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Type 2 diabetes mellitus and diabetic foot ulcers: an exploration of the health-related quality of life, diabetes knowledge and foot self-care management in Thailand

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Type 2 diabetes mellitus and diabetic foot ulcers: an exploration of the health-related quality of life, diabetes knowledge and foot self-care management in Thailand

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Abstract

The prevalence of type 2 diabetes mellitus (T2DM) and diabetic foot ulcers (DFUs) among the Thai population is rapidly increasing. Further, the evidence in the literature suggests that people who live with T2DM and DFUs have a poor health-related quality of life (HRQOL). Knowledge about diabetes and self-care management are key factors that contribute to the HRQOL of those affected. However, there is limited literature within the Thai context relating to HRQOL or knowledge about diabetes and self-care management among people with T2DM with and without DFUs.

The aims of this thesis were to: 1) investigate the HRQOL among Thai adults with T2DM with and without DFUs, 2) investigate the knowledge of diabetes among Thai adults with T2DM with and without DFUs, 3) understand self-care management knowledge and practices among Thai adults with T2DM and DFUs and 4) explore the experiences of Thai adults living with DFUs to obtain a better understanding of their experiences.

A sequential, explanatory mixed methods design was used. The quantitative phase consisted of a cross-sectional survey using validated instruments to investigate HRQOL, diabetes knowledge and self-care management. Participants were those with T2DM (with or without DFUs) who attended a diabetes clinic at a large tertiary hospital in northern Thailand. The qualitative phase involved semi-structured interviews with people with DFUs. The quantitative data were analysed using SPSS Version 24 and the qualitative data were analysed using thematic analysis.

A total of 502 patients with T2DM completed the cross-sectional survey. The mean score for perception of overall HRQOL was 61.18 (SD 18.74). Scores in the D-39 questionnaire indicated poor HRQOL. The use of insulin or combination of insulin and oral medication were found to be significant predictors of participants' rating of the overall severity of their diabetes. Knowledge relating to diabetes was poor, with participants obtaining a mean score of 42.39 % ± 15.45.

A subgroup analysis of 41 patients with DFUs using a DFU-specific HRQOL questionnaire was undertaken. The scores for these patients were higher than average, indicating good HRQOL. Less than one-third of patients with DFUs reported that they had received education about foot care management. In addition, self-care management practices relating to foot care were limited among those with DFUs. Qualitative data was analysed into two primary themes: 1) living with a DFU and 2) managing a DFU. Integration of the data revealed that the qualitative analysis supported the quantitative findings relating to HRQOL, knowledge of diabetes and the self-care management practices of people with and without DFUs.

This study has addressed a significant gap in the literature and highlighted the implications of living with T2DM and DFUs among Thai people. The findings provide important information on diabetes management in Thailand, particularly in the northern Thai context. The findings can assist policymakers to provide resources and develop strategies to improve the HRQOL, diabetes

knowledge and self-care management practices among people with T2DM with and without DFUs.

Acknowledgements

Thesis Certification

I, Saneh Khunkaew, declare that this thesis, submitted in partial fulfilment of the requirements for the conferral of Doctor of Philosophy, in the School of Nursing, in the Faculty of Sciences, Medicine and Health, University of Wollongong, is wholly my own work unless otherwise referenced or acknowledged. This document has not been submitted for qualifications at any other academic institution.

_____

Saneh Khunkaew

Date: 1st March 2019

Dedication

This work is dedicated to my parents Keaw and Sumalee Khunkaew. They are my inspiration and responsible for my passion for helping people with diabetes and diabetic foot ulcers have a better quality of life. I am committed to working to improve the health-related quality of life among Thai people.

This thesis is also dedicated to my fiancée, Miss Alisa Supsung, who has always been beside me providing support through the various stages of my PhD journey. Although she is not living in Australia, technology has made it possible for us to remain close.

Compendium of Publications

The chapters of this thesis have been prepared for publication as follows.

Peer review publications

Khunkaew S, Fernandez R, Sim J. Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis. Qual Life Res. 2018. doi:10.1007/s11136-018-2082-2 (Chapter 2, Part 2).

Khunkaew S, Sim J, Fernandez R. Knowledge and self-care management among adults with diabetic foot ulcers: an integrative review. SAGE Open Nursing. 2018. (SON-18-0093) (under review) (Chapter 2, Part 3).

Khunkaew S, Fernandez R and Sim J. Demographic and clinical predictors of health-related quality of life among people with type 2 diabetes mellitus living in northern Thailand: a cross-sectional study. Health Qual Life Outcomes. 2018. HQLO-D-18-00483 (under review) (Chapter 4).

Khunkaew S, Fernandez R, Sim J. Linguistic and psychometric validation of the Thai version of simplified Diabetes Knowledge Scale: a measure of knowledge of diabetes in a Thai population. SAGE Open Nursing. 2018; 4: 1–8. (Chapter 5).

Khunkaew S, Fernandez R, Sim J. Health-related quality of life and self-care management among people with diabetic foot ulcers in northern Thailand. SAGE Open Nursing. 2018; 5: 1–10 (Chapter 6).

Khunkaew S, Tungpunkom P, Sim J, Fernandez R. The experiences of people in northern Thailand living with diabetic foot ulcers: a descriptive qualitative study. Pac Rim Int J Nurs Res. 2018; 22(4):304–18. (Chapter 7).

Conference Presentations

Khunkaew S, Fernandez R, Sim J. The factors determining the low health-related quality of life among people living with diabetic foot ulcers: a systematic review. International Conference on Diabetes and Diabetic Nursing Care; 2017 Sep 20–21; Charlotte (US). Poster presentation, peer reviewed.

Khunkaew S, Tungpunkom P, Sim J, Fernandez R. An exploration of the experiences of people living with diabetic foot ulcers: a qualitative study. Sigma Theta Tau International (STTI) 29th International Nursing Research Congress; 2018 Jul 19–23; Melbourne (AU). Poster presentation, peer reviewed.

Khunkaew S, Fernandez R, Sim J. Translation and evaluation of the Thai version of the Simplified Diabetes Knowledge Scale, Sigma Theta Tau International (STTI) 29th International Nursing Research Congress; 2018 Jul 19–23; Melbourne (AU). Poster presentation, peer reviewed.

Khunkaew S, Fernandez R, Sim J. Quality of life among people with diabetes type 2 and self-care management behaviour of foot care: Thailand study. Global Experts Meeting on Diabetes, Hypertension & Metabolic Syndrome; 2018 Jul 30–31; Melbourne (AU). Oral presentation, peer reviewed.

List of Abbreviations

ABI	Ankle-brachial index
ABPI	Ankle-brachial pressure index
BMI	Body Mass Index
BP	Bodily pain
CASP	Critical Appraisal Skills Programme
CMA	Comprehensive meta-analysis
COPD	Chronic obstructive pulmonary disease
CRP	C- reactive Protein
CWIS	Cardiff Wound Impact Scale
D-39	Diabetes-39
DFS	Diabetes Foot Ulcer Scale
DFS-SF	Diabetes Foot Ulcer Scale–short form
DFUs	Diabetic foot ulcers
DM	Diabetes mellitus
ESCI	Emerging Science Citation Index
DPN	Diabetic peripheral neuropathy
ESKD	End-stage kidney disease
EQ-5D	Euro-QoL-5D Health Utility Index
FDS2	Fremantle Diabetes Study Phase II
FPG	Fasting plasma glucose
GDM	Gestational diabetes mellitus
GH	General health
GP	General practitioner
HbA$_{1c}$	Glycosylated haemoglobin

HDR	Higher degree research
HIV/AIDS	Human Immunodeficiency Virus/
	Acquired Immune Deficiency Syndrome
HREC	Human Research Ethics Committee
HRQOL	Health-related quality of life
IDLE	Ischemic disease of lower extremities
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
IWGDF	International Working Group on the Diabetic Foot
JBI	Joanna Briggs Institute
KAP	Knowledge, attitude and practice
MH	Mental health
NCDs	Non-communicable diseases
NDS	Neuropathy Disability Score
NSS	Neuropathy Symptom Score
OGTT	Oral glucose tolerance test
OHA	Oral hypoglycaemic agents
PAD	Peripheral artery disease
PF	Physical functioning
PRISMA	Preferred reporting items for systematic reviews and meta-analysis
PROMs	Patient report outcome measures
PVD	Peripheral vascular disease
QUANT	Quantitative
qual	Qualitative
RE	Role emotional

RP	Role physical
SCDNT	Self-Care Deficit Nursing Theory
SDSCA	Summary of diabetes self-care activities
SDKS	Simplified Diabetes Knowledge Scale
SD	Standard Deviation
SF	Social Functioning
SF-12	Medical Outcomes Short Form-12
SF-36	Medical Outcomes Short Form-36
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
T-SDKS	Thai Simplified Diabetes Knowledge Scale
US	United States of America
USD	United States Dollar
VT	Vitality
WHOQOL-BREF	World Health Organisation Quality-of-Life Scale (BREF)
WHOQOL-BRIEF-THAI	World Health Organisation Quality of Life Brief Thai version

List of Funding Sources Supporting this Thesis

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Chapter 1

Introduction

Type 2 diabetes mellitus (T2DM) occurs when the pancreas cannot effectively function to control blood glucose levels, due to a deficiency in insulin secretion, resistance to insulin or both, resulting in hyperglycaemia.[1,2] T2DM normally occurs in genetically susceptible people who are obese, older than 35 years of age[3] and physically inactive.[4]

The incidence and prevalence of T2DM has risen over time to become a major global public health problem. It is estimated that one in 11 adults has diabetes mellitus (DM), 90 % of whom have T2DM.[5] In 2017, the International Diabetes Federation (IDF) estimated there were 451 million people aged 18–99 years with diabetes worldwide.[6] T2DM can lead to increased morbidity and mortality[5], with specific complications including retinopathy, neuropathy, nephropathy and vascular disease.[7]

Diabetic foot ulcers (DFUs) are a serious health problem among people with T2DM. Approximately 15 % of people with T2DM develop a DFU[8], while 4.5 % of people who are newly diagnosed with T2DM have an existing DFU.[9,10] Further, DFUs may result in permanent disability, associated with diabetes wound infection and amputation. More than 50 % of people in the US with an amputation are reported to have T2DM.[2] Consequently, a DFU can have a significant effect on a person's health-related quality of life (HRQOL).[11,12]

Most people with diabetes mellitus live in low and middle-income countries, including Thailand.[6] The prevalence of T2DM and DFUs is increasing in this population. In 2013 in Thailand the prevalence of diabetes mellitus adjusted to the national population was 6.4% and this is projected to increase to 8.3% by 2035.[6] Thai people have many risk factors for T2DM and the subsequent complication of DFUs. As a Registered Nurse working in northern Thailand, I had observed that people living with T2DM, did not have the required knowledge to manage their diabetes mellitus and prevent potential complications. Many people did not wear appropriate shoes and often walked barefoot outside. In addition, the diet in this part of Thailand has glutinous rice and tropical fruits as the staple foods. This makes glycaemic control challenging for this population. It was clear to me, that the knowledge level of people with T2DM with and without DFUs was not well understood. This gap in knowledge about the HRQOL, knowledge of diabetes and self-care management strategies used by people with T2DM in my community motivated me to undertake this study.

Adressing this gap in knowledge will enable the development of effective strategies to improve HRQOL, diabetes knowledge and self-care management skills among Thai people with T2DM with and without DFUs. An in-depth exploration of the subpopulation of Thai adults with DFUs will also enable specific strategies to be developed for this unique

population. This knowledge will be used to provide recommendations for nurses and healthcare professionals to implement in clinical practice.

The principle objective of this research was to investigate the HRQOL, diabetes knowledge, self-care management practices and experiences of Thai people living with T2DM with and without DFUs. This thesis was undertaken using a mixed method approach in a tertiary teaching hospital in northern Thailand. This study has two distinct parts: (1) quantitative studies exploring the HRQOL, knowledge of diabetes and self-care knowledge and practices among people with T2DM with and without DFUs and (2) a qualitative study among a sub-section of participants from the quantitative study that explored the experiences of people living with DFUs.

Research aims, objectives and questions

The aims of the quantitative phase of this research were to investigate the:

1. HRQOL among Thai adults with T2DM with and without DFUs
2. knowledge of diabetes among Thai adults with T2DM with and without DFUs
3. self-care management knowledge and practices among Thai adults with T2DM and DFUs.

The aim of the qualitative phase of this research was to explore the experiences of Thai adults living with DFUs to explain the quantitative results and obtain a better understanding.

The specific research questions for this thesis were:

1. What is the HRQOL and the clinical and demographic predictors of HRQOL among Thai adults with T2DM?
2. What is the diabetes knowledge of Thai adults living with T2DM?
3. What is the HRQOL and self-care management practices among Thai adults living with T2DM and DFUs?
4. What are the experiences of Thai adults living with DFUs?

Research study overview

This study was undertaken using a sequential explanatory mixed methods design to investigate the HRQOL, diabetes knowledge and self-care management practices among people with T2DM with and without DFUs. The rationale for using a mixed methods design was to enable the strengths of both quantitative and qualitative approaches to be used to answer the research questions.[13,14]

Research significance

This study explores a gap in the literature relating to the experiences of Thai adults living with T2DM with and without DFUs. The findings provide important information on diabetes management in Thailand, particularly within the northern Thai context. This information may

assist policymakers to support and fund strategies to improve the HRQOL of people with T2DM with and without DFUs. The findings also support nurses and healthcare professionals to improve their own knowledge of diabetes and self-care management practices. Nurses and healthcare professionals could use this knowledge to develop programs and resources to improve care for people with T2DM with and without DFUs. Further, the findings from this study may result in improved HRQOL, diabetes knowledge and self-care management knowledge and practices among people with T2DM that could reduce the incidence of DFUs and subsequent complications.

Thesis Structure

This thesis is presented as a thesis by compilation. A summary of the research outcomes and publications in this project are presented in Figure 1.

This thesis is structured in compliance with the University of Wollongong's policy for Higher Degree Research thesis by compilation.[15] This thesis has nine chapters including six peer reviewed journal publications (two under review and four published). While each publication lists the whole research team as authors, as the first author on each publication I have provided the largest and most significant contribution to each publication. As the lead researcher, I have performed the literature reviews, data collection, data analysis and prepared all publications in accordance with each journal's requirements. The supervision panel provided guidance on the methodology and design of the project and supported me to achieve the above outputs. As required by the Higher Degree Research thesis by compilation policy[15], each publication is substantively different and addresses a different aspect of the research questions.

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┌─────────────────────────┐        ┌──────────────────────────────────┐
│    Literature Review     │ ────▶  │ Publication 1: Health-related      │
└─────────────────────────┘   ╲     │ quality of life among adults       │
              │                ╲    │ living with diabetic foot          │
              │                 ╲   │ ulcers: a meta-analysis.           │
              │                  ╲  └──────────────────────────────────┘
              │                   ╲ ┌──────────────────────────────────┐
              │                    ▶│ Publication 2: Knowledge and       │
              │                     │ self-care management among adults  │
              │                     │ with diabetic foot ulcers: an      │
              │                     │ integrative review.                │
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│                         Research Questions                              │
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┌─────────────────────────┐        ┌──────────────────────────────────┐
│ 1.What is the health-    │        │ Publication 3: Demographic and     │
│ related quality of life  │ ────▶  │ clinical predictors of health-     │
│ (HRQOL) and the clinical │        │ related quality of life among      │
│ and demographic          │        │ people with type 2 diabetes        │
│ predictors of HRQOL      │        │ mellitus living in northern        │
│ among Thai adults with   │        │ Thailand: a cross-sectional        │
│ type 2 diabetes mellitus │        │ study.                             │
│ (T2DM)?                  │        └──────────────────────────────────┘
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│ 2.What is the diabetes   │        │ Publication 4: Linguistic and      │
│ knowledge of Thai adults │ ────▶  │ psychometric validation of the     │
│ living with T2DM?        │        │ Thai version of Simplified         │
│                          │        │ Diabetes Knowledge Scale: a        │
│                          │        │ measure of knowledge of diabetes   │
│                          │        │ in a Thai population.              │
└─────────────────────────┘        └──────────────────────────────────┘
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┌─────────────────────────┐        ┌──────────────────────────────────┐
│ 3.What is the HRQOL and  │        │ Publication 5: Health-related      │
│ self-care management     │ ────▶  │ quality of life and self-care      │
│ practices among Thai     │        │ management among people with       │
│ adults living with DFUs? │        │ diabetic foot ulcers.              │
└─────────────────────────┘        └──────────────────────────────────┘
              │
┌─────────────────────────┐        ┌──────────────────────────────────┐
│ 4.What are the           │        │ Publication 6: The experiences of  │
│ experiences of Thai      │ ────▶  │ people in northern Thailand living │
│ adults living with DFUs? │        │ with diabetic foot ulcers: a       │
│                          │        │ descriptive qualitative study.     │
└─────────────────────────┘        └──────────────────────────────────┘
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Figure 1: Research outcomes and publications

Each publication has been formatted within the body of the thesis and is also included in published format in Appendix 5. Chapter 2 presents the background to this study in four parts. Part 1 includes background information about DM (specifically T2DM) and DFUs. Part 2 is a systematic review of the HRQOL of people with T2DM and DFUs as published in Quality of

Life Research journal (2018). Part 3 is an integrative review on the knowledge and self-care management skills of people with T2DM and DFUs. It has been submitted for review in the SAGE Open Nursing journal. Part 4 provides context-specific information on T2DM and DFUs in Thailand.

Chapter 3 provides an overview of the theoretical framework, methodology and methods used in this study. Ethical considerations are also described.

Chapter 4 presents a quantitative study on the demographic and clinical predictors of HRQOL among people with T2DM in Thailand. This chapter includes a publication submitted for review to the Health and Quality of Life Outcomes journal.

Chapter 5 presents a quantitative study on diabetes knowledge among people with T2DM in Thailand. The chapter includes a publication which has been published in SAGE Open Nursing (2018).

Chapter 6 presents a quantitative study that examines HRQOL and self-care management knowledge and practices among people who have both T2DM and DFUs in Thailand. The chapter includes a publication that has been published in SAGE Open Nursing (2018).

Chapter 7 presents a qualitative study on the experiences of people living with T2DM and DFUs in Thailand. The chapter includes a publication that has been published in the Pacific Rim International Journal of Nursing Research (2018).

Chapter 8 presents a summary of the integration of both the quantitative and qualitative components of this research project.

Chapter 9 provides a summary of the strengths and limitations of this study, the implications for practice and for further research. The chapter provides a conclusion to the study.

Chapter 2

Literature Review

This chapter is constructed in four parts. Part 1 provides a broad overview of DM, with a specific focus on T2DM and DFUs. The purpose is to provide an overview that sets the context for this study. Part 2 explores the HRQOL of people with a DFU. It presents a systematic review and meta-analysis of the literature published on the HRQOL among people with a DFU. Part 3 explores the knowledge and self-care management skills of people with a DFU. This section presents an integrative review of the literature on the topic. The final part explores the context in Thailand for people with T2DM and DFUs.

Part 1: DM and DFUs

Overview of DM

Diabetes Mellitus is a chronic disease that occurs when the pancreas cannot control blood glucose levels due to a deficiency of insulin, resistance to insulin, or both, which results in hyperglycaemia.[1,2] DM is classified by the American Diabetes Association (ADA)[16] into four categories:

1. Type 1 diabetes mellitus (T1DM), which results in β-cell destruction and an absolute insulin deficiency.
2. T2DM, which results in insulin resistance or insufficiency, or both.
3. Gestational DM, which occurs during the second or third trimester of pregnancy.
4. Specific types of diabetes that occur due to secondary conditions such as Cushing's syndrome, acromegaly and drug- or chemical-induced diabetes resulting from the treatment of HIV/AIDS or organ transplantation.

Prevalence of DM

Diabetes Mellitus is a major global public health problem. The International Diabetes Federation (IDF) estimates that the number of people with DM will increase to 592 million by 2035.[17] In the US, the prevalence of diabetes among older adults rose from 5.8 % (in 1988–1994) to 12.4 % (in 2005–2010).[18] In Canada, 7.6 % of the population is estimated to have diabetes.[19] In Australia, the Fremantle Diabetes Study Phase II (FDS2) survey in 2011–2012 found that 4.8 % or 1.1 million Australians had diabetes. Of these, 85.8 % had T2DM, 7.9 % had T1DM and 6.3 % had other types of DM.[20] The increasing prevalence of DM across the world is illustrated in Figure 2.

This study focuses on T2DM.
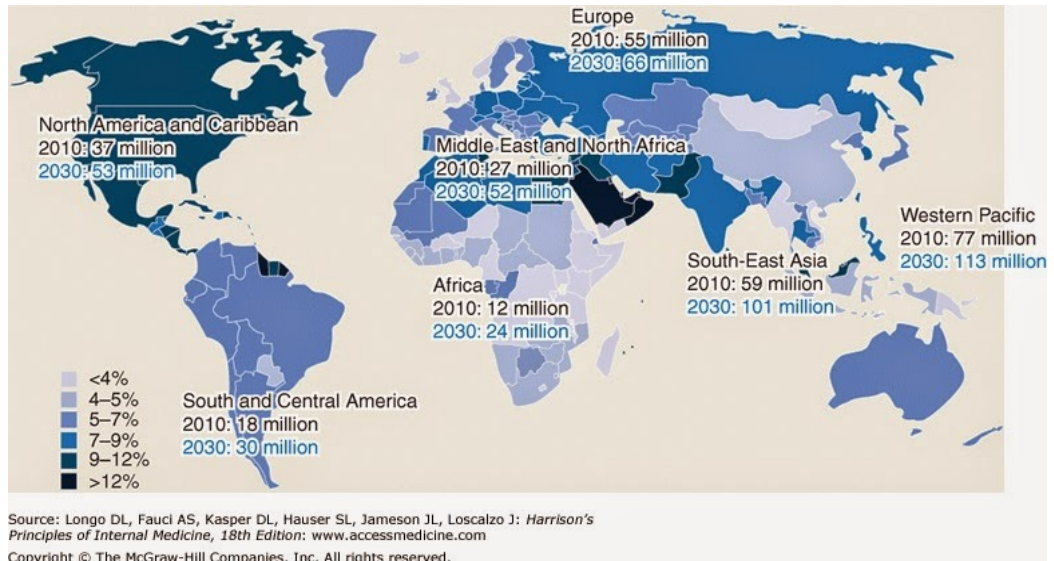
Figure 2: Prevalence of diabetes mellitus worldwide

(Source: Longo et al.[21] Chapter 344, p. 2970)

T2DM diagnostic criteria

T2DM is diagnosed using one of the following laboratory tests:[16]

- fasting plasma glucose (FPG)
- oral glucose tolerance test (OGTT) using 75 g of glucose in 300 ml of water with plasma glucose tested after two hours
- HbA$_{1c}$

The diagnostic criteria for T2DM has been developed by the ADA and is documented in Table 1.

Table 1: Diagnostic Criteria for Diabetes Mellitus

Test	Criteria
Fasting plasma glucose	≥ 126 mg/dL (7.0 mmol/L)*
2-h plasma glucose in 75-g OGTT	≥ 200 mg/Dl (11.1 mmol/L) during OGTT*
HbA$_{1c}$	≥ 6.5 % (48 mmol/mol)*
In a patient with classic symptoms of hyperglycaemia or hyperglycaemic crisis, a random plasma glucose ≥ 200 mg/dL (11.1 mmol/L).	

*Note: In the absence of unequivocal hyperglycaemia, results should be confirmed by repeat testing. (Source: American Diabetes Association 2018, S15[16])

In addition to the above criteria, individuals can be diagnosed as having pre-diabetes. Pre-diabetes occurs in patients who are developing T2DM. The diagnostic criteria for pre-diabetes[16] are divided into three types:

1. impaired fasting glucose (IFG)—fasting plasma glucose of 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.0 mmol/L)
2. impaired glucose tolerance (IGT) —2-hour plasma glucose following 75 g of oral glucose (OGTT) of 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L)
3. HbA$_{1c}$ of 5.7 %–6.4 % (39–47 mmol/mol).

Pathophysiology of T2DM

Type 2 Diabetes Mellitus results from insulin resistance and impaired pancreatic beta cell dysfunction.[22] If untreated, these two conditions can lead to hyperglycaemia (i.e., high blood glucose levels). This section describes the pathophysiology of T2DM, focusing on insulin resistance and beta cell (β-cell) dysfunction.

Insulin resistance

Insulin resistance occurs when cells do not respond to insulin and glucose is not able to enter the cells. The dysfunction of insulin receptors leads to hyperinsulinaemia to compensate and maintain the blood glucose levels. During this state, a lack of insulin response remains.[22] Insulin resistance is linked to increased lipid content of the liver and skeletal muscle and; therefore, is linked with obesity.[22] Guthrie and Guthrie[23] stated that triglycerides are toxic to β-cells and can lead to loss of β-cell function.

β-cell dysfunction

β-cell dysfunction is an important part of the pathogenesis of T2DM, as the β-cell progressively becomes unable to produce enough insulin to manage the hyperglycaemic state.[22] Over time, β-cells become exhausted and some die. This leads to a functional decline in the ability to respond to hyperglycaemia, as β-cell mass is reduced by 20 %–40 % in people with T2DM and some of the remaining β-cells do not function effectively.[22] The presence of high levels of fat, as seen with obesity, also effects β-cell function. People who are obese have an excessive release of free fatty acids and this is a major contributor to insulin resistance and β-cell destruction among people with T2DM.[22,23]

Complications of T2DM

People with T2DM have a high risk of complications, due to poor glycaemic control. The complications from T2DM affect different body systems.[22] For example, alterations in blood glucose levels affect the cardiovascular system, eyes, kidneys and the neurological system.[7] This section provides an overview of the complications of T2DM and how these can lead to the development of DFUs.

Longer term complications of T2DM relate to hyperglycaemia and insulin resistance.[22] Hyperglycaemia leads to changes in the structure and function of proteins that affect the microvascular blood supply (i.e., the small capillaries) and the macrovascular blood supply (i.e., the larger blood vessels).[22] In addition, hyperglycaemia causes neuropathies that damage peripheral neurons.[22] Insulin resistance that is frequently associated with long-term hyperglycaemia results in pro-inflammatory and pro-thrombotic states that lead to atherosclerosis, hypertension and heart disease.[24]

Coronary artery disease occurs due to macrovascular and pro-inflammatory and pro-thrombotic changes.[22] People with T2DM have a significantly higher risk of developing coronary artery disease and myocardial infarction. A nested case-control study examined 11,426 people with T2DM and found that 20 % of all participants had previously been diagnosed with a myocardial infarction.[25] The key results of the study showed that high HbA_{1c} values were significantly associated with a high risk of myocardial infarction (HR = 11.10; $p < .0001$) when compared to people with a normal HbA_{1c}.[25] Thus, people with T2DM who have myocardial infarction are more likely to develop congestive heart failure. Therefore, glycaemic control is important in minimising the risk of myocardial infarction and other complications from coronary artery disease.

Diabetic retinopathy is a problem with the microvascular blood supply in the retina. The micro circulation changes in the blood vessels result in retinal ischemia and a breakdown in blood flow to the retina.[26,27] Retinopathy is a major long-term complication of T2DM and can cause vision impairment and blindness.[28] Diabetic retinopathy affects about one in five people with diabetes.[28]

Diabetic nephropathy is caused by changes in the microvascular blood supply of the kidney.[26] Diabetic nephropathy is characterised by the presence of albumin in urine and the progressive loss of renal fuction.[26,29] Diabetic nephropathy occurs in about 20 %–30 % of people with T2DM and is the leading cause of end-stage kidney disease (ESKD) among people with diabetes.[30] In addition, hypertension that occurs due to atherosclerosis and coronary artery disease can further potentiate changes in the kidney function.[30]

Diabetic neuropathy is a common chronic complication of T1DM or T2DM. It is characterised by the presence of symptoms or signs of peripheral nerve dysfunction or autonomic nerve dysfunction. These symptoms occur due to microvascular changes that affect capillaries, neurovascular junctions, nerve function and conduction.[26]

This research focuses on people with T2DM, including those with and without a DFU.

Overview of DFUs

A DFU is an open wound commonly located underneath the foot. DFUs are a serious complication of T2DM.[31] People with T2DM who have a DFU have a 2.5 times higher risk of death when compared to people without a DFU.[31]

DFUs can occur when a person with T2DM experiences poor glycaemic control that results in

microvascular and macrovascular changes in the feet, as well as peripheral neuropathy.[32] The combination of poor circulation and diminished sensation places the person with T2DM at greater risk of minor trauma to the foot, although sustained pressure may also cause neuropathic ulceration.[33] Trauma can result from something as simple as tight shoes that cause painless ischemia and tissue breakdown.[34] Repetitive moderate stress that is induced during walking is a common cause of ulceration and lesions below the metatarsal heads and other pressure points in the foot.[34] The effect of repetitive stress due to walking is illustrated in Figure 3.

Figure 3: Diabetic neuropathic feet pressure points

(Source: Alavi et al.[35])

Prevalence of DFUs

The prevalence of DFUs among people with T2DM has been reported to be as high as 15 %.[8] In addition, the prevalence of a DFU in the lifetime of a person with DM is estimated to be as high as 25 %.[35] Global prevalence of DFUs varies by region. The overall prevalence is estimated to be 6.3 % globally (95 % CI: 5.4 %–7.3 %), with the prevalence in North America reported to be 13.0 % (95 % CI: 10.0 %–15.9 %). In Asia, the prevalence is reported as 5.5 % (95 % CI: 4.6 %–6.4 %), in Europe it is 5.1 % (95 % CI: 4.1 %–6.0 %), in Africa it is 7.2 % (95 % CI: 5.1 %–9.3 %) and in the Oceania region it is 3.0 % (95 % CI: 0.9 %–5.0 %).[36] People who have DM for more than 10 years are also more likely to develop a DFU.[37]

Pathophysiology of DFUs

Peripheral neuropathy, peripheral vascular disease, foot deformities, vascular insufficiency, trauma and prolonged infection may lead to development of DFUs among people with T2DM.[38] The pathway of abnormal wound healing relating to T2DM is illustrated in Figure 4. There are many biochemical abnormalities that can accelerate neuropathy and vascular foot changes.[35]
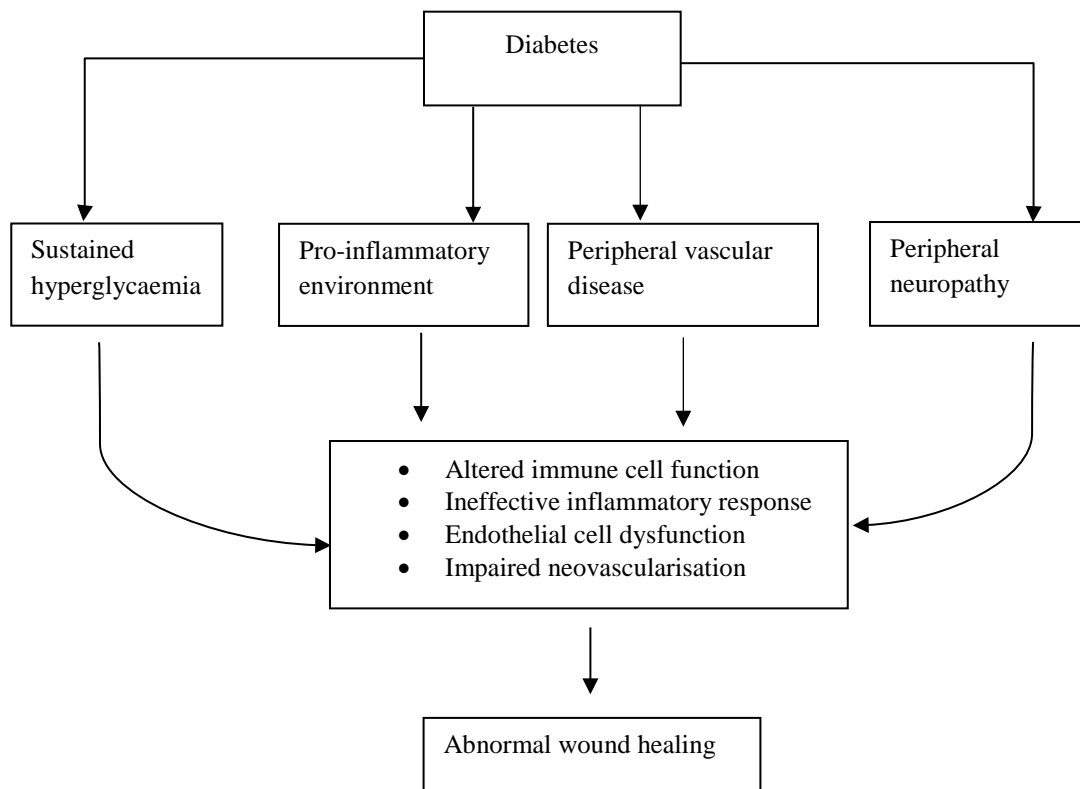
Figure 4: Wound healing disorders in diabetes

(Source: Rosyid[39])

Peripheral Neuropathy is a common disorder among people with T2DM. Peripheral neuropathy occurs due to hyperglycaemia that leads to structural changes and dysfunction in the peripheral circulation and neurons.[22] Peripheral neuropathy can be described in three ways that relate to the motor, sensory and autonomic functions of the nervous system.[38] These are:

1. motor neuropathy that occurs due to the motor neurons becoming damaged, resulting in difficulties with coordination and movement as well as the development of foot deformities (e.g., Charcot foot, hammer toe and claw toe)[38] In addition, motor neuropathy also leads to abnormal foot pressure and subsequent callus formation over pressure points when combined with undetected repetitive injuries. This pressure and callus formation leads to local tissue injury, inflammation, necrosis and foot ulceration.[35] (see Figure 5)

2. sensory neuropathy that leads to significant damage of the sensory nerves present in the extremities.[38] The inability to feel pressure or pain results in repetitive injuries and the potential development of DFUs. Exposure to heat, tight shoes and damage caused by foreign objects may cause DFUs to develop.[40] In addition, damage to sensory nerves affects skin integrity and provides a potential route for bacterial infection that can lead to DFUs that are difficult to heal.[38]

3. autonomic neuropathy that results in dysfunction of the sweat and sebaceous glands in the foot, resulting in dry skin that is susceptible to breakage.[38,41]
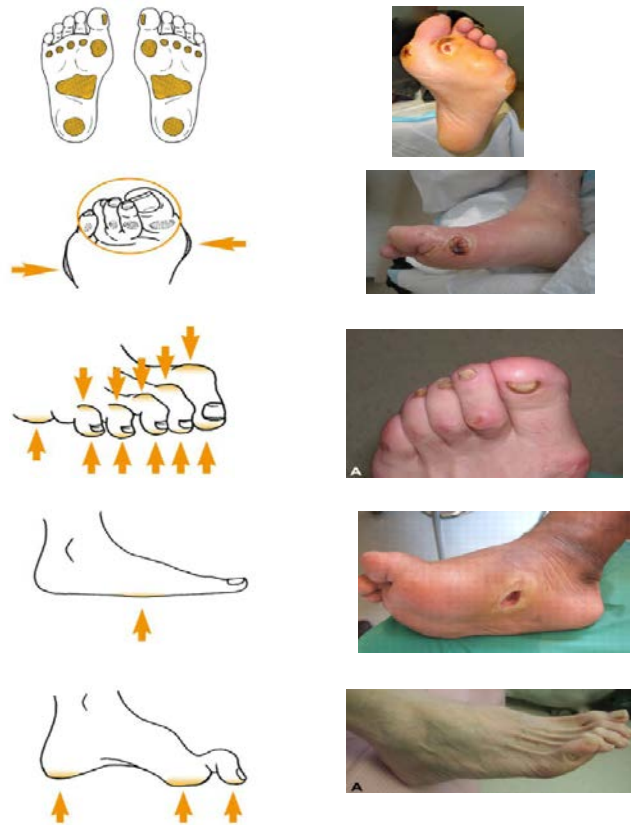
Figure 5: Common areas at risk for diabetic foot ulcer

(Source: Alavi et al.[35] and Schaper et al.[42])

Peripheral vascular disease (PVD) is an atherosclerotic occlusive disorder of the lower extremity.[38] The capillary basement membrane becomes thicker due to the constant presence of hyperglycaemia that leads to endothelial hyperplasia and, over time, decreased tissue perfusion and hypoxia of the lower limb.[22] Atherosclerotic blockages of large- and -medium-sized vessels also occur and can lead to acute or chronic ischemia.[38] A reduction in blood supply to the lower extremities leads to impaired wound healing that can cause long-term ulceration and expansion of the wound into surrounding tissues and bone structure.[38]

Classification of DFUs

The International Working Group on the Diabetic Foot (IWGDF) has developed a taxonomy regarding classification and diagnosis of DFUs.[43] This taxonomy allows all disciplines involved in the management of DFUs to have clear communication between multidisciplinary teams. The taxonomy is described in Table 2.

Table 2: International Working Group on the Diabetic Foot (IWGDF) Definitions

Diabetic foot	Infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of people with diabetes.
Foot lesion	Any abnormality associated with damage to the skin, nails or deep tissues of the foot.
Foot ulcer	Full thickness lesion of the skin of the foot.
A healed ulcer	Intact skin, meaning complete epithelisation of a previously ulcerated site.
Diabetic neuropathy	The presence of symptoms or signs of peripheral nerve dysfunction in people with diabetes, after exclusion of other causes.
Loss of protective sensation	Inability to sense light pressure, e.g., as applied with a 10 g Semmes-Weinstein monofilament.

Note: The full list of IWGDF definitions is available at:
http://iwgdf.org/guidelines/definitions-criteria-2015/. (Source: Bus et al.[43])

Classification systems for DFUs are used to describe ulcer characteristics such as depth, size, appearance and location. Classification systems are useful in managing DFUs. Clinicians use classification systems to guide accurate staging of the DFU, plan strategies for treatment and monitor wound healing. There are four commonly used systems for classifying DFUs: 1) the Meggitt-Wagner system (also called the Wagner Classification system/scale), 2) the Brodsky Depth-Ischemic Classification, 3) the University of Texas Classification and 4) the International Working Group Classification.[38]

The Meggitt-Wagner system is primarily based on the wound depth and the presence and location of wound infection.[44] The Brodsky Depth-Ischemic Classification was modified from the Wagner-Meggitt system and clearly differentiates between grades 2 and 3.[38] The University of Texas developed its classification system based on the Meggitt-Wagner system, with grades differentiated according to depth, wound infection and the presence of lower-limb ischemia.[38] Another classification system is the IWGDF classification system for predicting clinical outcomes.[38,45] This system is widely used to prevent lower-extremity complications in people with diabetes.[45] All four classification systems are compared in Table 3.

Table 3: Comparison of Four Diabetic Foot Classification Systems

Meggitt-Wagner[44]	Brodsky Depth-Ischemic Classification[38]	University of Texas Classification[38]	IWGDF[38]
Grade 0—No ulcer in a high-risk foot Grade 1—Superficial ulcer involving the full skin thickness but not underlying tissues Grade 2—Deep ulcer, penetrating down to ligaments and muscle, but no bone involvement or abscess formation Grade 3—Deep ulcer with cellulitis or abscess formation, often with osteomyelitis Grade 4—Localised gangrene Grade 5—Extensive gangrene involving the entire foot.	Grade 0—At risk, foot with previous ulcer that may cause new ulcer Ischemia grade: A. No ischemia B. Ischemia no gangrene C. Partial forefoot gangrene D. Total foot gangrene Grade 1—Superficial non-infected ulcer Ischemia grade: A. No ischemia B. Ischemia no gangrene C. Partial forefoot gangrene D. Total foot gangrene Grade 2—Deep ulcer with tendon or joint exposed (+/- infection) Ischemia grade: A. No ischemia B. Ischemia no gangrene C. Partial forefoot gangrene D. Total foot gangrene Grade 3—Extensive ulcer with bone exposed or deep abscess Ischemia grade: A. No ischemia B. Ischemia no gangrene C. Partial forefoot gangrene D. Total foot gangrene	Grade 0—Pre-or post-ulcerative lesion, completely epithelialised Stage A: without infection or ischemia Stage B: with infection Stage C: with ischemia Stage D: with infection and ischemia Grade 1—Superficial wound not involving tendon, capsule, or bone Stage A: without infection or ischemia Stage B: with infection Stage C: with ischemia Stage D: with infection and ischemia Grade 2—Wound penetrating to tendon or capsule Stage A: without infection or ischemia Stage B: with infection Stage C: with ischemia Stage D: with infection and ischemia Grade 3—Wound penetrating to bone or joint Stage A: without infection or ischemia Stage B: with infection Stage C: with ischemia Stage D: with infection and ischemia	Risk group 0—No neuropathy, no PVD Risk Group 1—Neuropathy, no-deformity PVD Risk Group 2—Neuropathy and deformity and/or PVD Risk Group 3—History pathology

Abbreviations: IWGDF: International Working Group on the Diabetic Foot, PVD: Peripheral Vascular Disease.

Implications of DFUs

DFUs are a significant healthcare problem. They are common and result in considerable suffering. In addition, DFUs are associated with high mortality, as well as high healthcare costs.[53]

A DFU places a significant burden on people's daily activities, particularly for those with chronic unhealed foot ulceration. DFUs can significant affect quality of life.[11,12] People with unhealed DFUs have poorer HRQOL when compared with those with healed DFUs ($p = < 0.05$) in five of the eight subscales of the Medical Outcomes Short Form-36 (SF-36) (i.e., physical functioning, role limitation—physical, general health, social functioning and mental health).[46] The SF-36 is a commonly used tool for assessing HRQOL.

Patients with non-healing DFUs also appear to become more socially isolated over time, which may be related to embarrassment about the condition.[47] DFUs are painful with acute pain occurring during dressings and while walking. The occurrence of pain among people with DFUs was studied in six hospitals in Oslo, Norway.[48] Ribu et al.[48] found that 57 % of participants with DFUs (n = 127) experienced pain while walking or standing and during the night.

Foot problems are a global health issue associated with increased morbidity and mortality.[49-51] As the prevalence of DM increases, so do foot complications and DFUs that lead to an increase in lower-extremity amputations. More than a half of all DFUs will become infected and require hospitalisation and 20 % of people with DFUs will require lower-extremity amputation.[51,52] In addition, Wu et al.[52] reported that 20 % of all amputees have DM and their amputation was associated with unhealed DFUs and infection.

Foot problems are also associated with high healthcare costs. It has been reported that the cost of amputation ranges between USD 35,000 and USD 45,000 in developed countries.[53] In the US, the total estimated cost of DM in 2007 was USD 116 billion, and approximately 33 % of this cost related to the treatment of DFUs.[54] Moreover, the cost of care for people with DFUs is 5.4 times higher than the cost of care for people without DFUs.[54]

Part 2: Health-related Quality of Life among Adults Living with Diabetic Foot Ulcers: A Meta-analysis

Preamble

This section presents a systematic review of the international literature (Publication 1) on the HRQOL among adults living with DFUs. This publication was originally prepared in 2016 and was updated in November 2018 to include all relevant literature prior to publication. Permission to include the publication within this thesis has been granted.

Abstract

Purpose: To undertake a systematic review of the literature to investigate the HRQOL among adults living with DFUs.

Methods: A systematic search of the medical and nursing/health content databases including MEDLINE, CINAHL, and PsycINFO was conducted up to November 2018. The methodological quality of each study was assessed independently by all authors using the Joanna Briggs Institute checklist. Data analysis was conducted using the Comprehensive Meta-analysis software. All analyses were performed using random-effects models and heterogeneity was quantified.

Results: A total of 12 studies were included in the review. Overall, the HRQOL of participants in the studies was poor on four of eight subscales in the SF-36: physical functioning (mean = 42.75, SE 1.5); role physical (mean = 20.61, SE 3.4); general health (mean = 39.52, SE 1.7); and vitality (mean = 45.73, SE 2.8). In addition, presence of pain, high levels of C-reactive protein (> 10 mg/l), ulcer size > 5 cm^2, ankle brachial index < 0.9, high glycosylated haemoglobin and body mass index > 25 kg/m^2 were associated with poorer HRQOL in people with DFUs.

Conclusions: This review has provided evidence indicating that people with DFUs have a significantly lower HRQOL. Evidence-based interventions to improve the HRQOL in this group of people is needed.

Keywords: Health-related quality of life, Diabetic foot ulcers, Nursing, Meta-analysis

Introduction

Diabetes mellitus is the most common metabolic disease and its prevalence is increasing rapidly. The International Diabetes Federation (IDF) has produced an estimate for 216 countries and territories on the prevalence rate of diabetes.[55] In 2015, 415 million people worldwide had diabetes, and this is expected to rise to 642 million by 2040.[55] The World Health Organisation (WHO) have also estimated that 422 million adults have diabetes and 1.5 million deaths are

caused by diabetes.[56] The prognosis of people with diabetes mellitus remains poor due to the changes in microvascular and macrovascular circulation that occurs with poor glycaemic control.[57] In adults, the most common complication associated with diabetes is diabetic foot ulcers (DFU) which occur due to neuropathy and decreased peripheral circulation.[7] The presence of DFUs can result in permanent disability   and more often amputations related to infection.[58]

Diabetic foot ulcers (DFUs) are a complication that affects up to 14.8 % of people with diabetes mellitus and up to 5.7 % of newly diagnosed diabetic patients.[56,57] Diabetic foot ulcers may cause nerve damage or foot deformity[7,32,56] leading to lower limb amputation. It is reported in the US, that more than 50 % of all amputees have diabetes mellitus type 2.[2] Recurrence of DFU's also poses a problem with recurrence occurring in 39 % of people in the first year and up to 18 % and 12.8 % in the second and third year, respectively.[59] Furthermore, DFUs that get infected can result in permanent disability which is associated with diabetes wound infection.

Living with DFUs has a significant impact on the health-related quality of life (HRQOL) of people with diabetes mellitus.[11,12,60] Boutoille et al.[61] found that people with DFUs had more pain compared to people who had amputations for DFUs ($p = 0.0029$). Using the Iranian version of Medical Outcome Study–Short Form (SF-36), Sanjari et al.[62] investigated the HRQOL in 54 diabetic patients with DFUs and 78 without DFUs. The results demonstrated poor physical functioning, higher bodily pain, and low HRQOL among patients with DFUs compared to those with diabetes and without DFUs.[62] In addition, low HRQOL has been associated with poor prognosis for a variety of health conditions including diabetes complications.[46,63]

Various demographic and clinical factors impact on the HRQOL of people with DFUs. While some studies suggest that males have poorer general health, physical function, and physical role limitation, others report contradictory findings.[11,64] Age also impacts the HRQOL of people with diabetes mellitus with older people having poorer HRQOL compared to younger people.[65] The length of time a person has had diabetes mellitus also impacts on HRQOL. People who have had diabetes mellitus for more than ten years have a poorer HRQOL compare to those with diabetes for a shorter period.[66] In addition, the following clinical characteristics have also been identified as predictors of poor HRQOL among people with type 2 diabetes mellitus: high glycosylated haemoglobin ($HbA_{1c} > 7.5$ %); lower haemoglobin ($Hbg < 13.8$ g/dL for men and 12.1 g/dL for women); high C-reactive protein levels (>10 mg/l); and low ankle-brachial index ($ABI < 0.9$).[67-69]

The literature relating to the HRQOL of people with DFUs and the factors affecting the HRQOL has not been synthesised to enable the development of evidence-based strategies to improve the quality of life of these patients. The purpose of this study was to delineate more precise HRQOL impacts on adults living with DFU by undertaking a systematic review of the literature. This systematic review will enhance the understanding of factors that lead to poor HRQOL among people with DFUs with the aim of improving diabetes care. Knowledge gained from this review will enable the researcher to identify the specific components of human functioning that impact upon HRQOL among people with DFUs. This will guide the researcher to make recommendations

for the development of strategies to improve the HRQOL among people with DFUs.

Methods

This study was conducted using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis) guidelines[70] and the Joanna Briggs Institute's (JBI) checklist for appraising the quality of each included study.[71,72] This systematic review followed the JBI and Cochrane guidelines.[71,72]

Data sources and study selection

To obtain the relevant published papers the databases searched included MEDLINE, CINAHL, and PsycINFO for publication in the English language up to November 2018. The search terms included: "diabet* foot ulcer" AND "quality of life" OR "QOL" OR "health-related quality of life" OR "HRQOL". An initial review of title and / or abstract was conducted to remove duplicates and exclude any articles that did not meet the inclusion criteria. The full text of the remaining papers were retrieved and read in full by the first author (SK) to determine whether the papers met the inclusion criteria. The second and third authors (JS and RF) read all papers and consensus decision-making was used to determine the final articles for inclusion in the review. The references lists of the included studies were reviewed to identify any further relevant studies.

Criteria for inclusion papers

To be eligible for inclusion, studies must have been published in English, used primary quantitative research methods, and include participants who were 18 years of age or older with a DFU. Studies that included participants who had diabetes but no DFUs were excluded. Additionally, if studies did not report data about DFUs separately the papers were excluded (See Figure 6).
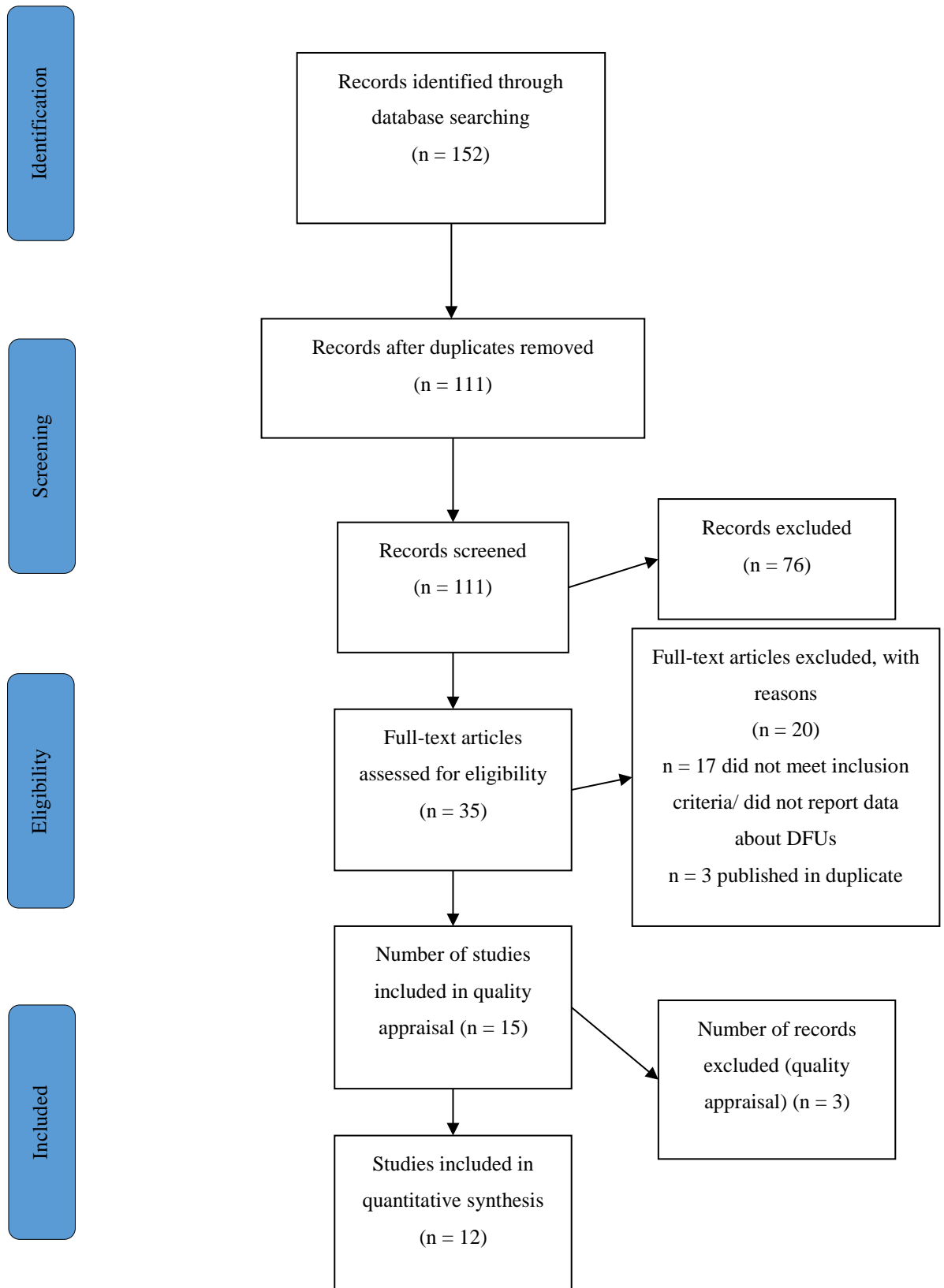
Figure 6: Process of paper selection – Prisma Flow diagram

(Source: Moher et al.[70])

Quality assessment

Critical appraisal of each article was undertaken by the first author (SK) and independently reviewed by the second (JS) and third authors (RF) using either the JBI checklist for cohort studies (11 questions)[71] or the JBI checklists for cross-sectional studies (eight questions).[72] Each question was allocated an outcome: yes, no, unclear, and not applicable. Only studies that had a yes response to more than 50 % of the questions were included in the review. There were no disagreements in the quality assessment of the individual studies among the three authors.

Data synthesis and analysis

Data were extracted from each article and included specific details about the sample, demographics, tools, settings, study methods, and reason for withdrawals and dropouts, as well as any outcomes of significance to the objective of the review. Data were extracted by the first author (SK) and checked by the other authors (JS and RF).

All analysis were undertaken using the Comprehensive Meta-analysis (CMA) version 2 software.[73] Subgroup analyses according to mean age was undertaken to assess whether differences in patient characteristics affected HRQOL. Two sensitivity analysis based on study design and sample size were performed. Heterogeneity was assessed using the X^2 test ($P < 0.1$ being defined as significant heterogeneity) and quantified using the I^2 test.[74] I^2 values of 25 %, 50 %, and 75 % represent low, moderate, and high heterogeneity.[74] Given that the random-effects model is more conservative and assists in controlling for unobserved heterogeneity, all analyses were conducted using a random-effects model, even if the I^2 was low.[75,76] To assess the potential for publication bias, the Egger's test was undertaken and funnel plots constructed for each domain to visualize possible asymmetry.[77] Where meta-analysis was not appropriate the results have been presented in a narrative form.

Results

Study selection

One hundred and fifty-two studies were identified through the search strategy (Figure 6) and were downloaded to Endnote© Version 8. Following removal of duplicates, the title and abstract of 111 studies were reviewed for eligibility and 76 articles were excluded as they did not meet the inclusion criteria. The full text of 35 studies were obtained for further evaluation and a further twenty studies were excluded as they did not meet the inclusion criteria (n = 17) or were published in duplicate (n = 3). Following assessment of the methodological quality of the remaining 15 studies a further three studies were excluded as combining studies of poor quality with those that were more rigorously conducted could lead to a false sense of precision of the results[78]. A total of 12 studies were included in the final review (Figure 6).

Study characteristics

The review included nine cross-sectional and two cohort studies. The studies were conducted in:

Brazil, Belgium, Czech Republic, Denmark, Germany, Italy, Slovenia, Spain, Sweden, Netherlands, London, Iran, Canada, England, and China. The age of the participants ranged between 45 years[46] and 70 years.[79] The number of participants in each study ranged from nine[61] to 1,232[80] The majority of the studies were carried out in European countries and were conducted primarily in clinical settings such as diabetes clinics.

Quality of included studies

The quality scores for the two cohort studies were eight and nine, respectively (maximum score obtainable is 11) and all nine cross-sectional studies obtain the maximum score of eight indicating high quality. The appraisal score for each study is documented in the methods column of Table 4. In all included studies, the exposure to the disease and the outcomes were measured in a valid and reliable way. The follow-up time was reported and ranged between six months[81] and 18 months[82] which was long enough for outcomes to occur. Appropriate statistical analysis was used in all included studies.

