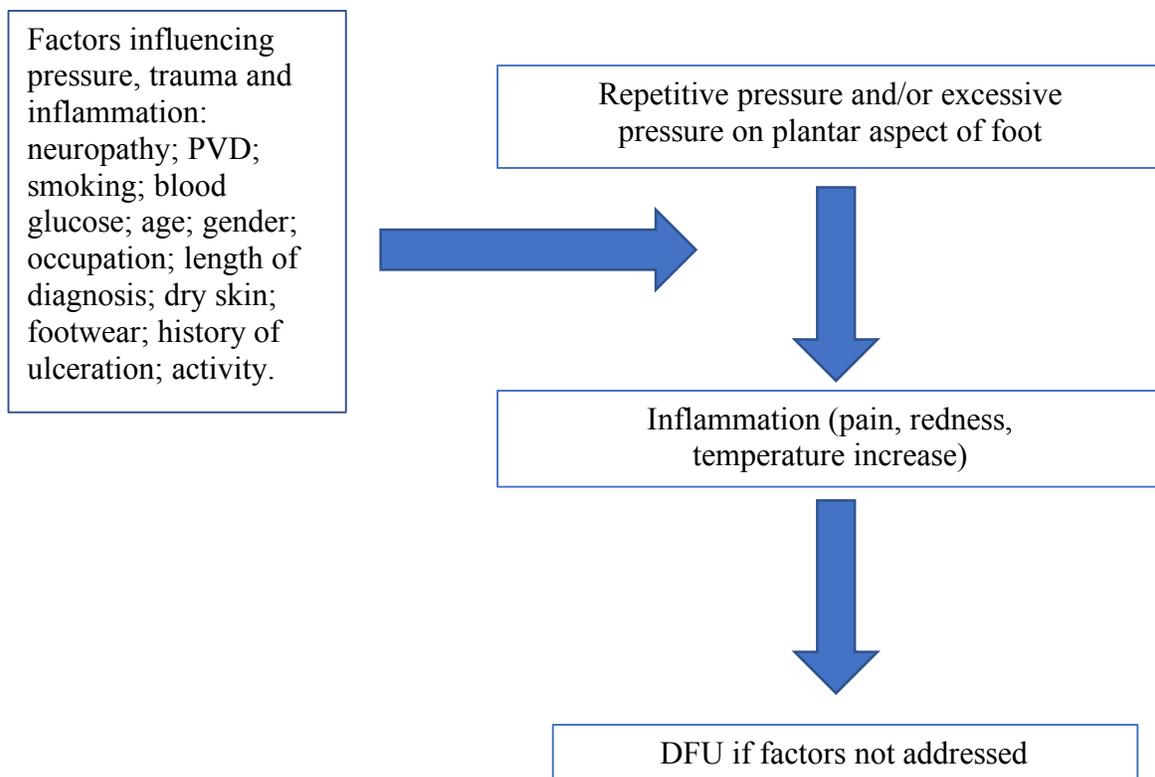
A well-conducted systematic review and meta-analysis of 67 studies that involved more than 800,000 participants world-wide reported the epidemiology of diabetic foot ulceration (Zhang et al. (2017). Using nine articles that provided data on characteristics of patients with diabetes that did not have a DFU with those that had a DFU, these authors reported that the common demographic and lifestyle factors associated with having diabetic foot complications were: older; lower body mass index; longer time since diagnosis; smoking; and retinopathy. These authors also reported that DFUs were more common in males than females and they suggested this may be due to men's employment requiring more physical work therefore putting more stress on their feet (Zhang et al. 2017). In spite of the variability in populations and geographical locations it appears that these demographic and lifestyle characteristics potentially contribute to the development of a DFU.

### **Process of Inflammation**

In order to understand where to intervene to prevent pressure and subsequent foot trauma, the process of inflammation must be understood. One of the body's first responses to an injury or infection is inflammation. The inflammatory response consists of: a release of chemical mediators; an increase in blood supply to the area; increased capillary permeability; and

migration of leukocytes from the capillaries into the interstitial space to the site of the injury (Rankin, 2004). There are five cardinal signs that characterize this process: heat; redness; swelling; pain; and loss of function (Armstrong, Lavery, Liswood, Todd, & Tredwell, 1997).

As shown in Figure 1.1 there are factors such as age, smoking, and occupation that influence pressure, trauma, and the associated inflammation on the plantar aspect of the foot. The inflammatory process will continue until the cause has been removed and/or the factors addressed and the healing process has begun. The individual with diabetes who has neuropathy may not feel the pain from repetitive stress and/or pressure on the feet, which is one of the cardinal signs of



*Figure 1. 1 Process of plantar inflammation for the diabetic foot. This figure illustrates the factors influencing pressure, trauma, and inflammation in the diabetic foot that if not addressed will lead to a DFU.*

inflammation. Without this he or she does not have the cues to reduce pressure on the bottoms of the feet, and as a result, is at risk for skin breakdown and ulceration.

### **Foot Self-Management Prevention Measures**

Knowledge of the pathophysiology of DFU and related factors helps to identify areas to address in relation to foot self-management. Two of the key ways to keep feet healthy is to have good diabetes control and not smoke. In other words, to maintain foot health it is vital for people with diabetes to control their blood sugar to prevent damage to blood vessels and nerves and avoid smoking which can further impair circulation (World Diabetes Foundation, 2014). A person must also participate in self-management prevention measures specific to feet that will help prevent areas of pressure and trauma and identify any areas of concern on the foot that should be addressed. In addition to diet control and not smoking there are three prevention measures that need to be followed: regular care of feet; appropriate footwear; and regular assessment from a health provider. The information in the following sections is promoted by Diabetes Canada, World Diabetes Foundation, and the IWGDF (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

**Regular care of feet.** Regular care of feet encompasses a number of activities for the person with diabetes with some of these needing to be carried out daily. It is recommended that people assess their feet daily; this includes checking between the toes and looking at the bottoms of their feet. A mirror can be used to assist people to assess areas that are difficult to view. As well, a support person can assist with this assessment. The person should look for any changes that occurred since the last self-assessment. Symptoms such as redness, tenderness, broken or peeling skin, dry and/or cracked skin, and callusing should be noted. If the person identifies any areas of concern or unexplained pain, they should make an appointment to see their health care provider (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

Daily hygiene with soap and water with thorough drying of the feet followed by moisturizing to prevent dry skin is recommended. People are cautioned to not put lotion between their toes as this can precipitate a warm moist environment causing skin maceration, which can result in skin breakdown. As well, to avoid burns the water temperature should be checked prior to bathing. Toenails should be trimmed and filed as needed, keeping the length of the nail at the top of the toe as cutting nails too short can result in trauma to the toe. Another reason nail care is so important is if a person's toenails are too long or have sharp edges, they can accidentally scratch themselves. As well, people should not use scissors or razor blades to cut corns or calluses or use a chemical agent to remove these as this can result in significant trauma to the foot. If a person has neuropathy it is recommended that they go to a professional health care provider to have their nails cut. It is also strongly recommended that people avoid pedicures as this activity could result in trauma and infection (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

Choice of socks is important and it is best for people not to wear socks that are too tight or that are knee high as circulation can be impaired and be a source of pressure that can contribute to skin breakdown. Natural fibre socks and seam-free socks are the best choice and for the person with neuropathy white socks are a good choice since if there is any bleeding it will be noted on the sock. If seams are irritating, it is suggested to turn the socks inside out to avoid trauma to the skin. Socks should be changed daily for hygiene purposes as this prevents bacterial growth on the skin that, if the person has a skin break, could lead to infection. Shoes should not be worn without socks as this can be a source of rubbing that could break the skin. Walking barefoot is considered a risky behaviour and footwear should be worn both inside and outside to lower the risk of trauma. It is also not recommended that people use hot water bottles or a heater

to warm their feet as these could result in a burn, especially for people with neuropathy (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

**Appropriate footwear.** Footwear that does not fit properly is one of the leading causes of injury to the foot due to pressure and repetitive stress. People with diabetes should avoid open toe and heel shoes and pointed toe shoes and consideration should be given to the shoes' length, width, and height. If a person has loss of sensation it is suggested that they have their shoes fitted by a certified footwear specialist. If a person has a foot deformity that causes abnormal loading of pressure, possibly resulting in a callus, orthotics should be considered. It is suggested that shoes be purchased later in the day since the feet tend to swell as the day progresses. Prior to putting shoes on it is recommended that people with diabetes shake them and check the inside with their hand to determine if there are any objects in the shoe or uneven seams that could cause irritation (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

**Regular assessment by a health care provider.** As discussed, it is important for people to assess their feet every day but it is also recommended for people with diabetes to have a yearly assessment by a health care provider to establish a baseline assessment and for regular monitoring to identify and address any risk factors. The frequency of this assessment should increase depending on the condition of the person's feet and presence of risk factors such as deformity and neuropathy. Foot screening or assessment by a health care provider has been shown to be effective for individuals with diabetes in preventing complications (Boulton et al., 2008; Chang et al., 2013). Diabetic foot screening involves assessing for a previous history of foot complications, deformity, pedal pulses, foot lesions, and neuropathy (Diabetes Canada, 2019a; IWGDF, 2015; World Diabetes Foundation, 2014).

## **Interventions for Foot Self-Management**

There is a great deal of information for people to learn in relation to foot self-management and diabetes; as a result, a large amount of effort has focused on the development of education strategies and interventions. However, education interventions have been met with limited success in preventing foot health complications. Use of secondary prevention educational strategies targeted at foot health has been an approach that has been used quite often to address lack of knowledge in individuals with diabetes and provide them with the information they need to care for their feet. A search of the literature identified two well-conducted Cochrane systematic reviews that examined the effectiveness of education interventions (Dorresteijn, Kriegsman, Assendelft, & Valk, 2014) and complex interventions that have an education component (Hoogeveen, Dorresteijn, Kriegsman & Valk, 2015) for preventing DFUs and focused on similar outcomes. Since these reviews were completed, one additional randomized controlled trial (RCT) and a non-randomized controlled trial (NRCT) have been published that focused on similar outcomes (Baba, Duff, Foley, Davis, & Davis, 2015; Monami et al., 2015). In addition, an NRCT published in 2011 had not been included in either systematic review. This study was presented as an RCT, however, because of issues with the random allocation process it was deemed to be an NRCT (Gershater, Pilhammar, Apelqvist, & Alm-Roijer, 2011). Studies were appraised utilizing the PHAC Critical Appraisal Toolkit (2014). Baba et al. (2015) was high quality and Monami et al. (2015) was deemed to be medium quality because of the lack of control for confounding variables with the statistical analysis. Gershater et al. (2011) was also deemed to be of medium quality due to participation and randomization issues.

For the majority of these studies the primary outcomes examined were foot ulceration and amputations. Secondary clinical or process outcomes were also examined such as: patient scores for foot care knowledge and behavior; callus occurrence; callus reduction; and number and length

of hospitalizations for foot complications. Authors of both reviews reported that effective self-management strategies to prevent DFUs were limited (Dorresteijn et al., 2014; Hoogeveen et al., 2015). This conclusion still holds as there has been limited intervention research focusing on the prevention of DFUs and amputation published since these reviews were completed. These studies will be presented below under the headings of education interventions and complex interventions.

**Education interventions.** Effectiveness of educational interventions for preventing DFUs and improving secondary outcomes were evaluated in the systematic review (Dorresteijn et al., 2014) and two additional studies (Baba et al, 2015; Monami et al., 2015). Dorresteijn et al. (2014) reviewed 12 RCTs and defined educational interventions as programs that had the goal of decreasing the incidence of DFUs and this definition was in keeping with the additional studies. All but one study out of fourteen was considered at high risk for bias.

The health care setting varied across the studies with five studies conducted in the community, three studies in primary care, and five studies conducted in secondary care, with one study uncategorized (Baba et al, 2015; Dorresteijn et al., 2014; Monami et al., 2015). There was high heterogeneity in the interventions in relation to duration and content. For example, the intervention group in one study in the systematic review had ten hours of foot care education while for two other studies the intervention group received one hour of education. There was also variation with the education received by the control group. For example, for one study the control group received general diabetes education and in another the control group only received written instructions, with another control group receiving no education.

Three types of interventions were identified: comprehensive diabetes education that included foot care education compared with usual care; individualized foot care education compared with no intervention; and intensive education compared to a short education

intervention. The findings of the systematic review and the two additional studies will be discussed in the following sections in relation to these categories.

***Comprehensive diabetes education that included foot care education compared with usual care.*** Three RCTs found in the systematic review were placed in this category and only one study reported findings related to the primary outcomes. For two of the studies, no baseline data about foot risk for ulceration was provided. For the other study, one of the inclusion criteria was that patients were insulin treated and baseline data for foot assessment was provided with 20 participants having a DFU or amputation at initial assessment. In this later study no significant effect was found for the primary outcome of foot ulceration and amputation with two participants in the intervention (n =83) and control (n = 63) group having a foot lesion after 1.5 years. No p values were reported for this study.

All three studies reported on various secondary outcomes. The first study reported significance in relation to foot care knowledge at six month follow-up (mean score 62 vs. 53, p = 0.001); however, there was no impact on foot appearance and foot care behaviour scores. The second study only measured knowledge and reported no significant improvement at approximately 12 -14 months follow-up. The third study did not report on the outcome of knowledge and reported no significant difference in the behavior scores (intervention 3.4-4.3 and control 3.6-4.1) and foot condition at approximately 18 months follow-up. For the latter two studies adherence to the intervention and follow-up was poor, which would impact on the findings (Dorresteijn et al., 2014).

***Individualized foot care education compared with no intervention.*** Two RCTs included in the systematic review were placed in this category and neither reported on the primary outcomes. For one study, there was no baseline foot assessment data provided (N = 167). For the other study, 70% of participants had loss of protective sensation, 67% had impaired circulation,

and 50% had a foot deformity (N=40). For secondary outcomes, both studies reported significant improvement in foot care behaviors ( $p < .01$ ) with only one of the studies reporting a significant improvement in foot care knowledge ( $p = .03$ ). For the other study with no baseline data provided, there was an increase in knowledge in the control group and not the intervention group with the control group also having a significant increase in foot care behaviors ( $p < .05$ ) (Borges & Ostwald, 2008; Dorresteijn et al., 2014). The researchers did not provide an explanation of the unexpected increase in the control group (Borges & Ostwald, 2008). The follow-up period was short for both studies ranging from one month to six weeks (Dorresteijn et al., 2014).

***Intensive education compared to a short education intervention.*** Six RCTs included in the systematic review and the more recently published RCT and NRCT were placed in this category (Baba et al, 2015; Dorresteijn et al., 2014; Monami et al. 2015). For Baba et al. (2015) the participants' level of risk for a DFU could not be determined. For all of the other studies, participants were at high risk for foot ulceration. Five of the eight studies reported on the primary outcomes. Of these five, three reported no significant differences, including the one study that was considered at low risk of bias. In that study, there was no reduction reported in DFUs (RR: 1.00; 95% CI 0.70-1.44) and the amputation rate (RR: 0.98; 95% CI 0.41-2.34) (Dorresteijn et al., 2014). The other two studies did report significant differences between the intervention and the control group. One study included in the systematic review reported a reduction in ulceration (RR: 0.31; 95% CI 0.14 - 0.66) and amputation (RR 0.33; 95% CI 0.15 - 0.76). However, over estimation of effect size may have occurred with this study as amputations were reported per limb and not per person (Dorresteijn et al., 2014). Monami et al. (2015) reported no participants in the intervention group developed DFUs whereas six participants in the control group developed ulcers (10% versus 0%,  $p = 0.012$ ). There were no amputations during this six-month study.

Six studies out of the eight reported on different secondary outcomes measured at different time periods with varying results (Baba et al, 2015; Dorresteijn et al., 2014; Monami et al. 2015). Four studies in the systematic review and the two additional studies reported on the outcome of knowledge. Two studies in the systematic review reported on knowledge at one month follow-up. One study compared the intervention and control group four weeks after the intervention and reported a significant difference in scores (intervention: mean 2.33 vs. control: mean 1.10,  $p = 0.028$ ). Another study reported a statistically significant difference in knowledge improvement for the intervention group and control group one month post intervention ( $p < .001$ ). This knowledge improvement was assessed again at six months with similar results. In the NRCT at the three month follow-up the group with the interactive education session reported that they had better understanding of foot complications than the group that received written education ( $p = 0.031$ ) (Baba et al., 2015). Two studies had follow-up at six months. One study in the systematic review reported an increase in knowledge scores at six months in both the intervention and control group but the difference was only significant for the control group ( $p=0.02$ ) (Dorresteijn et al., 2014). Monami et al. (2015) only measured change in knowledge at six months follow-up in the intervention group and reported that knowledge scores improved from pre to post intervention (20 vs. 23,  $p < 0.001$ ). Finally, one study in the systematic review reported a significant increase in the intervention group at one year follow-up (26.7 – 32.1,  $p = .004$ ).

Six studies reported on the outcome of foot behaviors and adherence and five of these studies were included in the systematic review (Baba et al, 2015; Dorresteijn et al., 2014). Three studies looked at short-term improvements. In one study there was no difference after four weeks between the intervention and control group for: checking feet ( $p = 0.203$ ); washing feet ( $p = 0.573$ ); and applying lotion; ( $p = 0.191$ ). The only significant difference between the intervention

and control group was on the behavior of wearing shoes and socks ( $p = 0.036$ ). After one-month post intervention another study assessed foot care behavior compliance and reported a significant increase in the intervention group ( $p < 0.001$ ) with a significant difference between the intervention and control group ( $p = 0.012$ ). The NRCT reported there was a trend to higher scores at three months follow-up for foot behavior between the written education group and the interactive education group, but this difference was not significant ( $p \geq 0.13$ ) (Baba et al., 2015).

Three studies in the systematic review looked at longer term improvements in relation to foot behavior and adherence. One study found a statistically significant improvement at six month follow-up of some behaviors in the intervention group such as hygiene (82.6% to 86.7%) and regularly trimming of nails (34.8%-80%). There was no significant difference in other behaviors such as daily foot inspection, use of a pumice stone for corns, and improvement in keeping nails shorter. However, this study had a small sample with a 40% drop out rate of participants. For foot care behavior a second study reported an increase in behavior scores for the intervention group after one-year follow-up (intervention 42 vs. control 38.7,  $p = 0.03$ ). However, there was only 72% follow-up in this study. In the third study the behavior scores improved significantly in the intervention group after one year follow-up (intervention 5.4 to 7 vs. control 5.3 to 6). However, this difference was not significant between the intervention and control group at seven-year follow-up (6.6 vs. 6.4).

Two of the six studies in the systematic review and the NRCT reported on foot condition. One study in the review reported presence of calluses at one-year follow-up; although not significantly reduced at the calcaneal region in the intervention group, callusing was reduced in other regions of the foot ( $p < 0.001$ ). Also, size of the callus initially improved at one-year follow-up in the intervention group in the calcaneal region (mean diameter, intervention from 40.5 mm

to 25.5 mm,  $p = 0.065$ ) and other regions of the foot (mean diameter, intervention from 16.6 mm to 11.4 mm,  $p < 0.001$ ). When these outcomes were assessed at seven year follow-up there was no difference between the intervention and control group. The second study considered foot problems that required treatment and reported that there was a significant reduction at one month ( $p < .001$ ). This improvement was maintained for six months, however the difference between the intervention group compared to the control group diminished at six months (Dorresteijn et al., 2014). The NRCT also reported on foot condition, finding that there was no difference between the written education group and interactive education at three months ( $p = .73$ ). However, at three months for the written education group the mean change in score for foot condition was significantly greater than it was for the interactive education group (-1.8 95% CI: -2.4 – 1.2) vs. (-.01 95% CI: -.7 to 0.4),  $p < .001$  (Baba et al., 2015).

**Summary.** The authors of the systematic review concluded that there was only one adequately powered RCT that reported on ulceration and amputation rates; this study did not show that education impacted those outcomes. There were several sources of variation among studies such as: level of risk of the participants for foot ulceration; setting; type of intervention and comparisons that were being made between the intervention and control group; and risk of bias (Dorresteijn et al., 2014). Three of the four studies that evaluated intensive education and one of two studies that evaluated comprehensive education reported no significant differences. Results from the other two were mixed, with one reporting a reduction in both DFUs and amputation (Dorresteijn et al., 2014) and the other reporting neither group having amputations but a significant difference in the DFU rate (Monami et al., 2015). All but one of the six studies were at high risk of bias. Applying the definitions of terms to rate evidence and the criteria for rating evidence as outlined in the PHAC toolkit (2014), the conclusion is drawn that there is

weak evidence that demonstrates that foot care education is effective in reducing DFUs and amputation or what type of education intervention, if any, is most effective.

There were mixed results for secondary outcomes and not all studies measured the same outcomes. Education does appear to impact knowledge, at least for periods of up to one year, with intensive strategies potentially being more effective. Five of the six studies that evaluated intensive education and reported on knowledge showed statistically significant differences in the intervention group compared to the control group; one did not. In contrast, significant differences between groups were found in one of the two studies that looked at individualized education and in one of the two studies that looked at comprehensive education.

Education also appeared to impact some foot care behaviour for periods up to a year, again with intensive programs being more effective. Two of the three comprehensive education studies that reported on foot behaviors found no difference. There were significant differences for this outcome with the other two categories of interventions. Two of the three studies evaluating individualized education programs and four of the six studies that evaluated intensive education interventions found statistically significant differences for some foot care behaviors, but not all.

Education also had some impact on foot condition, but the impact was less clear. Two out of three studies that evaluated comprehensive educational interventions found no statistically significant difference for foot condition. In contrast, three of the eight studies that evaluated intensive interventions reported statistically significant differences for foot condition. However, for one study the impact diminished at six months follow-up and for another although a difference was found at one year it was not sustained at seven-year follow-up.

Overall, there is direct evidence from multiple medium to high quality studies that education interventions made a difference for secondary outcomes; however, there are some inconsistencies in the findings. Applying the definitions of terms to rate evidence and the criteria

for rating evidence as outlined in the PHAC toolkit (2014), the conclusion is then drawn that there is moderate evidence that individualized and intensive educational interventions may in the short term positively impact foot care knowledge, foot care behaviors, and foot condition.

**Complex education interventions.** More complex interventions were evaluated in a well conducted systematic review (Hoogeveen et al., 2015). Complex interventions were defined as interventions that used an integrative approach that utilized two or more strategies and included at least two levels of care such as patient, health care provider, and/or health system. These authors reviewed six RCTs (Hoogeveen et al., 2015). One additional NRCT was found in the literature that was not included in the review (Gershater et al., 2011). The location of the interventions in the review and the NRCT varied; four took place in secondary care, two in primary care, and one in the community. The strategies used during the interventions also varied, for example, some strategies used were: frequent follow-up by a health care provider; education of health care providers; provision of orthopedic shoes and insoles; and interventions that were directed at preventing other diabetes related complications, such as eye exams. For some of the studies the control group received usual care, and this was not always defined. For other studies the control group received an education session or written instructions. Two categories of complex interventions were identified: education centred complex interventions compared to usual or less intensive programs; and comprehensive complex interventions compared to usual care (Hoogeveen et al., 2015). The findings will be discussed in the following sections in relation to these categories.

***Education centred complex interventions compared to usual or less intensive programs.***

Three studies included in the systematic review compared education centred complex interventions with usual care. Two of the studies took place in a primary care setting and the other was based in a community setting. Participants in these studies were at low to medium risk

for foot ulceration. Examples of patient level strategies used in the education centred complex interventions were distribution of educational material, telephone reminders, and behavioral contracts. Strategies were also directed at the health care provider and included education, a Semmes Weinstein Monofilament to assess for neuropathy, and referral guidelines. There were also strategies directed at the structure of the health care system such as follow-up by a podiatrist and assessment, treatment, and referral flow sheets.

Two of these studies reported on primary outcomes of ulceration and amputation. In one study there were no amputations in the one year follow-up and at seven year follow-up one amputation was reported in the intervention group and one ulceration in the control and intervention group. In the other study the odds ratio (OR) was 0.41 which showed that there were fewer DFUs in the intervention group; however, there was no statistically significant difference for amputations at one year follow-up (Hoogeveen et al., 2015).

More positive outcomes were reported in relation to the secondary outcomes for the three studies where more complex interventions were compared with usual care. Two out of three studies reported foot care knowledge scores. One study reported significant improvements in foot care knowledge for both the intervention (26.7 - 32.1;  $p < 0.001$ ) and control groups (26.1-29.2;  $p < 0.001$ ) at one-year follow-up. There was no difference between these groups at seven-year follow-up. The second study reported that knowledge scores significantly improved using a shorter follow-up timeframe of six months in both the intervention group (mean percentage improvement 1.09,  $p = 0.015$ ) and control group (mean percentage improvement 1.32,  $p = 0.002$ ) (Hoogeveen et al., 2015). However, in this study there was only 62% follow-up with participants.

Two of the three studies assessed foot care behaviors; both reported initial improvement in patients' foot care behaviors when these behaviors were assessed at one-year post intervention, with one reporting a statistically significant difference. One of these studies also conducted

follow-up at seven year and reported there was no difference between the two groups' behavior assessment scores (intervention group 6.6 and control group 6.4). The other study did not report baseline scores which impacts interpretation of these findings (Hoogeveen et al., 2015).

Another secondary outcome considered was foot condition. One of these three studies reported on the outcome of callus development. There was a significant reduction ( $p = 0.001$ ) in the size of the callus at one-year follow-up however, there was no significant difference in the prevalence of callus in this timeframe with calluses being present in 12% of participants in the intervention group and 15.5% of participants in the control group (RR: .78; 95% CI: 0.49-1.23). Podiatry care was an important component of this intervention. At seven-year follow-up there was still no difference in prevalence (Hoogeveen et al., 2015).

***Intensive and comprehensive complex interventions compared to usual care.*** Three studies from the systematic review and the additional NRCT were placed in this category and three reported on the primary outcomes (Gershater et al., 2011; Hoogeveen et al., 2015). Participants were at high risk for foot ulceration in two studies in the systematic review and in Gershater et al. (2011). In the third study in the systematic review the intervention was only provided to participants who were identified to be high risk after randomization (Hoogeveen et al., 2015). The settings for the three studies in the systematic review were an inpatient unit and two outpatient clinics, one being a dialysis outpatient unit and the other a diabetes clinic. The setting for Gershater et al. (2011) was a multidisciplinary foot clinic. The examples of strategies used in the intensive and comprehensive complex interventions were patient level strategies that included weekly foot care clinic appointments, ulceration risk assessment, and podiatry. There were also strategies directed at structure of the health care system such as reminder letters to patients to improve continuity of care, change in the services received, and use of a

multidisciplinary team. None of the strategies were directed at the health care provider in these interventions.

For one study in the systematic review there was no significant difference between ulceration for the two groups (RR: .69; 95% CI: 0.41 - 1.14). However, there was a significant difference for amputation, with seven amputations in the intervention group compared to twenty-three in the control group (RR: 0.3; 95% CI: 0.13 - 0.71). Another study did not report ulceration. This study did have a difference in the number of amputations, with no amputations in the intervention group and five in the control group. However, the significance of this difference was unclear as the amputations were counted as separate events even when on the same person. For the third study there was no significant difference in the number of amputations between the groups but there was a significant difference for ulceration with the intervention group having no ulceration and the control group having seven ( $p = 0.01$ ) (Hoogeveen et al., 2015). For the NRCT there was no significant difference for ulceration at six months follow-up between the intervention group and control group, 19 (48%) versus 22 (38%). No  $p$  values or confidence intervals were reported (Gershater et al., 2011).

For secondary outcomes only one of the four studies reported patient foot care behaviors. This study reported a significant difference at one year follow-up between the intervention group and control group for regular foot checks (RR: 1.63; 95% CI: 1.01 - 2.63), moisturizing feet (RR: 9.71; 95% CI: 2.45 - 38.56) and wearing socks and shoes that are appropriate (RR: 4.39; 95% CI: 1.87 - 10.32). Likewise, only one of the four studies reported on the outcome of foot care knowledge. A significant improvement was found in knowledge for both groups at two-year follow-up ( $p = 0.01$ ). As well, only one study of the four reported on hospital admission. There were more admissions in the control group and readmissions of the same patient were reported as

separate events. The authors of the review questioned the significance of this finding. No studies reported information on callus development and resolution (Hoogeveen et al., 2015).

**Summary.** The authors of the review concluded that there were no high-quality studies that tested complex interventions and based on their review the evidence was not sufficient to show that complex interventions were effective in preventing DFUs and amputations. Results of the studies were mixed. The variation in participants, settings, type of interventions and the comparisons being made may have been important factors impacting the findings. One of the two studies that evaluated education centred complex interventions reported no significant difference for ulceration and amputation at one year and seven year follow-up (Hoogeveen et al., 2015). One of two studies that evaluated an education centred complex intervention and one of three studies that evaluated an intensive intervention reported a significant reduction in DFUs. In relation to amputation both studies that evaluated education centred complex interventions and two of the three studies that evaluated intensive interventions reported an impact on the amputation rate. However, it is important to note that three of the studies that reported a reduction in ulceration did not report a significant difference with the outcome of amputation (Gershater et al., 2011; Hoogeveen et al., 2015). The meaning of this finding is unclear but length of follow-up and other variables not measured may be factors.

Applying the definitions of terms to rate evidence and the criteria for rating evidence as outlined in the PHAC toolkit (2014), the conclusion is drawn that there is weak evidence, from three low quality studies with contradictory findings, that complex interventions are effective in reducing DFUs and amputations. Furthermore, these studies did not provide evidence regarding what type of complex intervention, if any, is most effective.

There were mixed results in relation to the secondary outcomes and not all studies measured the same outcomes. Complex interventions do appear to impact knowledge, at least for

periods of up to two years. One of the three studies that evaluated an intensive intervention and two of the three studies that evaluated an education centred complex intervention reported a significant difference in knowledge with follow-up ranging from six months to two years. One study from each of these categories reported a significant difference for both the intervention group and control group; for the study in the education centred complex group this difference was not found at seven years follow-up.

Education appeared to impact some foot care behaviour for periods up to a year. One study in each category reported a significant difference in foot care behaviors at one year follow-up. The study that evaluated the education centred complex intervention also reported a significant difference for foot care behaviors in the control group at one year follow-up; at seven year follow-up the scores were similar for both groups.

Very limited results were reported for foot condition and readmission, so no trends could be identified. One of the three studies that evaluated an education centred complex intervention reported a significant difference in callus size at one year follow-up. However, there was no difference in prevalence of calluses at one year and seven year follow-up. For hospital readmission one study in the intensive category reported a significant difference between the intervention and control group.

Applying the definitions of terms to rate evidence and the criteria for rating evidence as outlined in the PHAC toolkit (2014), there is weak evidence from multiple studies that complex interventions made a difference for the secondary outcomes of knowledge with a trend that these interventions possibly improved foot behaviors for periods up to one year. As well, there was very limited evidence that these interventions impacted foot condition and hospital readmission.

**Overall summary.** From the appraisal of the education and complex foot self-management interventions the conclusion can be drawn that overall there was weak evidence that education and complex interventions decreased ulceration and amputation. However, there was moderate evidence that these interventions positively impacted secondary outcomes. It appears that education strategies with varying complexity should be considered a key strategy in improving foot health for people with diabetes and warrants further research. As well, it also highlights that education may not be enough. Strategies for early identification of inflammation could be incorporated into self-management interventions with the goal of preventing skin breakdown that can lead to ulceration.

### **Complexity of Self-Management**

It is perhaps not surprising that education effectiveness is limited as the number and nature of the foot care related self-management activities required by a person with diabetes is complex. Authors of a hybrid concept analysis of chronic disease self-management that considered both theoretical and patient perspectives defined chronic disease self-management as a daily process that is fluid and iterative where individuals utilized strategies that involved three system levels, intrapersonal, interpersonal, and environmental, to meet the needs that they have identified (Miller, Lasiter, Bartlett Ellis, & Buelow, 2015). Examples of the intrapersonal system were: assessing emotion and physical functioning; constant surveillance and making use of resources; recognizing that change can occur at any time and tolerating and being prepared for these interruptions; knowing signs and symptoms that may cause an illness exacerbation; and accepting and incorporating treatments and side effects as part of normal life. The interpersonal system was comprised of communicating with support persons and using these people as part of self-management. The environmental system involves partnering and communicating with health care providers to achieve optimal functioning and disease management (Miller et al., 2015). The

results of this concept analysis highlight the complexity of self-management in relation to foot health and that it is important to understand the factors that can impact on foot self-management.

For the purposes of this dissertation self-management is defined as “the ability of individuals and or their caregivers to engage in the daily tasks required to maintain health and well-being or to manage the physical, psychological, behavioral, and emotional sequelae of a chronic disease based on the knowledge of the condition, its consequences, and the plan of care co-developed with their health care team” (Simmons & Noonan, 2016, p.54). It is important to note the terms self-monitoring and self-care. Self-monitoring is an aspect of self-management and is defined as an awareness of symptoms and use of measurement and observations that provide information to direct independent action or seeking advice from an HCP (Wilde & Garvin, 2007). Different researchers report self-care and this term reflects a variety of self-management strategies.

**Factors that impact foot self-management.** The limited effectiveness of foot self-management interventions and the complexity of self-management suggest that it is vital to understand the factors that impact on self-management in order to understand the key areas that need to be addressed to ensure successful uptake of a self-management strategy. Two systematic reviews examined a total of 44 studies and explored different aspects of foot self-management (Coffey et al., 2019; Matricciani & Jones, 2015). Matricciani and Jones (2015) in their well-conducted systematic review analyzed eight cross-sectional, one cohort, and one qualitative study exploring the barriers and enablers to foot care for older people with diabetes. The majority of the studies were conducted in the United States (56%) with the remaining originating from the United Kingdom (22%), Australia (11%), and Germany (11%). The median age of participants was 67 years of age with the median duration of diabetes being 15.3 years. As discussed previously, Coffey et al. (2019) conducted a meta-synthesis of 42 qualitative publications and

identified factors that impacted self-management. The findings of both these reviews reinforced that foot self-management was complex in the areas of: physical barriers; knowledge and education; risk perception; social support; and interactions with health care providers. Other researchers explored self-efficacy and readiness as important factors that impact on foot self-management (Al Sayah, Soprovich, Qiu, Edwards, & Johnson, 2015; Khairnar, Kamal, Giannetti, Dwibedi, & McConaha, 2019). These factors will be explored in the following pages.

***Physical barriers.*** Both reviews identified physical challenges that made it difficult for people with diabetes to care for their feet. Matricciani and Jones (2015) reported that five studies identified physical barriers such as visual issues and limited mobility as barriers to foot care. Similarly, Coffey et al. (2019) reported physical limitations such as vision and mobility problems that impacted a person's ability to reach their feet. A recent 2019 qualitative study that used a focus group methodology to explore healthy seniors' experiences with managing their feet reported that foot self-care was difficult because of normal age-related changes to the foot such as thickened nails that were difficult to cut and dry skin. These would also be factors that impact foot self-management for a senior with diabetes (Miikkola, Lantta, Suhonen, & Stolt, 2019).

***Knowledge and education.*** Patients' knowledge level sometimes negatively impacted foot health. It was reported that for some patients there was a lack of knowledge of healthy foot behavior (Coffey et al., 2019; Matricciani & Jones, 2015). This lack of knowledge negatively impacted on self-care and as a result, individuals sometimes exposed their feet to greater risk. As well, patients had limited understanding about DFUs and were not clear on what a DFU was, the causes, outcomes, progression of a DFU, and if anything could be done about a DFU (Coffey et al., 2019).

Overall, both reviews reported that patients perceived education was positive (Coffey et al., 2019; Matricciani & Jones, 2015). Patients who had education demonstrated better foot care

practices. However, as noted above these may be only short-term changes. As well, patients appreciated foot health education from health care professionals (Coffey et al., 2019). It was noted by and Matricciani and Jones (2015) that patients who were at high risk for foot complications received foot education more often than patients who were at low risk for foot complications. Furthermore, some patients felt foot education was not a priority for health care professionals when first diagnosed (Coffey et al., 2019).

***Risk perception.*** Three studies identified by Matricciani and Jones (2015) reported that patients did not perform foot self-care activities as they did not consider them to be important. Coffey et al. (2019) identified several situations which reflected risk perception. Even when a person was knowledgeable about foot health, they would make poor choices in order for their lifestyle to not be impacted. For others, there was denial about their diagnosis of diabetes, and this impacted their participation in self-care activities. As well, since the disease was not visible, many people did not have cues to care for their feet and the other daily demands of self-management superseded caring for feet.

Footwear was identified as an issue for some patients. Orthopedic footwear and insoles were considered to be costly, uncomfortable, and unattractive. As a result, some people chose not to wear them despite knowing the recommended guidelines. However, for some people the value of the footwear to their foot health took precedence over any concern about fashion (Coffey et al., 2019).

***Social support networks.*** Matricciani and Jones (2015) reported that two studies identified the importance of social support in relation to foot health behaviors. This support was in the form of frequent contact in person and over the phone which was significantly associated with having a foot assessment completed by a health care provider. Social support from family in relation to advice and assistance was also an important factor in promoting self-care. Either

having a foot complication or knowing someone who did was a motivator to improve foot self-management (Coffey et al., 2019).

***Interactions with health care providers.*** Communication between the patient and health care provider was identified in two studies to be an both enabler and barrier of foot care practices. Clear communication had a positive impact on foot health practices. However, if a patient had a negative experience with a health care provider, they were more likely not to participate in positive foot health behaviors (Matricciani & Jones, 2015). It was noted by Coffey et al. (2019) that health care providers often did not provide information or advice on foot care which contributed to the lack of knowledge and the perception that foot care was not important. Health care providers who had an expertise in foot health were preferred by patients and regular appointments were helpful but participants indicated that access was limited sometimes due to cost and/or geography (Coffey et al., 2019).

***Self-efficacy.*** According to Bandura (2001), self-efficacy, which is an individual's belief that they have control and can make a change with their actions, impacts the choices they make and their perseverance in relation to life challenges. A well-conducted systematic review that included 154 studies and a meta-analysis that analyzed 204 studies reported that a person's self-efficacy impacted on health intentions and behaviors (Nafradi, Nakamoto, & Schulz, 2017; Sheeran et al., 2016). These reviews represent a wide variation of interventions, participants, and health conditions. Nafradi et al. (2017) analyzed observational and experimental research that considered the relationship between self-efficacy and medication adherence for various medical conditions such as cardiac disease, respiratory disease, renal disease, and endocrine disease. The majority of the studies originated in North America. Sheeran et al. (2016) included only studies with an experimental design that tested health related interventions that resulted in a significant difference in self-efficacy and attitudes and norms between the control group and the intervention

group. The volume of studies and the consistency of evidence reflects the importance of self-efficacy for self-management of disease. However, a search of the literature identified limited studies that focused on self-efficacy and foot self-management for people with diabetes. A number of the studies focused on developing countries and were not applicable to patients living in Canada. Only three studies were deemed relevant, one cohort study and two cross-sectional studies, and these studies did not support that self-efficacy impacted foot self-management. The high quality cohort study conducted in Alberta that used the Self-Efficacy for Managing Chronic Disease Scale reported that low self-efficacy was associated with higher prevalence of foot ulcers or infections (OR 2.7; 95% CI 1.7, 4.2) and amputations and gangrene (OR 1.7; CI 0.8, 3.6). Although it would be expected that high self-efficacy would translate into positive behavior, this was not the case as self-efficacy was not a predictor of good self-care ( $p = .105$ ) and having feet clinically assessed for lesions ( $p = .172$ ) and sensation ( $p = .108$ ) (Al et al., 2015). In comparison the two medium quality cross-sectional studies that used the Foot Care Confidence Scale reported that there was no association between self-efficacy and preventative foot self-care behavior (Perrin, Swerissen, & Payne, 2009; Wendling & Beadle, 2015). Given this limited research and that it is well accepted that self-efficacy impacts health behavior, more research is warranted that explores the relationship between self-efficacy and foot self-management.

***Readiness to change.*** Readiness to change or self-manage is a potential factor that can have an impact on foot self-management. The Transtheoretical Model (TTM) outlines that there are five stages of readiness to change. Precontemplation is identified as the stage where people do not intend to make any changes in the near future. In this stage individuals may lack awareness of the problem. The next stage is contemplation and in this stage individuals know they have a problem and are considering addressing it but have not yet conceived a plan. In this stage people consider the advantages and disadvantages of the problem and the plan to address the problem.