HRQOL assessment instruments

The HRQOL was measured using Medical Outcome Short Form (SF-36) in eight studies.[11,48,61,62,64,68,69,82] One study used both the Cardiff Wound Impact Scale (CWIS) and the Medical Outcome Short Form (SF-12)[79], one study used the SF-36 and the Diabetic Foot Ulcers Scale (DFS). [83] The WHOQOL-BREF[84] and Euro-Qol-5D questionnaire (EQ-5D)[80] were used in one study each (see Table 4). All HRQOL instruments used had satisfactory reliability and validity, and are accepted measures for assessing quality of life.[85]

Table 4: Summary Table

Reference	Country	Methods (quality score)	Sample size		Results Mean (SD)							
HRQOL measured using SF36												
					BP	**GH**	**MH**	**PF**	**RE**	**RP**	**SF**	**VT**
Boutoille et al.[61]	France	Retrospective cohort study (9/11)	9		33 (17)	35 (18)	62 (9)	62 (18)	63 (42)	25 (28)	53 (19)	59 (14)
Carlos De Meneses et al.[11]	Brazil	Cross-sectional study (8/8)	15		40.40 (14.80)	44.90 (24.76)	49.3 (26.69)	52.3 (29.02)	20.50 (26.93)	13.30 (26.50)	49.90 (26.38)	43.00 (26.38)
Garcia-Morales et al.[64]	Spain	Cohort study (8/8)	163		62.17 (31.97)	42.36 (18.09)	55.77 (22.28)	44.47 (24.68)	67.68 (44.04)	28.22 (40.45)	61.73 (29.45)	45.52 (21.86)
Sanjari et al.[62]	Iran	Cross-sectional study (8/8)	54		34.9 (26.4)	40.1 (16.2)	47.5 (22.1)	41.1 (22.6)	21.6 (31.1)	21.7 (31.1)	45.3 (24.6)	36.6 (19.6)
Yao et al.[69]	China	Cross-sectional study (8/8)	131		55.83 (28.02)	35.82 (19.93)	57.24 (19.73)	40.59 (25.12)	62.75 (41.66)	15.13 (26.28)	56.62 (21.76)	46.93 (19.66)
Ribu et al.[68]	Norway	Cross-sectional study (8/8)	127	*Patients with HbA1c ≥ 8.3*	54.7 (32.0)	38.5 (25.2)	67.9 (20.2)	48.1 (32.5)	50.0 (46.6)	21.4 (34.5)	61.4 (27.8)	41.1 (26.2)
				Patients with CRP(mg/l) >10	44.6 (29.1)	43.1 (29.1)	68.2 (21.3)	38.2 (27.7)	40.4 (44.6)	13.5 (26.1)	62.5 (31.9)	45.7 (27.5)
				Patients with ABI < 0.9	42.9 (27.3)	38.1 (21.8)	64.3 (21.2)	39.2 (27.2)	38.1 (42.3)	14.3 (29.2)	54.9 (26.4)	39.1 (23.6)

Reference	Country	Methods (quality score)	Sample size			Results							
Ribu et al.[48]	Norway	Cross-sectional study (8/8)	127	No pain	*Patients with no pain While walking / standing*	85.09 (23.27)	57.06 (25.41)	75.71 (21.83)	58.57 (31.60)	72.73 (39.49)	45.45 (42.60)	80.36 (22.75)	56.47 (25.55)
					During the night	76.06 (31.25)	56.16 (25.33)	78.67 (16.15)	58.47 (29.62)	72.46 (38.69)	39.89 (41.59)	82.65 (19.23)	56.25 (23.18)
				Pain A little / some of the time	*While walking / standing Mean (SD)*	53.95 (28.68)	47.11 (25.75)	73.38 (17.40)	54.59 (27.78)	53.66 (38.64)	21.25 (32.79)	67.86 (27.35)	50.60 (23.82)
					During the night Mean (SD)	47.61 (23.90)	41.84 (22.46)	65.77 (18.26)	50.40 (30.41)	41.13 (39.45)	17.39 (28.32)	55.47 (26.91)	45.61 (24.74)
				Pain Most or all of the time	*While walking / standing Mean (SD)*	33.87 (18.31)	34.13 (19.96)	62.82 (17.48)	42.46 (28.48)	41.67 (45.54)	14.67 (28.66)	56.25 (24.12)	37.50 (21.05)
					During the night Mean (SD)	32.48 (16.01)	33.57 (23.07)	63.37 (22.19)	42.66 (27.54)	46.91 (47.38)	15.18 (32.16)	59.91 (27.42)	33.57 (20.18)
Winkley et al.[82]	England	Prospective cohort study (11/11)	253		- Physical component score: 35.79 (12.89)					- Mental component score: 45.71 (15.71)				
Valensi et al.[83]	France	Cross-sectional study (8/8)	239 with DFUs and 116 without DFUs		- HRQOL was significantly lower among those with DFUs in all SF-36 domains (p= 0.0001)									

			(Total 355)					

HRQOL measured using SF12

Goodridge et al.[79]	Canada	Cross-sectional study (8/8)	104	- Physical component score: 35 (8)			- Mental component score: 50 (10)	

HRQOL measured using CWIS

Goodridge et al.[79]	Canada	Cross-sectional study (8/8)	104	- Well-being 35 ± 6 - Physical Symptom and Daily Living 58 ± 5 - Social Life 53 ± 6				

HRQOL measured using DFS

Valensi et al.[83]	France	Cross-sectional study (8/8)	239 with DFUs and 116 without DFUs (Total 355)	- Scores for DFS domains ranged from 41.2 (SD 28.0) for Daily Activities to 79.7 (SD 21.1) for Family Life - Age was significantly associated with several DFS domains including Daily Activities, Physical Health and Dependence. - An independent inverse relationship was found between good HRQOL in DFS domain of leisure and Wagner grade as well as the number of DFUs. - The more severe the Wagner grade, the poorer HRQOL on DFS domains of leisure (p=0.03); Side Effect (p=0.016); Daily Activities (p=0.009); Emotions (p=0.002); and Treatment (p=0.033)				

HRQOL measured using WHOQOL-BREF

Nemcová et al.[84]	Slovakia, Czech Republic, and Poland	Cross-sectional study (8/8)	525	WHOQOL-BREF domains	Total sample (n= 525) Mean (SD)	Slovakia (n= 129) Mean (SD)	Czech Republic (n= 102) Mean (SD)	Poland (n= 165) Mean (SD)	Hungary (n= 129) Mean (SD)
				Physical	11.32 (2.48)	11.31 (2.79)	11.80 (1.9)	12.35 (1.84)	9.64 (2.42)
				Psychological	12.86 (2.76)	13.33 (2.68)	13.82 (2.6)	13.59 (2.14)	10.68 (2.54)
				Social	13.10 (3.03)	13.60 (2.88)	13.92 (2.36)	14.02 (2.91)	10.77 (2.57)
				Environmental	12.83 (2.52)	12.70 (2.57)	13.25 (2.23)	13.80 (2.34)	11.40 (2.24)

HRQOL measured using Euro-Qol-5D								
Siersma et al.[80]	Belgium, Czech Republic, Denmark, Germany, Italy, Slovenia, Spain, Sweden, Netherlands, United Kingdom	Cross-sectional study (8/8)	1,232	EQ-5D index score: Mean 0.58, SD 0.33				
				Mobility (n=1132)	Self-care (n=1124)	Usual activities (n=1123)	Pain/ discomfort (n=1127)	Anxiety / depression (n=1128)
				None 31.9 % Some 62.6 % Severe 5.5 %	None 70.7 % Some 22.9 % Severe 6.4 %	None 48.7 % Some 39.0 % Severe 12.3 %	None 35.5 % Moderate 52.6 % Extreme 11.9 %	None 58.9 % Moderate 35.5 % Extreme 5.7 %

Abbreviations:

HRQOL: Health-related Quality of Life; SF – 36 = Medical Outcome Short Form – 36; DFS = Diabetic Foot Ulcer Scale; DFUs = Diabetic Foot Ulcers; CWIS = Cardiff Wound Impact Scale; SF-36 domains (BP = Bodily Pain, GH = General Health, MH = Mental Health, PF = Physical Functioning, RE = Role Emotional, RP = Role Physical, SF = Social Functioning, VT = Vitality); HbA_{1C} = Glycosylated Haemoglobin; CRP = C-reactive Protein; ABI = Ankle-brachial Index; EQ-5D = Euro-QoL-5D Health Utility Index; SF-12 = Medical Outcomes Short Form – 12. WHOQOL-BREF = World Health Organisation Quality-of-Life Scale

HRQOL

The results from the meta-analysis component of this systematic review are reported using the SF-36 domains. The SF-36 has eight domains and each domain has a minimum score of 0 and maximum of 100. Where meta-analysis was possible, study results were pooled and presented using means, standard estimates (SE) and forest plots. Forest plots for each of the eight domains are presented in Figure 7. For all other studies a narrative summary of results is provided.

Physical functioning – quality of life

Seven studies assessed physical functioning using the SF-36 instrument.[11,61,62,64,69,82,83] Two studies[82,83] did not provide data relating to Standard Deviation (SD) and were not included in the meta-analysis. Pooled data for five studies demonstrated a mean physical function score of 45.58 (SE 2.70; $I^2 = 70.4$ %). Subgroup analysis was undertaken which revealed that in studies that had patients with a mean age of greater than 65 years the mean physical function score was 50.56 (SE 10.68; $I^2 = 91.1$ %) and those involving patients with a mean age of less than 65 years, the mean physical function score was 43.89 (SE 1.75; $I^2 = 7.94$ %). Sensitivity analysis by study design indicated high heterogeneity among cohort studies ($I^2 = 87.1$ %) and low heterogeneity among cross-sectional studies ($I^2 = 11.6$ %). Further sensitivity analysis by sample size revealed low heterogeneity ($I^2 = 18.3$ %) when one study[61] with a small sample was removed. Hence, data for the four studies with large samples were pooled using a random-effects model which demonstrated a mean physical function score of 42.75 (SE 1.5) (See Figure 7).

Narrative analysis of the studies not included in the meta-analysis demonstrated significantly poorer HRQOL as indicated by lower mean scores on all SF-36 domains among those with DFUs compared to those without DFUs.[82,83] In the study using the SF-12 and CWIS instruments (n = 104), a mean score of 37 ± 10 for physical health of participants and a mean score of 58 ± 5 for physical symptoms and daily living was identified.[79] One study that used the WHOQOL-BREF in 525 participants reported a mean score of 11.32 ± 2.48 for physical health.[84] In the study that used the Euro-QoL-5D to assess HRQOL, 68.1 % of the people had mobility limitations and 29.3 % had self-care problems due to DFUs.[86]

Bodily pain – quality of life

Six studies investigated bodily pain using the SF-36 among people who had DFUs.[11,61,62,64,68,69] Five studies[11,61,62,64,69] were pooled in the meta-analysis; however, the results demonstrated high heterogeneity ($I^2 = 93.5$ %). Subgroup analysis by age, and sensitivity analysis by study design and sample size also revealed high heterogeneity ($I^2 > 92$ %). Therefore, using a random effect model, data from the five studies were pooled together which demonstrated a mean bodily pain score of 45.75 (SE 5.7).

An additional study examined the impact of pain severity during walking/standing or during the night on participants with DFU and found that pain had a significant impact ($p < 0.05$) on quality of life.[48] Another study assessed pain and discomfort using the Euro-QoL-5D and reported a high prevalence (84.5 %) of pain and discomfort among people with DFUs[86].

Social functioning – quality of life

Five studies investigated social functioning using the SF-36 among people who had DFUs.[11,61,62,64,69] Pooled data for five studies demonstrated a mean social functioning score of 54.09 (SE 3.2; $I^2 = 77.2$ %). Subgroup analysis revealed high heterogeneity ($I^2 = 88.4$ %) in studies that had patients with a mean age of less than 65 years. Sensitivity analysis by study design indicated high heterogeneity ($I^2 = 77.7$ %) among cross sectional studies and moderate heterogeneity among cohort studies ($I^2 = 40.4$ %). Further sensitivity analysis by sample size revealed high heterogeneity ($I^2 = 82.6$ %) when one study[61] with a small sample was removed. Hence, data were pooled for all five studies using a random-effect model.

One study that used the WHOQOL-BREF reported a mean score of 13.1 ± 3.03 for social health.[84] In the study that used the CWIS, 30 % of participants with DFUs had a decreased ability to enjoy their usual social life.[79]

Role emotional – quality of life

Five studies investigated role emotional using the SF-36 among people who had DFUs.[11,61,62,64,69] Pooled data for the five studies demonstrated high heterogeneity ($I^2 = 96.1$ %). Subgroup analysis revealed high heterogeneity ($I^2 = 97.7$ %) in studies that had patients with a mean age of less than 65 years. Sensitivity analysis by study design indicated high heterogeneity ($I^2 = 96.9$ %) among cross-sectional studies and low heterogeneity among cohort studies ($I^2 = 0$ %). Further sensitivity analysis by sample size revealed high heterogeneity ($I^2 = 97.0$ %) when the study with the small sample size[61] was removed. Hence, data were pooled for all five studies using a random-effects model which demonstrated a mean social functioning score of 46.67 (SE 11.1).

Mental health – quality of life

Seven studies[11,48,61,62,64,68,69] investigated mental health in people with DFUs. Five studies[11,61,62,64,69] were pooled in the meta-analysis, demonstrating a mean mental health score of 55.26 (SE 2.2; $I^2 = 70.3$ %). Subgroup analysis revealed high heterogeneity ($I^2 = 66.9$ %) in studies that had patients with a mean age of less than 65 years. Sensitivity analysis by study design indicated high heterogeneity among cross-sectional ($I^2 = 76.5$ %) and cohort studies ($I^2 = 69$ %). Further sensitivity analysis by sample size revealed high heterogeneity ($I^2 = 65.8$ %) when one study[61] with a small sample was removed. Hence, data were pooled for all five studies using a random effects model.

One study assessed the impact of unhealed foot ulcers on mental health using the SF-12 instrument

and CWIS tool. The mean score for mental health was 50 ± 10 (SF-12) and 35 ± 6 (CWIS).[79] Patients with unhealed ulcers were frustrated with healing and had anxiety about their wounds resulting in a marked negative impact on average well-being.[79] One study that used the WHOQOL-BREF reported a mean score of 12.9 ± 2.76 for psychological domain.[84] The final study[86] assessed anxiety and depression using the Euro-Qol-5D and reported that 41.2 % of participants had anxiety and depression due to DFUs.

Vitality – quality of life

Five studies investigated vitality using the SF-36 among people who had DFUs.[11,61,62,64,69] Pooled data for the five studies included in the meta-analysis revealed a mean vitality score of 45.73 (SE 2.8; $I^2 =$ 80.3 %). Subgroup analysis by age ($I^2 > 74$ %) and sensitivity analysis by study design and sample size also indicated high heterogeneity ($I^2 > 81$ %). Hence, data were pooled for all five studies using a random-effects model.

Role physical – quality of life

Five studies investigated role physical using the SF-36 among people who had DFUs.[11,61,62,64,69] The mean role physical score in the five studies included in the meta-analysis was 20.61 (SE 3.4; $I^2 = 68.3$ %). Subgroup analysis by age indicated low heterogeneity in studies that had patients with a mean age of greater than 65 years and high heterogeneity in patients with a mean age of less than 65 years ($I^2 = 55.5$ %). Sensitivity analysis by study design indicated low heterogeneity in both the cohort studies ($I^2 = 0$ %) and cross sectional studies ($I^2 = 3.8$ %). Further sensitivity analysis by sample size revealed high heterogeneity ($I^2 = 75.6$ %) when one study[61] with a small sample was removed. Hence, data were pooled for all five studies using a random-effects model.

General health – quality of life

Six studies[11,61,62,64,68,69] reported on general HRQOL. Pooled data for five studies[11,61,62,64,69] demonstrated a mean general health score of 39.52 (SE 1.7; $I^2 = 59.1$ %). Subgroup analysis by age demonstrated no heterogeneity. Sensitivity analysis by study design demonstrated low heterogeneity ($I^2 < 50$ %) and by sample size demonstrated high heterogeneity ($I^2 = 67.1$ %). Hence, data from all five studies were pooled using a random-effects model.

In the study by Goodridge et al.[79] mean scores for the well-being component was 35.5 (SD = 6). In addition, the study by Nemcová et al.[84] used the WHOQOL-BREF and reported that the mean score for environmental domain was 11.8 ± 2.52.
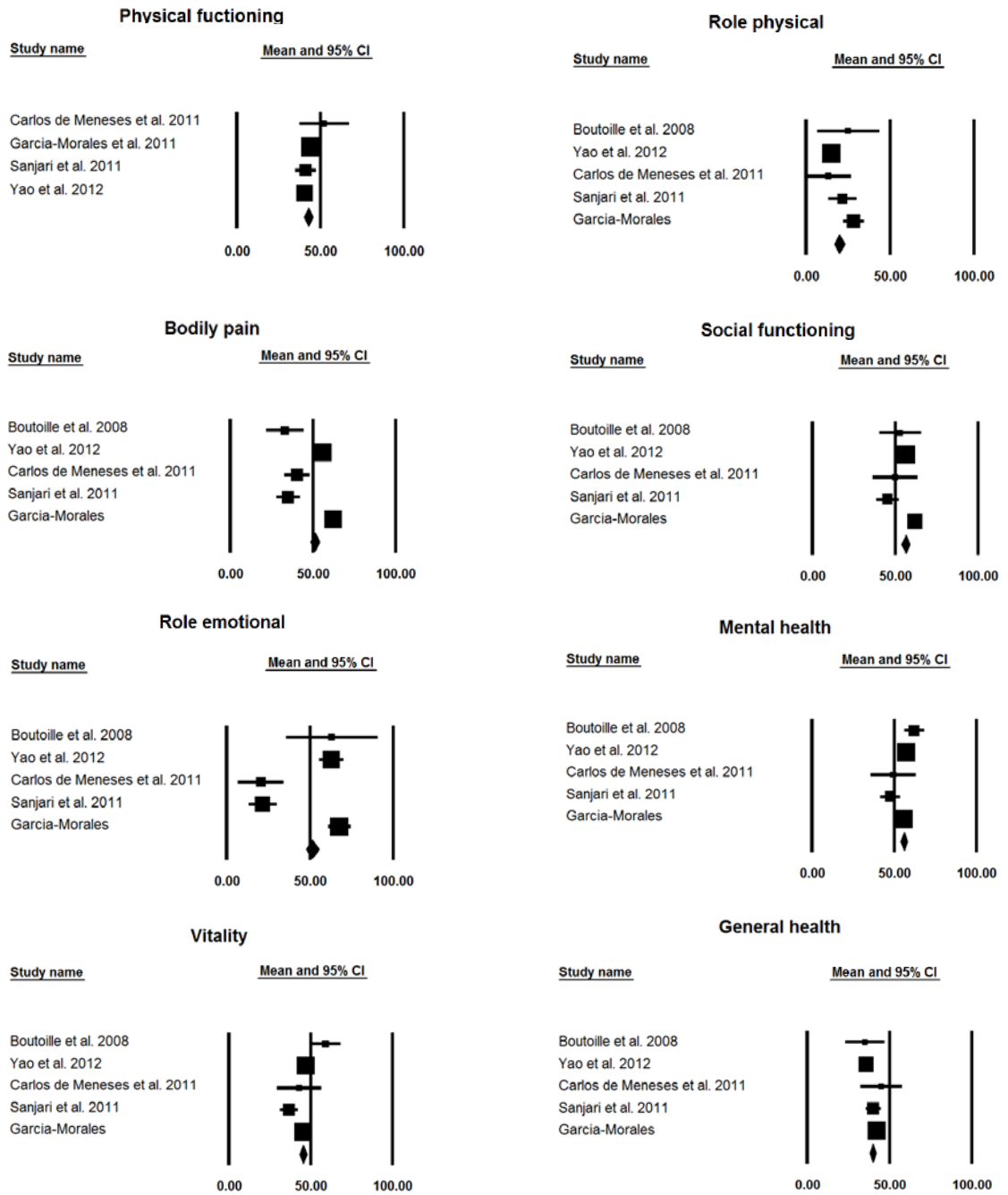
Figure 7: HRQOL according to the SF-36 domains

Predictors of HRQOL

Demographic characteristics

Age

Three[68,79,87] studies reported on demographic characteristics and HRQOL. In the three studies that reported on age, one study[79] reported that age was not a predictor of overall physical or mental health. In contrast, Ribu et al.[68] found that participants aged 67 years and above were more likely to have a lower role emotional score ($p < 0.05$) than those aged 40 to 66 years. Similarly, increased age was also a predictor of lower HRQOL relating to daily activities, physical health and dependence[83] as well as psychological and social well-being.[84]

Gender

Gender as a predictor of HRQOL was examined in four studies.[11,64,68,79] Gender was not a predictor of overall physical or mental health in one study[79]. In contrast, the study by Carlos De Meneses et al.[11] reported that women had a significantly higher overall HRQOL compared to men, however, there was no significant difference between the genders for subscales relating to role physical, social functioning, role emotional and physical functioning. In the remaining two studies, women had significantly lower score for vitality and mental health[68] and overall quality of life.[64]

Marital status

Marital status was not a predictor of HRQOL in participants with DFUs.[79] In one study,[79] marital status was not a predictor of HRQOL in participants with DFUs. However, in the second study, participants living with a partner had significantly higher HRQOL in the psychological and environmental domains.[84]

Body Mass Index (BMI)

Higher Body Mass Index (BMI) was associated with   lower scores in HRQOL relating to the mental health, general health[68,69] and the physical domains.[84]

DFU characteristics

Six studies[48,64,68,69,79,83] investigated the association between DFU characteristic and HRQOL in people with DFUs. The duration of time that a person had a DFU was a significant predictor of decreased physical health[64,79] and increased financial burden[83]. Severity of the DFU using the Wagner scale[88] was also a significant predictor of overall HRQOL in one study[69] and social functioning in another study.[83] Ulcer size greater than 5 cm^2 was significantly associated with poorer domain scores for physical functioning, role physical, role emotional, and mental health domains.[68] Two studies[48,84] investigated HRQOL among those who had pain related to their DFUs. The results demonstrated

significantly lower HRQOL in all domains including physical, social, emotional, psychological and general health among those who had pain.[48,84]

Clinical bio-markers

Two studies[68,69] reported data on clinical bio-markers as predictors of HRQOL in people with DFUs. A C-reactive protein (CRP) greater than 10 mg/l was significantly associated with lower scores on the following SF-36 domains: physical functioning, role physical, bodily pain, social functioning, and role emotional.[68] Ankle-Brachial Index (ABI) less than 0.9 was associated with lower scores in physical functioning, bodily pain, and social functioning domains.[68] Higher HbA$_{1C}$ levels were associated with lower scores on the vitality and general health domains.[69]

Publication bias

No evidence of funnel plot asymmetry was found for the majority of the HRQOL domains (Egger's test: physical functioning $p = 0.28$, social functioning $p = 0.20$, role emotional $p = 0.29$, mental health $p = 0.29$, vitality $p = 0.43$, role physical $p = 0.36$ and general health $p = 0.42$). Significant plot asymmetry was found only for bodily pain (Egger's test $p = 0.03$) which could be due to the small number of studies (see Figure 8).
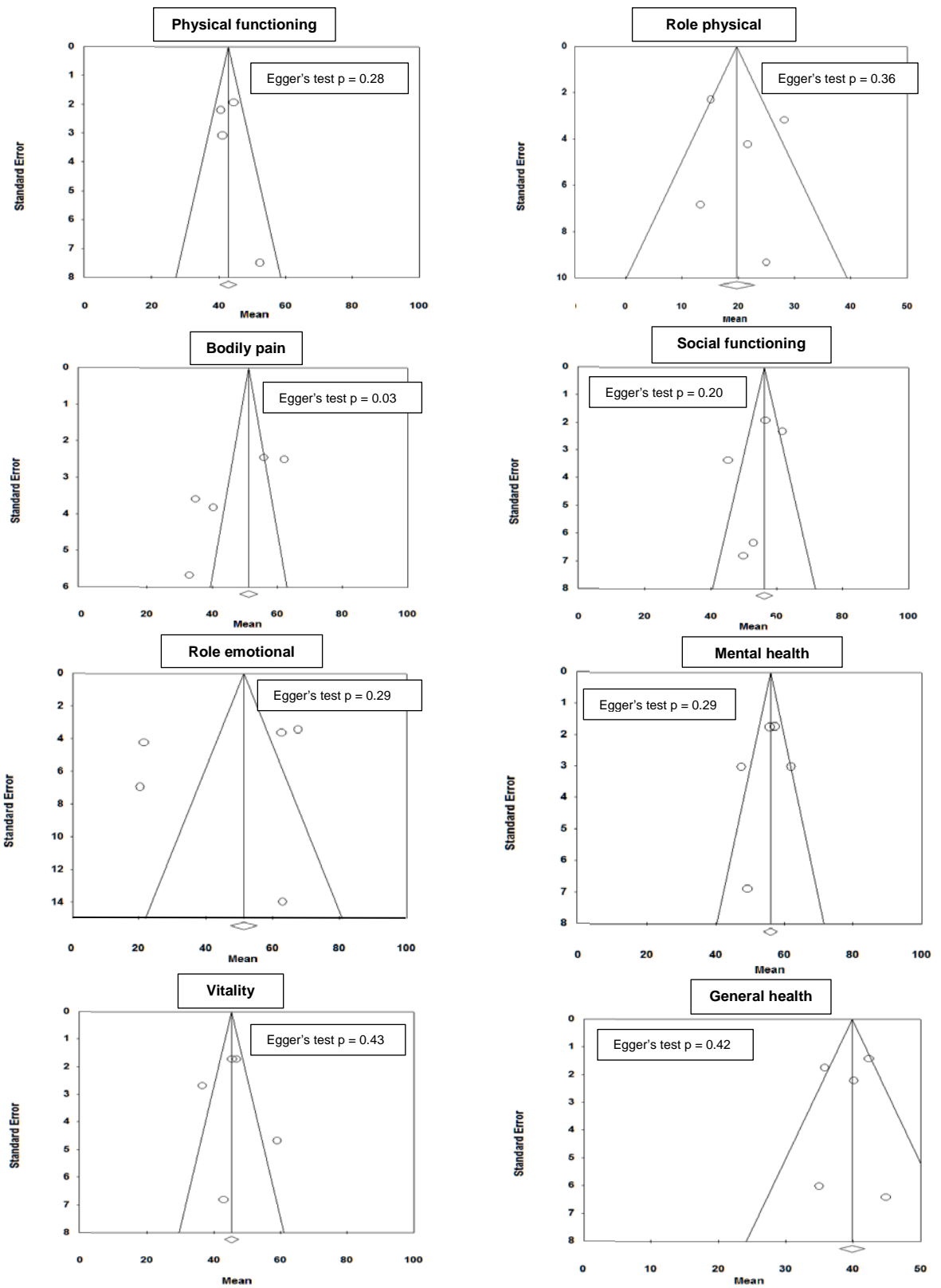
Figure 8: Funnel plot of standard error by mean score of SF-36

Discussion

Diabetic foot ulcers are a major complication of diabetes mellitus and have an impact on the HRQOL of people living with the disease. Following an extensive search of the literature, twelve studies that investigated the HRQOL of people with DFUs were included in the review. The studies included in the review used valid and reliable HRQOL instruments such as the SF-36, SF-12, Euro-Qol-5D, DFS and CWIS. However, the majority of the studies used the SF-36 instrument which is a generic instrument to measure a person's HRQOL and does not specifically focus on HRQOL for people with a DFU. The use of a disease-specific validated tool for people with DFUs such as the DFS or DFS-SF should be used in future studies to assess the HRQOL of people with DFUs.

All studies included in the review reported low scores for HRQOL in all domains for people with DFUs which is congruent with the literature on HRQOL of people with chronic venous leg ulcers.[89,90] The low scores for HRQOL could be due to various factors such as pain, severity of the ulcers, location of ulcers and foot deformation.[80] In this review, people with DFUs had increased bodily pain indicating poor HRQOL. This finding is consistent with the literature where pain has been reported as a predictor of poor HRQOL in people with chronic wounds.[91-93]

A high prevalence (84.5 %) of pain and discomfort among people with DFUs was also identified in this review.[86] This result is not unusual given that people with DFU have diabetic neuropathy that often results in significant pain.[94] The intensity of pain was also identified as having a significant impact on the quality of life of people with DFUs.

Pain was also reported to have a negative impact on social functioning and engagement in leisurely activities.[46] This result is congruent with the evidence obtained from the literature on people with chronic wounds where presence of pain due to leg ulcers prevented people from going out and staying in contact with friends and relatives[91] It is clear from this review that presence of pain has a significant impact on the HRQOL of life of people with DFUs. Therefore, pain management strategies should be implemented for improving HRQOL among people with DFUs. To improve HRQOL and mobility, people with DFUs should consult with an appropriate healthcare professional to provide foot care devices such as off-loading insoles that may minimise pain and discomfort while walking. In addition, pharmacological and non-pharmacological treatments for pain relief may be required to support people with DFUs to maintain mobility and improve HRQOL.

The review also identified low scores for social functioning among people with DFUs which is congruent with the literature.[95] A possible explanation for the low scores could be due to the person focusing on their DFU and its treatment hence not feeling able to socialise. Alternate reasons could be that these people are restricted in their work capacity hence not able to make social contacts. Irrespective of the reasons, it is vital that strategies are implemented to prevent people with DFUs from becoming socially isolated. Social support combined with family support can be effective in

reducing social isolation among people with DFU's.[96,97] Health-care professionals should support people with DFUs to remain active in their community.

The presence of pain, poor physical health and social isolation can often lead to poor psychological well-being of the person with DFU. In this review, the scores for HRQOL relating to mental health were low indicating poor mental health. This result is congruent with the published research indicating that poor physical functioning is directly related to the psychological well-being of people with chronic conditions.[98-100] Given that people with DFUs have poor mental health, access to psychosocial interventions both in the short and long term remains a priority for health services. Peer support groups have been effective in some cultures[101] and psychological support services may also be a useful strategy for some people with DFUs. Most services supporting people with DFU's do not have direct access to psychological support services but this type of service may be warranted given the poor mental health scores evident in this population.

Only three studies included in this review investigated if age was a predictor of HRQOL. The results on age identified contradictory findings with one study reporting that age was not a predictor[79] and the remaining two indicating that older age was a predictor of lower HRQOL relating to physical health and role emotional. This result may be due to factors related to ageing rather than diabetes and DFUs. Similarly, the evidence from this review surrounding gender differences in HRQOL remains inconclusive given that in one study females were identified to have lower HRQOL compared to males[64] and in another males were identified to have a poorer HRQOL.[11] Marital status was not a predictor of HRQOL. Targeted programs to address HRQOL in specific demographic groups could be created to provide appropriate strategies to support people with DFUs. An example of such strategies could include peer to peer support groups for people with DFUs who are experiencing difficulty in healing and have had DFUs for a longer period of time.[101]

In addition to the presence of pain, demographic factors and ulcer characteristics, ABI, and high levels of biomarkers such as CRP and HbA_{1c} have also been reported to be associated with low HRQOL in people with DFUs. This is consistent with the findings in this systematic review. Given these findings, it is important for nurses to be aware of these biomarkers and their association with HRQOL among people with DFUs. This knowledge may assist them to focus care and plan interventions that improve HRQOL.

Limitations

Several potential limitations in this review should be acknowledged. The limited amount of data reported in some studies prevented the inclusion of all studies in the meta-analysis. Second, publication bias may be present due to the inclusion of only studies published in the English language. In addition, some studies had a small sample size which may have impacted upon the results. Lastly, although the HRQOL was assessed using validated instruments, the information was obtained using

self-administered questionnaires and hence is susceptible to social desirability bias. Further large multi-centre research using the interview method for data collection is warranted to identify the HRQOL and the predictors of HRQOL in people with DFUs.

Implications for planning nursing care

Understanding the impact of the clinical characteristics of people with DFUs on their HRQOL is important for planning nursing care. High levels of CRP, ulcer size > 5 cm^2, ABI < 0.9, high levels of HbA$_{1C}$ and BMI > 25 kg/m^2 were associated with poorer HRQOL in people with DFUs.[68]

Currently there are no universally accepted systems for the classification of DFUs, however, the Wagner's DFU Grade Classification system[44] or the University of Texas DFU Classification system[38] are commonly used in the busy clinical settings. The routine use of either of these validated scales for classifying the severity of the DFU should be implemented in practice for the detection and monitoring of DFUs. Management of DFUs should include wound care management that aims to promote healing and minimise the length of time a person has a DFU. Wound care management is an important nursing strategy to improve HRQOL and validated scales for classifying DFU's can assist with monitoring progress in wound healing. It is important for healthcare professionals to implement strategies to improve the HRQOL of people with DFUs. These strategies could include conducting regular follow-ups and assessment of the clinical factors to prevent deterioration in HRQOL among individuals who have these clinical characteristics. A multidisciplinary-focused education programme for people with DFUs on the importance of maintaining glycaemic control and implementing self-care strategies is pivotal to improving care for people with DFUs and decreasing the impact DFUs have on HRQOL.

Focused programs are also required to prevent development of DFUs. This education should include targeted information relating to the importance of improving glycaemic control and HbA$_{1C}$ levels and implementing regular self-care management of their feet. In addition, it would also be beneficial if other healthcare professionals such as occupational therapists or physiotherapists could assess the patients' ability to undertake foot care management particularly as obesity and ageing may reduce mobility and flexibility and thus their ability to carry out these tasks even though they have the requisite knowledge to do so. When a person has a DFU, education and skill development are required to reduce ulcer size and prevent infections. The presence of infection particularly in the deep plantar spaces of the foot can cause pain and increase the time taken for the DFU to heal.[48] This is particularly important given that the findings of this review indicate a negative association between duration of time the person has a DFU and poorer HRQOL and a positive association between pain and poorer HRQOL. Promotion of HRQOL among patients who have a DFU should be part of routine care for this group of patients. It is evident from this systematic review that people with DFUs have a poorer HRQOL. Hence, this systematic review suggests that further research needs to be undertaken to investigate effective strategies to promote HRQOL in this group of people with DFUs.

Conclusion

Evidence obtained from this systematic review indicates that people with DFUs have a significantly lower HRQOL than those without DFUs. Using disease-specific instruments to examine HRQOL (for example the DFS or CWIS) is recommended. Disease-specific HRQOL instruments can assist the healthcare provider to make individualised decisions about care, identify the need for additional professional education and training, and help people with DFUs to recognise their own improvements / decline over time. Agreement on the most appropriate disease-specific tool in this group of people would enable future research to pool and / or compare data so that conclusions can be made about the most effective interventions. Implementation of evidence-based interventions focussing not only on the underlying pathology but also on the quality of life in this group of people is needed.

Part 3: Knowledge and Self-care Management among Adults with Diabetic Foot Ulcers: an Integrative Review

Preamble

The following integrative review of the published literature (Publication 2) synthesises the available research on the knowledge and self-care management skills of people who have T2DM and a DFU. An integrative review was chosen to enable synthesis of research using different research designs. Publication 2 was submitted to SAGE Open Nursing. This publication was originally prepared in 2016 and was updated in November 2018 to include all relevant literature prior to publication.

Abstract

Introduction: Diabetic foot ulcers have become a major public health problem and their prevalence is rapidly increasing. The purpose of this study was to synthesise the primary and secondary research to provide knowledge relating to diabetes self-care management for adults living with diabetic foot ulcers.

Methods: An integrative literature review was undertaken, using publications indexed in MEDLINE, CINAHL, PsycINFO and Scopus published up to November 2018. Primary and secondary research published in peer reviewed journals were appraised against quality assessment criteria using CASP checklist by one author and checked by a second author.

Results: Twelve papers met the selection criteria for synthesis. Three themes were identified: 1) Knowledge as an enabler 2) Actual foot self-care practices and 3) Impact of diversity on DFU development. This integrative review has identified the impact knowledge and foot-self-care management strategies can have on development of diabetic foot ulcers care.

Conclusion: These findings can assist healthcare providers to make decisions on the types of education and self-care management practices to educate people with diabetes.

Keywords: diabetes knowledge, diabetic foot ulcers, integrative review, nursing, self-care management

Introduction

Diabetes has become a major public health problem and its prevalence is rapidly increasing. In the United States, the prevalence of diabetes among older adults has risen from 5.8 % in 1988-1994 to 12.4 % in 2005-2010.[18] In Canada, the estimated prevalence of diabetes is 7.6 % of the population.[19] One of the major complications of diabetes if not managed appropriately is diabetic foot ulcers[102] normally caused from neuropathy. Diabetic foot ulcers are a major complication affecting up to 15 % of people with diabetes mellitus.[8] It has been reported that up to 4.5 % of people newly diagnosed with diabetes mellitus have diabetic foot ulcers.[9] Factors reported to cause foot ulcers among people with diabetes mellitus include changes in the bony structures of the foot, peripheral neuropathy and peripheral arterial disease.[10] Diabetic foot ulcers are the highest cause of hospitalization amongst people with diabetes mellitus.[103] In addition, up to 25 % of people with diabetic foot ulcer(s) require lower limb amputations.[37,104] Living with diabetic foot ulcers has a significant impact on the quality of life of the person affected and their families.[105]

Evidence suggests that in addition to control of blood glucose levels, providing patient education about strategies to reduce the incidence of diabetic foot ulcers will reduce amputations.[106-110] Foot care is an important part of diabetic foot ulcer prevention and should involve daily monitoring.[111] Numerous studies have investigated patients' perceptions of foot self-care practice, self-care behaviour and awareness, prevalence of risk factors in diabetic foot ulcers, and the prevention of diabetic foot ulcers.[112-116] The majority of these studies have focused on prevention of diabetic foot ulcers in residential aged care settings and in the general population. Quandt et al.[117] examined the link between diabetes knowledge, age, income, and literacy levels and found that older participants, people with low incomes, and individuals with low literacy levels, all had lower scores related to their diabetes knowledge. People with low literacy levels also have an increased risk of having diabetes complications particularly diabetic foot ulcers.[118]

There are a small number of studies that examine patient's knowledge and self-care management relating to diabetic foot ulcers. This literature review synthesises the existing studies on the knowledge and self-care management skills of people with diabetic foot ulcers. An integrative literature review technique was chosen to enable different study designs to be explored as part of the review.[119]

Purpose

The purpose of this integrative review was to synthesize primary and secondary research findings relating to diabetic foot care knowledge and self-care management skills of adults who have diabetic foot ulcers to inform future research on the phenomenon.

Methods

This study was conducted using Whittemore and Knafl[119] integrative review framework so that information from various study designs could be synthesized. The steps involved in the review were: problem identification; literature search; appraisal of methodological quality; data analysis; and presentation. The PICOS framework (Participants, Interventions, Comparisons, Outcomes, Study designs) was used to guide development of the research question and is presented in Table 5.[13]

Table 5: PICOS framework

PICOS (Participants, Interventions, Comparisons, Outcomes, Study designs)	
P	People with diabetic foot ulcers
I	Nil intervention
C	Nil comparatives
O	Self-care management and knowledge of DFUs and diabetes
S	Primary quantitative and qualitative research and secondary research

Data sources and keyword searches

A comprehensive search strategy was implemented to identify the relevant literature. The data sources were: MEDLINE, CINAHL, PsycINFO, and Scopus. A search of the electronic databases was conducted using the following key terms, truncation and Boolean combinations: "diabetic foot ulcer*" OR "diabetic foot sore*" OR "diabetic foot" OR "diabetic foot wound" AND "self care" OR "self management" OR "self-care" OR "self-management" AND knowledge. References from the selected studies were screened to identify any further studies which were not retrieved in the initial search.

Inclusion and exclusion criteria

Studies were included if they were published in English; used either primary research methods (quantitative and/or qualitative) or secondary research methods (systematic review and meta-analysis); were peer reviewed; published up to November 2018; included data on assessment of patient knowledge and self-care management of people with DFUs; and included participants aged 18 years or older. Studies that included people who did not have a diagnosis of type 2 diabetes mellitus and people with foot ulcers related to foot deformities and general injuries were excluded (see Table 6).

Table 6: Study Eligibility Criteria

Inclusion	Exclusion
Adult aged ≥ 18-year-old	Participants who did not have a diagnosis of T2DM
Published in English	Participants who did not have a diabetic foot ulcer
Peer reviewed	(DFU)
Primary and secondary research	Participants with foot ulcers related to an accident,
Type 2 diabetes mellitus with active foot ulcers	foot deformities and injuries
Assessment patient knowledge and self-care or self-care management	Did not describe the knowledge or self-care management in people with DFUs
Published up to 2017	Editorials, discussion papers, conference papers, expert opinions

Search outcomes

Results from all electronic database searches were downloaded into Endnote© Version X8.[120] The search identified 232 publications that were potentially relevant to the review (see Figure 9). Following removal of duplicates, 140 publications remained. Evaluation of the title and abstract of each article against the inclusion and exclusion criteria was undertaken by one author and then checked by a second author; this excluded an additional 119 publications. Full text copies of 21 potentially eligible studies were obtained. Two researchers read each article independently to determine if it met the inclusion and exclusion criteria. Nine studies were excluded as they did not assess patient knowledge (n = 1); or did not report specifically on people with diabetic foot ulcers (n = 8). Following this review 12 studies were included in this review.

Appraisal of methodological quality

Checklists from the Critical Appraisal Skills Programme (CASP) specific to the research design of each included study were used to appraise the methodological quality.[121] Appraisal of methodological quality was undertaken by one author (SK) and then independently reviewed by another author (JS). Any disagreements were resolved via discussion. Two studies were identified as low quality[122,123] but were included as they contributed to understanding of the problem being explored.

Data analysis

The data from all included studies were abstracted into a summary table by one author (SK) and then reviewed by all authors. Thematic analysis was used to compare and contrast the findings in each of the studies using the guidelines published by Braun and Clarke.[124] One author (SK) presented a potential thematic structure which was discussed and agreed with all authors.
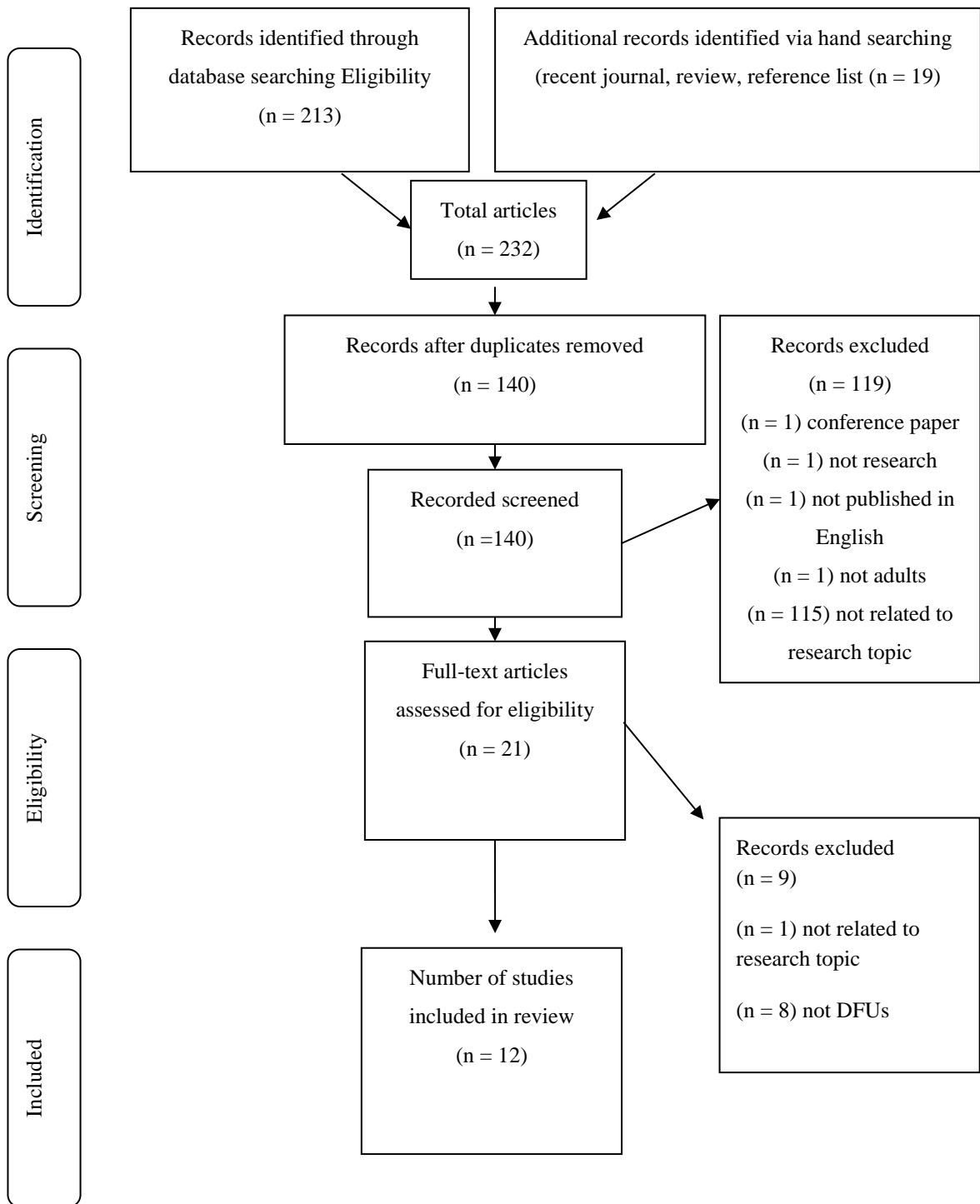
Figure 9: Process of paper selection - PRISMA Flow diagram

(Source: Moher et al.[70])

Results

A narrative summary of the included studies is presented in Table 7.

Included papers and demographics

A total of 12 studies were included in the final review (see Figure 9). The studies were conducted in a range of different countries including: India, Tanzania, Sweden, Ethiopia, Thailand, the United States of America, Slovakia, and the United Kingdom. The sample size in the included studies ranged from six[125] to 404.[126] The majority of the studies used a cross-sectional design (n = 8)[108,113,122,123,126-129] and four qualitative studies[97,125,130,131] were also included. No secondary research was identified that met the inclusion criteria.

Only three of the 12 studies had a population with a larger number of female participants.[122,126,127] Participants' age was not reported in all studies. Where reported, participants ranged in age from 18 to 86 years[97,122,130] with the mean age reported as varying between 49.8 to 61.08 years.[108,129] Seven studies included the clinical characteristics of participants and where provided these are summarised in table 3. The clinical characteristics included: duration of diabetes, duration of DFU, medications, presence of risk factors (neuropathy, peripheral vascular disease, smoking history, BMI), and HbA$_{1c}$. The presence and severity of DFU was reported in most studies with four studies explicitly using the Wagner classification system.[97,108,123,128] One study also used the University of Texas diabetic wound classification stages and grading tool.[123] The remaining studies stated that a person had a DFU but data on the severity of the DFU was not provided.

The key themes from the literature were: 1) Knowledge as an enabler 2) Actual foot self-care practices and 3) Impact of diversity on DFU development.

Table 7: Summary Table

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Chellan et al.[113]	To examine risk factors for DFU's; and evaluate relationship between knowledge, attitude and practice (KAP) of diabetic foot care between patients with and without DFUs	India	203 people (103 with DFUs; 100 without DFU)	A cross-sectional study	KAP questionnaire on diabetic foot care	67.5 % males 59.9 ±11.4 years 29.1 % on insulin 37.1 % on OHA 33.0 % on insulin + OHA DFU group had a DFU on the Wagner classification system for wounds but no summary data provided	• In DFU group, occurrence of DFU increased with duration of diabetes. Incidence of DFU at < 10 years of diabetes = 37.8 %; between 10-20 years = 58.8 %; > 20 years = 70.3 % (compared to 29.7% in non-DFU group who had diabetes > 20 years ($p < 0.001$)). • 30.1 % of people with DFUs had poor foot care knowledge (compared to 14.0 % in non-DFU group) • Poor foot care practice assessed in people with DFUs = 39.8 % patients (compared to 9.0 % of people without DFUs ($p < 0.001$)). • Risk factors of diabetic peripheral neuropathy; peripheral vascular disease; retinopathy; nephropathy; smoking; pan-chewing; alcohol consumption all significantly ($p < 0.001$) associated with DFU development

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Chithambo and Forbes[125]	To explore patient reasons for the delay in seeking help for foot problems related to diabetes.	England	6 people with DFUs	Interpretative Phenomenol-ogical Analysis	Qualitative interview guide	Age range (49 to 69 years) Duration of diabetes (8 months to 49 years) All with active DFU's (2 with history of amputations)	• Participants reported variations in information provided to them about foot risk. Those with more detailed information did not translate this into prompt action when they identified foot problems. • Those living alone or with vision impairments had difficulties completing foot care behaviours • Participants were able to detect foot problems but still delayed seeking help and necessary treatment. • Most common DFU presentation was a blister which participants tended not to regard as significant. • Two participants experienced delayed secondary referral by GP. The consequences of non-referral in primary care were one person being hospitalised for 3 months and the other 7 months.

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Chiwanga and Njelekela[126]	To determine current prevalence of DFU and assess knowledge and practices of foot care among patients attending public diabetes clinic.	Tanzania	404 people (62 with DFU; 342 without DFU)	A cross-sectional study	Knowledge assessed using open ended questions (Authors own tool – max. score =23) Summary of Diabetes Self-care Activities (SDSCA) measure Clinical measures: Modified Neuropathy Disability Score (NDS); Ankle brachial pressure index (ABPI); presence of DFU	55.4 % female 53.6 ± 12.7 years 15.3 % people had DFU (no Wagner scoring provided) 44 % people had peripheral neuropathy 15.0 % people had peripheral vascular disease	• The mean scores of knowledge on diabetes foot care was 11.2 ± 6.4 SD (Maximum score = 23). Scores were similar among people with and without DFU. • Higher means scores were associated with higher level of education, longer duration of diabetes, and having received information on foot care. • A total of 48.0 % of people had previously received information about foot care. Participants received education from nurses (83.5 %); doctors (16.6 %) and media (6.2 %). • Foot self-inspection were completed regularly (6-7days per week) by 37.9 % of patients. When a person had a DFU, this fell to 37.1 % of patients. • A total of 27.5 % of people reported having their feet examined by a doctor at least once since their initial diagnosis.

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Hjelm and Apelqvist[130]	To describe beliefs about health and illness among foreign-born people with DFUs regarding self-care and health-care seeking and, also to study whether there are dissimilarities related to origin.	Sweden	26 people with DFUs	A qualitative descriptive study	Semi-structured individual qualitative interviews	76.92 % males Aged 38-86 years old (median: 59.5 years) 13 born in European counties 12 born in Middle East 1 born in South America Duration of diabetes (median: 22 years; range: 8-36) Duration of DFUs (median: 7 years; range 0-14 years) DFU group reported complications but no DFU status provided	• Patients received limited advice or no advice at all concerning daily foot care. The healthcare providers said "take a foot bath and rub the feet". No more details were provided. • Some of participants sought help from professional podiatrists or physicians at the diabetes clinic or health-care centre. Others sought help in their home countries. • The wives of male patients were the key persons to perform self-care management procedures. • Self-care management was influenced by religious practices, particularly among Muslims. There was a positive influence on hygiene care related to praying in combination with rituals such as washing their feet and other parts of the body. • Limited knowledge about managing hyperglycaemia or hypoglycaemia was given when medication and treatment was changed.

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Khunkaew et al.[97]	To explore the experiences of Thai adults in northern Thailand living with DFUs	Thailand	13 people with DFUs	A qualitative descriptive study	Semi structured interview	Seven female and six male Average Age (years) was 63.46 years old (range 52-76 years). Wagner's Classification Grade 1 = 6 Grade 2 = 7	• Using a cotton bag or wearing a sock to protect the wound on their feet from dust was a common self-care management strategy. • Using the Phlong (to be clam) and Thum Jai (think positive) techniques can reduce stress from unhealed DFUs. • Sandals are a suitable footwear choice among Thai people because of the weather (which is hot and humid). • Moderating carbohydrate consumption was a strategy used by many participants. This involved avoiding having tropical fruits, dessert and sticky (glutinous) rice.

Mahakalkar et al.[123]	To evaluate the pattern of distribution of foot ulcers in diabetic foot patients.	India	30 people with diabetic foot ulcers	A cross-sectional study	Wagner's classification and University of Texas diabetic wound classification	70 % males Aged range (32-78 years) Duration of diabetes (8.20 ± 10.06 years) Wagner's classification Grade 1 n=5 Grade 2 n=6 Grade 3 n= 9 Grade 4 n=6 Grade 5 n= 4 University of Texas diabetic wound classification Stages & grading IA n= 3 IB n=4 IC n= 0 ID n=0 IIA n=1 IIB n=12 IIC n=0 IID n= 6 IIIA n= 0 IIIB n=0 IIIC n=0 IIID n= 4	• Foot ulcers were spread evenly across feet: left foot (50 %); right foot (46.7 %); both feet (3.3 %) • A high percentage of foot ulcers were at fifth metatarsal (53.3 %), followed by heel (26.7 %) and great toe (10 %) • The majority of the people had DFUs of Wagner grade 3 (Deep ulcer with abscess or osteomyelitis) and University of Texas diabetic wound classification of II B. • 20.0 % of participants had a prior amputation • 36.7 % of participants had foot deformity • 56.7 % of participants had insensitivity to 5.07 S-W monofilaments • 43.3 % of participants had impaired vibration • 40.0 % of participants had abnormal Achilles tendon reflex • 30.0 % of participants had impaired posterior tibial artery • 33.3 % of participants were found to have ankle-brachial index lower than 0.8 • 46.7 % of participants were found to regularly walk barefoot. • 13.3 % of participants had customised footwear

Mariam et al.[129]	To determine diabetic foot ulcers and associated factors among adult with diabetes mellitus	Ethiopia	279 people (38 DFUs; 241 without DFUs)	Cross – sectional study	A structured and pretested questionnaire (Author's own)	55.2 % males Mean age was 49.8 with SD ± 15.6 years 6.5 % smokers BMI between 18 and 24.5 kg/m^2 38.6 % had diabetes more than 6 years 13.6 % people had DFU (no Wagner scoring provided)	• The following factors were found to be significantly associated with DFUs: Residence (AOR= 2.57; 95 % CI: 1.42, 5.93), type of diabetes mellitus (AOR= 2.58; 95 % CI: 1.22, 6.45), overweight (AOR= 2.12; 95 % CI: 1.15, 3.10), obesity (AOR= 2.65; 95 % CI: 1.25, 5.83), foot self-care practice (AOR= 2.52; 95 % CI: 1.21, 6.53), and neuropathy (AOR= 21.76; 95 % CI: 8.43, 57.47). • People with diabetes living in rural areas were 2.75 times more likely to develop DFUs than those who live in an urban area (AOR= 2.57; 95 % CI: 1.42, 5.93). • People who had type 2 diabetes were 2.58 times more likely to develop DFUs than those who had type I diabetes (AOR= 2.58; 95 % CI: 1.22, 6.45). • Overweight diabetic patients were 2.12 times more likely to develop DFUs as compared to diabetic patients with normal weight (AOR= 2.12; 95 % CI: 1.15, 3.10). • Obese diabetic patients were 2.65 times more likely to develop diabetic foot ulcers as compared to diabetic patients with normal body mass index (AOR= 2.65; 95 % CI: 1.25, 5.83). • Diabetic patients who had not practiced foot self-care were 2.52 times more likely to develop

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
							diabetic foot ulcers than those diabetic patients who had practiced foot self-care (AOR= 2.52; 95 % CI: 1.21, 6.53). • Diabetic patients who had neuropathy were 21.7 times more likely to develop diabetic foot ulcers as compared to those diabetic patients without neuropathy (AOR= 21.76; 95 % CI: 8.43, 57.47)

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Navicharern[128]	To examine the correlation between diabetes self-management, fasting blood glucose and quality of life among patients with diabetic foot ulcers.	Thailand	80 people with diabetic foot ulcers	A cross-sectional study	WHOQOL-BRIEF-THAI and Summary of Diabetes Self-care Activities (SDSCA)	51.3 % males 37.5 % of DFUs had no income 35 % of DFUs were primary school education level 61.3 % had diabetes more than 10 years Severity of foot ulcers (Wagner grade) Level 1: 61.5 % Level 2: 25 % Level 3: 6.3 % Level 4: 2.1 % Level 5: 5.2 %	• SDSCA measures self-reported behaviours on last 7 days (High mean = high levels of adherence to the measured concept) • Highest mean score on SDSCA were for medication adherence (mean = 5.58); Diet control (mean = 4.16); hygiene and foot care (mean = 4.14) • Lowest mean score on SDSCA were for exercise (mean = 1.03) • "Moderate" scores of QOL were reported by 78.8 % of participants • There was a negative relationship between high fasting blood glucose levels and quality of life (r=-0.35, p <0.05). • High score in diabetes self-management were associated with higher quality of life (r=0.35, p< 0.05).

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Neil[122]	To illustrate the findings on self-care practices related to foot care of people with diabetes mellitus.	America	61 people live in rural area (24 with DFU; 37 without DFU)	A cross-sectional study	Modified Siriraj Foot – Care Score Questionnaire	49.18 % males Age range (18-81 years) Duration of diabetes (mean 8.5 years) Duration of having DFU (mean 2.5 years) 83 % people had DFU (no Wagner scoring provided)	• 78.3 % of people with foot ulcers checked their feet at least five times a week. • 79.2 % of people with foot ulcers cleaned their feet once a day. • 79.2 % of people with foot ulcers used soap and water to clean their feet. • 6.3 % of people with foot ulcers used knives or razor blades to cut their nails. • 17.4 % of people with foot ulcers did not wear shoes outside • 54.2 % of people with foot ulcers went barefoot inside the house.

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Nemcová and Hlinkova[108]	To evaluate the efficacy of diabetic foot care education.	Slovakia	100 people (52 with DFU; 48 without DFU)	A cross-sectional study	Using structured assessment based on the practical reasoning scheme	53 % males BMI overweight ≥ 25: (n=32) HbA$_{1c}$ 5.3 - 13.8 %: (n=73) Smoker: n = 27 57.9 % of people with DFUs: Wagner's grade 3-5	• People with diabetic foot ulcers had a higher level of knowledge (p = 0.028) regarding foot care (x = 80.37 %) than people with IDLE (x = 72.71 %). • People with IDLE were more willing and motivated to be educated than patients with diabetic foot ulcers (IDLE x = 78.55; DFS x = 70.43). • Regardless of education approach (group or individual) there was statistically significant (p = 0.037) difference in willingness and motivation to be educated following the education program. • The organisation and format of education (individual vs. group) impacted on willingness and motivation to participate (p = 0.001). • Education program was effective as all clinical parameters showed significant positive changes six months after education (p < 0.05).

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Searle et al.[131]	To explore the psychological impact on behavioural factors that influence both the incidence of chronic wounds and their progression.	The United Kingdom	44 people (26 with DFU; 18 without DFU)	Qualitative study	Interview	65.38 % male Mean age for people with DFUs was 67 years 69.23 % had DFUs related to T2DM 59.09 % of people had DFUs (no Wagner scoring provided)	• Participants with DFUs were often not able to recall key recommendations for foot care immediately following consultations. • Some participants did not understand the cause of DFUs and were unaware of how to prevent DFUs occurring. • Poor circulation was perceived to be the primary reason for amputations. Injuries or foot ulcers were only thought to lead to amputations in rare cases. • People with foot ulcers had difficulty engaging in the foot care management outside of the consultations with podiatrists. • Some podiatrists felt frustrated and unsupported to empower and build partnerships with people with foot ulcers.

Reference	Aim	Country	Sample	Methods	Instruments	Demographics & DFU status of participants	Findings
Sriussadaporn et al.[127]	To examine behaviour in self-care of the foot and foot ulcers in Thai non-insulin dependent diabetic patients.	Thailand	165 people (55 with DFU; 110 without DFU)	A cross-sectional study	Questionnaire foot-care management (Author's own)	76.4 % females DFU locations: 25.4 % at first toe and first metatarsal head, 18.4 % at lateral malleolus, 16.4 % at sole, 12.8 % at pretibial area, and 12.7 % fifth toe. Duration of DFU range 9-360 days (mean 36.4 ± 50.2 days) Of patients with DFU (n=55) 92.7 % had one DFU, 7.3 % had two DFUs, 89.1 % had concomitant infections, and 24.5 % had gangrene 54.5 % occurred on right leg	• Foot self-care management questionnaire had total score of 20. High mean scores indicate good self-care management practices. • The mean score in foot inspection, foot cleaning, nail care and use of footwear were lower in DFU group. • The Foot cleaning score was significantly lower in people with foot ulcers compared to people without foot ulcers (7.35 ± 0.21 vs 7.88 ± 0.11; $p < 0.05$). • The risk of developing foot ulcers was significantly increased by 2.5 fold with a total self-care score less than 15 (OR = 2.6, 95 % CI 1.3 – 5.6). • 38 % of participants were able to recognise the antecedent events of foot ulceration • 45.5 % of people with foot ulcers neglected their foot ulcers • 54.5 % of people with foot ulcers inappropriately care for their wounds

Abbreviations: ABPI = Ankle brachial pressure index; BMI = Body Mass Index; DFU = Diabetic Foot Ulcer; GP = General Practitioner; HbA$_{1c}$ = Glycosylated Haemoglobin; IDLE = Ischaemic Disease of Lower Extremities; KAP = Knowledge, Attitude and Practice; NDS = Neuropathy Disability Score; OHA = Oral Hypoglycaemic Agents; SDSCA = Summary of Diabetes Self-care Activities; T2DM = Type 2 Diabetes Mellitus; WHOQOL-BRIEF-THAI = World Health Organisation Quality of Life Brief Thai version

Theme 1: Knowledge as an enabler

Diabetic foot care knowledge has been identified as an enabling factor for prevention of a DFU. Two studies examined the knowledge levels of people living with diabetes and found deficiencies in knowledge of foot self-care among people with and without DFU's. One study undertaken in India with 103 participants identified that diabetic foot care knowledge was poor in 30.1 % of participants with DFUs in comparison to 14.0 % among those without DFUs.[113] Another study reported that having a DFU did not influence knowledge about foot care when compared to people without DFUs; this finding may have been influenced by the fact that only 48 % of people with a DFU in this study had received foot care education.[126] The impact of knowledge on foot self-care practices was examined by Sriussadaporn and colleagues[127] who found that 61.7 % of all participants with a DFU were unable to recognise the antecedents to developing their own foot ulcer. The source of educational information is also important. One study undertaken in a public diabetes clinic in Dar es Salaam in Tanzania reported that of the 194 participants (48 %) who had received foot care, education came from nurses (83.5 %); doctors (16.6 %); and other sources such as the media (6.2 %).[126]

In terms of willingness and motivation to be educated, one study used an educational intervention to measure knowledge and the impact it had on foot self-care practices.[108] Participants were allocated to either individual or group foot care education programs which included information on: diet and diabetes, self-assessment of their feet, footwear selection, solutions to problems with the feet, diabetic ischaemic disease of the lower extremities, and foot exercises.[108] Significantly higher levels of knowledge, willingness and motivation regarding foot care ($p = 0.028$) were identified after the intervention regardless of whether individual or group education was used.[108] The education program was deemed effective, as all reported clinical parameters showed significant positive improvements six months after the educational intervention.[108] No follow up was examined beyond this time point.

People with DFUs are reported to have low levels of knowledge about foot care which impacts on their awareness of their foot problem and perceptions about wound care. Three qualitative studies aimed to explore patient problems related to diabetic foot care.[125,130,131] People with DFUs were shown to be lacking awareness, were hardly able to recall what the healthcare providers had told them and had difficulty engaging in foot care management outside of consultations with podiatrists.[131] Another study also reported that people with DFUs tended not to regard their problems as significant.[125] Participants in Chithambo and Forbes[125] study did not convert the knowledge they had about DFUs into prompt action for treatment when they identified foot problems. In Hjelm and Apelqvist's[130] study patients reported receiving only limited or no advice at all concerning foot care. This translated into low levels of health-seeking practices within this population of overseas born Swedish residents. In contrast, Khunkaew et al.[97] found that people with DFUs used their knowledge to initiate self-care strategies. In the qualitative study of 13 individuals with DFUs, many participants reported using a cotton bag or a sock to protect the wound from dust when shoes were not available or not suitable.[97]

This action indicates that knowledge influenced the self-care management practices. In addition most respondents reported that they moderated their diet in an attempt to reduce their blood glucose levels by avoiding and/or moderating the quantity of tropical fruits, dessert and sticky rice that they consumed.[97]

Theme 2: Actual foot self-care practices

Foot self-care management practices are crucial to prevention and management of DFUs. Seven studies examined foot self-care practices. The Summary of Diabetes Self-Care Activities measure (SDSCA) was used by two studies.[126,128] One study[122] used the Modified Sriraj Foot-Care Score questionnaire and all other studies[113,123,127,129] used questionnaires developed by the research teams.

In the study by Chiwanga and Njelekela[126], foot self-inspection was completed regularly (defined as 6-7 days per week) by 37.9 % of all patients. In the group with an existing DFU this fell to 37.1 %.[126] People with DFUs reported some high-risk behaviours, such as: not inspecting the inside of shoes (69.4 %); walking barefoot outside (62.9 %); and using sharp instruments to cut nails (91.9 %).[126] In addition, shoe selection is important for people with DFUs. Shoes need to fit correctly and be breathable. A qualitative study undertaken in Thailand reported that sandals with heel straps were the most commonly selected shoe.[97] Participants reported that even though the government supplied shoes for people with diabetes in Thailand, participants did not wear them because of the climate in Thailand and their preference for shoes that were breathable.[97]

Neil[122] also reported high-risk behaviours among people who had DFUs: 17.4 % went barefoot outside the house; 54.2 % went barefoot inside the house; and 6.3 % used knives or razor blades to cut their nails. Navicharern[128] used mean scores to assess SDSCA responses where a maximum score was 7. The mean scores for self-management related to medication adherence was 5.58, diet control was 4.16 and hygiene and foot care was 4.14; the lowest mean score was for exercise (mean = 1.03).[128]

Similarly, findings from other self-report studies identified poor foot self-care management practices. Chellan and colleagues[113] identified that 39.8 % of patients with a DFU had poor foot-care practices in comparison to 9.0 % of people without a DFU ($p < 0.001$). In an Indian population of people with DFU's, 46.7 % of participants reported walking around barefoot on a regular basis and only 13.3 % of participants used customised footwear.[123] In an Ethiopian study of 279 participants (38 of whom had a DFU), diabetic patients who did not practice foot self-care practices were 2.52 times more likely to develop a DFU than those patients who did (OR = 2.52, 95 % CI 1.21-6.53).[129] Sriussadaporn et al.[127] reported that there was a significant difference in self-care practices between people with DFUs compared to people without DFUs (7.35 ± 0.21 vs 7.88 ± 0.11; $p < 0.05$). It was reported that 45.5 % of people neglected their foot ulcers and 54.5 % of people with foot ulcers used inappropriate methods or materials to care for their wounds.[127]

The cross-sectional studies that explore self-care management of DFUs do not examine why people with DFUs demonstrate poor self-care management practice. The qualitative studies included in this review provide some insight into this phenomenon. The study by Chithambo and Forbes[125] found that participants were able to detect foot problems when they occurred but still delayed seeking help because antecedents such as a blisters were not regarded as significant. Hjelm and Apelqvist[130] reported that patients received limited advice or no advice at all concerning daily foot care. The healthcare providers were reported by participants to give general advice and this type of advice was seen as unhelpful by participants.[130] Some healthcare providers, such as podiatrists, felt frustrated and unable to empower patients to engage in adequate foot care outside the consultation.[131] Similarly, participants were often unable to recall what the healthcare providers had told them and had great difficulty engaging in foot care management outside of the consultations.[131] For some participants this meant that they sought alternative sources of assistance with family members taking on a key role for diabetic foot care.[125,130] This reliance on others was successful in some cases but became problematic when the support person was not available to help or had another disability such as blindness or partial loss of vision.[125,130] In the study undertaken in Thailand[97], the wealth of family members played a role in the quality of wound care products chosen and in the use of specialist footwear. Participants who did not have access to additional funds to support care reported alarming practices such as the use of alcohol, herbal medicines and toothpaste on wounds as cleansing products.[97]

Theme 3: Impact of diversity on DFU development

Many studies explored the demographic, location and cultural differences among people with and without DFUs. Higher mean scores of knowledge about foot self-care management were related to participants' level of educational attainment, length of time they had diabetes and whether they had received education on foot self-care management by a healthcare provider.[126] Location was also found to be significant factor with 54.2 % of people living in rural areas going barefoot outside the house.[122] The practice of not wearing shoes outside and their rurality meant that rural participants were 2.75 times more likely to develop a DFU than those who lived in an urban area (OR= 2.57; 95 % CI: 1.42-5.93).[122] In addition, type of diabetes had an impact, with people who had been diagnosed with type 2 DM being 2.58 times more likely to develop DFUs than those who had type 1 DM (OR= 2.58; 95 % CI: 1.22-6.45).[129]

Comorbid conditions and foot deformity also impact on development of DFUs. Mahakalkar et al.[123] found that people with foot deformity (36.7 %), neuropathy (56.7 %), impaired vibration (43.3 %) impaired posterior tibial artery (30.0 %) and ankle-brachial index lower than 0.8 (33.3 %) were more likely to have foot ulcers. Mariam et al.[129] indicated that obese diabetic patients were 2.65 times more likely to develop diabetic foot ulcers (OR= 2.65; 95 % CI: 1.25-5.83); and people with neuropathy were 21.7 times more likely to develop DFUs (OR= 21.76; 95 % CI: 8.43-57.47) as compared to those diabetic patients without these complications.

The rationale for why people with demographic and cultural differences have different outcomes related to DFU development is not always clear. Chithambo and Forbes[125] identified that people who live alone or have vison impairments frequently find it difficult to participate in foot self-care management behaviours. Self-care management was found to be influenced by religious practices in the qualitative study undertaken by Hjelm and Apelqvist.[130] This was particularly the case among Muslim participants where a positive influence on hygiene was related to rituals around praying and washing of the feet at places of worship.[130] Similarly, Khunkaew et al.[97] found that Phlong (to be calm) and Thum Jai (think positive) were techniques that helped participants in Thailand to reduce stress from unhealed DFUs. Identification of culturally appropriate techniques such as this may assist people to manage and/or prevent DFU development.

Discussion

This integrative review was undertaken to synthesise the existing research to provide knowledge relating to diabetes self-care management for adults living with diabetic foot ulcers. Despite the extensive literature on management of diabetes there was limited literature on self-care knowledge and foot self-care management practices of adults living with diabetic foot ulcers. The findings of this integrative review suggest that the link between knowledge about self-care management practices and the use of self-care management strategies on a daily basis for people with DFUs is not clear. This is consistent with findings from a systematic review undertaken in 2012 which found that education programmes alone are insufficient and additional strategies for the prevention of DFUs are necessary.[107] This creates a challenge for healthcare professionals to identify how they can link knowledge about why a person needs to use self-care management practices and the actual use of those practices on a regular basis so that DFUs can be prevented. One study in this review[108] demonstrated that an educational intervention can play a significant role in improving knowledge if it is structured and delivered as part of a package of care. The program resulted in significant improvements in clinical characteristics at six month follow-up. Longer term follow up is required to evaluate the efficacy of this type of holistic education program.

The evidence from this review demonstrates that improved knowledge regarding foot care occurs when a person participates in formal education programs.[108] However, low literacy levels and socioeconomic status were factors that affect self-care management among people with DFUs.[126] For example, people who developed a blister did not take any further action to manage it as they did not recognise that it was significant in terms of foot self-care management.[125] This is similar to findings from Desalu et al.[132] among people with diabetes mellitus which found that 68.8 % of respondents were unaware of what they should do when they found redness/bleeding between their toes. As a result of this information, education programs need to be targeted at the needs of the individual, incorporated into routine care and evaluated so that the efficacy of education programs on an individual's knowledge of self-care management practices can be assessed as part of clinical care.

This integrative review should provide the impetus for healthcare professionals to review existing education programs and ensure that education programs are integrated into clinical care so that self-care knowledge in people with diabetic foot ulcers is enhanced. Education that is provided must be individualised and knowledge of participants must then be assessed as part of the program. The use of knowledge to then impact upon foot self-care management practices is pivotal to ensuring people with diabetes who are at risk of developing DFUs and people with an existing DFU practice effective foot self-care management practices. One challenge for healthcare professionals is to decide whether to educate people with diabetes who are at risk of developing DFU's in a group setting or on an individual basis. Further evidence is required to identify the efficacy of different approaches.

This review has shown that there are improvements that can be made to the coordination and integration of education on self-care management into clinical care for people with diabetes to prevent and manage DFUs. Specialist advice should be available to support people with their self-care knowledge requirements. Evidence suggests that when self-care education is provided and understood by participants that it impacts self-care practices.[108] Multi-disciplinary teams need to work together to design appropriate interventions to minimise complications that can occur from diabetes. All people with diabetes should receive education on self-care management to prevent diabetic foot ulcers.

There are a few limitations to this review. The majority of studies used cross-sectional design, and as a result could not assess the cause and effect of knowledge regarding self-care management in an adult living with diabetic foot ulcers. Only five studies used validated tools to assess knowledge and foot self-care management practices. In addition, there was no benchmarking between studies and limited data about the contents of education interventions which made it difficult to evaluate and compare the effectiveness of different diabetic foot care education programs. Another limitation of this review was the inability to identify any reliable evidence to demonstrate the impact of knowledge on self-care management of people with diabetic foot ulcers. Robust evidence is required to explore both the potential of quantitative and qualitative designs to inform the best methods of preventing foot ulcers amongst people living with diabetes mellitus.

Conclusion and recommendation

This integrative review has identified a number of factors that impact upon the effectiveness of diabetic foot care education programs among people with diabetic foot ulcers. Healthcare professionals need to design education and self-care management programs that combine clinical management and education into an integrated program that meets individual participant's needs. All healthcare professionals working in diabetes management settings should be educated about what causes DFUs and should integrate education into routine clinical care. This approach then needs to be rigorously evaluated. A specific focus on prevention of DFUs and the self-care management skills required by people with diabetes mellitus to prevent DFUs is required as part of routine care. Specific

attention on developing programs which can reduce DFUs in individuals with low literacy levels and in developing countries is also warranted.

Conflict of Interest Nil conflicts

Part 4: T2DM in the Thai Context

Background

Thailand is located in Southeast Asia and is classified as a country in the upper-middle income group.[133] Recently, successful economic development has led to urbanisation.[134] A large percentage of the population demonstrates low levels of physical activity and high carbohydrate consumption.[134] The status of DM in Thailand is similar to other countries, it is experiencing an increase in the number of people with diabetes.[135] Related factors include more people who are overweight or obese and physically inactive.[135,136] In addition, the population in Thailand is ageing.[137] This leads to a higher risk of non-communicable diseases (NCDs) such as T2DM.[137,138] A National Health Examination Survey was conducted in Thailand in 2009 and revealed that 7.5 % of people aged over 15 years had DM and an additional 7.5 % of people had impaired fasting glucose.[139] Although, the prevalence study did not specify diabetes type, it can be reasonably assumed that the vast majority of cases in Thailand are T2DM. A cohort study in Thailand examined the cumulative incidence of T2DM among 39,507 people who did not have DM at the beginning of the study. The overall cumulative incidence of T2DM in this cohort was 177 per 10,000 people (95 % CI 164 to 190).[140]

Thailand has a unique set of factors that influence the effectiveness of evidence-based strategies to manage T2DM. These factors include inadequate access to specialist treatment; the effect of Thai culture on managing risk factors; beliefs, including religious beliefs of individuals and socio-demographic factors.[116,141-143] The following section explores the specific factors identified as affecting people with T2DM and DFUs in Thailand with a focus on HRQOL, diabetes knowledge and self-care management skills.

HRQOL of people with T2DM

In a literature review undertaken in September 2018, two studies were identified that explored the HRQOL of people with T2DM in Thailand.[144,145] One study that focused on women reported a moderate satisfaction with life.[145] This study identified that the most significant factors that affected the HRQOL for women were cultural, financial and lack of family support.[145] In addition, a family-oriented diabetes education program that was based on theoretical underpinnings and delivered by nurses significantly improved the HRQOL of people with T2DM.[144]

Diabetes knowledge of people with T2DM

Only one Thailand study explored knowledge among people with T2DM.[144] This study examined a family-oriented self-management program aimed at improving self-efficacy, glycaemic control and quality of life among people with T2DM. The results showed that within the intervention group (measured at baseline, week 5 and week 13) participants had significantly increased diabetes

knowledge at week 5 and 13 ($p < 0.001$).

Self-care management among people with T2DM

Eight studies from Thailand investigated self-care management among people with T2DM.[141-144,146-149] A randomised controlled trial identified that a family-oriented self-management program improved patients' self-management score by 14.3 points over 13 weeks [β = 14.3, (95 % CI 10.7-17.90, $p < 0.001$)].[144] The same randomised controlled trial also identified that a self-management support program was effective in reducing mean HbA_{1c} (-0.14 %, 95 % CI = -0.02 to -0.26), reducing fasting plasma glucose (-6.37 mg/dl, -1.95 to -10.78), improving health behaviour (3.31 score, 2.27 to 4.34), and improving quality of life (1.41 score, 0.69 to 2.12) after 6 months.[147] Higher levels of social and family support were significantly associated with overall self-care management, physical activity and medication-taking behaviour in two studies[146,149] and were a key factor in the successful integration of disease management in participants' lives in the other studies.[141-143]

DFUs in Thailand

The high prevalence rate of T2DM in Thailand, leads to complications related to diabetes and, in particular, foot problems. A large comprehensive foot examination survey undertaken in Thailand found between 15 % and 26 % of participants with diabetes reported foot problems.[135] In addition, 5.9 % had a history of DFUs. In another study, 8.9 % of people with DFUs had lower-limb amputations arising from infected diabetic foot ulcers.[150] Preventing DFUs and managing foot problems are important activities for general practitioners (GPs), nurses, clinical staff and other healthcare providers in Thailand.

Management of DFUs among people with DM in Thailand is a major cause of hospitalisation for many. Often, long-term hospital stays are required for DFU management. These treatments are related to chronic wound care and lower-limb amputations.[151] Over 50 % of lower-limb amputations are associated with DFUs.[2] Evidence from a tertiary care hospital in Thailand that used a multidisciplinary approach to care found that 82.1 % of the admissions for DFUs achieved complete healing.[103] In this centre, the multidisciplinary team was led by a diabetologist using the model of care illustrated in Figure 10. Patients received a high standard of professional care, leading to excellent results for individual patients related to healing, as well as improved HRQOL. Unfortunately, this model of care is not widely used in Thailand due to the lack of specialists outside of this facility in Bangkok.[135] People with low incomes and those living in regional locations do not receive this model of care. Therefore, clinical guidelines need to be established to improve care in regional locations.
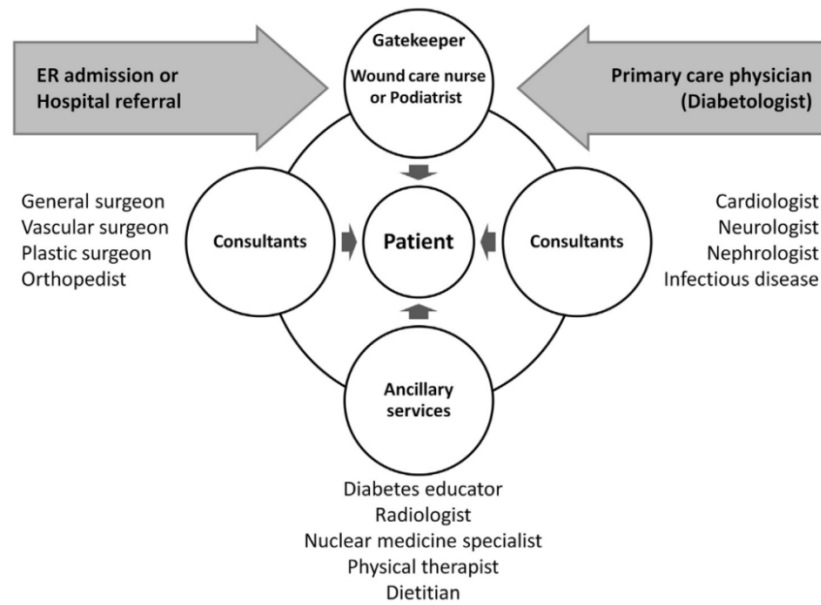
Figure 10: Diabetic foot ulcers management in a tertiary care hospital in Bangkok

(Source: Thewjitcharoen et al.[103])

Since the 1970s, the Thai government has developed and implemented a healthcare system, delivered necessary infrastructure at district level and trained a healthcare workforce to reduce NCDs.[152] In addition, the Thai government has established the Thailand Healthy Lifestyle Strategy 2011–2020 plan that aims to use a multi-sectoral approach to reduce the prevalence rate of NCDs including diabetes.[134]

Factors affecting care

Thailand has its own specific problems that are influenced by various factors including access to specialist treatments, culture, beliefs, religion and socio-demographic features of people with T2DM and DFUs.[116,141-143] Historically, Thailand has not had specialists that look after people with diabetic foot ulcers. Serious diabetic foot infections are generally managed by surgeons or orthopaedists.[135] This means that individuals in regional locations are usually seen by generalists and do not receive expert advice. Cultural factors also affect the management of DM. Lundberg and Thrakul[141] found that the Thai people they studied perceived that diabetes is related to their Buddhist beliefs. They believed that diabetes was caused by their action either in a past life (i.e., karma) or a current life. Hence, they accepted their disease and tried to change their lives by making amendments and following the Buddhist way of moderate eating.[143] Traditional Thai foods are mainly eaten with rice or glutinous rice that is high in carbohydrates.[143] People with diabetes try to eat less rice to reduce their carbohydrate consumption and thus control their blood glucose levels.[143] In addition to rice, Thai people also reduce the consumption of sweet tropical fruits such as durian, ripened mango, lychee, longan, orange, pineapple and rambutan (i.e., hairy lychee) to try to control their blood glucose levels.[143]

Many studies have been conducted to address the prevention and management of diabetes complications.[141-143] However, no previous study has investigated the HRQOL of Thai adults who have T2DM and the associations between HRQOL, diabetes knowledge and self-care management in this population. It is also evident that the experiences of Thai adults living with foot ulcers due to T2DM have not been previously studied. For this reason, this study sought to explore the HRQOL, diabetes knowledge, self-care management skills and lived experiences of Thai adults in a regional location with T2DM and with and without DFUs.

Summary

This chapter presents a discussion of the literature relating to T2DM and DFUs. This includes background related to DM, T2DM and DFUs and two publications that explore HRQOL, diabetes knowledge and self-care management of people with DFUs. In addition, specific issues related to the Thai context were described. The next chapter presents the methodology used in this project and explores the methods used to answer the research questions.

Chapter 3

Methodology

The purpose of this chapter is to present and explain the theoretical perspective and the methodology that has been used in this study. The study also presents the research methods including data collection, data analysis and ethical considerations.

Theoretical perspective

Self-care involves the individual's engagement in activities to maintain an optimum level of health and well-being.[153] In the context of diabetes, self-care involves seeking appropriate medical assistance, having knowledge of the illness or disease condition, effectively carrying out prescribed treatments, accepting the illness and learning to live with diabetes. Self-care deficit occurs when an adult is incapable or limited in providing continuous, effective self-care due to illness, injury or disease.[153] Nursing care may be needed when the patient is unable to provide effective self-care.[154]

For this study, the Orem self-care deficit nursing theory (SCDNT)[154] was adopted. According to Orem's Self-Care Deficit Nursing Theory:

- individuals should be responsible for their care and not reliant on others for care
- each individual is different
- nursing care is an action and collaboration between two or more people
- preventing illness requires the individual to successfully carry out self-care activities
- individuals require knowledge of their health condition in order to adopt self-care behaviours
- self-care and dependent care are behaviours learned within a sociocultural context.

Kumar[153] claims that the concept of self-care deficit is the balancing between the self-care agency and self-care demand. The balance between self-care agency and self-care demand can be seen in Figure 11.

Self-care agency is defined by Orem[154] as the ability of the individual to engage in self-care and take care of one's self. Therapeutic self-care demand includes the actions that are needed to be performed to maintain health and well-being.[153] In the context of this study, self-care agency refers to the capacity of the Thai individual to manage their diabetic medications, diet and physical activity, undertake blood glucose monitoring and care for their feet and DFUs (if present) (see Figure 11, b). Orem's self-care deficit nursing theory: The variations in self-care agency and self-care demand
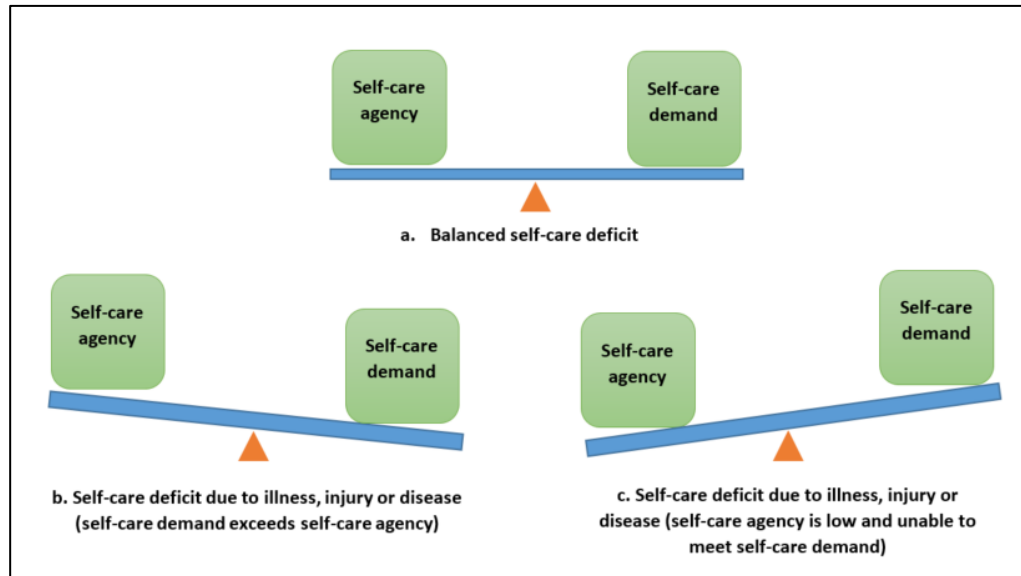
Figure 11: Orem's self-care deficit nursing theory: The variations in self-care agency and self-care demand

Therapeutic self-care demand refers to actions that need to be undertaken to prevent further complications of diabetes.[154] It is important for the individual to have the knowledge, attitudes and skills to engage in self-care relating to T2DM and DFUs [154] (see Figure 11, c). Therefore, the self-care deficit nursing theory will provide a useful conceptual framework to best formulate and conduct this proposed research to illuminate the need of self-care management in people with DFUs.

Methodological approach

This study was undertaken using a mixed methods approach. Mixed methods research is the combination of quantitative and qualitative methods in the same research project regardless of whether the dominant approach is a quantitative or qualitative method.[13,155,156] Creswell and Plano Clark[157] expanded on this definition by stating that:

> Mixed method research is a research design with a philosophical assumption as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of quantitative and qualitative approaches in many phases of the research process. As a method, it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single or series of studies. 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 (p. 5).

This definition clearly states the methods and philosophical orientation of this research design. Thus, the purpose of mixed methods research is to build on the strengths and reduce the weaknesses of both quantitative and qualitative approaches.[155,158] Further, it can lead to better understanding of complex phenomena such as nursing.[156] There are many studies undertaken using the mixed methods design[155] that have been used to address important nursing questions in

different areas such as nephrology[159], aged care[160], mental health[161], pediatric oncology[162] and chronic diseases (e.g., diabetes, chronic obstructive pulmonary disease [COPD] and cancer).[163,164] This study is conducted using an explanatory, sequential mixed methods research design.

Study design

Six mixed methods research design strategies have been reported in the literature.[165] These include: Sequential Explanatory Design, Sequential Exploratory Design, Sequential Transformative Design, Concurrent Triangulation Design, Concurrent Nested (Embedded) Design and Concurrent Transformative Design. This study used a sequential, explanatory mixed methods research design. This method has been widely used and accepted in nursing research projects.[161,163,166,167] In this method, the quantitative data is collected followed by the qualitative data collection. The purpose is to use the qualitative findings to explain the quantitative (i.e., significant or nonsignificant) results.[155]

Mixed methods notation system

Polit and Beck[13] described how Morse made an important contribution to conceptualising mixed methods research by 'proposing a notation system that has been adopted by virtually all writers across disciplines' (p. 609). The system involves notation for priority approach and sequencing.[168]

Priority approach is indicated by upper case and lower case letters. For example, QUAL/quan designates a mixed methods study in which the dominant approach is qualitative, while QUAN/qual designates a mixed methods study in which the dominant approach is quantitative. QUAL/QUAN designates a mixed methods study in which neither approach is dominant. Sequencing is indicated by the symbols → or +. The arrow designates a sequential approach. For example, QUAN → qual is the notation for a primarily quantitative mixed methods study in which quantitative data collection occurs first. When both approaches occur concurrently, a plus sign is used: i.e., QUAL + quan.

In this study, quantitative data was collected from Thai adults with T2DM with and without DFUs relating to HRQOL, knowledge of diabetes and self-care management. The qualitative data was collected to provide an explanation and an in-depth understanding of the quantitative data. Hence, the notation system for this study was QUAN → qual[155] (see Figure 11).
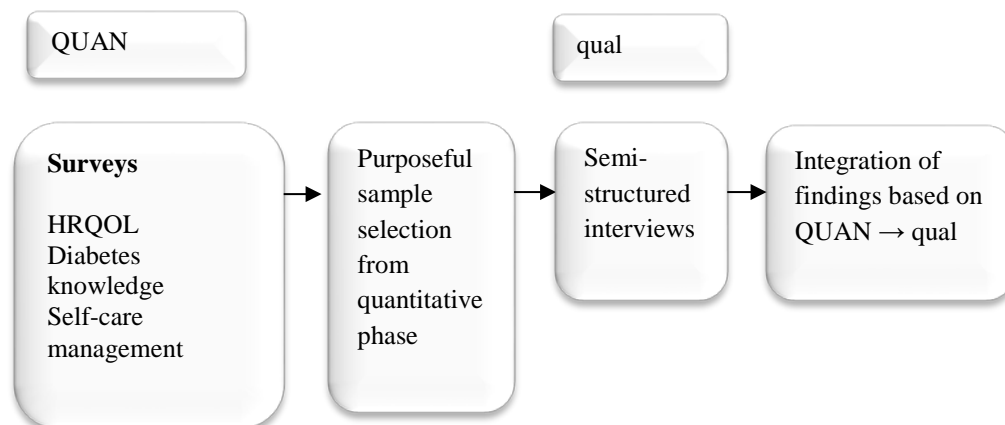
Figure 12: The sequential explanatory mixed methods design used in this research project

(Source: Creswell and Plano Clark[155] and Ivankova et al.[166])

Quantitative phase

The research questions in the quantitative phase of this project were to investigate the following:

1. What is the HRQOL and the clinical and demographic predictors of HRQOL among Thai adults with T2DM?
2. What is the diabetes knowledge of Thai adults living with T2DM?
3. What is the HRQOL and self-care management practices among Thai adults living with DFUs?

This phase of the research was undertaken using a cross-sectional survey. A cross-sectional survey measures the health characteristics of the participants in the study at a given point in time.[13,169] Polit and Beck[13] claim that cross-sectional studies are appropriate for describing the characteristic of phenomena or describing a relationship among phenomena at a fixed point in time.

Setting and Sample

The setting for this study was a diabetic outpatient clinic in Uttaradit Hospital in Uttaradit, Thailand. Uttaradit is located in the northern part of Thailand (500 kilometres from Bangkok and 250 kilometres south of Chiang Mai). Uttaradit Hospital is a public hospital in Uttaradit Province under the jurisdiction of Thailand's Ministry of Public Health. The hospital is the major medical centre for the province and patients with poorly controlled T2DM and/or complications from T2DM, such as DFUs, are referred to the diabetes outpatient clinic from the local district level hospitals.

Consecutive sampling was used to recruit participants in this study. Data was collected over a three-month period during 2016. Based upon attendance records at the clinic in preceding years, we anticipated that approximately 500 participants would be eligible to participate in this research.

Participants were provided with information about the study while in the waiting area of the diabetic outpatient clinic or in the diabetic foot screening room. Participants were only eligible to be included in the study if they met the inclusion criteria.

Inclusion criteria

People were included in the study if they were:

1. older than 18 years
2. attending the outpatient diabetes clinic at a specific tertiary teaching hospital
3. diagnosed with T2DM
4. willing to participate
5. able to read or understand the Thai language.

Exclusion criteria

People who had cognitive impairment or communication difficulties were excluded.

Data Collection

Nursing staff in the diabetes outpatient clinic provided all eligible participants with information about the study using a standardised script. The researcher or a trained research assistant then approached those willing to participate. Four research assistants were trained by the researcher to assist with data collection by attending a half-day workshop on data collection techniques and participating in a supervised mock data collection trial. The researcher or the research assistant then approached those willing to participate and written informed consent was obtained.

The cross-sectional study was undertaken using a self-administered questionnaire (see Appendix 2). Participants were asked if they wished to complete the questionnaire themselves or if they would prefer the interview method. The questionnaire took approximately 10-20 minutes to complete. The respondents completed the questionnaire in waiting area before going to see the doctor. For those who completed the questionnaire via the interview method, the researcher read the questions out loud to them and recorded their responses onto the paper questionnaire form.

Self-administered questionnaire

The self-administered questionnaire included questions relating to participant demographics, wound characteristics, HRQOL, knowledge of diabetes and self-care management of DFUs (see Table 8). A brief description of the instruments is presented below. A detailed description of the instruments is presented in the corresponding chapters. Permission to use the questionnaire (both English and Thai versions) was granted by the instrument developers.

All instruments that were not already available in the Thai language were translated into Thai using standard translation methods including back translation to ensure accuracy.[13] Further, a pilot study involving 30 patients was undertaken to examine the final survey.

Participant demographics

The following data were collected: gender, age, marital status, education, income, occupation, length of time since diagnosis with T2DM, current diabetes pharmacological treatment, most recent Glycosylated Haemoglobin A1c (HbA$_{1c}$), BMI and grade of foot ulcers (if present) using the Wagner[170] classification method.

HRQOL

HRQOL was assessed using the Diabetic-39 (D-39) survey[176] among all participants. Participants who had a DFU at the time of the survey also completed the Diabetic Foot Ulcer Scale-Short Form (DFS-SF)[177] to assess HRQOL (see Table 8).

Diabetic-39 (D-39)

The Diabetes-39 (D-39) questionnaire was used for assessing the HRQOL of participants. This questionnaire was developed by Boyer and Earp[171] and has been used for assessing HRQOL in people with diabetes.[85,172-174] The D-39 has been translated into many languages.[175] This study used the D-39 questionnaire that was translated into Thai by Songraksa and Lerkiatbundit[176]. The D-39 has five dimensions: diabetes control (13 items), anxiety and worry (4 items), social burden (6 items), sexual functioning (3 items), energy and mobility (10 items) and other health problems and diabetes complications (3 items).[171] The reliability of the D-39 questionnaire has been reported to be greater than 0.7.[176] A detailed description of this instrument is presented in Publication 3 (Chapter 4).

DFS-SF

HRQOL among people who had a DFU at the time of the survey was measured using the DFS-SF.[177] The DFS-SF contains a total of 29 items comprising six subscales: leisure (5 items), physical health (5 items), dependence or daily life (5 items), negative emotions (6 items), worries about ulcers and feet (4 items) and bothered by ulcer care (4 items).[177] The reliability of this questionnaire has been reported as greater than 0.74.[177] A higher score on the DFS-SF indicates better HRQOL. Although this questionnaire has been translated into many languages, the Thai version was not available; therefore, permission to use the DFS-SF was granted by Mapi Research Trust and a forward–backward translation into the Thai language was undertaken. A detailed description of this instrument is presented in Publication 5 (Chapter 6).

Knowledge of diabetes

The Simplified Diabetes Knowledge Scale (SDKS)[178] was used to assess participants' knowledge of diabetes. The SDKS was developed from the Michigan Diabetes Knowledge Scale[179] and consists of 20 items pertaining to diet, risk factors and self-management[178]. Values for Cronbach's alpha of the SDKS range from 0.69 to 0.71.[178] Given that a Thai version of the scale was not available, the SDKS was translated to the Thai language using forward–backward translation and was linguistically and psychometrically validated. The Thai version of the questionnaire, T-SDKS,

was administered to all participants. T-SDKS comprises of seven sections: socio-demographics (9 items), general knowledge of diabetes (8 items), risk factors (4 items), symptoms and complications (11 items), treatment and management (11 items), monitoring (5 items) and diabetes in women (3 items). For each section, the respondents were asked to answer 'Yes', 'No' or 'Don't know'. A detailed description of this instrument is presented in publication 4 (Chapter 5).

Self-care management

Only people with DFUs completed the VA-diabetes Foot Care Survey[180] to assess their self-care management knowledge and practices. There are three dimensions of behaviour examined in this survey: foot self-care, footwear and foot care-seeking behaviours. The instrument is scored on a 5 point Likert scale in which 1 = Not at all, 2 = Once or Twice a Month, 3 = Once a Week; 4 = Several Times a Week and 5 = Daily. Permission to translate this questionnaire was granted[180] and back translation was obtained by using a panel of bilingual nutritionists, nurses and clinicians.[13,181] A detailed description is presented in Publication 5 (Chapter 6).

Table 8: Survey Tools

Questionnaire	All participants	Participants with DFUs
Demographics	X	X
Diabetes-39	X	X
Thai Simplified Diabetes Knowledge Scale (T-SDKS)	X	X
Diabetic Foot Ulcers-Short Form	-	X
Self-care management	-	X

Statistical analysis

All data were entered into the SPSS software version 21.[182] Descriptive statistics were used to summarise demographic, HRQOL score, knowledge of diabetes and self-care management practices. Pearson product-moment correlation was used to examine the correlation between continuous variables such as HbA_{1c}, knowledge and HRQOL. Significant factors in the bivariate analysis were included in the multiple linear regression models to investigate the unique association of individual factors with the HRQOL score and knowledge of diabetes while adjusting for other covariates. A detailed description of the statistical analysis is presented in the Chapters 4 and 5.

Qualitative phase

The aim of the qualitative phase was to explore the experiences of Thai adults living with DFUs to explain the quantitative results and obtain a better understanding of their experiences. Face to face interviews were used in this phase of the research.

Setting and Sample

Interviews were conducted in a quiet place that ensured participants privacy. Most interviews were conducted in the participants' home or in a private room prior to, or following, their next appointment at the outpatient clinic.

Purposive sampling was used in this part of the study and all participants were recruited from the quantitative phase of the research project. Participants were recruited using the following inclusion criteria.

Inclusion criteria

People were recruited in the study if they:

1. participated in the quantitative component of this study
2. were aged over 18 years
3. were diagnosed with T2DM
4. had one or more DFUs
5. agreed to participate.

Exclusion criteria

People who had a cognitive impairment, people who were unable to consent to participate, and people who could not speak Thai were excluded.

Data collection and data analysis

A detailed description of the methods and data analysis is presented in Publication 6 (Chapter 7). In brief, a qualitative research approach using in-depth face-to-face interviews was selected to explore the experiences of Thai adults living with DFUs in northern Thailand. The interview guide was developed from phase 1 of the research and a systematic literature review. The interview schedule included a series of open-ended questions and is available in Appendix 4. Each participant was interviewed once for around 30-45 minutes. Interviews continued until data saturation occurred.

Thematic analysis was used to analyse responses with a constructivist orientation.[124] Based on this approach, the researcher gathered, analysed and interpreted the experiences, realities and meanings from the participants in this research in a way that was culturally appropriate and used the subjective experiences of their lives to construct knowledge and build understanding on this research question.[183,184] Data was audio-recorded and transcribed in Thai. Data analysis then occurred in the Thai language and was subsequently translated to English to ensure meaning was maintained following translation. A forward-and-back translation process was used and is described in Publication 6 (Chapter 7).

Data integration

Data integration involves combining data from the quantitative and qualitative components of the study to provide a unified view of the results. This study utilised the connection model of integration[154], since data gathered from the quantitative component (i.e., the survey) were used to inform the qualitative component of the study.[14,155] This aligns with the sequential, explanatory mixed methods design (QUAN → qual) used in this research project.

Data were collected using a quantitative survey for investigating the HRQOL, diabetes knowledge and self-care management practices of people with T2DM with and without DFUs. People with DFUs were then selected to participate in semi-structured interviews. The qualitative component did not commence until data analysis from the quantitative component had been completed. The data from the quantitative survey informed the questions in the semi-structured interviews. The final integration of the data involved merging the two datasets into a combined dataset so that the qualitative data could enhance the researcher's understanding of the quantitative results.[155] A detailed description of the integration of the findings is presented in the Chapter 8.

Ethical Considerations

This study was approved by the ethics committees of the University of Wollongong (HE 16/209) and Uttaradit Hospital, Thailand (NO. 21/2016 and NO. 7/2017) (Appendix 1). The study was conducted in accordance with the standards outlined by both the University of Wollongong and the Uttaradit Hospital, Thailand.

Risks of the study

This study was considered of low or negligible risk. All those who voluntarily took part in this research had a very low risk of experiencing any harm from participation and it had no effect on the treatment they received. During the interview, if any participant felt distressed or experienced discomfort, the interview could be ceased without penalty. If required, free counselling was provided to participants.

Consent

In the quantitative component, the participation information sheet was given to each potential participant by the researcher assistant at the diabetes outpatient clinic. Participation in the study was voluntary and the survey was distributed to all willing participants. The study purpose, methods of data collection, benefits and risks due to participation in the study were provided to willing participants by a second person using plain Thai language. The consent form was obtained prior to completion of the survey. Participants were also encouraged to contact the researcher or supervisor with any questions. The participant information sheets and consent forms used in this study are available in Appendix 3.

In the qualitative component, participants with a DFU were invited to participate in an interview. A consent form was signed by the participant and researcher prior to the interview and a copy was

retained by each (see Appendix 3). Participants were allocated pseudonyms prior to each interview and the pseudonym was used in the interview transcripts. Participants were informed that the interview would be recorded and permission for this was granted. Participants were informed of their right to stop the conversation with the researcher without penalty at any time.

Confidentiality

The researcher used code numbers for identifying individual surveys and a pseudonym was used on the interview transcripts. Any potential identifiers (i.e., name, location and place of work) were removed from transcripts, publications and reports.[13,155] The research assistant accessed participants' medical records to obtain clinical data related to demographics. Participants provided consent for this information to be obtained. Research assistants were employees at the diabetes outpatient clinic and had authority and approval to access this information. The researcher kept all data confidential. The data was analysed as a whole and no individual data was identifiable at any phase of the research project. All quantitative and qualitative data were stored in electronic files that were password protected.

Data storage and security

All documents and data files from the surveys and interviews were stored electronically on the researcher's PC using password encrypted security and were backed up on the University of Wollongong's secure network. All hard copy documents and audio-recorded files are stored in a locked filing cabinet for a period of five years following publication of the results. At the completion of this time frame, all electronic files and hard copy documents will be destroyed.

Summary

This chapter provides the theoretical and methodological approach used in this study. In addition, it provides a summary of the research design and the way in which a mixed methods design has been used within the study. The next four chapters present the results of this research project.

The chapters are presented as publications and address the research questions:

1. What is the HRQOL and the clinical and demographic predictors of HRQOL among Thai adults with T2DM? (Chapter 4)
2. What is the diabetes knowledge of Thai adults living with T2DM? (Chapter 5)
3. What is the HRQOL and self-care management practices among Thai adults living with DFUs? (Chapter 6)
4. What are the experiences of Thai adults living with DFUs? (Chapter 7)

Chapter 4

Results: Demographic and Clinical Predictors of HRQOL among Thai People with T2DM

This chapter presents Publication 3, 'Demographic and clinical predictors of health-related quality of life among people with type 2 diabetes mellitus living in northern Thailand: a cross-sectional study'. The publication addresses the research question: What is the HRQOL and the clinical and demographic predictors of HRQOL among Thai adults with T2DM?

The publication is currently under review at the BMC Journal, Health and Quality of Life Outcomes (indexed in CINAHL, MEDLINE, PsycINFO, PubMed, Scopus, Google Scholar and many more). The 2-Year Impact Factor (2017) was 2.3 and the 5-Year Impact Factor (2017) was 2.9.

Khunkaew S, Fernandez R, Sim J. Demographic and clinical predictors of health-related quality of life among people with type 2 diabetes mellitus living in northern Thailand: a cross-sectional study. Health Qual Life Outcomes. 2018. HQLO-D-18-00483 (under review).

Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a chronic disease which is a growing global health problem. However, research on the predictor of health-related quality of life (HRQOL) in Thailand is limited, in particular on the demographic and clinical characteristic in each HRQOL domain. Therefore, the aim of the present study was to determine the demographic and clinical predictors of health-related quality of life among people with type 2 diabetes mellitus (T2DM) in northern Thailand.

Methods: A cross-sectional study of people with T2DM at a large teaching hospital in northern Thailand was conducted. The HRQOL was evaluated using the Thai version of Diabetes-39. Descriptive analysis was used to summarise the demographic and HRQOL scores. Multiple regression analysis was used to determine the predictors of overall HRQOL and the predictors of each D-39 dimension.

Results: A total of 502 people with T2DM were recruited. Forty-one were identified as having diabetic foot ulcers. The mean score for perception of overall HRQOL was 61.18 (SD 18.74). Scores in the D-39 questionnaire showed a poor HRQOL among people with T2DM. The predictors of demographic and clinical characteristics of people with T2DM were calculated for overall HRQOL and all six domains.

Conclusion: These results demonstrate that people with T2DM have a poor HRQOL. The presence of diabetic foot ulcers and smoking status were identified as significant predictors of low HRQOL in the domains relating to diabetes control, social burden, and energy and mobility.

Presence of obesity, receiving insulin injection or a combination of insulin and oral medication were predictors of poor HRQOL in the domain of other health problems and diabetes complications. These findings allow for a nursing care plan for diabetes management to achieve optimal glycaemic control and improve their HRQOL.

Keywords: Health-related quality of life, Diabetes mellitus, Diabetic foot ulcer, Thailand, predictor and nursing

Introduction

Evidence indicates that there is an increasing prevalence of diabetes both in developed and developing countries.[8] In the United States, Selvin et al.[18] found that the prevalence of diabetes among older adults has risen from 5.8 % in 1988-1994 to 12.4 % in 2005-2010. Similarly, in Canada, Greiver et al.[19] estimated the prevalence of diabetes was 7.6 % of the population. In Thailand the number of people with diabetes is rapidly increasing due to changing lifestyle[135] with the estimated national prevalence of diabetes reported to be 9.6 % (2.4 million people).[185]

Living with diabetes has a significant impact on the Health-Related Quality of Life (HRQOL) of those affected.[86] The evidence demonstrates that people with diabetes have a poor quality of life particularly in physical and psychological functions[62] compared to those with no chronic illness.[12,60] Various demographic factors impact on the HRQOL of people with T2DM. While some studies suggest that males have a lower general health condition, physical function, and physical role limitation, others report contradictory findings.[11,64] Age also influences the HRQOL of people with diabetes, with older people having poorer HRQOL compared to younger people.[65,66,186] Income levels have also been reported to impact the HRQOL of people with T2DM.[187,188] Similarly, the length of time a person has had T2DM influences HRQOL with longer periods resulting in lower HRQOL.[66] People with T2DM who smoke have also been reported to have poorer HRQOL compared to non smokers.[189]

There are a range of clinical characteristics that impact on the HRQOL of people with T2DM. The use of insulin and / or oral anti diabetic medications have been identified as predictors of poor HRQOL among people with T2DM.[190] The cross-sectional study among Hong Kong Chinese adults with T2DM reported that BMI was negatively associated with the physical component summary (PCS-12).[191] Presence of diabetic foot ulcers (DFUs) has also been reported to have a negative effect on several domains of a person's HRQOL including daily and social activities.[192] Results from a recent systematic review that included 12 studies of people with DFUs identified that the HRQOL of participants in most of the studies was poor, particularly in physical functioning, role physical, general health, and vitality.[193] Furthermore, people experiencing pain due to a DFU have an even lower HRQOL.[80] In addition, people with abnormal biomedical indicators including Glycosylated Haemoglobin (HbA_{1c}) have also been reported to have poorer HRQOL.[194]

While there is a plethora of research on the HRQOL among people with diabetes living in

developed countries there is limited published literature in developing countries such as Thailand, despite the rapidly increasing prevalence of T2DM in that country. Therefore, the aim of this study was to determine the HRQOL and predictors of HRQOL in people with T2DM who are living in northern Thailand. This will help to inform strategies to improve HRQOL among people with T2DM and reduce the incidence of diabetes complications.

Methods

This study used a descriptive, cross-sectional design to determine demographic and clinical predictors of HRQOL among people attending the diabetes outpatient clinic at a large teaching hospital in northern Thailand. This study is part of a larger study assessing the HRQOL, diabetes knowledge and self-care management among Thai people with T2DM. Recruitment commenced on 13th September and was completed on 13th November 2016.

Sample

A consecutive sampling strategy was used to recruit participants. People were included in the study if they were: more than 18 years old; diagnosed with T2DM; willing to participate; and able to read or understand the Thai language. People who had cognitive impairment or communication difficulties were excluded.

Data collection

All eligible potential participants were informed about the study by a research assistant using a standardised script in plain Thai language. People were also advised that participation in the study was voluntary and that non-participation would not affect the care they received at the hospital. Informed consent was obtained from those who met the inclusion criteria and participants were asked if they wished to complete the survey themselves or if they wished to complete the survey using the interview method. Those who wished to complete the survey themselves were given a copy of the questionnaire and were asked to place the completed questionnaire in a secure box at the diabetic clinic. For those willing to participate using the interview method, a registered nurse conducted a 1-1 interview and obtained the data. The four registered nurses who assisted with data collection participated in a half-day workshop that included data collection techniques and a mock data collection trial supervised by the lead researcher. HRQOL was assessed using the Thai version of the Diabetes-39 questionnaire.

Data collection instruments

Data were collected relating to participant demographics, clinical characteristics and HRQOL. The demographic data collected included: gender; age; smoking status; marital status; education level; employment status; income; and occupation. The clinical characteristics data obtained were; length of time since diagnosis with T2DM; diabetes therapy; most recent glycosylated haemoglobin (HbA$_{1c}$); Body Mass Index (BMI); and presence of a DFU.

Health-related quality of life (HRQOL) was assessed using the Diabetes-39 questionnaire. The

Diabetes-39 was developed by Boyer and Earp[171] and has been widely used for assessing HRQOL in people with diabetes.[85,172-174] For this study the Thai version of the Diabetes-39 (D-39) questionnaire was used.[176] Each item is rated on a seven point Likert scale, ranging from "not affected at all" to "extremely affected".[176] The Thai version of the Diabetes-39 questionnaire assesses six distinct dimensions of diabetes related to HRQOL: diabetes control (13 items); anxiety and worry (4 items); social burden (6 items); sexual functioning (3 items); energy and mobility (10 items); and other health problems and diabetes complications (3 items).[176] The D-39 questionnaire also included an overall evaluation (2 items), which are self-perceived overall rating of HRQOL and self-perceived rating of severity of diabetes.[176] Overall HRQOL and Overall Severity of T2DM were included as individual items and assessed on a seven point Likert scale ranging from "highest quality" to "lowest quality" and "not severe at all" to "extremely severe".[176] Permission to use the D-39 questionnaire (English and Thai version) was granted by the instrument developers.

The overall reliability of this scale has been reported to be greater than 0.7.[176] Reliability for each dimension includes; energy and mobility (0.94); diabetes control (0.94); anxiety and worry (0.89); social burden (0.76); sexual functioning (0.88); and other health problems and diabetes complications (0.83).[176]

Ethical consideration

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.[195] The study was approved by University of Wollongong (HE16/209) and Uttaradit Hospital (21/2016).

Statistical analysis

All data were entered into Survey Monkey© and exported into the SPSS software version 21 (SPSS Inc., Chicago, IL, USA). The scores for each dimension, Overall HRQOL (1 item) and Overall Severity of T2DM (1 item) were transformed into 0 to 100 scales according to author guidelines.[176] The score closer to 0 indicates a better HRQOL and score closer to 100 a worse HRQOL.[176] Descriptive analysis was used to summarise demographic and HRQOL score. Univariate analysis was conducted to assess the relationship between each demographic and clinical variable on the HRQOL. Only the demographic and clinical variables that were significant in the univariate analysis were included in a standard multiple linear regression analysis to determine the predictor of HRQOL. The following demographic predictor variables were included in the regression model (a) Gender (b) age (c) marital status (d) education level (e) working status (f) income. Education level was recoded into binary variables; primary education and lower, and secondary and higher. The following clinical characteristic predictor variables were included in the regression model (a) smoking status (b) diabetes duration (c) HbA_{1c} and (d) BMI. The beta values and confidence intervals (95 %) were calculated in the multiple linear regression analyses. Statistical significance was set at $p < 0.05$.

Results

Participant characteristics

Of the 502 participants in the study, the majority were female (n = 305, 60.75 %). The mean age of the participants was 60.17 ± 10.70. The majority of the participants (n = 366) were living with a partner. The majority of participants were educated at elementary school level (n = 331). A third of the participants were employed and the majority (72.70 %) earned 0-10,000 baht/month. (Table 9)

The mean duration of diabetes was 9.87 (SD 8.13) years. The mean glycosylated haemoglobin (HbA$_{1c}$) level for participants was 7.78 % (61.5 mmol/mol) (SD 1.77) and the mean BMI was 26.96 kg/m^2 (SD 5.57). Of the 502 participants 41 were identified as having DFUs.

Table 9: Demographic data (n = 502)

Variables	Frequency (n = 502)
Age (mean ± SD)	60.17 ± 10.70
Gender	
Female	305
Smoker	30
Marital Status	
Living with partner	366
Highest Qualification	
Elementary school (Primary school)	331
Secondary school (High school)	79
Diploma and over	84
Employment Status	
Employed	349
Earnings per month	
0-10,000 Baht/month	365
More than 10,001 Baht/month	132
Occupation	
Farmer	94
Government worker	22
Housewives/husbands	160
Private employee	27
Business owner	64
Diabetes therapy	
Insulin	32
Oral medication	318
Combination of insulin and oral medication	143
Non pharmacologic treatment	8
Clinical characteristics	**Mean (SD)**
Diabetes duration (years)	9.87 ± 8.13
HbA$_{1c}$ (mg %)	7.78 ± 1.77
BMI	26.96 ± 5.57
Presence of DFUs (n)	41

Abbreviation: DFU, diabetic foot ulcers; HbA$_{1c}$, Glycosylated Haemoglobin A1c; BMI, Body Mass Index

Health-related quality of life

The mean score for the single item summarising participants overall HRQOL was 61.18 (SD 18.74) and the single item summarising participants overall severity of T2DM was 28.45 (SD 20.56). The mean scores for each subscale were: diabetes control 19.78 (SD 14.80); anxiety and worry 23.52 (SD 17.71); social burden 16.58 (SD 12.40); sexual functioning 15.89 (SD 19.28); energy and mobility 21.60 (SD 15.85); and other health problems and diabetes complications 21.43(SD 18.41). (Table 10).

Table 10: HRQOL among participants (n = 502)

D-39 dimension[a]	Mean (SD)
Diabetes control (13 items)	19.78 ± 14.80
Sexual functioning (3 items)	15.89 ± 19.28
Social burden (6 items)	16.58 ± 12.40
Anxiety and worry (4 items)	23.52 ± 17.71
Energy and mobility (10 items)	21.60 ± 15.85
Other health problems and diabetes complications (3 items)	21.43 ± 18.41
Overall evaluation	**Mean (SD)**
Self-perceived overall HRQOL (1 item)[a]	61.18 ± 18.74
Self-perceived overall severity (1 item)[b]	28.45 ± 20.56

Abbreviation: DFU, diabetic foot ulcers
[a]High score indicated poor HRQOL
[b]High score indicated severity of disease

Demographic and clinical characteristic predictors of HRQOL

Overall HRQOL

A multiple regression was performed for prediction of participants' overall rating of HRQOL (see Table 11). The following variables that were significant in the univariate analysis were included in the prediction model: education levels, income, and use of insulin only. The multiple correlation coefficient ($R = 0.14$) was significantly different from zero, $F = (3,495) = 3.52$, $p < 0.05$ and accounted for 2 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.021$, $R^2_{adj} = 0.015$). None of the three variables that were significant in the univariate analysis were found to be significant predictors of overall HRQOL.

Overall severity of T2DM

A multiple regression was performed for prediction of participants' rating of overall severity of their T2DM. The following variables that were significant in the univariate analysis were included in the prediction model: use of insulin only and use of combination of insulin and oral medication. The multiple correlation coefficient ($R = 0.21$) was significantly different from zero, $F = (2,501) = 11.753$, $p < 0.05$ and accounted for 4 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.045$, $R^2_{adj} = 0.041$). Both use of insulin or combination of insulin and oral medication were found to be significant predictors of participants' rating of the overall severity of their diabetes.