The third stage is preparation and in this stage people plan to take action in the next month and have had some unsuccessful attempts to make changes in the last year. The fourth stage is action and in this stage people made modifications to address their behavior sometime in the last day up until the previous six months. The final stage is maintenance and individuals in this stage work to maintain the changes that they made in the previous stage (Prochaska, DiClemente, & Norcross, 1992).

The TTM model has been used extensively in behavioral change modeling for many health issues such as chronic conditions (Prochaska, Redding, & Evers, 2015). There has been less research that has considered readiness to change as a predictor of self-management in diabetes in general and foot self-management. A recent 2019 medium quality cross-sectional study (N=210) that combined survey data with electronic health record data identified that the level of self-management behavior was associated with readiness to change diabetes self-management behavior ( $p < .01$ ) (Khairnar et al, 2019). Given these findings and lack of research related to readiness, diabetes, and foot self-management further research is warranted in this area.

**Summary.** Given the limited evidence of what works and the complexity of foot self-management, multi-modal interventions need to be developed which address the factors that impact on self-management such as knowledge, risk perception, and physical barriers. Specifically, interventions need to combine education that encompasses the different types of activities needed to look after feet well with self-assessment strategies to detect early signs of problems.

## **Infrared Thermometry as an Assessment Tool**

As previously discussed, one of the earliest signs of foot ulceration is inflammation, which is characterized by redness, pain, swelling, loss of function, and temperature increase. People with neuropathy may not experience pain or loss of function (Lavery et al., 2004). However, a temperature increase associated with inflammation can be subtle and is difficult for individuals and health care providers to detect by palpation (Murff, Armstrong, Lanctot, Lavery, & Athanasiou, 1998). As patients cannot rely on cues such as pain, consideration needs to be given to changing their understanding that signs of inflammation may constitute symptoms of a DFU or potential DFU (Vedhara et al., 2014). Self-monitoring of skin temperature using an infrared thermometer is a promising strategy for detecting early inflammation and preventing skin breakdown on the plantar aspects of the feet. Self-management strategies that focus on identifying and addressing early signs of inflammation, such as a temperature increase, may be effective in preventing skin breakdown. A CAIT is a promising assessment tool that will give people the ability to assess for early surface plantar inflammation so preventative action can be taken.

It is important to understand how infrared thermometry works and how this technology can be used to detect early inflammation. Infrared thermometry works on the principal of thermodynamics that all objects which have a temperature greater than absolute zero release infrared radiation (Enloe, Garnett, Miles, & Swanson, 2001). A person will release more infrared radiation when they have a fever, inflammation, or infection. An infrared thermometer will detect this infrared radiation by measuring skin temperature and using a sensor that converts the energy into an electrical signal that parallels a temperature reading. When the person is releasing more infrared radiation the temperature reading will be higher. This technology has been used

clinically to assess for changes in metabolic activity associated with systemic fever, local and deep inflammation, and repetitive trauma associated with DFUs (Sibbald et al., 2015).

Use of infrared thermography for the identification of inflammation with various conditions that have joint inflammation was first reported in the literature in the 1960s. At that time this unit measured infrared energy in black and white with cool areas showing as black and warm areas showing as white (Bergtholdt & Brand, 1976). In 1972 a group of researchers presented a paper that focused on the use of thermography as an early diagnostic tool for diabetic patients who had neuropathic inflammation of the joints or Charcot's foot (Sandrow, Torg, Lapayowker, & Resnick, 1972). In the late seventies infrared thermometry and thermography was promoted to detect inflammation on the plantar surface of the insensate foot in patients with Hansen's disease (Bergtholdt & Brand, 1976; Bergtholdt, 1979). The use of thermography equipment was difficult, however, because of the size and expense of the unit (Armstrong, 1998). The use of an infrared thermometer was more practical and convenient.

A study completed in the 1990s established that patients with Charcot's foot and neuropathic ulceration had infrared thermometry readings with differences greater than 4 degrees Fahrenheit (F) (2.2 degrees Celsius (C)) between the affected and non-affected foot (Armstrong et al., 1997). Intervention research conducted to date has used this difference as an indicator of inflammation (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007; Skafjeld et al., 2015). Van Netten et al. (2014) conducted a study in a clinical setting to consider the diagnostic value of foot temperature using an infrared camera (N=54). They assessed foot skin temperature, using thermal imaging, of three different groups of patients (complications requiring immediate treatment, complications requiring non-immediate treatment, and no complications). They constructed a receiver operating characteristics (ROC) curve and calculated sensitivity and specificity for different temperature cut-off values. They concluded that the optimal cut off for

identifying foot complication was 2.2 degrees Celsius (C) (4 degrees F). The sensitivity and specificity were reported to be 86% and 40% respectively, which indicated that the infrared temperature assessment was correctly identifying elevated foot temperatures associated with inflammation and did not generate many false negative measurements (Van Netten et al., 2014).

A recent study explored the validity of using a 2.2 degree C temperature threshold as an indicator for impending diabetic foot ulceration in terms of various parameters (i.e., having a >2.2 degree difference between the two feet for a single temperature measurement; having a >2.2 degree difference for two measurements on the same day; and having a > 2.2 degree difference for one measurement and for the measurement that was taken the same time on the next day) (Wijlens, Holloway, Bus & van Netten, 2017). Twenty patients with diabetes that were determined to be at risk for foot complications were asked to measure their foot temperatures at home four times a day for six consecutive days. Participants were asked to contact the researcher if they measured a temperature difference greater than 2.2 degrees. At this point the researcher would instruct the participant to rest and to contact the researcher if an elevated temperature was also measured on the second day. None of the participants developed a DFU during the study. A temperature difference between the left and right foot was found in 8.5% of the measurements. This difference decreased to 0.2% when measured the next day and when the participant rested. These researchers concluded as a single measurement this temperature difference was not valid but the validity improved when the temperature was measured on the second day. It is also important to note that the temperature difference was independent of activity, time of day, and environmental temperature (Wijlens et al., 2017).

The findings of these two studies showed that it is beneficial to use thermometry as the sensitivity is high (Van Netten et al., 2014; Wijlens et al., 2017). There were some true positives that were missed and this may be related to the superficiality of infrared temperature

measurement. It is important to recognize that infrared thermometry only measures surface temperature of the skin and it cannot identify deep inflammation, systemic versus local inflammation, and early versus late inflammation. As well, it should be understood that there may be alternative differences in temperature other than inflammation and early skin damage due to excessive pressure and trauma. For example, patients who have poor peripheral circulation may already have differences in temperature between their feet due to the reduced circulation. Therefore, for these patients infrared thermometry would not be a useful tool for detecting foot inflammation (Sibbald et al., 2015).

**Intervention research that utilized an infrared thermometer.** Various systematic reviews, which contained three RCTs, have indicated that the use of personal temperature monitoring with a medical grade infrared thermometer was an effective way to predict, and thus prevent DFUs (Arad, Fonseca, Peters, & Vinik, 2011; Houghton, Bower, & Chant, 2013; van Netten et al., 2015). The three RCTs included in these reviews as well as a pilot study published in 2015 will be discussed in detail in this section.

These four research studies, published between 2004 and 2015, focused on the effectiveness of interventions that utilized infrared thermometry as a self-assessment tool for the prevention of DFU. The \$700 TempTouch thermometer by Xilas Medical, which was equipped with a touch sensor tip that detected contact with the skin, was used in all studies. Three RCTs were conducted in the United States (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007) with a 24-month, 6-month, and 15-month intervention respectively. The pilot RCT, with one-year follow-up, was conducted in Norway (Skafjeld et al., 2015). All studies had two groups, an intervention and control group, with the exception of Lavery et al. (2007) that had three groups that were standard therapy, structured foot examination, and enhanced therapy that used the thermometer.

For all studies, a temperature difference between an area on the two feet of 2.2 degrees Celsius (4 degrees F) indicated that there was inflammation in the foot with the higher temperature. All studies had similar inclusion criteria with individuals 18-80 years of age being eligible. A main difference in the exclusion criteria was Lavery et al. (2004) who excluded patients with PVD whereas Armstrong et al. (2007), Lavery et al. (2007) and Skafjeld et al. (2015) included individuals with a certain level of PVD and measured ankle brachial index (ABI) to determine if the participant was eligible to participate in the study. Individuals were eligible to participate if the ABI was  $> 0.8$  (Armstrong et al., 2007) or  $> 0.7$  (Lavery et al., 2007; Skafjeld et al., 2015).

Details of these publications are presented in the literature summary table in Appendix A. Studies were appraised utilizing the PHAC Critical Appraisal Toolkit (2014). All three RCTs were appraised to be high quality (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). The pilot study was appraised to be of medium quality as it had low power (Skafjeld et al., 2015).

All three RCTs reported significantly fewer DFUs in the intervention group using the thermometer compared to the control group (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). In Lavery et al. (2004) the thermometry group ( $n = 44$ ) had significantly fewer diabetic foot complications and had a 2% ulceration rate versus the control group ( $n = 41$ ) that had a 20% ulceration rate (OR: 10.3; 95% CI: 1.2-85.3;  $p = 01$ ) (Lavery et al., 2004). Armstrong et al. (2007) ( $N=225$ ) reported the ulceration rate in the thermometry group was 4.7% compared to 12.2% in the control group (OR: 3.0; 95% CI: 1.0 to 8.5,  $p=.038$ ). For Lavery et al. (2007) the primary outcome of ulceration rate for each group was 29.3% for the standard care ( $n = 58$ ); 30.4% for the structured foot exam ( $n = 56$ ); and 8.5% for the enhanced therapy group ( $n = 59$ ) (Lavery et al., 2007). There were no significant differences between the two groups in the pilot

study at one year follow up with the intervention group (n=21) having 39% ulceration rate and the control group (n = 20) having a 50% ulceration rate. However, as mentioned previously, this study was underpowered and therefore the sample size was not large enough to detect statistically significant differences between the two groups (Skafjeld et al., 2015). It is interesting to note that in Lavery et al. (2007) the structured foot exam group had almost the same ulceration rate (30.4%) as the standard care group (29.3%) compared to the much lower rate in the group that used the thermometer (8.5%). This may indicate that a visual exam is not enough to detect early inflammation associated with ulceration and provide direction for action. Lavery et al. (2004) also measured QoL but found no differences between groups, using SF (36), even though there was reduced ulceration. Armstrong et al. (2007) also stated they measured concepts related to self-management, QoL, self-efficacy, satisfaction with care, and activity regulation, but did not publish those results.

Overall, these RCTs showed that the use of thermometry is a promising assessment tool to identify elevated surface skin temperature that is related to plantar inflammation and trigger individuals to modulate activity in order to prevent DFUs. A limitation of these research studies was that the researchers did not evaluate the strategy from the users' and health care providers' perspectives. Although Skafjeld (2015) reported that the intervention group had a high adherence rate it is unknown if individuals found temperature self-monitoring to be an assessment that they could easily incorporate into their routine or if they required help from family and friends to complete the assessment. The impact of the intervention on confidence, knowledge, QoL, and satisfaction was not clear and requires further exploration and will be addressed in this dissertation.

**Overview of CAIT validation study.** The thermometer used in the intervention studies described above cost approximately \$700, which can be prohibitively expensive and would decrease the accessibility for many individuals. A 2015 validation study compared inexpensive non-contact CAITs, that cost under \$100, to medical infrared thermometers and found them to be a reliable measure of skin temperature (Mufti, Coutts, & Sibbald, 2015). The researchers compared four different brands of non-contact CAITs (Mastercool, ATD, Mastercraft, and Pro-Point) with a clinical infrared thermometer Exergen DermaTemp (n=108). The participants included patients who did and did not have a wound infection. The temperature sites were uncovered for ten minutes before measurements were taken. Controlling for environmental conditions, researchers measured temperature of the wound and the opposite limb with each thermometer. Inter-rater reliability was assessed on 20 participants between the principal investigator and an experienced wound care nurse. The change in temperature was obtained by subtracting the target temperature from the contralateral temperature. Researchers reported that there was no statistically significant difference between the change in temperature values for the five thermometers. Post hoc analysis of a comparison of the medical grade Exergen Derma Temp with the four CAITs showed correlation coefficient values of greater than 0.95 (Mufti et al., 2015).

The authors argued that these findings showed that CAITs had reliable temperature readings from a clinical and practical perspective. As well, the authors proposed that the non-contact CAITs could also prevent the spread of infection because these thermometers could be held further from the wound when measuring a temperature and therefore contamination could be avoided. One of the authors explained in his experience the medical-grade thermometer had a higher risk of touching the skin during measurement and therefore could possibly transmit infection to other clients (Mufti et al., 2015). As well, CAITs are easy to use and this, plus the

low cost, may make them readily available to patients (Sibbald et al., 2015). However, this technology has not been used as part of an intervention as of yet, so further research is warranted to see if the CAIT will result in the same positive results as the medical grade thermometer.

### **Research Problem**

The incidence and prevalence of DFUs are high. For patients with diabetes and their families, a DFU is a devastating complication with a high cost to the health care system. Strategies are needed to address this health issue and decrease the incidence of DFUs. Multi-modal interventions are needed that take into account factors related to self-management as well as factors that have been identified to contribute to DFUs. Patients need to know appropriate strategies for reducing pressure and controlling risk factors, as well as assessment strategies for facilitating early identification of problems. As illustrated in Figure 1.2 a CAIT is one promising strategy to incorporate into a self-management intervention to help detect early inflammation.

Building on the pathophysiology previously discussed in Figure 1.1, Figure 1.2 shows the process of self-management in relation to the prevention of a DFU, with the potential role of a CAIT in preventing skin breakdown. Pressure and/or repetitive stress on the plantar surface of the feet can cause inflammation as evidenced by pain, redness, and a temperature increase. If a person can detect this inflammation, they can decrease the risk of skin breakdown by self-managing and taking appropriate action such as off-loading (e.g., resting), changing their shoes, and/or seeing his/her health care provider.

However, it may not be easy to detect inflammation. For example, a person's flexibility and vision will impact their ability to see their feet. As well, it is difficult to detect the subtle temperature change associated with inflammation. The person's ability to self-manage may also be influenced by factors such as knowledge, social support, and confidence. While multiple factors will ultimately impact a person's ability for both self-assessment and taking action,

having a tool to facilitate detecting inflammation is an important strategy for disrupting the pathway to DFU formation. For patients with diabetes a non-contact CAIT can be used as a self-management strategy to detect a temperature increase before skin breakdown occurs. A temperature increase of greater than 4 degrees F compared to the opposite limb is considered indicative of inflammation and a warning that the person is at risk for a potential DFU and should decrease activity (Sibbald et al., 2015). Once the temperature increase is identified, the individual can relieve pressure, for example by resting, until the temperature normalizes and inflammation decreases. If the temperature does not normalize in two days then a health care provider should be consulted.

To date, no research studies have tested the viability of using a CAIT as part of a self-management strategy. As well, foot self-management is complex and a better understanding is required in order to develop interventions that address this complexity and consider the local context. This dissertation will address these empirical gaps. A mixed methods research (MMR) study with three phases was undertaken. Patient engagement occurred at Phases 1 and 3 and provided insights into foot self-management and ensured that this research was relevant to patients' concerns. In Phase 1, patients, support persons, and health care providers shared their insights and knowledge regarding diabetic foot self-management. Obtaining these perspectives aided in refining the intervention, collecting the data, and evaluating the results. Phase 2 was the quantitative phase of the study and in this Phase a six-month pilot RCT was conducted that assessed the effectiveness of a CAIT as part of a foot care strategy. Phase 3 was the second qualitative phase, during which interviews were conducted with patients and health care providers to determine what was meaningful. An overview of the methods is presented in this chapter with further details and results in Chapters 2 and 3. The value and benefits of using a MMR approach rather than an RCT alone will be presented in Chapter 4.

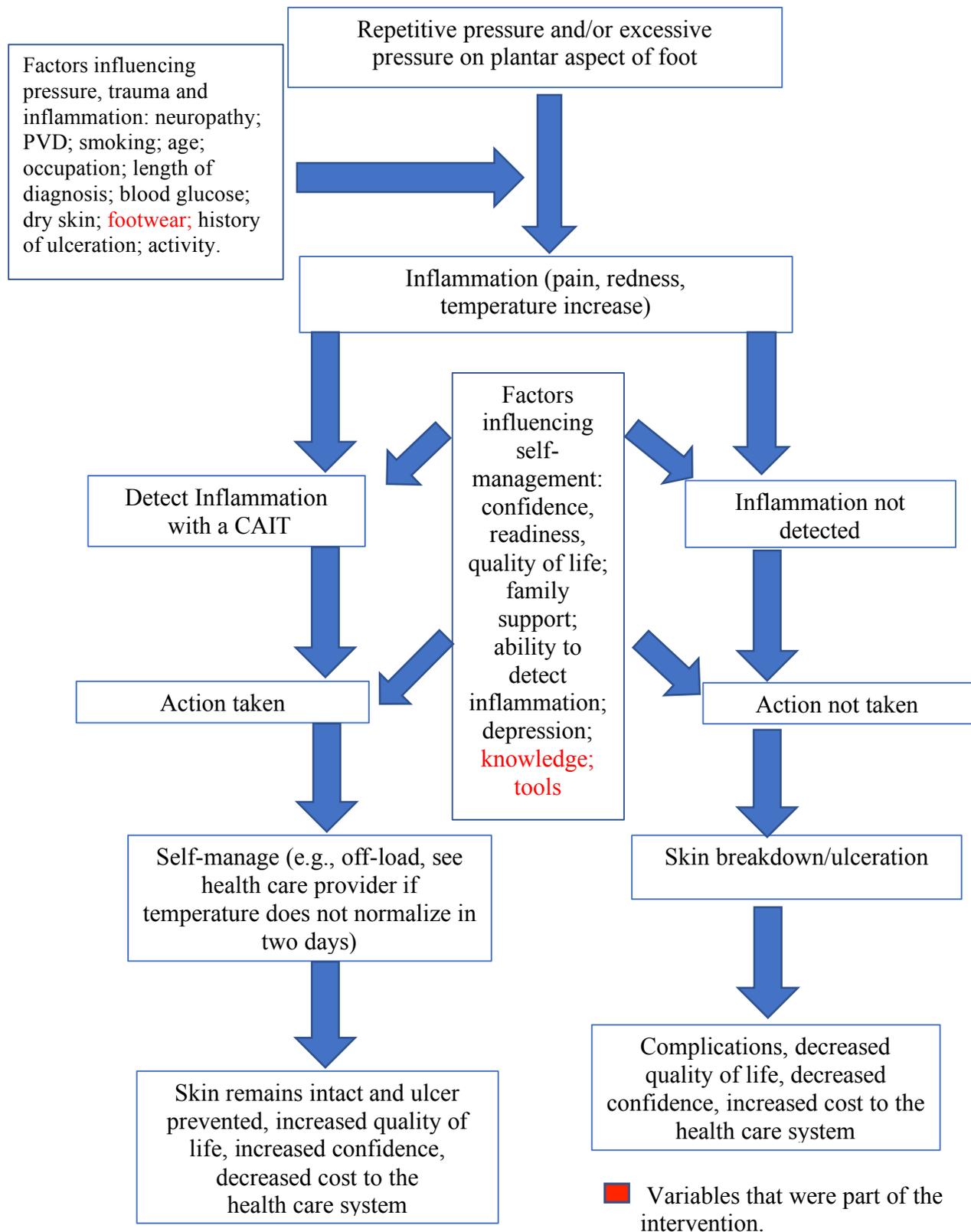


Figure 1. 2 Logic model. This figure illustrates the process of self-management in relation to prevention of DFU

## **Research Questions**

The overarching research question for this study is: What strategies are effective to help people with diabetes self-manage their foot health? The study has three separate phases, which were guided by the following specific research questions:

1. What are the issues related to self-management of feet? (Phases 1, 2, 3)
2. Does a foot health intervention that utilizes a CAIT improve foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention? (Phase 2)
3. What are the participants' experiences with foot health self-management and the intervention? (Phases 1, 2, and 3)

## **Intervention**

The intervention was comprised of an education component and daily completion and recording in a logbook of a foot assessment and the number of steps taken. The education was delivered one-on-one by the researcher. Teaching strategies utilized were the Canadian Association of Wound Care diabetic foot management YouTube video (<https://www.youtube.com/watch?v=xC-TqWvU0I>) and the World Diabetes Foundation Flipchart that was adapted with permission and presented using a laptop computer (World Diabetes Foundation, 2014). A hard copy of the presentation was provided to participants. A summary of the topics covered in the education module can be found in Appendix B. Both groups were provided with an inspection mirror with an extendable handle to assist with visualizing the bottom of the feet and a pedometer to measure daily activity. Additionally, the intervention group received a CAIT and were asked to record the temperature of each foot daily as well as a visual foot assessment. These assessments could be completed at whatever time of day that was convenient for them. Education on use of the CAIT was provided through

demonstration using a foot model and CAIT. The foot model was marked with a zigzag pattern on the plantar surface to illustrate the path that should be used when measuring temperature.

The support person was encouraged to attend the education session and was included in the teaching, especially if he/she would be assisting the participant to obtain temperature readings. The teaching points that were used by the researcher to ensure consistency when instructing the participant on how to use the thermometer and an accompanying handout for the participant can be found in Appendix C. The participant was also provided with a letter explaining the study to take to his/her health care provider. The letter can be found in Appendix D. The participant and support person were asked to demonstrate what they were taught regarding use of the thermometer. The return demonstration check list can be found in Appendix Q.

## **Methodology**

The overall methodology guiding this study was Mixed Methods. The qualitative phases (Phases 1 and 3) specifically were guided by Interpretive Description. Mixed Methods and Interpretive Description are complementary methodologies as they are underpinned by pragmatism (Cresswell, 2014; Thorne, 2016). Pragmatism is pluralistic and oriented towards what works and real-world practice, valuing both objective and subjective knowledge (Cresswell & Plano-Clark, 2018). The goal of Interpretive Description is to address real-world clinical practice issues and MMR is pluralistic and draws on both objective and subjective knowledge to answer the research questions.

**Mixed Methods.** MMR is a methodology that is used in the social, behavioral, and health sciences and involves the collection of both quantitative and qualitative data to answer the research questions. Data collected are integrated, which means the results are combined or merged, providing a more comprehensive answer to the research questions (Creswell, 2014).

MMR is distinguished from multiple methods research or multi-method design where two or more independent projects are conducted to answer the research question with no integration of the data (Morse, 2010).

This MMR study had three phases and used an exploratory sequence (Phase 1 to the development of the intervention) and an explanatory sequence (Phases 2 and 3). Patient engagement occurred in Phases 1 and 3 and provided insights into foot self-management, helping ensure that this research was relevant to patients' concerns. In Phase 1 (exploratory) patients, support persons, and health care providers shared their insights and knowledge regarding diabetic foot self-management. Obtaining patients' perspectives aided in refining the intervention, collecting the data, and evaluating the results. Phase 2 (explanatory) was the quantitative phase of the study and in this phase a six-month pilot RCT was conducted that assessed the effectiveness of a CAIT as part of a foot strategy. Phase 3 (explanatory) was the second qualitative phase, and interviews were conducted with patients to help further understand the Phase 1 and Phase 2 findings. Integration of data from all three phases occurred at the end of the study.

**Interpretive Description.** Interpretive description was used to guide Phases 1 and 3 of the study (Thorne, 2016). The aim of Interpretive Description is to bring a clinical perspective to evidence-based practice using qualitative methodology. This is an approach that is being used by many researchers in applied health disciplines. Interpretive Description was an appropriate method because nursing is an applied health discipline and clinical questions are being asked that can be answered using qualitative research. For Phase 1 questions related to self-management of foot health were asked. For Phase 3 questions were asked regarding participants' experiences with the intervention.

Theoretical scaffolding is a key term that is used in Interpretive Description and refers to the background knowledge used and the disciplinary orientation that the researcher takes in the

study. The theoretical scaffolding influences the direction of the study and has two components: the literature review; and what the researcher brings to the study known as disciplinary positioning. As the primary researcher, the theoretical scaffolding for this study was based on my understanding of foot self-management and diabetes in relation to the literature. Disciplinary positioning was influenced by central concepts in nursing and my expertise and clinical experience. When using Interpretive Description, I was grounded in central concepts in the discipline of nursing that guided the direction of the study, including data collection and analysis. These central concepts were person, health, environment, and nursing. I went beyond just describing what was happening in relation to the research questions and asked the questions: what does it mean; what can I do with these findings; why is it important? For Phase 1 the answer to these questions informed the intervention (Phase 2). Overall, the knowledge that is generated by this research will add to nurses' understanding of these central concepts in relation to self-management and foot health for people with diabetes.

A key difference between Interpretive Description and traditional qualitative methodologies is the goal of obtaining sufficient data and not data saturation. To say that data saturation was achieved is not in keeping with the nursing disciplinary view. For example, nurses' view of individuals is that there are many variations and everything about every possible way an individual will present with an illness or how they will react to an illness cannot be known. This premise recognizes that there is always more to study. Therefore, the goal when using Interpretive Description was to feel confident that sufficient data were obtained to report well-developed findings related to self-management and diabetes (Thorne, 2016).

## **Methods**

In the following section an overview of the study methods will be presented. Further details of the methods are provided in Chapters 2 and 3. Two patients representatives were members of the research committee and provided feedback throughout the study. Both representatives had experience related to diabetes and foot self-management; one patient representative provided support to a family member with diabetes and the other had neuropathy that resulted in foot ulceration. The role of the patient representatives will be further discussed in Chapter 4 (Manuscript 3).

**Phase 1 (Qualitative).** As discussed, the purpose of Phase 1 (exploratory sequence) was to explore issues related to engaging in self-management and use of the CAIT so that appropriate strategies could be incorporated into the intervention.

**Sampling.** Purposive convenience sampling was utilized in Phase 1 and patients, support persons, and health care providers were selected that informed the researcher about issues with foot self-management. To gain a comprehensive understanding of foot self-management, participants were selected who had a variety of experiences and characteristics, such as patients with diabetes with various foot health challenges and health care providers with different professional designations such as physicians and nurses.

**Recruitment.** Posters advertising the study were placed in clinical areas and potential participants interested in participating contacted the researcher directly. Managers and key contacts at clinics acted as intermediaries and provided information about the study to health care providers, patients and support persons and asked permission for the researcher to contact them about possible participation. The researcher followed up with the potential participants to determine if they were interested in participating. If the participant was interested in participating, informed consent was obtained.

Documents used in Phase 1 can be found in the following Appendices: recruitment script used by key contacts (Appendix E); information sheet provided to potential participants (Appendix F); locations for recruitment (Appendix G); inclusion/exclusion criteria (Appendix H); informed consent form (Appendix I);

**Data collection.** Semi-structured interviews lasting 20-60 minutes were conducted at a mutually convenient location. Interviews were taped and transcribed. The interview guides used in Phase 1 can be found in Appendix J.

**Data analysis.** Interview transcripts were analyzed using NVIVO, a qualitative software package (*NVIVO 11*, QRS International, Victoria, Australia). The analysis was guided by research questions 1 and 3 as stated above. Under the umbrella of Interpretive Description, *The Three Cs: Coding, Categorizing, and Concepts*, were used to analyze the data (Lichtman, 2013). The findings of Phase 1 were used to inform Phase 2. Chapter 2 presents the findings of Phase 1.

Twenty-four interviews were completed with 11 patients; 9 health care providers; and 4 support persons. All patients were Caucasian with 5 patients from a rural area and 6 patients from an urban area. The age range of patients was 50-74 years with length of time since diagnosis ranging from 1-44 years. With the exception of one health care provider, all health care providers were from an urban area. Three support persons were spouses and one was a paid caregiver. Two of the health care providers had diabetes and statements were analyzed from this perspective as appropriate. Demographic information about the sample was analyzed using descriptive statistics.

**Rigor.** Rigor was addressed in Phase 1 through adhering to strategies for promoting credibility that are applied when using Interpretive Description; epistemological integrity; analytical logic; representative credibility; and interpretive authority. Epistemological integrity was addressed through using a research question and use of sources and strategies to answer the question that were in keeping with the epistemological perspective. Representative credibility

was shown through gaining multiple perspectives from interviews conducted with patients, linked support person, and HCPs. Analytical logic was achieved through use of deep description in the analysis and presentation of findings and an audit trail that reflected the decision making that occurred during the research. Finally, interpretive authority was addressed through use of reflexive journaling during data collection with the goal of ensuring that the researcher's interpretations were trustworthy and were capturing truth that was external to the researcher's experience (Thorne, 2016).

**Phase 2 (Quantitative).** Phase 2 was the beginning of the explanatory sequence and in this phase a six-month pilot RCT was conducted. The purpose of Phase 2 was to assess if the use of a CAIT, as part of a multi-modal foot self-management strategy, improved foot outcomes. The recruitment, sample size, intervention, data collection, and measures will be presented in this section. The results of Phase 2 are included in the manuscript presented in Chapter 3.

**Recruitment.** Multiple strategies were used to recruit such as: posters and pamphlets placed in the recruitment areas; an advertisement placed in a local newspaper and on local cable television; and a radio interview. The poster and pamphlet can be found in Appendix K. Individuals interested in participating contacted the principal investigator. The script for screening can be found in Appendix L. If the individual was unable to read the thermometer the researcher determined if there was a support person who could assist the individual to do this on a daily basis. If the patient met the criteria, the researcher booked a time to meet the participant at his/her home or at the Nursing Skills Lab at Memorial University Faculty of Nursing to determine if he/she met the final inclusion criteria: category 2 or 3 of the International Diabetic Foot Risk Classification System (IWGDF, 2019); ankle brachial index > 0.08; and loss of sensation on 4 areas on the foot as identified by the monofilament test. Verbal consent was obtained to conduct the screening. If the patients met the criteria they were asked if they have any

concerns about being able to complete the study and if they thought they had time to meet the study requirements. Written consent was obtained for participation from patients who were interested. See Appendix M for the consent form for Phase 2.

As the response rate for recruitment was low in the initial six months of the study the inclusion/exclusion criteria were adjusted and approved through the ethics board. The first change was loss of sensation in at least 1 area on the foot as identified by the monofilament test instead of four. The second change was the addition of the presence of a deformity even if the monofilament test was normal (e.g., claw toe, prominent metatarsal head and/or or callus). The third change was an ankle brachial index  $> 0.07$  instead of 0.08. This third change was in keeping with the criteria used by Lavery et al. (2007). The intention of this revision was to increase recruitment while still including participants who could potentially benefit from identification of early inflammation with the thermometer. The tool being used to assess for neuropathy required participants to have four or more areas with loss of sensation and this may have been too restrictive. However, having one or more areas with a loss of sensation on the foot can be considered to be sensory neuropathy. Having a deformity and/or callus also puts a person at risk for inflammation and skin breakdown that could lead to a diabetic foot ulcer. Both of these conditions may be the result of motor neuropathy or autonomic neuropathy respectively and due to abnormal loading on the foot could result in inflammation. A person having either of these conditions, with or without sensation loss, could potentially benefit from being able to identify inflammation early.

**Sample size.** The findings of an RCT that used a similar intervention and investigated the effect of use of a medical grade thermometer on ulceration rate were used to calculate the sample size (Lavery et al., 2007). The sample size calculation was based on hypothesizing that the ulceration rate would be similar to our study with 8.5% in the intervention group and 29.3% in

the control group ulcerating. Using an alpha of .05 and a beta of .80 and allowing for a possible 10% loss of participants, 71 individuals were to be enrolled in each group in order to ensure 64 participants per group completed the study.

The timeframe for recruitment was August 2017 until October 2018. Recruitment was slow and additional strategies to increase recruitment such as expanding the recruitment locations and changing the inclusion and exclusion as outlined above were put in place. Due to difficulties with recruitment the targeted sample size was not achieved and Phase 2 was declared to be a pilot study with the goal of obtaining preliminary results and testing the methods. There were 26 participants enrolled in the control group and 34 enrolled in the intervention group.

***Intervention.*** Using a list of randomly generated numbers patients were assigned to the thermometer and education group and education-only group. Both received foot self-management education and the thermometer and education group received a CAIT as previously described. The content of the education was finalized following completion of Phase 1. Intervention fidelity was enhanced through use of a standardized video for foot education and provision of education by the same trained researcher.

***Revision to temperature measurement and the intervention.*** During the first 13 months of the study patients in the intervention group were instructed and provided with written instruction to detect inflammation by comparing the temperature measurement in the large display of the infrared thermometer after scanning their feet as this was thought to be the best measurement. This recorded a temperature of a single point on the foot, which was the last temperature measured. These instructions were sent to an expert in temperature monitoring for feedback prior to starting the study (Pat Coutts, personal communication, 2016). New information was obtained regarding the use of temperature measurement and infrared thermometry for detecting inflammation. Even when a "hotspot" was present and there was some

temperature difference within the scanned area, the important difference upon which to base clinical action is the difference between the scanned foot and opposite foot. However, a new study released in 2018 that used a CAIT to detect periwound infection identified that the maximum temperature reading mode is a better measure to detect inflammation (Mufti et al., 2018). This was confirmed with one of the researchers of that study (Pat Coutts, Personal Communication, October, 2018). Participants who were finished the intervention were informed of this new information and participants who were enrolled in the study were provided with education on how to use the maximum temperature mode (See Appendix N for letters with new information provided to participants). There were then three groups in the trial:

1. Control Group (no changes)
2. Intervention Group 1 (the last temperature reading). This group consisted of all patients who had completed the trial as of October 2018.
3. Intervention Group 2 (the maximum temperature reading). All new patients who enrolled after October 2018 as well as the patients that were in the intervention group at the time of the change.

In order to have a sufficient number in the maximum temperature intervention group, the patients newly enrolled following the change, were randomly allocated to the maximum temperature group or control group using a 3:1 ratio. Participants were taught to use the maximum temperature reading on the Mastercraft thermometer. This can be accessed after the foot is scanned by pressing mode on the thermometer until “max” appears in the display. The maximum temperature reading is the temperature displayed in a smaller size in the bottom right corner of the display.

At the time of the change the plan was to analyze the data for each of the two intervention groups based on whether they did the maximum temperature reading or the last temperature

reading and report results separately for each intervention group. The analysis was completed and showed no difference between the two groups. Therefore, the participants for each intervention arm were merged into a single thermometer and education group.

***Data collection.*** Data collection was the same for both groups with the addition of foot temperature measurement for the thermometer and education group. The initial one-hour intake session took place in the participant's home or at Memorial University Faculty of Nursing and included completing baseline assessments and distributing the orthotic assessment requisition, logbooks, and equipment. Use of two trained interviewers minimized information bias during data collection.

At the end of the initial visit a second 15-minute visit was booked with participants in the intervention group for one week later. The purpose of the second visit was to determine if the thermometer was being used correctly and the documentation was being completed as intended. This was also an opportunity to answer any questions. Next, the participant and support person were contacted one week later (i.e., week 2) via phone to check if there were any questions or concerns. If the participant's concerns could not be answered over the phone the investigator booked a time to visit the participant. The logbooks for participants in both groups were picked up on a monthly basis either by the investigator or research assistant. A tracking form was used to organize the timeframe for the phone calls and visits. Participants in the education-only group were contacted via phone one week after the initial visit to address any questions or concerns. At three months and six months another 30-minute appointment was made with all participants to complete assessments and questionnaires. The individual and group tracking forms for contacting and visiting participants can be found in Appendix O. Participants were advised to immediately contact his/her physician if an area of concern was identified. Also, participants were asked to

contact the investigator if he/she developed an ulcer. When participants completed the study an exit interview was conducted using a structured interview guide.

**Measurement.** The primary outcome was incidence of ulceration measured through physical assessment and self-report utilizing a standard definition of a DFU, “a full-thickness’ lesion of the skin, that is, a wound penetrating through the dermis” (Schaper, 2004, p.S90). Secondary outcomes were: completion of a visual foot assessment; completion of a temperature assessment; completion of any foot assessment (either visual or thermometer assessment); taking action based on the foot assessment; usability of the CAIT; and changes in satisfaction, QoL, and self-efficacy. Confounding variables were identified based on a review of the literature and that were found to be confounders in other studies related to thermometry and foot self-management. Factors that were potential confounders were: pedometer readings, HbA1C results, orthotic assessment, temperature, depression symptoms, and information collected in the participant profile.

The measures that were utilized for the thermometer and education group and the education-only group are summarized in Table 1.1. The only difference between the groups was that participants in the thermometer and education group measured foot temperature daily and completed the return demonstration for measuring temperature. The descriptions of the measures are found in Appendix P and the measures developed for this study are found in Appendix Q.

Table 1. 1 *Measures and Schedule of Data Collection*

Measure	Time to Complete Measure	Daily	Baseline	1 week	3 months	6 months	Exit
Logbook: <ul style="list-style-type: none"> <li>• Temperature readings</li> <li>• Pedometer readings</li> <li>• Foot self-assessment</li> <li>• Event</li> </ul>	5 minutes	✓					
Participant Profile	15 minutes		✓				
Return demonstration for temperature measurement	5-10 minutes		✓	✓		✓	
Orthotic Assessment	1 hour		✓				
Follow-up of orthodist's recommendations	5 minutes				✓	✓	
HbA1C * HbA1C will only be repeated if the result of the three-month check is elevated.	1-2 hours				✓	* ✓	
Foot screen using Simplified 60 Second Foot Screen (baseline, 3 and 6 months)	1 minute		✓		✓	✓	
Stages to Readiness to Change Tool	1 minute		✓				
Foot Care Confidence Scale (baseline, 3 and 6 months)	10 minutes		✓		✓	✓	
The QoL Enjoyment and Satisfaction Short Form (baseline, 3 and 6 months)	5 minutes		✓		✓	✓	
Patient Health Questionnaire (PHQ9)	5 minutes		✓		✓	✓	

Measure	Time to Complete Measure	Daily	Baseline	1 week	3 months	6 months	Exit
Nottingham Assessment of Functional Footcare	15 minutes		✓		✓	✓	
Exit Interview	20 minutes						✓

**Rigor.** Several strategies were used in Phase 2 to ensure methodological rigor in relation to three areas: sampling method, internal validity, and control of confounding. First, in relation to the sampling method, multiple recruitment strategies and locations were used to ensure that the sample was representative of the target population. Control of selection bias was addressed with a similar recruitment process and use of inclusion and exclusion criteria to ensure that the intervention and control group had similar baseline characteristics. Secondly, several strategies were also used to address internal validity. Misclassification bias was addressed by ensuring strong intervention integrity and by having one researcher deliver the intervention. Adequacy of information bias was ensured by having the primary researcher, who was an advanced foot care Registered Nurse, and a trained research assistant, who was also an advanced foot care Register Nurse, collect the data. As well, data collection instruments that had established reliability and validity were employed. Finally, control of confounding was addressed by: ensuring the control group and intervention group were comparable at baseline; having adequate randomization of participants to the control and intervention, and using logistic regression to analyze the data.

**Phase 3 (Qualitative).** At the end of the Phase 2 data collection, participants were recruited for Phase 3 (explanatory sequence). Semi-structured interviews were conducted with 9 RCT participants. The telephone script and consent can be found in Appendix R and the interview guide can be found in Appendix S. The interview with the participants was 30 – 60

minutes in duration and took place over the phone. The interviews were taped and the tapes were used to supplement interview notes. The data were analyzed using Interpretive Description.

Integration occurred at the end of Phase 3. Each data set was analyzed separately and then the “Fit of the Data Integration” was analyzed. This referred to the coherence of the qualitative and quantitative findings. Phase 3 findings were considered in relation to the results of Phases 1 and 2. Three possible outcomes were assessed during the analysis.

1. *Confirmation* occurs when the findings from both types of data confirm the results of the other. As the two data sources provide similar conclusions, the results have greater credibility.
2. *Expansion* occurs when the findings from the sources of data diverge and expand insights of the phenomenon of interest. For example, quantitative data may speak to the strength of associations while qualitative data may speak to the nature of those associations.
3. *Discordance* occurs if the qualitative and quantitative findings are inconsistent or disagree with each other (Fetters, Curry, & Creswell, 2013).

Completing the assessment of fit led to a better understanding of the Phase 1 and Phase 2 research findings.