Diabetes control

A multiple regression was performed for prediction of HRQOL in the diabetes control domain (13 items) for people with diabetes. The following variables that were significant in the univariate analysis were included in the prediction model: age, presence or absence of DFU, duration of diabetes, use of insulin only, use of a combination of insulin and oral medications, and smoking status. The multiple correlation coefficient ($R = 0.28$) was significantly different from zero, $F = (6,487) = 6.69$, $p < 0.05$ and accounted for 6.5 % of the variance in the dependent variable as explained by the set of independent variables ($R^2 = 0.076$, $R^2_{adj} = 0.065$). Younger age, longer duration of diabetes, smoking and those with DFUs had significantly poorer HRQOL relating to the diabetes control domain.

Sexual functioning

A multiple regression was performed for prediction of HRQOL related to sexual functioning (6 items). The following variables that were significant in the univariate analysis were included in the prediction model: gender, education levels and smoking status. The multiple correlation coefficient ($R = 0.37$) was significantly different from zero, $F = (3,502) = 27.68$, $p < 0.05$ and accounted for 14 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.142$, $R^2_{adj} = 0.137$). Non-smoking status and female gender were found to be significant predictors of higher HRQOL relating to sexual functioning.

Social burden

A multiple regression was performed for prediction of HRQOL in the social burden domain (6 items) among people with diabetes. The following variables that were significant in the univariate analysis were included in the prediction model: presence or absence of DFU, income, duration of diabetes, use of a combination of insulin and oral medications, and smoking status. The multiple correlation coefficient ($R = 0.22$) was significantly different from zero, $F = (5,487) = 5.16$, $p < 0.05$ and accounted for 5 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.05$, $R^2_{adj} = 0.041$). Shorter duration of diabetes, non-smoking status, and absence of DFUs were found to be significant predictors of higher HRQOL relating to social burden.

Anxiety and worry

A multiple regression was performed for prediction of HRQOL in the anxiety and worry domain (4 items) for people with diabetes. The following variables that were significant in the univariate analysis were included in the prediction model: presence or absence of DFU, income, use of a combination of insulin and oral medications, and smoking status. The multiple correlation coefficient ($R = 0.22$) was significantly different from zero, $F = (4,491) = 6.81$, $p < 0.05$ and accounted for 5 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.053$, $R^2_{adj} = 0.045$). Non-smoking status, and higher income levels were found to be significant predictors of higher HRQOL relating to anxiety and worry.

Energy and mobility

A multiple regression was performed for prediction of HRQOL in the energy and mobility domain (10 items) for people with diabetes. The following variables that were significant in the univariate analysis were included in the prediction model: presence or absence of DFU, income, duration of diabetes, use of insulin only, use of a combination of insulin and oral medications, and smoking status. The multiple correlation coefficient ($R = 0.31$) was significantly different from zero, $F = (6,486) = 8.58$, $p < 0.05$ and accounted for 9 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.096$, $R^2_{adj} = 0.085$). Shorter duration of diabetes, non-smoking status, absence of DFUs and non-use of insulin were found to be significant predictors of higher HRQOL relating to energy and mobility.

Other health problems and diabetes complication

A multiple regression was performed for prediction of HRQOL in the other health problems and diabetes complication domain (3 items) among people with diabetes. The following variables that were significant in the univariate analysis were included in the prediction model: presence or absence of DFU, income, duration of diabetes, use of insulin only, use of a combination of insulin and oral medications, and BMI. The multiple correlation coefficient ($R = 0.28$) was significantly different from zero, $F = (6,485) = 6.68$, $p < 0.05$ and accounted for 7 % of the variance in the dependent variable, as explained by the set of independent variables ($R^2 = 0.078$, $R^2_{adj} = 0.066$). Absence of DFUs, non-use of insulin and/or combination of insulin and oral medication and decreased BMI were found to be significant predictors of higher HRQOL relating to other health problems.

Table 11: Demographic and clinical characteristic predictors of Health-related quality of life

Model	Demographic and clinical characteristic predictors			
Diabetes control		Coeff.	95 % CI	Sig.
	$R^2 = 0.76$; Adj $R^2 = 0.65$)			
	(Constant)	56.595	40.818, 72.373	.000
	Age	-.224	-.354, -.094	.001
	Duration of diabetes	.208	.021, .395	.029
	Insulin only	5.341	-.136, 10.819	.056
	Combination of insulin and oral	2.825	-.332, 5.983	.079
	Smoking	-8.392	-13.806, -2.977	.002
	Presence of DFUs	-5.267	-10.009, -.525	.030
Sexual functioning	$R^2 = 0.14$; Adj $R^2 = 0.13$)			
	(Constant)	49.643	35.377, 63.908	.000
	Smoking	-9.229	-.335, .027	.008
	Gender	-12.124	-15.667, -8.582	.000
	Education level	2.748	-.853, 6.350	.134
Social burden	$R^2 = 0.05$; Adj $R^2 = 0.41$)			
	(Constant)	36.653	24.661, 48.645	.000
	Presence of DFUs	-4.272	-8.219, -.324	.034
	Income	-.853	-2.494, .788	.308
	Duration of diabetes	.167	.023, .311	.023
	Combination of insulin and oral	1.718	-.866, 4.303	.192
	Smoking	-6.529	-11.152, -1.906	.006
Anxiety and worry	$R^2 = 0.05$; Adj $R^2 = 0.045$)			
	(Constant)	58.556	41.819, 75.292	.000
	Presence of DFUs	-5.226	-10.809, .357	.066
	Income	-2.913	-5.219, -.607	.013
	Combination of insulin and oral	3.414	-.016, 6.845	.051
	Smoking	-11.195	-17.634, -4.756	.001
Energy and mobility	$R^2 = 0.096$; Adj $R^2 = 0.085$)			
	(Constant)	44.599	29.598, 59.599	.000
	Presence of DFUs	-5.792	-10.720, -.863	.021
	Income	-1.930	-3.986, 3.020	.066
	Duration of diabetes	.237	.053, .421	.012
	Combination of insulin and oral	3.255	-.075, 6.586	.055
	Smoking	-6.660	-12.425, -.896	.024
Other Health problems and diabetes complication	$R^2 = 0.078$; Adj $R^2 = 0.066$)			
	(Constant)	26.689	-4.148, 3.962	.000
	Presence of DFUs	-8.143	-.338, .033	.006
	Income	-.792	-3.203, 1.619	.519
	Duration of diabetes	2.387	-.082, .349	.224
	Insulin only	11.853	5.120, 18.585	.001
	Combination of insulin and oral	5.133	1.244, 9.022	.010
	BMI	.300	.016, .584	.038
Overall HRQOL	$R^2 = 0.021$; Adj $R^2 = 0.015$)			
	(Constant)	4.389	4.030, 4.748	.000
	Education level	.186	-.098, .470	.200
	Income	.127	-.071,	.207
	Insulin only	-.430	-.902, .042	.074
Overall severity	$R^2 = 0.045$; Adj $R^2 = 0.041$)			
	(Constant)	2.271	2.118, 2.424	.000
	Insulin only	.713	.200, 1.227	.007
	Combination of insulin and oral	.621	.344, .898	.000

Discussion

This cross-sectional study has contributed new knowledge related to the HRQOL and in particular has identified the predictors of HRQOL among people with T2DM in northern Thailand. In our study, participants had poor HRQOL in the domains relating to energy and mobility and other health problems and diabetes complications when compared to another study undertaken in the Thai population.[176] This could be due to the fact that our study was undertaken in northern Thailand compared to the other study using the Thai version of the D-39[176] which was undertaken in Southern Thailand. The lifestyles in these two regions are markedly different. Thailand is located in Southeast Asia, bordered by Laos on the North and East, Myanmar on the Northwest and west and Malaysia to the South[196] and these geographical features contribute to the cultural differences relating to religious beliefs, lifestyle, and foods that may have influenced the HRQOL.

In this study, the results obtained from the self-perceived HRQOL and disease severity mean score were 61.18 and 28.45. This result is consistent with the literature where studies have reported that people with T2DM do not perceive the relationship between HRQOL and severity of diabetes.[197,198] This is because people value their HRQOL but do not consider their diabetes to be severe. This discrepancy requires prompt education strategies to be implemented.

In this study age was a predictor of HRQOL in the domain relating to diabetes control with increasing age resulting in better HRQOL. This result is inconsistent with the literature where studies have reported that younger people with T2DM have better HRQOL compared to older people.[66,186] Our finding could be due to the fact that the majority of older people in our study were living with a partner, had help and support, and therefore could have been perceived to have a better quality of life relating to diabetes control. Further research should be undertaken in the older age group for a better understanding of why older Thai people had better rating for the diabetes control domain.

Previous studies that investigated the gender differences in HRQOL using other instruments identified females with T2DM having worse HRQOL.[62,189,199] This is contradictory to our results where the female gender was found to be a significant predictor of high HRQOL in relation to the domain of sexual functioning. These results are consistent to those published on the same instrument survey, which shows that women were perceived to have better HRQOL.[200] This appears to be because women are more active in self-care and preventive care; seeking up to date information and therefore adapting to their diagnosis.[201] In contrast, men may be less concerned about their health conditions and this impacts upon sexual activities more than women. Therefore, identifying strategies to improve HRQOL among Thai males with T2DM is important. Low income was a predictor in the anxiety and worry domain of HRQOL which is consistent with prior studies by Alfian[187] and Mngomezulu and Yang[188]. Those with high income may have more choice and be able to access higher quality medical care than people with a lower income.

This study found the presence of a DFU was a predictor of low HRQOL in the domains relating to diabetes control, social burden, anxiety and worry, energy and mobility and other health problems

and diabetes complications which is consistent with the literature.[12,62,79] People with DFUs incur nerve damage due to neuropathy and decreased peripheral circulation[7] which can result in severe pain which impairs their mobility and physical functioning. This may be because having a chronic wound can have a bad odour and large dressings, which can cause problems in a person's social life and therefore anxiety and depression. Our findings have provided additional information to support healthcare professionals to understand the impact that body perception, hygiene and culture can have on HRQOL. We would suggest that a nursing intervention should be implemented and focused on these domains for improving HRQOL among people with T2DM.

Treatment with insulin and combination of insulin therapy and oral medication was associated with poorer HRQOL in the domain of other health problems and diabetes complications and in perception of overall severity of diabetes (Table 11). This finding is consistent with previous studies.[176] Maddigan et al.[190] also reported poor HRQOL among people with T2DM who received insulin therapy or oral medication. Receiving this medication is an indication of poor glycaemic control and may indicate development of other co-morbidities such as heart disease, stroke and kidney disease which impact on vision, dexterity, ambulation, emotion and pain or discomfort which impair HRQOL.

These results indicate that evidence-based strategies need to be implemented to improve the overall HRQOL for adults with T2DM in northern Thailand. It is a challenge for healthcare providers to keep a wide range of factors in mind when establishing a nursing care intervention for people with T2DM. It is important to consider which factors affect HRQOL, particularly in different regions within Thailand. This approach would attempt to holistically improve physical, mental, social and spiritual needs as well as improving glycaemic control leading to better HRQOL.

Strength and limitations

The major strength of this study was the use of the Thai version of the Diabetes-39 which is a valid and reliable instrument for assessing the HRQOL among diabetic patients[171], compared to other studies which have used generic questionnaires for evaluating HRQOL.[11,61,62,69] Another strength was that the survey was able to be completed using the interview method. This meant that all eligible participants could complete the survey regardless of literacy levels. Thirdly, all interviewers were trained in the administration of the questionnaire which added to the robustness of the research methods. Despite the strengths of this study some of the limitations inherent in undertaking such a study need to be acknowledged. The study was undertaken using a non-random sample and was conducted at a specialist diabetic clinic which could influence the results. Further, large scale multi-centre studies need to be undertaken to investigate the HRQOL of people with T2DM in the various regions of Thailand. For future research a larger sample size and the use of a disease specific questionnaire is suggested.

Conclusions

The results of this study demonstrate that Thai people with T2DM have a poor HRQOL. None of the demographic or clinical characteristics are predictors of individual perceptions of overall HRQOL. However, in the domain of diabetes control, social burden, energy and mobility, and other health problems and diabetes complication domains, it was found that the presence of DFUs are potentially impacted by these dimensions. People with T2DM could not perform household chores and were unable to do what they wanted to do, as well as being unable to take care of daily activities. In these domains relating to diabetes control, sexual functioning, social burden, anxiety and worry and energy mobility, people who smoked had a significantly poorer HRQOL. People who were treated with insulin injection and a combination of insulin and oral medication tended to have poor HRQOL in the domain of other health problems and diabetes complication. Also, people with obesity had significantly poor HRQOL in this domain.

People with T2DM showed that their self-perceived HRQOL was poor. However, they do not consider diabetes to be a serious disease. Therefore, they do not perceive the relationship between HRQOL and disease severity. Hence there is an urgent need for evidence-based strategies to be implemented to prevent the diabetes complications of T2DM.

Chapter 5

Results: Diabetes Knowledge

This chapter presents publication 4, titled 'Linguistic and Psychometric Validation of the Thai Version of Simplified Diabetes Knowledge Scale: A Measure of Knowledge of Diabetes in a Thai Population'. The publication addresses the research question: What is the diabetes knowledge of Thai adults living with T2DM?

The publication has been published in SAGE Open Nursing, an open-access journal that is available online (Indexed in ProQuest, Google Scholar and Emerging Science Citation Index [ESCI]: Impact Factor [2017] = 0.59).

Khunkaew S, Fernandez R, Sim J. Linguistic and psychometric validation of the Thai version of Simplified Diabetes Knowledge Scale: a measure of knowledge of diabetes in a Thai population. SAGE Open Nursing. 2018; 4: 1–8. Available from: http://journals.sagepub.com/doi/full/10.1177/2377960818791849

Permission to include the publication within this thesis was granted.

Abstract

Purpose: To develop a linguistically and psychometrically validated Thai version of the Simplified Diabetes Knowledge Scale (T-SDKS) for adults with type 2 diabetes mellitus (T2DM).

Design: A cross-sectional study was carried out among people with T2DM.

Methods: Consecutive sampling was undertaken to recruit participants at the outpatient diabetes clinic of a hospital in northern Thailand.

Results: A total of 502 patients with T2DM were recruited. The mean age of the participants was 60.2 years, and 60.5 % were female. The T-SDKS attained a reliability coefficient of 0.79. The item-total correlation value was greater than 0.20 for each item, and the inter-item correlation ranged between 0.03-0.49. Respondents attained a mean percentage knowledge score of 42.39 % $\pm$ 15.45 on T-SDKS.

Discussion/Conclusions: The T-SDKS has demonstrated to be a brief and simple diabetes knowledge assessment tool to use in a busy clinical setting.

Implication for Practice: The findings can be used to improve health education interventions.

Introduction

An increasing prevalence of diabetes has been reported worldwide.[8,18] In the United States, Selvin et al.[18] found that the prevalence of diabetes among older adults had risen from 5.8 % in 1988-1994 to 12.4 % in 2005-2010. In Canada, Greiver et al.[19] estimated the population prevalence of diabetes to be 7.6 %. There is also an increasing prevalence of diabetes in developing countries.[202] Thailand is a developing country which is facing the problem of undiagnosed and late treatment of diabetes mellitus. Approximately 7.5 % of the Thai population have been diagnosed with diabetes, and an additional 35.4 % of the population have impaired fasting blood glucose levels.[203] Although diabetes is common in Thailand more than half of the population remain undiagnosed and hence may lack diabetes knowledge for self-management.[204]

Research has demonstrated that knowledge about the disease, medications, diet, glucose monitoring, and foot care is essential for self-care management among people with diabetes.[107,108,132,205,206] In a study undertaken on 307 participants in India with T2DM and a mean age of 55.6 years, only 23.8 % had good knowledge of diabetes and its management.[207] Another study undertaken on 515 patients in Bangladesh reported that 45.6 % participants with T2DM had good knowledge of diabetes.[208] The evidence also indicated that having knowledge was significantly associated with compliance to medication, non-pharmacological management[207] and glycaemic control.[208]

Knowledge can empower self-management hence, the assessment of diabetes knowledge is a fundamental aspect of diabetes care and assists in providing individualized diabetes education.[108] Despite the importance of knowledge for self-management there are few reliable and valid questionnaires that measure diabetes knowledge, particularly in the Thai language which can be used in the busy clinical setting.

The 20-item Simplified Diabetes Knowledge Scale (SDKS)[178] developed from the Michigan Diabetes Knowledge Scale[179] has been extensively used to measure knowledge about diabetes. The SDKS consists of 20 items pertaining to diet, risk factors and self-management. The patient is required to provide a yes or no response to each item. A high score of correct answers indicates high knowledge of diabetes. The internal reliability (Cronbach's alpha) for the SDKS ranged from 0.69 to 0.71.[178]

Given that a Thai version of the scale has not been developed, the aim of this study was to develop a linguistically and psychometrically validated Thai version of the Simplified Diabetes Knowledge Scale (T-SDKS) for adults with T2DM.

Methods

Instrument

Development of the T-SDKS

Permission to translate the SDKS (English version) was obtained from the instrument developers.

The SDKS was translated according to the World Health Organisation procedure for translation and adaptation of instruments[209]. Firstly, forward translation was undertaken by translating the scale from English to the Thai language to produce a version that was semantically and conceptually as close as possible to the original version. The translation was done independently by two people. The first person was a translator who was bilingual (English and Thai) and the second a Thai health professional who was familiar with the technical terms and had experience with translation from Thai to English. Secondly, an expert panel comprising of a Nutritionist and questionnaire development expert reviewed the primary version and compared it with the original version; changes were then made if required. The third step involved back translation of the Thai version of the questionnaire to English. This was undertaken independently by two bilingual Thai nurses. Both nurses had more than 20 years of nursing experience. The translated English version and the original English version were then compared to identify any discrepancies. The Thai version of the instrument was called the T-SDKS.

Pilot testing the T-SDKS

Pilot testing of the T-SDKS was undertaken on 30 Thai patients with T2DM who attended the diabetes clinic in the two weeks preceding the commencement of data collection. The T-SDKS was completed by 30 patients in a 1-1 interview with the researcher. In addition, the researcher asked the patients if the words/ expressions in the T-SDKS were easy to understand, relevant and did not cause offense. The researcher made notes of all the comments made by the patients. When comments were received from participants, the item was discussed with the expert panel who were involved in translation, and the panel provided recommendations for linguistic improvement. After the expert panel agreed on all the linguistic improvements, the final version of the T-SDKS was obtained for psychometric evaluation. In pilot testing, the overall self-administration for the T-SDKS questionnaire took on average 10 minutes to complete. Pilot testing of the T-SDKS was included in the institutional review board approval procedures for the larger study. Data from pilot testing was not included in the final analysis.

Study design, sample and setting

Recruitment for the study was undertaken between 13th September and 13th November 2016. A consecutive sample of patients attending the outpatient diabetes clinic at a large urban teaching hospital in northern Thailand were recruited to the study. This hospital provides health services to both rural and urban patients in the region. The inclusion criteria were: patients aged more than 18 years old; people attending the outpatient diabetes clinic; people diagnosed with T2DM; and, willingness to participate in the study. People who were unable to communicate in Thai were excluded.

Data collection

Information about the study was provided by an assistant researcher at the diabetes outpatient clinic. Written consent was obtained from all participants who were willing to participate in the study. The questionnaire was then distributed to participants. The questionnaire consisted of three

parts which included data on demographics (age, gender, education), clinical characteristics (diabetes duration, HbA$_{1C}$, BMI, diabetes therapy) and knowledge of diabetes. Data on clinical characteristics (up to six months) was collected from the medical records. For those willing to participate but who could not complete the questionnaire by themselves, a face to face interview was conducted to complete the survey. All interviewers were trained by the principal researcher and the interview took approximately 10 minutes.

Data analysis

Validity

Validity is a key criterion for evaluating how well an instrument measures what it is intended to measure. Face validity is used to measure how relevant, credible and acceptable the instrument is following the translation process.[13] An expert panel assessed the face validity of the translated T-SDKS. To ensure content validity, Thai clinicians and a dietitian reviewed the final Thai version of the instrument to assess its relevance, appropriateness, clarity, and comprehensiveness within the Thai context. They completed an open ended questionnaire that explored the comprehensiveness of the T-SDKS, ease of understanding and ease of completion; length of time taken to complete the instrument and any other issues.

All data were entered into Survey Monkey© and exported to SPSS version 21.1 for analysis. Categorical data were presented as percentages, and continuous data were presented as means and standard deviation (SD). Items-total correlations were used for testing the hypothesis construct total and then correlating the items with the total. Items with scores lower than 0.20 demonstrate weak correlation and are usually removed from a scale during development.[210] Also, the inter-item correlation was employed for testing the correlation in each item. The inter-item correlation value in the range between 0.30-0.70 but not over 0.8 was considered acceptable.[13]

Internal consistency

Internal consistency was used to assess the reliability of the T-SDKS. Internal consistency is a measure of the degree of correlation between the items in the instrument. It has been established that the items should correlate moderately with each other and should contribute independently to the overall score. A perfect correlation of 1.0 indicates that the questions are measuring an identical construct. Hence the inter-item correlation value in the range between 0.30-0.70 but not over 0.8 was considered acceptable.[13] The items were also examined for homogeneity of content using the corrected item-total correlations. Items with scores lower than 0.20 demonstrate weak correlation and are usually removed from a scale during development.[210] Although, the responses to the items in the T-SDKS were binary (Yes/ No) Cronbach's alpha has been reported to be suitable to establish the reliability of the instrument [211]. Hence the internal consistency was evaluated using the standard Cronbach α coefficient. The guideline by Tavakol and Dennick[212] was used to determine the values greater than or equal to 0.9 were considered as excellent, 0.8 to -<0.9 good, 0.7 to -<0.8 acceptable, 0.6 to -<0.7 questionable, 0.5 to -<0.6 poor and less than 0.5 unacceptable.

Ethical consideration

Participants provided informed written consent before participating in this study. This study was approved by the Human Research Ethics Committee (HREC) of both the University of Wollongong (HE16/209) and Uttaradit Hospital, Thailand (21/2016).

Results

Linguistic validation

Comparison of the original version and the back-translation of the SDKS identified two items that required modification in order to be suitable within the Thai context. Some words that were not related to Thai culture were changed. Item 3 originally asked: "A pound of chicken has more carbohydrate in it than a pound of potatoes." This was changed to "500 grams of chicken has more carbohydrate in it than 500 grams of rice." The word potatoes was changed to rice as rice is the staple food of the Thai people and pound was changed to gram as it is the metric unit for measurement commonly used in Thailand. In item 8 olive oil was changed to rice bran oil because olive oil is not commonly used in the Thai context.

A total of 506 patients with diabetes type 2 were invited to participate in the study and complete data were obtained from 502 patients (response rate = 99.2 %). Data cleaning was undertaken and missing data were identified for four patients. The cases with missing data were deleted list-wise.[213,214] Responses to all 20 items were obtained from 502 patients and were used in the final analysis. The sample size was considered to be adequate based on recommendations that a sample size of 300 or more is suitable for reliability testing due to reduced possibility of sampling error.[215,216] Of the sample, 305 (60.75 %) were females, and 197 (39.24 %) were males. The average age was 60.17 years (± 10.70 years) and the average duration of diabetes was 9.87 years (± 8.13 years). Data obtained from the medical records identified that the most recent mean glycosylated haemoglobin (HbA$_{1c}$) was 7.78 % (61.5 mmol/mol) (± 1.77), and mean body mass index was 26.96 (± 5.57) (Table 12).

Table 12: Demographics and Clinical Characteristics (n = 502)

Variables	All patients N = 502 Mean (SD)
Age (years)	60.17 ± 10.70
Gender	**Number (%)**
Female	305 (60.75)
Male	197 (39.24)
Highest Qualification	**Number (%)**
Elementary school (Primary school)	331 (65.73)
Secondary school (High school)	79 (15.73)
Diploma and over	84 (16.73)
Clinical characteristics	**Number (%)**
Diabetes duration (years)	9.87 ± 8.13
HbA1c (in %(mmol/mol)	7.78 (61.5) ± 1.77
BMI	26.96 ± 5.57
Diabetes therapy	**Number (%)**
Insulin	32 (6.37)
Oral medication	318 (63.34)
Combination of insulin and oral medication	143 (28.48)
Non pharmacologic treatment	8 (1.59)

Abbreviations: HbA_{1c}, Glycosylated Haemoglobin A1c; BMI, Body Mass Index

Reliability

The internal consistency for the full T-SDKS was high (Cronbach α = 0.79). The Cronbach's alpha was greater than 0.70 for each of the items. The corrected item to total correlations which is a measure of scale homogeneity was greater than 0.20, except for item 19. All items showed good internal consistency[210] (Table 13). The Cronbach's alpha values if the item were deleted were lower than the resulting coefficients in each item, indicating that the exclusion of the items did not increase the reliability of the instrument. The inter-item correlation matrix ranged between 0.03-0.49 (Table 14).

Knowledge relating to diabetes - Known groups validity

Overall the mean percentage of correct answers on the T-SDKS was 42.39 % ± 15.45. The questions which patients answered correctly were about knowledge relating to high blood pressure (88.7 %), numbness and tingling (75.7 %) and regular check-ups (87.8 %). In contrast, only 11.3 %, 12.8 % and 20.6 % of participants had knowledge about Glycosylated haemoglobin (HbA_{1c}) levels, attendance at clinic appointments and testing blood glucose (Table 13).

Table 13: Thai Version of Simplified Diabetes Knowledge Scale (T-SDKS) Item and Reliability Analysis

No	T-SDKS Item	T-SDKS All patients (n=502) n (% correct)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
1	The diabetes diet is a healthy diet for most people. *	338 (67.5)	.271	.786
2	Glycosylated haemoglobin (HbA$_{1c}$) is a test that measures your average blood glucose level in the past week.	56 (11.2)	.329	.783
3	500 grams of chicken has more carbohydrate in it than 500 grams of rice.	119 (23.7)	.399	.778
4	Orange juice has more fat in it than low fat milk.	195 (38.8)	.374	.780
5	Urine testing and blood testing are both equally as good for testing the level of blood glucose.	100 (19.9)	.362	.780
6	Unsweetened fruit juice raises blood glucose levels. *	170 (33.9)	.359	.781
7	A can of diet soft drink can be used for treating low blood glucose levels.	211 (42.0)	.445	.776
8	Using rice bran oil in cooking can help prevent raised cholesterol in the blood *	251 (50.0)	.398	.778
9	Exercising regularly can help reduce high blood pressure. *	445 (88.6)	.272	.785
10	For a person in good control exercising has no effect on blood sugar levels.	174 (34.7)	.362	.780
11	Infection is likely to cause an increase in blood sugar levels. *	256 (51.0)	.434	.775
12	Wearing shoes a size bigger than usual helps prevent foot ulcers.	140 (27.9)	.262	.786
13	Eating foods lower in fat decreases your risk for heart disease. *	347 (69.3)	.284	.786
14	Numbness and tingling may be symptoms of nerve disease. *	383 (76.3)	.373	.780
15	Lung problems are usually associated with having diabetes.	181 (36.1)	.430	.776
16	When you are sick with the flu you should test for glucose more often. *	132 (26.3)	.393	.778
17	High blood glucose levels may be caused by too much insulin.	175 (34.9)	.423	.777
18	If you take your morning insulin but skip breakfast your blood glucose level will usually decrease. *	215 (42.9)	.396	.778
19	Having regular check-ups with your doctor can help spot the early signs of diabetes complications. *	439 (87.6)	.260	.786
20	Attending your diabetes appointments stops you getting diabetes complications.	63 (12.6)	.184	.789

* Indicates that the TRUE response is the correct response

Table 14: Inter-Item Correlation Matrix

T-SDKS	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Item 15	Item 16	Item 17	Item 18	Item 19	Item 20
Item 1	1																			
Item 2	.179	1																		
Item 3	.189	.257	1																	
Item 4	.104	.171	.319	1																
Item 5	.191	.258	.244	.228	1															
Item 6	.088	.174	.204	.230	.155	1														
Item 7	.185	.257	.327	.245	.154	.287	1													
Item 8	.159	.151	.174	.187	.155	.168	.248	1												
Item 9	.088	.071	.106	.114	.157	.130	.186	.222	1											
Item 10	.120	.128	.177	.182	.165	.151	.160	.231	.253	1										
Item 11	.059	.168	.171	.158	.175	.169	.309	.281	.186	.269	1									
Item 12	.112	.168	.078	.040	.144	.110	.075	.147	.067	.219	.116	1								
Item 13	.078	.066	.103	.081	.092	.130	.160	.202	.129	.140	.174	.159	1							
Item 14	.117	.071	.095	.119	.192	.127	.166	.272	.114	.097	.280	.119	.225	1						
Item 15	.116	.226	.241	.191	.182	.191	.202	.161	.035	.082	.283	.087	.134	.289	1					
Item 16	.144	.164	.192	.171	.140	.149	.147	.184	.037	.210	.222	.176	.130	.179	.320	1				
Item 17	.126	.085	.191	.260	.109	.187	.220	.160	.067	.150	.212	.062	.129	.234	.327	.278	1			
Item 18	.148	.151	.180	.195	.108	.220	.221	.146	.121	.105	.203	.135	.103	.156	.275	.225	.497	1		
Item 19	.037	.007	.053	.093	.127	.180	.095	.072	.189	.150	.126	.103	.146	.166	.135	.150	.105	.089	1	
Item 20	.062	.001	.050	.070	.138	.005	.036	.019	.082	.148	.064	.126	.085	.134	.072	.085	.095	.095	.360	1

Discussion

The aim of this study was to develop a linguistically and psychometrically validated Thai version of Simplified Diabetes Knowledge Scale (T-SDKS) for adults with T2DM. The major strength of the study was the rigor in which the instrument was translated and validated. Forward and backward translation was undertaken according to the WHO guidelines. Validation was undertaken using expert, independent translators, discussion with an expert panel and interviews with patients. The content validity phase indicated that in order to be consistent with the Thai culture, some items required modification as simply translating and using a questionnaire in another linguistic context is not appropriate.[217] Hence, the unit of the measurement in item 3 was changed from pounds to grams which is the metric system commonly used in Thailand. In addition as most of the Thai people eat rice as a main meal[218] a pound of potatoes was changed into 500 grams of rice, and olive oil was changed to rice bran oil (item 8). These changes were made following extensive discussions with Thai dietitians and the research team. The large sample size was another strength of the study which enabled psychometric evaluation of the T-SDKS.

Measurement of reliability showed acceptable (Chronbach $\alpha = 0.79$) results for the T-SDKS.[212] This is similar to the original SDKS English version.[178]

Item 9 relating to high blood pressure had the highest percentage (88.6 %) of correct responses. The results obtained in this study are lower than other studies[178] where a larger percentage of people (96 %) had the correct answers. The majority of the participants in this study had high levels of knowledge relating to high blood pressure (88.6 %), numbness and tingling (76.3 %) and regular check-ups (87.6 %) which is not congruent with other studies. In the study by Collins et al.[178] the majority of the participants had knowledge relating to diabetes diet (96 %) and foods low in fat (95 %). These results could be due to the extensive prevention and awareness programs conducted in the UK[178] and indicate that some of these programs are not being conducted in the Thai context where our study was undertaken.

The results obtained in our study about knowledge of high blood pressure and need for regular check-ups could be due to the fact that a large proportion of people in Thailand have high blood pressure.[203] It is possible that participants in our study had received education about blood pressure management during routine visits to the GP.

Low levels of knowledge were demonstrated in the following items: Glycosylated hemoglobin (HbA$_{1c}$) (11.2 %), testing blood glucose (19.9 %) and clinic appointments (12.6 %) (Table 13). This low level of knowledge could be due to the fact that the majority of the participants had only primary education (65.73 % of all participants) which could also affect their health literacy levels as there is a strong association between educational attainment and health literacy.[219] It could be postulated that the participants had a caregiver looking after them who had knowledge relating to diabetes but as this was not investigated in this study it would require further investigation. Given the low literacy levels, strategies such as audio-visual aids could be used to supplement education to people with T2DM in the Thai setting. The T-SDKS takes less than 10 minutes to complete and

can be used in busy clinical clinic settings to identify patients with limited knowledge in order to provide targeted health education interventions.

Despite the strengths of the study, the limitations of this study need to be considered. Firstly the sample was recruited using a convenience sample from a single centre in northern Thailand. Secondly the majority of participants had only primary education which may have influenced their knowledge levels related to diabetes and hence caution needs to be used when generalising the results to the wider Thai population. In addition, the author had to use interview techniques for some participants with low literacy levels which may have led to potential bias in data collection. Therefore, further well designed research studies need to be undertaken to test the T-SDKS in a diverse sample of Thai people with T2DM. In addition, evaluation of the construct validity of the T-SDKS using a large sample is needed.

Further research is required to investigate whether the T-SDKS has comparable reliability and validity in this population group across other regions in Thailand.

Conclusion

The simplified (true/false) version of the T-SDKS provided an acceptable content validity and reliability for assessing diabetes knowledge in the Thai context. This instrument can be used as a diagnostic tool for targeted health education intervention in Thailand. The T-SDKS is a reasonably easy to use survey that measures general diabetes knowledge and also can be used in a busy clinical setting.

Chapter 6

Results: HRQOL and Self-Care Management among People with DFUs

This chapter presents Publication 5, titled 'Health-related quality of life and self-care management among people with diabetic foot ulcers'. The publication addresses the research question: What is the HRQOL and self-care management practices among Thai adults living with DFUs?

The publication has been published in SAGE Open Nursing which is open-access and available online (Indexed in ProQuest, Google Scholar and ESCI: Impact Factor [2017] = 0.59).

Khunkaew S, Fernandez R, Sim J. Health-related quality of life and self-care management among people with diabetic foot ulcers. SAGE Open Nursing. 2018; 5: 1–10. DOI: 10.1177/2377960819825751

Permission to include the publication within this thesis has been granted.

Abstract

Diabetic foot ulcers (DFUs) are a common complication of diabetes that impacts on the Health-related quality of life (HRQOL). Foot care is an important factor in the self-care management of patients with DFUs. The objective of this study was to investigate the HRQOL and foot-care management of people with DFUs. A cross-sectional study involving 41 people with DFUs was conducted at a large tertiary hospital in northern Thailand. The Diabetes Foot Ulcers Scale-Short Form (DFS-SF) and the VA-diabetes Foot Care Survey were used to assess the HRQOL and foot care management among people with DFUs. The majority of the participants were female (n = 24, 58.5 %) and the mean age was 62.13 years. The scores for HRQOL in the six domains were: leisure (66.95 ± 28.03); physical health (68.93 ± 28.51); dependence/daily life (80.08 ± 25.23); negative emotions (71.23 ± 29.48); worried about ulcers (62.20 ± 31.97); and bothered by ulcer care (69.36 ± 25.20). High scores indicate a high (good) HRQOL. Less than a third of the participants reported that they had received education about foot care management. Almost all participants reported that they washed their feet daily; however a large proportion did not test the water temperature or use lubricants on their feet. Most of the participants did not have a mirror for checking under their feet (48.8 %) and there was a lack of knowledge about how to use a mirror for foot inspections (51.2 %). This study provides guidance for clinicians on the content and delivery of diabetes education programs for people with diabetes (and DFUs) in northern Thailand. The findings provide guidance on existing knowledge and the need for programs to address barriers to foot self-care management both in terms of skills and attitudes.

Keywords: health-related quality of life, self-care management, diabetic foot ulcer, nurse, northern Thailand

Introduction

Diabetic foot ulcers (DFUs) are a common complication estimated to affect up to 25 % of people with diabetes mellitus globally.[220] DFUs are associated with increased mortality[31] with a 5 year mortality rate in people with newly diagnosed DFUs estimated to be 40%.[31] Evidence obtained from cross sectional studies[47,68,79] and systematic reviews[221] have reported decreased HRQOL among people with DFUs. Studies using the SF-36 have reported poor HRQOL in people with DFUs[46,47,222] when compared to people without DFUs.

Review of Literature

People with DFUs have a poorer HRQOL in the physical, financial and psychological domains.[61,62,64,83,223-226] People with DFUs who experience poor healing have poorer HRQOL in the mental health, social and physical domains.[227] In addition, a large multicentre study that included 10 different countries demonstrated that low HRQOL in patients with DFUs was a predictor of amputation and mortality.[86]

Poor HRQOL can be attributed to various factors including pain, fatigue, wound infections, frequent dressing changes, restricted mobility and social isolation. People with DFUs experience

severe pain related to diabetic peripheral neuropathy (DPN). A large multicentre study conducted in Norway reported that 75 % of people with DFUs experienced pain while walking and/or standing and also during the night.[48] However, there is controversy in the literature about the impact of pain on HRQOL with some studies indicating that pain is not a determinant of HRQOL.[48,225]

Lack of sleep due to pain, altered life circumstances or anxiety leading to fatigue have all been reported to contribute to poor HRQOL.[228] These factors may be exacerbated by attending clinic visits, hospitalisation and dressing changes.[229] Presence of wound infection has been reported as a predictor of poor HRQOL in patients with DFUs.[225] Restricted mobility due to difficulties in functioning, problems with footwear and amputations are reported to cause depression and anxiety, and social isolation among people with DFUs.[222,230-232] Poor psychosocial adjustment, and low self-perceptions have also been reported.[177]

Foot self-care management is a key to reducing mortality for people with DFUs.[233] Self-care knowledge can assist people with diabetes to assess their feet, seek help when needed and collaborate with healthcare providers to reduce the risk of foot ulcers.[234] Foot self-care practices among people with DFUs have been found to be poor.[113] In a cross-sectional survey of 352 patients in Nigeria, only a third had good knowledge of foot care and of these more than 60 % were not aware of the importance of checking the inside of their footwear or what action to take if they found redness or bleeding between their toes.[132]

The prevalence of DFUs among Thai people is rapidly increasing. In a large comprehensive foot examination survey undertaken in Thailand of people with diabetes, 15 to 26 % had foot problems.[135] In a study of amputees conducted in Thailand, 32 % of amputations were related to type 2 diabetes mellitus.[235] In addition, 2.2 % of people with DFUs have been reported to have had a history of amputation and 10.6 % were identified as high risk to develop further foot ulcers.[236] Despite the increasing prevalence of DFUs in Thailand, there is a dearth of research relating to HRQOL and foot care practices among Thai people with DFUs. A better understanding of the impact of a DFU on the person's HRQOL will enable clinicians to provide better care for these patients. In addition, identifying gaps in knowledge relating to foot self-care management will enable clinicians to provide patient education to reduce DFUs and the impact they have on HRQOL.

This study is part of a larger research project assessing the HRQOL, diabetes knowledge and self-care management among Thai people with diabetes mellitus. The objective of this study was to investigate the HRQOL and the self-care management behaviours among people with DFUs using a DFU specific instrument in a tertiary-level hospital in northern Thailand.

Methods

Design

A cross-sectional study was undertaken of people with DFUs attending a diabetic foot clinic.

Research question

What is the HRQOL and the self-care management behaviours among people with DFUs in a tertiary-level hospital in northern Thailand?

Sample

Consecutive sampling was used to recruit people attending the outpatient diabetes and foot clinic in northern Thailand. Data were collected between 13th September and 13th November in 2016.

Inclusion/exclusion criteria

Participants were recruited if they were: over 18 years; had one or more DFUs; attended the diabetic outpatient clinic; were willing to participate, and able to read/understand the Thai language. People who had cognitive impairment or communication difficulties and could not understand the Thai language were excluded. All potential participants were given a participant information sheet and informed consent was obtained prior to recruitment. Participation was voluntary.

Data collection

Information about the research was provided to eligible participants using a standardised script. Participants were invited to complete the survey by self-administration or interview. Participants who were unable to read or write had a 1:1 interview with the researcher to complete the survey. Self-administration took approximately 15 minutes and interviews took approximately 25 minutes to complete.

Data collection instruments

Data were collected relating to demographic and clinical characteristics, HRQOL and self-management behaviours relating to foot care. The demographic and clinical characteristics are included in Table 15.

Health-related quality of life

Health-related Quality of Life (HRQOL) was measured using the disease specific Diabetic Foot Ulcer Scale-Short Form (DFS-SF).[177] The DFS-SF was validated previously against the Diabetes Foot Ulcers Scale (DFS) and was reduced from 64 items to 29 items.[230] The 29 item DFS-SF comprises of six subscales: leisure (5 items), physical health (5 items), dependence/daily life (5 items), negative emotions (6 items), worries about ulcers/feet (4 items), and bothered by ulcer care (4 items).[177] Responses to each item are rated on a 5-point Likert scale ranging from 1 "not at all" or "none of the time" to 5 "a great deal" or "all of the time" or "extremely". Individual items on the DFS-SF are reverse coded and high scores on the DFS-SF indicate a high (good) HRQOL. The reliability of the DFS-SF has been reported to be greater than 0.7.[177] The DFS-SF has been reported to be acceptable for use in clinical settings.[85] A Thai version of the survey was not available, so permission to translate the DFS-SF into Thai was granted from the Mapi Research

Trust™ (Lyon, France). The standard process for forward and back translation was undertaken using a panel of bi-lingual nutritionists, nurses and clinicians.[13,181]

Self-management relating to foot care

Self-management relating to foot care was assessed using the VA-diabetes Foot Care Survey[180] which included sub-scales on education received about foot care, foot care practices and barriers to foot care. Education received about foot care comprised of 13 items that were scored on a 4-point scale that classified amount of knowledge (see Table 16). Practices relating to foot care were measured using 14 items and were scored on a 5-point scale that classified the frequency of the practices. Barriers to foot care were measured using 14 items and patients had to select the items that they considered were a barrier. Permission to translate the VA-diabetes Foot Care Survey was granted by Olson et al.[180]. The VA-diabetes Foot Care Survey was translated into Thai and standard translation methods were followed using a panel of bi-lingual nutritionists, nurses and clinicians.[13,181]

Ethical approval

All procedures performed in this research were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.[237] The study was approved by the Human Research Ethics Committee, University of Wollongong (HE 16/209) and Uttaradit Hospital, Thailand (21/2016).

Statistical analysis

All data were entered into SurveyMonkey© and then exported into SPSS version 21.0[182] for analysis. The scoring of the DFS-SF was based on the sum of all items; the raw items were reverse coded according to author guidelines. The scores for each dimension were transformed on a scale from 0-100, with high score indicating better HRQOL.[177] Descriptive statistics were used to summarise the demographic and clinical characteristics; HRQOL scores and self-care management relating to foot care.

Results

Sample characteristics

Data were obtained from 41 patients with DFUs who attended the foot clinic. The majority of the participants were female (n = 24, 58.5 %). The mean age of the participants was 62.13 years, 68.2 % of participants were living with a partner, 85.3 % were employed and 82.9 % were earning 0-10,000 Baht/month. Approximately half (48.8 %) of participants were using oral diabetic medications. The mean duration of diabetes was 11.99 ± 8.51 years, the mean Haemoglobin A1c (%) was 8.07 ± 2.08 , and the mean BMI was 27.92 ± 7.88 (see Table 15). All participants had DFUs that were Wagner's grade 1 (82.9 %) or grade 2 (17.1 %).

Table 15: Demographic and clinical characteristics

Variables	Percentage of people with DFUs (n=41)
Gender	
female	58.5
male	41.5
Smoker	7.3
Age (mean ± SD)	62.13 ± 9.53
Marital Status	
Living with partner	68.2
Not living with partner	31.7
Highest Qualification	
Elementary school (Primary school)	73.2
Secondary school (High school)	17.1
Diploma and over	7.3
Employment Status	
Unemployed	14.7
Employed	85.3
Earnings per month	
0-10,000 Baht/month	82.9
More than 10,001 Baht/month	17
Occupation	
Farmer	19.5
Government worker	0
Housewives/husbands	31.7
Private employee	4.9
Business owner	12.2
Diabetes therapy	
Insulin	12.2
Oral medication	48.8
Combination of insulin and oral medication	34.1
Non pharmacologic treatment	4.9
Clinical characteristics Mean (SD)	
Diabetes duration (years)	11.99 ± 8.51
HbA$_{1c}$ (mg %)	8.07 ± 2.08
BMI	27.92 ± 7.88
Wagner's Grade	
Grade 1	82.9
Grade 2	17.1

Abbreviations: DFU - diabetic foot ulcer; HbA$_{1c}$ - Glycosylated Haemoglobin A1c; BMI - Body Mass Index; SD - Standard Deviation
HRQOL

The scores for HRQOL for the six domains were: leisure (66.95 ± 28.03); physical health (68.93 ± 28.51); dependence/ daily life (80.08 ± 25.23); negative emotions (71.23 ± 29.48); worried about ulcers (62.20 ± 31.97); and bothered by ulcer care (69.36 ± 25.20) (Figure 12). High scores on the DFS-SF indicate a high (good) HRQOL.
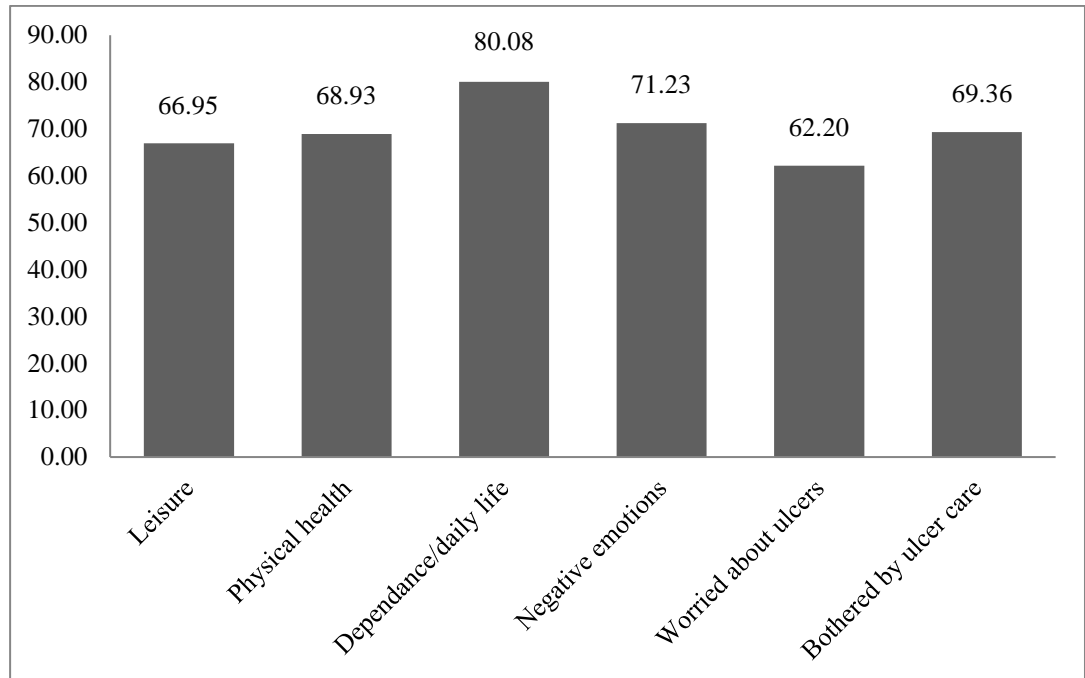
Figure 13: Diabetic Foot Scale-Short Form subscale scores for HRQOL among people with DFUs (n=41)

Note: High scores indicate a high (good) HRQOL.

Education received about foot care (VA-diabetes Foot Care Survey)

The findings provide a summary of the participants' recollection of the education they received about foot care and self-care management of their feet (see Table 16). A large percentage of participants reported that they received no education at all about using a special mirror to check under their feet (51.2 %); gently filing calluses (46.3 %); not cutting corns or calluses with scissors (43.9 %); cutting their toe nails (41.5 %); and avoiding extremes in temperature (either hot or cold) (34.1 %). Only 39.0 % of participants reported that they had received enough education about keeping their feet clean. Wearing shoes at all times is an important self-care management strategy for preventing DFUs. Only 12.2 % of participants reported that they received enough education on always wearing shoes, and a further 51.2 % received some education but would like to know more.

Table 16: Education Received on Foot Care Using VA-diabetes Foot Care Survey (n = 41)

Item (Item Number)	Nothing at all (%)	A little bit (%)	Some, but would like to know more (%)	Enough (%)
Using a special mirror (6)	51.2	2.4	39.0	7.3
Gently filing calluses (8)	46.3	4.9	34.1	14.6
Not cutting corns or calluses with scissors (10)	43.9	4.9	46.3	4.9
Cutting nails (9)	41.5	2.4	39.0	17.1
Avoiding hot/cold (7)	34.1	12.2	36.6	17.1
Always wearing shoes (4)	22.0	14.6	51.2	12.2
Keep skin moist (5)	19.5	12.2	48.8	19.5
Check feet regularly (1)	14.6	26.8	34.1	24.4
Not using drugstore chemicals or other remedies not ordered by healthcare providers (11)	14.6	19.5	39.0	26.8
Choosing proper shoes (3)	12.2	19.5	39.0	29.3
Whom to call for foot problems (13)	12.2	19.5	46.3	22.0
Keeping feet clean (2)	7.3	19.5	34.1	39.0
When to call for foot problems (12)	7.3	19.5	48.8	24.4

Barriers to foot care (VA-diabetes Foot Care Survey)

The findings summarise the perceived barriers by participants to undertaking self-care management of their feet (see Table 17). The most significant barriers to good foot care were not having a mirror to check their feet (48.8 %); not having the correct shoe inserts (41.5 %); and either knowing what to do but not knowing how to care for their feet (36.6 %) or not knowing how to care for their feet (34.1 %). Some of the items assessed attitudes and actions as barriers, such as: "I couldn't remember to do it" (26.8 %); "I didn't have time" (14.6 %); and "I didn't think it was important" (12.2 %). These items show that participants' understanding about why they were conducting self-care of their feet may have been missing.

Table 17: Perceived Barriers to Foot Care Using VA-diabetes Foot Care Survey (n = 41)

Item (Item Number)	Total n = 41 (%)
I didn't have a mirror (7)	48.8
I didn't have the right shoe inserts (6)	41.5
I know what to do, but I didn't know how to do it (2)	36.6
I didn't know what to do (1)	34.1
I couldn't remember to do it (9)	26.8
I didn't have the right shoes (5)	24.4
I needed professional help (10)	17.1
I needed help from family and friends (11)	17.1
I didn't have time (3)	14.6
I couldn't see well enough to do it (13)	14.6
I couldn't comfortably reach my feet to do it (14)	14.6
I didn't think it was important (12)	12.2
I couldn't afford it (4)	7.3
I didn't have a foot stool (8)	4.9

Foot care practices

These results summarise participants self-reported foot care practices (see Table 18). Nearly all participants reported that they washed their feet every day (97.6 %); and most never walked barefoot outside (78.9 %). However, 70.7 % of participants indicated that they walked barefoot inside their house. The activities which were not conducted by participants were: not testing the water temperature (87.8 %); not soaking feet for 10 minutes (85.4 %); not using lubricants (61.0 %); and not looking at the bottom of their feet (24.4 %). Trimming their toe nails once a week was performed by 75.6 % of participants. Drying between their toes was completed by 63.4 % of participants every day and 68.3 % of participants checked their shoes every day.

Table 18: Self-Reported Foot Care Practices Using VA-Diabetes Foot Care Survey (n = 41)

Items (item Number)	Not at all (%)	Daily (%)	Several times a week (%)	Once a week (%)	Once or twice a month (%)
Tested the water temperature (5)	87.8	2.4	2.4	7.3	0.0
Soaked feet for 10 min (4)	85.4	0.0	4.9	4.9	4.9
Walked barefoot outside (14)	78.9	17.1	0.0	0.0	4.9
Filed calluses (8)	75.6	2.4	4.9	4.9	12.2
Used lubricants (7)	61.0	22.0	0.0	9.8	7.3
Changed shoes (12)	56.1	22.0	9.8	2.4	9.8
Wore stocking (11)	43.9	36.6	9.8	7.3	2.4
Looked at the bottom feet (1)	24.4	53.7	9.8	7.3	4.9
Walked barefoot inside (13)	24.4	70.7	0.0	0.0	4.9
Checked between toes (2)	19.5	65.9	4.9	4.9	4.9
Dried between toes (6)	19.5	63.4	9.8	4.9	2.4
Checked shoes (10)	12.2	68.3	7.3	7.3	4.9
Washed feet (3)	0.0	97.6	0.0	0.0	2.4
Trimmed nails (9)	0.0	4.9	0.0	70.7	24.4

Discussion

To the best of our knowledge, this is the first study undertaken to investigate the HRQOL, self-reported knowledge on foot care, actual foot care practices and barriers to foot care in people living with DFUs in northern Thailand. For participants in this study, scores in all HRQOL domains were high. This result is contradictory to that reported in a cross-sectional study conducted in South India where patients with DFUs had poor HRQOL on all six domains, (mean scores ranging between 33.6-44.3).[238] This result may relate to the fact that participants in our study had less severe DFU's with Wagner's Grade 1 and Grade 2 DFUs only.

This study used the disease-specific instrument, DFS-SF for assessing the HRQOL among people with DFUs. The DFS-SF captures the specific problems relating to diabetes complications. In our study, participants reported high HRQOL in the domains relating to leisure, physical health and dependence/ daily life which is similar to other published studies.[83,239,240] This result is interesting as the high HRQOL in the domain relating to dependence/daily life could be due to the fact that the participants had family or social support to assist with daily living activities. In addition, most

of the participants have lived with DFUs for an average of two years which could mean that over time they learnt to adapt and promote their independence in tasks such as cooking, dressing, and organising their daily life.

Low scores indicating poor HRQOL were observed in the domain "worried about ulcers" which is congruent with the literature.[83,240] It could be postulated that the poor HRQOL in this domain may be due to people being concerned about the development of further ulcers, the existing ulcers not healing, development of wound infection and the fear of amputation. Care of a foot ulcer can require multiple visits to foot clinics over a long period of time before the ulcer heals. Finding time to attend the clinics might also be a cause of concern as the majority of the participants were employed.

Education about foot care

Only a third of the participants indicated that they had received education about the various aspects of foot care. Nearly half the participants indicated that they did not know about using mirrors to check the toes, cutting toenails, and not using scissors to cut corns or calluses. This lack of knowledge is reflected in the poor practices relating to foot care with just over half the participants indicating that they checked and dried between the toes, and trimmed their toenails. The low rates relating to checking the feet and toes regularly could be due to the lack of resources such as mirrors and foot stools, and lack of assistance to undertake foot care. Furthermore, participants indicated that they were unaware of what to do/who to call if they did find a foot problem. This provides insight into the nature of education that participants had received and the need for education and behaviour change to achieve good self-care management practices among people with DFUs.

A large proportion of participants indicated that they walked barefoot inside the house but not outside the house. This could be due to the fact that walking barefoot inside the house is culturally appropriate for Thai people.[241] Almost all participants indicated that they washed their feet every day; this could be due to the habitual rituals for Thai people to wash their feet. The majority of the participants reported that they did not test the water temperature. This question may have been misinterpreted as formally testing the water temperature with a thermometer. Testing the water temperature with an elbow is a practical way to test the water temperature prior to bathing and/or soaking. The results from this study indicate that strategies that are culturally appropriate to improve knowledge relating to foot care are required. This would include knowing when and who to call for foot problems, the process of checking feet regularly and keeping skin moist. Including information on why this is important may assist with behaviour change.

Barriers to foot care

Surprisingly, the biggest barrier to foot care was not having a mirror to check the base of the feet. Other studies have found that people with DFUs who did not practise foot self-care were 2.52 time more likely to develop DFUs.[129] The process of regularly checking the feet is important for

prevention and early recognition of problems. Many people with DFUs cannot reach and see under their feet, so a mirror is an important piece of equipment for foot self-care practices.

The importance of good knowledge relating to foot care is vital for the management of DFUs. In this study low knowledge of foot care was reported by more than a third of the participants. These results are significantly poor when compared to that reported in the literature. The poor knowledge could be due to the fact that nearly three quarters of participants in the study had only primary school education. Low levels of education and health literacy have previously been associated with poor foot self-care practices.[126] In addition, it is possible that participants did not receive appropriate education when they visited health professionals. This may be due to lack of time for the patient and the health professional and/or lack of resources. Usual care in Thailand involves people who are newly diagnosed with diabetes mellitus attending an outpatient appointment to receive follow-up care related to knowledge of diabetes, self-care management and treatment of DFUs (if present). Diabetes outpatient clinics are usually very busy and over-crowded.[242] In addition, specialist positions such as Podiatrists and Diabetes Educators are often filled by Nurses in rural areas where such specialists are not available. The American Diabetes Association (ADA) recommends providing Diabetes Self-Management education and training to those people who are diagnosed with diabetes mellitus.[243] It is not clear if these recommendations are always fulfilled in all outpatient clinics in Thailand. In addition to not having adequate knowledge, not having the right shoes and a mirror to check the feet were identified as barriers by nearly half of the participants. Improving education and providing advice for selecting shoes and providing appropriate resources (such as mirrors) should be implemented so that participants can ensure they have the equipment they need to protect their feet. The provision of education about good self-care management of the feet is an important strategy for preventing DFUs and assisting healing of DFU's.

Strengths and limitations

The strength of the study was the rigor in which it was conducted. Firstly, the use of a validated disease specific instrument to measure HRQOL enabled data to be captured that is specific to DFUs. In most studies examining HRQOL in people with DFUs, generic tools such as the SF-36 are used.[11,61,62,64,68,69] Secondly, the questionnaire was available for self-report and as an interview so that participants with literacy issues were also included. The limitations of this study relate to sampling. Although the sample size is small (41), 100 % of people with a DFU who attended the Outpatient Diabetes Clinic at Uttaradit hospital over the study period agreed to participate in the survey. The small sample size means that the findings may not be representative of all people with DFUs in Thailand. Secondly, this study was undertaken in one hospital in northern Thailand and the majority of the participants had low grade DFU's (Grade 1 and 2) as measured by the Wagner's Classification scale. Finally, the data were obtained through a survey which was cross-sectional in nature and only enabled those receiving treatment at the foot clinic during the recruitment period to participate. Future research should focus on large, well-designed multicentre trials to investigate the HRQOL and foot self-management practices of Thai people with DFUs of

varying severities.

Implications for practice

The findings have implications for healthcare professionals who provide education to people with diabetes mellitus, to healthcare professionals who provide education to people with DFUs, to policy makers and funding bodies. This study underlines the significance of foot self-care management practices on HRQOL among people who have diabetes (both with and without DFUs). The findings from this study can be used to develop diabetes education programs for people with diabetes in northern Thailand. Education programs must provide practical skills and education about why activities are important so that participants understand the need for the self-care management and the impact it has on preventing / healing DFUs.

Conclusions

This is the first study that has investigated HRQOL and foot self-care practices of people with DFUs in northern Thailand. The results indicate the need for individualised and focused foot care education that includes self-care management practices to improve HRQOL.

Chapter 7

Results: Experiences of People with a DFU

This chapter presents Publication 6, 'The experiences of people in northern Thailand living with diabetic foot ulcers: a descriptive qualitative study'. This publication explores the findings from the qualitative component of this mixed methods study. The publication addresses the research question: What are the experiences of Thai adults living with DFUs?

The publication was published in the Pacific Rim International Journal of Nursing Research. The journal is indexed in CINAHL, Scopus, Google Scholar and TCI group 1.

Permission to include the publication within the thesis has been granted.

Abstract

Diabetic foot ulcers are a main cause of morbidity related to type 2 diabetes. Living with a diabetic foot ulcer has a significant impact on health-related quality of life and has a negative impact on daily living among people with the condition. The aim of this study was to explore the experiences of Thai adults living with diabetic foot ulcers using a descriptive qualitative design. Participants were recruited from the outpatient diabetes and foot clinic at a tertiary teaching hospital in northern Thailand from January to April 2017. In-depth interviews were conducted with 13 participants using a semi-structured interview guide. Thematic analysis was used to identify the participants' experiences and two themes were identified: 1. living with a diabetic foot ulcer and 2. managing a diabetic foot ulcer. The findings enhance the knowledge of healthcare professionals and the public to understand the experience of having diabetic foot ulcers and contribute to understanding how to manage a diabetic foot ulcer based on the participant's experiences in the Thai context. Nurses must provide knowledge and self-care skills as part of routine care to improve health-related quality of life for people with diabetic foot ulcers.

Keywords: Diabetic foot ulcers, Health related quality of life, Qualitative study, Self-care management, Wound care

Introduction

Diabetes Mellitus)DM(is a chronic disease that occurs due to an abnormality in the metabolism of protein, carbohydrate and fat. Primarily, the pancreas cannot effectively function to control blood glucose levels because of a deficiency of insulin being secreted or resistance to insulin or both and this results in hyperglycaemia.[1] Diabetes has become a major global public health problem. The International Diabetes Federation)IDF(has produced an estimate for 216 countries and territories on the rate of diabetes and anticipates that the number of people with diabetes will increase dramatically to 522 million by 2030.[202]

The impact of diabetes on health in Thailand is similar to other countries. Thailand is experiencing increasing numbers of people with diabetes related to poor diet, obesity, physical inactivity and an ageing society.[135,136] Diabetes is now the fourth highest cause of mortality in all ages in Thailand and is rising in both males and females who die from complications related to high blood glucose levels.[136] Diabetic foot ulcers)DFUs(are the one of the major complications of diabetes mellitus resulting from damage to nerves in the foot due to microvascular and macrovascular changes.[32] The prevalence of DFUs has been reported to be as high as 15 % in people with type 2 diabetes.[8] Foot ulceration can result in foot deformity, permanent disability and more often amputation.[58] It is reported in the USA, that more than 50 % of all amputees have diabetes mellitus.[2] A DFU can cause a significant impact on the quality of life of patients' living with type 2 diabetes.

In Thailand, the National Health Examination Survey undertaken in Thai adults reported the prevalence of people with diabetes was 10.1 %.[203] Complications from diabetes are a serious issue in Thailand particularly in relation to diabetic foot problems. A cross-sectional study of 593 patients with type 2 diabetes in one hospital in Thailand identified that the prevalence of DFUs was 3.4 %.[236] In addition, 2.2 % of patients had a history of amputation and 10.6 % were identified as high risk of developing foot ulcers.[236] Reutrakul and Deerochanawong[135] reported that 15-26 % of people with diabetes had foot problems, 22 % were identified as high-risk of developing a foot ulcer during a comprehensive foot examination, and 5.9 % had a previous history of DFU.

Literature Review

Health-related quality of life)HRQOL(has been identified as a goal of health and well-being[244] and is the quality of life of an individual relative to their health or disease status. There are four dimensions which include physical, social, psychological, and spritual factors.[244] In Asia, a number of studies have investigated patients' perceptions of foot self-care practice, self-care behaviour and awareness, prevalence of risk factors in diabetic foot ulcers, ethnicity and the strategies used to prevent diabetic foot ulcers.[112,113,115,116,245] Linkages have been made between presence of DFU and low health related quality of life.[60] Chellan et al.[113] found in their study of 203 participants)103 with DFU and 100 without DFU(that the incidence of DFU was inversely related)p < 0.001(to participants' practicing diabetic foot care.

Historically, Thailand has not had specialists who look after people with DFUs, with diabetic foot

ulcers and infections being managed by surgeons or orthopaedists.[135] The lack of specialist care in Thailand is a major cause of the prevalence of DFUs. In research undertaken by Aekplakorn et al.[139] it was found that the prevalence rate of diabetes in Thailand is increasing. The estimated national prevalence of diabetes in Thai adults was 6.4 % in 2013[17], and is said to have been one of the top five common chronic diseases in Thailand.[246]

The experiences of Thai adults living with diabetic foot ulcers need to be explored in context. Religion and spirituality are the core principle of Thai beliefs. Some rural Thai people also believe in traditional healing, black magic, herbal remedies and supernatural causes of illness.[247] These beliefs may impact on the experiences of people living with type 2 diabetes. This is supported by previous studies among people with type 2 diabetes in Thailand which have identified many factors that impact upon daily living such as culture, belief, religion and education level.[116,141-143] Diet also impacts upon managing type 2 diabetes and preventing complications. In Thailand, most people eat food with rice or glutinous rice that is high in carbohydrates. In addition, there are many kinds of tropical fruits, including durian, ripened mango, lychee, longan, orange, pineapple and rambutan[143] that people eat all year round. These fruits contain high amounts of carbohydrates that impact on optimal glycaemic control. There is a limited amount of literature exploring the experience of Thai adults living with diabetic foot ulcers. In addition, little is known about how people with DFUs in Thailand access and then use information from healthcare professionals about managing their diabetes and wound care. In this study, qualitative interviews were conducted among people with DFU's to provide a deeper understanding of the specific context of DFU's on health related quality of life.

This study was undertaken as part of a doctoral dissertation exploring health related quality of life among people with type 2 diabetes in northern Thailand. The project used a sequential, mixed methods design to examine health related quality of life, self-care skills and knowledge of diabetes among people with and without diabetic foot ulcers. The research reported in this paper constitutes phase two of the project which used qualitative data to explore the lived experiences of people with diabetic foot ulcers.

Aim of the study

The aim of this study was to explore the experiences of northern Thai people living with diabetic foot ulcers in northern Thailand and strategies they used to manage their diet and wound care.

Methods

A descriptive qualitative research approach was used to explore the in-depth, rich experiences of people living with diabetic foot ulcers in Thailand. This approach was chosen to enable the researcher to gather, analyse and interpret the experiences, realities and meanings from the participants in this research in a way that is culturally appropriate and uses subjective experiences of their lives to construct knowledge and build understanding on this research question.[183,184]

Sample and setting

Participants were recruited from the outpatient clinic at a large teaching hospital in Uttaradit province in northern Thailand during the three-month period from January to April 2017. All participants were recruited from a larger study examining health-related quality of life of diabetic people with and without foot ulcers that was undertaken as part of a doctoral dissertation.

Participants were recruited if they met the following inclusion criteria: participated in phase 1 of this study; aged over 18 years; diagnosed with type 2 diabetes; had one or more diabetic foot ulcers; and agreed to participate. People, who had a cognitive impairment, were unable to consent to participate, and people who could not speak Thai were excluded. Participants were approached by a trained research assistant who provided information to potential participants who met the inclusion criteria during a routine check-up at the outpatient clinic. If they agreed, the researcher then contacted the participants by phone and made an appointment for an interview either at their home or their next appointment at the outpatient clinic. All participants were informed of the study and written consent was obtained prior to participating in the interview.

Ethical consideration

This study was approved by the Human Research Ethics Committees of the University of Wollongong)HE16/209(and Uttaradit Hospital)7/2017(prior to data collection. Information about the study was read out to all participants, and each participant provided verbal and written consent to participate in the study. All data was de-identified using pseudonyms and stored in an electronic file with password protection as per NHMRC Guidelines.[248]

Data collection

Interviews were conducted in the Thai language at each of the participant's home. The interviews were semi-structured with the question guide developed from a pilot study of 10 people and a systematic literature review. The interviews began with general questions to build rapport and confidence between interviewer and the interviewee.[249] The interview guide contained open-ended questions, and in-depth questions such as: "How did you feel after you were informed by the doctor that you had a foot ulcer because of DM?", How would you describe your quality of life after your diagnosis with diabetes mellitus?", "How have you changed your diet since you were diagnosed with diabetes mellitus?", and "How do you live with your foot ulcers?" Based on the patients' narratives, and descriptions, topics were explored in depth with probing and clarifying questions which were used to gain additional details about the phenomena being examined.

Recruitment of participants continued until data saturation was achieved.[250] Thematic mapping was used to assess for data saturation at the completion of interviews. The research team identified data saturation at 10 interviews and an additional 3 interviews were held to ensure that no new information was obtained. The interviews were conducted over 30-50 minutes and were recorded and transcribed verbatim. Patient name, personal details and any other identifying data were omitted during transcription. Field notes were made after each interview. Confidentiality was

maintained at all times by using pseudonyms, de-identifying data and secure storage of all data.

Data analysis

Thematic analysis was undertaken in this study using a constructivist orientation using Braun and Clark's[124] guidelines for thematic analysis. The following six phases of thematic analysis were used:

Phase 1: The Principal Researcher)PI(transcribed all audio recorded interview data verbatim in Thai. The data was then discussed with an experienced qualitative expert who is bilingual)Thai and English(to ensure translation accuracy. The PI then read and re-read the data several times to achieve familiarisation.

Phase 2: Coding. Two researchers identified data that was considered pertinent to the research questions and coded all data items line-by-line in Thai to ensure the sense of meaning was retained.

Phase 3: Searching for themes. This phase involved analyzing all collected codes)Thai version(and identifying similarities and relevance to the research questions. This phase was iterative and involved reviewing all codes in a continuous process of searching for meaning. Thematic mapping was used for visualising and considering the linkages and relationships between themes.

Phase 4: Reviewing themes. Two researchers re-checked the relationship for both the coded extract and the full data set. This ensured the themes accurately reflected what was evident in the data set as a whole.[124] During this phase, the researchers developed initial thematic mapping by grouping codes with similar content into categories and grouping categories with similar concepts into themes. Following translation of all themes and extracts into English, this process was checked to ensure congruence of the extracts with the themes.

Phase 5: Defining and naming themes. The preliminary thematic mapping was translated into English and presented to the full research team which then explored the naming of themes, the choice of extracts and discussed how each chosen extract supported theme development and demonstrated meaning.

Phase 6: Writing up. The PI selected the extracts from each theme to illustrate meaning in each theme. The extracts clearly identified important concepts within the theme and presented a lucid example of the point being made in the English version.

The data analysis process was carried out manually by tabulating, listing, grouping, and mapping the data in Microsoft Word version 2010®. The data was presented to the full research team multiple times to ensure that themes were a true reflection of the participant's experiences)individually and collectively(and that the extracts used to explore each theme were illustrative of the data.

Trustworthiness

Trustworthiness and integrity have been described by Koch[251], Crowe et al.[252] and Sandelowski[253] for addressing rigor and validity of qualitative research and included the concepts of credibility, dependability, and transferability.[254] Credibility refers to confidence in the truth of the data and interpretation from the researcher. This study used mapping for visualising the linkages and relationships between themes. Initial thematic mapping was developed by two authors in Thai and then confirmed by two authors in English. The final thematic mapping was agreed by all researchers. Dependability involves ensuring that the data collection and data analysis procedures are worthy of trust. The interviews were transcribed verbatim in the Thai language by the PI and the transcription process was checked for accuracy by listening to excerpts of the MP3 recording by another author who speaks the Thai language. Furthermore, the process of naming themes was checked for the identification of categories and themes. Finally, all the excerpts were translated into English, checked for accuracy of translation with three researchers and then discussed with all researchers. Transferability refers to whether the findings can be applied to other settings or groups.[13,251] To enhance transferability, this study carefully recruited participants who were currently living with one or more diabetic foot ulcers. Even though qualitative data is not easily generalised to large groups it can be used to build knowledge and understanding of the experiences of Thai people who have diabetic foot ulcers.

Findings

A total of 40 participants were approached to participate in interviews. Twenty six participants declined to participate for a range of reasons and one potential participant passed away. Thirteen patients were interviewed in this study: seven females and six males. The mean age was 63.46 years old (range 52-76 years). Six participants had foot ulcers that were classified by the Wagner classification system as grade 1 and seven participants had grade 2 foot ulcers. The Wagner Classification system is widely used to grade diabetic foot ulcers and is primarily based on the wound depth, the presence and location of wound infection and has grades ranging from 0 to 5.[38] All participants had completed primary school level education and all participants were Buddhists. The characteristics of the participants are summarised in Table 19.

Table 19: The Demographic Characteristics of Participants

Pseudonyms	Age Gender	Marital status	Prior / current occupation	Level of Education	Wagner grade of current DFU	History of previous DFU	History of amputation for DFU
Ban	70 F	Married	House wife	Primary school	2	No	1st toe nail at the right foot
Chee	52 M	Married	Butcher	Primary school	2	No	No
Dan	76 M	Married	Farmer	Primary school	1	No	No
Fang	64 M	Divorce	Farmer	Primary school	2	Yes	1st and 2nd toe nail at both left and right foot
Kat	70 F	Married	House wife	Primary school	1	No	No
Makam	65 F	Widows	House wife	Primary school	1	No	No
Pakad	52 F	Single	Labour	Primary school	2	Yes	5th toe nail at left and right foot
Pete	61 F	Widows	House wife	Primary school	1	Yes	No
Pitoon	64 M	Married	Labour	Primary school	1	No	No
Rat	62 F	Married	House wife	Primary school	2	Yes	1st and 2nd toe nail of right foot
San	57 M	Married	Farmer	Primary school	2	Yes	No
Sawang	68 F	Married	Farmer	Primary school	1	No	No
Team	64 M	Married	Unemployed	Primary school	2	Yes	BK amputation at left leg 2nd and 3rd toe nail of left foot

Note; M = Male; F = Female

Themes

Data analysis identified two themes. The first theme "Living with diabetic foot ulcers (DFUs)" included four subthemes: Physical impacts of DFU; Emotional impacts of DFU; Socio-economic impacts of DFU; and Managing diet. The second theme explored concepts around "Managing a diabetic foot ulcer (DFU)".

Theme 1: Living with DFUs

Participants reported consequences related to their physical, emotional and socio-economic experiences as well as managing their diet.

Sub-theme 1: Physical impacts of DFU

Participants described a range of different experiences related to the physical component of their life. Many participants experienced energy and mobility limitations such as not being able to walk comfortably and getting tired easily. This sub-theme describes the experiences of people living with DFUs relating to physical dimensions.

A. Energy and mobility limitations

Diabetic foot ulcers (DFUs) created a physical energy limitation for participants. Some reported that they were unable to maintain 100 % of energy levels and were always easily tired: *"My energy is never up to 100 %. I always feel like I have 60-70 % of my strength. Every time I work I feel tired."* (Kat). One participant described this experience of limited energy and mobility as causing breathing difficulties when trying to overcome these limitations.

> My energy level is very low and everything I do makes me feel tired. Even if I wish to do small things it will make me very tired. When I worked, my breathing became heavy and it was hard to inhale. (Sawang).

> I can walk around the house, but I find doing any type of housework is difficult. This is due to constant muscle ache. I'm unable to work due to constant muscle pain. (Dan).

The permanent disability from amputation due to DFUs influenced the limitation of movement. Some participants used orthotics for support while they were walking and many also mentioned they had to walk carefully to avoid new foot ulcers.

> ...Right now, I can't walk properly. I need the help of a walking stick to get around. I can't walk for a long distance. I'm scared of falling, and if I fell, I would be in trouble.)Pakad(.

B. Foot protection

Protecting the feet became an important consideration for most participants. In Thailand, the hospital provides shoes for people who have foot deformities or are at a high risk of developing foot ulcers. However, these shoes were not considered comfortable by many participants. One participant had an amputation below the left knee and of the toe nail on the right foot. He used a

prosthesis on his left leg and wore a diabetic shoe on his right foot but reported that he remained uncomfortable when he walked. Hence, the diabetic shoe was not a successful choice for protecting his feet.

> I quite rarely wear the diabetes shoes the hospital provided. The reason is that they are quite thick and uncomfortable for me. I then found sandals that are a good fit and comfortable for me. (Team).

This was a familiar experience for other participants who tried to purchase other shoes for their everyday use. One participant had lost the sensation in his feet so he chose to wear sandals.

> I select nice shoes such as sandals but not slippers. I select shoes/sandals that are not too big or too small. (Rat).

Participants described how the weather in Thailand (which is hot and humid), makes sandals a more popular choice than the heavy shoes provided by the hospital.

Participants described how families who could afford to buy special shoes often did so.

> My daughter bought special shoes for me. They have nodules in each one to massage my feet as I walk. (Ban).

Similarly, participants talked about using special protective mechanisms.

> I used the cotton bag to protect the wound on my feet from the dust. My young brother made the bag for me. I use it when I go out or when I go to see the doctor at the hospital. (Ban).

Some participants also used special socks.

> I wear a special sock that will protect my feet from dust and water. It is not totally waterproof, but it does work for me. (San).

Sub-theme 2: Emotional impacts of DFU

Having a DFU had a significant impact on the mental health of participants and were associated with negative emotions such as fear and worry about requiring an amputation. Many participants described feeling overwhelmed and troubled at the thought of leg amputation. One participant had experienced partial toenail amputations and was unable to walk or work.

> What can I do? I have had both big toe nails amputated. I thought, it is just only my toe nails and not my legs. If it was my legs I would not be able to walk or work. (Fang).

Participants frequently expressed the impact of fear on their mental health and wellbeing. Two participants described their "anxiety" when they had new foot ulcers, the fear being that these wounds might result in long term healing problems and even the possibility of amputation.

> If I get foot ulcers they should be dressed immediately. If not it will cause trouble. I am very fearful of amputation. Diabetic foot ulcers are not small ulcers but very deep wounds. (Kat).

I have had diabetic foot ulcers for 2 years (frowned heavily). All this time I am worrying about amputation. The doctor x-rayed me and, lucky me, it wasn't infected to the bone. There is no need for amputation. (Pete).

Interlinked with this fear was a feeling of depression, particularly when it related to having DFUs that were hard to heal.

I'm so bored (made a long sound). So, I've no idea how to deal with diabetic foot ulcers. If I'm going to die, I'll die (sad eyes). I've lived with diabetic foot ulcers for many years. (Dan).

Despite these negative emotions, participants described their coping strategies such as staying calm and reducing stress from unhealed DFUs. Most participants had DFUs that were unhealed for longer than six months. One participant described how coping strategies were used. The first one he called "Phlong".

Phlong is like be calm or not think in the negative way. (Team).

The strategy of "Phlong" was used to focus thinking in a positive way and help calm oneself. Other participants reflected similar experiences, particularly when calming themselves to reduce the stress or engaging in positive thinking.

I have to be calm and be happy. If I am thinking too much it will cause me stress. Then I do not think too much. I do enjoy what I am doing. When I feel tired, I then take a break for a minute then continue working in my garden or with my housework. (San).

Another strategy was called "Thum Jai" *(think positive)* which was used in isolation or in combination with "Phlong". One participant described the way she used these as an easy and effective way to stay calm and reduce stress in her case.

Just let it be. I might not suffer at all. If it's going to happen, I will just let it happen. My advantage is that I am not easily stressed. So, it will not bother me anymore. Actually, it has not happened to me for very long. When I ″Thum Jai″ (think positive) it goes away. (Rat).

As a coping strategy, "Phlong" and "Thum Jai" appeared to alleviate the personal loss that people experienced due to stress from unhealed DFUs. It is culturally appropriate to use these strategies to assist with calming their mind as all participants were Buddhists. In addition, these strategies appeared to lead to positive thinking and stress management activities. Even though, "Phlong" and "Thum Jai" are culturally specific strategies for Thai people who practice Buddhism, they may provide some insight into strategies that can be successful in other cultures.

Sub-theme 3: Socio-economic impacts of DFU

Participants commented that they had to make lifestyle changes on a daily basis. A significant impact was when they described not being able to participate normally in a social setting. Sometimes the reason for social isolation and withdrawal from social events related to embarrassment. Even participating in a community event for a short time caused personal

discomfort, withdrawal from the environment and/or interactions and a desire to stay home.

> Everyone is looking at me. I'm afraid that they feel I am disgusting. Well, I decided to stay at home rather than socialise with them. Also, I just joined their event for a short time then I returned home. (Pete).

Participants described the impact that having a DFU had on their ability to work and or participate in their usual household activities. One participant had to stop work and wait until the foot ulcers healed. This was because he was afraid to get them dirty and they would take longer to heal.

> Normally, I would do work every day, such as farming or gardening. But diabetic foot ulcers are a big problem for me (point to his right foot). I can't go anywhere because of diabetic foot ulcers. I am afraid to get them wet because that will make them hard to heal. I have to wait at home till they are healed. (Fang).

A further lifestyle change was caused by a limited capacity to work due to low energy levels which resulted in low income. For example, a participant described the impact having a DFU had on his income.

> Every year I make baskets for sale. However, since 2015 I lacked the energy to do anything and have no income. (Dan).

Some participants reported that they needed to change their lifestyle because of amputation from previous DFUs infection. Having a DFU affects a person's normal life which makes resumption of normal activities difficult. Even though the government provides funding for people with disabilities in Thailand, participants reported that it was not enough.

> I receive the funding for disability for 800 baht/month (~ US$ 25.58) from the government but it is not enough for me. I need to do work at home to cover my daily expenses. (Pakad).

The majority of participants described that social support was crucial for the management of DFUs. This included peer groups helping each other such as giving advice, caring, and taking care on a daily basis. The most common type of support described was assisting in preparing food, assitance with outings or to see the doctor, and visiting in the home.

> My relatives, neighbours and communities come to visit quite often. Somedays we do not see each other. Then they will come and see me, or ask someone near my house if I am ok. (Dan).

Professional supports from nurses or doctors were also described as necessary to manage their DFUs. The local nurses followed up the patients after they were discharged from hospital.

> Sometimes, the local nurse visits me and dresses my wound. (Pete).

Some participants went to see their family doctor for a check-up and assistance with controlling blood glucose levels.

> I always follow the suggestions of my family doctor. (Ban).

Despite the social withdrawal described previously, participants received social support in a variety of different ways. These included professional support by nurses or doctors, community peer groups, and families.

Sub-theme 4: Managing diet

Dietary management for people with DFUs is important to achieve glycaemic control. Managing portion size appeared to be the most challenging concept for most participants. Participants described how they tried to reduce the quantity of tropical fruits, desserts, and rice. Even though they knew about impact of tropical sweet fruits on their blood glucose level, it was difficult for them to reduce their consumption of them.

> I ate a cluster of cultivated bananas and 4 durians. Then my blood sugar level was 400 (mg %). (Pitoon).

> I ate durian a lot, then my blood sugar level was high almost 450 (mg %). (Ban).

> I eat oranges, santols, mangosteens, rambutans everything too much (haha). Then I know my blood sugar will be so high. For example, oranges, when I eat them, they are so good and feel fresh. The doctor told me to reduce the quantity. (Kat).

Some participants also learned from their experiences about over consumption of tropical fruits. One reported that he developed foot ulcers during the durian season and he could not manage his urge to eat the fruit.

> I get foot ulcers during durian season around July. Also, I sell the durian and eat it while I travel from place to place. Probably, this is the reason I have high blood sugar levels. (San).

Participants described other foods they avoided. They called them "Ahan Sa Lang" (These are foods which are not recommended for diabetes). Participants described how they tried to avoid these foods which included fermented foods high in sodium and gas. Dietitians recommend that people with DFUs also avoid bamboo shoot, acacia, pickles, fermented fish, and beef [255]. Some of the participants described their experiences after eating prohibited foods.

> Beef, I don't eat it anymore. My toe nail was amputated because of it. When I ate it my toe nail became blistered. After, this it became an ulcer. So, I stopped eating beef. (Pakad).

> The cause of her hospital admission was she ate beef and acacias. Finally, it blistered and then became an ulcer with much pus. (Pete).

The majority of the participants agreed that dietary control was beneficial and described how they reduced the quantity of their consumption of carbohydrates and sweets.

> I tried to reduce the amount of dessert and sweet foods. Previously, I ate one small bowl but at the moment I eat only 1-2 spoons. (Chee).

I ate sticky rice around 10 baht (~ US$ 0.32) reduced from 20 baht (~ US$ 0.64). (Pitoon).

Similar strategies were used for desserts and rice. Because Thai people normally eat jasmine rice or glutinous rice every meal, participants described how they reduced the quantity of what they consumed. *"I only ate one ladle of rice and that's it. I don't eat more than one ladle of rice"* (Fang).

Blood glucose fluctuations such as hyper- and hypoglycaemia are a common complication in diabetes mellitus. However, optimal glycaemic control should ensure that the symptoms are not experienced very often. Participants described how having hypo and hyperglycaemia was a problematic experience for them and narrated their strategies for self-management and identifying the signs and symptoms of hyper and hypoglycaemia.

When my blood sugar level is high, I felt I was staggering, my vision was blurred. I couldn't see the TV screen clearly especially letters. It seemed like I was blind. (Pitoon).

When my blood sugar level is low, it is all sweaty at the back of the neck (pointing to his neck) and also my forehead. It was just like I had stepped out of the shower. (Pitoon).

When my blood sugar level is high, I feel exhausted and can't do anything. (Kat).

Other participants shared their strategies to protect against hypoglycaemia.

When I get low blood sugar I need to eat something. Then I went to have some ice cream, just one scoop. The sweating stopped and was gone. (Pitoon).

Hyper and hypoglycaemia are serious complication in diabetes and indicate poor glycaemic control. Participants developed their own strategies to manage these complications.

Theme 2: Managing a DFU

All participants described several ways to manage a DFU, including following advice from health professionals, using herbal remedies, and for some people using local wisdom and/or traditional healing.

All participants had a DFU that required wound care. Participants were also focused on looking after themselves to avoid getting new foot ulcers. The standard procedures of wound care were applied by most participants. Saline solutions, alcohol and betadine were widely used for dressing wounds.

I'm using an alcohol and saline solution for wound dressing. I then cover the wound with gauze. I do this every evening after showering. (Fang).

It was apparent however, that some of the participants misunderstood how to dress a wound and used alcohol directly on the wound.

Normally, I used alcohol and saline dressing every day at home. I used a cotton bud with saline to clean my wound then paint with alcohol every day in the morning and evening. (Pakad).

This participant had lost some of the sensation in her feet and could not feel any irritations from alcohol but expressed that she felt cleaner with the use of alcohol.

Most participants learnt how to dress their wounds from nurses by using antiseptic solutions.

I cleaned my wound every day with antiseptic solution and saline. I follow the instruction that I've learnt from nurses. (Kat).

Some participants could afford to buy additional supplies for wound healing. Hydrogel was the most common product used to supplement routine wound care prescribed by nurses. Several participants described how they used hydrogel.

It's like a jelly. After I cleaned my wound, I always put it in. Then, paint the alcohol around and cover with gauze. (Sam).

It's like a jelly. It was stimulating and my wound healed quickly. My son bought it for me from Bangkok. I used it after cleaning wound in the usual way. (Team).

Complementary wound care was also used by many participants. In the Thai culture, people use herbal oil remedies to maintain health and well-being. Some participants believed that these could help them to improve numbness in the wound and reduce wound size.

By applying herbal oil remedies to my feet there has been a big improvement. The numbness has gone and the wound size has shrunk. (Pitoon).

I applied toothpaste on her wound (her daughter). It seemed to heal quickly. Currently, it is not dry. There is a lot of pus on it. She was admitted to hospital for dressing the wound every day. (Pete).

Similarly, participants described how family members were often seeking a herbal drink for them for controlling blood glucose levels and improving wound care.

My grandson bought the herb (tea) to me for reducing the blood sugar levels. I tried to drink it but it doesn't work. (Dan).

In some cases participants described the herbal remedies as affective but they also expressed caution in using this method of controlling blood sugar levels.

Some neighbours visited me and recommended some herbs. They said the herbs would reduce my blood sugar levels. It works for them. Currently, the neighbour has 110)mg %(of her blood glucose. The herb looks like grass with small white flowers. Oh! When I first drank it. I urinated a lot and it was painful.)Ban(.

Pak Chaing Da (type of herb). This herb gives me complications when I drink it. I get hypoglycaemia after I drink it for two days. Please be careful. (Ban).

Furthermore, local wisdom influenced participants who had a strong belief in faith healing. This

lead to some participants seeking the help of a holy doctor who was considered able to heal through the use of herbs and holy water.

> If I go to see the doctor and drain the pus the wound would become infected. Then I wouldn't go. I only go to see the holy doctor... I did not do anything. I just drank the holy water then the wound become dry. (Makam).

The belief in the holy doctor (spiritual healer) is an alternative for people who do not believe in conventional treatments for DFUs. One participant had experienced a wound which was not healing and the doctor planned to amputate his leg. This participant turned to the holy doctor for help.

> I thought the holy doctor may help me. I went to see holy doctor, because the doctor told me to accept amputation. The holy doctor chewed the cumin and put it into the wound...When I went to the primary care unit the nurse told me not to put anything into the wound because it may cause an infection. (Fang).

Consequently, his wound became infected and the doctor needed to debride his wound to drain the pus. Fang had long-term dressings undertaken in the hospital and the primary care unit. Eventually the infection was cleared and he did not have to have an amputation.

In summary, participants described how modifying their everyday life experiences became difficult when they were diagnosed with a DFU due to old habits being hard to change, uncertainty about the benefits of changing diet and the reality and inconvenience of daily foot ulcer management procedures. Transition and life events had a significant effect on their HRQOL and diabetes control, which in turn affected their wound healing.

Discussion

This study explored the experiences of adults in northern Thailand who are living with DFUs. The findings contribute to the understanding of the consequences and experiences of DFUs based on their experiences and perceptions. In addition, the findings provide information on the application of evidence-based practices in the Thai context for people living with a DFU. Most of the themes found in this study are common to diabetes populations with a negative and/or positive impact, e.g. limited energy and mobility, cultural impact, spiritual impact, and self-care management.[141-143,256] However, there were themes identified which are unique to the Thai population. All participants described how their old habits were hard to change. Furthermore, the emotional state, lifestyle and belief of local wisdom were key elements experienced by individuals who had poor self-care management practices and poor wound healing.

Living with DFUs

Most participants, particularly people with DFUs, are affected both physically and mentally. Consistent with European studies[46,68,225], all participants reported low HRQOL which had an

impact on their physical functioning, role emotional, role physical and general health. Similarly, this study found that DFUs cause limitations in energy and mobility, and mental state which had a negative impact on work and everyday activities. The fear of amputation was a significant burden that impacted on people's emotions. Therefore, both physical and mental impacts should be considered when planning care for people with DFUs.

Another challenge for a healthcare provider is providing appropriate advice about diet glycaemic control. Previous eating habits are difficult to change among people with DFUs attempting to manage their blood glucose levels. This is supported by Lundberg and Thrakul[141] who describe diet as challenging to change. Moderation in eating is consistent with following the Buddhism concept of moderation. In this study people with DFUs tried to control their diets by moderating their diet and avoiding prohibited foods. This included not overeating, managing portion sizes, avoiding drinking alcohol and promoting healthy behaviours by reducing the quantity of rice and dessert.

DFUs are widely considered to be a severe complication of diabetes which causes impaired mobility and mortality.[235] In the Thai context, Buddhism is the core principle of Thai beliefs. The Buddhist philosophy can support individuals to adopt coping strategies which can assist lifestyle changes and lead to a calmer way of being. This study found that the coping strategies of "Phlong" and "Thum Jai" were effective among people with DFUs. This may be because it reduced their feelings of stress, worry, and fear. Thus, healthcare providers need to understand the impact of cultural beliefs and cultural backgrounds as a basis for assisting patients to apply these strategies for improving HRQOL.

Managing a DFU

This research has provided insight into the management of DFUs in the Thai context. Surprisingly, there were a large amount of variations in wound care practices identified in this study. Local wisdom and cultural beliefs had an impact on DFU management. Participants' beliefs appeared to impact on their disease and wound healing.[141] This study found that treatment from a holy shaman was associated with chronic wound healing and/ or severe infection. It is noted that the healthcare provider should be aware of a person's spiritual/ cultural beliefs so that they can assist the individual in getting appropriate treatments in conjuction with their beliefs.

This study is a part of a larger piece of research which has explored the HRQOL among Thai adults living with DFUs in northern Thailand. The results of this qualitative study have explored the lived experiences of people living with and managing their DFUs and the impact this can have on HRQOL.

Limitations

This study involved a small sample of participants in only one province of Thailand. As a result caution should be taken in generalising these findings to other populations. The diversity of partipants (ages, educational levels and treatment of diabetes) made comparisons between participants difficult but this diversity also provided a rich overview of how DFUs impact on HRQOL among Thai adults. Further research should be undertaken to explore the impact of social and cultural norms among people with DFUs and the impact this has on everyday living, wound healing, wound management strategies and HRQOL.

Conclusion and implications for nursing practice

The findings of this study provide additional knowledge for persons working in diabetes clinics who are providing foot care and diabetes management for people with DFUs. Understanding the lived experiences of Thai people with DFUs will assist healthcare professionals to ensure that cultural and spiritual beliefs are considered when developing a collaborative plan of care for individuals with DFUs. In addition, this study provides insight into the actual wound management practices used by Thai people who have a DFU. This knowledge can be used to improve education practices and ensure self-care management strategies are understood by people with DFUs who manage their own wound dressings at home. Additional training for healthcare professionals working in diabetes foot care may be required to improve service delivery to ensure improved outcomes for people with DFUs in Thailand.

Chapter 8

Integration of Findings

This thesis commenced with a systematic review of the evidence to identify (and explore) the factors associated with HRQOL among people with DFUs (Chapter 2, Part 2). An integrative review about diabetes knowledge and self-care management among people with DFUs was also undertaken (Chapter 2, Part 3). Results of the systematic review demonstrated that people with DFUs had poor HRQOL in four of eight subscales in the SF-36 domains: physical functioning, role physical, general health and vitality. In addition, presence of pain, high levels of CRP (> 10 mg/l), ulcer size > 5 cm^2, ankle-brachial index < 0.9, high glycosylated haemoglobin and BMI > 25 kg/m^2 were associated with poorer HRQOL in people with DFUs. Results from the integrative review found that people with DFUs have a lack of knowledge on diabetes and self-care management and do not prioritise self-care management practices in their daily routines. In addition, demographic, geographical location and cultural differences affected DFU development.

These reviews confirm that there was limited evidence that investigated the HRQOL, diabetes knowledge and self-care management among Thai people with T2DM with and without DFUs. Hence, a sequential, explanatory mixed method study was undertaken to investigate the following questions:

1. What is the HRQOL and the clinical and demographic predictors of HRQOL among Thai adults with T2DM? (See Chapter 4)
2. What is the diabetes knowledge of Thai adults living with T2DM? (See Chapter 5)
3. What is the HRQOL and self-care management practices among Thai adults living with DFUs? (See Chapter 6)
4. What are the experiences of Thai adults living with DFUs? (See Chapter 7)

The quantitative phases consisted of cross-sectional surveys investigating the HRQOL, diabetes knowledge and self-care management practices among people with T2DM at a large tertiary hospital in northern Thailand. The qualitative phase involved interviews of people who had both T2DM and a DFU.

This chapter will provide a summary of the findings and integrate the quantitative and qualitative components of the project. Orem's self-care deficit nursing theory[154] has been used to demonstrate how the findings have been integrated (see Figure 14).
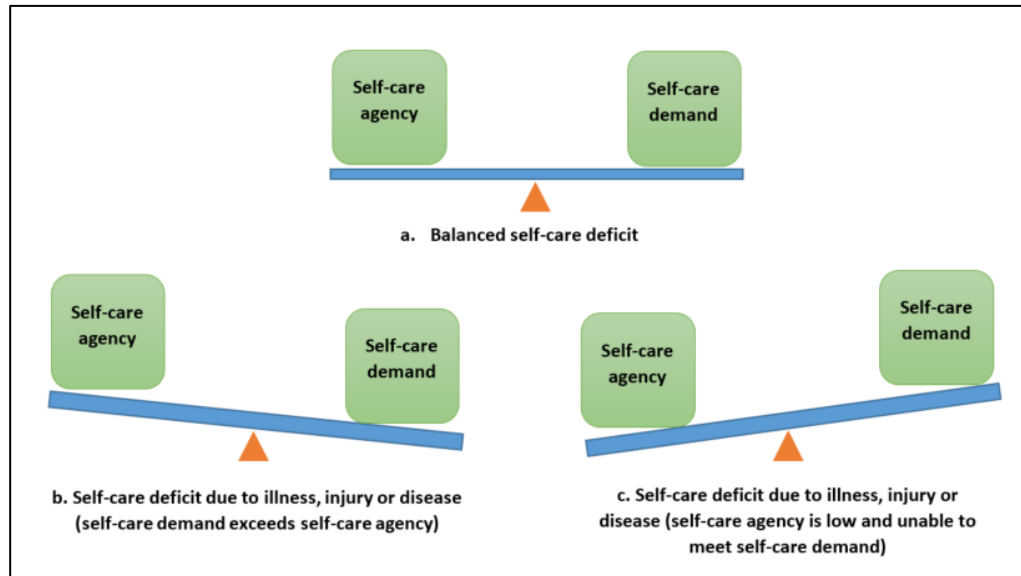
Figure 14: Orem's self-care deficit nursing theory: The variations in self-care agency and self-care demand

Self-care deficit: HRQOL among Thai adults with T2DM with and without DFUs

The results demonstrated that people with T2DM have a poor HRQOL. The mean scores for each subscale were: diabetes control 19.78 (SD 14.80), anxiety and worry 23.52 (SD 17.71), social burden 16.58 (SD 12.40), sexual functioning 15.89 (SD 19.28), energy and mobility 21.60 (SD 15.85) and other health problems and diabetes complications 21.43 (SD 18.41). The mean score for perception of overall HRQOL using the D-39 was 61.18 (SD 18.74).

The presence of DFUs and smoking status were identified as significant predictors of low HRQOL in the domains relating to diabetes control, social burden and energy and mobility. In addition, the presence of obesity, receiving insulin injections or a combination of insulin and oral medication were all predictors of poor HRQOL in the domain of other health problems and diabetes complications.

When HRQOL was measured among people with DFUs, participants reported high scores, demonstrating high HRQOL in all domains of the DFS-SF. The mean scores were: leisure (66.95 ± 28.03), physical health (68.93 ± 28.51), dependence or daily life (80.08 ± 25.23), negative emotions (71.23 ± 29.48), worried about ulcers (62.20 ± 31.97) and bothered by ulcer care (69.36 ± 25.20). Participants in the qualitative study reported physical limitations that affected their energy levels and mobility that then affected their HRQOL. Some excerpts from comments that illustrate this point are included below:

> My energy level is very low and everything I do makes me feel tired. Even if I wish to do small things it will make me very tired. When I worked, my breathing became heavy and it was hard to inhale. (Sawang)

> I can walk around the house, but I find doing any type of housework is difficult. This is due to constant muscle ache. I'm unable to work due to constant muscle pain. (Dan)

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These quotes demonstrate the concept of self-care deficit and describe the relationship between the self-care agency and self-care demand.[154] Both Dan and Sawang have partial self-care deficits which require assistance so that they can achieve their self-care requirements and improve their HRQOL (see figure 14).

The findings from the qualitative study help us to understand the experiences of people with T2DM and a DFU in Thailand. It was clear from the qualitative data that living with a DFU was difficult to manage for participants in this study. However, individuals identified strategies that they used to stay calm and reduce the stress resulting from unhealed DFUs. *Phlong* (i.e., to be calm or not think in the negative way) and *Thum Jai* (i.e., to think positively) were used to stay calm and reduce stress. These strategies were culturally appropriate for people in Thailand.

> I have to be calm and be happy. If I am thinking too much it will cause me stress. Then I do not think too much. I do enjoy what I am doing. When I feel tired, I then take a break for a minute then continue working in my garden or with my housework. (San)

> Just let it be. I might not suffer at all. If it's going to happen, I will just let it happen. My advantage is that I am not easily stressed. So, it will not bother me anymore. Actually, it has not happened to me for very long. When I *Thum Jai* it goes away. (Rat)

Both *Phlong* and *Thum Jai* are examples of using self-care agency. Healthcare professionals can support people with T2DM with and without foot ulcers to improve their self-care agency by improving their skills in

Self-care deficit: Diabetes knowledge

People with T2DM attained a mean percentage score of diabetes knowledge of 42.4 %. Participants with T2DM demonstrated a lack of knowledge about glycosylated haemoglobin (HbA$_{1c}$) levels (11.3 % correct), the importance of attending clinic appointments (12.8 % correct) and testing blood glucose levels (20.6 % correct).

A lack of diabetes knowledge puts people with T2DM at a higher risk of developing a DFU and those with a DFU may have difficulties with wound healing based on their limited knowledge. Participants in the qualitative study reported the use of herbal medicines and the use of faith healers for glycaemic control. These strategies can put participants at risk of adverse outcomes and may indicate a knowledge deficit. Some excerpts from participants' comments are included below.

> Some neighbours visited me and recommended some herbs. They said the herbs would reduce my blood sugar levels. It works for them. Currently, the neighbour has 110 (mg %) of her blood glucose. The herb looks like grass with small white flowers. Oh! When I first drank it. I urinated a lot and it was painful. (Ban)

> My grandson bought the herb [tea] to me for reducing the blood sugar levels. I tried to drink it but it doesn't work. (Dan)

The limited knowledge of participants in this study indicates a self-care deficit. Self-care agency

can be improved when people have appropriate knowledge to initate self-care activities. Education programs should include culturally appropriate information and support patients to understand why self-management practices are required, so that patients can ensure they can manage both their T2DM and any wounds due to DFUs. This is challenging for healthcare professionals to manage, as it is clear that current strategies for education about self-care management and wound care are not always effective. Home visits and additional appointments to demonstrate wound care practices may be required. All education should be culturally appropriate and consider the patient's spiritual beliefs.

Self-care deficit: HRQOL and self-care management among people with DFUs

This study examined the HRQOL and self-care management knowledge and practices among people with DFUs. Within the sample, 41 patients had one or more DFUs and they completed the DFS-SF and the VA-Diabetes Foot Care Survey. The mean score for HRQOL was low in the domain of worried about ulcers (62.20 ± 31.97) and bothered by ulcer care (69.36 ± 25.20). In the qualitative study, most participants were worried about their ulcers and were concerned with wound care and management of their DFU. One participant who had a new DFU described how concerned he was and how diligently he cleaned his wound:

> I cleaned my wound every day with antiseptic solution and saline. I follow the instruction that I've learnt from nurses. (Kat)

The results from the quantitative study reported that less than one-third of the participants had received education about foot self-care management. In the qualitative study, participants described how they learned from nurses to dress their wounds using antiseptic solutions. Some participants described practices that included applying alcohol directly on the wound.

> I used alcohol and saline dressing every day at home. (Pakad)

This appeared to be due to misinterpreting the nurses' instructions. Personal wealth of either the participant or their family also played a part in self-care management relating to wound care. Some participants could afford to buy additional supplies (e.g., Hydrogel) for wound healing .

> It's like a jelly. It was stimulating and my wound healed quickly. My son bought it for me from Bangkok. I used it after cleaning wound in the usual way. (Team)

Some participants also described the use of herbal remedies and other substances (e.g., toothpaste) for wound care.

> By applying herbal oil remedies to my feet there has been a big improvement. The numbness has gone and the wound size has shrunk. (Pitoon)

> I applied toothpaste on her [daughter's] wound. It seemed to heal quickly. Currently, it is not dry. There is a lot of pus on it. She was admitted to hospital for dressing the wound every day. (Pete)

Other participants used spiritual healers as an alternative treatment. One participant had a wound that was not healing and the doctor planned to amputate his leg. This participant turned to a 'holy doctor' for help.

> I thought the holy doctor may help me. I went to see holy doctor, because the doctor told me to accept amputation. The holy doctor chewed the cumin and put it into the wound. When I went to the primary care unit, the nurse told me not to put anything into the wound because it may cause an infection. (Fang)

This broad range of experiences illustrates that improvements are needed in the way in which people with DFUs are educated on wound care practices. Orem's self-care deficit theory can be used to identify how and when healthcare services can be used to support HRQOL, diabetes knowledge and self-care management.

Summary

This chapter integrates the quantitative and qualitative findings. This is in keeping with the sequential explanatory, mixed methods design in which QUAN → qual was used to provide an explanation and an in-depth understanding of the survey results.

Chapter 9

Recommendations and Conclusion

This thesis has explored the phenomenon of HRQOL, diabetes knowledge and self-care management among Thai people with T2DM with and without DFUs. Four publications were developed to summarise the findings and each publication has included both a discussion and a conclusion section. To minimise duplication, the discussion and conclusions from each paper have not been presented in this chapter. This chapter addresses the strengths and limitations of the study and provides recommendations for practice and further research.

Strengths of study

The major strength of this study relates to the use of a sequential explanatory mixed methods design to answer the research questions. The use of a mixed methods design adds strength to the research outcomes, as each method of the study complements the other.[155] Another strength involves the translation of all the questionnaires into the Thai language using the World Health Organisation procedure for translation and adaptation of instruments.[209] The translation and validation of the T-SDKS questionnaire is a unique feature of this study, as this instrument is now available for use within the Thai context. An additional strength includes recruitment of 100 % of all eligible participants by using consecutive sampling techniques. Further, the use of disease specific tools (i.e., D-39 and DFS-SF) adds rigour to the findings. Finally, the collection of data from interviews as well as self-completed questionnaires enables the inclusion of all eligible participants regardless of their literacy levels in the quantitative component of this project.

Dissemination of the findings has occurred in a timely fashion. Four journal articles have been published prior to submission of this thesis. An additional two articles are undergoing peer review.

Limitations of study

The limitations of this study relate to the recruitment of participants. Only one diabetes outpatient department in northern Thailand was used to recruit participants. Despite the recruitment of a large sample of participants over a consecutive three-month period, we cannot assume that this sample is representative of the general population who have T2DM with or without a DFU. Despite the use of rigorous methods to undertake the study, the findings may not be transferable to other regions in Thailand or internationally, due to the diversity of the communities. The study was also time-limited, as it was undertaken as a doctoral project. Hence, despite recruiting 502 participants, only a small sub-sample of patients with DFUs (n = 41) were recruited. Further large-scale studies are needed to investigate the HRQOL, diabetes knowledge and self-care management practices of Thai people with T2DM and DFUs.

Implications for practice

It is evident from this review that the HRQOL, diabetes knowledge and self-care management practices of Thai people with and without DFUs can be improved. This study has provided several recommendations for practice that mainly relate to education about diabetes and resource utilisation. These recommendations are applicable for all patients with T2DM to improve self-care management under the Universal Health Care Coverage Scheme in Thailand. Based on the findings of this study and evidence obtained from the literature, the following recommendations for practice have been developed.

Recommendations for education of people with T2DM

1. All people with T2DM require education on diabetes and self-care management strategies. Education should include information on; diet, need for regular exercise, management of risk factors, how to use insulin, use of HbA1c to monitor glycaemic control, the need for regular follow-up appointments, and the importance of regular blood glucose testing to manage day to day symptoms. Education about diabetes and self-care management for people with T2DM is an important strategy that leads to improved HRQOL.

2. Education on foot care and foot assessment must be incorporated into education programs on managing T2DM, so that people have the required knowledge to identify early diabetic foot problems and seek healthcare support for early intervention.

3. Education and self-care management strategies should be individualised and include the cultural practices and beliefs of the individual with T2DM. For example, coping strategies such as *Phlong* and *Thum Jai* have been reported to reduce the psychological burden people experience when they have a chronic wound.

4. Healthcare providers should consider religious beliefs when developing education programs for people with T2DM. For example, the Buddhist philosophy supports moderation in carbohydrate intake, healthy lifestyle including mental health and a calmer way of being on a daily basis.

5. Health professionals should include family members as well as the person with T2DM, as diabetes education programs affect daily routines and everyday practices.

Recommendations for healthcare providers

1. Clinicians should use the T-SDKS when evaluating the diabetes knowledge of people with T2DM. The information from the T-SDKS can then assist healthcare providers to develop individualised programs for people with T2DM.

2. People with T2DM should be provided with basic equipment (such as a mirror) and knowledge on how to use the equipment for routine foot assessment, so that DFUs can be prevented. Such equipment also enables early detection of foot ulceration and monitoring of wound healing when a DFU occurs.

3. Healthcare professionals need education to ensure that they understand that people with T2DM and a DFU who are undergoing treatment with insulin only, or a combination of

insulin and oral medications, have a poor HRQOL. Healthcare professionals can then support people with T2DM to integrate self-care management into their daily routine and prevent DFU development.

4. The social and family support systems for people with T2DM must be evaluated by healthcare professionals as part of routine care. Self-help groups are recommended to assist people living with T2DM to improve their psychological support systems and supplement existing social and family networks.

5. Anxiety and worry about developing foot ulcers are major concerns for people with T2DM. Strategies to reduce anxiety and worry about DFUs should be included with routine care.

6. A multidisciplinary approach to T2DM management and monitoring of DFUs is required as part of routine care. Regular follow-up appointments are required to effectively manage DFUs of all grades once they have developed. This includes instruction on evidence-based wound care practices and referral to primary healthcare units when required.

Recommendations for further research

This study has identified new knowledge to improve nursing care for Thai adults living with T2DM and DFUs. The study has also identified recommendations for further research. First, given the cultural and economic diversity within the various regions of Thailand, a large-scale national study is warranted to investigate the HRQOL, diabetes knowledge and self-care management practices of Thai people living with T2DM and, in particular, those living with DFUs. Such a study will enable the development of strategies that are targeted at vulnerable groups. Family support plays an important role in the HRQOL and life satisfaction of women with T2DM.[146] Further research should investigate the effect of family support among people with DFUs across all regions of Thailand.

While it is evident that education relating to T2DM is vital, further research is needed to identify the most effective and efficient approaches to providing education that is culturally sensitive. Similarly, as T2DM and DFUs are chronic conditions, research is needed into methods of achieving and sustaining lifelong self-care management practices. In addition, changes are required to the healthcare system and policies to support and sustain self-care management that will, in turn, improve HRQOL. Further research should also be undertaken to test the diabetes knowledge questionnaire (T-SDKS) in a diverse sample of Thai people with T2DM to enhance the reliability and validity of the instrument.

Finally, future research should explore the appropriate roles and responsibilities of the healthcare team, including physicians, nurses and allied health professionals to develop and promote strategies to build capacity for working as a multidisciplinary team and ensuring culturally appropriate practices and beliefs are incorporated into diabetes management programs.

Conclusion

The prevalence of T2DM and DFUs among the Thai population is rapidly increasing. This study was undertaken as part of a doctoral program to investigate the HRQOL, diabetes knowledge and self-care management practices of patients with T2DM, with and without DFUs, using a mixed methods sequential explanatory design. The study has demonstrated the usefulness of using a mixed methods approach to investigate the growing problem of T2DM and DFUs in northern Thailand. As this was a thesis by compilation, journal papers have been developed to present the findings. The thesis presented a review of the literature that provided the current state of knowledge of the questions being investigated. A detailed description of the study methodology and research methods has been provided in addition to the Orem's self-care theory, the theoretical framework underpinning the study.

Findings from the studies were integrated to answer the research questions. The findings revealed that there is limited evidence that focuses on the Thai population living with T2DM with and without DFUs. The self-reported HRQOL of life of people with T2DM as assessed using validated instruments was low; however, analysis of qualitative data revealed the strategies that people used to cope with their DFUs. The knowledge relating to diabetes was poor and self-care management practices require improvement for the prevention and management of DFUs.

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APPENDIX 1: ETHICS APPROVAL

HREC Approval of Amendment for Study Phase 1

UNIVERSITY
OF WOLLONGONG
AUSTRALIA

12 July 2016

Professor Fernandez
School of Nursing
Faculty of Science, Medicine and Health
University of Wollongong

Dear Professor Fernandez,

Thank you for your response dated 6 July 2016 to the HREC review of the application detailed below.

The Committee notes that:

1. *An amendment application will be provided prior to the commencement of Phase 2.*
2. *Researcher declaration forms will be provided prior to new researchers engaging in the project.*
3. *A letter of support from Uttardit Hospital is provided when advice of ethics approval is received.*

I am pleased to advise that the application has been approved.

Ethics Number:	HE16/209
Project Title:	Quality of life and diabetes self-care knowledge of Thai farmers living with diabetic foot ulcers
Researchers:	Professor Ritin Fernandez, Mr Saneh Khunkaew, Dr Jenny Sim, Miss Alisa Supsung
Documents Approved:	Initial NEAF (submitted 13/05/2016)
	Response dated 6 July 2016
	Participant Information Sheet - Phase 1 Survey V2 – 06/07/2016
	Consent Form – Phase 1 Survey V2 – 06/07/2016
	Phase 1 Survey Tool
Approval Date:	12 July 2016
Expiry Date:	11 July 2017

The HREC has reviewed the research proposal for compliance with the *National Statement* and approval of this project is conditional upon your continuing compliance with this document.

Approval by the HREC is for a twelve month period. Further extension will be considered on receipt of a progress report prior to expiry date. Continuing approval requires:

- The submission of a progress report annually and on completion of your project. The progress report template is available at http://www.uow.edu.au/research/ethics/UOW009385.html. This report must be completed, signed by the researchers and the appropriate Head of Unit, and returned to the Research Services Office prior to the expiry date.
- Approval by the HREC of any proposed changes to the protocol including changes to investigators involved
- Immediate report of serious or unexpected adverse effects on participants
- Immediate report of unforeseen events that might affect continued ethical acceptability of the project.

If you have any queries regarding the HREC review process, please contact the Ethics Unit on phone 4221 3386 or email rso-ethics@uow.edu.au.

Yours sincerely,

Professor Colin Thomson
Chair, UOW & ISLHD Health and Medical
Human Research Ethics Committee

The University of Wollongong/Illawarra Shoalhaven Local Health District Health and Medical HREC is constituted and functions in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research.*

HREC Approval of Amendment for Study Phase 2

Subject: HREC Approval of Amendment to Application 2016/209

Dear Professor Fernandez,

I am pleased to advise that the amendment request for an additional researcher submitted to the application detailed below has been approved.

Please note, a response is still expected for the request to change in the inclusion criteria for phase 2 of the study.

Ethics Number: 2016/209

Amendment Approval Date: 20/12/2016

Expiry Date: 11/07/2017

Project Title: Quality of life and diabetes self-care knowledge of Thai farmers living with diabetic foot ulcers

Researchers: Fernandez Ritin; Khunkaew, Saneh; Sim, Jenny; Supsung, Alisa; Tungpunkom, Patraporn

Documents Approved: Researcher Declaration Form

Amendments Approved: Addition of Patraporn Tungpunkom to research team

The HREC has reviewed the research proposal for compliance with the National Statement on Ethical Conduct in Human Research and approval of this project is conditional upon your continuing compliance with this document. Compliance is monitored through progress reports; the HREC may also undertake physical monitoring of research.

Please remember that in addition to submitting proposed changes to the project to the HREC prior to implementing them the HREC requires:

* Immediate report of serious or unexpected adverse effects on participants.
* Immediate report of unforeseen events that might affect the continued acceptability of the project.
* The submission of an annual progress report and a final report on completion of your project.

If you have any queries regarding the HREC review process or your ongoing approval please contact the Ethics Unit on 4221 3386 or email rso-ethics@uow.edu.au.

Yours sincerely,

Susan Thomas

Dr Susan Thomas,
Chair, UOW & ISLHD Health and Medical Human Research Ethics Committee

IRB Approval of Amendment for Study in Thailand – Phase 1

โรงพยาบาลอุตรดิตถ์
Uttaradit Hospital   NO.21/2016

The Ethics Committee for Research in Human Subjects

Uttaradit Hospital , 38 Jesda Bodin Road, Tait , Mueang District Uttaradit Thailand

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List of Approved Documents

1. Study Title : Ref.No. 21/2016 : Quality Life and Diabetes Self-Care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers.

   Study Duration :   6 month

2. Name List and Location of Key Researcher :

   Major ; Mr.Saneh Khunkaew, Prof.Ritin Fernandez amd Dr.Jenny Sim

       Boromarajonani College of Nursing,

       38 Jesda Bodin Road, Tait , Mueang District

       Uttaradit 53000

3. Documents Approved :

Documents filed	Document reference
Full Proposal	date 13 September 2016
Patient Information Sheet / Informed Consent Form (Age 18 years old)	date 13 September 2016
Assent Form (Age 10 – 15 years old)	date 13 September 2016
Case Record Form	date 13 September 2016
Principal Investigator Curriculum vitae	date 13 September 2016

4. Approval Period :   13 September 2016 - 13 September 2017

   Signature :

   (Dr.Asani Pamarapa, M.D.)