**Rigor.** Rigor was addressed in Phase 3 as it was in Phase 1 through adhering to strategies for promoting credibility that are applied when using Interpretive Description; epistemological integrity; analytical logic; representative credibility; and interpretive authority. Epistemological integrity was addressed through using a research question and use of sources and strategies to answer the research question that were in keeping with the epistemological perspective. Representative credibility was shown through gaining multiple perspectives from interviews conducted with patients who could best answer the Phase 3 questions. Analytical logic was

achieved through use of deep description in the analysis and presentation of findings and an audit trail that reflected the decision making that occurred during the research. Finally, interpretive authority was addressed through use of discussion with research team members during data collection with the goal of ensuring that the researcher's interpretations were trustworthy and were capturing truth that was external to the researcher's experience (Thorne, 2016).

### **Ethical Considerations**

Ethical approval was obtained from the Newfoundland and Labrador Health Research Ethics Authority (HREA) and the Research Proposals Approval Committee (RPAC). Informed consent was obtained from participants. The consent form for Phase 1 can be found in Appendix I, the consent form for Phase 2 can be found in Appendix M, and the telephone consent for Phase 3 can be found in Appendix R. The HREA approval letter can be found Appendix T.

### **Funding**

This research was funded by grants from NL-SUPPORT, Healthcare Foundation, and the College of Registered Nurses of Newfoundland and Labrador.

### **Outline of Dissertation**

This dissertation follows a manuscript format. Chapter 1 provides an introduction to the research and overviews of the background and rationale for conducting this research and presents a detailed literature review. The manuscript in Chapter 2 presents the exploratory sequence and presents the qualitative findings on the experiences that people with diabetes have managing foot health. The manuscript in Chapter 3 presents the explanatory sequence and an integration of the findings from Phases 2 and 3. Chapter 4 presents a methodological article that illustrates, through discussion of this study, the synergy between MMR and patient-oriented research. Chapter 5 is the final chapter and presents a summary of the findings and the implications for the intervention, practice, policy, education, and research.

## References

- Al Sayah, F., Soprovich, A., Qiu, W., Edwards, A. L., & Johnson, J. A. (2015). Diabetic foot disease, self-care and clinical monitoring in adults with type 2 diabetes: The Alberta's caring for diabetes (ABCD) cohort study. *Canadian Journal of Diabetes, 39 Suppl 3*, S120-6. doi:10.1016/j.cjcd.2015.05.006 [doi]
- Alavi, A., Sibbald, R. G., Mayer, D., Goodman, L., Botros, M., Armstrong, D. G., . . . Kirsner, R. S. (2014). Diabetic foot ulcers: Part I. pathophysiology and prevention. *Journal of the American Academy of Dermatology, 70*(1), 1.e1-18; quiz 19. doi:10.1016/j.jaad.2013.06.055 [doi]
- Arad, Y., Fonseca, V., Peters, A., & Vinik, A. (2011). Beyond the monofilament for the insensate diabetic foot: A systematic review of randomized trials to prevent the occurrence of plantar foot ulcers in patients with diabetes. *Diabetes Care, 34*(4), 1041-1046. doi:10.2337/dc10-1666 [doi]
- Armstrong, D. G. (1998). Infrared dermal thermometry: The foot and ankle stethoscope. *The Journal of Foot and Ankle Surgery: Official Publication of the American College of Foot and Ankle Surgeons, 37*(1), 75-76. doi:S1067-2516(98)80016-1 [pii]
- Armstrong, D. G., Boulton, A. J. M., & Bus, S. A. (2017). Diabetic foot ulcers and their recurrence. *The New England Journal of Medicine, 376*(24), 2367-2375. doi:10.1056/NEJMra1615439 [doi]
- Armstrong, D. G., Holtz-Neiderer, K., Wendel, C., Mohler, M. J., Kimbriel, H. R., & Lavery, L. A. (2007). Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. *The American Journal of Medicine, 120*(12), 1042-1046. doi:S0002-9343(07)00739-5 [pii]

- Armstrong, D. G., Lavery, L. A., Liswood, P. J., Todd, W. F., & Tredwell, J. A. (1997). Infrared dermal thermometry for the high-risk diabetic foot. *Physical Therapy*, 77(2), 169-75; discussion 176. Retrieved at <https://academic.oup.com/ptj>
- Baba, M., Duff, J., Foley, L., Davis, W. A., & Davis, T. M. (2015). A comparison of two methods of foot health education: The Fremantle diabetes study Phase II. *Primary Care Diabetes*, 9(2), 155-162. doi:10.1016/j.pcd.2014.05.004 [doi]
- Bandura, A. (2001). Social cognitive theory: An agentic perspective. *Annual Review of Psychology*, 52, 1-26. doi:10.1146/annurev.psych.52.1.1 [doi]
- Bergtholdt, H. T. (1979). Temperature assessment of the insensitive foot. *Physical Therapy*, 59(1), 18-22. Retrieved at <https://academic.oup.com/ptj>
- Bergtholdt, H. T., & Brand, P. W. (1976). Temperature assessment and plantar inflammation. *Leprosy Review*, 47(3), 211-219. Retrieved from <http://leprev.ilsl.br/arquivo.php>
- Botros, M., Kuhnke, J., Embil, J., Goettl, K., Morin, C., Parsons, L., . . . Evans, R. (2019). *Best practice recommendations for the prevention and management of diabetic foot ulcers*. Canada: Wounds Canada. Retrieved from <https://www.woundscanada.ca/docman/public/health-care-professional/bpr-workshop/895-wc-bpr-prevention-and-management-of-diabetic-foot-ulcers-1573r1e-final/file>
- Borges, W. J., & Ostwald, S. K. (2008). Improving foot self-care behaviors with Pies Sanos. *Western Journal of Nursing Research*, 30(3), 325-341 doi: 10.1177/0193945907303104.
- Boulton, A. J. (2013). The pathway to foot ulceration in diabetes. *The Medical Clinics of North America*, 97(5), 775-790. doi:10.1016/j.mcna.2013.03.007 [doi]

- Boulton, A. J., Armstrong, D. G., Albert, S. F., Frykberg, R. G., Hellman, R., Kirkman, M. S., . . . Task Force of the Foot Care Interest Group of the American Diabetes Association. (2008). Comprehensive foot examination and risk assessment. *Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists*, 14(5), 576-583. doi:G22H443105711257 [pii]
- Boulton, A. J., Vileikyte, L., Ragnarson-Tennvall, G., & Apelqvist, J. (2005). The global burden of diabetic foot disease. *Lancet (London, England)*, 366(9498), 1719-1724. doi:S0140-6736(05)67698-2 [pii]
- Boulton, A. J., Vinik, A. I., Arezzo, J. C., Bril, V., Feldman, E. L., Freeman, R., . . . American Diabetes Association. (2005). Diabetic neuropathies: A statement by the american diabetes association. *Diabetes Care*, 28(4), 956-962. doi:28/4/956 [pii]
- Chang, C., Peng, Y., Chang, C., & Chen, M. (2013). Useful screening tools for preventing foot problems of diabetics in rural areas: A cross-sectional study. *BMC Public Health*, 13(1), 612. <https://doi.org/10.1186/1471-2458-13-612>
- Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal*, 16(1), 183-210. doi:10.1111/iwj.13010 [doi]
- Creswell, J. W. (2014). *A concise introduction to mixed methods research*. United States: Sage Publications.
- Creswell, J. W., & Plano-Clark, V. L. (2018). *Designing and conducting mixed methods research* (3<sup>rd</sup> ed.). Los Angeles: Sage publications.
- Critical Appraisal Skills Program. (2018). *CASP qualitative checklist*. Retrieved from <https://casp-uk.net/casp-tools-checklists/>

- Diabetes Canada. (2015a). *Why action is needed to prevent amputation in Ontario*. Retrieved from [https://www.diabetes.ca/getmedia/0fba059a-2652-424f-941d-2f7686e26597/Amputation\\_Prevention\\_Infographic\\_ON\\_8-5x11\\_3.pdf.aspx](https://www.diabetes.ca/getmedia/0fba059a-2652-424f-941d-2f7686e26597/Amputation_Prevention_Infographic_ON_8-5x11_3.pdf.aspx)
- Diabetes Canada. (2015b). *Why action is needed to prevent amputation in Prince Edward Island*. Retrieved from [https://www.diabetes.ca/getmedia/2a4fae08-571a-4a0a-b54e-b50a8eab5961/Amputation\\_Prevention\\_Infographic\\_PE\\_8-5x11\\_4.pdf.aspx](https://www.diabetes.ca/getmedia/2a4fae08-571a-4a0a-b54e-b50a8eab5961/Amputation_Prevention_Infographic_PE_8-5x11_4.pdf.aspx)
- Diabetes Canada. (2018). *The economic impact of offloading devices for the prevention of amputation in Newfoundland and Labrador*. Retrieved from [https://www.diabetes.ca/getmedia/de240fb7-c11a-41f4-9739-c62eae55f22e/Economic-Impact-of-Offloading-Devices-on-DFU-Costs-in-NL\\_FINAL.pdf.aspx](https://www.diabetes.ca/getmedia/de240fb7-c11a-41f4-9739-c62eae55f22e/Economic-Impact-of-Offloading-Devices-on-DFU-Costs-in-NL_FINAL.pdf.aspx)
- Diabetes Canada. (2019a). *A step towards good health*. Retrieved from <https://www.diabetes.ca/diabetes-and-you/healthy-living-resources/foot-care/a-step-towards-good-health>
- Diabetes Canada. (2019b). *Position statement: Amputation prevention*. Retrieved from <https://diabetes.ca/advocacy---policies/our-policy-positions/amputation-prevention>
- Dorresteijn, J. A., Kriegsman, D. M., Assendelft, W. J., & Valk, G. D. (2014). Patient education for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews*, 12, CD001488. doi:10.1002/14651858.CD001488.pub5 [doi]
- Enloe, C. L., Garnett, E., Miles, J., & Swanson, S. (Eds.). (2001). *Physical science: What the technology professional needs to know (vol. 7)*. New York: John Wiley & Sons.
- Fetters, M. D., Curry, L. A., & Creswell, J. W. (2013). Achieving integration in mixed methods designs-principles and practices. *Health Services Research*, 48(6 Pt 2), 2134-2156. doi:10.1111/1475-6773.12117 [doi]

- Gershater, M. A., Pilhammar, E., Apelqvist, J., & Alm- Roijer, C. (2011). Patient education for the prevention of diabetic foot ulcers. *European Diabetes Nursing*, 8(3), 102-107b.  
<https://doi.org/10.1002/edn.189>
- Guariguata, L., Whiting, D. R., Hambleton, I., Beagley, J., Linnenkamp, U., & Shaw, J. E. (2014). Global estimates of diabetes prevalence for 2013 and projections for 2035. *Diabetes Research and Clinical Practice*, 103(2), 137-149. doi:10.1016/j.diabres.2013.11.002 [doi]
- Harvard Medical School. (2018). *Foot care basics: Preventing and treating common foot conditions*. Stanford Connecticut: Author.
- Hoban, C., Sareen, J., Henriksen, C. A., Kuzyk, L., Embil, J. M., & Trepman, E. (2015). Mental health issues associated with foot complications of diabetes mellitus. *Foot and Ankle Surgery : Official Journal of the European Society of Foot and Ankle Surgeons*, 21(1), 49-55. doi:10.1016/j.fas.2014.09.007 [doi]
- Hoogeveen, R. C., Dorresteijn, J. A., Kriegsman, D. M., & Valk, G. D. (2015). Complex interventions for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews*, 8, CD007610. doi:10.1002/14651858.CD007610.pub3 [doi]
- Hopkins, R. B., Burke, N., Harlock, J., Jegathisawaran, J., & Goeree, R. (2015). Economic burden of illness associated with diabetic foot ulcers in Canada. *BMC Health Services Research*, 15, 13-015. doi:10.1186/s12913-015-0687-5 [doi]
- Houghton, V. J., Bower, V. M., & Chant, D. C. (2013). Is an increase in skin temperature predictive of neuropathic foot ulceration in people with diabetes? A systematic review and meta-analysis. *Journal of Foot and Ankle Research*, 6(1), 31-1146-6-31. doi:10.1186/1757-1146-6-31 [doi]

- International Diabetes Federation. (2017). *IDF clinical practice recommendation on the diabetic foot - 2017*. Belgium: International Diabetes Federation. Retrieved from <https://www.idf.org/e-library/guidelines/119-idf-clinical-practice-recommendations-on-diabetic-foot-2017.html>
- International Working Group on the Diabetic Foot (IWGDF). (2015). *Prevention and management of foot problems in diabetes: A summary guidance for daily practice 2015, based on the IWGDF guidance documents*. International Working Group on the Diabetic Foot. Retrieved from [https://iwgdfguidance.org/wp-content/uploads/2017/10/website\\_summary-1.pdf](https://iwgdfguidance.org/wp-content/uploads/2017/10/website_summary-1.pdf)
- International Working Group on the Diabetic Foot (IWGDF). (2019). *IWGDF guidelines on the prevention and management of diabetic foot disease*. Retrieved from <https://iwgdfguidelines.org/>
- Joanna Briggs Institute. (2017). *Critical appraisal checklist for systematic reviews*. Retrieved from [http://joannabriggs-webdev.org/assets/docs/critical-appraisal-tools/JBI\\_Critical\\_Appraisal-Checklist\\_for\\_Systematic\\_Reviews2017.pdf](http://joannabriggs-webdev.org/assets/docs/critical-appraisal-tools/JBI_Critical_Appraisal-Checklist_for_Systematic_Reviews2017.pdf)
- Jupiter, D. C., Thorud, J. C., Buckley, C. J., & Shibuya, N. (2016). The impact of foot ulceration and amputation on mortality in diabetic patients. I: From ulceration to death, a systematic review. *International Wound Journal*, 13(5), 892-903. doi:10.1111/iwj.12404 [doi]
- Khairnar, R., Kamal, K. M., Giannetti, V., Dwibedi, N., & McConaha, J. (2019). Barriers and facilitators to diabetes self-management in a primary care setting - patient perspectives. *Research in Social & Administrative Pharmacy : RSAP*, 15(3), 279-286. doi:S1551-7411(17)30943-9 [pii]

- Khunkaew, S., Fernandez, R., & Sim, J. (2018). Health-related quality of life among adults living with diabetic foot ulcers: A meta-analysis. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, doi:10.1007/s11136-018-2082-2 [doi]
- Laing, P. (1998). The development and complications of diabetic foot ulcers. *American Journal of Surgery*, 176(2A Suppl), 11S-19S. doi:S0002-9610(98)00182-2 [pii]
- Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., . . . Agrawal, C. M. (2004). Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care*, 27(11), 2642-2647. doi:27/11/2642 [pii]
- Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Athanasiou, K. A., . . . Agrawal, C. M. (2007). Preventing diabetic foot ulcer recurrence in high-risk patients: Use of temperature monitoring as a self-assessment tool. *Diabetes Care*, 30(1), 14-20. doi:30/1/14 [pii]
- Lazzarini, P. A., Pacella, R. E., Armstrong, D. G., & van Netten, J. J. (2018). Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabetic Medicine: A Journal of the British Diabetic Association*, 35 (9), doi:10.1111/dme.13680 [doi]
- Lichtman, M. (2013). Making meaning from your data. *Qualitative Research in Education. A User's Guide*. (3<sup>rd</sup> ed). Thousand Oaks: Sage Publications.
- Matricciani, L., & Jones, S. (2015). Who cares about foot care? Barriers and enablers to foot self-care practices among non-institutionalised older adults diagnosed with diabetes. An integrative review. *The Diabetes Educator*, 41(1), 106-117. doi:10.1177/0145721714560441

- Miikkola, M., Lantta, T., Suhonen, R., & Stolt, M. (2019). Challenges of foot self-care in older people: A qualitative focus-group study. *Journal of Foot and Ankle Research, 12*, 5-019. doi:10.1186/s13047-019-0315-4 [doi]
- Miller, W. R., Lasiter, S., Bartlett Ellis, R., & Buelow, J. M. (2015). Chronic disease self-management: A hybrid concept analysis. *Nursing Outlook, 63*(2), 154-161. doi:10.1016/j.outlook.2014.07.005 [doi]
- Monami, M., Zannoni, S., Gaias, M., Nreu, B., Marchionni, N., & Mannucci, E. (2015). Effects of a short educational program for the prevention of foot ulcers in high-risk patients: A randomized controlled trial. *International Journal of Endocrinology, 2015*, 615680. doi:10.1155/2015/615680 [doi]
- Morse, J. (2010). Procedures and practice of mixed methods design: Maintaining control, rigor, and complexity. In A. Tashakkori & C. Teddlie. *Mixed methods in social and behavioral research*. Sage.
- Mufti, A., Coutts, P., & Sibbald, R. G. (2015). Validation of commercially available infrared thermometers for measuring skin surface temperature associated with deep and surrounding wound infection. *Advances in Skin & Wound Care, 28*(1), 11-16. doi:10.1097/01.ASW.0000459039.81701.b2 [doi]
- Mufti, A., Somayaji, R., Coutts, P., & Sibbald, R. G. (2018). Infrared skin thermometry: Validating and comparing techniques to detect periwound skin infection. *Advances in Skin & Wound Care, 31*, 607-611. doi:10.1097/01.ASW.0000527352.75716.70 [doi]
- Murff, R. T., Armstrong, D. G., Lanctot, D., Lavery, L. A., & Athanasiou, K. A. (1998). How effective is manual palpation in detecting subtle temperature differences? *Clinics in Podiatric Medicine and Surgery, 15*(1), 151-154. Retrieved from <https://www.podiatric.theclinics.com/>

- Nafradi, L., Nakamoto, K., & Schulz, P. J. (2017). Is patient empowerment the key to promote adherence? A systematic review of the relationship between self-efficacy, health locus of control and medication adherence. *PloS One*, *12*(10), e0186458. doi:10.1371/journal.pone.0186458 [doi]
- Newfoundland and Labrador Centre for Health Information. (2017). *Report on diabetes and diabetes amputation*. St. John's, Newfoundland and Labrador.
- Perrin, B. M., Swerissen, H., & Payne, C. (2009). The association between foot-care self efficacy beliefs and actual foot-care behaviour in people with peripheral neuropathy: A cross-sectional study. *Journal of Foot and Ankle Research*, *2*, 3-1146. doi:10.1186/1757-1146-2-3 [doi]
- Plummer, E. S., & Albert, S. G. (2008). Diabetic foot management in the elderly. *Clinics in Geriatric Medicine*, *24*(3), 551-567. Retrieved from [https://www.geriatric.theclinics.com/article/S0749-0690\(08\)00020-7/fulltext](https://www.geriatric.theclinics.com/article/S0749-0690(08)00020-7/fulltext)
- Prochaska, J. O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change. applications to addictive behaviors. *The American Psychologist*, *47*(9), 1102-1114. Retrieved from <https://www.apa.org/pubs/journals/amp/>
- Prochaska, J. O., Redding, C. A., & Evers, K. E. (2015). The transtheoretical model and stages of change. *Health behavior: Theory, research, and practice*, 125-148.
- Public Health Agency of Canada. (2014). *Infection and prevention control guidelines: Critical appraisal toolkit*. Retrieved from [http://publications.gc.ca/site/archivee-archived.html?url=http://publications.gc.ca/collections/collection\\_2014/aspc-phac/HP40-119-2014-eng.pdf](http://publications.gc.ca/site/archivee-archived.html?url=http://publications.gc.ca/collections/collection_2014/aspc-phac/HP40-119-2014-eng.pdf)
- Rankin, J. A. (2004). Biological mediators of acute inflammation. *AACN Clinical Issues*, *15*(1), 3-17. doi:00044067-200401000-00002 [pii]

- Sandrow, R. E., Torg, J. S., Lapayowker, M. S., & Resnick, E. J. (1972). The use of thermography in the early diagnosis of neuropathic arthropathy in the feet of diabetics. *Clinical Orthopaedics and Related Research*, 88, 31-33. Retrieved from [https://journals.lww.com/clinorthop/Citation/1972/10000/The\\_Use\\_of\\_Thermography\\_in\\_the\\_Early\\_Diagnosis\\_of.4.aspx](https://journals.lww.com/clinorthop/Citation/1972/10000/The_Use_of_Thermography_in_the_Early_Diagnosis_of.4.aspx)
- Schaper, N. C. (2004). Diabetic foot ulcer classification system for research purposes: A progress report on criteria for including patients in research studies. *Diabetes/Metabolism Research and Reviews*, 20 Suppl 1, S90-5. doi:10.1002/dmrr.464 [doi]
- Shaw, J. E., & Boulton, A. J. (1997). The pathogenesis of diabetic foot problems: An overview. *Diabetes*, 46 Suppl 2, S58-61. Retrieved from <http://diabetes.diabetesjournals.org/>
- Sheeran, P., Maki, A., Montanaro, E., Avishai-Yitshak, A., Bryan, A., Klein, W. M., . . . Rothman, A. J. (2016). The impact of changing attitudes, norms, and self-efficacy on health-related intentions and behavior: A meta-analysis. *Health Psychology : Official Journal of the Division of Health Psychology, American Psychological Association*, 35(11), 1178-1188. doi:2016-28683-001 [pii]
- Sibbald, R. G., Mufti, A., & Armstrong, D. G. (2015). Infrared skin thermometry: An underutilized cost-effective tool for routine wound care practice and patient high-risk diabetic foot self-monitoring. *Advances in Skin & Wound Care*, 28(1), 37-44; quiz 45. doi:10.1097/01.ASW.0000458991.58947.6b [doi]
- Simmons, L.A., & Noonan, D. (2017). Self-management. In J.F Gidden (Ed). *Concepts of nursing practice*. (pp. 54-60). Elsevier.
- Singh, N., Armstrong, D. G., & Lipsky, B. A. (2005). Preventing foot ulcers in patients with diabetes. *Jama*, 293(2), 217-228. doi:293/2/217 [pii]

- Singleton, J. R., Smith, A. G., & Bromberg, M. B. (2001). Increased prevalence of impaired glucose tolerance in patients with painful sensory neuropathy. *Diabetes Care*, 24(8), 1448-1453. Retrieved from <http://care.diabetesjournals.org/content/diacare/24/8/1448.full.pdf>
- Skafjeld, A., Iversen, M. M., Holme, I., Ribu, L., Hvaal, K., & Kilhovd, B. K. (2015). A pilot study testing the feasibility of skin temperature monitoring to reduce recurrent foot ulcers in patients with diabetes--a randomized controlled trial. *BMC Endocrine Disorders*, 15, 55-015. doi:10.1186/s12902-015-0054-x [doi]
- Statistics Canada. (2017). *Diabetes by age group and sex [table]*. Retrieved from <http://www.statcan.gc.ca/tables-tableaux/sum-som/101/cst01/health53a-eng.htm>.
- Tabak, A. G., Herder, C., Rathmann, W., Brunner, E. J., & Kivimaki, M. (2012). Prediabetes: A high-risk state for diabetes development. *Lancet (London, England)*, 379 (9833), 2279-2290. doi:10.1016/S0140-6736(12)60283-9 [doi]
- Tchero, H., Kangambega, P., Lin, L., Mukisi-Mukaza, M., Brunet-Houdard, S., Briatte, C., . . . Rusch, E. (2018). Cost of diabetic foot in France, Spain, Italy, Germany and United Kingdom: A systematic review. *Annales D'Endocrinologie*, 79(2), 67-74. doi:S0003-4266(17)30959-9 [pii]
- Thorne, S. (2016). *Interpretive description*. New-York: Routledge.
- van Netten, J. J., Price, P. E., Lavery, L. A., Monteiro-Soares, M., Rasmussen, A., Jubiz, Y., . . . International Working Group on the Diabetic Foot (IWGDF). (2015). Prevention of foot ulcers in the at-risk patient with diabetes: A systematic review. 32 (Supp 1). *Diabetes/Metabolism Research and Reviews*, doi:10.1002/dmrr.2701 [doi]

- van Netten, J. J., Prijs, M., van Baal, J. G., Liu, C., van Der Heijden, F., & Bus, S. A. (2014). Diagnostic values for skin temperature assessment to detect diabetes-related foot complications. *Diabetes technology & therapeutics*, *16*(11), 714-721. doi: 10.1089/dia.2014.0052
- van Schie, C., & Slim, F. J. (2012). Biomechanics of the diabetic foot: The road to foot ulceration. In A. Veves, J. M. Giurini & F. W. LoGerfo (Eds.), *The diabetic foot: Medical and surgical management*. (3rd ed., pp. 203-216). New-York: Springer.
- Vedhara, K., Dawe, K., Wetherell, M. A., Miles, J. N., Cullum, N., Dayan, C., . . . Campbell, R. (2014). Illness beliefs predict self-care behaviours in patients with diabetic foot ulcers: A prospective study. *Diabetes Research and Clinical Practice*, *106*(1), 67-72. doi:10.1016/j.diabres.2014.07.018 [doi]
- Ward, M. M. (2013). Estimating disease prevalence and incidence using administrative data: Some assembly required. *The Journal of Rheumatology JID - 7501984*, *40*(8), 1241-1243. doi:10.3899/jrheum.130675
- Ware, J.E., Snow, K., Kosinski, M., & Gandek, B. (1993). *SF36 manual and health: Manual and interpretation guide*. Boston: The New-England Medical Centre. Retrieved from [https://www.researchgate.net/publication/313050850\\_SF-36\\_Health\\_Survey\\_Manual\\_Interpretation\\_Guide/download](https://www.researchgate.net/publication/313050850_SF-36_Health_Survey_Manual_Interpretation_Guide/download)
- Wendling, S., & Beadle, V. (2015). The relationship between self-efficacy and diabetic foot self-care. *Journal of Clinical & Translational Endocrinology*, *2*(1), 37-41. doi:10.1016/j.jcte.2015.01.001 [doi]

- Wijlens, A. M., Holloway, S., Bus, S. A., & van Netten, J. J. (2017). An explorative study on the validity of various definitions of a 2.2 degrees C temperature threshold as warning signal for impending diabetic foot ulceration. *International Wound Journal*, *14*(6), 1346-1351. doi:10.1111/iwj.12811 [doi]
- Wilde, M. H., & Garvin, S. (2007). A concept analysis of self-monitoring. *Journal of Advanced Nursing*, *57*(3), 339-350. doi: 10.1111/j.1365-2648.2006.04089.x
- World Diabetes Foundation. (2014). *Diabetes footcare flipchart*. World Diabetes Foundation. Retrieved from <https://www.worlddiabetesfoundation.org/files/diabetes-foot-care-flipchart>
- Zhang, P., Lu, J., Jing, Y., Tang, S., Zhu, D., & Bi, Y. (2017). Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis (dagger). *Annals of Medicine*, *49*(2), 106-116. doi:10.1080/07853890.2016.1231932 [doi]

## **Chapter 2: Patient, Support Person and Health Care Provider Perspectives on Foot Self-Management for Patients with Type 1 and Type 2 Diabetes: Personal Challenges**

Kathleen Stevens RN, PhD(c)

Donna Moralejo RN, PhD

Steven Ersser RN, PhD

Cathy MacLean MD

### **Introductory Statement**

Chapter 2 contains a manuscript that presented the qualitative results from Phase 1 of the Mixed Methods Research. In Phase 1 foot self-management was explored from the perspective of the patient, support person, and health care provider. The target audience for this manuscript is health care providers who work with patients with diabetes.

### **Authorship Statement**

KS (the primary researcher) and DM contributed to the conception and research design. DM guided the research study. KS contributed to data collection, analysis, and interpretation and wrote the manuscript. SE contributed to data analysis. DM, CM, and SE reviewed the manuscript and revisions were made by KS based on feedback. DM, CM, and SE gave final approval of the revised manuscript.

### **Key Words**

Type 1 diabetes, Type 2 diabetes, foot health, self-management, experiences, Interpretive Description

### **Funding**

This research was funded by grants from NL-SUPPORT, Healthcare Foundation, and the College of Registered Nurses of Newfoundland and Labrador.

## Abstract

**Objectives:** The purpose of this study was to explore the experiences of self-management of feet for patients with diabetes from the perspective of the patient, support person, and health care provider.

**Methods:** A qualitative approach was used to guide this study. Semi-structured interviews were completed with 11 patients, 4 support persons, and 9 health care providers. Interpretive Description was used to guide data collection and analysis.

**Results:** The overarching theme from the interviews was that self-management of diabetes and specifically foot health is complex. Six sub-themes were identified. Four sub-themes confirmed what is known in the literature: knowledge of foot self-management; physically unable to provide footcare; footwear; and support. The remaining two sub-themes, readiness to self-manage feet and communicating with HCPs, offered new insights related to self-management of foot health.

**Conclusion:** The findings have important implications for clinical practice that can be categorized as the 3Rs: *rapport, readiness, and reinforce*. Rapport with patients and support persons is vital in creating an environment where foot health concerns can be addressed. Readiness to self-manage foot health is an important concept; health care providers can capitalize on a patient's level of readiness, regularly tailoring foot education to a patient's needs. Reinforcing positive foot health with patients and support persons is an important role for all health care providers.

## CHAPTER 2

### Introduction

Patients with diabetes are at high risk for poor foot health. Diabetic foot ulcers (DFUs) and amputations have been identified as a large and preventable cause of the global burden of disease (Lazzarini, Pacella, Armstrong, & van Netten, 2018) with significant physical, psychological, and social impacts for the patient as well as high costs for the health care system (Coffey, Mahon, & Gallagher, 2019; Hoban et al., 2015; Hopkins, Burke, Harlock, Jegathisawaran, & Goeree, 2015; Khunkaew, Fernandez, & Sim, 2018). Self-management is an important aspect of maintaining foot health and preventing these complications. Foot self-management requires the person to engage in many activities such as regular daily care, wearing appropriate footwear, and seeking an assessment from a health care provider (HCP). Consequently, prevention is certainly not straight forward and this may be a factor in the limited success of foot self-management interventions in preventing DFUs and amputations (Baba, Duff, Foley, Davis, & Davis, 2015; Dorresteijn, Kriegsman, Assendelft, & Valk, 2014; Hoogeveen, Dorresteijn, Kriegsman, & Valk, 2015; Monami et al., 2015). A key to understanding foot self-management is unpacking this complexity by exploring patients' experiences with this process. However, there have been limited studies conducted in the Canadian context that have explored foot self-management.

This paper will focus on Phase 1 of a larger three-phase mixed methods study that tested the effectiveness of a multi-modal self-management strategy to prevent DFUs. The purpose of Phase 1 was to explore the experiences of self-management of feet from the perspective of the patient, their linked support person, and HCPs to inform the intervention that was delivered and evaluated in Phase 2.

## **Objective**

The research objective for Phase 1 was to explore what are the issues related to self-management of feet for people with diabetes from the perspective of patients, support persons, and HCPs.

## **Methods**

Interpretive Description was used to guide the analysis of this study (Thorne 2016). Interpretive Description aims to bring a clinical perspective to evidence-based practice using qualitative methodology. With this methodology, the researcher is grounded in central concepts in the discipline of nursing, and these guide the direction of the study, including data collection (interview questions) and analysis. Participants' experiences with foot self-management were explored and patterns, commonalities, and variations of people's experiences concerning self-management were identified. It is important to note that the goal of Interpretive Description is not data saturation but to have sufficient data to report well-developed findings related to foot self-management. This is in keeping with the nursing disciplinary view that every individual's response to illness is unique, and all the variations cannot be known.

**Setting and participants.** To gain a greater understanding of the complexity of foot self-management this issue was explored from the perspectives of patients, support persons, and HCPs. There were three eligible groups of participants: (1) patients that were residents of Newfoundland and Labrador, 18 years and over, and identified as either having type 1 or type 2 diabetes; (2) support persons of the patients who were either a family member, friend, or home support worker who assisted the patient daily; and (3) HCPs who cared for eligible diabetic patients.

Purposive convenience sampling was used and participants were selected that would inform the researcher about issues with foot self-management. To gain a comprehensive understanding of foot self-management, participants were selected who had a variety of experiences and characteristics, such as patients with diabetes with various foot health challenges and HCPs with different professional designations such as physicians and nurses. Participants were recruited through public and private clinics, such as diabetes care clinics and podiatry clinics, using posters and information sheets that were provided by HCPs who acted as intermediaries.

**Procedures.** Interviews occurred as participants were recruited and were either scheduled by telephone or at a mutually-convenient location. Recruitment continued until there were sufficient data to report well-developed findings related to foot self-management. After reviewing the study with the participant written consent was obtained. Interviews were semi-structured and the length of participant interviews was 20-90 minutes. Except for two married couples who preferred to be interviewed together participants were interviewed individually. All interviews were audio recorded and transcribed verbatim.

The interview guides are shown in Table 2.1. The interview guides for the three groups were based on a review of the literature and feedback from a patient representative on the research committee and experts in the area of diabetes and foot health, self-management, and qualitative research. To understand the researcher's role in data collection a reflexive journal was completed after each interview.

Table 2. 1 *Interview guides for patients, support persons, and health care providers*

<b>Patients</b>	<b>Support Person</b>	<b>Health Care Provider</b>
<ol style="list-style-type: none"> <li>1. Tell me about looking after your feet.</li> <li>2. Do you know when you should rest?</li> <li>3. How confident do you feel about looking after your feet?</li> <li>4. What do you look for when you check your feet?</li> <li>5. How often do you look at your feet?</li> <li>6. What do you do if you find something wrong with your feet?</li> <li>7. What do you think are risk factors for ulceration?</li> <li>8. Have you had education related to foot management?</li> <li>9. What kind of footwear do you wear?</li> <li>10. Does anyone help you care for your feet?</li> <li>11. Are there any challenges that make it difficult for you to look after your feet?</li> <li>12. Who do you go to if you have a problem?</li> <li>13. What suggestions do you have for helping people with diabetes that would make checking their feet easier?</li> </ol>	<ol style="list-style-type: none"> <li>1. Tell me about helping your family member/friend/client to look after their feet.</li> <li>2. What do you do to help your family member/friend/client?</li> <li>3. How often do you help them?</li> <li>4. Do you find it time consuming to help your family member/friend/client with their feet?</li> <li>5. Do you find it stressful to help your family member/friend/client with their feet?</li> <li>6. What do you find helpful?</li> <li>7. What did you find least helpful?</li> <li>8. Are there any challenges that make it difficult for you to help look after your family member/friend/client's feet?</li> <li>9. What suggestions do you have for helping people with diabetes improve foot self-assessment?</li> </ol>	<ol style="list-style-type: none"> <li>1. Tell me about caring for people with diabetes in relation to foot management.</li> <li>2. In your experience is the patient's support system helpful in foot management?</li> <li>3. In relation to foot management what do you think patients with diabetes find most helpful?</li> <li>4. Are there any barriers that make it difficult for patients with diabetes to look after their feet?</li> <li>5. What suggestions do you have for helping patients improve foot self-assessment?</li> <li>6. Do you educate your patients about foot health and self-management?</li> <li>7. Do you follow-up with your patients?</li> <li>8. What do you tell your patients about foot ulcers?</li> <li>9. What is the role of different health providers in relation to feet?</li> <li>10. Do you have any suggestions for making it easier for patients to talk to their health care provider?</li> </ol>

**Data analyses.** Demographic information about the sample was analyzed using descriptive statistics. Interview transcripts were analyzed using NVIVO, a qualitative software package (NVIVO 11, QRS International, Victoria, Australia). The analysis was guided by the research objective. Under the methodological umbrella of Interpretive Description, the analytic framework of, The Three Cs: Coding, Categorizing, and Concepts, were used to analyze the data (Lichtman, 2013). This approach was iterative and used the following steps: Step 1) Initial coding, going from step responses to summary ideas of the responses; Step 2) Revisiting initial coding; Step 3) Developing an initial list of categories; Step 4) Modifying the initial list based on additional rereading; Step 5) Revisiting categories and subcategories; and Step 6) Moving from categories to concepts or themes.

The initial findings were shared with members of the research team, which included a patient representative who is a support person for a family member who has diabetes. The purpose of this consultation was to see if the experience of managing feet was captured accurately in the analysis.

**Ethics.** Ethical approval was obtained from the Newfoundland and Labrador Health Research Ethics Authority and written consent was obtained from participants before completing the interview. To ensure confidentiality any identifying information was removed from the transcripts.

## **Results**

**Participants' characteristics.** A total of 24 interviews were completed with 11 patients, 9 HCPs, and 4 support persons. As shown in Table 2.2 all patients were Caucasian with 4 patients from a rural area and 7 patients from an urban area. The age range of patients was 50-74 years with the length of time since diagnosis ranging from 1-44 years. The professional designation of t

Table 2. 2 *Patient Characteristics (N=11)*

Characteristic		#s
Setting	Urban	7
	Rural	4
Gender	Male	5
	Female	6
Type of Diabetes	Type 1	3
	Type 2	6
	Unclear	2
Age Range Years (mean 64.6)	50-54	1
	55-59	1
	60-64	4
	65-69	2
	70-74	3
Time Since Diagnosis (years)	1-9	2
	10-19	4
	20-29	1
	30-39	3
	40-44	1

the HCPs were: wound care consultant; diabetes educator; dermatologist; podiatrist; and family physician. Except for one HCP, all HCPs were from an urban area. Three support persons were spouses and one was a paid caregiver. Two of the HCPs had diabetes and statements were analyzed from the HCP or patient perspective as appropriate.

**Interview results.** The overarching theme was that self-management of diabetes and specifically foot health was complex from the perspective of patients, support persons, and HCPs. Multiple factors impacted self-management and a patient might often have multiple personal challenges to negotiate to meet foot health needs. One patient referred to self-management as “you have to manage your own destiny” which suggested that he believed his choices and behaviors impacted his disease outcome. Another patient described his self-management experience as sometimes “wandering off” but then he would start following a positive self-management plan again. What was clear from the data was that many factors impacted this

destiny and whether there would be a positive or negative outcome. The analysis identified that there were personal challenges that negatively impacted foot self-management; furthermore, patients also utilized resources that supported self-management. Underpinning these themes was the common perspective of patients, support persons, and HCPs that dealing with diabetes was a challenge for patients from the initial diagnosis to the ongoing management. Patients had to deal with physical impacts such as retinopathy, dialysis, ulcers, and amputations. As well as these there were psychological impacts such as fear, denial, weariness, and frustration. These perspectives should be kept in mind to provide context to the sub-themes related to foot self-management.

Six sub-themes related to foot self-management were identified. Four sub-themes confirmed what is known in the literature: 1) knowledge of foot self-management; 2) footwear; physically unable to provide footcare; and 4) social support. Patients, support persons, and HCPs identified a lack of knowledge of foot self-management as a personal challenge and having this knowledge was a resource. A common view of HCPs was that most patients have a very limited understanding of foot management because of their lack of education. As a result of a lack of knowledge, patients did not know the potential impact of diabetes on foot health. Several patients expressed that they had limited or no formal education about foot self-management; this sometimes led to patients having poor foot health maintenance practices. Also, this resulted in patients having foot complications and not realizing it or not knowing how to deal with foot complications such as calluses and corns. Some patients did express confidence in looking after their feet, but a strong knowledge base did not always seem to accompany such confidence. When patients knew how to care for their feet and diabetes it was a resource. An HCP indicated that when people were provided with education many patients were more “proactive.”

Footwear was identified by all three groups as a possible challenge because of the cost, discomfort, and the issue of fashion. Appropriate footwear was also viewed as a resource with one patient identifying appropriate footwear as the most helpful strategy in looking after her feet. All three groups identified that being physically unable to provide foot care was a personal challenge to patients. Physical challenges related to vision, mobility, dexterity and /or co-morbidities, as these factors made it difficult for patients to care for their feet. Support was identified as a challenge and a resource for patients by all three groups. An HCP commented that a patient who had a lack of support may live alone or their family did not help them with their feet. Support from a spouse, family member, and a hired caregiver was also an important resource to people for diabetes and foot management. Support was in the form of providing physical care; assessing feet; encouraging and comforting the patient; advocating; and seeking information about foot health. In the opinion of one HCP the patient's support system was the most helpful resource for a person with diabetes for foot management. One patient commented that his spouse, although supportive, sometimes enabled unhealthy behaviors. The remaining two sub-themes were readiness to self-manage feet and communicating with HCPs; these offered new insights compared to what has been reported in the literature and thus are now discussed in more detail.

**Readiness to Self-Manage Foot Health.** There was variation in the responses of participants of the three groups concerning readiness to self-manage. Being ready and open to learning about foot self-management was viewed as a resource whereas not being ready to make changes was a personal challenge. Although the participants did not refer to this as explicitly as 'readiness', it was clear from the patient and support person interviews that there was a continuum related to patient readiness to not only manage foot health but to self-manage diabetes

in general, with some patients doing little and others being more motivated. One of the HCPs provided an example of this continuum.