   Chairman

"We confirm that we are an ethics committee constituted in agreement and in accordance with the ICH-GCP"

IRB Approval of Amendment for Study in Thailand – Phase 2

โรงพยาบาลอุตรดิตถ์
Uttaradit Hospital   NO.7/2017

The Ethics Committee for Research in Human Subjects

Uttaradit Hospital , 38 Jesda Bodin Road, Tait , Mueang District Uttaradit Thailand

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List of Approved Documents

1. Study Title : Ref.No. 7/2017 : Quality of Life and Diabetes Self-Care Knowledge
   of Thai Adults Living with Diabetic Foot Ulcers

   Study Duration :   6 month

2. Name List and Location of Key Researcher :

   Major ; Mr.Saneh Khunkaew, Prof.Ritin Fernandez and Dr.Jenny Sim

   Boromarajonani College of Nursing,
   38 Jesda Bodin Road, Tait , Mueang District
   Uttaradit 53000

3. Documents Approved :

Documents filed	Document reference
Full Proposal	date 16 January 2017
Patient Information Sheet / Informed Consent Form (Age 18 years old)	date 16 January 2017
Case Record Form	date 16 January 2017
Principal Investigator Curriculum vitae	date 16 January 2017

4. Approval Period :   16 January 2017 - 16 January 2018

   Signature :

   (Dr.Asani Pamarapa, M.D.)

   Chairman

   "We confirm that we are an ethics committee constituted in agreement and
   in accordance with the ICH-GCP"

APPENDIX 2: SURVEY INSTRUMENTS

Survey Instrument English Version

Instructions:

This survey is divided into five sections.
Section 1: Demographic

Section 2: Health Related Quality of Life

Section 3: Diabetes Knowledge

Section 4: Quality of Life Specific to Foot Ulcers

Section 5: Self-care management of diabetes foot ulcers

Please answer in every questions followed by the instruction in each part.

Note: All yours data will be analysed as whole information, no individual data will be identifiable any part of the research project.

Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 1: Demographics

1. Gender

◯ Male ◯ Female

2. How old are you?

[   ]

3. What is you marital status? (Please check only one option)

◯ Single ◯ Divorce

◯ Married ◯ Widow

4. What is your highest level of education? (Please check only one option)

◯ Primary School ◯ Diploma ◯ Masters Degree

◯ High School ◯ Bachelors Degree ◯ Doctoral Degree

5. What is your current employment status? (Please check only one option)

◯ Unemployed ◯ Housewives/Househusband

◯ Self employed ◯ Retired

Other (please specify)

[   ]

6. How much do you earn per month? (Please check only one option)

◯ 0-10,000 Baht/month ◯ 10,001 – 20,000 Baht/month ◯ more 20,000 Baht/month

7. What is your occupation? (Please check only one option)

◯ Farmer ◯ Homemaker ◯ Business

◯ Government employee ◯ Private empolyee

◯ Other (please specify)

[   ]

8. What health insurance do you have? (Please check only one option)

○ Universal Health Cover   ○ Government Health Cover

○ Social Health Cover

○ Other (please specify)

[   ]

9. How long have you been diagnosed with diabetes?

○ .... Months   ○ ....Years

10. What type of diabetes? (Please check only one option)

○ Diabetes type 1   ○ Diabetes type 2   ○ Gestational Diabetes Mellitus

Other (please specify)

[   ]

11. What kind of diabetes therapy are you undergoing? (Please check only one option)

○ Insulin injection only   ○ Combination of insulin
                                   injection and oral medication
○ Oral medication only
                                ○ Nondrug treatment

12. What is your most recent Glycosylated Haemoglobin A1c (HbA1c) (in mg%)

[   ]

13. Has a doctor or nurse ever told you that you had the following? (check all that apply)

☐ Nerve damage in your feet or legs   ☐ Stroke

☐ Problems with circulation in your feet or legs   ☐ Cancer

☐ Sores (ulcers) on your feet that did not heal in one   ☐ Kidney failure
   month
                                              ☐ Chronic lung disease
☐ Heart attack
                                              ☐ Problems with depression
☐ Congestive heart failure
                                              ☐ Problems with drugs or alcohol
☐ Surgery to fix narrowed blood vessels in your heart

☐ Surgery to fix narrowed blood vessels in your feet or
   legs

14. What is your height? (in cms)

[   ]

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15. What is your weight? (in kgs)

[ ]

16. Do you currently smoke?

◯ Yes   ◯ No

If Yes, How many cigarettes do you smoke per day?

[ ]

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Section 2: Quality of Life of Patients with Diabetes (Diabetes-39)

For each of the following questions we want to know how your quality of life has been affected. Please answer the question by putting a cross (X) somewhere on the line following each question. The line starts at number 1 and a cross here means that your quality of life has not been affected at all. The line ends at 7 and a cross here means that your quality of life has been affected extremely affected. Place your cross on the line at the point which you think best describes how your quality of live has been affected in the past month.

17. DURING THE PAST MONTH, HOW MUCH WAS THE QUALITY OF YOUR LIFE AFFECTED BY: (Please cross only one option)

○ 1.Your daily medication for your diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 2. Worries about money matters

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 3. Limited energy levels

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 4. Following your doctor's prescribed treatment plan for diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 5. Food restrictions required to control your diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 6. Concerns about your future

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 7. Other health problems besides diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 8. Stress or pressure in your life

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

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○ 9. Feeling of weakness

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 10. Restrictions on how far you can walk

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 11. Any daily exercise for your diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 12. Loss or blurring of vision

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 13. Not being able to do what you want

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 14. Having diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 15. Losing control of your sugar levels

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 16. Other illnesses besides diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

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Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 2: Quality of Life of Patients with Diabetes (Diabetes-39)

For each of the following questions we want to know how your quality of life has been affected. Please answer the question by putting a cross (X) somewhere on the line following each question. The line starts at number 1 and a cross here means that your quality of life has not been affected at all. The line ends at 7 and a cross here means that your quality of life has been affected extremely affected. Place your cross on the line at the point which you think best describes how your quality of live has been affected in the past month.

18. DURING THE PAST MONTH, HOW MUCH WAS THE QUALITY OF YOUR LIFE AFFECTED BY: (Please cross only one option)

○ 17. Testing your blood sugar levels

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 18. The time required to control your diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 19. The restrictions your diabetes places on your family and friends

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 20. Being embarrassed because you have diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 21. Diabetes interfering with your sex life

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 22. Feeling depressed or low

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 23. Problems with sexual functioning

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 24. Getting your diabetes well controlled

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

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○ 25. Complication from your diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 26. Doing things that your family and friends don't do

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 27. Keeping a record of your sugar levels

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 28. The need to eat at regular intervals

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 29. Not being able to do housework or other jobs around the house

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 30. A decreased interest in sex

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 31. Having to organize your daily life around diabetes

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 32. Needing to rest often

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

19. DURING THE PAST MONTH, HOW MUCH WAS THE QUALITY OF YOUR LIFE AFFECTED BY: (Please cross only one option)

○ 33. Problems in climbing stairs or walking up steps

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 34. Having trouble caring for yourself (dressing, bathing, or using the toilet)

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 35. Restless sleep

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 36. Walking more slowly than others

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 37. Being identified as a diabetic

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 38. Having diabetes interfere with your family life

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

○ 39. Diabetes in general

Not affected at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely affected

20. OVERALL RATINGS (Please cross only one option)

○ Indicate you overall rating of quality of life

Lowest quality | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Highest quality

21. OVERALL RATINGS (Please cross only one option)

○ How severe do you think your diabetes is?

Not severe at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Extremely severe

Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 3: Knowledge of Diabetes (MKQ T-F version)

22. Here are 20 statements about diabetes, some are true statements and some are false. Please read each statement and then indicate whether you think it is true or false by ticking either TRUE or FALSE. If you do not know the answer please tick DON'T KNOW.

	True	False	Don't Know
1. The diabetes diet is a healthy diet for most people	○	○	○
2. Glycosylated haemoglobin (HbA1c) is a test that measures your average blood glucose level in the past week.	○	○	○
3. A 500 grams of chicken has more carbohydrate in it than a 500 grams of rice.	○	○	○
4. Fruit juice has more fat in it than low fat milk.	○	○	○
5. Urine testing and blood testing are both equally as good for testing the level of blood glucose.	○	○	○
6. Unsweetened fruit juice raises blood glucose levels.	○	○	○
7. A can of diet soft drink can be used for treating low blood glucose levels.	○	○	○
8. Using rice bran oil in cooking can help lower the cholesterol in your blood.	○	○	○
9. Exercising regularly can help reduce high blood pressure.	○	○	○
10. For a person in good control, exercising has no effect on blood sugar levels.	○	○	○
11. Infection is likely to cause an increase in blood sugar levels.	○	○	○
12. Wearing shoes a size bigger than usual helps prevent foot ulcers.	○	○	○
13. Eating foods lower in fat decreases your risk for heart disease.	○	○	○
14. Numbness and tingling may be symptoms of nerve disease.	○	○	○
15. Lung problems are usually associated with having diabetes.	○	○	○

	True	False	Don't Know
16. When you are sick with the flu you should test for glucose more often.	○	○	○
17. High blood glucose levels may be caused by too much insulin.	○	○	○
18. If you take your morning insulin but skip breakfast your blood glucose level will usually decrease.	○	○	○
19. Having regular check-ups with your doctor can help spot the early signs of diabetes complications.	○	○	○
20. Attending your diabetes appointments will stop you getting diabetes complications.	○	○	○

23. Do you have Foot Ulcer ? (To be completed by Research Assistant) (Please check only one option)

○ Yes   ○ No   ○ Unsure

24. Grade of foot ulcers (If present) using Wagner (1981) classification method (Please check only one option)

○ Grade 1   ○ Grade 3   ○ Grade 5

○ Grade 2   ○ Grade 4

Thank you for completing Part 1 of this survey. If you have a foot ulcer related to Diabetes Mellitus please complete part 2 of this survey on the following pages.

Section 4: Quality of Life of Patients with Diabetic Foot Ulcer/s (DSF-SF)

These questions ask about the effect your foot ulcers may have on your daily life and well-being. Answer every question by ticking one option in each line. If you are unsure about how to answer a question, please give the best answer you can.

25. How much have your foot ulcer problems: (Please check only one option)

	Not at all	A little bit	Moderately	Quite a bit	A great deal
Stopped your from doing the hobbies and recreational activities that you enjoy	○	○	○	○	○
Changed the kinds of hobbies and recreational activities that you enjoy doing	○	○	○	○	○
Stopped you from getting away for a holiday or a weekend break	○	○	○	○	○
Made you choose a different kind of weekend, vacation, or holiday, than you would have preferred	○	○	○	○	○
Meant that you had to spend more time planning and organizing leisure activities	○	○	○	○	○

26. Because of your foot ulcers, how often have you felt: (Please check only one option)

	Not at all 1	A little bit 2	Moderately 3	Quite a bit 4	A great deal 5
Fatigued or tired	○	○	○	○	○
Drained	○	○	○	○	○
That you had difficulty sleeping	○	○	○	○	○
Pain while walking or standing	○	○	○	○	○
Pain during the night	○	○	○	○	○

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27. Because of your foot ulcers, how often have you: (Please check only one option)

	Not at all 1	A little bit 2	Moderately 3	Quite a bit 4	A great deal 5
Had to depend on others to help you look after yourself (such as washing and dressing yourself)	○	○	○	○	○
Had to depend on others to do household chores (such as cooking, cleaning or laundry)	○	○	○	○	○
Had to depend others to get out of the house	○	○	○	○	○
Had to spend more time planning or organising your daily life	○	○	○	○	○
Felt that doing anything took longer than you would have liked	○	○	○	○	○

28. Because of your foot ulcers, have you felt: (Please check only one option)

	Not at all 1	A little bit 2	Moderately 3	Quite a bit 4	A great deal 5
Angry because you were not able to do what you wanted to you	○	○	○	○	○
Frustrated by others doing things for you when you would rather do things yourself	○	○	○	○	○
Frustrated because you were no able to do what you wanted to do	○	○	○	○	○
Worried that your ulcer(s) will never heal	○	○	○	○	○
Worried you may have to have an amputation	○	○	○	○	○
Worried about injury to your feet	○	○	○	○	○
Depressed because you were not able to do what you wanted to do	○	○	○	○	○
Worried about getting ulcers in the future	○	○	○	○	○
Angry this has happened to you	○	○	○	○	○
Frustrated because you have difficulty getting about	○	○	○	○	○

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29. Because of your foot ulcers problems, how often were you bothered by: (Please check only one option)

	Not at all 1	A little bit 2	Moderately 3	Quite a bit 4	A great deal 5
Having to keep weight off your foot ulcer	○	○	○	○	○
The amount of time involved in caring for your foot ulcer (including dressing changes, waiting for the home health care nurse, and keeping the ulcer clean)	○	○	○	○	○
The appearance, odour or leakping of your ulcer	○	○	○	○	○
Having to depend on others to help care for your foot ulcer	○	○	○	○	○

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Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 5: Self-care management Diabetic Foot Ulcers

30. In the past 12 months, how often have you had any of the following symptoms or problems? (Please check only one option)

	Never	Sometimes	Often
Numbness of your feet	○	○	○
Tingling sensation (pins & needles) in your feet	○	○	○
Burning pain in your feet	○	○	○
Problems with your balance or falling	○	○	○
Pain in your thigh or calf muscles when walking that is relieved with a few minutes rest	○	○	○

31. In the past 12 months, have you had any of the following on either foot? (Please check only one option)

	Yes	No
Callus(es) (very thick skin)	○	○
Corn(s) (thick skin, that may be painful or irritating, usually on the little toe, tops of toes or between toes)	○	○
Thick toenail(s) (toenails that are difficult to trim)	○	○
Ingrown toenail(s) (toenail that grows into flesh)	○	○
Athletes' foot (fungal disease on feet)	○	○
Cracks (fissures) on heel(s)	○	○
Foot ulcers (sores that did not heal in one month)	○	○

32. Are you able to see the bottoms (soles) of both your feet? (Please check only one option)

○ Yes   ○ No

33. If you answered No to the above question, check all the reasons that apply

☐ Poor vision   ☐ Joint, arthritis, hip or knee problems   ☐ Overweight

Other (please specify)

[   ]

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34. Check if you now have any of the foot problems pictured below. (check all that apply)

	Yes	No
Hammer or Claw Toes (Cocked-up toes)	○	○
Large Bunion, (Large, displaced great toe joint)	○	○
Charcot Foot (Fractures and dislocations in any of the 5 marked areas that resulted in size and shape changes to your foot)	○	○

Hammer or Claw Toes, Bunion, Charcot
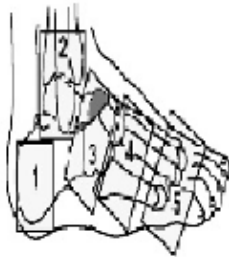
Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 5: Self-care management Diabetic Foot Ulcers

Part A: General health and Diabetes care

35. Have you ever had an amputation of a toe, foot, part, or all of your leg?

○ Yes, please answer question 36 and 37   ○ No, please answer question 38

36. If yes, check which side(s) of the body:

	Right	Left	Both Right and Left
Toe(s) only	○	○	○
Part or all of a foot	○	○	○
Leg, below the knee	○	○	○
Leg, above the knee	○	○	○

37. Was this amputation a result of:

	Yes	No
Trauma/Other injuries	○	○
Diabetes	○	○

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Section 5: Self-care management Diabetic Foot Ulcers

Part B: Your Self Foot Care

38. In the past 4 weeks, how often have you done the following activities for your feet? (check one response for each line)

	Daily	Several Times a Week	Once a Week	Once or Twice a Month	Not at All
Looked at the bottom of feet for cuts, calluses and sores	○	○	○	○	○
Checked between toes for cracks in the skin	○	○	○	○	○
Washed feet	○	○	○	○	○
Soaked feet for more than 10 minutes	○	○	○	○	○
Tested the water temperature with your hand or elbow before putting feet in water	○	○	○	○	○
Dried between toes after washing	○	○	○	○	○
Used lubricants (lotion) on your feet	○	○	○	○	○
Filed calluses	○	○	○	○	○
Trimmed nails	○	○	○	○	○
Checked inside of shoes for rough edges or objects	○	○	○	○	○
Wore stockings with your shoes	○	○	○	○	○
Changed your shoes during the day	○	○	○	○	○
Walked barefoot or in stockings inside your house	○	○	○	○	○
Walked barefoot outside	○	○	○	○	○

39. Who did the following foot care for you in the past 12 months? (check all that apply)

	I did	Family member	Nurse/Doctor	No One
Look at the bottom of my feet for cuts, calluses and sores	○	○	○	○
Check between my toes for cracks in the skin	○	○	○	○
File my calluses	○	○	○	○
Trim my nails	○	○	○	○
Check the inside of my shoes for rough edges or objects	○	○	○	○

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Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 5: Self-care management Diabetic Foot Ulcers

Part C: Education About Your Feet

40. How much have you ever been taught about taking care of your feet? (Please check only one option per line)

	Nothing at All	A Little Bit	Some, But Would Like to Know More	Enough
Checking your feet regularly	○	○	○	○
Keeping your feet clean	○	○	○	○
How to choose proper shoes	○	○	○	○
Wearing shoes or slippers at all times	○	○	○	○
How to keep your skin moist	○	○	○	○
Using a special mirror to see the bottom of your feet	○	○	○	○
Avoiding very hot and very cold temperatures to your feet	○	○	○	○
Gently filing calluses	○	○	○	○
Cutting nails according to the shape of your toe	○	○	○	○
Not cutting corns and calluses with scissors or knives	○	○	○	○
Not using drugstore chemicals or other remedies not ordered by your provider	○	○	○	○
When to call a health care provider if you have a foot ulcer	○	○	○	○
Whom to call if you have a foot ulcer	○	○	○	○

41. Check any of the following that kept you from taking the care of your feet in the last 12 months. (check all that apply)

☐ I didn't know what to do   ☐ I didn't have a foot stool

☐ I know what to do, but I didn't know how to do it   ☐ I couldn't remember to do it

☐ I didn't have time   ☐ I needed professional help

☐ I couldn't afford it   ☐ I needed help from family and friends

☐ I didn't have the right shoes   ☐ I didn't think it was important

☐ I didn't have the right shoe inserts   ☐ I couldn't see well enough to do it

☐ I didn't have a mirror   ☐ I couldn't comfortably reach my feet to do it

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42. Which of the following professionals provided education or information about your feet in the past 12 months? (check all that apply)

	How Often? Once	How Often? More than Once
Primary care provider	○	○
Foot doctor (podiatrist, surgeon)	○	○
Member of the diabetes care team (nurse, doctor, educator)	○	○
Rehabilitation specialist (physical therapist, kinesiologist, prosthetist, orthotist)	○	○

Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 5: Self-care management Diabetic Foot Ulcers

Part D: Your Professional Foot Care

43. Have you had your feet checked? (Please check only one option)

○ Yes ○ No

44. If you have answered "Yes" to the above question, (Please check only one option)

○ Out Patient Clinic ○ Foot Clinic

○ Other (please specify)

[   ]

45. In the last 12 months, in what health care settings did you get your foot care? (check only one)

○ Diabetes Outpatient ○ Both Diabetes Outpatient and Other Health Care Professionals

○ Other Health Care Professionals

○ I did not get foot care

46. During the last 12 months, did the professional you saw for your foot care at the Diabetes Outpatient Clinic …(check one in each row)

	YES, more than once	YES, at least once	NO
Ask you about numbness or tingling in your feet	○	○	○
Look at your feet with your shoes and socks off	○	○	○
Examine the tops and the bottoms of your feet	○	○	○
Look between your toes	○	○	○
Test the feeling in your feet with a tuning fork or monofilament (a bendable nylon "fiber" on a handle)	○	○	○
Shave your calluses	○	○	○
Trim your toenails	○	○	○
Look at your shoes	○	○	○
Tell you how to select proper shoes	○	○	○

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Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers (Patient Version)

Section 5: Self-care management Diabetic Foot Ulcers

Part G: Your Footwear

47. In the past 4 weeks, what percent of the time that you were out of bed did you … (please put a percentage rating for each statement below that will give a total of a 100%)

Go barefoot

[ ]

Wear shoes your doctor ordered

[ ]

Wear open shoes (Sandals) or Slippers (thongs)

[ ]

Total 100%

[ ]

48. Do you have difficulty fitting into shoes from regular stores?

○ Yes   ○ No

49. Do you know who to contact for problems with your shoes?

○ Yes   ○ No

50. Has a health care provider recommended that you wear a certain type of footwear within the last 12 months? (check one)

○ Yes   ○ No

51. In the last 12 months, have you worn the shoes your doctor recommended? (Please check only one option)

○ Yes, all the time.   ○ Yes, some of the time.

○ Yes, most of the time.   ○ No

52. If "No", what prevents you from wearing the shoes your doctor ordered? (check all that apply)

☐ The shoes hurt my feet   ☐ I didn't buy the shoes   ☐ I don't like the way the shoes look

☐ The shoes don't fit well   ☐ The shoes make my feet hot   ☐ The shoes wore out and were not replaced

Thank you for participating in this survey.

Survey Instrument Thai Version

UNIVERSITY
OF WOLLONGONG
AUSTRALIA

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

คำชี้แจงข้อมูลสำหรับอาสาสมัคร

คำชี้แจง

1. แบบสอบถามแบ่งเป็น 5 ตอน คือ

   ตอนที่ 1 ข้อมูลส่วนบุคคล

   ตอนที่ 2 แบบวัดคุณภาพชีวิตสำหรับผู้ป่วยโรคเบาหวาน

   ตอนที่ 3 แบบวัดความรู้สำหรับผู้ป่วยโรคเบาหวาน

   ตอนที่ 4 แบบวัดคุณภาพชีวิตสำผู้ป่วยโรคเบาหวานที่มีแผลที่เท้า

   ตอนที่ 5 แบบวัดการจัดการดูแลแผลเบาหวานที่เท้าด้วยตนเอง

2. กรุณาตอบแบบสอบถามทุกข้อตามคำอธิบายแต่ละขั้นตอน

หมายเหตุ: ข้อมูลของท่านจะถูกปิดเป็นความลับ และจะใช้เฉพาะสำหรับการวิจัยครั้งนี้เท่านั้น

1

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ตอนที่ 1 ข้อมูลส่วนบุคคล

1. เพศ

☐ ชาย ☐ หญิง

2. คุณอายุเท่าไหร่ ....ปี................เดือน

3. สถานะภาพสมรส (โปรดเลือกเพียงคำตอบเดียว)

☐ โสด ☐ สมรส ☐ หย่า ☐ หม้าย

4. การศึกษาสูงสุดของคุณอยู่ระดับใด (โปรดเลือกเพียงคำตอบเดียว)

☐ ประถมศึกษา ☐ มัธยมศึกษา ☐ อาชีวศึกษา (ปวช/ปวส)

☐ ปริญญาตรี ☐ ปริญญาโท ☐ ปริญญาเอก

☐ อื่นๆ (โปรดระบุ)...

5. สถานะการทำงานของคุณเป็นอย่างไร ? (โปรดเลือกเพียงคำตอบเดียว)

☐ ว่างงาน ☐ ประกอบธุระกิจส่วนตัว

☐ พ่อบ้าน/แม่บ้าน ☐ เกษียณอายุ

☐ อื่นๆ (โปรดระบุ)...

6. คุณมีรายได้เฉลี่ยต่อเดือนเท่าไหร่ ? (โปรดเลือกเพียงคำตอบเดียว)

☐ 0 – 10,000 บาท/เดือน ☐ 10,001 – 20,000 บาท/เดือน

☐ มากกว่า 20,00 บาท/เดือน

7. คุณประกอบอาชีพอะไร ? (โปรดเลือกเพียงคำตอบเดียว)

☐ เกษตรกร ☐ ข้าราชการ

☐ พ่อบ้าน/แม่บ้าน ☐ พนักงานบริษัทเอกชน

☐ ประกอบธุระกิจส่วนตัว ☐ อื่นๆ (โปรดระบุ).........................

8. สิทธิการรักษาพยาบาล? (โปรดเลือกเพียงคำตอบเดียว)

☐ บัตรประกันสุขภาพถ้วนหน้า (บัตรทอง) ☐ ประกันสังคม

☐ เบิกได้ ☐ อื่นๆ (โปรดระบุ)............................

9. ระยะเวลาที่ทราบว่าเป็นโรคเบาหวาน........................ปี................เดือน

2

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

10. คุณเป็นโรคเบาหวานแบบใด? (โปรดเลือกเพียงคำตอบเดียว)

☐ โรคเบาหวานแบบที่ 1   ☐ โรคเบาหวานแบบที่ 2

☐ โรคเบาหวานขณะตั้งครรภ์   ☐ อื่นๆ(โปรดระบุ)...

11. คุณได้รับการรักษาโรคเบาหวานด้วยวิธีใดต่อไปนี้ (โปรดเลือกเพียงคำตอบเดียว)

☐ ฉีดยาอินซูลินเท่านั้น   ☐ รับประทานยาท่านั้น

☐ ใช้ยารับประทานร่วมกับยาฉีดอินซูลิน   ☐ ไม่ใช้ยาใดๆ

12. ระดับน้ำตาลสะสม (ฮีโมโกลบินไกลโคซิเลท (HbA1C)) ล่าสุดของคุณเท่าไหร่? (มิลลิกรัมเปอร์เซนต์)

.....................................mg%

13. แพทย์หรือพยาบาลของคุณเคยบอกคุณว่าคุณมีอาการใดบ้างต่อไปนี้ (เลือกได้มากกว่า 1 ข้อ)

☐ เส้นประสาทที่เท้าหรือขาถูกทำลาย

☐ ปัญหาด้านการไหลเวียนของเลือดที่เท้าหรือขา

☐ ปัญหาแผลที่เท้า ซึ่งไม่สามารถรักษาให้หายได้ภายในหนึ่งเดือน

☐ หัวใจวาย

☐ หัวใจล้มเหลว

☐ การผ่าตัดเพื่อรักษาเส้นเลือดตีบที่หัวใจ

☐ การผ่าตัดเพื่อรักษาเส้นเลือดตีบที่เท้าหรือขา

☐ เส้นเลือดสมองแตก/ตีบ/ตัน

☐ มะเร็ง

☐ ไตวาย

☐ โรคปอดเรื้อรัง

☐ ปัญหาโรคซึมเศร้า

☐ ปัญหาการใช้ยา/สารเสพติด หรือ สุรา

14. คุณสูงเท่าไหร่? ....เซนติเมตร

15. คุณหนักเท่าไหร่?.................................กิโลกรัม

16. ปัจจุบันคุณสูบบุหรี่หรือไม่?

☐ สูบ   ☐ ไม่สูบ

ถ้าสูบ คุณสูบวันละกี่มวน...

3

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ตอนที่ 2 แบบวัดคุณภาพชีวิตสำหรับผู้ป่วยโรคเบาหวาน

ในแต่ละคำถามต่อไปนี้ ต้องการทราบว่าคุณภาพชีวิตของท่านถูกกระทบโดยปัจจัยเหล่านี้มากน้อยเพียงใด โดยให้ท่านทำเครื่องหมาย กากบาท (X) ลงในตัวเลขที่กำหนดให้ในแต่ละข้อ ในตัวเลขเริ่มต้น จากหมายเลข 1 ถ้าหากทำเครื่องหมาย กากบาท (X) นี้ หมายถึงไม่มีผลกระทบต่อคุณภาพชีวิตของท่านเลย และ สิ้นสุดที่หมายเลข 7 ถ้าหากทำเครื่องหมายกากบาท (X) ตำแหน่งนี้ หมายถึง มีผลกระทบต่อคุณภาพชีวิตอย่างมาก กรุณาทำเครื่องหมายกากบาท (X) บนตัวเลือกที่สามารถอธิบายได้ดีที่สุดว่า ในช่วง 1 เดือนที่ผ่านมาสิ่งต่างๆ ต่อไปนี้มีผลกระทบต่อคุณภาพชีวิตของท่านมากน้อยเพียงใด

17. ในช่วง <u>1เดือน ที่ผ่านมา</u> สิ่งต่าง ๆ ต่อไปนี้มีผลกระทบต่อคุณภาพชีวิต<u>ของท่าน</u>มากน้อยเพียงใด

    1. การรับประทานยารักษาโรคเบาหวานทุกวัน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

    2. ความวิตกกังวลเรื่องการเงิน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

    3. ร่างกายมีเรี่ยวแรงจำกัด

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

    4. การต้องปฏิบัติตามแผนการรักษาโรคเบาหวานของแพทย์

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

4

5. การต้องจำกัดอาหารเพื่อควบคุมโรคเบาหวาน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

6. ความกังวลเกี่ยวกับอนาคตของท่าน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

7. ปัญหาสุขภาพอื่นนอกจากโรคเบาหวาน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

8. ความเครียดหรือความกดดันในชีวิตของท่าน

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

9. ความรู้สึกอ่อนเพลียอ่อนล้า

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

10. ข้อจำกัดในเรื่องระยะทางที่ท่านสามารถเดินได้

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

11. การต้องออกกำลังกาย

1	2	3	4	5	6	7

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

5

12. การมองไม่เห็นหรือสายตามัวมองภาพไม่ชัด

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

13. การไม่สามารถทำในสิ่งที่ตัวท่านเองต้องการ

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

14. การที่ท่านเป็นโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

15. การไม่สามารถควบคุมระดับน้ำตาลในเลือดได้

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

16. ความเจ็บป่วยอื่นนอกจากโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

17. การตรวจวัดระดับน้ำตาลของตัวท่าน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

18. เวลาที่ต้องใช้ไปเพื่อควบคุมโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

6

19. ผลที่มีต่อครอบครัวและเพื่อนของท่าน เนื่องจากข้อจำกัดที่เกิดขึ้นจากการที่ท่านเป็นโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

20. ความรู้สึกอับอายเนื่องจากตัวเองเป็นโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

21. โรคเบาหวานรบกวนการทำกิจกรรมทางเพศของท่าน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

22. ความรู้สึกหม่นหมองหรือซึมเศร้า

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

23. ปัญหาเกี่ยวกับสมรรถภาพทางเพศ

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

24. การควบคุมโรคเบาหวานให้ได้ดีอย่างต่อเนื่อง

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

25. โรคแทรกซ้อนจากโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

7

26. การต้องทำในสิ่งซึ่งครอบครัวท่านหรือเพื่อนท่านไม่ทำ

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

27. การจดและเก็บบันทึกระดับน้ำตาลในเลือด

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

28. การจำเป็นต้องรับประทานอาหารให้ตรงตามเวลาอย่างสม่ำเสมอ

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

29. การไม่สามารถทำงานบ้านหรืองานอื่น ๆ รอบบ้าน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

30. ความสนใจเรื่องเพศลดลง

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

31. การที่ท่านต้องคอยจัดเวลา หรือวางแผนการทำกิจกรรมต่าง ๆ โดยคำนึงถึงโรคเบาหวานเป็นหลัก

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

32. การจำเป็นต้องพักบ่อย ๆ

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

8

33. ปัญหาในการเดินขึ้นบันได

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

34. มีความยากลำบากในการดูแลตนเอง (เช่น แต่งตัว อาบน้ำ หรือเข้าส้วม)

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

35. การนอนหลับไม่สนิท

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

36. การเดินได้ช้ากว่าคนอื่น

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

37. การถูกเรียก หรือระบุว่าเป็นผู้ป่วยโรคเบาหวาน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

38. การเป็นโรคเบาหวานรบกวนชีวิตครอบครัวของท่าน

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

39. โรคเบาหวานในภาพรวม

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

ไม่มีผลกระทบเลย   มีผลกระทบอย่างมาก

9

18. การประเมินคะแนนในภาพรวม

1. กรุณาทำเครื่องหมายกากบาท(X) บนตำแหน่งที่ท่านคิดว่าตรงกับคุณภาพชีวิตในภาพรวมของท่าน

1	2	3	4	5	6	7

คุณภาพชีวิตแย่ที่สุด   คุณภาพชีวิตดีที่สุด

2. กรุณาทำเครื่องหมายกากบาท(X) บนตำแหน่งที่ท่านคิดว่าตรงกับความรุนแรงของโรคเบาหวานของท่าน

1	2	3	4	5	6	7

ไม่รุนแรงเลย   รุนแรงมาก

ตอนที่ 3 แบบวัดความรู้สำหรับผู้ป่วยโรคเบาหวาน

ข้อความต่อไปนี้เป็นข้อความเกี่ยวกับความรู้เรื่องโรคเบาหวาน มีทั้งหมด 20 ข้อ ซึ่งมีทั้ง "**จริง**" และ "**ไม่จริง**" กรุณาอ่านข้อความแต่ข้อความต่อไปนี้ ถ้าคุณมีความเห็นว่า "**จริง**" หรือ "**ไม่จริง**" ให้ใช้เครื่องหมาย (√) ที่ช่อง "**จริง**" หรือ "**ไม่จริง**" แต่ถ้าคุณไม่รู้ ให้ใช้เครื่องหมาย (√) ที่ช่อง "**ไม่รู้**"

ข้อคำถาม	จริง	ไม่จริง	ไม่รู้
1. อาหารสำหรับโรคเบาหวานเป็นอาหารเพื่อสุขภาพของคนส่วนใหญ่	☐	☐	☐
2. การตรวจหาน้ำตาลสะสมในเลือด (ฮีโมโกลบินไกลโคซิเลท(HbA1c)) เป็นการทดสอบเพื่อวัดระดับน้ำตาลในเลือด (Blood glucose levels) ของคุณช่วงสัปดาห์ก่อนหน้านั้น	☐	☐	☐
3. ไก่ 500 กรัมมีปริมาณคาร์โบไฮเดรตมากกว่าข้าว 500 กรัม	☐	☐	☐
4. น้ำส้มมีปริมาณไขมันมากกว่านมไขมันต่ำ	☐	☐	☐

10

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ข้อคำถาม	จริง	ไม่จริง	ไม่รู้
5. การทดสอบปัสสาวะ และ การทดสอบเลือด ทั้งสองอย่างเป็นการวัดระดับน้ำตาลในเลือด (Blood glucose levels) ได้ดีพอ ๆ กัน	☐	☐	☐
6. น้ำผลไม้ที่ไม่เติมน้ำตาลทำให้ระดับน้ำตาลในเลือด (Blood glucose levels) สูงขึ้น	☐	☐	☐
7. ดื่มน้ำอัดลมไม่ผสมน้ำตาล 1 กระป๋อง จะช่วยรักษาระดับน้ำตาลในเลือดต่ำ (hypoglycaemia)	☐	☐	☐
8. การใช้น้ำมันมะกอกประกอบอาหาร สามารถช่วยลดระดับคอเลสเตอรอลในเลือดได้	☐	☐	☐
9. การออกกำลังกายเป็นประจำ จะช่วยลดระดับความดันโลหิตสูง	☐	☐	☐
10. สำหรับคนที่ดูแลตัวเองอย่างดีแล้ว, การออกกำลังกายไม่ได้มีผลอะไรต่อระดับน้ำตาลในเลือด (Blood glucose levels)	☐	☐	☐
11. การติดเชื้ออาจส่งผลให้ระดับน้ำตาลในเลือดสูงขึ้น	☐	☐	☐
12. การใส่รองเท้าที่ใหญ่กว่าเท้าตัวเองจะช่วยป้องกันการเป็นแผลที่เท้า	☐	☐	☐
13. การกินอาหารไขมันต่ำช่วยลดความเสี่ยงต่อการเป็นโรคหัวใจ	☐	☐	☐
14. อาการชาและอาการเหน็บชา (อาการเหมือนมีของแหลมทิ่ม) ลักษณะอาการแบบนี้ อาจเป็นสัญญาณบ่งชี้ถึงโรคเส้นประสาท	☐	☐	☐
15. ปัญหาทางปอดมักเกี่ยวข้องกับการเป็นโรคเบาหวาน	☐	☐	☐
16. เมื่อคุณป่วยด้วยโรคหวัด คุณควรตรวจสอบระดับน้ำตาลในเลือด (Blood glucose levels) บ่อยขึ้น	☐	☐	☐
17. ระดับน้ำตาลในเลือด (Blood glucose levels) สูงอาจเกิดขึ้นเพราะใช้ยาฉีดอินซูลินมากเกินไป	☐	☐	☐
18. หากคุณใช้ยาฉีดอินซูลินในตอนเช้า แต่ไม่ได้รับประทานอาหารเช้าระดับน้ำตาลในเลือด (Blood glucose levels) คุณมักจะต่ำลง	☐	☐	☐

11

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ข้อคำถาม	จริง	ไม่จริง	ไม่รู้
19. การให้แพทย์ตรวจเป็นประจำ จะทำให้พบโรคแทรกซ้อนที่เกิดขึ้นจากโรคเบาหวานได้ตั้งแต่เนิ่น ๆ	☐	☐	☐
20. การไปตามนัดที่แพทย์กำหนดจะทำให้คุณ ไม่มีโรคแทรกซ้อนที่เกิดขึ้นจากโรคเบาหวาน	☐	☐	☐

<u>ให้ผู้ช่วยวิจัยเป็นผู้ตอบ</u>

คุณมีแผลที่เท้าหรือไม่ ? (โปรดเลือกเพียงคำตอบเดียว)

☐ เป็น   ☐ ไม่เป็น   ☐ ไม่แน่ใจ

ให้ระบุระดับของแผลที่เท้า (ถ้ามีแผล) โดยใช้วิธีการวัดของ แว็กเนอร์ (Wagner 1981) (โปรดเลือกเพียงคำตอบเดียว)

☐ ระดับ 1   ☐ ระดับ 2   ☐ ระดับ 3   ☐ ระดับ 4   ☐ ระดับ 5

ขอบคุณที่ตอบคำถามส่วนที่ 1 หากคุณเป็นแผลที่เท้า ที่เกิดจากโรคเบาหวาน กรุณาตอบคำถามส่วนที่ 2 ซึ่งอยู่
หน้าถัดไป >>>>>>>>

12

คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ตอนที่ 4 แบบวัดคุณภาพชีวิตสำหรับผู้ป่วยโรคเบาหวานที่มีแผลที่เท้า

คำถามต่อไปนี้มีเพื่อวัดคุณภาพชีวิตสำหรับผู้ป่วยโรคเบาหวานที่มีแผลที่เท้า ว่าแผลที่เท้าของคุณส่งผลกระทบ
ต่อชีวิตประจำวันและคุณภาพชีวิตของคุณอย่างไร กรุณาอ่านข้อคำถามอย่างรอบคอบและนึกถึงผลกระทบที่
เกิดจากแผลที่เท้าของคุณ ตอบคำถามทุกคำถามโดยเลือกเพียงคำตอบเดียวในแต่ละข้อ หากคุณไม่แน่ใจ กรุณา
เลือกคำตอบที่ดีที่สุดเท่าที่คุณทำได้

1. ปัญหาแผลที่เท้าของคุณส่งผลกระทบเพียงใด? (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากที่เดียว
1.1 ทำให้คุณต้องหยุดจากกิจกรรมหรือ นันทนาการที่คุณชื่นชอบ	☐	☐	☐	☐	☐
1.2 ทำให้ต้องเปลี่ยนกิจกรรมหรือ นันทนาการที่คุณชื่นชอบ	☐	☐	☐	☐	☐
1.3 ทำให้คุณต้องหยุดจากการไปท่องเที่ยว ช่วงวันหยุด	☐	☐	☐	☐	☐
1.4 ทำให้คุณต้องเปลี่ยนกิจกรรมหรือการ ท่องเที่ยวช่วงวันหยุดเป็นแบบที่คุณไม่ ค่อยชอบ	☐	☐	☐	☐	☐
1.5 ทำให้คุณต้องใช้เวลามากขึ้นในการ วางแผนทำกิจกรรมนันทนาการ	☐	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

2. เนื่องจากแผลที่เท้าของคุณ คุณรู้สึกแบบนี้บ่อยเพียงใด? (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากทีเดียว
2.1 เหนื่อยล้า	☐	☐	☐	☐	☐
2.2 รู้สึกหมดเรี่ยวแรง	☐	☐	☐	☐	☐
2.3 นอนหลับไม่สนิท	☐	☐	☐	☐	☐
2.4 ปวดขณะเดิน หรือยืน	☐	☐	☐	☐	☐
2.5 ปวดตอนกลางคืน	☐	☐	☐	☐	☐

3. เนื่องจากแผลที่เท้าของคุณ ข้อต่อไปนี้เกิดขึ้นบ่อยมากน้อยเพียงใด? (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากทีเดียว
3.1 ต้องพึ่งพาผู้อื่นให้ช่วยดูแล เช่น ในการอาบน้ำแต่งตัว	☐	☐	☐	☐	☐
3.2 ต้องพึ่งพาผู้อื่นให้ช่วยทำงานบ้าน เช่น ทำกับข้าว, ทำความสะอาดบ้าน, หรือ ซักผ้า	☐	☐	☐	☐	☐
3.3 ต้องพึ่งพาผู้อื่นให้ช่วยพาคุณออกนอกบ้าน	☐	☐	☐	☐	☐
3.4 ต้องใช้เวลามากขึ้นในการวางแผนทำกิจกรรมในแต่ละวัน	☐	☐	☐	☐	☐
3.5 รู้สึกว่าการทำกิจกรรมแต่ละอย่างใช้เวลามากกว่าปกติ	☐	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

4. เนื่องจากแผลที่เท้าของคุณ คุณมีความรู้สึกแบบนี้บ่อยเพียงใด? (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากทีเดียว
4.1 รู้สึกโกรธที่คุณไม่สามารถทำในสิ่งที่คุณต้องการได้	☐	☐	☐	☐	☐
4.2 รู้สึกหงุดหงิดที่ต้องให้คนอื่นทำสิ่งต่างๆ แทน แทนที่คุณจะทำได้เอง	☐	☐	☐	☐	☐
4.3 รู้สึกหงุดหงิดเพราะว่า คุณไม่สามารถทำในสิ่งที่คุณต้องการ	☐	☐	☐	☐	☐

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากทีเดียว
4.4 รู้สึกกังวลว่าแผลจะไม่หาย	☐	☐	☐	☐	☐
4.5 รู้สึกกังวลว่าอาจจะถูกตัดขา	☐	☐	☐	☐	☐
4.6 รู้สึกกังวลเกี่ยวกับการบาดเจ็บที่เท้าของคุณ	☐	☐	☐	☐	☐
4.7 รู้สึกซึมเศร้าที่คุณไม่สามารถทำในสิ่งที่คุณต้องการได้	☐	☐	☐	☐	☐
4.8 รู้สึกกังวลว่าจะเกิดแผลขึ้นในอนาคต	☐	☐	☐	☐	☐
4.9 รู้สึกโกรธที่มีแผลที่เท้า	☐	☐	☐	☐	☐
4.10 รู้สึกหงุดหงิดเพราะคุณทำอะไรๆ ได้ลำบากมากขึ้น	☐	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

5. เนื่องจากแผลที่เท้าของคุณ คุณมีความรู้สึกแบบนี้บ่อยเพียงใด? (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เลย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากทีเดียว
5.1 รู้สึกต้องเลี่ยงการลงน้ำหนักตรงเท้าที่มีแผล	☐	☐	☐	☐	☐
5.2 รู้สึกต้องใช้เวลาในการดูแลแผล รวมทั้งการเปลี่ยนผ้าพันแผล, การรอคอยพยาบาลที่มาเยี่ยมบ้าน, และการดูแลแผลให้สะอาด	☐	☐	☐	☐	☐
5.3 รู้สึกรำคาญ เกี่ยวกับลักษณะแผลภายนอก, กลิ่น หรือ น้ำหนองที่ไหลจากแผล	☐	☐	☐	☐	☐
5.4 รู้สึกเป็นภาระ ให้ผู้อื่นต้องมาดูแลแผลที่เท้า	☐	☐	☐	☐	☐

ตอนที่ 5 แบบวัดการจัดการดูแลแผลเบาหวานที่เท้าด้วยตนเอง

ภาค ก: ข้อมูลสุขภาพทั่วไปเกี่ยวกับโรคเบาหวานที่เท้า

1. ในช่วง 12 เดือนที่ผ่านมา คุณมีอาการ/ปัญหาเหล่านี้เกิดขึ้นกับคุณมากน้อยเพียงใด (โปรดเลือกเพียงคำตอบเดียว)

	ไม่เคย	บางครั้ง	เป็นประจำ
1.1 อาการชาบริเวณเท้า	☐	☐	☐
1.2 อาการเหมือนมีของแหลมๆ มาทิ่มบริเวณเท้า	☐	☐	☐
1.3 ปวดและแสบร้อนบริเวณเท้า	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

	ไม่เคย	บางครั้ง	เป็นประจำ
1.4 ปัญหาการทรงตัวและ การหกล้ม	☐	☐	☐
1.5 ปวดกล้ามเนื้อบริเวณต้นขา/น่อง ซึ่งหากพักสัก 2-3 นาที อาการเหล่านี้จะดีขึ้น	☐	☐	☐

2   ในช่วง 12 เดือนที่ผ่านมา คุณมีอาการเหล่านี้ที่เท้าหรือไม่ (โปรดเลือกเพียงคำตอบเดียว)

	มี	ไม่มี
2.1 หนังด้าน	☐	☐
2.2 ปุ่มตาปลา (ผิวหนังหนา ซึ่งเจ็บปวดหรือระคายเคือง มักเป็นที่นิ้วก้อย, บน นิ้วเท้าหรือระหว่างนิ้วเท้า)	☐	☐
2.3 เล็บหนา (เล็บเท้าที่หนาและตัดยากมาก)	☐	☐
2.4 เล็บคุด (เล็บเท้าที่จิกเข้าไปในเนื้อ)	☐	☐
2.5 เชื้อราที่เท้า	☐	☐
2.6 ส้นเท้าแตก	☐	☐
2.7 แผลที่เท้า (แผลที่ไม่สามารถหายภายใน 1 เดือน)	☐	☐

3   คุณสามารถมองเห็นส้นเท้าทั้งสองข้าง ของคุณหรือไม่? (โปรดเลือกเพียงคำตอบเดียว)

☐ เห็น   ☐ ไม่เห็น

4   หากคุณตอบ "ไม่เห็น" ในข้อคำถามข้างต้น กรุณาเลือกเหตุผลทุกอย่างที่เกี่ยวข้อง

☐ สายตาพร่ามัว   ☐ ปัญหาเกี่ยวกับไขข้อ/สะโพก/หัวเข่า และ ข้ออักเสบ

☐ น้ำหนักเกิน   ☐ อื่นๆ (โปรดระบุ)...

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

5   กรุณาตรวจสอบเท้าของคุณ ถ้าคุณมีปัญหาดังภาพต่อไปนี้ (โปรดเลือกทุกข้อที่เกี่ยวข้อง)

นิ้วเท้าเอียงเหมือนค้อน   ตาปลาขนาดใหญ่ที่เท้า   กระดูกนิ้วเท้าผิดรูป

(กระดูกหักผิดรูป เกิดขึ้นได้ใน 5 ตำแหน่งที่เกิดขึ้น
ดังภาพ ทำให้เท้าของคุณเปลี่ยนรูปร่างและขนาด)
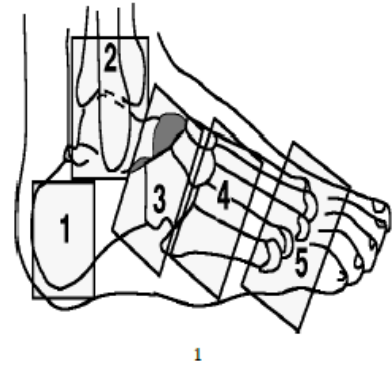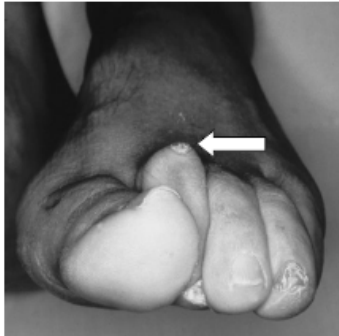
□ มี   □ ไม่มี   □ มี   □ ไม่มี   □ มี   □ ไม่มี

คุณเคยโดนตัดนิ้วเท้า/เท้า/ขาเป็นบางส่วน/ขาทั้งท่อน หรือไม่?

□ เคย (กรุณาตอบคำถามข้อ 7 และ 8)   □ ไม่เคย (กรุณาตอบคำถามข้อ 9)

6   หากคุณตอบ "เคย" กรุณาระบุว่าข้างใด หากโดนตัดทั้ง 2 ข้าง ให้ระบุทั้ง 2 ข้าง

	ขวา	ซ้าย	ทั้ง ขวา และซ้าย
6.1 นิ้วเท้าเท่านั้น	□	□	□
6.2 เท้าบางส่วนหรือทั้งท่อน	□	□	□

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

	ขวา	ซ้าย	ทั้ง ขวา และซ้าย
6.3 ขา, ใต้หัวเข่า	☐	☐	☐
6.4 ขา, เหนือหัวเข่า	☐	☐	☐

7 การตัดขาครั้งนั้นเป็นผลเนื่องมาจากข้อใด?

	ใช่	ไม่ใช่
7.1 เกิดจากการบาดเจ็บหรือ บาดแผลอื่นๆ	☐	☐
7.2 เกิดจากโรคเบาหวาน	☐	☐

ภาค ข: การดูแลเท้าด้วยตนเอง

9. ในช่วง 4 สัปดาห์ที่ผ่านมา คุณทำกิจกรรมเหล่านี้บ่อยเพียงใด (กรุณาเลือกเพียงคำตอบเดียว)

	ทุกวัน	หลายครั้ง ต่อสัปดาห์	สัปดาห์ละ ครั้ง	ครั้งหรือสอง ครั้งต่อสัปดาห์	ไม่เคยเคย ทำ
9.1 ตรวจดูส้นเท้า เพื่อขูดผิวหนังหยาบกร้าน หรือตรวจดูแผลที่เท้า	☐	☐	☐	☐	☐
9.2 ตรวจซอกนิ้วเท้าเพื่อดูรอยแตกของผิวหนัง	☐	☐	☐	☐	☐
9.3 ล้างเท้า	☐	☐	☐	☐	☐
9.4 แช่เท้าในน้ำนานเกินกว่า 10 นาที	☐	☐	☐	☐	☐
9.5 ใช้มือหรือข้อศอกจุ่มวัดอุณภูมิของน้ำ ก่อน จุ่มเท้าในน้ำ	☐	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

	ทุกวัน	หลายครั้ง ต่อสัปดาห์	สัปดาห์ละ ครั้ง	ครั้งหรือสอง ครั้งต่อสัปดาห์	ไม่เคยเคย ทำ
9.6 ซับซอกเท้าให้แห้ง หลังจากล้างเท้าทุกครั้ง	☐	☐	☐	☐	☐
9.7 ใช้โลชั่น หรือ ครีมทาเท้า	☐	☐	☐	☐	☐
9.8 ขูดรอยหยาบกร้าน	☐	☐	☐	☐	☐
9.9 ตัดแต่งเล็บ	☐	☐	☐	☐	☐
9.10 ตรวจดูข้างในรองเท้าว่ามีมุมแข็งหรือวัสดุ อื่นๆ อยู่ในรองเท้าก่อนใส่รองเท้า	☐	☐	☐	☐	☐
9.11 ใส่ถุงเท้าเมื่อใส่รองเท้า	☐	☐	☐	☐	☐
9.12 เปลี่ยนรองเท้าในระหว่างวัน	☐	☐	☐	☐	☐
9.13 เดินเท้าเปล่า หรือใส่เพียงถุงเท้าเมื่อเดินอยู่ ภายในบ้าน	☐	☐	☐	☐	☐
9.14 เดินเท้าเปล่าเมื่อเดินอยู่นอกบ้าน	☐	☐	☐	☐	☐

10. ใครเป็นผู้ดูแลเท้าให้คุณในช่วง 12 เดือนที่ผ่านมา (โปรดตอบทุกข้อคำถาม)

	ตัวเอง	คนใน ครอบครัว	พยาบาล/ แพทย์	ไม่มี
10.1 ตรวจดูสันเท้า เพื่อดูผิวหนังหยาบกร้านหรือเป็นแผล	☐	☐	☐	☐
10.2 ตรวจซอกนิ้วเท้าเพื่อดูรอยแตกของผิวหนัง	☐	☐	☐	☐
10.3 ขูดรอยหยาบกร้าน	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

	ตัวเอง	คนใน ครอบครัว	พยาบาล/ แพทย์	ไม่มี
10.4 ตัดแต่งเล็บ	☐	☐	☐	☐
10.5 ตรวจดูข้างในรองเท้าว่ามีมุมแข็งหรือวัสดุอื่นๆ อยู่ใน รองเท้าก่อนใส่รองเท้า	☐	☐	☐	☐

ภาค ค: ความรู้เกี่ยวกับเท้าของตนเอง

11. คุณเคยได้รับความรู้เกี่ยวกับการดูแลเท้าของคุณมากน้อยเพียงใด? (กรุณาเลือกเพียงคำตอบเดียว)

	ไม่มี เลย	นิด หน่อย	มีบ้าง, แต่ต้องการทราบ เพิ่มเติม	มีความรู้ เพียงพอ
11.1 การตรวจดูเท้าเป็นประจำ	☐	☐	☐	☐
11.2 การดูแลรักษาเท้าให้สะอาด	☐	☐	☐	☐
11.3 การเลือกรองเท้าที่เหมาะสม	☐	☐	☐	☐
11.4 การใส่รองเท้าหรือรองเท้าแตะตลอดเวลา	☐	☐	☐	☐
11.5 การดูแลผิวหนังให้ชุ่มชื้น	☐	☐	☐	☐
11.6 การใช้กระจกลักษณะพิเศษ เพื่อมองส้นเท้า ด้านล่าง	☐	☐	☐	☐
11.7 การหลีกเลี่ยงไม่ให้เท้าสัมผัสอุณภูมิที่ร้อน หรือเย็นเกินไป	☐	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า				
	ไม่มี เลย	นิด หน่อย	มีบ้าง, แต่ต้องการทราบ เพิ่มเติม	มีความรู้ เพียงพอ
11.8 การขูดรอยหยาบกร้านออกเบาๆ	☐	☐	☐	☐
11.9 การตัดเล็บให้เหมาะมกับนิ้วเท้า	☐	☐	☐	☐
11.10 การไม่ใช้กรรไกรหรือมีดตัดตาปลาและ รอยหยาบกร้าน	☐	☐	☐	☐
11.11 การไม่ซื้อยาตามร้านขายยาหรือ การรักษา แบบอื่นที่นอกเหนือจากแพทย์สั่ง	☐	☐	☐	☐
11.12 เวลาที่ควรมาพบแพทย์เมื่อมีแผลที่เท้า	☐	☐	☐	☐
11.13 บุคคลที่ควรโทรหาเมื่อคุณมีแผลที่เท้า	☐	☐	☐	☐

12. ข้อใดต่อไปนี้ เป็นเหตุผลที่ทำให้คุณไม่ได้ดูแลเท้าของตัวเองในช่วง 12 เดือนที่ผ่านมา (กรุณาเลือกเหตุผล ทุกอย่างที่เกี่ยวข้องอย่างที่เกี่ยวข้อง)

☐ ฉันไม่รู้ว่าควรทำอะไร   ☐ ฉันรู้ว่าควรทำอะไร แต่ไม่รู้ว่าจะทำอย่างไร

☐ ฉันไม่มีเวลา   ☐ ฉันไม่มีเงิน

☐ ฉันไม่มีรองเท้าที่เหมาะ   ☐ ฉันไม่มีแผ่นใส่รองเท้าที่เหมาะสม

☐ ฉันไม่มีกระจก เพื่อช่วยมองเท้า   ☐ ฉันไม่มีเก้าอี้/ม้านั่ง เวลาใส่รองเท้า

☐ ฉันจำไม่ได้   ☐ ฉันจำเป็นต้องได้รับความช่วยเหลือจากผู้เชี่ยวชาญ

☐ ฉันจำเป็นต้องได้รับความช่วยเหลือจาก   ☐ ฉันไม่คิดว่ามันสำคัญ

เพื่อนบ้านหรือคนในครอบครัว   ☐ ฉันมองส่วนที่ต้องทำไม่ค่อยเห็น

☐ ฉันเอื้อมไปจับเท้าตัวเองไม่ค่อยไหว

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13. ในช่วง 12 เดือนที่ผ่านมาผู้เชี่ยวชาญใดต่อไปนี้ให้ข้อมูลแก่คุณเรื่องเท้าบ่อยแค่ไหน (เลือกทุกข้อที่ถูก)

	ครั้งเดียว	มากกว่าหนึ่งครั้ง
13.1 โรงพยาบาลส่งเสริมสุขภาพตำบล	☐	☐
13.2 แพทย์หรือศัลยแพทย์ด้านเท้า	☐	☐
13.3 สมาชิกในทีมคลินิกเบาหวาน (แพทย์, พยาบาล, หรือ อาจารย์พยาบาล)	☐	☐
13.4 ผู้เชี่ยวชาญด้านการฟื้นฟูสมรรถภาพ (นักกายภาพบำบัด)	☐	☐

ภาค จ: การดูแลเท้าจากผู้เชี่ยวชาญ

14. คุณเคยได้รับการตรวจเท้าหรือไม่ (โปรดเลือกเพียงคำตอบเดียว)

☐ เคย   ☐ ไม่เคย

15. หากคุณคำถามข้างต้น "เคย" (โปรดเลือกเพียงคำตอบเดียว)

☐ คลินิกเบาหวาน แผนกผู้ป่วยนอก   ☐ คลินิกเท้า

☐ สถานพยาบาลอื่นๆ   ☐ ฉันไม่เคยได้รับการตรวจเท้า

16. ในช่วง 12 เดือนที่ผ่านมา คุณเข้ารับการดูแลเท้าที่สถานพยาบาลใด (โปรดเลือกเพียงคำตอบเดียว)

☐ คลินิกเบาหวาน แผนกผู้ป่วยนอก   ☐ สถานพยาบาลอื่นๆ

☐ คลินิกเบาหวาน แผนกผู้ป่วยนอก และสถานพยาบาลอื่นๆ

☐ ฉันไม่ได้รับการดูแลเท้า

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

17. ในช่วง 12 เดือนที่ผ่านมา บุคลากรทางการแพทย์ที่คุณไปปรึกษาเกี่ยวกับการดูแลเท้า ที่คลินิกเบาหวาน แผนกผู้ป่วยนอกได้ทำสิ่งใดต่อไปนี้หรือไม่? (โปรดเลือกเพียงคำตอบเดียวในแต่ละข้อ)

	ทำมากกว่า 1 ครั้ง	ทำอย่างน้อย 1 ครั้ง	ไม่เคยทำ
17.1 ถามคุณเกี่ยวกับอาการชาหรืออาการเหมือนมีของแหลมที่บริเวณเท้า	☐	☐	☐
17.2 สังเกตุเท้าของคุณหลังจากที่คุณถอดรองเท้าและถุงเท้าออก	☐	☐	☐
17.3 ตรวจสอบเท้าของคุณทั้งด้านบนและด้านล่าง	☐	☐	☐
17.4 ตรวจซอกเท้าของคุณ	☐	☐	☐
17.5 ตรวจสอบความรู้สึกของเท้าด้วยซ่อมเสียงหรืออโนฟิลาเมนท์ (เชือกไนลอนที่เป็นเส้นๆ งอได้มีด้ามจับ)	☐	☐	☐
17.6 ขูดผิวหนังที่หยาบกร้านให้คุณ	☐	☐	☐
17.7 ตัดแต่งเล็บให้คุณ	☐	☐	☐
17.8 ตรวจดูรองเท้าของคุณ	☐	☐	☐
17.9 แนะนำการเลือกรองเท้าที่เหมาะสม	☐	☐	☐

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ภาค จ: การใส่รองเท้าของคุณ

18. ในช่วง 4 สัปดาห์ที่ผ่านมา คุณทำข้อความต่อไปนี้กี่เปอร์เซนต์เมื่อคุณลุกออกจากเตียง? (โปรดระบุความถี่เป็นเปอร์เซนต์)

เดินเท้าเปล่า ....%

ใส่รองเท้าที่แพทย์สั่งให้ ....%

ใส่รองเท้าแบบเปิดส้น เช่นรองเท้าแตะ หรือ รองเท้าใส่ในบ้าน ....%

รวม 100%

19. คุณมีปัญหาในการหารองเท้าที่ใส่ได้พอดีจากร้านค้าทั่วไปหรือไม่? (เลือกเพียงคำตอบเดียว)

☐ มี ☐ ไม่มี

20. คุณรู้หรือไม่ว่าต้องติดต่อใครเมื่อมีปัญหาเกี่ยวกับรองเท้า (เลือกเพียงคำตอบเดียว)

☐ รู้ ☐ ไม่รู้

21. ในช่วง 12 เดือนที่ผ่านมา มีผู้เชี่ยวชาญด้านสุขภาพเคยแนะนำให้คุณใส่รองเท้าแบบพิเศษหรือไม่? (เลือกเพียงคำตอบเดียว)

☐ มี ☐ ไม่มี

22. ในช่วง 12 เดือนที่ผ่านมา คุณได้ใส่รองเท้าที่แพทย์แนะนำให้หรือไม่? (โปรดเลือกเพียงคำตอบเดียว)

☐ เคย ใส่ตลอดเวลา ☐ เคย ใส่เป็นบางครั้ง

☐ เคย ใส่เกือบทุกวัน ☐ ไม่เคยใส่เลย

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คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

23. หาก "ไม่เคยใส่เลย" มีเหตุผลอะไรที่ทำให้ไม่ได้ใส่รองเท้า

☐ รองเท้าทำให้เท้าของฉันเจ็บ   ☐ รองเท้าใส่ได้ไม่พอดี

☐ ฉันไม่ได้ซื้อรองเท้าตามแพทย์แนะนำ   ☐ รองเท้าทำให้ฉันรู้สึกร้อน

☐ ฉันไม่ชอบลักษณะของรองเท้านั้น   ☐ รองเท้าคู่นั้นเก่ามากแล้ว และฉันยังไม่ได้เปลี่ยนคู่
ใหม่/ซื้อคู่ใหม่

*********ขอบคุณสำหรับความร่วมมือในการสำรวจครั้งนี้*********

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APPENDIX 3: INFORMATION SHEETS AND CONSENT FORMS

Information Sheets Phase 1: English Version

UNIVERSITY OF WOLLONGONG
AUSTRALIA

School of Nursing, Faculty of Sciences, Medicine and Health

PARTICIPATION INFORMATION SHEET - PHASE 1 SURVEY

Title of Study:

Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers

Researcher: Saneh Khunkaew	**Supervisors**: 1. Prof. Ritin Fernandez
Ph: +62 435 239002	2. Dr. Jenny Sim
Email: sk054@uowmail.edu.au	**Ph**: +61 2 91131200

You are invited to participate in a research project aimed to investigate the quality of life and diabetes self-care knowledge among Thai adults including farmers with diabetes mellitus. Whether you wish to participate in this study is your choice; you do not have to join if you do not want to.