Some patients are asking questions more about how can I and when should I? As opposed to what's the information? Like some people just want the information and they want to leave and they'll do what they want with it when they're ready. But some people you can tell are taking it and their wheels are spinning like how can I apply this to myself and how should I apply this. (HCP)

The point was also made by a HCP that sometimes a patient was ready to self-manage one area but not another "It's whatever is affecting them at that moment that they feel is most important to them. And for some people, it's not foot care." It appeared that readiness to self-manage foot health was sometimes not a priority in relation to some other areas of diabetes self-management and readiness was viewed as being individual. This variation can be seen between patients' answers to the questions "tell me about managing your feet?" One patient who had diabetes for 22 years shared her well-established routine.

.....You know after 22 years of dealing with this but what I do with my feet is I shower practically daily and I have a pumice stone in my shower so while I'm in the shower I will always you know touch them up and get rid of any additional you know skin that's there. And then when I get out of the shower like they're the first thing that I moisturize you know when they're still wet kind of thing and that's been my routine. (Patient)

However, a patient who had diabetes for 8 years felt that his feet did not require any attention because he had no foot problems. He stated, "I never had no problems with my feet, none whatsoever." When asked if he checked them every day he said "No, no because I don't feel them tender. I feel my feet are no different than they were 20 years ago." Another patient, when

asked about his foot care routine, stated "I just keep them clean and keep my nails you know, cut. That's pretty much it."

As a result of this variation, an HCP stated it is important to provide information to patients that support their foot self-management but it was up to them to follow the suggestions.

You know some people are, they take the information and they run with it and they say, 'Oh yeah I'll call [name] the foot care nurse'. So I think the suggestions help. I think some people do take heed to it. Some more might not. Some more might think that it's not beneficial to them but to each his own, right. (HCP)

Deterioration in a patient's condition was identified by HCPs as sometimes being the reason why patients began to take more interest in their foot self-management.

I find once people have a wound they're more likely to self-manage, right because they know what they went through for to heal a wound before so they're more likely to try to prevent having another one especially when they know the percentage of people who end up with amputations and stuff like that. (HCP)

In contrast, self-management could be complicated by having neuropathy. Only one HCP pointed out that when patients are unable to feel pain they are sometimes not as motivated to self-manage their wound.

Interestingly, there seemed to be differences between HCPs' and patients' opinions on the timing of education. HCPs felt when first diagnosed it was overwhelming for patients to receive foot health education. However, patients expressed that they would like this information early. A patient who had an amputation felt that he would have liked to have known about the possibility of the complications that could occur. He stated, "Right up front you should be told." When patients were asked if it would have been too much information to learn about foot self-

management during the initial teaching one patient suggested it would be helpful to “break it into a couple of sessions, let it sink in.” When another patient was asked if they felt overwhelmed with all the information they stated “a little, but not concerning my feet.”

**Communication Between Patients and HCPs.** Communicating with HCPs was identified as a challenge and a resource for patients, support persons, and HCPs. This sub-theme seemed more relevant to patients and HCPs as often the support person did not attend appointments with their family member.

A common pattern was that patients and support persons valued positive communication with their nurse or physician. One patient talked about being able to call or email their diabetes educator. The same patient described the relationship that he had with his family physician in this way. “So I find him good and he’ll listen to you. When you’re talking to him, he listens.” When asked what was the most helpful for foot management a patient discussed their health care team.

Most helpful would probably be like reminders from like my health care team because I mean I don’t know, feet aren’t something you’re thinking about all the time but when my nurse or my doctor says to me, like how are your feet? Have you had any issues? Then I’ll be like, oh yeah! It’s been awhile. I should probably do a check. So I would say most helpful would probably be like the gentle little reminders from my health care team.

(Patient)

For the patient, communicating with the HCP was sometimes a challenge related to the provider’s approach and behavior. One patient expressed his disappointment with the HCP’s behavior during an education session.

.... first session I went to I should have stayed home because the lady that was doing it, she wouldn’t even make eye contact with you. She was one of these ladies who was

looking at the ceiling all the time and before she finished up she reached in her bag, in her purse and hauled out a tin of regular Coke. (Patient)

Another aspect of communication with HCPs that was a challenge was the lack of consistency in information provided. One support person who was assisting with care of a DFU expressed frustration regarding the varying information that he was receiving related to caring for the wound.

From the HCP perspective, a common pattern was that HCPs communicated with patients about foot health using varying strategies such as encouraging, repeating, explaining, recommending, and discussing information. The potential complexity of this communication was evident as one HCP shared that patients often did not communicate up front that there were any issues with their feet. It was only when the HCP asked did they find out that there was a concern. These communications seemed to be more one-sided than reciprocal. Rapport presented a variation of this pattern as it allowed a more reciprocal pattern of communication. Building a rapport with the patient was identified as a helpful resource to promote positive foot health by one HCP.

So every time they come in we have a little chat and you know basically building a rapport and then they become more comfortable with asking questions and I think they overall feel more comfortable coming back because they know I'm checking their foot or their feet and they know if they're noticing anything appear on their foot that they can call and come in and I guess the reassurance of knowing that I'm looking to make sure there is nothing going on (HCP)

## Discussion

People with diabetes are at risk of lower-limb complications, and effective foot health self-management is vital to prevent these complications. Foot self-management is complex, and this study provided an understanding of the experience of foot self-management for patients in the Canadian context from the perspective of the patient, support person, and HCP. Exploration of the process of foot self-management confirmed that: foot health education is important, but patients are not always getting it; patients may be physically unable to care for their feet and therefore need support; and footwear and social support are important factors that impact on foot self-management. These findings, along with new insights gained from the sub-themes of readiness to self-manage feet and communicating with HCPs, have implications for clinical practice and can be abstracted and categorized as the 3Rs: *rapport, readiness, and reinforce*.

First, it is important that HCPs establish a *rapport* with both patients and support persons. If support persons are not attending appointments HCPs can encourage the patient to bring their support person. From the literature, we know clear communication with HCPs has been reported to have a positive impact on foot health behaviors whereas if patients had a negative experience with an HCP they were more likely not to participate in healthy foot behaviors (Matricciani, & Jones, 2015). HCPs can assess their communication and teaching style to ensure that they are encouraging the development of rapport with the patient and support person. In this study, the HCPs' behaviors that patients reported as contributing to a positive experience were being respectful, being accessible, listening, and providing gentle reminders about foot self-management. As patients do not always "communicate up front" about foot health issues, it is key that HCPs ask patients about their foot health to determine the extent of foot health needs. If patients and support persons are comfortable, they will be more forthcoming regarding any issues or challenges they are experiencing, ask questions, and participate in a discussion of their foot

health needs. For example, patients may communicate that they need the information to care for certain foot conditions such as calluses or indicate that they are physically unable to care for their feet.

Second, HCPs can assess and capitalize on a patient's level of *readiness*. Readiness to self-manage foot health is an important concept to consider when working with a patient. As shown in the findings, there is a continuum of readiness, and understanding a patient's level of readiness can help tailor education to their needs. Some tools can be used to assess readiness such as the stage of change tool (Peterson & Hughes, 2002) and approaches to facilitate self-management such as motivational interviewing (Ekong & Kavookjian, 2016) and strengths-based care (Gottlieb, 2012). It is important for HCPs to recognize that whatever a patient's level of readiness, education about foot health could be beneficial. Opportunities for foot health education may be missed if it is only provided when a patient has been established in a treatment plan, is asking for information, and/or is presenting with a foot issue. The findings showed that HCPs were concerned about overwhelming patients with information and, in contrast, patients and support persons wanted to know about foot health and potential complications earlier such as when they were diagnosed. Considering this, HCPs should regularly assess knowledge and provide teaching about caring for feet tailored to the patient's needs. It is up to the patient whether or not they follow the direction provided. A HCP can quickly assess the patient's foot knowledge and behaviors using three priority questions based on recommended guidelines and build on the answers to these questions: 1) Do you look at your feet and moisturize your feet daily?; 2) Do you smoke?; 3) Do you wear supportive footwear? (International Working Group on the Diabetic Foot, 2019). Responses to these questions would provide an opportunity to address a lack of knowledge and discuss risky behavior and appropriate actions with the patient and the support person. Models or posters that show foot complications could be incorporated

into teaching. As well, the provision of reliable resources to patients and support persons that can be referenced later such as the Diabetes Canada handout *Foot care: A step towards good health*, is vital (Diabetes Canada, 2019).

Third, HCPs can *reinforce* key messages related to foot health and foot care as this would convey that foot health is important. Asking patients and support persons if they have a concern about foot health provides an opportunity not only for assessment, but for reinforcement of positive foot health and teachable moments. As well, checking to ensure that patients and support persons understand educational content and correcting misconceptions is key. One of the behaviors identified to be a resource by a patient was the gentle reminders about caring for her feet that she received from her HCP. All HCPs have a role in reinforcing these messages. Therefore, whatever the reason for a patient's visit it is important to ask about foot health and reinforce healthy behaviors.

In addition to clinical practice, this study also is important for HCP curricula, health policy, and research. Information regarding foot health and potential barriers and challenges to foot health for people with diabetes needs to be present in HCP education programs. Policy makers need to consider funding for education initiatives to support self-management as well as access to foot health services and supports such as orthopedic shoes. These policies would help overcome many of the physical and financial barriers identified in this study. Finally, further research needs to focus on whether barriers to foot health vary across Canada with different populations, such as indigenous and immigrant populations, in order to develop relevant programs. As well, research needs to move beyond description and focus on the development of strategies and interventions that support positive foot health.

This study demonstrates the criteria required for credibility in Interpretive Description (Thorne, 2016). Representative credibility was achieved by capturing the experience of foot self-

management from three different perspectives, the patient, support person, and HCP. Other major strengths related to representative credibility were that patients with type 1 and type 2 diabetes with varying length of time since diagnosis were interviewed, as were participants from rural and urban areas. Achieving analytic logic was addressed through the use of an audit trail and verbatim in-depth description. Finally, interpretive authority was addressed through the use of regular reflexive journaling during data collection. One important limitation to note is that Canada has universal health care and the delivery of care varies across provinces so the challenges and resources related to diabetes self-management may not be transferable to other provinces and health care systems.

## **Conclusion**

The 3Rs, *rapport*, *readiness*, and *reinforce*, reflect simple strategies that can potentially save feet. Even though foot self-management for patients with diabetes is complex and impacted by many factors, the 3Rs are strategies that HCPs can incorporate into clinical practice that can support foot health needs. First, build *rapport* with patients and support persons. This establishes a connection and enables better and clearer communication regarding foot health needs. Second, regularly assess for the level of *readiness* and use this information to tailor patient education about foot health. Third, view foot health education as a responsibility of all HCPs. Utilize every opportunity with patients and support persons to *reinforce* key messages about foot health. With more attention to the 3Rs, positive foot-self-management can be promoted with patients with diabetes.

## References

- Baba, M., Duff, J., Foley, L., Davis, W. A., & Davis, T. M. (2015). A comparison of two methods of foot health education: The Fremantle diabetes study phase II. *Primary Care Diabetes, 9*(2), 155-162. doi:10.1016/j.pcd.2014.05.004 [doi]
- Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal, 16*(1), 183-210. doi:10.1111/iwj.13010 [doi]
- Diabetes Canada. (2019). *A step towards good health*. Retrieved from <https://www.diabetes.ca/diabetes-and-you/healthy-living-resources/foot-care/a-step-towards-good-health>
- Dorresteijn, J. A., Kriegsman, D. M., Assendelft, W. J., & Valk, G. D. (2014). Patient education for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews, 12*, CD001488. doi:10.1002/14651858.CD001488.pub5 [doi]
- Ekong, G., & Kavookjian, J. (2016). Motivational interviewing and outcomes in adults with type 2 diabetes: a systematic review. *Patient education and counseling, 99*(6), 944-952  
<https://doi.org/10.1016/j.pec.2015.11.022>
- Gottlieb, L. N. (2012). *Strengths-based nursing care: Health and healing for person and family*. New-York: Springer Publishing Company.
- Hoban, C., Sareen, J., Henriksen, C. A., Kuzyk, L., Embil, J. M., & Trepman, E. (2015). Mental health issues associated with foot complications of diabetes mellitus. *Foot and Ankle Surgery : Official Journal of the European Society of Foot and Ankle Surgeons, 21*(1), 49-55. doi:10.1016/j.fas.2014.09.007 [doi]

- Hoogeveen, R. C., Dorresteijn, J. A., Kriegsman, D. M., & Valk, G. D. (2015). Complex interventions for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews*, 8, CD007610. doi:10.1002/14651858.CD007610.pub3 [doi]
- Hopkins, R. B., Burke, N., Harlock, J., Jegathisawaran, J., & Goeree, R. (2015). Economic burden of illness associated with diabetic foot ulcers in Canada. *BMC Health Services Research*, 15, 13-015. doi:10.1186/s12913-015-0687-5 [doi]
- International Working Group on the Diabetic Foot (IWGDF). (2019). *IWGDF guidelines on the prevention and management of diabetic foot disease*. Retrieved from <https://iwgdfguidelines.org/>
- Khunkaew, S., Fernandez, R., & Sim, J. (2018). Health-related quality of life among adults living with diabetic foot ulcers: A meta-analysis. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, doi:10.1007/s11136-018-2082-2 [doi]
- Lazzarini, P. A., Pacella, R. E., Armstrong, D. G., & van Netten, J. J. (2018). Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabetic Medicine: A Journal of the British Diabetic Association*, doi:10.1111/dme.13680 [doi]
- Lichtman, M. (2013). Making meaning from your data. *Qualitative Research in Education. A User's Guide*. (3<sup>rd</sup> ed). Thousand Oaks: Sage Publications.
- Matricciani, L., & Jones, S. (2015). Who care about foot care? Barriers and enablers to foot self-care practices among non-institutionalised older adults diagnosed with diabetes. An integrative review. *The Diabetes Educator*, 41(1), 106-117. doi:10.1177/0145721714560441

Monami, M., Zannoni, S., Gaias, M., Nreu, B., Marchionni, N., & Mannucci, E. (2015). Effects of a short educational program for the prevention of foot ulcers in high-risk patients: A randomized controlled trial. *International Journal of Endocrinology*, 2015, 615680. doi:10.1155/2015/615680 [doi]

Peterson, K. A., & Hughes, M. (2002). Readiness to change and clinical success in a diabetes educational program. *The Journal of the American Board of Family Practice*, 15(4), 266-271. Retrieved from <https://www.jabfm.org/>

Thorne, S. (2016). *Interpretive description*. New-York: Routledge.

### **Chapter 3: Effectiveness of a Foot Self-Management Intervention that Utilized Commercially Available Infrared Thermometers: Mixed Methods Research Incorporating a Pilot RCT**

Kathleen Stevens RN, PhD(c)  
Donna Moralejo RN, PhD  
Steven Ersser RN, PhD  
Cathy MacLean MD

#### **Introductory Statement**

Chapter 3 contains a manuscript that presents the results of a mixed methods research study which incorporated a pilot randomized controlled trial that tested the effectiveness of a foot self-management intervention that utilized commercially-available infrared thermometers. The target audiences for this manuscript are health care providers who work with patients with diabetes such as diabetes educators, health policy makers, and health care provider educators.

#### **Authorship Statement**

KS (the primary researcher) and DM contributed to the conception and research design. DM guided the research study. KS contributed to data collection, analysis, and interpretation and wrote the manuscript. DM, SE and CM contributed to data analysis. DM, CM, and SE reviewed the manuscript and revisions were made based on feedback. DM, CM, and SE gave final approval of the revised manuscript.

#### **Key words**

Type 1 diabetes, Type 2 diabetes, mixed methods research, foot health, infrared thermometer, self-management

#### **Funding**

This research was funded by grants from NL-SUPPORT, Healthcare Foundation, and the College of Registered Nurses of Newfoundland and Labrador.

## Abstract

**Objective:** The purpose of this study was to evaluate the effectiveness of a foot self-management strategy that utilized a commercially-available infrared thermometer (CAIT) for prevention of diabetic foot ulcers in people with diabetes.

**Research Design and Methods:** In this six-month pilot randomized controlled trial, Phase 2 of a three phase mixed methods research study, 62 participants were randomized to a thermometer and education group (n=34) and an education-only group (n=26). Both groups received foot care education and completed an orthotic assessment with a certified orthotist. All participants completed a foot inspection daily, tracked their number of steps using a pedometer, and recorded their steps and assessment in a logbook. The thermometer and education group also recorded their daily temperature assessment. A temperature difference of greater than 4 degrees Fahrenheit (F) between the two feet prompted participants to rest their feet. If the temperature difference did not decrease to below 4 degrees F in two days participants were directed to see their health care provider. Phase 3 of the study, which was qualitative, explored the Phase 2 results to gain further understanding of the findings.

**Results:** The strategy resulted in improved foot assessment and action. Phase 2 analysis showed that the thermometer and education group had significantly more days with any assessment completed than the education-only group (150.98/180 vs. 119.84/180,  $p = .02$ ). Phase 3 findings offered further explanation that the thermometer engaged participants, prompted action, and offered reassurance regarding foot health.

**Conclusions:** A CAIT is an available tool that could support foot self-management for people with diabetes. Specifically, the use of a CAIT may offer several benefits such as promoting and providing structure for a foot assessment and direction for action.

## CHAPTER 3

### Introduction

Lower limb complications related to diabetes are a significant and preventable cause of the global burden of disease (Lazzarini, Pacella, Armstrong, & van Netten, 2018). Over a decade ago, the estimated lifetime incidence of a diabetic foot ulcer (DFU) for people with diabetes was estimated to be 25% (Singh, Armstrong, & Lipsky, 2005). In a 2017 systematic review and meta-analysis that included 67 publications from 33 countries with a date range from 1991 to 2015, the global prevalence of DFUs was reported to be 6.3% [95% CI: 5.4-7.3] (Zhang, et al., 2017). With the number of people with diabetes increasing, the incidence of complications can be expected to rise, unless preventative actions are taken. Several factors contribute to the development of a DFU, with pressure and trauma being the most important. These lesions most often occur when the patient has two or more risk factors, such as peripheral neuropathy and vascular disease (Alavi et al., 2014; Boulton, 2013; International Working Group on the Diabetic Foot (IWGDF), 2015; van Schie & Slim, 2012).

A DFU represents a significant crisis for a person with diabetes and their family. A large body of literature supports that DFUs have physical, psychological, and social impacts on the patient and support persons (Coffey, Mahon, & Gallagher, 2019; Hoban et al., 2015; Khunkaew, Fernandez, & Sim, 2018). DFUs and related complications are costly to health care systems (Tchero et al., 2018). The International Diabetes Federation (IDF), in its *2017 Clinical Practice Recommendations for the Diabetic Foot*, has therefore argued that more focus needs to be on the prevention of DFUs because the disability, suffering, and cost implications are high (IDF, 2017). An essential aspect of maintaining foot health is self-management and self-monitoring (Boulton et al., 2008; Chang, Peng, Chang, & Chen, 2013). Self-management is defined as “the ability of individuals and or their caregivers to engage in the daily tasks required to maintain health and

well-being or to manage the physical, psychological, behavioral, and emotional sequelae of a chronic disease based on the knowledge of the condition, its consequences, and the plan of care co-developed with their health care team (Simmons & Noonan, 2016, p.54). Self-monitoring is an aspect of self-management and is defined as an awareness of symptoms and use of measurement and observations that provide information to direct independent action or seeking advice from an HCP (Wilde & Garvin, 2007).

In order to prevent DFUs, effective self-management strategies and programs need to be developed and implemented. The monitoring of plantar temperature is a promising strategy to prevent DFUs that could be incorporated into self-management. Various systematic reviews, which contained three randomized controlled trials (RCTs), indicated that the use of personal temperature monitoring with a medical-grade infrared thermometer was an effective way to predict and prevent DFUs (Arad, Fonseca, Peters, & Vinik, 2011; Houghton, Bower, & Chant, 2013; van Netten et al., 2015), however, these thermometers are prohibitively expensive for many people, costing approximately \$700 dollars. A commercially-available infrared thermometer (CAIT), that costs in the range of \$30-100, has been validated against the medical grade thermometer. This cost-effective device could also be used to detect a plantar temperature increase associated with inflammation before skin breakdown occurs (Mufti, Coutts, & Sibbald, 2015). Once the increase in temperature is identified, the individual can address the underlying source of inflammation by relieving pressure, for example by resting, until the temperature normalizes and inflammation decreases (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). If the temperature does not normalize in two days, then a physician or health care provider (HCP) associated with a diabetes clinic, should be consulted. It is important to recognize that infrared thermometry only measures surface temperature of the skin and it cannot identify deep inflammation, systemic versus local inflammation, and early versus late inflammation. As

well, it should be understood that there may be alternative differences in temperature other than inflammation and early skin damage due to excessive pressure and trauma. For example, patients who have poor peripheral circulation may already have differences in temperature between their feet due to the reduced circulation. Therefore, for these patients infrared thermometry would not be a useful tool for detecting foot inflammation (Sibbald et al., 2015).

This article summarizes the results of a mixed methods research (MMR) study that explored foot self-management of people with diabetes and tested a multi-modal intervention to prevent DFUs. One of the primary objectives of this study was to evaluate if a foot health intervention, that utilized a CAIT, improved foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention. Multi-modal self-management strategies which focus on identifying and addressing early signs of inflammation, such as a temperature increase, may be useful in improving foot outcomes and preventing skin breakdown and potential DFUs and amputation.

### **Research Questions**

The overarching research question for this study is: What strategies are effective to help people with diabetes self-manage their foot health? The study has three separate phases, which were guided by the following specific research questions. Phase 2 addressed all three research questions and whereas Phase 3 addressed research questions 2 and 3.

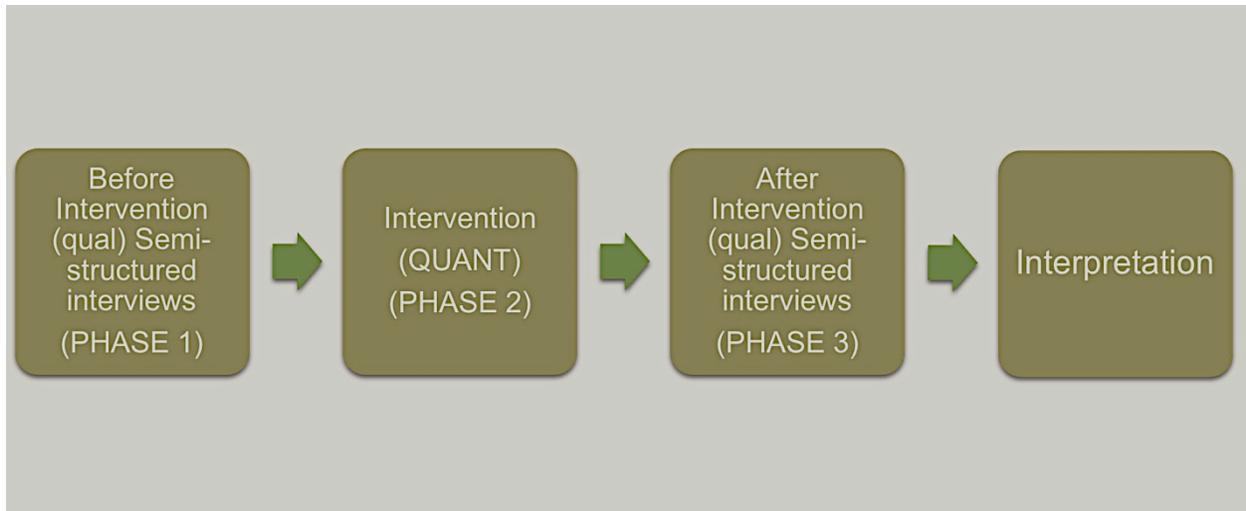
1. Does a foot health intervention that utilizes a CAIT improve foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention?
2. What are the issues related to self-management of feet? What are the issues related to self-management of feet?
3. What are the participants' experiences with foot health self-management and the intervention?

## **Primary and Secondary Outcomes**

1. Primary outcome: presence or absence of a DFU.
2. Secondary outcomes: completion of a visual foot assessment, completion of a temperature assessment, completion of any assessment (either a visual or temperature assessment), action based on the foot assessment, usability of the CAIT, identification of a foot concern, and quality of life (QoL).

## **Research Design and Methods**

This three-phase study employed an MMR approach using an exploratory and explanatory model, as shown in Figure 3.1. In Phase 1 (exploratory), self-management was explored using qualitative methods with patients, linked support persons, and HCPs, and what was learned informed the intervention (N=24 participants). Results from Phase 1 are reported elsewhere. In Phase 2, a six-month RCT was conducted that tested the effectiveness of the intervention with 62 patients assigned to an education and thermometer group or education-only group (See Figure 3.2). In Phase 3 (explanatory), participants were interviewed regarding their experiences in order to gain further clarity regarding Phase 2 results. The timeframe for recruitment for Phase 2 was August 2017 until October 2018. Data collection for Phase 2 ended in August 2019 and Phase 3 was conducted in October 2019. Results of Phases 2 and 3 are reported here.



*Figure 3. 1:* Mixed methods exploratory and explanatory model

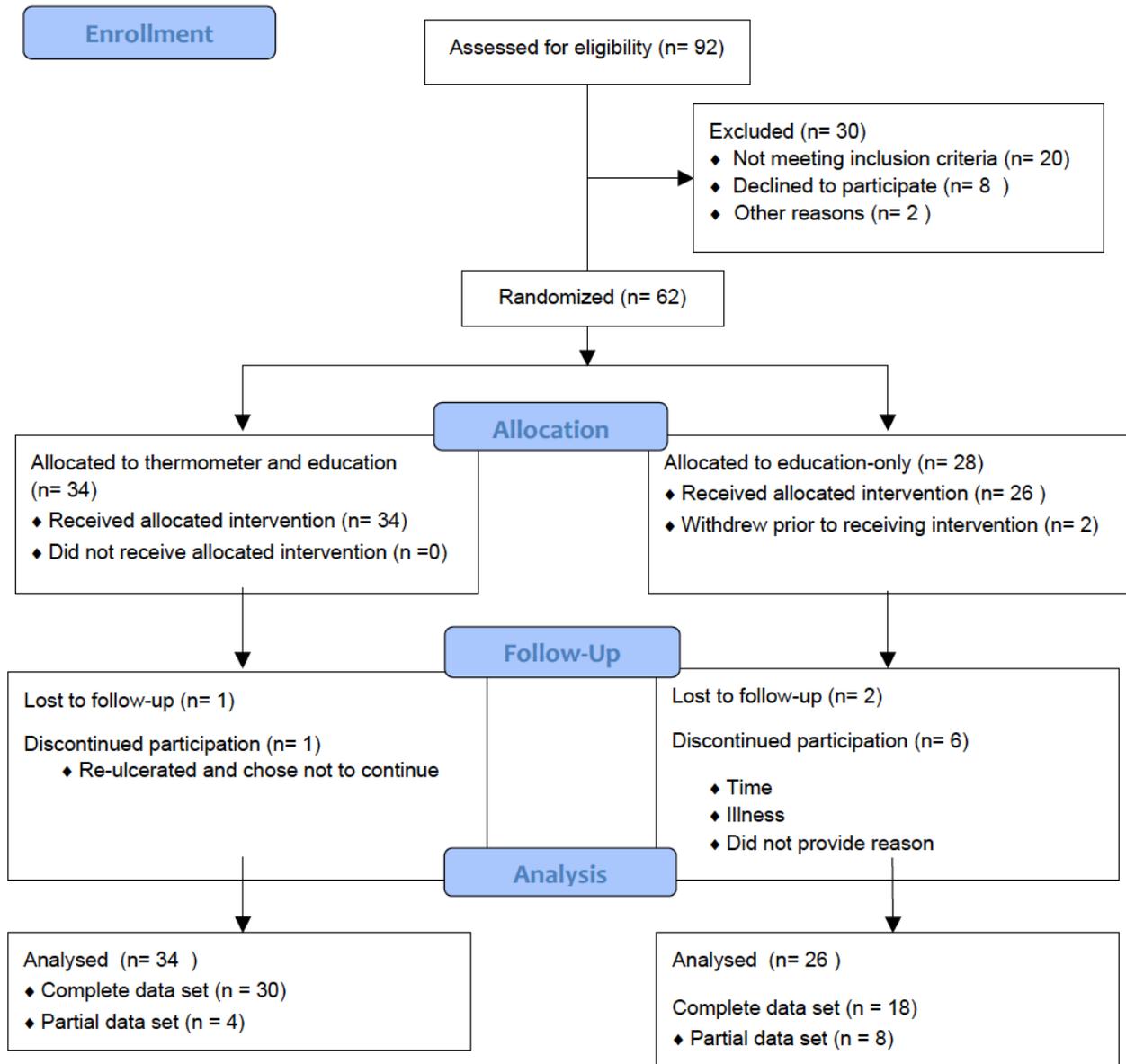


Figure 3. 2: Consort flow diagram

## **Phase 2 Setting and Sample**

Participants were recruited from clinics and geographical areas served by the Eastern Health in St. John's, Newfoundland and Labrador (NL), Canada. Ethical approval was obtained from the Health Research Ethics Authority. Inclusion criteria were: able to read and speak English; reachable by telephone; 18 years of age or older; history fits with International Diabetic Foot Risk Classification System category 2 (decreased sensation on four areas of the foot, decreased blood supply, or foot deformity) or category 3 (previous ulcer or amputation). Exclusion criteria were: ulcer; amputation site that was not healed; foot infection; Charcot's arthropathy; pregnant or breastfeeding; major health condition; unable to walk without assistance; unable to read the thermometer and document the assessment and no support person to assist; and severe peripheral vascular disease as evidenced by an ankle brachial index (ABI) < 0.8.

As the response rate for recruitment was low in the initial six months of the study, the inclusion and exclusion criteria were adjusted and approved through the ethics board. The changes were loss of sensation in at least one area on the foot as identified by the monofilament test rather than four and/or deformity (e.g., claw toe, prominent metatarsal head) and/or or callus; and an ABI > 0.7 rather than 0.8. The intention of this revision was to increase recruitment while still including participants who could potentially benefit from the identification of early inflammation with the thermometer.

The sample size was calculated using an alpha of .05 and a beta of .80 and assuming the NL population had similar ulceration rates as a previous study that used a similar intervention: 8.5% in the intervention group and 29.3% in the control group (Lavery et al., 2007). To allow for a possible 10% loss of participants, 71 individuals were to be enrolled in each group in order to ensure 64 participants per group completed the study.

Recruitment was slow, and additional strategies to increase recruitment were put in place, such as expanding the recruitment locations and changing the inclusion and exclusion criteria as outlined above. Due to difficulties with recruitment the target sample size was not achieved and Phase 2 was declared to be a pilot study with the goal of obtaining preliminary results and testing the methods. There were 34 participants enrolled in the education and thermometer group and 28 enrolled in the education-only group. Participants were allocated to either group using a list of randomly generated numbers. In the education-only group 6 participants discontinued participation due to illness, time, and unknown reasons. In the thermometer and education group 1 participant discontinued participation because of re-ulceration. This was an ulcer that had recently healed prior to enrolling in the study. The thermometer and education group had one participant who did not respond and was lost to follow-up and the education-only group had two (See Figure 3.2).

### **Phase 2 Intervention, Data Collection and Analyses**

After obtaining consent, participants in both groups received education, completed an orthotic assessment, and had a foot assessment completed by an advanced foot care nurse at baseline, three, and six months. The education was provided in video format utilizing the Canadian Association of Wound Care diabetic foot management YouTube video (<https://www.youtube.com/watch?v=xC-TqWvU0I>) and one-on-one teaching utilizing the World Diabetes Foundation Flipchart that was adapted with permission and presented using a laptop computer. A hard copy of the presentation was provided to participants. Both groups were provided with an inspection mirror with an extendable handle to assist with visualizing the bottom of the feet, and a pedometer to measure daily activity. Additionally, the education and thermometer group received a CAIT. Education on the use of the CAIT was provided through a demonstration using a foot model and CAIT. The foot model was marked with a zigzag pattern

on the plantar surface to illustrate the path that should be used when measuring temperature. Participants were directed that if there was a temperature difference of greater than 4 degrees F between the two feet, to rest their feet and recheck it the next day. If the temperature was still elevated in 48 hours, the participants were directed to see their HCP.

Nine outcomes were measured in multiple ways. The primary outcome of presence or absence of a DFU was assessed using the 60 Second Foot Screen (Sibbald et al., 2012) and self-report. The secondary outcomes completion of a visual foot assessment, completion of a temperature assessment, and completion of any assessment (either visual or a temperature assessment), identification of a concern, and QoL were measured using the Nottingham Assessment of Functional Footcare Revised (NAFF) 2015, self-report logbook data, and the exit interview results. Completing any assessment was calculated as the percentage of days out of the total potential days in the study (180 days) that a participant recorded either a temperature assessment, visual assessment, or both in the logbooks. Taking action, which was defined as doing something to address an identified foot concern based on the foot assessment, was measured using logbook data and the exit interview results. Examples of taking action are resting, changing shoes, and/or seeing a healthcare provider. A foot concern was defined as an elevated temperature, unexplained pain, and any issue identified during the visual assessment such as a break in the skin. Usability of the CAIT was measured using the return demonstration data, logbook data, and exit interview results.

Table 3.1 summarizes the measures used and schedule of data collection in Phase 2. The 60 Second Foot Screen, the Nottingham Assessment of Functional Footcare Revised (NAFF) 2015, the Foot Care Confidence Scale, the Patient Health Questionnaire 9 (PHQ9), and the Quality of Life Enjoyment and Satisfaction Short Form (Q-LES-SF) were used at baseline, three, and six months to evaluate foot condition, behavior and knowledge, self-efficacy, depression, and

quality of life (QoL) and satisfaction, respectively. All are valid and reliable tools (Kroenke, Spitzer, & Williams, 2001; Senussi, Lincoln, & Jeffcoate, 2011; Sibbald et al., 2012; Sloan, 2002; & Stevanovic, 2011). For the purpose of this research two questions were added to the 12 item scale Foot Care Confidence Scale that specifically addressed foot inflammation. Based on Phase 1 findings that showed that patients had various stages of readiness to manage diabetes, the Stages to Readiness to Change tool based on the Transtheoretical Model was administered at baseline. Although validity and reliability have not been reported, this is a tool that has been shown to be successful in categorizing patients with diabetes into a stage of change prior to an intervention (Peterson & Hughes, 2002). Both groups completed a visual foot assessment daily and recorded this information in a logbook for 180 days. The education and thermometer group also recorded foot temperature. An exit interview was completed with each participant at the end of Phase 2.

Other variables were also measured. Potential confounders were measured in this study and were identified based on research studies that found these variables to be confounders. Measurement of these variables allowed for comparisons with other key studies and to control for confounding. Factors that were potential confounders were: daily pedometer readings, HbA1C results, orthotic assessment, temperature, depression symptoms, and information collected in the participant profile. The purpose of the pedometer reading was to assess a participant's activity level before and after a temperature increase/and or ulceration. The findings related to the pedometer readings will be reported in future articles. Two theoretical concepts were also measured, self-efficacy which relates to the Social Cognitive Theory and readiness which relates to The Transtheoretical Model. These theories suggest that these concepts are important factors related to self-management (Khairnar, Kamal, Giannetti, Dwibedi, & McConaha, 2019; & Sheeran et al., 2016).

Table 3. 1 *Measures and Schedule of Data Collection*

Measure	Time to Complete Measure	Daily	Baseline	1 week	3 months	6 months	Exit
Logbook: <ul style="list-style-type: none"> <li>• Temperature readings</li> <li>• Pedometer readings</li> <li>• Foot self-assessment</li> <li>• Event</li> </ul>	5 minutes	✓					
Participant Profile	15 minutes		✓				
Return demonstration for temperature measurement	5-10 minutes		✓	✓		✓	
Orthotic Assessment	1 hour		✓				
Follow-up of orthodist's recommendations	5 minutes				✓	✓	
HbA1C * HbA1C will only be repeated if the result of the three-month check is elevated.	1-2 hours				✓	*✓	
Foot screen using Simplified 60 Second Foot Screen (baseline, 3 and 6 months)	1 minute		✓		✓	✓	
Stages to Readiness to Change Tool	1 minute		✓				
Foot Care Confidence Scale (baseline, 3 and 6 months)	10 minutes		✓		✓	✓	
The QoL Enjoyment and Satisfaction Short Form (baseline, 3 and 6 months)	5 minutes		✓		✓	✓	
Patient Health Questionnaire (PHQ9)	5 minutes		✓		✓	✓	

Measure	Time to Complete Measure	Daily	Baseline	1 week	3 months	6 months	Exit
Nottingham Assessment of Functional Footcare	15 minutes		✓		✓	✓	
Exit Interview	20 minutes						✓

We used t-tests to evaluate differences in means for some variables, such as the numbers of days a foot assessment was completed and duration of diabetes. Chi square and Fisher’s exact test were used for differences in proportion, such as the percentage of days a foot assessment was completed. An alpha of 0.05 and 95% confidence interval (CI) were used for all analyses. Logistic regression was utilized to determine variables that contributed to foot assessment. All the analyses were conducted using the intent to treat approach. Stata 14.2 was used to analyze the data (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP).

### Phase 3 Methods

At the end of the data collection of Phase 2, participants were recruited for Phase 3 (explanatory sequence). Only participants who indicated during the Phase 2 exit interview that they were open to be contacted for a Phase 3 interview were eligible. Following analysis of Phase 1 and 2 findings the Phase 3 interview guide was developed and focused on areas that required further explanation. Taking into consideration which participants could best answer the Phase 3 questions, participants were recruited for Phase 3 using purposive convenience sampling. Participants were contacted by telephone or email and if they agreed to complete an interview a mutually convenient time was set. After obtaining verbal consent, semi-structured interviews were conducted with 9 RCT participants. The interviews with the participants were 30 – 60

minutes in duration and took place over the phone. The interviews were audiotaped and the tapes were used to supplement interview notes. The data were analyzed using Interpretive Description.

## **Results**

**Sample Characteristics.** Table 3.2 summarizes the characteristics of the participants in Phase 2. There were no differences between the two groups at baseline except for insulin. The education and thermometer group and education-only group were very similar with no significant differences in age, gender, and duration of diabetes. There was a significant difference between the two groups in relation to insulin with more participants in the thermometer and education group taking insulin. In relation to foot characteristics, over 30% of each group were moderate to high risk for foot ulceration, according to the International Working Group on the Diabetic Foot Risk Stratification (IWGDF, 2019). Nine participants were interviewed in Phase 3, six participants from the thermometer and education group and three from the education-only group.

Table 3. 2 Phase 2 Patient Characteristics

<b>Characteristic</b>	<b>Thermometer and Education % (n) <sup>1</sup></b>	<b>Education-only % (n) <sup>1</sup></b>
Gender	Male <b>52.84</b> (18) Female <b>47.06</b> (16)	Male <b>57.69</b> (15) Female <b>42.31</b> (11)
Age in years (mean)	66.2 (range 38-80)	65.69 (range 49-86)
Marital Status	Single <b>8.82</b> (3) Married <b>67.65</b> (23) Widowed <b>11.76</b> (4) Divorced <b>11.76</b> (4)	Single <b>15.38</b> (4) Married <b>80.77</b> (21) Widowed <b>3.85</b> (1) Divorced <b>0</b>
Income		
< \$20000	<b>9.68</b> (3)	<b>20</b> (5)
\$20,000-100,000	<b>80.65</b> (25)	<b>60</b> (15)
>\$100,000	<b>9.68</b> (3)	<b>20</b> (5)
Education (highest level completed)		
Elementary	<b>2.94</b> (1)	<b>0</b>
High School	<b>35.29</b> (12)	<b>11.54</b> (3)
Post-Secondary	<b>35.29</b> (12)	<b>50</b> (13)
Some University	<b>2.94</b> (1)	<b>0</b>
Degree	<b>23.53</b> (8)	<b>38.46</b> (10)
Comorbidities	No <b>11.76</b> (4) Yes <b>88.24</b> (30)	No <b>0</b> Yes <b>100</b> (28)
Type of Diabetes	Type 1 <b>5.88</b> (2) Type 2 <b>94.12</b> (32)	Type 1 <b>15.38</b> (4) Type 2 <b>84.62</b> (22)
Duration of Diabetes (years)	13.88 (mean) 0-54 (range)	17.92 (mean) 0-48 (range)
Taking insulin	No <b>70.59</b> (24) Yes <b>29.41</b> (10)	No <b>34.62</b> (9) Yes <b>65.38</b> (17)
Fisher's exact p = 0.009		
Had Previous Foot Ulcer	<b>5.88</b> (2)	<b>11.54</b> (3)
Neuropathy	<b>38.24</b> (13)	<b>46.15</b> (12)
Foot Risk Classification <sup>2</sup>		
Very low	<b>61.76</b> (21)	<b>53.85</b> (14)
Low	<b>2.94</b> (1)	<b>11.54</b> (3)
Moderate	<b>29.41</b> (10)	<b>26.92</b> (7)
High	<b>5.88</b> (2)	<b>7.69</b> (2)
Stage of Change		
Precontemplation	<b>2.94</b> (1)	<b>0</b>
Contemplation	<b>5.88</b> (2)	<b>3.85</b> (1)
Change/Preparation	<b>11.76</b> (4)	<b>23.08</b> (6)
Action	<b>35.29</b> (12)	<b>38.46</b> (10)
Maintenance	<b>44.12</b> (15)	<b>34.62</b> (9)
PHQ9 <sup>3</sup> Depression Category:		

Characteristic	Thermometer and Education % (n) <sup>1</sup>	Education-only % (n) <sup>1</sup>
Mild:	23.53 (8)	15.38 (4)
Moderate:	11.76 (4)	3.85 (1)
Moderately Severe:	5.88(2)	3.85 (1)
Severe:	5.88(2)	7.69 (2)
No Depression:	52.94(18)	69.23(18)
Adequate foot care behavior (NAFF Revised)	61.76	65.38

<sup>1</sup> % (n) is the proportion and number of participants in the thermometer and education group (n = 34) and the education-only group (n =26) who had the identified characteristics.

<sup>2</sup> Foot risk classification was based on International Diabetic Foot Risk Classification System

<sup>3</sup> Levels of depression were categorized according to the PHQ9 (Patient Health Questionnaire)

<sup>4</sup> Adequate Foot care behavior was based on NAFF Revised 2015 (Nottingham Assessment of Functional Footcare)

**Diabetic Foot Ulcers.** At the end of six months, there were no differences between the two groups for DFUs, with only one person in the intervention group re-ulcerating and withdrawing from the study at month two.

**Improved foot assessment.** As shown in Table 3.3, Phase 2 results showed that the thermometer and education group had more days than the education-only group where any foot assessment was completed (150.98 vs. 119.84, p =.02). Any assessment was defined as either completing a visual assessment and/or the temperature assessment. The category of greater than 80% was identified by the researchers as being a desirable goal and measure of appropriate behavior. The thermometer and education group had more days where any assessment was completed than the education-only group, 67% vs. 50% respectively completed the logbook on 80% or more of the days. Only 17.7% of the thermometer and education group, compared to 42.3% of the education-only group recorded their assessment on fewer than 60% of the days (p = .05).

Table 3. 3 *Logbook data*

<b>Data</b>	<b>Thermometer and Education</b>	<b>Education-only</b>
Total days visual assessment (mean)	114.8	119.85
Total days temperature assessment (mean)	150.97	--
Total days any assessment	150.97	119.85
Percentage of participants who completed the assessment >80 of the days <b>% (n)<sup>1</sup></b>	<b>67.65 (23)</b>	<b>50 (12)</b>
Total days of concern (mean)	20.38	33.38
Number of days with a concern <b>% (n)<sup>2</sup></b>	n = 34 0-30 <b>81.82 (27)</b> 31-60 <b>6.06 (2)</b> 61-90 <b>6.06 (2)</b> 91-120 (0) 121-150 <b>3.03 (1)</b> 150-181 <b>5.08 (3)</b>	n = 26 0-30 <b>73.08 (19)</b> 31-60 <b>7.69 (2)</b> 61-90 <b>7.69 (2)</b> 91-120 (0) 121-150 <b>3.03 (1)</b> 150-181 <b>7.69 (2)</b>
Number of days of action <b>% (n)<sup>3</sup></b>	n = 27 0-30 <b>59.26 (16)</b> 31-60 <b>14.81 (4)</b> 61-90 <b>14.81 (4)</b> 91-120 (0) 121-150 <b>3.7 (1)</b> 150-181 <b>7.41 (2)</b>	n = 25 0-30 <b>48 (12)</b> 31-60 <b>8 (2)</b> 61-90 <b>16 (4)</b> 91-120 (0) 121-150 <b>12 (3)</b> 150-181 <b>16 (4)</b>

<sup>1</sup> % (n) is the proportion and number of participants in the thermometer and education group (n = 34) and the education-only group (n = 25) who completed an assessment in 0-59, 60-79, or > 80% of the 180 days.

<sup>2</sup> % (n) is the proportion and number of participants in the thermometer and education group (n = 34) and the education-only group (n = 26) who identified a concern in the logbooks on the specified number of days.

<sup>3</sup> (n) is the proportion and number of participants in the thermometer and education group (n = 27) and the education-only group (n = 25) who recorded an action in the logbooks on the specified number of days.

Logistic regression was conducted to assess the effect of the following variables on completing an assessment on 80% or more vs. less than 80% of the days: group (thermometer and education and education-only group); age; gender; marital status; education; income; occupation; type of diabetes; number of years with diabetes; taking insulin; history of a foot ulcer; neuropathy; foot risk classification; stage of change; depression (at baseline), and co-

morbidities. Although at baseline there was a significant difference in insulin use between the two groups, in the final model, only group was a significant predictor with number of years with diabetes as an important confounder. When years with diabetes was controlled for, group significantly predicted whether an exam was completed more than 80% of the time (OR: 3.54; 95% CI: 1.11 – 11.29;  $p = 0.032$ ). Overall, however, the model explained less than 10% of the variation ( $R^2 = 0.0989$ ).

Analysis of the Phase 2 logbooks showed that participants often completed the temperature reading without indicating that they assessed their feet. It was unclear what was happening; therefore, this finding was explored further in Phase 3. Results showed that participants also looked at their feet when they took their temperature, either prior to taking the temperature or as they were taking the temperature. One participant described the temperature check and visual check as going "hand in hand." As well, participants shared that, when first getting used to the thermometer, they would look at their feet even more if they got a temperature difference.

**Improved actions based on foot assessment.** Both the Phase 2 logbook data and the exit interview results, summarized in Table 3.3 and 3.4, showed that the CAIT had the potential to provide patients with direction for taking actions such as choosing appropriate activities, resting, re-assessment, and seeing an HCP. These results were explored further in Phase 3 to gain a further understanding of the interpretation of the CAIT readings. Participants in Phase 3 shared that a temperature reading of less than 4 degrees F provided reassurance that their feet were fine. One participant said that when the reading was less than 4 degrees F she felt she was “good to go” and do whatever activity she had planned such as dancing. In contrast, a temperature of greater than 4 degrees F heightened concern and prompted action such as: resting, further

investigating, rechecking, looking, and going to see an HCP. For example, one participant said that if it was greater than 4 degrees F, he would cancel going for a walk that day.

*Table 3. 4* Exit Interview Results for Thermometer Group

Question	Result % (n) <sup>1</sup>
Will you continue to use the thermometer?	No <b>3.45</b> (1) Yes <b>58.62</b> (17) Sometimes <b>31.03</b> (9) Rarely <b>6.90</b> (2)
Was it easy to use the thermometer?	Yes <b>100</b> (25)
Did you change what you plan to do based on what you found when you checked the temperature of your feet?	No <b>77.78</b> (21) Yes <b>22.22</b> (6) (participants indicated they rested, relaxed, rechecked later in day, went to bed earlier, decreased walking)
Would you recommend a thermometer to another person who had diabetes?	No <b>6.90</b> (2) Yes <b>93.10</b> (27)
Used thermometer correctly? (n =25)	Yes <b>48</b> (12) Partially <b>48</b> (12) Did not observe = 1
Did you provide the study letter to your HCP?	Yes <b>67.86</b> (19) No <b>32.14</b> (9) – two people who said no indicated that they told their physicians about the study. Unsure (1)

<sup>1</sup> % (n) is the proportion and number of participants in the thermometer and education group (n = 29)

**Use of the thermometer.** The results of the Phase 2 exit interviews showed that 96.8% of participants in Phase 2 indicated they would continue to use the CAIT but 37.9% indicated that they would only use it sometimes or rarely. Furthermore, 93.1% said they would recommend the thermometer to a person with diabetes (See Table 3.4). Reasons why participants in Phase 2 stated they would use the thermometer were to: see if there was inflammation; keep a record and have a baseline assessment; help monitor for hot spots; identify any issues; and find out the difference. They also indicated they would use it because it was practical and part of their regime. Those who said that they would use it sometimes indicated that they would do it to "keep an eye

on things," to see if there was anything wrong such as an infection, or if they noticed any redness, or had pain.

In Phase 3, these findings were explored further to gain clarity regarding whether or not the thermometer was a useful technology for participants. Participants in Phase 3 shared that taking their temperature was a prompt to look at their feet, prompted a more thorough foot check, raised their awareness of their feet, and made them feel more involved in their foot assessment. One participant discussed how recording the temperature increased the structure of her assessment. Another participant stated that it gave her more of an acute awareness of the surface of her foot.

All but one of the six participants from the thermometer and education group interviewed in Phase 3 used the thermometer since completing the study. Reasons provided by participants for using the thermometer were curiosity, habit, another step in the inspection process, and concern after completing the visual foot assessment. One participant said that it allowed her to have confidence in her ability to determine if the issue she identified was a serious matter or not. Two participants shared that they had a schedule for using the thermometer; one participant used it weekly and another stored the thermometer with his blood pressure kit and checked it every couple of weeks. Other participants used it more sporadically, such as when they identified a concern with a visual inspection.

We utilized the Q-LES-SF to measure QoL. There were no differences between the two groups or within groups for the QoL scores. This finding potentially indicated that additional self-management activities did not impact the QoL of participants and thus would not be expected to discourage use of the thermometer. When asked in Phase 3 about the addition of self-management activities, a participant who used the thermometer said there was a time

commitment to incorporate the thermometer and assessment into her schedule. However, she did not see this as negative, and she adjusted her schedule as needed.

**Issues using the thermometer.** During Phase 2 data collection and analysis, issues with using the thermometer were identified by the researcher and participants related to: lack of clarity regarding the purpose of the thermometer; interpreting the findings and taking action based on the assessment; and the logistics of using the CAIT.

***Lack of clarity regarding thermometer purpose.*** In Phase 2, some of the answers provided by participants during the exit interview as to why they would use the thermometer indicated a lack of clarity regarding the goal of using the thermometer. For example, one participant indicated that it helped to know if feet were working right and if the temperature was too low. This answer indicated that the participant thought foot temperature needed to be a specific number, like body temperature. One participant clearly stated that she did not understand the benefit of the thermometer. Based on these findings, participants' understanding was further explored in Phase 3. When asked what information the thermometer provided, some participants in Phase 3 were clear that the thermometer helped identify inflammation or infection. One participant articulated that the thermometer helped identify hot spots that could lead to complications such as an ulcer. Another participant framed it as something that could be going on that her eyes could not see, and the thermometer helped her with this. However, other answers were vaguer, with one participant stating that a temperature difference would tell him that he needed to rest his feet. One participant who never identified a temperature difference in Phase 2 stated that the thermometer did not provide any information.

***Interpreting the findings and taking action.*** There were also issues identified in Phase 2 with participants interpreting the findings of the temperature assessment and taking appropriate action. There was often mismatched reporting noted in the logbooks about the thermometer

reading and taking action; sometimes participants had a greater than 4 degree F temperature difference between their feet but did not indicate whether or not they changed their activity level. Why participants did not change their activity level when they measured a temperature difference of greater than 4 degrees F was explored further in Phase 3. One participant stated that when he got a temperature difference, he would look for other reasons why his foot temperature would be increased, such as the temperature of the room. Another participant considered that he might have done something wrong when checking the temperature, and it resulted in an inaccurate reading. When this was explored further with this participant, he indicated that a temperature reading greater than 4 degrees F alone would not stop him from going on his walk. If the temperature difference was accompanied by pain and tenderness, he would still go for his walk. If he could see something on his foot that could be aggravated by a walk, he would change his routine. As well, whether or not the symptoms were transient or persistent also determined whether or not this participant would change his walking routine.

Participants often noted a concern with their feet but did not take action. This finding was explored further in Phase 3. Participants in Phase 3 indicated several reasons why they did not take action when they noted a concern. One reason was they thought maybe the concern was caused by something else (e.g., "make up a reason for it happening"). Another reason was that the foot issue was a concern but not enough to take action. They would watch it. One participant pointed out that he was treated for the swelling with medication and that his doctor sent him for circulation tests for the redness, and everything was fine. So even though participants noted a concern, they were possibly: judging that it was not enough of a concern to warrant action; taking action but not viewing it as action (medication); and/or still recording the assessment finding even though they had a diagnostic procedure that ruled out anything of concern.

The issue of not taking action may have also been related to lack of clarity regarding what should be considered a foot concern that needed to be addressed. It was clear from Phases 1 and 2 that participants were not always clear on what would be a foot concern, and therefore this finding was explored further in Phase 3. When Phase 3 participants were asked what they would consider a concern on their foot, participants identified a wide variety of issues. They initially reflected on the current condition of their feet, and some of the concerns they had were related to: skin (dry, cracked, corn); structure (bunionette, loss of fat pad); redness and discolouration; and feelings in their feet (tingling). One participant highlighted stability as a concern. Most participants indicated that a break in the skin on one of their feet would be a concern, and said that they would go to their doctor right away if they noted this during an assessment. One man said he would wait a couple of days to see if the concern worsened. For other issues, there was a waiting period to see if it was a persistent or transient issue before participants would take action to go see an HCP. One participant said she would wait if she had a bruise, especially if she knew it was not related to diabetes. Similarly, two participants shared that they would be willing to wait and see if it settled back to normal. One participant said she was willing to wait three days, and another said a month. One person indicated he would go to his podiatrist, and two participants said that an issue with going the same day to see their physician was the difficulty of getting an appointment, as sometimes it took more than a week to get an appointment.

***Logistics of using the CAIT.*** During the Phase 2 teaching sessions and the return demonstrations, the researcher noted issues related to using the thermometer. Some participants had difficulty completing the temperature reading because of physical challenges such as flexibility, arthritis, carpal tunnel syndrome, and vision loss. As well, using the thermometer and obtaining an accurate temperature reading required participants to complete several steps. A return demonstration during the Phase 2 exit interview showed that half the participants were

using the thermometer correctly and the remaining participants were completing only some aspects of the assessment correctly. Some of the issues noted by the researcher were: having the thermometer too far or close to the foot; not having the thermometer on the correct settings; not recording the correct reading; and not scanning the whole foot. A participant in Phase 3 highlighted the complexity of completing a thermometer reading when he stated:

There were four or five things that I had to do to make sure I was taking it right. It had to be a certain distance from the foot, it had to stay on the foot. They might have been one little step that I didn't do correctly so this might be the reason it might not be giving me the correct temperature reading. (Participant)

**Knowledge of foot self-management.** Knowledge of foot self-management improved in both groups. The NAFF (Revised 2015) was used as a measure of knowledge application at baseline, three, and six months. Foot self-care behavior was defined as the actions a person performs to keep his/her feet healthy. In this study, a NAFF score over 50 indicated adequate foot care behavior (Senussi et al., 2011). The thermometer and education group and the education-only group had similar scores at baseline, 61.76% vs. 65.36% respectively, and both were much improved at 6 months, 82.76% vs. 94.74% respectively. When comparing daily foot checks the thermometer and education group and the education-only group also had similar scores at baseline, 35.29% vs. 29.62 respectively, and both were much improved at six months, 75.86% vs. 65% respectively.

As reported previously, there was no significant difference within or between groups for QoL. However, when a participant was asked in Phase 3 if being in the study improved her QoL she shared that it did because it prevented problems and she had experienced some foot issues in the past. She expanded on this saying that the knowledge she gained has helped her identify a

problem and take action to deal with it. She was not going to let the problem go any further than the first day that there was any indication of trouble.

## **Discussion**

A multi-modal intervention was delivered in this study with demonstrated benefits for diabetes foot self-management. Although ulceration was a primary outcome there was only one participant in the thermometer and education group who had an ulcer. As this was a re-ulceration of a wound that had recently healed prior to enrollment, it was not a good indicator of the impact of the intervention. One of the most important benefits of the intervention was promoting assessment and engagement of foot self-management without being a burden. The results showed more days of assessment being completed in the thermometer education group compared to the education-only group. However, as shown in the logistic regression analysis, the factors contributing to this result are unclear. The findings also showed that the intervention engaged participants in their foot self-management. Participants reported feeling more involved in their foot assessment and feeling reassured about the condition of their feet when they measured a temperature difference less than 4 degrees F.

The use of the CAIT did not seem to be a burden for participants in relation to additional self-management activities. There were no changes in the QoL scores in Phase 2. As well, in Phase 3 a participant in the thermometer education group shared that knowing about diabetes and foot health, as well as how to use the CAIT to prevent complications, in her opinion, improved her QoL. The high adherence rate in the thermometer education group may also reflect that the intervention did not add too much to daily self-management. This finding is in keeping with Skajfeld et al. (2016), who reported that participants using the thermometer had a high adherence rate. Similar to this study these authors reported that 67% of participants recorded the temperature assessment on 80% or more of the time (Skajfeld et al., 2016). Follow-up interviews

conducted in Phase 3 showed that since completing the study, participants did not use the thermometer every day but used it periodically and planned to continue to use it. This may show that the thermometer is a tool that can be incorporated into long-term foot self-management for people with diabetes.

Another benefit identified from using the CAIT, was the potential to provide direction for taking appropriate action to self-manage feet. Participants reported that when they obtained a temperature difference greater than 4 degrees F they took such actions as rested, changed their choice of activity, re-assessed their feet, increased their vigilance, and saw their HCP. Likewise, Lavery et al. (2004) concluded that use of the thermometer provided patients with “actionable information” (p.2646). Gauging the amount of activity also seemed to be a benefit. In this study participants decided to cancel physical activity, such as a walk, or go ahead with plans to be active based on the result of their temperature reading. It is interesting to note that in Lavery et al. (2007) the structured foot exam group had almost the same ulceration rate as the standard care group with the thermometer group having much less ulceration. This may indicate that a visual exam is not enough to detect early inflammation associated with ulceration and provide direction for action. It was suggested by Lavery et al. (2007) that the use of an infrared thermometer would allow patients to decide their safe activity level, similar to how a glucometer reading allows a patient to decide the correct dose of insulin.

For the person with diabetes at risk for foot complications, taking the appropriate action based on foot assessment findings is crucial. The thermometer may provide information that would help a person with diabetes make the best decisions for their foot health. Other research using thermometry showed that participants were less likely to have a foot ulcer if they recorded their foot temperature at least 50% of the time (OR 50.0,  $p = 0.001$ ) (Lavery et al., 2007). With a

six month intervention, as used in this study, the length of follow-up was not enough to assess the impact of the intervention on the incidence of foot ulceration.

Increase in knowledge of foot self-management was also a benefit identified from this study. Specifically, participants in both groups had improved knowledge and behavior, and it is apparent that the value of education is very important. This is in keeping with other research that reported that education is positive (Coffey et al., 2019; Maticciani & Jones, 2015) and that patients appreciated foot health education from HCPs (Coffey et al., 2019). As well, two systematic reviews concluded that education strategies, with varying complexity, should be considered a key strategy in improving foot health for people with diabetes (Dorresteijn, Kriegsman, Assendelft, & Valk, 2014; Hoogeveen, Dorresteijn, Kriegsman & Valk, 2015).

Although it was clear that the CAIT potentially offered benefits, there were several issues related to using the CAIT, such as: not understanding the purpose of the thermometer; misinterpreting the findings; not taking action based on the assessment; and the logistics of using the CAIT. Some participants were uncertain regarding the purpose of the thermometer and that a temperature difference greater than 4 degrees F identified inflammation that could lead to skin breakdown. Sometimes, when participants had a temperature difference, rather than consider that there could be an issue with their feet, they looked for other reasons that could be causing the temperature increase. This reasoning may be linked to lack of clarity regarding the purpose of the assessment. Taking action based on the findings of the temperature assessment was also an issue with only 22.2% of participants reporting that they changed what they planned to do based on the temperature reading. There was a gap in this research related to understanding the decision-making process that led to action or no action. Decision-making related to taking action should be explored in future research taking into consideration behaviour modification. Furthermore, structural equation modeling should be used in future research to determine the contribution of

multiple components to taking action. The logistics of using the thermometer also presented challenges for some participants. Participants had a lot to remember when completing the temperature assessment. There were several steps to complete, such as: having the foot up, waiting five minutes after removing the socks, having the thermometer the correct distance from the foot, ensuring the laser stays on the foot, and using the correct settings. Even with providing teaching, completing two return demonstrations (baseline and one week after enrolling in the study), by the end of the six months, only half were following the directions correctly. Sometimes a participant's physical challenges such as a sore shoulder or knee made it difficult to complete the temperature assessment. For participants who had a linked support person to complete the temperature assessment, these challenges were minimal or non-existent. These findings have implications for patient education and the importance of regular follow-up. HCPs should reinforce with patients the purpose of the thermometer assessment and regularly evaluate how patients are using the thermometer.

It is essential to highlight that although participants in the study did not perform the temperature assessment every day, they still benefited. These findings lead to the question of what the optimal schedule should be to complete a foot assessment. It may be that this schedule needs to be individualized for patients based on their foot assessment. Currently, it is recommended that patients assess their feet daily to pick up on any changes as complications, such as a DFU, progress quickly. Until the efficacy of having individualized scheduling of foot assessment and temperature measurement is established, HCPs should continue to reinforce the importance and rationale for the daily assessment. This could be a focus of future research.

There were also several challenges identified concerning the process of taking action to address the findings of the foot assessment. First, interpreting the visual inspection was an issue. It was apparent that some participants were not clear about what assessment findings would be

considered a concern. Most participants identified that a break in the skin was a concern that required attention from their HCP. However, some participants did not view findings such as bruising and pain as a concern requiring attention, and were comfortable waiting to see if these settled back to normal and whether the symptoms were transient or persistent. The decision to wait and see if a concern settled back to normal and not take action may be related to the challenge of getting an appointment to see an HCP. Participants in Phase 3 highlighted this challenge. Often it could take a week or more for a patient to see their HCP. This limited access would make it difficult for patients to follow what they were directed to do, which is to get their feet checked immediately by an HCP if there was a concern. It also may be related to the perception of risk, which is a highly variable concept. The variability of the answers may reflect that people perceive risk concerning their foot health in different ways.

These findings have implications for patient education and policy. HCPs should reinforce with patients what assessment findings would be a foot concern and what would be the appropriate action, whether it be waiting and watching their foot closely or seeing an HCP right away. As well, consideration should be given to the concept of teach-back to identify a gap in knowledge. Teach-back is a patient education technique that can be utilized to see if patients have understood all the concepts that the HCP tried to convey, and has been shown to be effective in chronic disease management (Dinh, Bonner, Clark, Ramsbothan, & Hines, 2016). Incorporated into this approach could be two key messages, such as what are foot concerns and when should a patient see their HCP. In relation to the thermometer, if patients are using the CAIT as an assessment tool, their process of completing the measurement should be evaluated regularly by an HCP to ensure it is being performed correctly.

These findings also have broader implications for policy in several areas. First, improved access is needed to foot health services for patients with diabetes, as a foot issue can progress

very quickly to a foot complication such as a foot ulcer. As identified in this study, patients sometimes had to wait a week or more to see their HCP. Without quick access to an HCP, patients will have to go to an emergency room and may need to receive home care due to dressing changes. These are all more costly options. Open-access scheduling where primary HCPs keep some appointments available for patients who need to be seen the same day may be a potential solution. Authors of a recent systematic review that included 11 studies reported that open-access scheduling reduced wait times for patients in all studies reviewed (Ansell, Crispo, Simard & Bjerre, 2017). A scheduling policy that supports open-access scheduling for primary care should be considered. This policy should incorporate education for support staff regarding why it is so vital to provide same-day access to patients who have a foot concern. Secondly, to increase access, more team-based care with strong collaboration may be beneficial. With this approach, patients may seek out someone else other than their physician, such as an advanced foot care nurse or podiatrist, when they have a foot problem, thus increasing access.

There were several strengths of this study. This is the first study to report on the use of a CAIT as part of a multi-modal intervention. The recruitment of a broad-based community sample of people with diabetes rather than just using diabetes clinics ensured participants had targeted characteristics. As well, all participants had a foot assessment completed by an advanced foot care nurse at baseline, three and six months. Furthermore, intervention integrity was maintained through one researcher completing the education module with participants. Also, the use of an MMR approach allowed for testing of an intervention that was developed based on patients' experiences in a local context. Furthermore, greater understanding of the delivery and impact of the intervention and foot self-management was gained through Phase 3. Finally, by utilizing logistic regression, confounding variables were controlled in the analysis. The study also had limitations. First, the study had low power to assess the outcome of DFU. Secondly, the length of

the intervention was only six months. A longer intervention would have permitted assessment of the long-term impacts of the strategy. Finally, as most variables measured were self-report, the potential for social desirability bias may have been an issue.

## **Conclusion**

In summary, this MMR that incorporated a pilot RCT, contributes to refining the work on the use of infrared thermometry and prevention of foot complications, and suggests that the use of a CAIT is an available tool that could support foot self-management for people with diabetes. Specifically, the use of a CAIT may offer several benefits, such as promoting and providing structure for a foot assessment and direction for action. We look forward to more intervention research that builds on this research and tests the use of the CAIT with a larger sample size and utilizing a longer intervention.

## References

- Alavi, A., Sibbald, R. G., Mayer, D., Goodman, L., Botros, M., Armstrong, D. G., . . . Kirsner, R. S. (2014). Diabetic foot ulcers: Part I. pathophysiology and prevention. *Journal of the American Academy of Dermatology*, *70*(1), 1.e1-18; quiz 19.  
doi:10.1016/j.jaad.2013.06.055 [doi]
- Ansell, D., Crispo, J. A., Simard, B., & Bjerre, L. M. (2017). Interventions to reduce wait times for primary care appointments: a systematic review. *BMC health services research*, *17*(1), 295.
- Arad, Y., Fonseca, V., Peters, A., & Vinik, A. (2011). Beyond the monofilament for the insensate diabetic foot: A systematic review of randomized trials to prevent the occurrence of plantar foot ulcers in patients with diabetes. *Diabetes Care*, *34*(4), 1041-1046.  
doi:10.2337/dc10-1666 [doi]
- Armstrong, D. G., Holtz-Neiderer, K., Wendel, C., Mohler, M. J., Kimbriel, H. R., & Lavery, L. A. (2007). Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. *The American Journal of Medicine*, *120*(12), 1042-1046. doi:S0002-9343(07)00739-5 [pii]
- Boulton, A. J. (2013). The pathway to foot ulceration in diabetes. *The Medical Clinics of North America*, *97*(5), 775-790. doi:10.1016/j.mcna.2013.03.007 [doi]
- Boulton, A. J., Armstrong, D. G., Albert, S. F., Frykberg, R. G., Hellman, R., Kirkman, M. S., Task Force of the Foot Care Interest Group of the American Diabetes Association. (2008). Comprehensive foot examination and risk assessment. *Endocrine Practice: Official Journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists*, *14*(5), 576-583. doi:G22H443105711257 [pii]

- Chang, C., Peng, Y., Chang, C., & Chen, M. (2013). Useful screening tools for preventing foot problems of diabetics in rural areas: A cross-sectional study. *BMC Public Health*, *13*(1),612. <https://doi.org/10.1186/1471-2458-13-612>
- Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal*, *16*(1), 183-210. doi:10.1111/iwj.13010 [doi]
- Dinh, T. T. H., Bonner, A., Clark, R., Ramsbotham, J., & Hines, S. (2016). The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease: a systematic review. *JBHI database of systematic reviews and implementation reports*, *14*(1), 210-247.
- Dorresteijn, J. A., Kriegsman, D. M., Assendelft, W. J., & Valk, G. D. (2014). Patient education for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews*, *12*, CD001488. doi:10.1002/14651858.CD001488.pub5 [doi]
- Hoban, C., Sareen, J., Henriksen, C. A., Kuzyk, L., Embil, J. M., & Trepman, E. (2015). Mental health issues associated with foot complications of diabetes mellitus. *Foot and Ankle Surgery : Official Journal of the European Society of Foot and Ankle Surgeons*, *21*(1), 49-55. doi:10.1016/j.fas.2014.09.007 [doi]
- Hoogeveen, R. C., Dorresteijn, J. A., Kriegsman, D. M., & Valk, G. D. (2015). Complex interventions for preventing diabetic foot ulceration. *The Cochrane Database of Systematic Reviews*, *8*, CD007610. doi:10.1002/14651858.CD007610.pub3 [doi]
- Houghton, V. J., Bower, V. M., & Chant, D. C. (2013). Is an increase in skin temperature predictive of neuropathic foot ulceration in people with diabetes? A systematic review and meta-analysis. *Journal of Foot and Ankle Research*, *6*(1), 31-1146-6-31. doi:10.1186/1757-1146-6-31 [doi]

- International Diabetes Federation. (2017). *IDF clinical practice recommendation on the diabetic foot - 2017*. Belgium: International Diabetes Federation. Retrieved from <https://www.idf.org/e-library/guidelines/119-idf-clinical-practice-recommendations-on-diabetic-foot-2017.html>
- Khairnar, R., Kamal, K. M., Giannetti, V., Dwibedi, N., & McConaha, J. (2019). Barriers and facilitators to diabetes self-management in a primary care setting - patient perspectives. *Research in Social & Administrative Pharmacy : RSAP*, 15(3), 279-286. doi:S1551-7411(17)30943-9 [pii]
- Khunkaew, S., Fernandez, R., & Sim, J. (2018). Health-related quality of life among adults living with diabetic foot ulcers: A meta-analysis. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, doi:10.1007/s11136-018-2082-2 [doi]
- International Working Group on the Diabetic Foot (IWGDF). (2015). *Prevention and management of foot problems in diabetes: A summary guidance for daily practice 2015, based on the IWGDF guidance documents*. International Working Group on the Diabetic Foot. Retrieved from [https://iwgdfguidance.org/wp-content/uploads/2017/10/website\\_summary-1.pdf](https://iwgdfguidance.org/wp-content/uploads/2017/10/website_summary-1.pdf)
- International Working Group on the Diabetic Foot (IWGDF). (2019). *IWGDF guidelines on the prevention and management of diabetic foot disease*. Retrieved from <https://iwgdfguidelines.org/>
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606-613. Retrieved from <https://www.springer.com/journal/11606>

- Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., . . . Agrawal, C. M. (2004). Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care*, 27(11), 2642-2647. doi:27/11/2642 [pii]
- Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Athanasiou, K. A., . . . Agrawal, C. M. (2007). Preventing diabetic foot ulcer recurrence in high-risk patients: Use of temperature monitoring as a self-assessment tool. *Diabetes Care*, 30(1), 14-20. doi:30/1/14 [pii]
- Lazzarini, P. A., Pacella, R. E., Armstrong, D. G., & van Netten, J. J. (2018). Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabetic Medicine: A Journal of the British Diabetic Association*, doi:10.1111/dme.13680 [doi]
- Matricciani, L., & Jones, S. (2015). Who cares about foot care? Barriers and enablers to foot self-care practices among non-institutionalised older adults diagnosed with diabetes. An integrative review. *The Diabetes Educator*, 41(1), 106-117. doi:10.1177/0145721714560441
- Mufti, A., Coutts, P., & Sibbald, R. G. (2015). Validation of commercially available infrared thermometers for measuring skin surface temperature associated with deep and surrounding wound infection. *Advances in Skin & Wound Care*, 28(1), 11-16. doi:10.1097/01.ASW.0000459039.81701.b2 [doi]
- Peterson, K. A., & Hughes, M. (2002). Readiness to change and clinical success in a diabetes educational program. *The Journal of the American Board of Family Practice*, 15(4), 266-271. Retrieved from <https://www.jabfm.org/>

Senussi, M., Lincoln, N., & Jeffcoate, W. (2011). Psychometric properties of the Nottingham Assessment of Functional Footcare (NAFF). *International Journal of Therapy and Rehabilitation*, 18(6), 330-334. Retrieved

<https://journals.lww.com/intjrehabilres/pages/default.aspx>

Sheeran, P., Maki, A., Montanaro, E., Avishai-Yitshak, A., Bryan, A., Klein, W. M., . . .

Rothman, A. J. (2016). The impact of changing attitudes, norms, and self-efficacy on health-related intentions and behavior: A meta-analysis. *Health Psychology :Official Journal of the Division of Health Psychology, American Psychological Association*, 35(11), 1178-1188. doi:2016-28683-001 [pii]

Sibbald, R. G., Ostrow, B., Lowe, J., Ayello, E. A., Alavi, A., Botros, M., ... & Smart, H.

(2012). Screening for the high-risk diabetic foot: a 60-second tool (2012)©:

diabetes. *Wound Healing Southern Africa*, 5(2), 72-82. Retrieved from

<http://woundhealingsa.co.za/index.php/WHSA>

Simmons, L.A., & Noonan, D. (2017). Self-management. In J.F Gidden (Ed). *Concepts of nursing practice*. (pp. 54-60). Elsevier.

Singh, N., Armstrong, D. G., & Lipsky, B. A. (2005). Preventing foot ulcers in patients with diabetes. *Jama*, 293(2), 217-228. doi:293/2/217 [pii]

Skafjeld, A., Iversen, M. M., Holme, I., Ribu, L., Hvaal, K., & Kilhovd, B. K. (2015). A pilot study testing the feasibility of skin temperature monitoring to reduce recurrent foot ulcers in patients with diabetes--a randomized controlled trial. *BMC Endocrine Disorders*, 15, 55-015. doi:10.1186/s12902-015-0054-x [doi]

Sloan, H.L. (2002). Developing and testing of the foot care confidence scale. *Journal of Nursing Measurement*. 10 (3), 207-218. Retrieved from

<https://www.springerpub.com/journal-of-nursing-measurement.html>

- StataCorp. (2015). *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.
- Stevanovic, D. (2011). Quality of life enjoyment and satisfaction questionnaire-short form for quality of life assessments in clinical practice: A psychometric study. *Journal Psychiatric Mental Health Nursing*, 18(8):744-750. doi: 10.1111/j.1365-2850.2011.01735.x [doi].
- Tchero, H., Kangambega, P., Lin, L., Mukisi-Mukaza, M., Brunet-Houdard, S., Briatte, C., . . . Rusch, E. (2018). Cost of diabetic foot in France, Spain, Italy, Germany and United Kingdom: A systematic review. *Annales D'Endocrinologie*, 79(2), 67-74. doi:S0003-4266(17)30959-9 [pii]
- Van Netten, J. J., Price, P. E., Lavery, L. A., Monteiro-Soares, M., Rasmussen, A., Jubiz, Y., . . . International Working Group on the Diabetic Foot (IWGDF). (2015). Prevention of foot ulcers in the at-risk patient with diabetes: A systematic review. *Diabetes/Metabolism Research and Reviews*, doi:10.1002/dmrr.2701 [doi]
- van Schie, C., & Slim, F. J. (2012). Biomechanics of the diabetic foot: The road to foot ulceration. In A. Veves, J. M. Giurini & F. W. LoGerfo (Eds.), *The diabetic foot: Medical and surgical management*. (3<sup>rd</sup>ed., pp. 203-216). New-York: Springer.
- Wilde, M. H., & Garvin, S. (2007). A concept analysis of self-monitoring. *Journal of Advanced Nursing*, 57(3), 339-350. doi: 10.1111/j.1365-2648.2006.04089.x
- Zhang, P., Lu, J., Jing, Y., Tang, S., Zhu, D., & Bi, Y. (2017). Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis (dagger). *Annals of Medicine*, 49(2), 106-116. doi:10.1080/07853890.2016.1231932 [doi]

## **Chapter 4: Research into Prevention of Foot Problems Related to Diabetes: The Synergy of Patient-Oriented Research and Mixed Methods Research**

Kathleen Stevens RN, PhD(c)  
Donna Moralejo RN, PhD  
Steven Ersser RN, PhD  
Cathy MacLean MD

### **Introductory Statement**

Chapter 4 contains a manuscript that considered the benefits of using a patient-oriented and mixed methods research approach when developing self-management interventions for patients with non-communicable diseases. This is illustrated using examples from a patient-oriented and mixed methods research study that tested a foot self-management strategy for patients with diabetes. The target audience for this manuscript is health care providers who work with patients with non-communicable diseases, researchers, and those who may not be familiar with the advantages of using mixed methods research and patient-oriented research over a randomized controlled trial alone.

### **Authorship Statement**

KS (the primary researcher) and DM contributed to the conception and research design. DM guided the research study. KS contributed to data collection, analysis, and interpretation and wrote the manuscript. DM, SE, and CM contributed to data analysis. DM, CM, and SE reviewed the manuscript and revisions were made based on feedback. DM, CM, and SE gave final approval of the revised manuscript.

### **Key Words**

Diabetes, foot health, self-management, mixed methods research, patient-oriented research.

### **Funding**

This research was funded by grants from NL-SUPPORT, Healthcare Foundation, and the College of Registered Nurses of Newfoundland and Labrador.

## **Abstract**

With the increase in the number of people with non-communicable diseases and the rising cost of health care, nurses need cost-effective interventions they can use when working with this population that are proven to support self-management. To accomplish this, nurse researchers can employ patient-oriented research to develop and test interventions that are practical and meet patient needs. Mixed methods research is an approach that can help operationalize patient-oriented research. This article describes how we used patient-oriented and mixed methods research to develop and test an intervention to prevent foot complications for patients with diabetes. We argue that instead of employing a randomized controlled trial alone, this methodological approach offered more. The synergy achieved by using patient-oriented research strategies and an exploratory and explanatory mixed methods sequence resulted in the development and testing of a patient-centred intervention, and provided greater clarity about the impact of the intervention and foot self-management for people with diabetes.

Keywords: patient-oriented, mixed methods, diabetes, foot self-management

## CHAPTER 4

### Background and Purpose

A strategic priority of the International Council of Nurses (ICN) is the prevention and control of non-communicable diseases (NCDs) (ICN, 2019). Worldwide there is an increase in the number of NCDs such as diabetes, heart disease, stroke, cancer, and chronic lung disease (World Health Organization (WHO), 2018). Globally 71% of deaths are attributed to these diseases, and 15 million people between the ages of 30 and 69 die yearly as a result of an NCD (WHO, 2018). Along with the increase in NCDs is the rising cost of health care. Many countries are spending a large percentage of their Gross Domestic Product on health care. The United States and Canada are spending 17.2% and 10.4%, respectively (Canadian Institute for Health Information (CIHIb), 2018). Since 2014 in Canada, there has been an increase of 1.4% per year in health care spending (Canadian Institute of Health Information (CIHIa), 2018).

To manage the care of patients with NCDs, nurses require cost-effective interventions that work. Therefore, the focus of research needs to be on the development and testing of practical interventions that meet patients' needs. A randomized controlled trial (RCT) is an appropriate design to test how well an intervention works, and attention can be paid to methodological rigor. However, this is often not enough because an RCT may not capture why the intervention is working or why it is not working. Therefore, researchers need to know more about patient circumstances and the local context to help explain results. Designing interventions that are patient-oriented would allow researchers to identify potential issues and address these as part of the intervention.

Patient-oriented research (POR) refers to “a continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes” (Canadian Institute of Health Research (CIHR), 2014, para.11). The patient is defined as person, family

member, or friend that has experience with the health issue (CIHR, 2014). Mixed methods research (MMR) is an approach that can help operationalize POR and ensure that practical interventions are developed and tested. In MMR, both quantitative and qualitative data are collected and then integrated to provide more comprehensive evidence than could be obtained from either qualitative or quantitative data. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone (Cresswell & Plano-Clark, 2018).