If you decide to participate in this research, we would ask you to complete a survey. This survey should take no more than 20-30 minutes of your time. The questions will ask you about yourself, your health-related quality of life knowledge about diabetes and how you care for yourself related to your diabetes mellitus. Also, the researcher will access your medical records to obtain your medical history. For most of the questions you will have to tick a box.

If you are participating in this study, your name will not be recorded and / or identified on any information collected for this study. You will be allocated a code number that will be used by the researchers to analyse the information you provide. The documents and information will only be accessible by research team members and will be stored securely.

Participation in this study is voluntary so you can choose if you want to participate. You can also change your mind and withdraw yourself from this study at any time. However all information that you have provided will be retained as we have no way of identifying your information. Non participation and / or withdrawal from the study will not affect your treatment or care.

This study has received Human Research Ethics approval from the University of Wollongong Research Ethics committee (Aproval Number HE16/209). If at any time you have any concerns or complaints regarding the way in which this research is or has been conducted please contact the University of Wollongong Ethic Officer on +61 2 4221 3386 or email rso-ethics@uow.edu.au. Also, the local contact is the Uttaradit Hospital Ethic Officer on +66 55 832 601.

If you agree to participate in the survey, you will be asked to sign the participant Consent form and a copy of this form will be given to you.

Thank you.

Version 2: 04-07-2016

Consent form Phase 1: English version

UNIVERSITY OF
WOLLONGONG
AUSTRALIA

University of Wollongong; Faculty of Sciences, Medicine and Health

CONSENT FORM - PHASE 1 SURVEY

Researcher: Saneh Khunkaew   **Supervisors**: 1. Prof Ritin Fernandez

Ph: +61 435 239002   2. Dr. Jenny Sim

Email: sk054@uowmail.edu.au   Ph: +61 2 91131200

I have been given information about the study "Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers" and discussed the research project with Saneh Khunkaew, who is conducting this research as part of a Doctor of Philosophy (PhD.), at the University of Wollongong.

I understand that, if I consent to participate in this project I will be asked the following:
(a) personal information (such as age, medical history, and behaviour that relates to my diabetes mellitus)
(b) information about the my quality of life and Diabetes self-care knowledge.

(c) to provide consent to access my hospital records

I have had the opportunity to ask Saneh Khunkaew any questions I may have about the research and my participation.

I understand that my participation in this research is voluntary, I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect my treatment or care by the Uttaradit Hospital in any way.

If I have any enquiries about the research, I can contact Saneh Khunkaew (+61 435 239002) or Prof Ritin Fernandez (+61 2 91131200) or if I have any concerns or complaints regarding the way the research is or has been conducted; I can contact the Complaints Officer, Human Research Ethic Committee, Research Services Office, University of Wollongong on +61 2 4221 4457. Also, the local contact is the Uttaradit Hospital Ethics Officer on +66 55 832 601.

By signing below I am indicating my consent to participate in the study "Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers", conducted by Saneh Khunkaew as it has been described to me in the information sheet and in discussion with Saneh Khunkaew. I understand that the data collected from my participation will be used for a PhD thesis and journal publications and I consent for it to be used in that manner.

Signature   Date

..../.............../.........

Name (please print)

Version 2: 04-07-2016

Information sheets Phase 2: English version

UNIVERSITY OF WOLLONGONG
AUSTRALIA

School of Nursing, Faculty of Sciences, Medicine and Health

PARTICIPATION INFORMATION SHEET – INTERVIEW
(Researcher version: Script for Telephone conversation)

Title of Study:

Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers

Researcher: Saneh Khunkaew   **Supervisors:** 1. Prof Ritin Fernandez
Ph: +61 435 239002   2. Dr. Jenny Sim
                                                             3. A/P Patraporn Tungpunkom
Email: sk054@uowmail.edu.au   Ph: +61 2 91131200

My name is SANEH KHUNKAEW and I am a Postgraduate student in the School of Nursing and Midwifery at The University of Wollongong, Australia. I am currently undertaking a research thesis for my Doctor of Philosophy (Ph.D.) entitled 'Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers'. The purpose of this research is to explore the experiences of Thai people living with foot ulcers due to diabetes mellitus. You are invited to participate since you have already completed the first part of this project which was completing a survey at Uttaradit Hospital in Thailand.

If you decide to join in this research, you will be given information relevant to the study. Also, you will be interviewed individually at a private area in your home or at Uttaradit Hospital in the next appointment. The interview will involve asking you some questions about: (a) you, your diabetes mellitus and your foot ulcer/s (b) your experiences of having a diabetic foot ulcer and (c) information about how you live with foot ulcers due to diabetes mellitus. We are particularly targeting diabetes patients who have diabetic foot ulcers to try and learn more about their experiences. The interview will take 20-30 minutes of your time.

If you agree to participate in this study, the interview will be audio recorded. Your name and any identifying details will be removed from any written summaries of your interview. A pseudonym will then be assigned to protect your privacy. All information collected from you will be saved using that pseudonym in all files and documents. The documents and information will be securely stored and only be accessible by members of the research team.

Participation in this study is voluntary so you should choose if you want to participate. You can also change your mind and withdraw yourself from this study at any time. All information relating to you will also be withdrawn from the study. Non participation and / or withdrawal from the study will not affect your treatment or care.

If at any time you have any concerns or complaints regarding the way in which this research is or has been conducted please contact the secretary of the University of Wollongong Human Research Ethic Committee on +61 2 4221 4457. Also, the local contact is the Uttaradit Hospital Ethic Officer on +66 55 832 601.

Thank you

If there are any questions or concerns you have about this project please do not hesitate to contact the researcher. Mr. SANEH KHUNKAEW School of Nursing University of Wollongong Northfields Avenue WOLLONGONG NSW 2522 TEL.+61 435 239002 E-MAIL: sk054@uowmail.edu.au

If at any time you have any concerns or complaints regarding the way in which this research is or has been conducted please contact the secretary of the University of Wollongong Human Research Ethic Committee on +61 2 4221 4457. Also, the local contact is the Uttaradit Hospital Ethic Officer on +66 55 832 601.

Thank you

UNIVERSITY OF WOLLONGONG
AUSTRALIA

School of Nursing, Faculty of Sciences, Medicine and Health

PARTICIPATION INFORMATION SHEET – INTERVIEW

(Assistant Researcher version: Script for Telephone conversation)

Title of Study:

Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers

Researcher: Saneh Khunkaew	**Supervisors:** 1. Prof Ritin Fernandez
Ph: +61 435 239002	2. Dr. Jenny Sim
	3. A/P Patraporn Tungpunkom
Email: sk054@uowmail.edu.au	Ph: +61 2 91131200

My name is .... and I am a research assistant for a research project entitled: 'Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers'.

The purpose of this research is to explore the experiences of Thai people living with foot ulcers due to diabetes mellitus. You are invited to participate since you have already completed the first part of this project which was completing a survey at Uttaradit Hospital in Thailand.

If you decide to join in this research, you will be given information relevant to the study. Also, you will be interviewed individually at a private area in your home or at Uttaradit Hospital in the next appointment. The interview will involve asking you some questions about: (a) you, your diabetes mellitus and your foot ulcer/s (b) your experiences of having a diabetic foot ulcer and (c) information about how you live with foot ulcers due to diabetes mellitus. We are particularly targeting diabetes patients who have diabetic foot ulcers to try and learn more about their experiences. The interview will take 20-30 minutes of your time.

If you agree to participate in this study, the interview will be audio recorded. Your name and any identifying details will be removed from any written summaries of your interview. A pseudonym will then be assigned to protect your privacy. All information collected from you will be saved using that pseudonym in all files and documents. The documents and information will be securely stored and only be accessible by members of the research team.

Participation in this study is voluntary so you should choose if you want to participate. You can also change your mind and withdraw yourself from this study at any time. All information relating to you will also be withdrawn from the study. Non participation and / or withdrawal from the study will not affect your treatment or care.

Consent form Phase 2: English version

UNIVERSITY OF WOLLONGONG
AUSTRALIA

School of Nursing, Faculty of Sciences, Medicine and Health

CONSENT FORM – PHASE 2 INTERVIEWS

Researcher: Saneh Khunkaew
Ph: +61 435 239002

Email: sk054@uowmail.edu.au

Supervisors: 1. Prof Ritin Fernandez
2. Dr. Jenny Sim
3. A/P Patraporn Tungpunkom
Ph: +61 2 91131200

I have been given information about the study "Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers" and discussed the research project with Saneh Khunkaew, who is conducting this research as part of a Doctor of Philosophy (PhD.), at the University of Wollongong.

I understand that, if I consent to participate in this project I will be asked questions about the following:
(a) you, your diabetes mellitus and your foot ulcer/s
(b) your experiences of having a diabetic foot ulcer and
(c) information about how you live with foot ulcers due to diabetes mellitus.

I have had the opportunity to ask Saneh Khunkaew any questions I may have about the research and my participation. I am delighted to participate on my time whether at home or at Diabetic foot clinic.

I understand that my participation in this research is voluntary, I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of my consent will not affect my treatment or care by the Uttaradit Hospital in any way.

If I have any enquiries about the research, I can contact Saneh Khunkaew (+61 435 239002) or Prof Ritin Fernandez (+ 61 2 91131200) or if I have any concerns or complaints regarding the way the research is or has been conducted; I can contact the Complaints Officer, Human Research Ethic Committee, Research Services Office, University of Wollongong on +61 2 4221 4457. Also, the local contact is the Uttaradit Hospital Ethic Officer on +66 55 832 601.

By signing below, I am indicating my consent to participate in the study "Quality of Life and Diabetes Self-care Knowledge of Thai People Living with Diabetic Foot Ulcers", conducted by Saneh Khunkaew as it has been described to me in the information sheet and in discussion with Saneh Khunkaew. I understand that the data collected from my participation will be used for a PhD thesis and journal publications and I consent for it to be used in that manner.

Signature   Date

..../............./.........

Name (please print)

....

Information sheet Phase 1: Thai version

เอกสารแนะนำสำหรับอาสาสมัคร - ระยะที่ 1

Title of Study: คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

(Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers)

ผู้วิจัย: นายเสน่ห์ ขุนแก้ว

Ph: +61 435 239002

Email: sk054@uowmail.edu.au

ที่ปรึกษางานวิจัย: 1. Prof. Ritin Fernandez

2. Dr. Jenny Sim

Ph: +61 2 91131200

ท่านเป็นหนึ่งในผู้ที่ได้รับเชิญให้เข้าร่วมการวิจัยเรื่อง "คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า" เพื่อศึกษาคุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า ทั้งนี้การตัดสินใจเข้าร่วมหรือไม่เข้าร่วมในการวิจัยนี้ ถือเป็นความสมัครใจของท่าน

หากท่านตัดสินใจเข้าร่วมในการวิจัยในครั้งนี้ ท่านจะได้รับแบบสอบถาม ซึ่งประกอบด้วยข้อคำถามทั้งแบบเติมข้อความสั้นๆ และแบบเลือกตอบ ใช้เวลาในการทำประมาณ 20-30 นาที ข้อคำถามประกอบไปด้วยข้อมูลส่วนบุคคล, คุณภาพชีวิตเกี่ยวกับโรคเบาหวาน, ความรู้, คุณภาพชีวิตเกี่ยวกับโรคเบาหวานที่เท้าและ การจัดการดูแลเท้าด้วยตนเอง ผู้วิจัยจะมีการเข้าถึงเวชระเบียนและประวัติการรักษาในอดีตที่เกี่ยวข้องด้วย

หากท่านตัดสินใจเข้าร่วมในการศึกษาครั้งนี้ ชื่อของท่านจะไม่ถูกบันทึก และข้อมูลต่างๆ จะถูกเก็บเป็นความลับโดยไม่สามารถพาดพิงถึงท่านได้ โดยผู้วิจัยจะใช้รหัส หมายเลขแทนการบันทึกชื่อ-สกุล เอกสารและข้อมูลของท่านจะเข้าถึงได้เฉพาะคณะผู้วิจัยเท่านั้นและจะถูกจัดเก็บไว้ในตู้เก็บเอกสาร ที่มีกุญแจล็อคอย่างแน่นหนา

การเข้าร่วมในการวิจัยครั้งนี้ ถือเป็นความสมัครใจของท่าน ท่านสามารถเปลี่ยนใจ หรือยุติการเข้าร่วมการวิจัยในครั้งนี้ได้ทุกเวลา การเข้าร่วมหรือการยุติของท่านจะไม่มีผลต่อการรักษาพยาบาลในโรงพยาบาลอุตรดิตถ์

การศึกษาในครั้งนี้ได้รับการ รับรองจาก คณะกรรมจริยธรรมวิจัยในมนุษย์ มหาวิทยาลัยวูลองกอง ประเทศออสเตเลีย (approval number HE16/209) หากท่านมีข้อสงสัย หรือคำถามสามารถติดต่อมายังศูนย์จริยธรรมวิจัยในมนุษย์ มหาวิทยาลัยวูลองกอง ประเทศออสเตเลียเบอร์ โทรศัพท์ +61 2 4221 3386 หรือ อีเมล rso-ethics@uow.edu.au หรือ ศูนย์จริยธรรมวิจัยในมนุษย์โรงพยาบาลอุตรดิตถ์ โทรศัพท์ +66 55 832 601

เมื่อท่านยินยอมเข้าร่วมการวิจัยในครั้งนี้ ท่านจะ ได้รับเอกสารเพื่อลงนามแสดงความยินยอมเข้าร่วมการวิจัย และท่านจะได้รับสำเนาเอกสารเก็บไว้เป็นหลักฐาน

นายเสน่ห์ ขุนแก้ว

นักศึกษาปริญญาเอก

Title of Study: คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

(Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers)

ผู้วิจัย: นายเสน่ห์ ขุนแก้ว   ที่ปรึกษางานวิจัย: 1. Prof. Ritin Fernandez

Ph: +61 435 239002   2. Dr. Jenny Sim

Email: sk054@uowmail.edu.au   Ph: +61 2 91131200

            ข้าพเจ้า นายเสน่ห์ ขุนแก้ว นักศึกษาปริญญาเอก สาขาพยาบาล มหาวิทยาลัยวูลองกอง ประเทศออสเตเลีย
ขณะนี้กำลังศึกษาวิจัยเรื่อง
"คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า" วัตถุประสงค์เพื่อ
ศึกษาประสบการณ์ของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า
ท่านเป็นหนึ่งในผู้ที่ถูกรับเชิญเข้าวิจัยตั้งแต่ท่านทำแบบสอบถามครบสมบูรณ์ในระยะที่ 1 ณ โรงพยาบาลอุตรดิตถ์
            หากท่านตัดสินใจเข้าร่วมการวิจัยท่านจะได้รับข้อมูลที่เกี่ยวข้องกับการศึกษาวิจัยในครั้งนี้ การสัมภาษณ์
จะถูกสัมภาษณ์ในห้องที่มีความเป็นส่วนตัวที่โรงพยาบาลอุตรดิตถ์ในวันนัดพบแพทย์ หรือ ที่บ้านของท่านเอง ในการสัมภาษณ์
ท่านจะถูกถามเกี่ยวกับ (ก) ข้อมูลส่วนบุคคลเกี่ยวกับโรคเบาหวานและเบาหวานที่เท้า (ข)
ประสบการณ์การเป็นโรคเบาหวานที่เท้า (ค) ข้อมูลเกี่ยวกับการจัดการดูแลเท้าของท่าน การสัมภาษณ์ในครั้งนี้จะใช้เวลา 20-30
นาทีโดยประมาณ
            หากท่านตัดสินใจเข้าร่วมในการศึกษาครั้งนี้ บทสัมภาษณ์จะถูกบันทึก
โดยที่ชื่อของท่านจะไม่ถูกบันทึกอยู่ในบทสัมภาษณ์นี้ นามสมมติ จะถูกนำมาใช้แทนชื่อจริง
โดยที่ไม่มีใครสามารถพาดพิงถึงตัวท่านได้ ข้อมูลของท่านจะถูกจัดเก็บไว้ในไฟล์อิเล็กทรอนิก
โดยจะต้องใช้รหัสผ่านในการเข้าถึง ผู้วิจัยและทีมเท่านั้นสามารถเข้าถึงข้อมูลนี้ได้
            การเข้าร่วมในการวิจัยครั้งนี้ถือเป็นความสมัครใจของท่าน ท่านสามารถเปลี่ยนใจ
หรือยุติการเข้าร่วมการวิจัยในครั้งนี้ได้ทุกเวลา
การเข้าร่วมหรือการยุติของท่านจะไม่มีผลต่อการรักษาพยาบาลในโรงพยาบาลอุตรดิตถ์
            หากท่านมีข้อสงสัย หรือคำถามสามารถติดต่อมายังศูนย์จริยธรรมวิจัยในมนุษย์มหาวิทยาลัยวูลองกอง
ประเทศออสเตเลีย เบอร์โทรศัพท์ +61 2 4221 3386 หรือ อีเมล rso-ethics@uow.edu.au หรือ
ศูนย์จริยธรรมวิจัยในมนุษย์โรงพยาบาลอุตรดิตถ์ โทรศัพท์ +66 55 832 601

School of Nursing, Faculty of Sciences, Medicine and Health

เอกสารแนะนำสำหรับอาสาสมัคร - ระยะที่ 2

(สำหรับผู้ช่วยผู้วิจัย: บทสนทนาในโทรศัพท์)

Title of Study: คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

(Quality of Life and Diabetes Self-care Knowledge of Thai Farmers Living with Diabetic Foot Ulcers)

ผู้วิจัย: นายเสน่ห์ ขุนแก้ว   ที่ปรึกษางานวิจัย: 1. Prof. Ritin Fernandez

Ph: +61 435 239002   2. Dr. Jenny Sim

Email: sk054@uowmail.edu.au   Ph: +61 2 91131200

ข้าพเจ้า............................ ผู้ช่วยผู้วิจัยเรื่อง

"คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า" วัตถุประสงค์เพื่อ
ศึกษาประสบการณ์ของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า

ท่านเป็นหนึ่งในผู้ที่ถูกรับเชิญเข้าวิจัยตั้งแต่ท่านทำแบบสอบถามครบสมบูรณ์ในระยะที่ 1 ณ โรงพยาบาลอุตรดิตถ์

หากท่านตัดสินใจเข้าร่วมการวิจัยท่านจะได้รับข้อมูลที่เกี่ยวข้องกับการศึกษาวิจัยในครั้งนี้ การสัมภาษณ์
จะถูกสัมภาษณ์ในห้องที่มีความเป็นส่วนตัวที่โรงพยาบาลอุตรดิตถ์ในวัดนัดพบแพทย์หรือ ที่บ้านของท่านเอง ในการสัมภาษณ์
ท่านจะถูกถามเกี่ยวกับ(ก) ข้อมูลส่วนบุคคลเกี่ยวกับโรคเบาหวานและเบาหวานที่เท้า(ข)
ประสบการณ์การเป็นโรคเบาหวานที่เท้า(ค) ข้อมูลเกี่ยวกับการจัดการดูแลเท้าของท่าน การสัมภาษณ์ในครั้งนี้จะใช้เวลา 20-30
นาทีโดยประมาณ

หากท่านตัดสินใจเข้าร่วมในการศึกษาครั้งนี้ บทสัมภาษณ์จะถูกบันทึก
โดยที่ชื่อของท่านจะไม่ถูกบันทึกอยู่ในบทสัมภาษณ์นี้ นามสมมติ จะถูกนำมาใช้แทนชื่อจริง
โดยที่ไม่มีใครสามารถพาดพิงถึงตัวท่านได้ ข้อมูลของท่านจะถูกจัดเก็บไว้ใน ไฟล์อิเล็กทรอนิก
โดยจะต้องใช้รหัสผ่านในการเข้าถึง ผู้วิจัยและทีมเท่านั้นสามารถเข้าถึงข้อมูลนี้ได้

การเข้าร่วมในการวิจัยครั้งนี้ถือเป็นความสมัครใจของท่าน ท่านสามารถเปลี่ยนใจ
หรือยุติการเข้าร่วมการวิจัยในครั้งนี้ ได้ทุกเวลา

การเข้าร่วมหรือการยุติของท่านจะไม่มีผลต่อการรักษาพยาบาลในโรงพยาบาลอุตรดิตถ์

หากท่านมีข้อสงสัย หรือคำถามสามารถติดต่อ นายเสน่ห์ ขุนแก้ว โทรศัพท์+61 435 239002 อีเมล
sk054@uowmail.edu.au หรือติดต่อมายังศูนย์จริยธรรมวิจัยในมนุษย์ มหาวิทยาลัยวูลองกอง ประเทศออสเตเลียเบอร์โทรศัพท์
+61 2 4221 3386 หรือ อีเมล rso-ethics@uow.edu.au หรือ ศูนย์จริยธรรมวิจัยในมนุษย์ โรงพยาบาลอุตรดิตถ์ โทรศัพท์+66 55
832 601

School of Nursing, Faculty of Sciences, Medicine and Health

เอกสารยินยอมเข้าร่วมการวิจัย - ระยะที่ 1

ผู้วิจัย: นายเสน่ห์ ขุนแก้ว   ที่ปรึกษางานวิจัย: 1. Prof. Ritin Fernandez

Ph: +61 435 239002   2. Dr. Jenny Sim

Email: sk054@uowmail.edu.au   Ph: +61 2 91131200

ข้าพเจ้าได้รับข้อมูลเกี่ยวการศึกษาวิจัยเรื่อง

"คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า"
และได้พูดคุยข้อสงสัยกับนายเสน่ห์ ขุนแก้ว นักศึกษาปริญญาเอกมหาวิทยาลัยวูลองกอง ประเทศออสเตเลีย
ผู้ที่เป็นผู้วิจัยหลักเรียบร้อยแล้ว

ข้าพเจ้ายินยอมเข้ามาเป็นส่วนหนึ่งของการวิจัยในครั้งนี้ และ ยินยอมให้ถาม/สืบค้น ดังนี้:

(ก) ข้อมูลส่วนบุคคล (เช่น อายุ ประวัติการรักษาและพฤติกรรมที่เกี่ยวข้องกับโรคเบาหวาน)

(ข) ข้อมูลเกี่ยวกับคุณภาพชีวิตและความรู้เกี่ยวกับโรคเบาหวาน

(ค) ข้อมูลในเวชระเบียนของโรงพยาบาล

ข้าพเจ้าได้สอบถามข้อสงสัยต่างๆ กับ นายเสน่ห์ ขุนแก้วเกี่ยวกับเข้าร่วมในงานวิจัยในครั้งนี้แล้ว

ข้าพเจ้าเข้าใจในการเข้าร่วมในการวิจัยครั้งนี้ถือเป็นความสมัครใจของข้าพเจ้าเอง ข้าพเจ้าสามารถเปลี่ยนใจ
หรือยุติการเข้าร่วมการวิจัยในครั้งนี้ได้ทุกเวลา
ซึ่งการเข้าร่วมหรือการยุติของข้าพเจ้าจะไม่มีผลต่อการรักษาพยาบาลในโรงพยาบาลอุตรดิตถ์

ถ้าข้าพเจ้ามีข้อสงสัย หรือคำถามข้าพเจ้าสามารถติดต่อนายเสน่ห์ ขุนแก้ว โทรศัพท์+61 435 239002 อีเมล
sk054@uowmail.edu.au หรือติดต่อมายังศูนย์จริยธรรมวิจัยในมนุษย์ มหาวิทยาลัยวูลองกอง ประเทศออสเตเลียเบอร์โทรศัพท์
+61 2 4221 3386 หรือ อีเมล rso-ethics@uow.edu.au หรือ ศูนย์จริยธรรมวิจัยในมนุษย์โรงพยาบาลอุตรดิตถ์ โทรศัพท์+66 55
832 601

ก่อนที่ข้าพเจ้าจะลงนามยินยอมเข้าร่วมงานวิจัยในครั้งนี้ นายเสน่ห์
ขุนแก้วได้ชี้แจงข้อมูลที่เกี่ยวข้องกับการศึกษาในครั้งนี้ให้ข้าพเจ้าทราบแล้ว
ข้าพเจ้ารับทราบว่าข้อมูลเหล่านี้จะถูกนำไปใช้ในการศึกษาระดับปริญญาเอกและตีพิมพ์แพร่ในวารสาร
และข้าพเจ้ายินยอมให้ใช้ข้อมูลดังกล่าวได้

....

(   )   (นายเสน่ห์ ขุนแก้ว)

ชื่อ-สกุล และลายมือชื่อผู้เข้าร่วมวิจัย   ชื่อ-สกุล และลายมือชื่อผู้วิจัย

วัน/เดือน/ปี_____   วัน/เดือน/ปี_____

School of Nursing, Faculty of Sciences, Medicine and Health

เอกสารยินยอมเข้าร่วมการวิจัย - ระยะที่ 2

ผู้วิจัย: นายเสน่ห์ ขุนแก้ว   **ที่ปรึกษางานวิจัย:** 1. Prof. Ritin Fernandez

Ph: +61 435 239002   2. Dr. Jenny Sim

Email: sk054@uowmail.edu.au   **Ph:** +61 2 91131200

ข้าพเจ้าได้รับข้อมูลเกี่ยวการศึกษาวิจัยเรื่อง

"คุณภาพชีวิตและความรู้ในการดูแลตนเองเกี่ยวกับโรคเบาหวานของชาวนาไทยที่เป็นโรคเบาหวานที่เท้า"
และได้พูดคุยข้อสงสัยกับนายเสน่ห์ ขุนแก้ว นักศึกษาปริญญาเอกมหาวิทยาลัยวูลองกอง ประเทศออสเตเลีย
ผู้ที่เป็นผู้วิจัยหลักเรียบร้อยแล้ว

ข้าพเจ้ายินยอมเข้ามาเป็นส่วนหนึ่งของการวิจัยในครั้งนี้ และ ยินยอมให้สอบถามได้ ดังนี้:

(ก) ข้อมูลเกี่ยวโรคเบาหวาน/โรคเบาหวานที่เท้า

(ข) ประสบการณ์เกี่ยวกับโรคเบาหวานที่เท้า

(ค) ประสบการณ์การดูแลแผลเบาหวานที่เท้า

ข้าพเจ้าได้สอบถามข้อสงสัยต่างๆ กับ นายเสน่ห์ ขุนแก้วเกี่ยวกับเข้าร่วมในงานวิจัยในครั้งนี้แล้ว
ข้าพเจ้ายินยอมเข้าร่วมการวิจัยในขณะที่ไปพบแพทย์ หรือที่บ้าน (หรือที่ๆสะดวกสำหรับข้าพเจ้าเอง)

ข้าพเจ้าเข้าใจในการเข้าร่วมในการวิจัยครั้งนี้ถือเป็นความสมัครใจของข้าพเจ้าเอง ข้าพเจ้าสามารถเปลี่ยนใจ
หรือยุติการเข้าร่วมการวิจัยในครั้งนี้ได้ทุกเวลา

ซึ่งการเข้าร่วมหรือการยุติของข้าพเจ้าจะ ไม่มีผลต่อการรักษาพยาบาลใน โรงพยาบาลอุตรดิตถ์

ถ้าข้าพเจ้ามีข้อสงสัย หรือคำถามข้าพเจ้าสามารถติดต่อ นายเสน่ห์ ขุนแก้ว โทรศัพท์+61 435 239002 อีเมล
sk054@uowmail.edu.au หรือติดต่อ มายังศูนย์จริยธรรมวิจัยในมนุษย์ มหาวิทยาลัยวูลองกอง ประเทศออสเตเลียเบอร์โทรศัพท์
+61 2 4221 3386 หรือ อีเมล rso-ethics@uow.edu.au หรือ ศูนย์จริยธรรมวิจัยในมนุษย์โรงพยาบาลอุตรดิตถ์ โทรศัพท์+6655
832 601

ก่อนที่ข้าพเจ้าจะลงนามยินยอมเข้าร่วมงานวิจัยในครั้งนี้ นายเสน่ห์
ขุนแก้วได้ชี้แจงข้อมูลที่เกี่ยวข้องกับการศึกษาในครั้งนี้ให้ข้าพเจ้าทราบแล้ว
ข้าพเจ้ารับทราบว่าข้อมูลเหล่านี้จะถูกนำไปใช้ในการศึกษาระดับปริญญาเอกและตีพิมพ์แพร่ในวารสาร
และข้าพเจ้ายินยอมให้ใช้ข้อมูลดังกล่าวได้

....

(..)   (นายเสน่ห์ ขุนแก้ว)

ชื่อ-สกุล และลายมือชื่อผู้เข้าร่วมวิจัย   ชื่อ-สกุล และลายมือชื่อผู้วิจัย

วัน/เดือน/ปี_____   วัน/เดือน/ปี_____

APPENDIX 4: INTERVIEW GUIDE

Quality of Life and Diabetes Self-care Knowledge of Thai Adults Living with Diabetic Foot Ulcers (English Version)

Semi-structured interview guides

Warming up question:

Good morning/afternoon

1. How are you?

2. How long have you been diagnosed with diabetes?

3. What is your most recent HbA1c or FBS?

4. What kind of diabetes therapy are you undergoing?

5. Have you had any complications related with diabetes and treatment adverse effect?

First diagnosed with diabetes foot ulcers:

1. How did feel after you were informed by the doctor that you had a foot ulcer because of DM?

Probing questions

a. How do you manage your foot ulcers?

b. Who helps you with your foot ulcer management?

c. How do you feel about managing your foot ulcers?

d. Do you have any special foot wear that you use?

e. How did you feel when you wore it?

Quality of life

1. How would you describe your quality of life after your diagnosis with diabetes mellitus?

Probing questions

a. What about your energy levels?

b. Do you have other health problems that affect your quality of life?

c. Are you able to do what you want?

d. Do you worry about anything because of your foot ulcers?

e. What type of social support do you have in managing your diabetic foot ulcer?

Diabetes Diet

How have you changed your diet since you were diagnosed with diabetes mellitus?

Probing questions

a. Have you changed your food timing?

b. Have you changed the type of food that you eat?

Self-care management

1. How do you live with your foot ulcers?

Probing questions

1. What strategies do you recommend for other people with the same problems with foot ulcers?

2. What else would you like to tell me about your experiences with diabetic foot ulcers?

Quality of Life and Diabetes Self-care Knowledge of Thai Adults Living with Diabetic Foot Ulcers (Thai Version)

Semi-structured interview guides

<u>Quality of Life and Diabetes Self-care Knowledge of Thai Adults Living with Diabetic Foot</u>

<u>Ulcers (Thai version) Semi-structure interview guides</u>

<u>คำถามเริ่มบทสนทนา</u>

สวัสดีครับ คุณลุง/ป้า...

1. วันนี้สบายดีมั้ยครับ?

2. เป็นหวานมากี่ปีแล้วครับ?

3. พอจะจำได้มั้ยครับว่ามีค่าน้ำตาลในเลือดเท่าไหร่? หรือ ตอนที่วัดหลังจากอดน้ำอดอาหารละครับ?

4. แล้วตอนนี้รักษาเบาหวานด้วยวิธีไหนครับ?

5. มีโรคแทรกซ้อน หรือ ผลเสียจากการรักษา ที่เกิดจากโรคเบาหวานมั้ยครับ?

<u>การถูกวินิจฉัยครั้งแรกด้วยแผลจากโรคเบาหวาน:</u>

1. คุณลุง/ป้า...มีความรู้สึกอย่างไรเมื่อคุณหมอ ได้บอกว่าคุณลุง/ป้า...มีแผลที่เท้าเกิดจากโรคเบาหวาน?

<u>คำถามเจาะลึก:</u>

ก. คุณลุง/ป้า...มีการจัดการเกี่ยวกับแผลที่เท้าอย่างไรครับ?

ข. ใครเป็นคนช่วย คุณลุง/ป้า...ดูแลจัดการแผลที่เท้าครับ?

ค. คุณลุง/ป้า...มีความรู้สึกอย่างไรเกี่ยวกับการจัดการดูแลแผลของตัวเอง?

ง. คุณลุง/ป้า...มีรองเท้าพิเศษสำหรับผู้ป่วยโรคเบาหวานมั้ยครับ?

จ. คุณลุง/ป้า...มีความรู้สึกอย่างไรบ้างเวลาใส่รองเท้าพิเศษสำหรับผู้ป่วยโรคเบาหวาน?

<u>คุณภาพชีวิต:</u>

1. คุณลุง/ป้า...พอจะอธิบายให้ผมทราบได้ไหมครับว่ามีคุณภาพชีวิต/ความเป็นอยู่เป็นอย่างไรหลังจากเป็นแผลจาก
เบาหวาน?

<u>คำถามเจาะลึก:</u>

ก. กำลังวงชาลคลงบ้างมั้ยครับ?

ข. คุณลุง/ป้า...มีปัญหาสุขภาพอื่นๆอีกมั้ยครับที่ส่งผลต่อคุณภาพชีวิต?

ค. คุณลุง/ป้า...สามารถทำในสิ่งที่ต้องการจะทำมั้ยครับ?

ง. คุณลุง/ป้า...มีความกังวลเรื่องอื่นอิกมั้ยครับ จากการมีแผลที่เท้า?

จ. การช่วยเหลือจากสังคมประเภทใดที่เข้ามาช่วย คุณลุง/ป้า... ในการดูแลแผลที่เท้าบ้างครับ?

อาหารเบาหวาน:

1. คุณลุง/ป้า...ได้มีการเปลี่ยนแปลงตัวเองในการรับประทานอาหารอย่างไรบ้างหลังจากทราบว่าเป็นเบาหวาน?

คำถามเจาะลึก:

ก. คุณลุง/ป้า...ได้มีการปรับเปลี่ยนเวลามื้ออาหารบ้างไหมครับ?

ข. คุณลุง/ป้า...ได้มีการปรับเปลี่ยนชนิดของอาหารบ้างไหมครับ?

การดูแลตัวเอง:

1. คุณลุง/ป้า...มีการใช้ชีวิตอย่างไรเมื่อต้องอยู่กับแผลที่เกิดจากเบาหวาน?

คำถามเจาะลึก:

ก. หากต้องแนะนำคนอื่นๆที่มีปัญหาคล้ายๆกัน คุณลุง/ป้าจะแนะนำอย่างไรบ้างครับ?

ข. มีอะไรอีกมั้ยครับที่ คุณลุง/ป้า... อยากจะบอกเล่าประสบการณ์เกี่ยวกับการแผลที่เกิดจากเบาหวานที่เท้า?

APPENDIX 5: PUBLICATIONS

Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis. (Chapter 2)

REVIEW

CrossMark

Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis

Saneh Khunkaew[1] · Ritin Fernandez[1,2] · Jenny Sim[1]

Abstract

Purpose To undertake a systematic review of the literature to investigate the HRQOL among adults living with DFUs.

Methods A systematic search of the medical and nursing/health content databases including MEDLINE, CINAHL, and PsycINFO was conducted up to November 2018. The methodological quality of each study was assessed independently by all authors using the Joanna Briggs Institute checklist. Data analysis was conducted using the Comprehensive Meta-analysis software. All analyses were performed using random-effects models and heterogeneity was quantified.

Results A total of 12 studies were included in the review. Overall, the HRQOL of participants in the studies was poor on four of eight subscales in the SF-36: physical functioning (mean $= 42.75$, SE 1.5); role physical (mean $= 20.61$, SE 3.4); general health (mean $= 39.52$, SE 1.7); and vitality (mean $= 45.73$, SE 2.8). In addition, presence of pain, high levels of C-reactive protein (> 10 mg/L), ulcer size > 5 cm^2, Ankle Brachial Index < 0.9, high glycosylated haemoglobin and body mass index > 25 kg/m^2 were associated with poorer HRQOL in people with DFUs.

Conclusions This review has provided evidence indicating that people with DFUs have a significantly lower HRQOL. Evidence-based interventions to improve the HRQOL in this group of people is needed.

Keywords Health-related quality of life · Diabetic foot ulcers · Nursing · Meta-analysis

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Linguistic and psychometric validation of the Thai version of simplified Diabetes Knowledge Scale: a measure of knowledge of diabetes in a Thai population. (Chapter 5)

Linguistic and Psychometric Validation of the Thai Version of Simplified Diabetes Knowledge Scale: A Measure of Knowledge of Diabetes in a Thai Population

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Abstract

Purpose: To develop a linguistically and psychometrically validated Thai version of the Simplified Diabetes Knowledge Scale (T-SDKS) for adults with Type 2 diabetes mellitus (T2DM).

Design: A cross-sectional study was carried out among people with T2DM.

Methods: Consecutive sampling was undertaken to recruit participants at the outpatient diabetes clinic of a hospital in Northern Thailand.

Results: A total of 502 patients with T2DM were recruited. The mean age of the participants was 60.2 years, and 60.5% were female. The T-SDKS attained a reliability coefficient of .79. The item-total correlation value was greater than 0.20 for each item, and the inter-item correlation ranged between 0.03 and 0.49. Respondents attained a mean percentage knowledge score of 42.39% ± 15.45 on T-SDKS.

Discussion/conclusions: The T-SDKS has demonstrated to be a brief and simple diabetes knowledge assessment tool to use in a busy clinical setting.

Implication for practice: The findings can be used to improve health education interventions.

Keywords

diabetes knowledge, Thai population, cultural characteristic, transcultural nursing

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Introduction

An increasing prevalence of diabetes has been reported worldwide (Meetoo, 2014; Selvin, Parrinello, Sacks, & Coresh, 2014). In the United States, Selvin et al. (2014) found that the prevalence of diabetes among older adults had risen from 5.8% in 1988–1994 to 12.4% in 2005–2010. In Canada, Greiver et al. (2014) estimated the population prevalence of diabetes to be 7.6%. There is also an increasing prevalence of diabetes in developing countries (Whiting, Guariguata, Weil, & Shaw, 2011). Thailand is a developing country which is facing the problem of undiagnosed and late treatment of diabetes mellitus. Approximately 7.5% of the Thai population have been diagnosed with diabetes, and an additional 35.4% of the population have impaired fasting blood glucose levels (Aekplakorn, 2011). Although diabetes is common in Thailand, more than half of the population remain undiagnosed and hence may lack diabetes knowledge for self-management (Gakidou et al., 2011).

Research has demonstrated that knowledge about the disease, medications, diet, glucose monitoring, and foot care is essential for self-care management among

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people with diabetes (Ajala, English, & Pinkney, 2013; Desalu et al., 2011; Dorresteijn, Kriegsman, Assendelft, & Valk, 2012; Nemcova & Hlinkova, 2013; Rodbard, 2016). In a study undertaken on 307 participants in India with Type 2 diabetes mellitus (T2DM) and a mean age of 55.6 years, only 23.8% had good knowledge of diabetes and its management (Chavan et al., 2015). Another study undertaken on 515 patients in Bangladesh reported that 45.6% participants with T2DM had good knowledge of diabetes (Islam et al., 2015). The evidence also indicated that having knowledge was significantly associated with compliance to medication, nonpharmacological management (Chavan et al., 2015), and glycemic control (Islam et al., 2015).

Knowledge can empower self-management; hence, the assessment of diabetes knowledge is a fundamental aspect of diabetes care and assists in providing individualized diabetes education (Nemcova & Hlinkova, 2013). Despite the importance of knowledge for self-management, there are few reliable and valid questionnaires that measure diabetes knowledge, particularly in the Thai language which can be used in the busy clinical setting.

The 20-item Simplified Diabetes Knowledge Scale (SDKS; Collins, Mughal, Barnett, Fitzgerald, & Lloyd, 2011) developed from the Michigan Diabetes Knowledge Scale (Fitzgerald, 1998) has been extensively used to measure knowledge about diabetes. The SDKS consists of 20 items pertaining to diet, risk factors, and self-management. The patient is required to provide a yes or no response to each item. A high score of correct answers indicates high knowledge of diabetes. The internal reliability (Cronbach's α) for the SDKS ranged from .69 to .71 (Collins et al., 2011).

Given that a Thai version of the scale has not been developed, the aim of this study was to develop a linguistically and psychometrically validated Thai version of the SDKS (T-SDKS) for adults with T2DM.

Methods

Instrument

Development of the T-SDKS. Permission to translate the SDKS (English version) was obtained from the instrument developers. The SDKS was translated according to the World Health Organization (2016) procedure for translation and adaptation of instruments. First, forward translation was undertaken by translating the scale from English to the Thai language to produce a version that was semantically and conceptually as close as possible to the original version. The translation was done independently by two people. The first person was a translator who was bilingual (English and Thai) and the second a Thai health professional who was familiar with the

technical terms and had experience with translation from Thai to English. Second, an expert panel comprising a nutritionist and questionnaire development expert reviewed the primary version and compared it with the original version; changes were then made if required. The third step involved back translation of the Thai version of the questionnaire to English. This was undertaken independently by two bilingual Thai nurses. Both nurses had more than 20 years of nursing experience. The translated English version and the original English version were then compared to identify any discrepancies. The Thai version of the instrument was called the T-SDKS.

Pilot testing the T-SDKS. Pilot testing of the T-SDKS was undertaken on 30 Thai patients with T2DM who attended the diabetes clinic in the 2 weeks preceding the commencement of data collection. The T-SDKS was completed by 30 patients in a one-to-one interview with the researcher. In addition, the researcher asked the patients if the words or expressions in the T-SDKS were easy to understand, relevant, and did not cause offense. The researcher made notes of all the comments made by the patients. When comments were received from participants, the item was discussed with the expert panel who were involved in translation, and the panel provided recommendations for linguistic improvement. After the expert panel agreed on all the linguistic improvements, the final version of the T-SDKS was obtained for psychometric evaluation. In pilot testing, the overall self-administration for the T-SDKS questionnaire took on average 10 minutes to complete. Pilot testing of the T-SDKS was included in the institutional review board approval procedures for the larger study. Data from pilot testing were not included in the final analysis.

Study design, sample, and setting. Recruitment for the study was undertaken between September 13, 2016, and November 13, 2016. A consecutive sample of patients attending the outpatient diabetes clinic at a large urban teaching hospital in Northern Thailand were recruited to the study. This hospital provides health services to both rural and urban patients in the region. The inclusion criteria were patients aged more than 18 years old, people attending the outpatient diabetes clinic, and people diagnosed with T2DM and willingness to participate in the study. People who were unable to communicate in Thai were excluded.

Data collection. Information about the study was provided by an assistant researcher at the diabetes outpatient clinic. Written consent was obtained from all participants who were willing to participate in the study. The questionnaire was then distributed to participants. The questionnaire consisted of three parts which included

data on demographics (age, gender, and education), clinical characteristics (diabetes duration, HbA1C, body mass index [BMI], and diabetes therapy), and knowledge of diabetes. Data on clinical characteristics (up to 6 months) were collected from the medical records. For those willing to participate but could not complete the questionnaire by themselves, a face-to-face interview was conducted to complete the survey. All interviewers were trained by the principle researcher and the interview took approximately 10 minutes.

Data analysis

Validity. Validity is a key criterion for evaluating how well an instrument measures what it is intended to measure. Face validity is used to measure how relevant, credible, and acceptable the instrument is following the translation process (Polit & Beck, 2012). An expert panel assessed the face validity of the translated T-SDKS. To ensure content validity, Thai clinicians and a dietitian reviewed the final Thai version of the instrument to assess its relevance, appropriateness, clarity, and comprehensiveness within the Thai context. They completed an open-ended questionnaire that explored the comprehensiveness of the T-SDKS, ease of understanding and completion, length of time taken to complete the instrument, and any other issues.

All data were entered into Survey Monkey© and exported to SPSS version 21.1 for analysis. Categorical data were presented as percentages, and continuous data were presented as means and standard deviation. Item-total correlations were used for testing the hypothesis construct total and then correlating the items with the total. Items with scores lower than 0.20 demonstrate weak correlation and are usually removed from a scale during development (Streiner & Norman, 2003). Also, the inter-item correlation was employed for testing the correlation in each item. The inter-item correlation value in the range between 0.30 and 0.70 but not over 0.8 was considered acceptable (Polit & Beck, 2012).

Internal consistency. Internal consistency was used to assess the reliability of the T-SDKS. Internal consistency is a measure of the degree of correlation between the items in the instrument. It has been established that the items should correlate moderately with each other and should contribute independently to the overall score. A perfect correlation of 1.0 indicates that the questions are measuring an identical construct. Hence, the inter-item correlation value in the range between 0.30 and 0.70 but not over 0.8 was considered acceptable (Polit & Beck, 2012). The items were also examined for homogeneity of content using the corrected item-total correlations. Items with scores lower than 0.20 demonstrate weak correlation and are usually removed from a scale

during development (Streiner & Norman, 2003). Although the responses to the items in the T-SDKS were binary (Yes or No), Cronbach's α has been reported to be suitable to establish the reliability of the instrument (Sharma, 2016). Hence, the internal consistency was evaluated using the standard Cronbach α coefficient. The guideline by Tavakol and Dennick (2011) was used to determine the values greater than or equal to 0.9 that were considered as excellent, 0.8 to −<0.9 good, 0.7 to −<0.8 acceptable, 0.6 to −<0.7 questionable, 0.5 to −<0.6 poor, and less than 0.5 unacceptable.

Ethical consideration. Participants provided informed written consent before participating in this study. This study was approved by the Human Research Ethics Committee of both the University of Wollongong (HE16/209) and Uttaradit Hospital, Thailand (21/2016).

Results

Linguistic Validation

Comparison of the original version and the back-translation of the SDKS identified two items that required modification in order to be suitable within the Thai context. Some words that were not related to Thai culture were changed. Item 3 originally asked: "*A pound of chicken* has more carbohydrate in it than *a pound of potatoes*." This was changed to "500 grams of chicken has more carbohydrate in it than 500 grams of rice." The word potatoes was changed to rice as rice is the staple food of the Thai people and pound was changed to gram as it is the metric unit for measurement commonly used in Thailand. In Item 8, olive oil was changed to rice bran oil because olive oil is not commonly used in the Thai context.

A total of 506 patients with T2DM were invited to participate in the study, and complete data were obtained from 502 patients (response rate = 99.2%). Data cleaning was undertaken, and missing data were identified for four patients. The cases with missing data were deleted list-wise (Manly & Wells, 2015; Osborne, 2013). Responses to all 20 items were obtained from 502 patients and were used in the final analysis. The sample size was considered to be adequate based on recommendations that a sample size of 300 or more is suitable for reliability testing due to reduced possibility of sampling error (Anthoine, Moret, Regnault, Sébille, & Hardouin, 2014; Nunnally, 1994). Of the sample, 305 (60.75%) were females and 197 (39.24%) were males. The average age was 60.17 years (±10.70 years), and the average duration of diabetes was 9.87 years (±8.13 years). Data obtained from the medical records identified that the most recent mean glycosylated hemoglobin (HbA1c) was 7.78% (61.5 mmol/mol; ±1.77), and mean BMI was 26.96 (±5.57; Table 1).

Table 1. Demographics and Clinical Characteristics ($n = 502$).

Variables	All patients ($N = 502$)
Age (years), mean ± SD	60.17 ± 10.70
Gender, n (%)	
Female	305 (60.75)
Male	197 (39.24)
Highest qualification, n (%)	
Elementary school (primary school)	331 (65.73)
Secondary school (high school)	79 (15.73)
Diploma and over	84 (16.73)
Clinical characteristics, n (%)	
Diabetes duration (years)	9.87 ± 8.13
HbA1c (in %[mmol/mol])	7.78 (61.5) ± 1.77
Body mass index	26.96 ± 5.57
Diabetes therapy, n (%)	
Insulin	32 (6.37)
Oral medication	318 (63.34)
Combination of insulin and oral medication	143 (28.48)
Nonpharmacologic treatment	8 (1.59)

Note. HbA1c = glycosylated hemoglobin A1c.

Reliability

The internal consistency for the full T-SDKS was high (Cronbach $\alpha = .79$). The Cronbach's α was greater than .70 for each of the items. The corrected item to total correlations which is a measure of scale homogeneity was greater than 0.20, except for Item 19. All items showed good internal consistency (Streiner & Norman, 2003; Table 2). The Cronbach's α values if the item were deleted were lower than the resulting coefficients in each item, indicating that the exclusion of the items did not increase the reliability of the instrument. The inter-item correlation matrix ranged between 0.03 and 0.49 (Table 3).

Knowledge Related to Diabetes Known Groups Validity

Overall, the mean percentage of correct answers on the T-SDKS was $42.39\% \pm 15.45$. The questions which patients answered correctly were about knowledge related to high blood pressure (88.7%), numbness and tingling (75.7%), and regular checkups (87.8%). In contrast, only 11.3%, 12.8%, and 20.6% of participants had knowledge about glycosylated hemoglobin (HbA1c) levels, attendance at clinic appointments, and testing blood glucose (Table 2).

Table 2. Thai Version of Simplified Diabetes Knowledge Scale (T-SDKS) Item and Reliability Analysis.

No	T-SDKS item	T-SDKS All patients ($n = 502$) n (% correct)	Corrected item-total correlation	Cronbach's α if item deleted
1	The diabetes diet is a healthy diet for most people.[a]	338 (67.5)	.271	.786
2	Glycosylated hemoglobin (HbA1c) is a test that measures your average blood glucose level in the past week.	56 (11.2)	.329	.783
3	500 grams of chicken has more carbohydrate in it than 500 grams of rice.	119 (23.7)	.399	.778
4	Orange juice has more fat in it than low fat milk.	195 (38.8)	.374	.780
5	Urine testing and blood testing are both equally as good for testing the level of blood glucose.	100 (19.9)	.362	.780
6	Unsweetened fruit juice raises blood glucose levels.[a]	170 (33.9)	.359	.781
7	A can of diet soft drink can be used for treating low blood glucose levels.	211 (42.0)	.445	.776
8	Using rice bran oil in cooking can help prevent raised cholesterol in the blood[a]	251 (50.0)	.398	.778
9	Exercising regularly can help reduce high blood pressure.[a]	445 (88.6)	.272	.785
10	For a person in good control exercising has no effect on blood sugar levels.	174 (34.7)	.362	.780
11	Infection is likely to cause an increase in blood sugar levels.[a]	256 (51.0)	.434	.775
12	Wearing shoes a size bigger than usual helps prevent foot ulcers.	140 (27.9)	.262	.786
13	Eating foods lower in fat decreases your risk for heart disease.[a]	347 (69.3)	.284	.786
14	Numbness and tingling may be symptoms of nerve disease.[a]	383 (76.3)	.373	.780

Table 2. Continued.

No	T-SDKS item	T-SDKS All patients ($n=502$) n (% correct)	Corrected item-total correlation	Cronbach's α if item deleted
15	Lung problems are usually associated with having diabetes.	181 (36.1)	.430	.776
16	When you are sick with the flu you should test for glucose more often.[a]	132 (26.3)	.393	.778
17	High blood glucose levels may be caused by too much insulin.	175 (34.9)	.423	.777
18	If you take your morning insulin but skip breakfast your blood glucose level will usually decrease.[a]	215 (42.9)	.396	.778
19	Having regular checkups with your doctor can help spot the early signs of diabetes complications.[a]	439 (87.6)	.260	.786
20	Attending your diabetes appointments stops you getting diabetes complications.	63 (12.6)	.184	.789

[a]The TRUE response is the correct response.

Discussion

The aim of this study was to develop a linguistically and psychometrically validated T-SDKS for adults with T2DM. The major strength of the study was the rigor in which the instrument was translated and validated. Forward and backward translation was undertaken according to the World Health Organization guidelines. Validation was undertaken using expert, independent translators, discussion with an expert panel, and interviews with patients. The content validity phase indicated that in order to be consistent with the Thai culture, some items required modification as simply translating and using a questionnaire in another linguistic context is not appropriate (Wang, Lee, & Fetzer, 2006). Hence, the unit of the measurement in Item 3 was changed from pounds to grams which is the metric system commonly used in Thailand. In addition, as most of the Thai people eat rice as a main meal (Aekplakorn et al., 2015), a pound of potatoes was changed into 500 grams of rice, and olive oil was changed to rice bran oil (Item 8). These changes were made following extensive discussions with Thai dietitians and the research team. The large sample size was another strength of the study which enabled psychometric evaluation of the T-SDKS.

Measurement of reliability showed acceptable (Cronbach $\alpha = .79$) results for the T-SDKS (Tavakol & Dennick, 2011). This is similar to the original SDKS English version (Collins et al., 2011).

Item 9 related to high blood pressure had the highest percentage (88.6%) of correct responses. The results obtained in this study are lower than other studies (Collins et al., 2011) where a larger percentage of people (96%) had the correct answers. The majority of the participants in this study had high levels of knowledge related to high blood pressure (88.6%), numbness and tingling (76.3%), and regular checkups (87.6%) which is not congruent with other studies. In the study by Collins et al. (2011), the majority of the participants had knowledge related to diabetes diet (96%) and foods low in fat (95%). These results could be due to the extensive prevention and awareness programs conducted in the United Kingdom (Collins et al., 2011) and indicate that some of these programs are not being conducted in the Thai context where our study was undertaken.