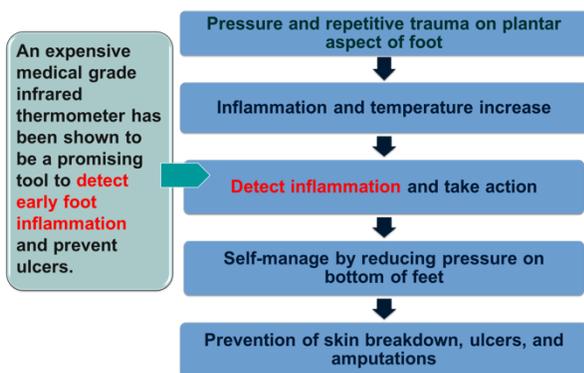
In this article we will highlight how the use of MMR and POR to develop and test an intervention provided a synergy that would not have been gained through the use of only one approach. For this study, the premise for the intervention was based on the literature. By using MMR and POR, data collection and the implementation of the intervention were enhanced, and greater understanding was gained about the effectiveness of the intervention. First, an overview of the study background and method will be presented. Next, specific examples that illustrate the effect of using this methodological approach will be described.

### **Overview of the Study**

The intervention developed was for the promotion of foot self-management and prevention of diabetic foot ulcers (DFUs) for patients with diabetes. Self-management is defined as “the ability of individuals and or their caregivers to engage in the daily tasks required to maintain health and well-being or to manage the physical, psychological, behavioral, and emotional sequelae of a chronic disease based on the knowledge of the condition, its consequences, and the plan of care co-developed with their health care team (Simmons & Noonan, 2016, p.54). This is an important intervention because diabetes and resulting foot complications are increasing. Approximately 2.3 million people in Canada have diabetes (Statistics Canada, 2017). For people with diabetes nerve damage, poor circulation, and local

pressure contribute to skin breakdown and ulcer formation, which can lead to amputation (International Working Group on the Diabetic Foot, 2015). In a 2017 systematic review and meta-analysis that included 67 publications from 33 countries with a date range from 1991 to 2015, the global prevalence for DFUs was reported to be 6.3% [95% CI: 5.4-7.3] (Zhang et al., 2017).

Effective self-management strategies that prevent skin breakdown and detect early signs of skin breakdown are needed. The process of skin breakdown is caused by pressure and repetitive stress on the bottom of the foot, which will lead to inflammation. If this inflammation is not detected, it can lead to skin breakdown (van Schie & Slim, 2012). A temperature difference of greater than 4 degrees Fahrenheit (F) or higher between the left and right foot indicates inflammation (Mufti, Coutts, & Sibbald, 2015). If this inflammation is detected, a person can rest until the inflammation decreases. An expensive \$700 infrared thermometer is a promising strategy to detect early foot inflammation and prevent ulcers (Armstrong et al., 2007; Lavery et al., 2004; Lavery et al., 2007). A commercially-available infrared thermometer (CAIT), that costs ranges between \$30 and \$100, was validated against the medical-grade thermometer but not widely tested in practice (See Figure 4.1).



*Figure 4. 1* Prevention of plantar skin breakdown and the infrared thermometer. This figure illustrates the process of plantar skin breakdown and how the thermometer can detect inflammation.

Based on the current research literature, it would have been appropriate for us to conduct an RCT and evaluate the CAIT in practice. An RCT would have told us about the CAIT effectiveness. However, foot-self management is complex and impacted by many factors (Coffey, Mahon, & Gallagher, 2019; Matricciani & Jones, 2015). The addition of daily thermometer readings needed to be understood in the wider and local context, and was best explored using POR strategies and qualitative and quantitative data that could be collected using an MMR design. Therefore, a POR and MMR research study was designed and received ethics approval from the Newfoundland and Labrador Health Research Ethics Authority.

The research questions were:

1. What are the issues related to self-management of feet?
2. Does a foot health intervention that utilizes a CAIT improve foot outcomes?
3. What are the participants' experiences with foot health self-management and the intervention?

To best answer these questions, an MMR study was designed to support the development and testing of an intervention that attempted to address the multiple factors impacting self-management and foot health. The MMR study had three phases with exploratory and explanatory sequences. For sequential designs, the intent is to have one phase build on the other (Cresswell & Plano-Clark, 2018). In Phase 1 self-management was explored and semi-structured interviews were completed with 12 patients, 9 health care providers (HCPs), and 4 support persons, and were analyzed using Interpretive Description. The exploratory sequence involved the use of Phase 1 results to inform the development of a multi-modal intervention that was tested using an RCT (Phase 2). In the pilot RCT the intervention group (n = 34) received foot education and a thermometer to assess foot temperature, and the control group (n =26) received foot education only. Participants monitored their feet and completed daily logbooks for six months. Exit interviews were conducted with participants. Following completion of the pilot RCT, Phase 3 semi-structured qualitative interviews were conducted with Phase 2 participants (N = 9). The focus of the interviews was on Phases 1 or 2 findings that we determined required further explanation. The explanatory sequence involved the integration of results from all phases.

The MMR was also patient oriented. We invited a support person of a patient with diabetes and a patient with neuropathy to join the research team. These patient representatives contributed in several ways. The patient representatives reviewed the findings of Phase 1 and provided feedback on these findings that ensured that the themes were being captured clearly. This feedback also helped inform the intervention and both patient representatives participated in a pilot education session prior to the start of Phase 2. For example, they provided feedback on the clarity of the PowerPoint presentation and several revisions were made to the content and slides based on their suggestions. Another important way that the patient representatives contributed to the study was providing advice regarding locations for recruitment and recruitment materials

such as the poster and pamphlet used in Phase 2. Finally, the representatives reviewed a draft of the final dissertation and provided feedback.

## Results

**Examples from the exploratory sequence.** The findings from Phase 1 reinforced the complexity of self-management and foot health and informed the intervention, which was conducted in Phase 2. Specifically, Phase 1 findings identified the personal challenges experienced and system barriers encountered by patients concerning foot self-management, as well as their educational needs and what resources were considered to be a support. These findings and the feedback received from the patient representatives provided an increased understanding of the factors impacting on self-management and informed the intervention. Table 4.1 outlines how the findings from Phase 1 impacted the intervention and RCT methods (Phase 2). These examples will be discussed in the following paragraphs.

Table 4. 1 *Exploratory Model and the Impact on the Intervention and RCT Method (Phase 2)*

Findings from Phase 1	Impact on intervention and RCT method (Phase 2)
1. Patients had limited knowledge of diabetes and foot health and care of feet.	1. A comprehensive education component was included as part of the intervention.
2. Patients had difficulty assessing the bottoms of their feet.	2. A mirror was provided to each participant.
3. Support persons played an important role in self-management.	3. Support persons were encouraged to attend the education session.
4. Patients had varying degrees of readiness to make change and self-manage.	4. To measure readiness for change a questionnaire, was incorporated into data collection.

***Addition of a comprehensive education component.*** In the initial planning of the study, it was decided that there would be an educational component incorporated into the intervention that focused on how to care for feet with a diagnosis of diabetes. The findings from Phase 1 reinforced this decision but also highlighted that patients had limited understanding of the prevalence of diabetes, how diabetes impacted feet, what a DFU was, and how they occurred. As a result, this content was incorporated into the education component that was delivered to both groups. The education component was piloted with the patient representatives and further refined based on their feedback.

***Addition of a mirror.*** Another important Phase 1 finding was patients had difficulty reaching and examining the bottom of their feet due to co-morbidities such as arthritis. To address this problem, participants in both the intervention and control group were provided with an inexpensive long-handled mirror that was purchased at a hardware store and was used for visualizing engines. The mirror could be angled to help visualize different parts of the foot and had a telescopic handle. Additionally, the participants had the option of turning on a small light that was built into the mirror to aid in examining their feet.

***Critical role of support persons.*** Phase 1 results reinforced the critical role the linked support person can potentially have in supporting self-management for some patients. Based on this, support persons were encouraged to attend the education session and assist the participants with their assessments and data collection.

***Measure of readiness.*** Finally, the analysis of the interviews from Phase 1 showed that in general patients had varying degrees of readiness to make changes related to the self-management of diabetes. Based on this finding we recognized that this was a potential factor influencing self-management of foot health; therefore, we decided to add a measurement of readiness to baseline Phase 2 data collection. Although validity and reliability has not been established, this tool was

based on the Transtheoretical Model and was used successfully in a research study related to diabetes education to categorize patients into a stage of change (Peterson & Hughes, 2002).

**Examples from the explanatory sequence.** Interviews were conducted in Phase 3 to help us further understand the Phases 1 and 2 findings. Findings from all three phases were analyzed in relation to one another, and the data were assessed for three possible outcomes: confirmation, expansion, and discordance. Confirmation occurs when the findings from one phase confirm the findings from another phase. This similar conclusion provides greater credibility to the results. Discordance occurs if the qualitative and quantitative findings are inconsistent or disagree with each other. Finally, expansion occurs when the findings from the phases diverge and expand the understanding of the concepts of interest (Fetters, Curry & Creswell, 2013). No occurrences of discordance were identified when considering Phase 1 and Phase 2 findings. Any instances of confirmation between Phase 1 and Phase 2 were not explored further in Phase 3. The focus of Phase 3 was expansion because several findings were identified that we felt required further explanation; Table 4.2 shows a selection of Phase 1 and 2 findings that were explored further in Phase 3 and the results of the data collection. These findings will be discussed further below.

Table 4. 2 *Explanatory Model Examples of Integration Across the Three Phases*

<b>Phase 1 findings (N=24)</b>	<b>Phase 2 findings (N=62)</b>	<b>Goal of Phase 3</b>	<b>Phase 3 findings (N=9)</b>
1. Participants thought that the thermometer would be a useful tool.	Number of days any foot assessment intervention vs. control group ( <b>150.98 vs. 119.84, p =.02</b> )  For intervention group: Temperature reading completed out of 180 days (M = <b>150</b> , SD = 43)	To explain the connection between the thermometer and visual foot assessment	Participants indicated the thermometer: <ul style="list-style-type: none"> <li>• prompted looking at feet</li> <li>• provided more structure</li> <li>• made them feel more involved</li> <li>• provided reassurance when the temperature difference was &lt; 4 F</li> </ul>

Phase 1 findings (N=24)	Phase 2 findings (N=62)	Goal of Phase 3	Phase 3 findings (N=9)
	Foot assessment completed out of 180 days (M = <b>114 days</b> , SD = 64)		and heightened vigilance when it was > 4 F
2. Participants were unsure about what would be considered a concern.	<p>Mismatched reporting in relation to the foot assessment</p> <p>For example, number of days concern often did not equal the number of days action, discrepancy about what was viewed as an action.</p>	To explain participants understanding of a concern and why they did and did not take action	<p>Breaks in the skin were a concern that participants would have assessed right away by an HCP.</p> <p>Participants would wait to see if “things settled back” for findings such as pain, tenderness, colour change, and bruising.</p> <p>A temperature difference &gt; 4F was considered a concern for some participants in the intervention group.</p>
3. There was a continuum related to patient readiness to not only manage foot health but to self-manage diabetes in general.	<p>Stage of Change</p> <ul style="list-style-type: none"> <li>• Precontemplation: <b>1.67%</b> (1)</li> <li>• Contemplation: <b>5%</b> (3)</li> <li>• Preparation: <b>16.67%</b> (10)</li> <li>• Action: <b>36.67%</b> (22)</li> <li>• Maintenance: <b>40%</b> (24)</li> </ul> <p>Changes made to diabetes management during study: Intervention group: <b>58%</b> Control group: <b>50%</b></p>	To explain more about readiness and foot self-management	Participants from the preparation, action, and maintenance stages were interviewed. All were interested in finding out more about diabetes management regardless of stage of change.

***Thermometer and foot assessment.*** Participants in Phase 1 interviews felt that the thermometer could be a useful tool. Analysis of the data from Phase 2 showed that there was a significant difference between participants in the intervention and the control group regarding completion of any foot assessment. However, there was mismatched reporting in the logbooks with participants in the intervention group recording completion of the temperature reading an average of 150/180 days and only recording completion of the visual assessment an average of 114/180 days. It was not clear whether participants were only completing the thermometer assessment on some days, or whether the thermometer and visual assessment were completed together and this was an issue of recording. What we learned in Phase 3 was that the thermometer assessment and visual assessment went "hand in hand," and participants were looking at their feet when they completed the temperature assessment, even though they did not record it. Along with this explanation, we gained greater clarity into the participants' experience with the thermometer. We learned that using the thermometer prompted a visual assessment, provided structure to the foot assessment, made the participant feel more involved in their foot self-management, and provided reassurance or increased vigilance related to their foot health, depending on if the temperature difference was greater or less than 4 degrees F.

***Understanding a foot concern and taking action.*** It was apparent from the Phase 1 interviews that participants had a lack of understanding related to what a foot concern was and what the appropriate action would be. As a result, various foot concerns and the appropriate action were included in the Phase 2 teaching session. An analysis of the logbooks in Phase 2 showed that participants would record a concern, but did not indicate that they took action to address the concern. As well, there were discrepancies noted regarding what was considered an action. For example, some participants considered putting cream on their feet as taking action, and others did not record this as an action. Phase 3 findings showed that participants clearly

understood that a break in the skin was a concern and were able to identify some other assessment findings that would constitute a concern. In relation to action, a break in the skin was a concern that would prompt them to see their HCP. However, with other concerns, such as pain and tenderness, they were willing to wait and see if these issues settled back to normal.

***Readiness to manage foot health.*** As discussed previously, we found in Phase 1 that there was a continuum of readiness to self-manage diabetes and we added a measurement of readiness to the Phase 2 data collection. As shown in Table 4.2, we found in Phase 2 that most participants were in the action and maintenance stage, and over half of the participants made changes to their diabetes management during the six-month pilot RCT. Based on this analysis, we decided that the concept of readiness to self-manage foot health required further explanation. Therefore, in Phase 3, participants from the preparation, action, and maintenance stages were interviewed. The Phase 3 findings showed that regardless of the stage of change, participants were interested to learn about how to manage diabetes and were open to making changes.

## **Discussion**

When we reflected on the use of this methodological approach it was clear the benefit that was gained from utilizing POR and MMR. In relation to the exploratory sequence, we were pleased that we made the additions to the intervention, as data collected during the exit interviews for the RCT (Phase 2) and Phase 3 confirmed that these changes strengthened the intervention. The majority of participants indicated in the exit interview for Phase 2 that the education provided and the awareness they developed about their foot health were the best parts of the strategy. Some of the participants in the exit interviews identified the mirror as one of the best parts of the intervention, and some of the Phase 3 participants indicated that they were still using a mirror. In relation to support persons, several spouses attended the Phase 2 education session and were involved in helping the participants throughout the study. Two of the support persons

who attended the education session tracked their steps using a pedometer for the duration of the study; this appeared to be an additional encouragement to participants. Finally, insight regarding readiness to change and foot self-management was gained when the results related to this variable were explored in Phase 3.

The value in completing the explanatory sequence (Phase 3) was that it helped to understand and gain further clarity about Phases 1 and 2 results. If we had not conducted Phase 3, we would not have understood the extent of the value of using the CAIT. Specifically, we would not have known that participants felt that it prompted foot assessment, provided reassurance about the results of the assessment, and directed action. Secondly, without Phase 3, we would not have understood that even with education, patients may still have difficulty identifying and taking appropriate action for foot concerns. Finally, we would not have understood that regardless of the stage of readiness, participants were still interested in exploring changes to improve their diabetes management.

We did experience some challenges with taking an MMR approach. Cresswell and Plano-Clark (2018) outline two challenges in using MMR that we encountered in this research in relation to skills and time. This research was conducted for partial fulfillment of a PhD program and the primary researcher was a novice researcher. Although this was a tremendous learning experience it required that the student learn POR, quantitative methods, qualitative methods, and how to integrate the findings. Also, the amount of time it took to conduct this study was a challenge. With MMR time is required to collect and analyze two different types of data and then integrate this data (Cresswell & Plano-Clark, 2018). The duration of the study was further increased by using both the exploratory and explanatory sequence with two points of integration. The time commitment required was also a challenge for the patient representatives and researchers.

## **Conclusion**

This paper described the development and testing of an intervention informed by POR and MMR and extends nursing knowledge about the benefit of using these synergistic methodologies. Research that is patient oriented is vital to ensure that interventions are developed and tested that are real-world and practical. MMR provides an effective methodological structure for POR. The additions to the study based on Phase 1 results added to the intervention, and Phase 3 was instrumental in explaining the results of Phases 1 and 2. It is clear that if only an RCT had been conducted, an intervention that was not as strongly patient oriented would have been tested, and as a result less understanding would have been gained about the intervention and diabetes foot self-management. The synergy that we achieved through using POR and two MMR models resulted in the testing of a more patient-oriented intervention and much greater clarity about the impact of the intervention and foot self-management. This knowledge can inform future research and be used to improve interventions and practices that will prevent devastating and costly foot and limb complications for patients with diabetes. Overall, considering the benefits highlighted with this study, this methodological approach offers many benefits for the development and testing of all types of nursing interventions for different populations.

## References

- Armstrong, D. G., Holtz-Neiderer, K., Wendel, C., Mohler, M. J., Kimbriel, H. R., & Lavery, L. A. (2007). Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. *The American Journal of Medicine*, *120*(12), 1042-1046. doi:S0002-9343(07)00739-5 [pii]
- Canadian Institute for Health Information. (2018). *How has health spending growth changed over the last 40+ years?* Retrieved from <https://www.cihi.ca/en/health-spending/2018/national-health-expenditure-trends/how-has-health-spending-growth-changed-over-the-last-40-years>
- Canadian Institute for Health Information. (2018). *How much does Canada's spending compare internationally?* Retrieved from <https://www.cihi.ca/en/health-spending/2018/national-health-expenditure-trends/how-does-canadas-health-spending-compare-internationally>
- Canadian Institute of Health Research. (2014). *Canada's strategy for patient-oriented research – patient engagement framework*. Retrieved from <http://www.cihr-irsc.gc.ca/e/48413.html>
- Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal*, *16*(1), 183-210. doi:10.1111/iwj.13010 [doi]
- Creswell, J. W., & Plano-Clark, V. L. (2018). *Designing and conducting mixed methods research* (3<sup>rd</sup> ed.). Los Angeles: Sage publications.
- Fetters, M. D., Curry, L. A., & Creswell, J. W. (2013). Achieving integration in Mixed methods designs – principles and practices. *Health Services Research*, *48*(6), 2134-2156. <http://doi.org/10.1111/1475-6773.12117>

International Council of Nurses. (2019). Strategic priorities. Retrieved from

<https://www.icn.ch/nursing-policy/icn-strategic-priorities>

International Working Group on the Diabetic Foot (IWGDF). (2015). *Prevention and management of foot problems in diabetes: A summary guidance for daily practice 2015, based on the IWGDF guidance documents*. International Working Group on the Diabetic Foot. Retrieved from [https://iwgdfguidance.org/wp-content/uploads/2017/10/website\\_summary-1.pdf](https://iwgdfguidance.org/wp-content/uploads/2017/10/website_summary-1.pdf)

Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Armstrong, D. G., . . . Agrawal, C. M. (2004). Home monitoring of foot skin temperatures to prevent ulceration. *Diabetes Care*, 27(11), 2642-2647. doi:27/11/2642 [pii]

Lavery, L. A., Higgins, K. R., Lanctot, D. R., Constantinides, G. P., Zamorano, R. G., Athanasiou, K. A., . . . Agrawal, C. M. (2007). Preventing diabetic foot ulcer recurrence in high-risk patients: Use of temperature monitoring as a self-assessment tool. *Diabetes Care*, 30(1), 14-20. doi:30/1/14 [pii]

Matricciani, L., & Jones, S. (2015). Who care about foot care? Barriers and enablers to foot self-care practices among non-institutionalised older adults diagnosed with diabetes. An integrative review. *The Diabetes Educator*, 41(1), 106-117. doi:10.1177/0145721714560441

Mufti, A., Coutts, P., & Sibbald, R. G. (2015). Validation of commercially available infrared thermometers for measuring skin surface temperature associated with deep and surrounding wound infection. *Advances in Skin & Wound Care*, 28(1), 11-16. doi:10.1097/01.ASW.0000459039.81701.b2 [doi]

- Peterson, K. A., & Hughes, M. (2002). Readiness to change and clinical success in a diabetes educational program. *The Journal of the American Board of Family Practice*, 15(4), 266-271. Retrieved from <https://www.jabfm.org/>
- Simmons, L.A., & Noonan, D. (2017). Self-management. In J.F Gidden (Ed). *Concepts of nursing practice*. (pp. 54-60). Elsevier.
- Statistics Canada. (2017). *Diabetes by age group and sex [table]*. Retrieved from <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/health53a-eng.htm>
- van Schie, C., & Slim, F. J. (2012). Biomechanics of the diabetic foot: The road to foot ulceration. In A. Veves, J. M. Giurini & F. W. LoGerfo (Eds.), *The diabetic foot: Medical and surgical management*. (3rd ed., pp. 203-216). New-York: Springer.
- World Health Organization. (2018). Non communicable diseases. Retrieved from <https://www.who.int/en/news-room/fact-sheets/detail/noncommunicable-diseases>
- Zhang, P., Lu, J., Jing, Y., Tang, S., Zhu, D., & Bi, Y. (2017). Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis (dagger). *Annals of Medicine*, 49(2), 106-116. doi:10.1080/07853890.2016.1231932 [doi]

## CHAPTER 5: SUMMARY

### Introduction

This dissertation study was a patient-oriented research (POR) and mixed methods research (MMR) study that explored foot self-management for people with diabetes and tested a multi-modal intervention to prevent diabetic foot ulcers (DFUs). Given the prevalence, costs to the health care system, and implications of DFUs, it is vital to prevent this complication and support patients in their foot self-management. Foot self-management is a challenging issue because of the multitude of risk factors involved. People with diabetes are at risk for DFUs due to changes related to circulation, sensation, skin, and musculoskeletal structure. The pathway to foot ulceration involves a combination of these risk factors and pressure and/or repetitive stress on the plantar surface of the foot. Due to neuropathy, patients with diabetes may not feel pain related to pressure and repetitive stress and, therefore, not have the sensory cues needed to rest and prevent skin breakdown. Furthermore, structural and skin changes on the foot also make a person with diabetes susceptible to skin breakdown due to pressure and stress. A variety of actions are required to address the risk factors.

Foot health education and infrared thermometry are two strategies that have been shown in the literature to be effective in supporting foot self-management. Education should include content related to: diabetes control; the importance of not smoking; how to care for and assess feet; appropriate footwear; and the importance of regular assessment from a health care provider (HCP). While education has a broad focus, infrared thermometry focuses on one important aspect. The use of a medical-grade infrared thermometer can help people at risk identify the inflammation associated with repetitive stress and pressure and take appropriate action to relieve the pressure and help prevent skin breakdown. However, these thermometers are costly. A

commercially-available infrared thermometer (CAIT) was validated against the medical-grade thermometer but had not been tested as part of a self-management strategy.

It would have been appropriate to conduct a randomized controlled trial (RCT) that tested a self-management intervention that used a CAIT. However, foot self-management is complex, and it was determined that this research needed to go beyond using an RCT only and also conduct an exploratory study that addressed factors impacting foot self-management in a local context. Therefore, a POR and a sequential MMR study that incorporated a pilot RCT was conducted. The goal of a POR approach is to improve patient outcomes by engaging patients in research to determine their priorities (Canadian Institute of Health Research, 2014). The use of these two approaches and incorporating a pilot RCT provided the opportunity to develop and test a practical patient-oriented intervention, obtain preliminary results, and test the methods.

The overarching MMR question for this study was, what strategies are effective in helping people with diabetes self-manage their foot health? This study had three separate phases that were guided by three research questions:

1. What were the issues related to the self-management of feet?
2. Does a foot health intervention that utilized a CAIT improve foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention?
3. What were the participants' experiences with foot health self-management and the intervention?

This MMR study used an exploratory sequence (Phase 1 to the development of the intervention) and an explanatory sequence (Phases 2 and 3). The results of the MMR were presented in three separate manuscripts. Manuscript 1 presented the Phase 1 findings and can be found in Chapter 2. Manuscript 2 presented the Phases 2 and 3 findings and can be found in

Chapter 3. Manuscript 3 is a methodological article that considered the benefits of using a POR and MMR research approach and can be found in Chapter 4. Chapter 5 provides a synopsis of the key findings, followed by recommendations for the intervention, practice, policy, education, and research.

### **Synopsis of Key Results**

A synopsis of the key results from the exploratory and explanatory sequence will be presented in the following paragraphs.

#### **Results from the exploratory sequence (Phase 1 to development of the intervention).**

The exploratory sequence was conducted in Phase 1 and addressed research question 1. Self-management was explored in semi-structured interviews with patients, linked-support persons, and HCPs with the goal of informing the intervention that was developed and tested in Phase 2. The data were analyzed using Interpretive Description, and the overarching theme from the interviews was that self-management of diabetes and foot health is complex. Manuscript 1 (Chapter 2) presented data related to the sub-themes of personal challenges and resources identified by participants such as knowledge of foot self-management; physically unable to provide footcare; footwear; social support; readiness to self-manage feet; and communicating with HCPs. Sub-themes related to system barriers such as cost, access to services, and coordination of care will be addressed in future manuscripts.

Phase 1 findings led to the development of the intervention that was delivered in Phase 2 in several ways. For example, based on the finding that patients lacked knowledge about diabetes and foot health, a more comprehensive education module than was originally planned was incorporated into the intervention. As well, based on the finding that patients had difficulty visually assessing their feet due to co-morbidities, a long handled mirror with a light was incorporated into the intervention. The findings of Phase 1 were summarized in Manuscript 1

(Chapter 2), while how Phase 1 findings informed the development of the intervention was presented in Manuscript 3 (Chapter 4).

**Results from the explanatory sequence (Phases 2 and 3).** The explanatory sequence was conducted in Phases 2 and 3. Research question 2, which asked whether the intervention improved foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention, was partially answered by the RCT conducted in Phase 2. The findings showed that the intervention that utilized a CAIT with education had the potential to improve foot outcomes for individuals with diabetes who are at risk for foot complications compared to an education-only intervention. The key findings from the RCT were that the strategy resulted in improved foot assessment, with the thermometer and education group having significantly more days with any assessment completed than the education-only group. As well, the logbook data showed that some participants reduced their activity when they had a temperature difference greater than 4 degrees F. Furthermore, results showed that the thermometer was a tool that participants felt they could use for foot self-management as 96.8% of participants indicated that they would continue to use the thermometer.

The Phase 2 exit interviews and Phase 3 provided data to answer research questions 1 and 3 that focused on the issues related to foot self-management and the participants' experiences with the intervention. The exit interviews and Phase 3 results expanded on the Phase 2 findings by offering a further explanation that the thermometer engaged participants, prompted action, and offered reassurance regarding foot health. Chapters 3 (Manuscript 2) and 4 (Manuscript 3) further discussed the findings from the explanatory sequence. Future publications will address other results from the explanatory sequence, such as findings related to readiness, confidence to manage foot health, and footwear.

**Synergy of POR and MMR.** The benefit of using a combined POR and MMR approach was apparent in this study. As opposed to doing an RCT alone, a synergy was achieved by using POR strategies and a sequential MMR design with an exploratory and explanatory sequence. This methodological approach resulted in the development and testing of a patient-centred intervention within a local context and provided a greater understanding about intervention effectiveness, diabetes, and foot self-management. For example, if this approach had not been used, the importance of including a comprehensive education module would not have been understood. As well, the benefits and challenges of using the CAIT would not have been as clearly understood. Chapter 4 presented a methodological article that explored the synergy that was achieved in this study as the result of using MMR design and POR.

### **Strengths and Limitations of the Study**

As discussed in the three manuscripts, there are strengths and limitations of this research. A strength of Phase 1 (Manuscript 1) was that this sequence of the study demonstrated the criteria required for credibility in Interpretive Description (Thorne, 2016) such as representative credibility, analytic logic, and interpretive authority. One important limitation noted was that Canada has universal health care and the delivery of care varies across provinces, so the challenges and resources related to diabetes self-management may not be transferable to other provinces and health care systems.

Strengths and limitations of Phases 2 and 3 were discussed in Manuscripts 2 and 3. There were several strengths noted. This is the first study to report on the use of a CAIT as part of a multi-modal foot self-management intervention. The recruitment of a broad-based community sample of people with diabetes rather than only using diabetes clinics ensured participants had targeted characteristics. As well, all participants had a foot assessment completed by an advanced foot care nurse at baseline, three and six months. Intervention integrity was maintained through

one researcher completing the education module with participants. Also, the use of a POR and MMR approach allowed for the developments and testing of an intervention that was based on patients' experiences in a local context. Furthermore, greater understanding of the delivery and impact of the intervention and foot self-management was gained through Phase 3. Finally, by utilizing logistic regression confounding variables were controlled in the analysis. There were also limitations noted. First, the study had low power to assess the outcome of DFU. Secondly, the length of the intervention was only six months. A longer intervention and follow-up period would have permitted assessment of the long-term impacts of the strategy. Finally, as most variables measured were self-report the potential for social desirability bias may have been an issue.

## **Recommendations**

In this section, recommendations will be presented based on the findings of this research for the development of a diabetes foot self-management program and the nursing domains of practice, policy, education, and research.

**Diabetes foot self-management program.** Based on the findings and the researchers' experience delivering the intervention, there are several recommendations related to the further development of this foot self-management program. First, it is recommended the intervention should be delivered as a series of one-on-one sessions that are HCP led as opposed to one session. As was discussed in Chapter 1, patients appreciated foot health education that is delivered by an HCP (Coffey et al., 2019). This was also the researchers' experience in this study and several participants in the exit interviews shared that the approach used and the contact with an HCP were two of the best parts of the intervention. As well, taking this approach, more content could be covered and information could be reinforced as the sessions progressed. Furthermore, a series of sessions would allow time for patients to begin to integrate foot self-

management into their daily activities and ask questions of the HCP as needed. During this study, participants asked questions about foot health when monthly logbooks were picked up and during the three month and six month interviews. This reflects the need for patients to have content reinforced and the opportunity to ask questions. The structure of the program should also allow support persons to attend the education sessions. As noted, inclusion of the linked support persons in the education session for this study was a positive aspect of this intervention. Associated costs of the intervention and implications of delivering the intervention in a group setting and using other delivery modalities should be explored in future research.

Secondly, videos that are based on best practices should be incorporated into the intervention that can be accessed by participants after the education sessions through a program website. Use of this method of delivery of content will provide consistency of information, and videos could be used as reference material for participants after and between sessions. The videos should have a local context so they are more applicable to patients and include important topics related to foot self-management such as: the impact of diabetes on foot health; foot concerns and the appropriate action; daily and regular care of feet; the importance of appropriate footwear; how to communicate with an HCP about foot health; and use of the thermometer. The CAIT video should address: the purpose of the thermometer; how to use the thermometer to assess foot temperature; interpretation of the results; how to complete the logbooks; and how to troubleshoot the thermometer. All of these topics were included in the intervention in this study and deemed to be important.

Thirdly, as patients in this study were not always clear about content that was covered in the teaching session, the concept of teach-back should be integrated into the education sessions to ensure that patients have understood essential concepts related to foot health and use of the CAIT. Finally, as participants sometimes were not using the thermometer correctly, even with a

return demonstration and a follow up assessment, frequent evaluation by an HCP should be incorporated into the revision of this intervention to ensure that the thermometer is being used correctly. This could be determined on an individual basis.

**Practice.** The results of this study have implications for practice. Study results showed that participants did not ever have or rarely had a foot assessment completed by an HCP, and for many participants foot health was not a topic that they discussed with their HCP. Therefore, it is recommended that HCPs conduct regular foot assessments, as per clinical practice guidelines, with patients with diabetes to determine and address risk status. HCPs should discuss foot health with patients and be aware of foot self-management resources that are available and make appropriate referrals based on the foot assessment. To support foot health, HCPs should also support and encourage patients and support persons to complete a foot self-management program, such as the program presented earlier.

The results indicated that foot self-management for patients with diabetes is complex. Specifically, from Phase 1, it was found that patients experienced personal challenges and encountered system barriers as well as utilized resources that support foot-self management. As recommended in Manuscript 1 (Chapter 2), HCPs should be aware of this complexity and should consider the 3Rs: *rappor*t, *readiness*, and *reinforcement* when interacting with patients with diabetes. First, establishing *rappor*t with patients and support persons is crucial for them to be comfortable discussing foot health. Secondly, HCPs can appraise and capitalize on *readiness*, and should frequently assess knowledge and provide tailored teaching about caring for feet when patients are diagnosed. Thirdly, HCPs should frequently *reinforce* key messages related to foot health and foot care as this would convey that foot health is important.

**Policy.** The findings of this study also hold implications for policymakers. Participants indicated that they had difficulty accessing foot health programs and services due to availability and cost. Therefore, government policymakers should develop policies and fund programs and services that support foot health for patients with diabetes to prevent costly and devastating foot complications. A team based approach should be supported in primary care policy. For example, teams that include physicians, advanced foot care nurses, diabetes educators, and podiatrists should be utilized. As well, this policy should allow for group visits and preventative education sessions in family practice locations. This would further increase access to preventative foot care education and services. This policy change would need to be supported by further policy revisions related to remuneration, as the current fee for service model for physicians does not encourage these types of services. In keeping with this policy change, diabetes foot self-management programs, such as was described earlier, should be developed and funded. Also, policies should be put in place that fund professional foot health services for patients with diabetes that provide assessment, cutting and trimming of nails, and orthopedic footwear and inserts. This is especially important for people with diabetes who are unable to care for their feet.

Participants also indicated that it was difficult to get a same-day appointment with their HCP and may need to wait a number of days before being seen. Considering the importance of early intervention to prevent complications such as foot ulcers and amputations, administrators of primary care clinics and services should develop a scheduling policy that supports open-access scheduling. Policy implementation should include education of clinic staff regarding the importance of same-day appointments for patients with diabetes that have a foot concern. This policy would ensure that patients that have identified a foot issue can see their HCP for assessment the same day they have identified a concern.

**Education.** The results of this study have implications for educators regarding HCP curriculum content. HCPs need to know multiple aspects related to diabetes and foot health. Specifically, curriculum content should address the complexity of diabetes foot health and the personal challenges, system barriers, and potential resources patients with diabetes may deal with concerning foot self-management. Also, curriculum content should include how to complete a diabetes foot screening assessment and how to teach patients with diabetes how to care for their feet. Furthermore, content needs to stress the importance of the 3Rs in relation to diabetes and foot health: developing *rapport*, assessing and capitalizing on *readiness*, and *reinforcing* key information about diabetes and foot health with patients. Finally, content should include the possibility of using a CAIT as another tool for assessment and supporting foot self-management.

**Research.** The results of this study have implications for future research. In relation to the CAIT studies need to be conducted to examine the optimal technique to measure foot temperature and detect inflammation. To ensure a well-powered study recruitment of participants should employ multiple strategies that capitalize on local media. It is also recommended that future research focus on understanding decision making related to foot self-management and why patients take action or do not take action, taking into consideration behaviour modification. Furthermore, structural equation modeling should be used in future research to determine the contribution of multiple components to taking action.

Future research might benefit from employing a POR and MMR approach to develop and test patient-oriented interventions that can be utilized by HCPs to help patients manage chronic diseases such as diabetes. It is clear from this research study that incorporating Phase 1 findings into the intervention, such as the comprehensive education module and the mirror, strengthened the intervention. This came through in the exit interviews and Phase 3 findings where patients shared that these were aspects of the intervention that they found to be the most beneficial. Also,

utilizing a POR and MMR approach, future research needs to address the gap in the literature related to understanding the experience of foot health self-management in Canada with other populations, such as indigenous groups and immigrant populations. The findings of these studies can be utilized to develop interventions for these populations that ensure that contextual issues are addressed. Finally, the foot health self-management program, which was presented earlier, should be tested with a sufficiently powered sample size and longer follow-up period to assess for longer-term outcomes such as DFUs and amputations.

## **Conclusion**

In summary, the partnering of POR and MMR is valuable for developing and testing self-management interventions that nurses can use to help support patients with chronic disease. This sequential MMR study provided increased understanding regarding the experiences of foot self-management for patients with diabetes. Understanding of these experiences helped develop a foot self-management intervention that used a CAIT and comprehensive foot education. The testing of this intervention was not long enough to determine if it prevented foot complications such as DFUs. However, findings showed that the use of the CAIT worked to support foot self-management in that it prompted patients to complete a foot assessment, provided direction to take action based on the assessment, and offered reassurance about foot status. It was determined that the CAIT is an affordable, available, and usable tool that can be added to a patient's self-management tool kit. Based on these findings, recommendations were made concerning program development, practice, policy, education, and research.

## References

- Canadian Institute of Health Research. (2014). Canada's strategy for patient-oriented research – patient engagement framework. Retrieved from <http://www.cihr-irsc.gc.ca/e/48413.html>
- Coffey, L., Mahon, C., & Gallagher, P. (2019). Perceptions and experiences of diabetic foot ulceration and foot care in people with diabetes: A qualitative meta-synthesis. *International Wound Journal*, 16(1), 183-210. doi:10.1111/iwj.13010 [doi]
- Thorne, S. (2016). *Interpretive description*. New-York: Routledge.

**Appendix A**  
**Literature Summary Table**

Table 1 Continued

*Studies Testing the Utilization of Infrared Thermometry as a Self-Assessment Tool in the Prevention of Diabetic Foot Ulcers*

Author	Participants/Methods/Outcome Measures	Results	Comments
<p><b>Armstrong et al. (2007)</b></p> <p>Design: Randomized Controlled Trial</p>	<p><b>Participants</b></p> <ul style="list-style-type: none"> <li>• 225 participants with type 2 diabetes who were at high risk for foot ulceration</li> <li>• 18 month physician blinded trial</li> <li>• Participants assigned to standard therapy or dermal therapy</li> <li>• There were no significant differences between the two groups on age, length of diagnosis, history of amputation, extent of sensory neuropathy, or activity level.</li> </ul> <p><b>Methods</b></p> <ul style="list-style-type: none"> <li>• Each group received therapeutic footwear, foot education, and regular foot care, performed and recorded a foot daily foot assessment.</li> <li>• Dermal therapy group used an infrared thermometer and measured temperature on 6 sites twice daily. If a temperature difference of &gt; 4 degrees between two sites on each foot was identified participants were instructed to inform the study nurse and to rest until the temperature went back to normal.</li> </ul> <p><b>Outcome Measures</b></p> <ul style="list-style-type: none"> <li>• Foot ulceration (primary outcome)</li> <li>• Secondary objectives of the research: type of ulcer, health related quality of life, self-efficacy, satisfaction with care, adjustment of activity (these outcomes were not addressed in this article).</li> </ul>	<ul style="list-style-type: none"> <li>• 8.4% (n=19) participants had an ulcer during the study period.</li> <li>• Ulceration rate in Standard Therapy group (12.2%) vs. Dermal Therapy (4.7%), OR 3, CI 1-8.5, p=.038</li> <li>• Proportional hazards regression analysis: there was a longer period to ulceration in the dermal therapy group (Risk classification, age, minority status adjusted for).</li> <li>• Participants that ulcerated recorded a temperature difference that was 4.8 times greater in the week prior to ulceration compared to a random sample.</li> </ul>	<ul style="list-style-type: none"> <li>• Overall Rating: <b>Moderate</b></li> <li>• Unclear how many participants were in each group.</li> <li>• Sophisticated statistical analysis used.</li> <li>• Majority of participants enrolled in study were risk group 2.</li> <li>• Results suggest that the thermometer helped participants identify inflammation early and adjust activity to prevent ulceration.</li> </ul>

Author	Participants/Methods/Outcome Measures	Results	Comments
<p><b>Lavery et al. (2007)</b></p> <p>Design: Randomized Controlled Trial</p>	<p><b>Participants</b></p> <ul style="list-style-type: none"> <li>• 173 participants with a previous history of foot ulceration</li> <li>• 15 month physician blinded multi-center trial</li> <li>• Participants assigned to: standard therapy (n= 58); structured foot examination (n=56); or enhanced therapy (n=59).</li> <li>• There were no significant differences between the three groups on age, length of diagnosis, history of amputation, extent of sensory neuropathy, or activity level.</li> </ul> <p><b>Methods</b></p> <ul style="list-style-type: none"> <li>• Each group received therapeutic footwear, foot education, and regular footcare.</li> <li>• Structured therapy group completed and recorded daily foot inspection in the logbook. If any foot abnormalities were identified by the participants in the standard therapy or the foot examination group participants were instructed to immediately contact the study nurse. The enhanced therapy group used an infrared thermometer to measure and record 6 sites on each foot daily. If a temperature difference of greater than 4 degrees between two sites on each foot was identified participants were instructed to inform the study nurse and to rest until the temperature went back to normal.</li> </ul> <p><b>Outcome Measures</b></p> <ul style="list-style-type: none"> <li>• Foot ulceration (primary outcome)</li> <li>• Questionnaire evaluating use of prescribed shoes and insoles (reliability and validity unknown)</li> <li>• Neurological and vascular assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Less ulceration reported in the enhanced therapy group compared with the structured foot examination or standard therapy.</li> <li>• Enhanced therapy (8.5%) vs. standard therapy (29.3%) p = 0.0046</li> <li>• Enhanced therapy (8.5%) vs. structured foot examination (30.4%) p = 0.0029</li> <li>• Patients in standard therapy were 4.37 % more likely to have an ulceration compared to the enhanced therapy group</li> <li>• Patients in the structured examination group were 4.37 % more likely to have an ulceration compared to the enhanced therapy group.</li> <li>• Patient in all three groups reported adherence to wearing customized footwear (Structured Therapy 89.5%; Enhanced</li> </ul>	<ul style="list-style-type: none"> <li>• Overall Rating: <b>Moderate</b></li> <li>• Physician blinded study</li> <li>• Random allocation used</li> <li>• ANOVA for independent samples used and unclear how confounding variables were controlled for in the analysis.</li> </ul>

Author	Participants/Methods/Outcome Measures	Results	Comments
<p><b>Lavery et al. (2004)</b> Design: Randomized Controlled Trial</p>	<p><b>Participants</b></p> <ul style="list-style-type: none"> <li>• 85 participants who fit the classification of diabetic foot risk (2 or 3).</li> <li>• 6 month intervention</li> <li>• Participants assigned to either: standard therapy (n= 41) or enhanced therapy (n= 44)</li> <li>• There were no significant differences between the two groups on age, length of diagnosis, history of amputation, extent of sensory neuropathy, or activity level or category of foot risk</li> </ul> <p><b>Methods</b></p> <ul style="list-style-type: none"> <li>• Standard therapy group (STG) received therapeutic footwear, foot education, and regular assessment by a podiatrist.</li> <li>• The enhanced therapy group (ETG) had the same intervention as the STG with the addition of an infrared thermometer to measure foot temperatures in the am and pm.</li> <li>• A greater than 4 degree F difference between the two feet was indicative of inflammation and the foot was at risk for ulceration. If this temperature difference was measured the participants were directed to reduce walking and contact the study nurse.</li> </ul> <p><b>Outcome Measures</b></p> <ul style="list-style-type: none"> <li>• Foot complications</li> <li>• Short form health form (SF36) was used at the beginning and end of the study to measure functional impairment (reliable and valid tool)</li> </ul>	<p>Therapy 83%; Structured Foot Examination 73.2%).</p> <ul style="list-style-type: none"> <li>• ANOVA was used to analyze continuous variables; Fisher's exact test for dichotomous variables (alpha = .05)</li> <li>• Patients in the ETG had significantly less diabetic foot complications than the STG</li> <li>• ETG 2% compared to the STG 20% (p = .01; odd ration 10.3, 95% CI 1.2-85.3).</li> <li>• The STG had 7 ulcers and 2 Charcot fractures. 2 patients had infections and local foot amputations.</li> <li>• Patients in STG were 10.3 times more likely to have a complication</li> <li>• ETG had 1 ulcer</li> <li>• No significant difference in either group pre and post intervention or</li> </ul>	<ul style="list-style-type: none"> <li>• Overall Rating: <b>Moderate</b></li> <li>• unclear how confounding variables were controlled for in the analysis.</li> <li>• Authors refer to the study as a pilot in text of the article</li> <li>• Findings suggest that self-assessment of foot temperature monitoring can help prevent foot complications and amputations.</li> </ul>

Author	Participants/Methods/Outcome Measures	Results	Comments
<p><b>Skafgeld et al. (2015)</b></p> <p>Design: Randomized Controlled Trial (pilot)</p>	<p><b>Participants</b></p> <ul style="list-style-type: none"> <li>• 45 participants with a previous ulceration and neuropathy</li> <li>• 1 year intervention, single blind, Norway, hospital setting</li> <li>• Participants randomized to: intervention (n= 21) or control (n= 20) (block randomization used)</li> <li>• There were no significant differences between the two groups on demographic factors. There was a higher rate of nephropathy and vascular risk factors in the intervention group.</li> </ul> <p><b>Methods</b> (Nurse led intervention)</p> <ul style="list-style-type: none"> <li>• Both groups provided education regarding foot care and recorded daily foot assessment. The intervention group was provided with a thermometer and education to measure temperature; participated in counseling every 3 months that provided support regarding using the thermometer.</li> <li>• If the participant had a &gt; 2 degree C difference between the two feet they were instructed to contact the study nurse and decrease their activity.</li> </ul> <p><b>Outcome Measures</b> (reliability and validity of many measures unknown)</p> <ul style="list-style-type: none"> <li>• 3 months: Readiness to perform skin temperature measurements using the Trans Theoretical Model assessed.</li> <li>• Baseline and end of study: sociodemographics; lifestyle; diabetes related variables</li> <li>• End of study: frequency of orthotic footwear use.</li> <li>• Clinical exams at baseline and end of study (BMI, foot examination, ABI, monofilament; vibration; nail changes, HbA1C, urinary albumin/creatinine ratio)</li> <li>• Adherence to foot assessment and temperature monitoring</li> <li>• Foot ulcer as per Wagner classification system.</li> </ul>	<p>between groups on the SF36</p> <ul style="list-style-type: none"> <li>• 67% (14/21) of the intervention group recorded foot assessment and temperature more than 80% of the time. In the control group 70% (14/20) recorded foot assessment more than 80% of the time.</li> <li>• No significant difference in the intervention and control in relation to ulceration (intervention group 39%; control group 50%).</li> <li>• No significant difference in the Kaplan Meier Survival curve between the two groups (p=0.407).</li> <li>• Customized footwear was worn by 24% of the sample (5/21 in the intervention group and 7/20 in the control) (p=.858).</li> </ul>	<ul style="list-style-type: none"> <li>• Overall Rating: <b>Moderate</b></li> <li>• Confounding variables were not controlled for in the analysis.</li> <li>• Low power</li> <li>• Reliability and validity of tools not provided.</li> <li>• Did not report the results of readiness to perform skin temperature measurement, use, or diabetes related variables.</li> <li>• The authors concluded that home temperature monitoring with counseling with the intention of preventing foot complications could be effective in Norway.</li> </ul>

## **Appendix B**

### **Summary of Topics Covered in Education Module**

1. Risk of foot complication with a diagnosis of diabetes.
  - a. Presentation of incidence and prevalence numbers (provincial, national, and global).
2. How to recognize diabetic foot problems.
  - a. Definition of diabetic foot
  - b. Various foot conditions caused by diabetic foot
3. Causes of diabetic foot
  - a. Overview of why people with diabetes develop foot problems:
    - i. Decreased circulation
    - ii. Neuropathy
4. What patients should do when they have diabetic foot focusing on:
  - a. Controlling blood sugar, following diet and exercise recommendations, and taking medication
  - b. The “dos” and “do nots” of managing feet (daily care, appropriate footwear, not smoking, regular foot assessment by a healthcare provider).
5. The major role of tobacco in the development of peripheral vascular disease and how this increases the risk of amputation for people with diabetes.
6. Summary of key messages.
7. Overall key message: Diabetic foot ulcers and amputation can be prevented

## Appendix C

### Teaching Points Used for Participants in the Thermometer Group

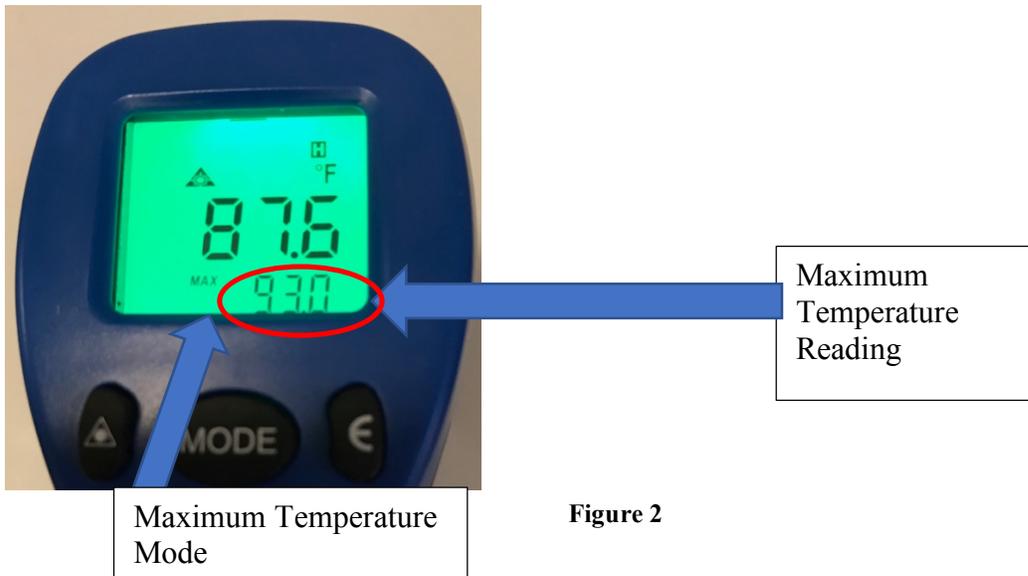
1. Take off socks and shoes and wait 5 minutes before doing the temperature reading. This gives time for the feet to return to their normal temperature and will give a truer reading.
2. Make sure the thermometer is on Fahrenheit setting. The F will show in the display window.
3. Hold the thermometer 6 inches or 15 cm away from your left foot. The thermometer is measuring the temperature below the area of light.
4. Squeeze the handle on the thermometer and trace a zigzag over the bottom of your left foot (see Figure 1). When you have finished the zigzag line, immediately release the handle of the thermometer. You will hear a beep. You can measure temperature over thick skin.



Figure 1

5. Look at the display window to get the temperature reading of your left foot. You will use the maximum temperature reading. This can be done by pressing mode on the thermometer until

you see “max” in the display. The maximum temperature reading is the temperature displayed in a smaller size in the bottom right corner of the display (see figure 2). Write this reading in the logbook.



**Figure 2**

6. Measure the temperature of your right foot in the same way and record this reading in the logbook.
7. In the logbook write in the difference in temperature between the two feet. See sample log entry below.
8. If you find a temperature difference greater than 4° Fahrenheit between the left foot and right foot you should rest and decrease the pressure on your feet until the temperature difference between your two feet is less than 4° Fahrenheit. This temperature difference may indicate inflammation.
9. If you miss a day then leave that day blank and continue recording on the next day.
10. Call your health care provider: if you have a temperature difference of more than 4° Fahrenheit more than two days in a row; have any redness break in the skin on your feet; and have any unexplained pain.

## Appendix D

### Letter to Health Care Provider

Dear Health Care Provider

I am writing to let you know why your patient is assessing the temperature of his/her feet as this information may be helpful to you. Your patient is participating in a six-month randomized controlled trial that is assessing the use of a commercially available infrared thermometer to identify inflammation in feet before skin breakdown occurs that could lead to a diabetic foot ulcer. There is no clinical care as part of this study.

The patient measures the temperature of the bottoms of both feet daily and the results are compared. If there is a difference of more than 4 degrees Fahrenheit between the two feet the patient has been instructed to take the pressure off the bottoms of their feet for two days, by resting or decreasing activity, until the temperatures difference drops to less than 4 degrees. If the temperatures difference between the two feet remains more than 4 degrees Fahrenheit for two days it is recommended that the patient see their health care provider as this may indicate that he/she is at risk for skin breakdown.

If you have any questions about this research study please contact me.

Sincerely,

Kathleen Stevens RN PhD (c)

Principal Investigator

777-8137

*\* This letter was put in an envelope that was not sealed and given to the participant to take to a health care provider he/she was consulting about a foot temperature increase that had not resolved in two days.*

## Appendix E

### Recruitment Script for Phase 1

#### **Verbal script for key contacts (nurses, physicians, and podiatrist) to recruit *patients* for Phase 1**

A PhD nursing student is doing a study about the use of a low-cost infrared thermometer that can be bought at a hardware store as a self-assessment tool to prevent diabetic foot ulcers. This study has three phases and you are being asked to take part in Phase 1. If you agree, you would be asked to participate in a 20-minute interview about your experiences looking after your feet. Your experiences are important to this research even if you do not have any foot complications.

Here is an information sheet about the study. **(Give time for the potential participant to read)**

Would you be interested in hearing more about the study and being contacted by the student?

#### **Verbal script for key contacts (nurses, physicians, and podiatrist) to recruit *support persons* for Phase 1**

A PhD nursing student is doing a study about the use of a low-cost infrared thermometer that can be bought at a hardware store as a self-assessment tool to prevent diabetic foot ulcers. This study has three phases and you are being asked to take part in Phase 1. If you agree, you would be asked to participate in a 20-minute interview about your experiences helping a person with diabetes care for his/her feet. Your experiences are important to this research even if the person you are helping does not have any foot complications.

Here is an information sheet about the study. **(Give time for the potential participant to read)**

Would you be interested in hearing more about the study and being contacted by the student?

## Appendix F

### Phase 1 Information Sheet Provided to Potential Participants

#### **TITLE: Foot Intervention Study Utilizing Commercially Available Infrared Thermometers With Individuals With Diabetes Using a Mixed Methods Research Approach**

##### **What is the purpose of this study?**

The purpose of this study is to find out if using a low-cost infrared thermometer that can be purchased at a hardware store will help prevent skin breakdown on feet for people who have diabetes. This study has three phases and you are being asked to take part in Phase 1. The purpose of Phase 1 is to find out about problems people with diabetes experience trying to take care of their feet. We also want to find out what people think about using the thermometer. This information will then be used to modify the foot self-management program that will be used in Phase 2.

##### **Why is this study important?**

People with diabetes need to look after their feet in order to prevent diabetic foot ulcers because they cause pain. However, even when they really want to care for their feet the signs of redness, heat, and skin problems are often missed. What may be needed is a tool that will help people with diabetes realize they have inflamed skin on their feet that may break down. Research has shown that when people with diabetes took their foot temperature they developed fewer ulcers.

##### **What will happen if I participate?**

This study is part of a bigger study with three phases and you are being asked to take part in Phase 1. If you are an individual with diabetes you will be asked to agree to an interview to talk about the problems you experience in trying to take care of your feet. If you are a support person or health care provider you will be asked to talk about your experiences in helping someone with diabetes care for their feet. You will also be asked questions about what you think about using the thermometer. This information will then be used to help make the program that will be used in Phase 2 better. A 20 minute face-to-face interview with the researcher will occur at a place and time that is good for you. These interviews will be taped. Your answers are confidential.

##### **Are there any risks and discomforts?**

There are no known risks of being in the study.

##### **Are there any benefits?**

It is not known if this study will help you. This study will give you the opportunity to share your experiences and insights. This may help to develop or change a program about self-care of feet for people with diabetes.

If you have any questions about taking part in this study, you can meet with the researcher who is in charge of the study. That person is:

**Kathleen Stevens 777-8137**

Or you can talk to someone who is not working on the study at all, but can talk to you about your rights as a person taking part in a research study. This person can be reached through:

Ethics Office

Health Research Ethics Authority

709-777-6974 or by email at [info@hrea.ca](mailto:info@hrea.ca)

## **Appendix G**

### **Locations for Recruitment**

Participants were recruited from:

Eastern Health Diabetes Centre

Wound Care Clinic

Community Health St. John's Region

Family Physician Clinics

Nurse Practitioner Clinics

Podiatry Clinics

Vascular Clinic

Tiffany Village

Kenny's Pond

Bishop Meaden Manor

Babb Manor

Senior's Resource Centre

Mt. Pearl Senior's Independence Group

Community Centres

Eastern Health inpatient units

Endocrinologist Clinics

Bariatric clinic

Diabetes Pump Clinic

Chronic Disease Management Program

Pharmacists who are Certified Diabetes Educators and are doing teaching with diabetes clients

(Shopper's Drug Mart; Lawton's Drugs)

Eastern Health Dieticians

Dieticians who see private clients

Private foot care nurses

Foot Care Nurses Interest group

Homecare Businesses

Diabetes Canada NL Facebook Page

Orthotic Businesses

Health Gyms

## **Appendix H**

### **Inclusion and Exclusion Criteria**

#### **Health Care Providers (Phase 1 and 3)**

Inclusion criteria are:

1. Provide care to diabetic individuals (Phase 1 only)
2. Work in one of the following areas: Eastern Health Diabetes Centre, Wound Care Clinic, and Community Health St. John's Region; Family Physician Clinics; Nurse Practitioner Clinics; and Podiatry Clinics (Phase 1 only)
3. Were consulted by participants during the intervention (Phase 3 only)

#### **Patients (All Phases)**

Inclusion criteria are:

1. Able to read and speak English
2. Reachable by telephone
3. 18 years of age and older
4. Fit category 2 or 3 of the International Diabetic Foot Risk Classification System;
5. Loss of sensation in at least 1 area on the foot as identified by the monofilament test and/or deformity (i.e. claw toe, prominent metatarsal head) and/or or callus (Phase 2)

Exclusion criteria are:

1. Ulcer (Phase 2 only)
2. Amputation sites not healed
3. Foot infections (Phase 2 only)
4. Charcot arthropathy (Phase 2 only)
5. Pregnancy and/or breastfeeding (pregnancy causes changes to feet; these women may find the demands of the study too great in consideration of the life changes they are experiencing)
6. Major health conditions
7. Inability to read the thermometer and no support person available to assist the participant with temperature reading and documentation on a daily basis
8. Severe peripheral vascular disease (PVD), as evidenced by non-palpable pulses or an ankle brachial index of  $< 0.7$  on either extremity
9. Unable to walk without assistance.

#### **Family/Support Persons (Phase 1 and 3)**

Inclusion criteria are:

1. 18 years of age and older (Phase 1 and 3).
2. Able to read and speak English (Phase 1 and 3).
3. Reachable by telephone (Phase 1 and 3).
4. Provides frequent tangible support to an individual with diabetes such as assisting with activities of daily living (Phase 1 and 3).
5. Assisted a participant during Phase 2 of the study (Phase 3).

## Appendix I

### Informed Consent Form Phase 1

#### Consent to Take Part in Research

**TITLE: Foot Intervention Study Utilizing Commercially Available Infrared Thermometers With Individuals With Diabetes Using a Mixed Methods Research Approach**

**Investigators:**

**Kathleen Stevens RN, PhD(c)**

**Phone number: 777-8137**

**Donna Moralejo RN, PhD**

**Phone number: 777-7493**

**Steven Ersser RN, PhD**

**Cathy MacLean MD**

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your usual health care

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, you can think about it for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researcher will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

#### **1. Introduction/Background:**

People with diabetes need to look after their feet in order to prevent diabetic foot ulcers because they cause pain. However, even when they really want to care for their feet the signs of redness, heat, and skin problems are often missed. What may be needed is a tool that will help people with diabetes realize they have inflamed skin on their feet that may break down. Research has shown that when people with diabetes took their foot temperature they had fewer ulcers. The

temperature gave an early warning sign of skin that was at risk for breakdown. If the temperature was high, it could be brought back to normal by taking pressure off the bottoms of his/her feet (e.g., resting) or going to see a doctor or nurse. However, these studies used a thermometer that many people would not be able to afford to buy.

## **2. Purpose of study:**

The purpose of this study is to find out if using a low-cost infrared thermometer that can be purchased at a hardware store helps to lower the number of foot ulcers.

## **3. Description of the study procedures:**

This study is part of a bigger study with three phases and you are being asked to take part in Phase 1. Face to face interviews will take place over six-weeks with patients, support persons, and health care providers that care for patients who are at risk to get a foot ulcer. The purpose of these interviews is to find out about problems people with diabetes experience trying to take care of their feet. Also, to find out what people think about using the thermometer. This information will then be used to help make the program that will be used in Phase 2 better. The researcher may contact you after the interview by telephone to ask you some follow-up questions related to the information you shared. These interviews will be taped. Your answers are confidential. A person who will keep the information private will write out the taped interview. Once the write-up is complete I will remove any names or identifying information from the write-up and the tape will be erased.

## **4. Length of time:**

The interview will take 20 minutes to complete at a place that is good for you.

## **5. Possible risks and discomforts:**

There are no known risks of being in the study.

## **6. Benefits:**

It is not known if this study will help you. This study may help to develop or change a program about self-care of feet for people with diabetes. As a thank-you for participating in the study you will be given a \$25 Shoppers Drug Mart gift card.

## **7. Liability statement:**

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

## **8. What about my privacy and confidentiality?**

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records.

When you sign this consent form you give us permission to

- Collect information from you
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

### **Access to records**

The members of the research team will see study records that have your name on them. Other people may need to look at the study records that have your name. This might include the research ethics board. You may ask to see the list of these people. They can look at your records only when supervised by a member of the research team.

### **Use of your study information**

The researchers will collect and use only the information they need for this research study.

- Information from study interviews

Your name and contact information will be kept secure by the researchers. It will not be shared with others without asking you first. Your name will not appear in any reports or articles as a result of this study.

Information collected for this study will be kept for five years.

Information collected and used by the research team will be kept in a locked filing cabinet that can only be opened by the researcher and the researcher's PhD supervisor in the researcher's office at Memorial University's School of Nursing. Kathleen Stevens is the person who will make sure the information is locked in the cabinet and safe.

If you decide to stop being in the study, the research team will still use the information collected up to that time. It may not be removed. This information will only be used for this study.

### **Seeing your records**

You may ask the researcher to see the information that has been collected about you.

**1. Questions or problems:**

If you have any questions about taking part in this study, you can meet with the researcher who is in charge of the study. That person is:

**Kathleen Stevens 777-8137**

Or you can talk to someone who is not working on the study at all, but can talk to you about your rights as a person taking part in a research study. This person can be reached through:

Ethics Office

Health Research Ethics Authority

709-777-6974 or by email at [info@hrea.ca](mailto:info@hrea.ca)

After signing this consent you will be given a copy.

## Signature Page

### **TITLE: Foot Intervention Study Utilizing Commercially Available Infrared Thermometers With Individuals with Diabetes Using a Mixed Methods Research Approach**

#### **Investigators:**

**Kathleen Stevens RN, PhD(c)      Phone number: 777-8137**

**Donna Moralejo RN, PhD      Phone number: 777-7493**

**Steven Ersser RN, PhD**

**Cathy MacLean MD**

#### **To be filled out and signed by the participant:**

Please check as appropriate:

I have read the consent Yes { }    No { }

I have had the chance to ask questions/to discuss this study. Yes { }    No { }

I have received satisfactory answers to all of my questions. Yes { }    No { }

I have received enough information about the study. Yes { }    No { }

I have spoken to Kathleen Stevens and she has answered my questions Yes { }    No { }

I understand that I am free to withdraw from the study Yes { }    No { }

- at any time
- without having to give a reason
- without affecting my future care (for Patients)

I understand that it is my choice to be in the study and that I may not benefit. Yes { }    No { }

I understand how my privacy is protected and my records kept confidential Yes { }    No { }

I agree to take part in this study. Yes { }    No { }

I agree to be taped Yes { }    No { }

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Name printed

\_\_\_\_\_  
Year Month Day

#### **To be signed by the investigator or person obtaining consent**

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

\_\_\_\_\_  
Signature of investigator

\_\_\_\_\_  
Name printed

\_\_\_\_\_  
Year Month Day

Telephone number: \_\_\_\_\_

Signature of investigator

Name printed

Year Month Day

Telephone number: \_\_\_\_\_

## **Appendix J**

### **Phase 1 Interview Guides**

#### **Patient Interview**

The interview will be introduced by telling the participant of the researcher's interest in his/her experience managing and checking their feet. The researcher will also explain the rationale for using a CAIT for foot assessment and the purpose of the proposed study. The participant will be encouraged to talk about anything that will help the researcher understand his/her experience with foot management and what the participant thinks will help people better self-manage their feet and complete temperature assessment with a CAIT.

The following questions will be used during the interview as a guide to data collection. Prompts such as "can you tell me more about that?" and "please go on" will be utilized.

1. How old are you?
2. How long have you had diabetes?
3. Tell me about looking after your feet.
4. What have you used or done before?
5. What do you find helpful?
6. What did you find least helpful?
7. What do you feel in your feet?
8. Do you know when you should rest?
9. How confident do you feel about looking after your feet?
10. What do you look for when you check your feet?
11. How often do you look at your feet?
12. What do you do if you find something wrong with your feet?
13. Have you ever had a diabetic foot ulcer?
14. What do you think are risk factors for ulceration?
15. What do you know about foot ulcers and the risks?
16. Have you had education related to foot management?
17. What kind of footwear do you wear?
18. Does anyone help you care for your feet?
19. Are there any challenges that make it difficult for you to look after your feet?
20. Who do you go to if you have a problem?
21. What suggestions do you have for helping people with diabetes that would make checking their feet easier?
22. What do you think about using a CAIT for foot assessment?
23. What do you think will help make the CAIT easier for people to use?
24. What do you think will make the CAIT hard to use?
25. Is this log book for measuring temperature and foot assessment clear and easy to use?

## Support Person Interview

The interview will be introduced by telling the support person of the researcher's interest in his/her experience managing and checking the feet of the participant. The researcher will also explain the rationale for using a CAIT for foot assessment and the purpose of the proposed study. The support person will be encouraged to talk about anything that will help the researcher understand his/her experience with helping the patient with foot management and what the participant thinks will help people better self-manage their feet and complete temperature assessment with a CAIT.

The following questions will be used during the interview as a guide to data collection. Prompts such as "can you tell me more about that?" and "please go on" will be utilized.

10. Tell me about helping your family member/friend/client to look after their feet.
11. What do you do to help your family member/friend/client?
12. How often do you help them?
13. Do you find it time consuming to help your family member/friend/client with their feet?
14. Do you find it stressful to help your family member/friend/client with their feet?
15. What have you used or done before?
16. What do you find helpful?
17. What did you find least helpful?
18. Are there any challenges that make it difficult for you to help look after your family member/friend/client's feet?
19. What suggestions do you have for helping people with diabetes improve foot self-assessment?
20. What do you think about using a CAIT for foot assessment?
21. What do you think will help make the CAIT easier for people to use?
22. What do you think will make the CAIT hard to use?

## Health Care Provider Interview

The interview will be introduced by telling the health care provider of the researcher's interest in how people with diabetes manage their feet and their experiences with patients in relation to foot self-management. The researcher will also explain the rationale for using a CAIT for foot assessment and the purpose of the proposed RCT. The health care provider will be encouraged to talk about anything that will help the researcher understand his/her experiences and what the health care provider thinks will help individuals with diabetes better self-manage their foot health needs and complete temperature assessment with a CAIT.

The following questions will be used during the interview as a guide to data collection. Prompts such as "can you tell me more about that?" and "please go on" will be utilized.

11. What is your professional designation?
12. Where do you work?
13. Tell me about caring for people with diabetes in relation to foot management.
14. In your experience is the patient's support system helpful in foot management?
2. In relation to foot management what do you think patients with diabetes find most helpful?
3. In relation to foot management what did you think patient with diabetes find least helpful?
4. Are there any barriers that make it difficult for patients with diabetes to look after their feet?
5. What suggestions do you have for helping people with diabetes improve foot self-assessment?
10. Do you educate your patients about foot self-management?
11. Do you follow-up with your patients?
12. What do you tell your patients about foot ulcers?
13. Do you educate your patients about foot health?
23. What is the role of different health providers in relation to feet?
24. Do you have any suggestions for making it easier for patient to talk to their health care provider?
25. What do you think about using a CAIT for foot assessment?
26. What do you think will help make the CAIT easier for people to use?
27. What do you think will make the CAIT hard to use?
28. Would it be helpful to you in making decisions about patient care to have a patient who uses a CAIT to track foot temperature?
29. Is this log book for measuring temperature and foot assessment clear and easy to use?

## **Appendix K**

### **Pamphlet and Poster for Phase 2 Recruitment**

## About the Researcher

I am a Registered Nurse and a fourth-year student in the doctoral nursing program at Memorial University School of Nursing. I taught the Advanced Footcare Management Program for Nurses at the Centre for Nursing Studies for eight years. My research interest is focused on improving foot health for people who have chronic disease.

## Contact Information

If you have any questions about this study or would like to participate, please contact Kathleen Stevens at local telephone:

**(709) 777-8685**

or by email at:

**kathleen.stevens@mun.ca**

My faculty supervisor, Dr. Donna Moralejo, can be reached at: **(709) 864-3603** or **moralejo@mun.ca**

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through: Ethics Office Health Research Ethics Authority **(709) 777-6974** or by email at **info@hrea.ca**



Funding provided by



## Memorial University

# RESEARCH INTO PREVENTION OF FOOT PROBLEMS RELATED TO DIABETES



Research Investigator

## Kathleen Stevens

Doctoral Student  
School of Nursing  
Memorial University  
St. John's, NL



### **Why this research is important?**

- Diabetic foot ulcers are a major health problem for people with diabetes.
- Preventing foot ulcers will help decrease pain and suffering for people with diabetes and decrease health care costs.
- It is hard for people with diabetes to recognize the early signs of inflammation that leads to ulcers.
- What may be needed is a tool that will help people detect early inflammation so they will know when they should take pressure off the bottoms of their feet by resting.

### **What is the purpose of this research?**

- The purpose of this study is to determine if using a low -cost infrared thermometer that can be purchased at a hardware store is helpful for finding early inflammation.

### **How long is the study?**

- The study is six months long.

### **What will I have to do if I take part in the study?**

- You will be assigned like the flip of a coin to one of two groups.
- One group will get teaching about caring for feet and be given a pedometer to measure how many steps they take each day.
- The other group will receive the same teaching and a pedometer plus use a commercially available infrared thermometer to measure foot temperature daily.
- Take part in a footwear assessment.
- Complete three sets of questionnaires.
- Have bloodwork taken for HbA1C.

### **What is the risk ?**

- There are no known risks of being in this study.

### **Are there any benefits if I take part in the study?**

- You may benefit from the study by getting education and tools to look after your feet.
- If the findings of the study show that the thermometer helps prevent foot ulcers you will be offered the thermometer in appreciation of your time and effort.

### **Has this study been approved by an ethics committee?**

- This study has been reviewed and approved by the provincial Health Research Ethics Board

# ARE YOU INTERESTED IN LEARNING ABOUT LOOKING AFTER YOUR FEET?



## Research Study for adults with Type 1 and Type 2 diabetes

Purpose: To find out if foot care education and checking foot temperature with a low cost infrared thermometer that can be bought at a hardware store will help to detect inflammation and prevent skin breakdown on feet for adults 18 years and older who have diabetes.

### In this 6-month study people will be asked to:

- Check their feet every day. They may or may not be in the group that uses the infrared thermometer provided.
- Measure how many steps they take each day with a pedometer provided.
- Take part in three one-hour meetings with the researcher. These sessions will be used for learning about caring for feet, completing foot checks, and completing a set of questionnaires.
- Have a foot and shoe assessment completed by a professional.
- Have 1-2 HbA1C blood checks.

### Participant information is strictly confidential

For more information about this study, or to volunteer for this study, please contact:

Kathleen Stevens RN PhD (c)  
Phone: (709) 777-8685  
Email: [kathleen.stevens@mun.ca](mailto:kathleen.stevens@mun.ca)



This study has been reviewed and approved by the provincial Health Research Ethics Board and the Eastern Health Research Proposals Approval Committee

### Funding provided by



## Appendix L

### Script for Screening for Phase 2

#### First Stage of Screening:

##### Script for Telephone Call

My name is Kathleen Stevens and I am a nurse and PhD student at Memorial University School of Nursing. I would like to thank-you for agreeing to be contacted about the research study I am completing for my university program. This phone call will only take about 5 minutes of your time. This study is trying to find out if a program that measures foot temperature is a way to prevent sores on feet that can become foot ulcers in people with diabetes. There are certain requirements that an individual needs to have to be part of this study. If it's ok I would like to ask you some questions to find out if you would meet the requirements. Based on your answers I may ask to come and visit you to do an assessment of your feet.

1. Are you normally able to be reached by telephone?
2. Are you over 18 years of age?
3. Do you have a sore or ulcer on your feet right now?
4. Are you pregnant and/or breastfeeding?
5. Do you have any other health conditions?
6. Do you read and speak English?
7. Are you able to walk without the assistance of a wheelchair or crutches?

#### **If the potential participant does not meet these inclusion/exclusion criteria the following will be communicated:**

The rules of the study require that participants (*identify the criteria that the individual did not meet*) so unfortunately I cannot invite you to take part. Do you have any questions for me? I would like to thank-you for your time.

**or**

#### **If the potential participant does meet these inclusion/exclusion criteria the following will be communicated:**

Based on your answers to these questions you seem to meet the requirements for the study. I need to now assess your feet. I would like to meet with you in your home to do this. This visit should only take 15 minutes of your time. Could we arrange a time for me to visit?

#### Second Stage of Screening:

##### Script to Obtain Verbal Consent for Foot Screening when visiting potential participant

To find out if you can take part in this study I will need to ask you a few questions about your foot health history. As well, I will need to look at your feet and check the sensation in your feet. As well, to check your circulation I will need to check your blood pressure in your arms and legs. This assessment will take only 10 minutes. By completing these assessments you will be giving your consent to participate in this screening.

**If the potential participant does meet the final inclusion/exclusion criteria after the foot screening the following will be communicated:**

Based on the results of your foot assessment you meet the requirement for the study. The next steps are to sign the consent form for the study and arrange a time to complete the first interview.

**Or**

**If the potential participant does not meet the final inclusion/exclusion criteria after the foot screening the following will be communicated:**

The rules of the study require that participants (*identify the criteria that the individual did not meet*) so unfortunately I cannot invite you to take part. Do you have any questions for me? I would like to thank-you for your time.

## Appendix M

### Consent to Take Part in a Clinical Trial

**TITLE: Foot Intervention Study Utilizing Commercially Available Infrared Thermometers With Individuals with Diabetes Using a Mixed Methods Research Approach**

**Investigators:**

**Kathleen Stevens RN, PhD(c)**

**Phone number: 864-7100**

**Donna Moralejo RN, PhD**

**Phone number: 864-3603**

**Steven Ersser RN, PhD**

**Cathy MacLean MD**

#### **Part A: General information**

##### **Introduction**

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your usual health care.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

We do not know if taking part in this study will help you. You may feel better. On the other hand, it might not help you at all. It might even make you feel worse. We can't always predict these things. We will always give you the best possible care no matter what happens.

If you have been in another research study in the last year you should tell the investigator.

#### **Part B. Explaining this trial**

##### **1. Why am I being asked to join this study?**

You are considered a possible participant for this trial because you have diabetes and may have increased risk for foot complications.

**2. What is the purpose of this study?**

The purpose of this study is to find out if a program that helps someone look after their feet that uses a low-cost infrared thermometer (e.g., that can be bought at a hardware store) is helpful to prevent foot ulcers.

**3. What is being tested?**

A foot self-management strategy that uses commercially-available infrared thermometers (e.g., that can be purchased at a hardware store) is being tested. Wound care experts are promoting these thermometers as an assessment tool.

**4. How many people will take part in this study?**

All participants will be recruited from: Eastern Health Diabetes Centre, Wound Care Clinic, and Community Health St. John's Region; Family Physician Clinics; Nurse Practitioner Clinics; and Podiatry Clinics. A total of 142 people are expected to take part.

**5. How long will I be in the study?**

You will be in the study six months. During this time you will complete and record a foot assessments and a pedometer reading each day. You will be expected to complete an assessment by a shoe specialist and have blood work taken for HbA1C. Transportation will be provided for you if you are unable to travel to have these assessments completed. The investigator will visit you three-four times during the six months. Each visit will last up to 1 hour-1hour 15 minutes.

**6. How is the trial being done?**

You will be assigned like the flip of a coin to one of two groups. Both groups will receive foot care education and be given a pedometer to measure activity and a mirror with an extendable handle to help check your feet. One group will receive the same education and a pedometer plus use a commercially available infrared thermometer to measure foot temperature daily as part of checking feet.

**7. What will happen if I take part in this trial?**

- You will have a footwear assessment completed by a certified orthodist to check your footwear and see what can be done to improve your footwear. It will be up to you whether or not to follow any suggestions made.

- You will complete three sets of questionnaires (beginning of the study, three months, and six months). It will take approximately 50-60 minutes to complete each set of questionnaires.
- The set of questionnaires consists of:
  - Participant Profile (first set only)
  - Identification of Stage of change (first set only)
  - Adapted Foot Care Confidence Scale
  - Nottingham Assessment of Functional Footcare
  - Patient Health Questionnaire
  - Quality of Life Enjoyment and Satisfaction Questionnaire
- You will have HbA1C bloodwork at three months and possibly six months if the three-month result is above 8.5. You will be informed of the results by phone and provided with a copy of your HbA1c result(s) at the next appointment or by email or regular mail; it is recommended that you discuss these results with your physician.
- You will record every day a foot assessment and how many steps you took each day (pedometer reading). If you are in the group using the thermometer you will also record daily foot temperatures. This will take 5-10 minutes daily.
- If you have a large problem with your feet during the study it will be suggested that you see your doctor.
  - If you are using the thermometer when this happens you will stop using the thermometer and still collect the other information and complete the questionnaires.
  - If you are in the group that does not use the thermometer there will be no change for you.
- You will be told to see your health care provider if you get skin breakdown on your feet.
- You will be told to see your health care provider and be given contact information for the 24 hour Mental Health Crisis Line if your answers to some of the questions mean that you could be depressed.
- If you get pregnant during the study we will talk to you about staying in the study.

When it will happen	What will happen	Time required
Visit in your home or at MUN School of Nursing to see if you meet the requirements of the study	<ul style="list-style-type: none"> <li>• Foot check and blood pressure measurement in arm and leg to find out about blood circulation.</li> </ul>	30 minutes
First visit (either at your home or MUN School of Nursing):	<ul style="list-style-type: none"> <li>• Questionnaires</li> <li>• Foot assessment</li> <li>• Foot education</li> <li>• Teaching on how to use the pedometer</li> </ul>	60-75 minutes

beginning of study	<ul style="list-style-type: none"> <li>Teaching on how to use the thermometer if in that group</li> </ul>	
Beginning of Study: orthotic assessment at an orthopedic footwear store	<ul style="list-style-type: none"> <li>To find out about footwear needs. Completed by a certified orthodist</li> </ul>	60 minutes
Daily	<ul style="list-style-type: none"> <li>Measure your steps with a pedometer</li> <li>Check your feet for redness and skin breakdown</li> <li>Measure your foot temperature with a thermometer if in this group</li> <li>Record if you go to your doctor about your feet</li> </ul>	10 minutes/day
Visit at one week for people in thermometer group (either at your home or MUN School of Nursing)	<ul style="list-style-type: none"> <li>To check on how thermometer is being used</li> <li>Answer any questions</li> </ul>	10 minutes
Second visit: three months (either at your home or MUN School of Nursing)	<ul style="list-style-type: none"> <li>Questionnaires</li> <li>Foot assessment</li> <li>To check on how thermometer is being used</li> </ul>	45-60 minutes
Bloodwork at Eastern Health lab: three months	<ul style="list-style-type: none"> <li>HbA1C check at an Eastern Health Lab.</li> <li>HbA1C is a blood test that shows the average level of blood glucose over the previous three months</li> </ul>	1-2 hours
Bloodwork at Eastern Health lab: six months	<ul style="list-style-type: none"> <li>HbA1C check at an Eastern Health Lab if the three month level is higher than 8.5</li> </ul>	1-2 hours
Third visit: six months (either at your home or MUN School of Nursing)	<ul style="list-style-type: none"> <li>Questionnaires</li> <li>Foot Assessment</li> </ul>	75 minutes

**8. Are there risks to the study?**

There are no known risks of being in the study.

**9. Are there other choices?**

If you choose not to enter the study you can speak to your family doctor or community health nurse about options for you.

**10. What happens at the end of the study?**

- At the end of this study the thermometer, pedometer, and mirror with an extendable handle will be yours to keep. If you are in the group not using the thermometer you will be offered a thermometer and education about how to use it if study findings show that it was helpful for preventing foot ulceration.
- You may be asked to complete another interview about your experiences with the intervention at the end of the six months. This interview will last one hour. Another consent will be completed for this interview.

**11. What are my responsibilities?**

If you take part in this study you will be expected to:

- complete the daily checks and logbooks
- complete all the assessments as scheduled
- come to all appointments as planned
- follow the directions of the investigator
- report all medications that you are taking or plan to take
- report any changes in your health
- report any problems you think might be related to taking part in the study

**12. Can I be taken out of the trial without my consent?**

Yes. You may be taken out of the study at any time if:

- you do not follow the directions of the investigator
- you are not completing the daily checks and logbooks
- your doctor feels participation in the program is harming your health
- there is new information which shows being in this study may not be in your best interest
- Health Canada or the ethics committee or investigators decides to stop the study

**13. What about new information?**

It is possible that we will get new information about using thermometers as part of checking feet while you are in the study. You will be told about any such new information. You will be asked whether you want to continue taking part in this trial.

**14. Will it cost me anything?**

Payment

You will not be paid to be in the study. There is no charge for the study devices (thermometer, pedometer, mirror with extendable handle) or for any tests.

Injury related to being in the research study

If you become ill or injured because of taking part in this study, medical care will be available at no added cost to you.

Other costs

It will cost you to travel to have the footwear and bloodwork assessment completed.

However, if you are unable to cover this cost transportation will be provided for you.

**15. What about my privacy and confidentiality?**

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records. If you agree, your family doctor will be told that you are taking part in this study.

When you sign this consent form you give us permission to

- Collect information from you
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

### **Access to records**

The investigators and members of the research team will see the study records that identify you by name.

Other people may need to look at your study records and information that identifies you. This might include

- the research ethics board for quality purposes
- Health Canada

They can look at your study records only when supervised by a member of the research team.

### **Use of your study information.**

The research team will collect and use only the information they need to find out about the safety and usefulness of the program that uses the thermometer.

#### **This information will include your**

- age
- sex
- marital status
- education completed
- occupation
- income level
- support system
- medical conditions
- medications
- the results of tests and procedures during the study
- information from study interviews and questionnaires
- health practices
- blood glucose
- other co-morbidities

Your name and contact information will be kept secure by the research team in Newfoundland and Labrador. It will not be shared with others without your permission. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will be kept as long as required by law. This could be 5 years or more.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the researchers. It may not be removed. This information will only be used for the purposes of this study.

Information collected and used by the research team will be kept in a locked filing cabinet that can only be opened by the researcher and the researcher's PhD supervisor in the researcher's office at Memorial University's School of Nursing. Kathleen Stevens is the person who will make sure the information is locked in the cabinet and safe.

Your access to records

You have the right to see the information that has been collected about you.

**16. What are my rights?**

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

You can talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Ethics Office at 709-777-6974

Email: [info@hrea.ca](mailto:info@hrea.ca)

This study has been reviewed and given ethics approval by the Newfoundland and Labrador Health Research Ethics Board.

**17. Declaration of financial interest**

Research funds are being obtained to cover the cost of conducting the study. There will be no charges to your private insurance or to MCP.

**18. What about questions or problems?**

If you have any questions about taking part in this study, you can ask your doctor. You can also meet with the investigator who is in charge of the study.

That person is:

Kathleen Stevens RN (777-8685)

After you have signed this consent form, you will be given a copy.

**Signature Page**

**TITLE: Foot Intervention Study Utilizing Commercially Available Infrared Thermometers With Individuals with Diabetes Using a Mixed Methods Research Approach**

**Investigators:**

**Kathleen Stevens RN, PhD(c)**

**Phone number: 777-8685**

**Donna Moralejo RN, PhD**

**Phone number: 864-3603**

**Steven Ersser RN, PhD**

**Cathy MacLean MD**

**To be filled out and signed by the participant:**

Please check as appropriate:

- I have read the consent. Yes  No
- I have had the opportunity to ask questions/to discuss this study. Yes  No
- I have received satisfactory answers to all of my questions. Yes  No
- I have received enough information about the study. Yes  No
- I have spoken to Kathleen Stevens and she has answered my questions. Yes  No
- I understand that I am free to withdraw from the study Yes  No
- at any time
  - without having to give a reason
  - without affecting my future care
- I understand that it is my choice to be in the study and that I may not benefit. Yes  No
- I understand how my privacy is protected and my records kept confidential. Yes  No
- I agree that my family doctor can be notified of my participation in this study Yes  No
- I agree to take part in this study. Yes  No

---

Signature of participant                      Name printed                      Year Month Day

---

Signature of person conducting                      Name printed                      Year Month Day  
the consent discussion

**To be signed by the investigator:**

I have explained this study to the best of my ability. I invited questions and gave answers. I believe that the participant fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study.

---

Signature of investigator                      Name Printed                      Year Month Day

**Appendix N**  
**Letters with New Information**



## A Letter with New Information

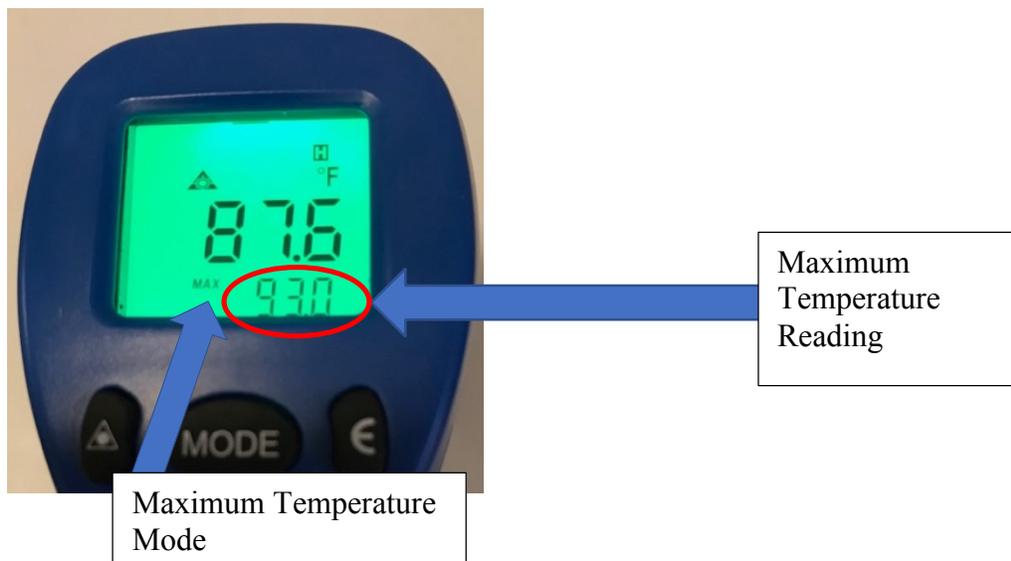
**Title: Utilizing commercially available infrared thermometers to prevent foot ulcers in patients with diabetes - A mixed methods approach**

### Addendum # 1 to the Patient Informed Consent, Version August 2018

---

You have signed consent to take part in this study. This letter provides new information that we have learned since this study started regarding temperature measurement and the Mastercraft infrared thermometer. After scanning each foot you were taught to record the reading in the large display of the thermometer. It has recently come to my attention that this reading does not provide you with the best information to detect inflammation. A new study released in 2018 found that the maximum temperature reading is a better measure to detect inflammation. This has been confirmed with one of the researchers of that study.

The process of scanning your feet would still be the same. However, the temperature that you compare would now be the maximum temperature reading for the scan. This can be accessed after you scan your foot by pressing mode on the thermometer until you see “max” in the display. The maximum temperature reading is the temperature displayed in a smaller size in the bottom right corner of the display. Please see the picture below.



Please be assured that the information collected from your participation is very valuable to the study and will help refine the intervention. If you would like me to visit to demonstrate how to

measure your foot temperature with the thermometer using the maximum temperature mode  
please let me know and we can make arrangements to discuss the new reading.

*All other information from the main consent remains unchanged.*

Sincerely,  
Kathleen Stevens

**Funding Provided by**





## A Letter with New Information

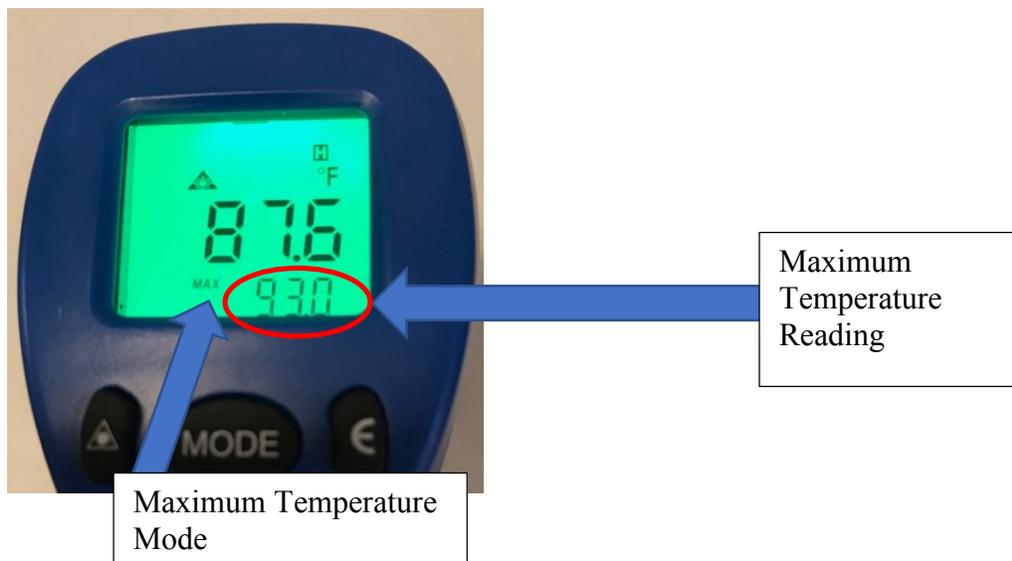
Title: Utilizing commercially available infrared thermometers to prevent foot ulcers in patients with diabetes - A mixed methods approach

### Addendum # 1 to the Patient Informed Consent, Version August 2018

---

You have signed consent to take part in this study. This letter provides new information that we have learned since this study started regarding temperature measurement and the Mastercraft infrared thermometer. After scanning each foot you were taught to record the reading in the large display of the thermometer. It has recently come to my attention that this reading does not provide you with the best information to detect inflammation. A new study released in 2018 found that the maximum temperature reading is a better measure to detect inflammation. This has been confirmed with one of the researchers of that study.

The process of scanning your feet would still be the same. However, the temperature that you compare would now be the maximum temperature reading for the scan. This can be accessed after you scan your foot by pressing mode on the thermometer until you see “max” in the display. The maximum temperature reading is the temperature displayed in a smaller size in the bottom right corner of the display. Please see the picture below.



Please be assured that the information collected from your participation to date is very valuable to the study. We will now be able to analyze the data using the original measure as well as the



**Appendix O**

**Individual and Group Tracking Forms**

**Name:** \_\_\_\_\_

**Code:** \_\_\_\_\_

**Phone Number:** \_\_\_\_\_(H) \_\_\_\_\_(C)

**Address:** \_\_\_\_\_ **Email**  
**address:** \_\_\_\_\_

**Orthotic Assessment Complete**  
Date \_\_\_\_\_

**HbA1C Complete**  
Date \_\_\_\_\_

**Date of screening phone call:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date of initial visit:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date of 1 week visit:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date of first phone call:** \_\_\_\_\_

**Date of first log book pick up:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date of 2nd log book pick up:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Month 3 visit and log book pick up:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Date of 4<sup>th</sup> log book pick up:**

---

---

**Date of 5<sup>th</sup> log book pick up:**

---

---

**Month 6 visit/log book pick up/exit interview:**

---

---

---

<b>Date and Time of Visits/Phone Calls</b>									
Code	First Visit	1 week visit	2 week (phone call)	1 month visit	2 month visit	3 month visit	4 month visit	5 month visit	6 month visit

## **Appendix P**

### **Description of Measures**

#### **Logbooks**

The logbook was used daily to record: temperature readings of both feet; pedometer readings; foot assessment findings; and events. It was estimated the logbook would take 5 minutes per day to complete. Foot temperatures were measured with the CAIT using the Fahrenheit scale. The number of steps taken each day was measured using the Ozeri 4X<sup>3</sup> Motion Activity Tracker. This pedometer automatically reset at midnight and kept a weekly log by storing seven days of activity. Participants were asked to log the pedometer reading at bedtime each day or before midnight. The purpose of the pedometer reading was to assess a participant's activity level before and after a temperature increase and/or ulceration. For the daily foot assessment participants inspected their feet daily using a hand-held extendable mirror to look for redness, broken skin, and bleeding. As well, any tenderness or pain was recorded. Finally, participants recorded any event that occurred. An event was defined as any time the participant needed to take action to address an issue with their foot. This could have been due to a temperature difference between the two feet that is greater than 4 degrees Fahrenheit, redness, tenderness, and/or broken skin. The action may have been resting or consulting a health provider. The templates for the logbook for the control and intervention group can be found in Appendix Q.

#### **Participant Profiles**

The Participant Profile was completed at the intake interview and recorded such information as: demographic information; Physician's name and contact information; history of

glucose control; and use of orthopedic footwear. This profile took 15 minutes to complete. The Participant Profiles for the control and intervention group can be found in Appendix Q.

### **Return Demonstration**

Participants in the intervention group were asked to perform a return demonstration using the CAIT to check temperature of their feet at baseline, one week, and six months. The return demonstration took 5-10 minutes to complete. The skills checklist that was used for the return demonstration can be found in Appendix Q.

### **Orthotic Assessment**

Participants had an orthotic assessment completed by a certified orthodist at intake. This assessment was of no cost to the participant and took one hour to complete. It was up to the participant to follow the recommendations. The orthodist forwarded a copy of the recommendations to the investigator.

### **Follow-up of Orthotic Recommendations**

A follow-up of the orthodist recommendations was completed at three and six months to determine if the participant acted upon any of the recommendations from the orthodist. This assessment took 5 minutes to complete. The follow-up form for the orthodic recommendations can be found in Appendix Q.

### **HbA1C Measurement**

HbA1C was measured at three months in an accredited Eastern Health laboratory and was assessed as an indicator of glycemic control. Eastern Health processed the HbA1C and did not send the result to the physician. The result was only sent to the principal investigator who informed the participant of the result by phone and provided the participant with a copy of the result(s) at the next appointment or by email or regular mail. It was recommended that the

participant discuss the result(s) with his/her physician. This bloodwork check was of no cost to the participant and took approximately 1-2 hours to complete. If the participant's HbA1C was 8.5 or over at three months it was repeated at six months. This number was chosen as the upper end of the target for HbA1C in the Canadian Diabetes Association clinical practice guidelines for individuals with type 1 and type 2 diabetes is 8.5 (Canadian Diabetes Association, 2013).

### **Foot Screen**

Participants were assessed at intake, baseline, and three months using the validated Simplified 60 Second Foot Screen (Sibbald et al., 2012). This screening took one minute to complete.

### **Self-Efficacy**

An adapted version of the Foot Care Confidence Scale (FCCS) was utilized to measure self-efficacy and took 10 minutes to complete. The conceptual underpinning of this scale is social cognitive theory. The intent of this scale was to measure confidence or self-efficacy that people with diabetes have caring for their feet. This scale was administered at baseline, three, and six months. This scale had a Cronbach's Alpha of 0.92 and demonstrated strong content validity (Sloan, 2002). For the purpose of this research two questions were added to the 12 item scale that specifically address foot inflammation. Each item on the scale was rated using a five point Likert scale with 1 being strongly not confident and 5 being strongly confident. The minimum score is 14 and the maximum score is 70.

### **Quality of Life**

The Quality of Life Enjoyment and Satisfaction Short Form was administered at baseline, three, and six months and took 5 minutes to complete. The participant was asked how satisfied he/she has been with areas such as physical health and mood. The rating scale ranged from very

poor (1) to very good (5). The first 14 items were tallied to obtain a score. The categories, medication and independence are tallied separately. The minimum raw score is 14 and the maximum is 70. This questionnaire demonstrated strong internal consistency (0.90), and test-retest reliability (0.93) (Stevanovic, 2011).

### **Depression Symptoms**

Depression was measured using the Patient Health Questionnaire (PHQ(9)) at baseline, three, and six months and took 5 minutes to complete. This scale has nine items and each item was given a score of 0-3. The range of scores were 0-27 and indicated the severity of depression categorized as mild, moderate, moderately severe, and severe depression with the cut-off scores of 5, 10, 15, and 20 respectively. This scale has a reported Cronbach's alpha of 0.89 and strong construct and criterion validity (Kroenke, Spitzer, & Williams, 2001). If a participant's score indicated that he/she has depression symptoms the investigator suggested that the participant see a health care provider. As well, the investigator provided the participant with contact information for the mental health crisis line.

### **Foot Care Behavior**

The Nottingham Assessment of Functional Footcare Revised 2015 (NAFF Revised 2015) was used to measure foot self-care behaviors at baseline, three and six months and took 15 minutes to complete (University of Nottingham, 2015). Foot self-care behavior was defined as the actions a person performs to keep his/her feet healthy. This tool has 26 questions and the total score that can be obtained is 78. The NAFF Revised 2015 is a revision of the NAFF 29 assessment. The revisions to the tool were minor with two questions deleted that were not reflective of current teaching and changes in wording to questions that related to footwear. Considering these minor changes, it is assumed the psychometrics of the tool remained

acceptable after the revisions. The reported internal consistency of the NAFF 29 questionnaire was acceptable (0.61) and the test retest reliability was good (0.91). This scale has been reported to be reliable over time. For the purpose of this study a score of less than 50 was categorized as inadequate foot care behavior and a score over 50 indicated good foot care behavior (Senussi, Lincoln, & Jeffcoate, 2011).

### **Exit Questionnaire**

Phase 1 and Phase 2 informed the exit questionnaire and was utilized at the end of the intervention and took 20-60 minutes to complete. The purpose of this questionnaire was to determine the participant's experiences with the intervention. It was administered at the end of the intervention to all participants. It also involved a return demonstration to assess how the participants used the CAIT. The interview guides for the exit questionnaire can be found in Appendix S.

### **Stages to Readiness to Change**

A tool based on the Transtheoretical Model was administered at baseline. Although validity and reliability had not been reported, this is a tool that has been shown to be successful in categorizing patients with diabetes into a stage of change prior to an intervention (Peterson & Hughes, 2002).

## References for Measures

- Canadian Diabetes Association Clinical Practice Guidelines Expert Committee., Imran, S.A., Rabasa-Lhoret, R., Ross, S. (2013). Targets for glyceic control. *Canadian Journal of Diabetes*. 2013;37 Suppl 1:S31-4. doi: 10.1016/j.jcjd.2013.01.016 [doi].
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ- 9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606-613. Retrieved from <https://www.springer.com/journal/11606>
- Peterson, K. A., & Hughes, M. (2002). Readiness to change and clinical success in a diabetes educational program. *The Journal of the American Board of Family Practice*, 15(4), 266-271. Retrieved from <https://www.jabfm.org/>
- Senussi, M., Lincoln, N., & Jeffcoate, W. (2011). Psychometric properties of the Nottingham Assessment of Functional Footcare (NAFF). *International Journal of Therapy and Rehabilitation*, 18(6), 330-334. Retrieved <https://journals.lww.com/intjrehabilres/pages/default.aspx>
- Sibbald, R. G., Ostrow, B., Lowe, J., Ayello, E. A., Alavi, A., Botros, M., ... & Smart, H. (2012). Screening for the high-risk diabetic foot: a 60-second tool (2012)©: diabetes. *Wound Healing Southern Africa*, 5(2), 72-82. Retrieved from <http://woundhealingsa.co.za/index.php/WHSA>
- Sloan, H.L. (2002). Developing and testing of the foot care confidence scale. *Journal of Nursing Measurement*. 10 (3), 207-218. Retrieved from <https://www.springerpub.com/journal-of-nursing-measurement.html>

Stevanovic, D. (2011). Quality of life enjoyment and satisfaction questionnaire-short form for quality of life assessments in clinical practice: A psychometric study. *Journal Psychiatric Mental Health Nursing*. 18(8):744-750. doi: 10.1111/j.1365-2850.2011.01735.x [doi].

University of Nottingham. (2015). Nottingham assessment of functional footcare revised 2015. 2015. Retrieved from <https://www.nottingham.ac.uk/medicine/documents/publishedassessments/naff29withcodes.pdf>

## **Appendix Q**

### **Phase 2 Measures**

- Appendix Q1 Logbook Intervention and Control Group**
- Appendix Q2 Participant Profile Intervention and Control Group**
- Appendix Q3 Return Demonstration for Temperature Measurement**
- Appendix Q4 Follow-up of Orthodist Recommendations**
- Appendix Q5 Exit Questionnaire**

**Appendix Q1**

**Monthly Logbook Intervention Group**

### Instructions

Please follow the steps below to get the temperature reading of your feet, to complete the foot check, and to complete the logbook. Check the temperature of your feet daily at whatever time is easiest for you and record the time in the logbook.

1. Take off socks and shoes and wait 5 minutes before doing the temperature reading. This gives time for the feet to return to their normal temperature and will give a truer reading.
2. Make sure the thermometer is on Fahrenheit setting. The F will show in the display window.
3. Hold the thermometer 6 inches or 15 cm away from your left foot. The thermometer is measuring the temperature below the area of light.
4. Squeeze the handle on the thermometer and trace a zigzag over the bottom of your left foot (see Figure 1). When you have finished the zigzag line, immediately release the handle of the thermometer. You will hear a beep. You can measure temperature over thick skin.



Figure 1

- Look at the display window to get the temperature reading of your left foot. You will use the maximum temperature reading. This can be viewed by pressing mode on the thermometer until you see "max" in the display. The maximum temperature reading is the temperature displayed in a smaller size in the bottom right corner of the display (see figure 2). Write this reading in the logbook.

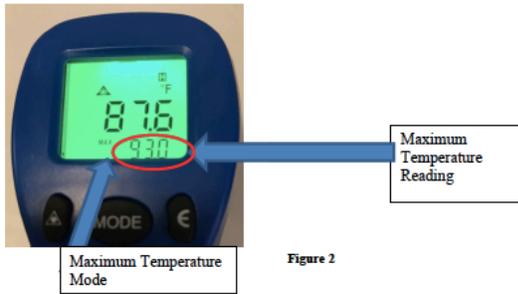


Figure 2

- Measure the temperature of your right foot in the same way and record this reading in the logbook.
- In the logbook write in the difference in temperature between the two feet. See sample log entry below.
- If you find a temperature difference greater than 4° Fahrenheit between the left foot and right foot you should rest and decrease the pressure on your feet until the temperature difference between your two feet is less than 4° Fahrenheit. This temperature difference may indicate inflammation.
- If you miss a day then leave that day blank and continue recording on the next day.

Measurement	Sunday	Monday	Tuesday	Wednesday
Time of foot check	8:00 am	12:00 am	4:00 pm	10:00 am
Temperature reading of feet (°F)	Left <b>80</b>	Left <b>82</b>	Left <b>80</b>	Left <b>81</b>
	Right <b>82</b>	Right <b>82</b>	Right <b>84</b>	Right <b>83</b>
	Difference <b>2</b>	Difference <b>0</b>	Difference <b>4</b>	Difference <b>2</b>

- Use the long handled mirror and look at the bottom of your feet and record what you see in the logbook.
- At the end of the day record the total number of steps taken that day in the space provided. The number of steps can be measured using a pedometer or other step counter.
- If you do something based on what you found when you completed the foot check write this under event in the logbook (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream).
- If you miss a day then leave that day blank and continue recording on the next day.

**Call your Health Provider if you:**

- Find a temperature difference between your two feet of greater than 4° Fahrenheit for two days in a row.
- Notice any redness or break in the skin on your feet.
- Have unexplained pain in your feet.

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Temperature reading of feet (°F)	Left _____ Right _____ Difference _____						
Did you change your amount of activity based on the temperature reading?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider, rested, changed shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Temperature reading of feet (°F)	Left _____ Right _____ Difference _____						
Did you change your amount of activity based on the temperature reading?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider, rested, changed shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Temperature reading of feet (°F)	Left _____ Right _____ Difference _____						
Did you change your amount of activity based on the temperature reading?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider, rested, changed shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Temperature reading of feet (°F)	Left _____ Right _____ Difference _____						
Did you change your amount of activity based on the temperature reading?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider, rested, changed shoes, put on cream)							

### Instructions

Please follow the steps below for completing the foot check and logbook. Check your feet whatever time of day is easiest for you and record the time in the logbook.

1. Take off shoes and socks.
2. Use the long handled mirror and look at the bottom of your feet and record what you see in the logbook.
3. At the end of the day record the total number of steps taken that day in the space provided. The number of steps can be measured using a pedometer or other step counter.
4. If you do something based on what you found when you completed the foot check write this under event in the logbook (e.g., visited healthcare provider with a concern about your feet, rested, changed shoes, put on cream).
5. If you miss a day then leave that day blank and continue recording on the next day.

Call your Health Provider if you:

- Notice any redness or break in the skin on your feet.
- Have unexplained pain in your feet.

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream)							

Month \_\_\_\_\_ Dates \_\_\_\_\_

Measurement	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time of foot check							
Areas of concern noted on your feet?	<input type="checkbox"/> Yes <input type="checkbox"/> No						
If yes, describe (check all that apply)	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change	<input type="checkbox"/> redness <input type="checkbox"/> tenderness <input type="checkbox"/> broken skin <input type="checkbox"/> peeling skin <input type="checkbox"/> rubbing skin <input type="checkbox"/> thick skin <input type="checkbox"/> dry skin <input type="checkbox"/> blister <input type="checkbox"/> bleeding <input type="checkbox"/> pain <input type="checkbox"/> color change
Step counter reading							
Event (e.g., visited healthcare provider with a concern about your feet, rested, change shoes, put on cream)							

## **Appendix Q2**

### **Participant Profile Control and Intervention Group**

**Participant Profile: Control Group**

Code: \_\_\_\_\_

Date of Intake Interview: \_\_\_\_\_

Date of Semi-Structured Interview: \_\_\_\_\_

Dates of Monthly Contact: \_\_\_\_\_

Age: \_\_\_\_\_

Marital Status: \_\_\_\_\_

Occupation at Present: \_\_\_\_\_

Education Level (highest level completed): Junior High-School \_\_\_

High School \_\_\_

Post-Secondary \_\_\_

University Degree \_\_\_

Income Level: < 20000 \_\_\_

20000-100,000 \_\_\_

> 100,000 \_\_\_

Year diagnosed with diabetes: \_\_\_\_\_ Type 1 diabetes  Type 2 diabetes

Last fasting glucose: date: \_\_\_\_\_ value: \_\_\_\_\_

Last HbA1C: date: \_\_\_\_\_ value: \_\_\_\_\_

How often do you rest your feet? \_\_\_\_\_

Orthopedic shoes: yes  no

Orthopedic insoles: yes  no

How often do you wear orthopedic shoes? \_\_\_\_\_

How often do you wear orthopedic insoles? \_\_\_\_\_

Normal foot-care practices

---

---

---

**Other co-morbidities**

Heart disease

Peripheral Vascular Disease

Stroke

Hyperthyroidism

High blood pressure

High cholesterol

Kidney disease

Arthritis

Depression

Other \_\_\_\_\_

Other \_\_\_\_\_

**Medications**

Insulin

Oral hypoglycemic

Steroids

Anticoagulants

NSAIDS

Other

---

---

---

Smoker? yes  no

How many per day? \_\_\_\_\_

Support system

---

---

---

<b>Item</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
1. Provided with basic foot care education			
2. Watched Video			
3. Support person present during education Relationship			
4. Provided with log book and instruction			
5. Provided with pedometer and instruction			
6. Provided with extendable mirror			
7. Opportunity provided for questions			

Questions asked:

Notes:

**Participant Profile: Intervention Group**

Code: \_\_\_\_\_

Date of Intake Interview: \_\_\_\_\_

Date of Semi-Structured Interview: \_\_\_\_\_

Dates of Monthly Contact: \_\_\_\_\_

Age: \_\_\_\_\_

Marital Status: \_\_\_\_\_

Occupation at Present: \_\_\_\_\_

Education Level (highest level completed): Junior High-School \_\_\_

High School \_\_\_

Post-Secondary \_\_\_

University Degree \_\_\_

Income Level: < 20000 \_\_\_

20000-100,000 \_\_\_

> 100,000 \_\_\_

Year diagnosed with diabetes: \_\_\_\_\_ Type 1 diabetes  Type 2 diabetes

Last fasting glucose: date: \_\_\_\_\_ value: \_\_\_\_\_

Last HbA1C: date: \_\_\_\_\_ value: \_\_\_\_\_

How often do you rest your feet? \_\_\_\_\_

Orthopedic shoes: yes  no

Orthopedic insoles: yes  no

How often do you wear orthopedic shoes? \_\_\_\_\_

How often do you wear orthopedic insoles? \_\_\_\_\_

Normal foot-care practices

---

---

---

**Other co-morbidities**

Heart disease

Peripheral Vascular Disease

Stroke

Hyperthyroidism

High blood pressure

High cholesterol

Kidney disease

Arthritis

Depression

Other \_\_\_\_\_

Other \_\_\_\_\_

**Medications**

Insulin

Oral glyemic

Steroids

Anticoagulants

NSAIDS

Other

---

---

---

Smoker? yes  no

How many per day? \_\_\_\_\_

**Support system**

---

---

---

Item	Yes	No	Comments
1. Provided with basic foot care education			
2. Watched Video			
3. Support person present during education Relationship _____			
4. Support person will assist participant with temperature reading \ <input type="checkbox"/> n/a			
5. Provided with log book and instruction			
6. Provided with pedometer and instruction			
7. Provided with extendable mirror			
7. Provided with CAIT and instruction			
8. Satisfactory return demonstration completed with CAIT			
9. Opportunity provided for questions			
10. Appointment made for next visit in one week Date: _____ Time: _____			

Questions asked:

Notes:

## **Appendix Q3 Return Demonstration for Temperature Measurement**

### Return Demonstration Checklist for Thermometer Use

Step	Completed (yes or no)
1. Takes off socks and shoes and waits 5 minutes before doing the temperature reading.	
2. Makes sure the thermometer is on Fahrenheit setting.	
3. Holds the thermometer 6 inches or 15 cm away from the foot.	
4. Squeezes the handle on the thermometer and traces a zigzag over the bottom of the foot.	
5. When finished tracing the zigzag line immediately releases the handle of the thermometer.	
6. Looks at the display window to get the temperature reading of the foot and writes this reading in the log book.	
7. Measures the temperature of the other foot in the same way and records this reading in the log book.	
8. In the log book records the difference in temperature between the two feet.	

**Appendix Q4 Follow-up Orthodist Recommendations**

**Follow-up Form for Orthotic Recommendations**

**Participant code number** \_\_\_\_\_

**Date Assessment Completed** \_\_\_\_\_

**Recommendations:**

---

---

---

---

---

---

---

---

---

---

**Three Month Follow-up:**

---

---

---

---

---

---

---

---

---

---

**Six Month Follow-up:**

---

---

---

---

---

---

---

---

---

---

## **Appendix Q5 Exit Questionnaire**

### **Exit Questionnaire**

#### **Questions common to intervention and control group**

1. Did you like the strategy?
2. What were the best parts of the strategy?
3. What are the worst parts of the strategy?
4. How can it be improved?
5. When did you perform your foot check?
6. Did you use the information from your foot checks when you went to see your doctor?
7. Prior to this foot education what other foot care education did you receive?
8. What was the most important information that you have learned?
9. Do you think that you will continue with the daily foot checks?
10. Did you ask your doctor to examine your feet since starting the study?
11. Have you made any changes to your diabetes management?
12. Did you get help with the foot assessment?

### **Questions for the intervention group**

1. Will you continue to use the thermometer? Why or Why not?
2. Was it easy to read the thermometer?
3. Did you change what you plan to do based on what you found when you checked the temperature of your feet?
4. Would you recommend a thermometer to another person who has diabetes?
5. Could you please show me how you used the thermometer?
6. Did you provide the study letter to your health provider?

**\*\*would you be ok to be contacted for Phase 3?**

## Appendix R

### Phase 3 Telephone Consent and Script

At the last interview you indicated I could contact you if I had any further questions. In the final phase of my study I want to interview participants about their experiences with foot self-management during and since completing the program that was delivered in Phase 2. As a participant in Phase 2 your experience is very important.

As you are considering this there are a few things you may need to know. I am asking you to complete a telephone interview. Your answers are confidential and will only be known to the researcher, the researchers PhD supervisor and the research assistant. I will not put your name on the interview and no one will be able to determine your identity from your answers. If you have any questions, concerns, or comments about the interview questions please feel free to let me know or contact me by e-mail or by phone. I will be taking notes during the interview. The interview will be taped and I will use the tape to supplement my notes. The tape will then be erased.

You may have questions about access to the data. Only the researcher, the researcher's PhD supervisor, and the two research assistants will have access to the data. All data will be stored in a locked cabinet in the Nursing Research Unit at the MUN Faculty of Nursing and on a computer or a flash drive that is password protected and encrypted.

I also should let you know that you are free to participate or not in this interview. It will not affect your follow up care. You do not have to answer all the questions to remain in the study. This interview should take only about 30 minutes.

There are no expected risks or discomforts for you in completing this interview. This interview may help to increase understanding of the findings of Phase 1 and 2 of the study.

If you have any concerns about the study you can talk to someone who is not involved with the study at all but can advise you on your rights as a participant in a research study. This person can be reached through:

Ethics Office  
Health Research Ethics Authority  
709-777-6974 or by email at [info@hrea.ca](mailto:info@hrea.ca)

Do you consent to participate in the interview and this part of the study? Is now a good time or can we schedule a time to complete the interview?

## Appendix S

### Phase 3 Interview Guide

The interview will be introduced by telling the participant of the researcher's interest in his/her experience with foot self-management during and after completing the study. The participant will be encouraged to talk about anything that will help the researcher understand his/her experience with foot management.

The following questions will be used during the interview as a guide to data collection. Prompts such as "can you tell me more about that?" and "please go on" will be utilized.

#### **Question for participants who were in the control and intervention group:**

##### **Purpose of Questions: To clarify what participants considered a foot health concern.**

1. What would you consider a concern on your foot?
2. If you noted a concern how long would you wait to see a health care provider?
3. When you noted a concern in your logbook why did you not take action?
4. Were the logbooks helpful to you? Why or why not?

##### **Purpose of Questions: to understand the impact of additional self-management activities**

5. Did you find that having to look at your feet daily felt like you increased the time you had to spend on your diabetes self-management? Why or Why not?
6. Do you view your foot self-management as being as important as other parts of your diabetes self-management?
7. Did strengthening your foot self-management improve your quality of life? Why or why not?

##### **Purpose of Question: To understand why positive foot behaviors decreased from 3-6 months.**

8. Why did your foot care behavior decrease with time?

##### **Purpose of Questions: To clarify if participants understood the importance of footwear.**

9. What is your understanding of the importance of foot wear?
10. Have you made any changes in behavior in relation to wearing orthopedic shoes and insoles?
11. Why did you follow the orthodist's suggestions? Why didn't you follow the orthodist's suggestions?
12. You said that you purchased orthopedic soles and insoles – have you found these useful? Why or why not?

**Purpose of Questions: To determine if participants who were moderate to high risk changed the amount of time they rested.**

13. Do you pay more attention to making you sure that you rest your feet?
14. Is that a change from before?
15. How did you know you should rest your feet?
16. How often do you rest your feet during the day?

**Purpose of Questions: To understand more about readiness and foot self-management.**

17. Why did you decide to volunteer to be in a study about diabetes and foot health?
18. Do you feel during or after completing the study you were interested in finding out about other ways to self-manage your diabetes? Why or why not?
19. The more time you had in the study did you find that it was easier or harder to complete the foot assessment and log books? Why or why not?
20. Are you dealing with any problems related to diabetes and how has this impacted on foot self-management?
21. Have you continued with the changes you made to your diabetes management that you made during the study?
22. You indicated when you started the study that you were (fill in as it relates to the stage of change)
23. How do you see readiness as a factor in making changes in your diabetes management? in talking with your physician?
24. How do you see readiness as a factor in talking with your physician?
25. What do you recommend to physicians or HCPs in terms of readiness to self-manage foot health?

**Purpose of Questions: To explore if the intervention improved communication between participants and HCPs about foot health**

26. What do you think would be a foot issue that you should take to your HCP?
27. If you spoke to your physician about your foot health what was their response?
28. Did the study provide you with an opportunity to talk to your HCP about your foot health?
29. If yes did you talk about a problem or foot health in general?
30. Is this a conversation that you have continued with your physician?
31. Did you feel comfortable asking questions? Why or why not?
32. How did your physician present information about foot health?

**Purpose of Questions: To gain further understanding regarding confidence and foot health**

1. Do you feel more confident looking after your feet? How? Why?
2. Is feeling confident important to you?
3. When you look back on your knowledge of foot health prior to starting the study do you feel that your confidence is different?

4. Comparing before the study and after are there some areas that you are more confident in and others that you are less? (i.e. Cutting your own toenails)
5. Do you feel more confident in managing your diabetes? Your health in general? (other illnesses or health issues)?
6. Are there areas where you think you need more support?

**Question for participants who used the thermometer:**

**Purpose of Questions: Was the thermometer useful for prompting or facilitating a foot assessment?**

1. When you took your temperature reading during the study did you also look at your feet?
2. Did using the thermometer prompt you to look at your feet?
3. Did using the thermometer make you feel more involved in your foot assessment?

**Purpose of Questions: Was the thermometer was useful for taking action to prevent foot complications”**

4. Have you used the thermometer since completing the study? If yes, when?
5. Why did you decide to use the thermometer?
6. What information does it provide? What did you do with the information?

**Purpose of Questions: Did the thermometer provided reassurance about foot health?**

7. Do you find it reassuring that the thermometer provides technology to monitor your foot health (make sure your feet are ok)?
8. How did it make you feel when you got a temperature difference more than 4 degrees Fahrenheit? Less than 4 degrees Fahrenheit? Why?

**Appendix T**  
**Ethics Approval Letter**



**Ethics Office**  
**Suite 200, Eastern Trust Building**  
**95 Bonaventure Avenue**  
**St. John's, NL**  
**A1B 2X5**

June 22, 2016

Office 912  
Centre for Nursing Studies  
Southcott Hall  
100 Forest Road  
St. John's, NL  
A1A 1E5

Dear Ms. Stevens:

**Researcher Portal File # 20170291**  
**Reference # 2016.155**

**RE: "Utilizing commercially available infrared thermometers to prevent foot ulcers in patients with diabetes - A mixed methods approach"**

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Health Research Ethics Board (HREB). *Full board approval* of this research study is granted for one year effective **June 9, 2016**.

**This is your ethics approval only. Organizational approval may also be required.** It is your responsibility to seek the necessary organizational approval from the Regional Health Authority (RHA) or other organization as appropriate. You can refer to the HREA website for further guidance on organizational approvals.

This is to confirm that the HREB reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Revised consent form to take part in clinical trial, approved
- Revised consent form phase 1, approved
- Recruitment poster, approved
- Simplified 60 second foot, approved
- Quality of Life Enjoyment and Satisfaction Short Form, approved
- PHQ(9), approved
- Adapted Foot Care Confidence Scale, approved
- Nottingham Assessment of Functional Foot care, approved

**MARK THE DATE**

**This approval will lapse on June 9, 2017.** It is your responsibility to ensure that the Ethics Renewal form is

submitted prior to the renewal date; you may not receive a reminder. The Ethics Renewal form can be found on the Researcher Portal as an Event form.

*If you do not return the completed Ethics Renewal form prior to date of renewal:*

- **You will no longer have ethics approval**
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*
- *Lapse in ethics approval **may result in interruption or termination of funding***

**You are solely responsible for providing a copy of this letter**, along with your approved HREB application form; to **Research Grant and Contract Services** should your research depend on funding administered through that office.

Modifications of the protocol/consent are not permitted without prior approval from the HREB. **Implementing changes without HREB approval may result in your ethics approval being revoked, meaning your research must stop.** Request for modification to the protocol/consent must be outlined on an amendment form (available on the Researcher Portal website as an Event form) and submitted to the HREB for review.

The HREB operates according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), the Health Research Ethics Authority Act (HREA Act) and applicable laws and regulations.

**You are responsible** for the ethical conduct of this research, notwithstanding the approval of the HREB.

We wish you every success with your study.

Sincerely,



Dr Fern Brunger (Chair, Non-Clinical Trials Health Research Ethics Board)  
Ms. Patricia Grainger (Vice-Chair, Non-Clinical Trials Health Research Ethics Board)

CC: D Moralejo