The results obtained in our study about knowledge of high blood pressure and need for regular checkups could be due to the fact that a large proportion of people in Thailand have high blood pressure (Aekplakorn, 2011). It is possible that participants in our study had received education about blood pressure management during routine visits to the general practitioner.

Low levels of knowledge were demonstrated in the following items: glycosylated hemoglobin (HbA1c; 11.2%), testing blood glucose (19.9%), and clinic appointments (12.6%; Table 2). This low level of knowledge could be due to the fact that the majority of the participants had only primary education (65.73% of all participants) which could also affect their health literacy levels as there is a strong association between educational attainment and health literacy (Wannasirikul, Termsirikulchai, Sujirarat, Benjakul, & Tanasugarn, 2016). It could be postulated that the participants had a caregiver looking after them who had knowledge related to diabetes; but as this was not investigated in this study, it would require further investigation. Given the low literacy levels, strategies such as audiovisual aids could be used to supplement education to people with T2DM in the Thai setting. The T-SDKS takes less than 10 minutes to complete and can be used in busy clinical clinic settings to identify patients with limited knowledge in order to provide targeted health education interventions.

Table 3. inter-item Correlation Matrix.

T-SDKS	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13	Item 14	Item 15	Item 16	Item 17	Item 18	Item 19	Item 20
Item 1	1																			
Item 2	.179	1																		
Item 3	.189	.257	1																	
Item 4	.104	.171	.319	1																
Item 5	.191	.258	.244	.228	1															
Item 6	.088	.174	.204	.230	.155	1														
Item 7	.185	.257	.327	.245	.154	.287	1													
Item 8	.159	.151	.174	.187	.155	.168	.248	1												
Item 9	.088	.071	.106	.114	.157	.130	.186	.222	1											
Item 10	.120	.128	.177	.182	.165	.151	.160	.231	.253	1										
Item 11	.059	.168	.171	.158	.175	.169	.309	.281	.186	.269	1									
Item 12	.112	.168	.078	.040	.144	.110	.075	.147	.067	.219	.116	1								
Item 13	.078	.066	.103	.081	.092	.130	.160	.202	.129	.140	.174	.159	1							
Item 14	.117	.071	.095	.119	.192	.127	.166	.272	.114	.097	.280	.119	.225	1						
Item 15	.116	.226	.241	.191	.182	.191	.202	.161	.035	.082	.283	.087	.134	.289	1					
Item 16	.144	.164	.192	.171	.140	.149	.147	.184	.037	.210	.222	.176	.130	.179	.320	1				
Item 17	.126	.085	.191	.260	.109	.187	.220	.160	.067	.150	.212	.062	.129	.234	.327	.278	1			
Item 18	.148	.151	.180	.195	.108	.220	.221	.146	.121	.105	.203	.135	.103	.156	.275	.225	.497	1		
Item 19	.037	.007	.053	.093	.127	.180	.095	.072	.189	.150	.126	.103	.146	.166	.135	.150	.105	.089	1	
Item 20	.062	.001	.050	.070	.138	.005	.036	.019	.082	.148	.064	.126	.085	.134	.072	.085	.095	.095	.360	1

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Despite the strengths of the study, the limitations of this study need to be considered. First, the sample was recruited using a convenience sample from a single center in Northern Thailand. Second, the majority of participants had only primary education which may have influenced their knowledge levels related to diabetes and, hence, caution needs to be used when generalizing the results to the wider Thai population. In addition, the author had to use interview techniques for some participants with low literacy levels which may have led to potential bias in data collection. Therefore, further well-designed research studies need to be undertaken to test the T-SDKS in a diverse sample of Thai people with T2DM. In addition, evaluation of the construct validity of the T-SDKS using a large sample is needed.

Further research is required to investigate whether the T-SDKS has comparable reliability and validity in this population group across other regions in Thailand.

Conclusion

The simplified (true or false) version of the T-SDKS provided an acceptable content validity and reliability for assessing diabetes knowledge in the Thai context. This instrument can be used as a diagnostic tool for targeted health education intervention in Thailand. The T-SDKS is a reasonably easy to use survey that measures general diabetes knowledge and also can be used in a busy clinical setting.

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Health-related quality of life and self-care management among people
with diabetic foot ulcers in northern Thailand. (Chapter 6)

Health-Related Quality of Life and Self-Care Management Among People With Diabetic Foot Ulcers in Northern Thailand

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Abstract

Diabetic foot ulcers (DFUs) are a common complication of diabetes that impacts on the health-related quality of life (HRQOL). Foot care is an important factor in the self-care management of patients with DFUs. The objective of this study was to investigate the HRQOL and foot care management of people with DFUs. A cross-sectional study involving 41 people with DFUs was conducted at a large tertiary hospital in Northern Thailand. The Diabetic Foot Ulcer Scale-Short Form and the VA-Diabetes Foot Care Survey were used to assess the HRQOL and foot care management among people with DFUs. The majority of the participants were female ($n = 24$, 58.5%), and the mean age was 62.13 years. The scores for HRQOL in the six domains were as follows: leisure (66.95 ± 28.03), physical health (68.93 ± 28.51), dependence or daily life (80.08 ± 25.23), negative emotions (71.23 ± 29.48), worried about ulcers (62.20 ± 31.97), and bothered by ulcer care (69.36 ± 25.20). High scores indicate a high (good) HRQOL. Less than a third of the participants reported that they had received education about foot care management. Almost all participants reported that they washed their feet daily; however, a large proportion did not test the water temperature or use lubricants on their feet. Most of the participants did not have a mirror for checking under their feet (48.8%), and there was a lack of knowledge about how to use a mirror for foot inspections (51.2%). This study provides guidance for clinicians on the content and delivery of diabetes education programs for people with diabetes (and DFUs) in Northern Thailand. The findings provide guidance on existing knowledge and the need for programs to address barriers to foot self-care management both in terms of skills and attitudes.

Keywords

health-related quality of life, self-care management, diabetic foot ulcer, nurse, Northern Thailand

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Introduction

Diabetic foot ulcers (DFUs) are a common complication estimated to affect up to 25% of people with diabetes mellitus globally (Boulton, 2010). DFUs are associated with increased mortality (Walsh, Hoffstad, Sullivan, & Margolis, 2016) with a 5-year mortality rate in people with newly diagnosed DFUs estimated to be 40% (Walsh et al., 2016). Evidence obtained from cross-sectional studies (Goodridge et al., 2006; Nabuurs-Franssen, Huijberts, Nieuwenhuijzen Kruseman, Willems, & Schaper, 2005; Ribu, Hanestad, Moum, Birkeland, & Rustoen, 2007b) and systematic reviews (Khunkaew, Fernandez, & Sim, 2017) have reported decreased HRQOL among people with DFUs. Studies using the SF-36 have reported poor HRQOL in people with DFUs (Meijer et al., 2001; Nabuurs-Franssen et al., 2005; Ribu, Birkeland, Hanestad, Moum, & Rustoen, 2008) when compared with people without DFUs.

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Review of Literature

People with DFUs have a poorer HRQOL in the physical, financial, and psychological domains (Boutoille, Feraille, Maulaz, & Krempf, 2008; Garcia-Morales et al., 2011; Ikem, Ikem, & Ola, 2009; Jaksa & Mahoney, 2010; Ribu, Hanestad, Moum, Birkeland, & Rustoen, 2007a; Sanjari et al., 2011; Valensi, Girod, Baron, Moreau-Defarges, & Guillon, 2005; Yekta, Pourali, & Ghasemi-Rad, 2011). People with DFUs who experience poor healing have poorer HRQOL in the mental health, social, and physical domains (Löndahl, 2012). In addition, a large multicenter study that included 10 different countries demonstrated that low HRQOL in patients with DFUs was a predictor of amputation and mortality (Siersma et al., 2014).

Poor HRQOL can be attributed to various factors including pain, fatigue, wound infections, frequent dressing changes, restricted mobility, and social isolation. People with DFUs experience severe pain related to diabetic peripheral neuropathy. A large multicenter study conducted in Norway reported that 75% of people with DFUs experienced pain while walking or standing and also during the night (Ribu et al., 2006). However, there is controversy in the literature about the impact of pain on HRQOL with some studies indicating that pain is not a determinant of HRQOL (Ribu et al., 2007a; Ribu et al., 2006).

Lack of sleep due to pain, altered life circumstances, or anxiety leading to fatigue have all been reported to contribute to poor HRQOL (Castro-Sánchez et al., 2011). These factors may be exacerbated by attending clinic visits, hospitalization, and dressing changes (Khalid, 2014). Presence of wound infection has been reported as a predictor of poor HRQOL in patients with DFUs (Ribu et al., 2007a). Restricted mobility due to difficulties in functioning, problems with footwear, and amputations are reported to cause depression and anxiety and social isolation among people with DFUs (Abetz, Sutton, Brady, McNulty, & Gagnon, 2002; Ashford, McGee, & Kinmond, 2000; Carrington et al., 2001; Meijer et al., 2001). Poor psychosocial adjustment and low self-perceptions have also been reported (Bann, Fehnel, & Gagnon, 2003).

Foot self-care management is a key to reducing mortality for people with DFUs (Aljasem, Peyrot, Wissow, & Rubin, 2001). Self-care knowledge can assist people with diabetes to assess their feet, seek help when needed, and collaborate with health-care providers to reduce the risk of foot ulcers (Glasgow et al., 2001). Foot self-care practices among people with DFUs have been found to be poor (Chellan et al., 2012). In a cross-sectional survey of 352 patients in Nigeria, only a third

had good knowledge of foot care, and of these, more than 60% were not aware of the importance of checking the inside of their footwear or what action to take if they found redness or bleeding between their toes (Desalu et al., 2011).

The prevalence of DFUs among Thai people is rapidly increasing. In a large comprehensive foot examination survey undertaken in Thailand of people with diabetes, 15% to 26% had foot problems (Reutrakul & Deerochanawong, 2016). In a study of amputees conducted in Thailand, 32% of amputations were related to type 2 diabetes mellitus (Settakorn et al., 2005). In addition, 2.2% of people with DFUs have been reported to have had a history of amputation, and 10.6% were identified as high risk to develop further foot ulcers (Sarinnapakorn, Sunthorntepwarakul, Deerochanawong, Niramitmahapanya, & Napartivaumnuay, 2016). Despite the increasing prevalence of DFUs in Thailand, there is a dearth of research relating to HRQOL and foot care practices among Thai people with DFUs. A better understanding of the impact of a DFU on the person's HRQOL will enable clinicians to provide better care for these patients. In addition, identifying gaps in knowledge relating to foot self-care management will enable clinicians to provide patient education to reduce DFUs and the impact they have on HRQOL.

This study is part of a larger research project assessing the HRQOL, diabetes knowledge, and self-care management among Thai people with diabetes mellitus. The objective of this study was to investigate the HRQOL and the self-care management behaviors among people with DFUs using a DFU-specific instrument in a tertiary-level hospital in Northern Thailand.

Methods

Design

A cross-sectional study was undertaken of people with DFUs attending a diabetic foot clinic.

Research Question

What is the HRQOL and the self-care management behaviors among people with DFUs in a tertiary-level hospital in Northern Thailand?

Sample

Consecutive sampling was used to recruit people attending the outpatient diabetes and foot clinic in Northern Thailand. Data were collected between September 13 and November 13 in 2016.

Inclusion or Exclusion Criteria

Participants were recruited if they were over 18 years, had one or more DFUs, attended the diabetic outpatient clinic, were willing to participate, and able to read or understand the Thai language. People who had cognitive impairment or communication difficulties could not understand the Thai language were excluded. All potential participants were given a participant information sheet, and informed consent was obtained prior to recruitment. Participation was voluntary.

Data Collection

Information about the research was provided to eligible participants using a standardized script. Participants were invited to complete the survey by self-administration or interview. Participants who were unable to read or write had a 1:1 interview with the researcher to complete the survey. Self-administration took approximately 15 minutes, and interviews took approximately 25 minutes to complete.

Data Collection Instruments

Data were collected relating to demographic and clinical characteristics, HRQOL, and self-management behaviors relating to foot care. The demographic and clinical characteristics are included in Table 1.

Health-Related Quality of Life

Health-related quality of life (HRQOL) was measured using the disease-specific Diabetic Foot Ulcer Scale-Short Form (DFS-SF; Bann et al., 2003). The DFS-SF was validated previously against the DFS and was reduced from 64 items to 29 items (Abetz et al., 2002). The 29-item DFS-SF comprises six subscales: leisure (5 items), physical health (5 items), dependence or daily life (5 items), negative emotions (6 items), worries about ulcers or feet (4 items), and bothered by ulcer care (4 items; Bann et al., 2003). Responses to each item are rated on a 5-point Likert-type scale ranging from 1 *not at all* or *none of the time* to 5 *a great deal* or *all of the time* or *extremely*. Individual items on the DFS-SF are reverse coded, and high scores on the DFS-SF indicate a high (good) HRQOL. The reliability of the DFS-SF has been reported to be greater than .7 (Bann et al., 2003). The DFS-SF has been reported to be acceptable for use in clinical settings (Hogg, Peach, Price, Thompson, & Hinchliffe, 2012). A Thai version of the survey was not available, so permission to translate the DFS-SF into Thai was granted from the Mapi Research Trust™ (Lyon, France). The standard process for forward and

Table 1. Demographic and Clinical Characteristics.

Variables	Percentage of people with DFUs ($n = 41$)
Gender	
Female	58.5
Male	41.5
Smoker	7.3
Age (mean ± SD)	62.1 ± 9.5
Marital status	
Living with partner	68.2
Not living with partner	31.7
Highest qualification	
Elementary school (primary school)	73.2
Secondary school (high school)	17.1
Diploma and over	7.3
Employment status	
Unemployed	14.7
Employed	85.3
Earnings per month	
0–10,000 Baht/month	82.9
More than 10,001 Baht/month	17
Occupation	
Farmer	19.5
Government worker	0
Housewives or husbands	31.7
Private employee	4.9
Business	12.2
Diabetes therapy	
Insulin	12.2
Oral medication	48.8
Combination of insulin and oral medication	34.1
Nonpharmacologic treatment	4.9
Clinical characteristics, mean (SD)	
Diabetes duration (years)	12.0 ± 8.5
HbA1c (in mg%)	8.1 ± 2.1
BMI	27.9 ± 7.9
Wagner's grade	
Grade 1	82.9
Grade 2	17.1

Note. DFU = diabetic foot ulcer; HbA1c = glycosylated hemoglobin A1c; BMI = body mass index; SD = standard deviation.

back translation was undertaken using a panel of bilingual nutritionists, nurses, and clinicians (Polit & Beck, 2012; Van Nes, Abma, Jonsson, & Deeg, 2010).

Self-Management Relating to Foot Care

Self-management relating to foot care was assessed using the VA-Diabetes Foot Care Survey (Olson et al., 2009),

which included subscales on education received about foot care, foot care practices, and barriers to foot care. Education received about foot care comprised of 13 items that were scored on a 4-point scale that classified amount of knowledge (see Table 2). Practices relating to foot care were measured using 14 items and were scored on a 5-point scale that classified the frequency of the practices. Barriers to foot care were measured using 14 items, and patients had to select the items that they considered were a barrier. Permission to translate the VA-Diabetes Foot Care Survey was granted by Olson et al. (2009). The VA-Diabetes Foot Care Survey was translated into Thai, and standard translation methods were followed using a panel of bilingual nutritionists, nurses, and clinicians (Polit & Beck, 2012; Van Nes et al., 2010).

Ethical Approval

All procedures performed in this research were in accordance with the ethical standards of the institutional or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (Rickham, 1964). The study was approved by the Human Research Ethics Committee, University of Wollongong (HE 16/209) and Uttaradit Hospital, Thailand (21/2016).

Statistical Analysis

All data were entered into SurveyMonkey© and then exported into SPSS version 21.0 (SPSS Inc., Chicago, IL) for analysis. The scoring of the DFS-SF was based on the sum of all items; the raw items were reverse coded

according to author guidelines. The scores for each dimension were transformed on a scale from 0 to 100, with high score indicating better HRQOL (Bann et al., 2003). Descriptive statistics were used to summarize the demographic and clinical characteristics: HRQOL scores and self-care management relating to foot care.

Results

Sample Characteristics

Data were obtained from 41 patients with DFUs who attended the foot clinic. The majority of the participants were female ($n = 24$, 58.5%). The mean age of the participants was 62.1 years, 68.2% of participants were living with a partner, 85.3% were employed, and 82.9% were earning 0 to 10,000 Baht/month. Approximately half (48.8%) of participants were using oral diabetic medications. The mean duration of diabetes was 12.0 ± 8.5 years, the mean hemoglobin A1c (%) was 8.1 ± 2.1, and the mean body mass index was 28.0 ± 7.9 (see Table 1). All participants had DFUs that were Wagner's Grade 1 (82.9%) or Grade 2 (17.1%).

Health-Related Quality of Life

The scores for HRQOL for the six domains were as follows: leisure (66.95 ± 28.03), physical health (68.93 ± 28.51), dependence or daily life (80.08 ± 25.23), negative emotions (71.23 ± 29.48), worried about ulcers (62.20 ± 31.97), and bothered by ulcer care (69.36 ± 25.20; Figure 1). High scores on the DFS-SF indicate a high (good) HRQOL.

Table 2. Education Received on Foot Care Using the VA-Diabetes Foot Care Survey ($n = 41$).

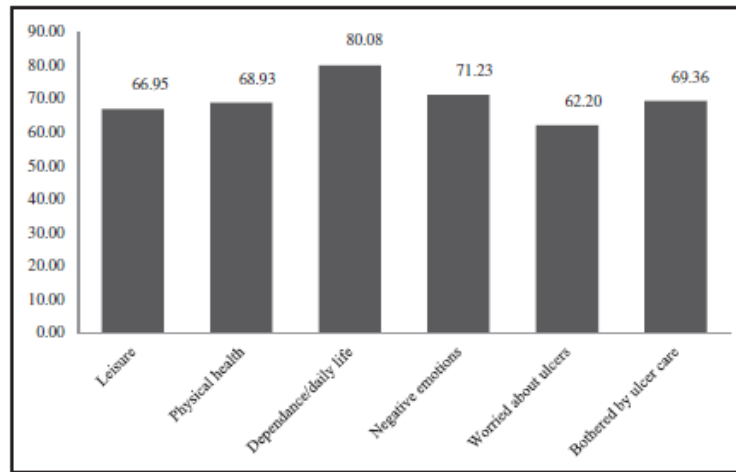| Item (item number)	Nothing at all (%)	A little bit (%)	Some, but would like to know more (%)	Enough (%)
Using a special mirror (6)	51.2	2.4	39.0	7.3
Gently filing calluses (8)	46.3	4.9	34.1	14.6
Not cutting corns or calluses with scissors (10)	43.9	4.9	46.3	4.9
Cutting nails (9)	41.5	2.4	39.0	17.1
Avoiding hot or cold (7)	34.1	12.2	36.6	17.1
Always wearing shoes (4)	22.0	14.6	51.2	12.2
Keep skin moist (5)	19.5	12.2	48.8	19.5
Check feet regularly (1)	14.6	26.8	34.1	24.4
Not using drugstore chemicals or other remedies not ordered by health-care providers (11)	14.6	19.5	39.0	26.8
Choosing proper shoes (3)	12.2	19.5	39.0	29.3
Whom to call for foot problems (13)	12.2	19.5	46.3	22.0
Keeping feet clean (2)	7.3	19.5	34.1	39.0
When to call for foot problems (12)	7.3	19.5	48.8	24.4

Figure 1. Diabetic Foot Scale-Short Form subscale scores for HRQOL among people with DFUs (n=41). High scores indicate a high (good) HRQOL

Education Received About Foot Care (VA-Diabetes Foot Care Survey)

The findings provide a summary of the participants' recollection of the education they received about foot care and self-care management of their feet (see Table 2). A large percentage of participants reported that they received no education at all about using a special mirror to check under their feet (51.2%), gently filing calluses (46.3%), not cutting corns or calluses with scissors (43.9%), cutting their toe nails (41.5%), and avoiding extremes in temperature (either hot or cold; 34.1%). Only 39.0% of participants reported that they had received enough education about keeping their feet clean. Wearing shoes at all times is an important self-care management strategy for preventing DFUs. Only 12.2% of participants reported that they received enough education on always wearing shoes, and a further 51.2% received some education but would like to know more.

Barriers to Foot Care (VA-Diabetes Foot Care Survey)

The findings summarize the perceived barriers by participants to undertaking self-care management of their feet (see Table 3). The most significant barriers to good foot care were not having a mirror to check their feet (48.8%), not having the correct shoe inserts (41.5%), and either knowing what to do but not knowing how to care for their feet (36.6%) or not knowing how to care for their feet (34.1%). Some of the items assessed attitudes and actions as barriers such as "I couldn't remember to do it" (26.8%), "I didn't have time"

Table 3. Perceived Barriers to Foot Care Using VA-Diabetes Foot Care Survey (n=41).

Item (item number)	Total n=41 (%)
I didn't have a mirror (7)	48.8
I didn't have the right shoe inserts (6)	41.5
I know what to do, but I didn't know how to do it (2)	36.6
I didn't know what to do (1)	34.1
I couldn't remember to do it (9)	26.8
I didn't have the right shoes (5)	24.4
I needed professional help (10)	17.1
I needed help from family and friends (11)	17.1
I didn't have time (3)	14.6
I couldn't see well enough to do it (13)	14.6
I couldn't comfortably reach my feet to do it (14)	14.6
I didn't think it was important (12)	12.2
I couldn't afford it (4)	7.3
I didn't have a foot stool (8)	4.9

(14.6%), and "I didn't think it was important" (12.2%). These items show that participants understanding about why they were conducted self-care of their feet may have been missing.

Foot Care Practices

These results summarize participants self-reported foot care practices (see Table 4). Nearly all participants

Table 4. Self-Reported Foot Care Practices Using VA-Diabetes Foot Care Survey ($n = 41$).

Items (item number)	Not at all (%)	Daily (%)	Several times a week (%)	Once a week (%)	Once or twice a month (%)
Tested the water temperature (5)	87.8	2.4	2.4	7.3	0.0
Soaked feet for 10 minutes (4)	85.4	0.0	4.9	4.9	4.9
Walked barefoot outside (14)	78.9	17.1	0.0	0.0	4.9
Filed calluses (8)	75.6	2.4	4.9	4.9	12.2
Used lubricants (7)	61.0	22.0	0.0	9.8	7.3
Changed shoes (12)	56.1	22.0	9.8	2.4	9.8
Wore stocking (11)	43.9	36.6	9.8	7.3	2.4
Looked at the bottom feet (1)	24.4	53.7	9.8	7.3	4.9
Walked barefoot inside (13)	24.4	70.7	0.0	0.0	4.9
Checked between toes (2)	19.5	65.9	4.9	4.9	4.9
Dried between toes (6)	19.5	63.4	9.8	4.9	2.4
Checked shoes (10)	12.2	68.3	7.3	7.3	4.9
Washed feet (3)	0.0	97.6	0.0	0.0	2.4
Trimmed nails (9)	0.0	4.9	0.0	70.7	24.4

reported that they washed their feet every day (97.6%), and most never walked barefoot outside (78.9%). However, 70.7% of participants indicated that they walked barefoot inside their house. The activities which were not conducted by participants were not testing the water temperature (87.8%), not soaking feet for 10 minutes (85.4%), not using lubricants (61.0%), and not looking at the bottom of their feet (24.4%). Trimming their toe nails once a week was performed by 75.6% of participants. Drying between their toes was completed by 63.4% of participants every day and 68.3% of participants checked their shoes every day.

Discussion

To the best of our knowledge, this is the first study undertaken to investigate the HRQOL, self-reported knowledge on foot care, and actual foot care practices and barriers to foot care in people living with DFUs in Northern Thailand. For participants in this study, scores in all HRQOL domains were high. This result is contradictory to that reported in a cross-sectional study conducted in South India where patients with DFUs had poor HRQOL on all six domains (mean scores ranging between 33.6 and 44.3; Sekhar, Thomas, Unnikrishnan, Vijayanarayana, & Rodrigues, 2015). This result may relate to the fact that participants in our study had less severe DFUs with Wagner's Grade 1 and Grade 2 DFUs only.

This study used the disease-specific instrument, DFS-SF for assessing the HRQOL among people with DFUs. The DFS-SF captures the specific problems relating to diabetes complications. In our study, participants reported high HRQOL in the domains relating to leisure,

physical health, and dependence or daily life, which is similar to other published studies (Hui, Yee-Tak Fong, Yam, & Yuk Ip, 2008; Macioch et al., 2017; Valensi et al., 2005). This result is interesting as the high HRQOL in the domain relating to dependence or daily life could be due to the fact that the participants had family or social support to assist with daily living activities. In addition, most of the participants have lived with DFUs for an average of 2 years, which could mean that over time they learnt to adapt and promote their independence in tasks such as cooking, dressing, and organizing their daily life.

Low scores indicating poor HRQOL were observed in the domain "worried about ulcers," which is congruent with the literature (Hui et al., 2008; Valensi et al., 2005). It could be postulated that the poor HRQOL in this domain may be due to people being concerned about the development of further ulcers, the existing ulcers not healing, the development of wound infection, and the fear of amputation. Care of a foot ulcer can require multiple visits to foot clinics over a long period of time before the ulcer heals. Finding time to attend the clinics might also be a cause of concern as the majority of the participants were employed.

Education About Foot Care

Only a third of the participants indicated that they had received education about the various aspects of foot care. Nearly half the participants indicated that they did not know about using mirrors to check the toes, cutting toenails, and not using scissors to cut corns or calluses. This lack of knowledge is reflected in the poor practices relating to foot care with just over half the participants

indicating that they checked and dried between the toes and trimmed their toenails. The low rates relating to checking the feet and toes regularly could be due to the lack of resources such as mirrors and foot stools and lack of assistance to undertake foot care. Furthermore, participants indicated that they were unaware of what to do or who to call if they did find a foot problem. This provides insight into the nature of education that participants had received and the need for education and behavior change to achieve good self-care management practices among people with DFUs.

A large proportion of participants indicated that they walked barefoot inside the house but not outside the house. This could be due to the fact that walking barefoot inside the house is culturally appropriate for Thai people (Rerkasem, 2011). Almost all participants indicated that they washed their feet every day; this could be due to the habitual rituals for Thai people to wash their feet. The majority of the participants reported that they did not test the water temperature. This question may have been misinterpreted as formally testing the water temperature with a thermometer. Testing the water temperature with an elbow is a practical way to test the water temperature prior to bathing or soaking. The results from this study indicate that strategies that are culturally appropriate to improve knowledge relating to foot care are required. This would include knowing when and who to call for foot problems, the process of checking feet regularly and keeping skin moist. Including information on why this is important may assist with behavior change.

Barriers to Foot Care

Surprisingly, the biggest barrier to foot care was not having a mirror to check the base of the feet. Other studies have found that people with DFUs who did not practice foot self-care were 2.52 times more likely to develop DFUs (Mariam et al., 2017). The process of regularly checking the feet is important for prevention and early recognition of problems. Many people with DFUs cannot reach and see under their feet, so a mirror is an important piece of equipment for foot self-care practices.

The importance of good knowledge relating to foot care is vital for the management of DFUs. In this study, low knowledge of foot care was reported by more than a third of the participants. These results are significantly poor when compared with that reported in the literature. The poor knowledge could be due to the fact that nearly three quarters of participants in the study had only primary school education. Low levels of education and health literacy have previously been associated with poor foot self-care practices (Chiwanga & Njelekela, 2015). In addition, it is possible that participants did

not receive appropriate education when they visited health professionals. This may be due to lack of time for the patient and the health professional or lack of resources. Usual care in Thailand involves people who are newly diagnosed with diabetes mellitus attending an outpatient appointment to receive follow-up care related to knowledge of diabetes, self-care management, and treatment of DFUs (if present). Diabetes outpatient clinics are usually very busy and overcrowded (Tantitharanukul & Throngjai, 2018). In addition, specialist positions such as Podiatrists and Diabetes Educators are often fulfilled by nurses in rural areas where such specialists are not available. The American Diabetes Association recommends providing Diabetes Self-Management education and training to those people who are diagnosed with diabetes mellitus (Powers et al., 2017). It is not clear whether these recommendations are always fulfilled in all outpatient clinics in Thailand. In addition to not having adequate knowledge, not having the right shoes and a mirror to check the feet were identified as barriers by nearly half of the participants. Improving education and providing advice for selecting shoes and providing appropriate resources (such as mirrors) should be implemented so that participants can ensure they have the equipment they need to protect their feet. The provision of education about good self-care management of the feet is an important strategy for preventing DFUs and assisting healing of DFUs.

Strengths and Limitations

The strength of the study was the rigor in which it was conducted. First, the use of a validated disease-specific instrument to measure HRQOL enabled data to be captured that is specific to DFUs. In most studies examining HRQOL in people with DFUs, generic tools such as the SF-36 are used (Boutoille et al., 2008; Carlos De Meneses, Blanes, Francescato Veiga, Gomes, & Ferreirai, 2011; Garcia-Morales et al., 2011; Ribu et al., 2007b; Sanjari et al., 2011; Yao et al., 2012). Second, the questionnaire was available for self-report and as an interview so that participants with literacy issues were also included. The limitations of this study relate to sampling. Although the sample size is small (41), 100% of people with a DFU who attended the Outpatient Diabetes Clinic at Uttaradit Hospital over the study period agreed to participate in the survey. The small sample size means that the findings may not be representative of all people with DFUs in Thailand. Moreover, this study was undertaken in one hospital in Northern Thailand, and the majority of the participants had low-grade DFUs (Grades 1 and 2) as measured by the Wagner's Classification Scale. Finally, the data were obtained through a survey, which was cross-sectional in

nature and only enabled those receiving treatment at the foot clinic during the recruitment period to participate. Future research should focus on large, well-designed multicenter trials to investigate the HRQOL and foot self-management practices of Thai people with DFUs of varying severities.

Implications for Practice

The findings have implications for health-care professionals who provide education to people with diabetes mellitus, to health-care professionals who provide education to people with DFUs, and to policy makers and funding bodies. This study underlines the significance of foot self-care management practices on HRQOL among people who have diabetes (both with and without DFUs). The findings from this study can be used to develop diabetes education programs for people with diabetes in Northern Thailand. Education programs must provide practical skills and education about why activities are important so that participants understand the need for the self-care management and the impact it has on preventing or healing DFUs.

Conclusions

This is the first study that has investigated HRQOL and foot self-care practices of people with DFUs in Northern Thailand. The results indicate the need for individualized and focused foot care education that includes self-care management practices to improve HRQOL.

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The experiences of people in northern Thailand living with diabetic foot ulcers: a descriptive qualitative study. (Chapter 7)

The Experiences of people in Northern Thailand living with Diabetic Foot Ulcers: A Descriptive Qualitative Study

Saneh Khunkaew*, Patraporn Tungpunkom, Jenny Sim, Ritin Fernandez

Abstract: Diabetic foot ulcers are a main cause of morbidity related to type 2 diabetes. Living with a diabetic foot ulcer has a significant impact on health-related quality of life and has a negative impact on daily living among people with the condition. The aim of this study was to explore the experiences of Thai adults living with diabetic foot ulcers using a descriptive qualitative design. Participants were recruited from the outpatient diabetes and foot clinic at a tertiary teaching hospital in Northern Thailand from January to April 2017. In-depth interviews were conducted with 13 participants using a semi-structured interview guide.

Thematic analysis was used to identify the participants' experiences and two themes were identified: 1) living with a diabetic foot ulcer and 2) managing a diabetic foot ulcer. The findings enhance the knowledge of healthcare professionals and the public to understand the experience of having diabetic foot ulcers and contribute to understanding how to manage a diabetic foot ulcer based on the participant's experiences in the Thai context. Nurses must provide knowledge and self-care skills as part of routine care to improve health-related quality of life for people with diabetic foot ulcers.

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Introduction

Diabetes Mellitus (DM) is a chronic disease that occurs due to an abnormality in the metabolism of protein, carbohydrate and fat. Primarily, the pancreas cannot effectively function to control blood glucose levels because of a deficiency of insulin being secreted or resistance to insulin or both and this results in hyperglycaemia.[1] Diabetes has become a major global public health problem. The International Diabetes Federation (IDF) has produced an estimate for 216 countries and territories on the rate of diabetes and anticipates that the number of people with diabetes will increase dramatically to 522 million by 2030.[2]

The impact of diabetes on health in Thailand is similar to other countries. Thailand is experiencing increasing numbers of people with diabetes related to poor diet, obesity, physical inactivity and an ageing

society.[3,4] Diabetes is now the fourth highest cause of mortality in all ages in Thailand and is rising in both males and females who die from complications related to high blood glucose levels.[4] Diabetic foot ulcers (DFUs) are the one of the major complications of diabetes mellitus resulting from damage to nerves in the foot due to microvascular and macrovascular changes.[5] The prevalence of DFUs has been reported to be as high as 15% in people with type 2 diabetes.[6] Foot ulceration can result in foot deformity, permanent disability and more often amputation.[7] It is reported in the USA, that more than 50% of all amputees have diabetes mellitus.[8] A DFU can cause a significant impact on the quality of life of patients' living with type 2 diabetes.

In Thailand, the National Health Examination Survey undertaken in Thai adults reported the prevalence of people with diabetes was 10.1%.[9] Complications from diabetes are a serious issue in Thailand particularly in relation to diabetic foot problems. A cross-sectional study of 593 patients with type 2 diabetes in one hospital in Thailand identified that the prevalence of DFUs was 3.4%.[10] In addition, 2.2% of patients had a history of amputation and 10.6% were identified as high risk of developing foot ulcers.[10] Reutrakul and Deerochanawong[3] reported that 15–26% of people with diabetes had foot problems, 22% were identified as high-risk of developing a foot ulcer during a comprehensive foot examination, and 5.9% had a previous history of DFU.

Literature review

Health-related quality of life (HRQOL) has been identified as a goal of health and well-being[11] and is the quality of life of an individual relative to their health or disease status. There are four dimensions which include physical, social, psychological, and spritual factors.[11] In Asia, a number of studies have investigated patients' perceptions of foot self-care practice, self-care behaviour and awareness, prevalence

of risk factors in diabetic foot ulcers, ethnicity and the strategies used to prevent diabetic foot ulcers.[12–16] Linkages have been made between presence of DFU and low health related quality of life.[17] Chellan, Srikumar[16] found in their study of 203 participants (103 with DFU and 100 without DFU) that the incidence of DFU was inversely related (p < 0.001) to participants' practicing diabetic foot care.

Historically, Thailand has not had specialists who look after people with DFUs, with diabetic foot ulcers and infections being managed by surgeons or orthopaedists.[3] The lack of specialist care in Thailand is a major cause of the prevalence of DFUs. In research undertaken by Aekplakorn et al.[18] it was found that the prevalence rate of diabetes in Thailand is increasing. The estimated national prevalence of diabetes in Thai adults was 6.4% in 2013,[19] and is said to have been one of the top five common chronic diseases in Thailand.[20]

The experiences of Thai adults living with diabetic foot ulcers need to be explored in context. Religion and spirituality are the core to Thai beliefs. Some rural Thai people also believe in traditional healing, black magic, herbal remedies and supernatural causes of illness.[21] These beliefs may impact on the experiences of people living with type 2 diabetes. This is supported by previous studies among people with type 2 diabetes in Thailand which have identified many factors that impact upon daily living such as culture, belief, religion and education level.[14,22–24] Diet also impacts upon managing type 2 diabetes and preventing complications. In Thailand, most people eat food with rice or glutinous rice that is high in carbohydrates. In addition, there are many kinds of tropical fruits, including durian, ripened mango, lychee, longan, orange, pineapple and rambutan,[22] that people eat all year round. These fruits contain high amounts of carbohydrates that impact on optimal glycaemic control. There is a limited amount of literature exploring the experience of Thai adults living with diabetic foot ulcers. In addition, little is known about how people with DFUs in Thailand

access and then use information from health care professionals about managing their diabetes and wound care. In this study, qualitative interviews were conducted among people with DFU's to provide a deeper understanding of the specific context of DFU's on health related quality of life.

This study was undertaken as part of a doctoral dissertation exploring health related quality of life among people with type 2 diabetes in Northern Thailand. The project used a sequential, mixed methods design to examine health related quality of life, self-care skills and knowledge of diabetes among people with and without diabetic foot ulcers. The research reported in this paper constitutes phase two of the project which used qualitative data to explore the lived experiences of people with diabetic foot ulcers.

Aim

The aim of this study was to explore the experiences of Northern Thai people living with diabetic foot ulcers in Northern Thailand and strategies they used to manage their diet and wound care.

Methods

A descriptive qualitative research approach was used to explore the in-depth, rich experiences of people living with diabetic foot ulcers in Thailand. This approach was chosen to enable the researcher to gather, analyse and interpret the experiences, realities and meanings from the participants in this research in a way that is culturally appropriate and uses subjective experiences of their lives to construct knowledge and build understanding on this research question.[25,26]

Sample and Setting

Participants were recruited from the outpatient clinic at a large teaching hospital in Uttaradit province in Northern Thailand during the three-month period from January to April 2017. All participants were recruited from a larger study examining health-related quality of life of diabetic people with and without foot ulcers that was undertaken as part of a doctoral dissertation.

Participants were recruited if they met the following inclusion criteria: participated in phase 1 of this study; aged over 18 years; diagnosed with type 2 diabetes; had one or more diabetic foot ulcers; and agreed to participate. People who had a cognitive impairment were unable to consent to participate, and people who could not speak Thai were excluded. Participants were approached by a trained research assistant who provided information to potential participants who met the inclusion criteria during a routine check-up at the outpatient clinic. If they agreed, the researcher then contacted the participants by phone and made an appointment for an interview either at their home or their next appointment at the outpatient clinic. All participants were informed of the study and written consent was obtained prior to participating in the interview.

Ethical consideration

This study was approved by the Human Research Ethics Committees of the University of Wollongong (HE16/209) and Uttaradit Hospital (7/2017) prior to data collection. Information about the study was read out to all participants, and each participant provided verbal and written consent to participate in the study. All data was de-identified using pseudonyms and stored in an electronic file with password protection as per NHMRC Guidelines.[27]

Data collection

Interviews were conducted in the Thai language at each of the participant's home. The interviews were semi-structured with the question guide developed from a pilot study of 10 people and a systematic literature review. The interviews began with general questions to build rapport and confidence between interviewer and the interviewee.[28] The interview guide contained open-ended questions, and in-depth questions such as: "How did you feel after you were informed by the doctor that you had a foot ulcer

because of DM?", How would you describe your quality of life after your diagnosis with diabetes mellitus?", "How have you changed your diet since you were diagnosed with diabetes mellitus?", and "How do you live with your foot ulcers?" Based on the patients' narratives, and descriptions, topics were explored in depth with probing and clarifying questions which were used to gain additional details about the phenomena being examined.

Recruitment of participants continued until data saturation was achieved.[29] Thematic mapping was used to assess for data saturation at the completion of interviews. The research team identified data saturation at 10 interviews and an additional 3 interviews were held to ensure that no new information was obtained. The interviews were conducted over 30–50 minutes and were recorded and transcribed verbatim. Patient name, personal details and any other identifying data were omitted during transcription. Field notes were made after each interview. Confidentiality was maintained at all times by using pseudonymous, de–identifying data and secure storage of all data.

Data analysis

Thematic analysis was undertaken in this study using a constructivist orientation using Braun and Clark's[30] guidelines for thematic analysis. The following six phases of thematic analysis were used:

Phase 1: The Principal Researcher (PI) transcribed all audio recorded interview data verbatim in Thai. The data was then discussed with an experienced qualitative expert who is bilingual (Thai and English) to ensure translation accuracy. The PI then read and re–read the data several times to achieve familiarisation.

Phase 2: Coding. Two researchers identified data that was considered pertinent to the research questions and coded all data items line–by–line in Thai to ensure the sense of meaning was retained.

Phase 3: Searching for themes. This phase involved analyzing all collected codes (Thai version) and identifying similarities and relevance to the research questions. This phase was iterative and involved reviewing all codes in a continuous process of searching for meaning. Thematic mapping was used for visualising and considering the linkages and relationships between themes.

Phase 4: Reviewing themes. Two researchers re–checked the relationship for both the coded extract and the full data set. This ensured the themes accurately reflected what was evident in the data set as a whole.[30] During this phase, the researchers developed initial thematic mapping by grouping codes with similar content into categories and grouping categories with similar concepts into themes. Following translation of all themes and extracts into English, this process was checked to ensure congruence of the extracts with the themes.

Phase 5: Defining and naming themes. The preliminary thematic mapping was translated into English and presented to the full research team which then explored the naming of themes, the choice of extracts and discussed how each chosen extract supported theme development and demonstrated meaning.

Phase 6: Writing up. The PI selected the extracts from each theme to illustrate meaning in each theme. The extracts clearly identified important concepts within the theme and presented a lucid example of the point being made in the English version.

The data analysis process was carried out manually by tabulating, listing, grouping, and mapping the data in Microsoft Word version 2010®. The data was presented to the full research team multiple times to ensure that themes were a true reflection of the participant's experiences (individually and collectively) and that the extracts used to explore each theme were illustrative of the data.

Trustworthiness

Trustworthiness and integrity have been described by Koch,[31] Crowe et al.[32] and Sandelowski[33] for addressing rigor and validity of qualitative research and included the concepts of credibility,

dependability, and transferability.[34] **Credibility** refers to confidence in the truth of the data and interpretation from the researcher. This study used mapping for visualising the linkages and relationships between themes. Initial thematic mapping was developed by two authors in Thai and then confirmed by two authors in English. The final thematic mapping was agreed by all researchers. **Dependability** involves ensuring that the data collection and data analysis procedures are worthy of trust. The interviews were transcribed verbatim in the Thai language by the PI and the transcription process was checked for accuracy by listening to excerpts of the MP3 recording by another author who speaks the Thai language. Furthermore, the process of naming themes was checked for the identification of categories and themes. Finally, all the excerpts were translated into English, checked for accuracy of translation with three researchers and then discussed with all researchers. **Transferability** refers to whether the findings can be applied to other settings or groups.[31,35] To enhance transferability, this study carefully recruited participants who were currently living with one or more diabetic foot ulcers.

Even though qualitative data is not easily generalised to large groups it can be used to build knowledge and understanding of the experiences of Thai people who have diabetic foot ulcers.

Findings

A total of 40 participants were approached to participate in interviews. Twenty six participants declined to participate for a range of reasons and one potential participant passed away. Thirteen patients were interviewed in this study: seven females and six males. The mean age was 63.46 years old (range 52–76 years). Six participants had foot ulcers that were classified by the Wagner classification system as grade 1 and seven participants had grade 2 foot ulcers. The Wagner Classification system is widely used to grade diabetic foot ulcers and is primarily based on the wound depth, the presence and location of wound infection and has grades ranging from 0 to 5.[36] All participants had completed primary school level education and all were Buddhists. The characteristics of the participants are summarised in **Table 1**.

Table 1   The demographic characteristics of participants

Pseudonyms	Age Gender	Marital status	Prior/ current occupation	Level of Education	Wagner grade of current DFU(s)	History of previous DFU(s)	History of amputation for DFU(s)
Ban	70 F	Married	House wife	Primary school	2	No	1st toe nail at the right foot
Chee	52 M	Married	Butcher	Primary school	2	No	No
Dan	76 M	Married	Farmer	Primary school	1	No	No
Fang	64 M	Divorce	Farmer	Primary school	2	Yes	1st and 2nd toe nail at both left and right foot
Kat	70 F	Married	House wife	Primary school	1	No	No
Makam	65 F	Widows	House wife	Primary school	1	No	No
Pakad	52 F	Single	Labour	Primary school	2	Yes	5th toe nail at left and right foot
Pete	61 F	Widows	House wife	Primary school	1	Yes	No
Pitoon	64 M	Married	Labour	Primary school	1	No	No
Rat	62 F	Married	House wife	Primary school	2	Yes	1st and 2nd toe nail of right foot
San	57 M	Married	Farmer	Primary school	2	Yes	No
Sawang	68 F	Married	Farmer	Primary school	1	No	No
Team	64 M	Married	Unemployed	Primary school	2	Yes	BK amputation at left leg 2nd and 3rd toe nail of left foot

Note; M = Male; F = Female

Themes

Data analysis identified two themes. The first theme "Living with diabetic foot ulcers (DFUs)" included four subthemes: Physical impacts of DFU; Emotional impacts of DFU; Socio–economic impacts of DFU; and Managing diet. The second theme explored concepts around "Managing a diabetic foot ulcer (DFU)".

Theme 1: Living with Diabetic Foot Ulcers (DFUs)

Participants reported consequences related to their physical, emotional and socio–economic experiences as well as managing their diet.

Sub–theme 1: Physical impacts of DFU

Participants described a range of different experiences related to the physical component of their life. Many of them experiences energy and mobility limitations such as not being able to walk comfortably and getting tired easily. This sub–theme describes the experiences of people living with DFUs relating to physical dimensions.

A. Energy and mobility limitations

Diabetic foot ulcers (DFUs) created a physical energy limitation for participants. Some reported that they were unable to maintain 100% of energy levels and were always easily tired: *"My energy is never up to 100%. I always feel like I have 60–70% of my strength. Every time I work I feel tired."* (Kat). One participant described this experience of limited energy and mobility as causing breathing difficulties when trying to overcome these limitations.

> *My energy level is very low and everything I do makes me feel tired. Even if I wish to do small things it will make me very tired. When I worked, my breathing became heavy and it was hard to inhale.* (Sawang).

> *I can walk around the house, but I find doing any type of housework is difficult. This is due to constant muscle ache. I'm unable to work due to constant muscle pain.* (Dan).

The permanent disability from amputation due to DFUs influenced the limitation of movement. Some participants used orthotics for support while they were walking and many also mentioned they had to walk carefully to avoid new foot ulcers.

> *...Right now, I can't walk properly. I need the help of a walking stick to get around. I can't walk for a long distance. I'm scared of falling, and if I fell, I would be in trouble.* (Pakad).

B. Foot protection

Protecting the feet became an important consideration for most participants. In Thailand, the hospital provides shoes for people who have foot deformities or are at a high risk of developing foot ulcers. However, these shoes were not considered comfortable by many participants. One participant had an amputation below the left knee and of the toe nail on the right foot. He used a prosthesis on his left leg and wore a diabetic shoe on his right foot but reported that he remained uncomfortable when he walked. Hence, the diabetic shoe was not a successful choice for protecting his feet.

> *I quite rarely wear the diabetes shoes the hospital provided. The reason is that they are quite thick and uncomfortable for me. I then found sandals that are a good fit and comfortable for me.* (Team).

This was a familiar experience for other participants who tried to purchase other shoes for their everyday use. One participant had lost the sensation in his feet so he chose to wear sandals. *"I select nice shoes such as sandals but not slippers. I select shoes/sandals that are not too big or too small"* (Rat). Participants described how the weather in Thailand (which is hot and humid), makes sandals are more popular choice than the heavy shoes provided by the hospital.

Participants described how families who could afford to buy special shoes often did so. *"My daughter*

bought special shoes for me. They have nodules in each one to massage my feet as I walk" (Ban).

Similarly, participants talked about using special protective mechanisms. "*I used the cotton bag to protect the wound on my feet from the dust. My young brother made the bag for me. I use it when I go out or when I go to see the doctor at the hospital.*" (Ban). Some participants also used special socks. "*I wear a special sock that will protect my feet from dust and water. It is not totally waterproof, but it does work for me*" (San).

Sub-theme 2: Emotional impacts of DFU

Having a DFU had a significant impact on the mental health of participants and were associated with negative emotions such as fear and worry about requiring an amputation. Many participants described feeling overwhelmed and troubled at the thought of leg amputation. One participant had experienced partial toenail amputations and was unable to walk or work.

> *What can I do? I have had both big toe nails amputated. I thought, it is just only my toe nails and not my legs. If it was my legs I would not be able to walk or work.* (Fang).

Participants frequently expressed the impact of fear on their mental health and wellbeing. Two participants described their "anxiety" when they had new foot ulcers, the fear being that these wounds might result in long term healing problems and even the possibility of amputation.

> *If I get foot ulcers they should be dressed immediately. If not it will cause trouble. I am very fearful of amputation. Diabetic foot ulcers are not small ulcers but very deep wounds.* (Kat).

> *I have had diabetic foot ulcers for 2 years* (frowned heavily). *All this time I am worrying about amputation. The doctor x-rayed me and,*

lucky me, it wasn't infected to the bone. There is no need for amputation. (Pete).

Interlinked with this fear was a feeling of depression, particularly when it related to having DFUs that were hard to heal.

> *I'm so bored* (made a long sound). *So, I've no idea how to deal with diabetic foot ulcers. If I'm going to die, I'll die* (sad eyes). *I've lived with diabetic foot ulcers for many years.* (Dan).

Despite these negative emotions, participants described their coping strategies such as staying calm and reducing stress from unhealed DFUs. Most participants had DFUs that were unhealed for longer than six months. One participant described how coping strategies were used. The first one he called "Phlong". "*Phlong is like be calm or not think in the negative way*" (Team). The strategy of "Phlong" was used to focus thinking in a positive way and help calm oneself. Other participants reflected similar experiences, particularly when calming themselves to reduce the stress or engaging in positive thinking.

> *I have to be calm and be happy. If I am thinking too much it will cause me stress. Then I do not think too much. I do enjoy what I am doing. When I feel tired, I then take a break for a minute then continue working in my garden or with my housework.* (San).

Another strategy was called "Thum Jai" (think positive) which was used in isolation or in combination with "Phlong". One participant described the way she used these as an easy and effective way to stay calm and reduce stress in her case.

> *Just let it be. I might not suffer at all. If it›s going to happen, I will just let it happen. My advantage is that I am not easily stressed. So, it will not bother me anymore. Actually, it has not happened to me for very long. When I "Thum Jai"* (think positive) *it goes away.* (Rat).

As a coping strategy, "Phlong" and "Thum Jai" appeared to alleviate the personal loss that people experienced due to stress from unhealed DFUs. It is culturally appropriate to use these strategies to assist with calming their mind as all participants were Buddhists. In addition, these strategies appeared to lead to positive thinking and stress management activities. Even though, "Phlong" and "Thum Jai" are culturally specific strategies for Thai people who practice Buddhism, they may provide some insight into strategies that can be successful in other cultures.

Sub-theme 3: Socio-economic impacts of DFU

Participants commented that they had to make lifestyle changes on a daily basis. A significant impact was when they described not being able to participate normally in a social setting. Sometimes the reason for social isolation and withdrawal from social events related to embarrassment. Even participating in a community event for a short time caused personal discomfort, withdrawal from the environment and/or interactions and a desire to stay home.

> *Everyone is looking at me. I'm afraid that they feel I am disgusting. Well, I decided to stay at home rather than socialise with them. Also, I just joined their event for a short time then I returned home.* (Pete).

Participants described the impact that having a DFU had on their ability to work and or participate in their usual household activities. One participant had to stop work and wait until the foot ulcers healed. This was because he was afraid to get them dirty and they would take longer to heal.

> *Normally, I would do work every day, such as farming or gardening. But diabetic foot ulcers are a big problem for me* (point to his right foot). *I can't go anywhere because of diabetic foot ulcers. I am afraid to get them wet because that will make them hard to heal. I have to wait at home till they are healed.* (Fang).

A further lifestyle change was caused by a limited capacity to work due to low energy levels which resulted in low income. For example, a participant described the impact having a DFU had on his income. *"Every year I make baskets for sale. However, since 2015 I lacked the energy to do anything and have no income."* (Dan).

Some participants reported that they needed to change their lifestyle because of amputation from previous DFUs infection. Having a DFU affects a person's normal life which makes resumption of normal activities difficult. Even though the government provides funding for people with disabilities in Thailand, participants reported that it was not enough. *"I receive the funding for disability for 800 baht/ month (~ US$ 25.58) from the government but it is not enough for me. I need to do work at home to cover my daily expenses"* (Pakad).

The majority of participants described that social support was crucial for the management of DFUs. This included peer groups helping each other such as giving advice, caring, and taking care on a daily basis. The most common type of support described was assisting in preparing food, assitance with outings or to see the doctor, and visiting in the home.

> *My relatives, neighbours and communities come to visit quite often. Somedays we do not see each other. Then they will come and see me, or ask someone near my house if I am ok.* (Dan).

Professional supports from nurses or doctors were also described as necessary to manage their DFUs. The local nurses followed up the patients after they were discharged from hospital. *"Sometimes, the local nurse visits me and dresses my wound"* (Pete). Some participants went to see their family doctor for a check-up and assistance with controlling blood glucose levels. *"I always follow the suggestions of my family doctor"* (Ban). Despite the social withdraw described previously, participants received social support

in a variety of different ways. These included professional support by nurses or doctors, community peer groups, and families.

Sub-theme 4: Managing diet

Dietary management for people with DFUs is important to achieve glycaemic control. Managing portion size appeared to be the most challenging concept for most participants. Participants described how they tried to reduce the quantity of tropical fruits, desserts, and rice. Even though they knew about impact of tropical sweet fruits on their blood glucose level, it was difficult for them to reduce their consumption of them.

> *I ate a cluster of cultivated bananas and 4 durians. Then my blood sugar level was 400 (mg%). (Pitoon).*

> *I ate durian a lot, then my blood sugar level was high almost 450 (mg%). (Ban).*

> *I eat oranges, santols, mangosteens, rambutans everything too much (haha). Then I know my blood sugar will be so high. For example, oranges, when I eat them, they are so good and feel fresh. The doctor told me to reduce the quantity. (Kat).*

Some participants also learned from their experiences about over consumption of tropical fruits. One reported that he developed foot ulcers during the durian season and he could not manage his urge to eat the fruit.

> *I get foot ulcers during durian season around July. Also, I sell the durian and eat it while I travel from place to place. Probably, this is the reason I have high blood sugar levels. (San).*

Participants described other foods they avoided. They called them "ahan sa lang" (These are foods which are not recommended for diabetes). Participants described how they tried to avoid these foods which included fermented foods high in sodium and gas. Dietitians recommend that people with DFUs also avoid bamboo shoot, acacia, pickles, fermented fish, and beef.[37] Some of the participants described their experiences after eating prohibited foods.

> *Beef, I don't eat it anymore. My toe nail was amputated because of it. When I ate it my toe nail became blistered. After, this it became an ulcer. So, I stopped eating beef. (Pakad).*

> *The cause of her hospital admission was she ate beef and acacias. Finally, it blistered and then became an ulcer with much pus. (Pete).*

The majority of the participants agreed that dietary control was beneficial and described how they reduced the quantity of their consumption of carbohydrates and sweets.

> *I tried to reduce the amount of dessert and sweet foods. Previously, I ate one small bowl but at the moment I eat only 1-2 spoons. (Chee).*

> *I ate sticky rice around 10 baht (~ US$ 0.32) reduced from 20 baht (~ US$ 0.64). (Pitoon).*

Similar strategies were used for desserts and rice. Because Thai people normally eat jasmine rice or glutinous rice every meal, participants described how they reduced the quantity of what they consumed. *"I only ate one ladle of rice and that's it. I don't eat more than one ladle of rice"* (Fang).

Blood glucose fluctuations such as hyper- and hypoglycaemia are a common complication in diabetes mellitus. However, optimal glycaemic control should ensure that the symptoms are not experienced very often. Participants described how having hypo and hyperglycaemia was a problematic experience for them and narrated their strategies for self-management and identifying the signs and symptoms of hyper and hypoglycaemia.

> *When my blood sugar level is high, I felt I was staggering, my vision was blurred. I couldn't*

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see the TV screen clearly especially letters. It seemed like I was blind. (Pitoon).

When my blood sugar level is low, it is all sweaty at the back of the neck (pointing to his neck) and also my forehead. It was just like I had stepped out of the shower. (Pitoon).

When my blood sugar level is high, I feel exhausted and can't do anything. (Kat).

Other participants shared their strategies to protect against hypoglycaemia.

When I get low blood sugar I need to eat something. Then I went to have some ice cream, just one scoop. The sweating stopped and was gone. (Pitoon).

Hyper and hypoglycaemia are serious complication in diabetes and indicate poor glycaemic control. Participants developed their own strategies to manage these complications.

Theme 2: Managing a diabetic foot ulcer

All participants described several ways to manage a DFU, including following advice from health professionals, using herbal remedies, and for some people using local wisdom and/or traditional healing.

All participants had a DFU that required wound care. Participants were also focused on looking after themselves to avoid getting new foot ulcers. The standard procedures of wound care were applied by most participants. Saline solutions, alcohol and betadine were widely used for dressing wounds. "I'm using an alcohol and saline solution for wound dressing. I then cover the wound with gauze. I do this every evening after showering" (Fang).

It was apparent however, that some of the participants misunderstood how to dress a wound and used alcohol directly on the wound. "Normally, I used alcohol and saline dressing every day at home. I used a cotton bud with saline to clean my wound then paint with alcohol every day in the morning and evening" (Pakad). This participant had lost some of the sensation in her feet and could not feel any irritations from alcohol but expressed that she felt cleaner with the use of alcohol.

Most participants learnt how to dress their wounds from nurses by using antiseptic solutions. "I cleaned my wound every day with antiseptic solution and saline. I follow the instruction that I've learnt from nurses" (Kat). Some participants could afford to buy additional supplies for wound healing. Hydrogel was the most common product used to supplement routine wound care prescribed by nurses. Several participants described how they used hydrogel.

It's like a jelly. After I cleaned my wound, I always put it in. Then, paint the alcohol around and cover with gauze. (Sam).

It's like a jelly. It was stimulating and my wound healed quickly. My son bought it for me from Bangkok. I used it after cleaning wound in the usual way. (Team).

Complementary wound care was also used by many participants. In the Thai culture, people use herbal oil remedies to maintain health and well-being. Some participants believed that these could help them to improve numbness in the wound and reduce wound size.

By applying herbal oil remedies to my feet there has been a big improvement. The numbness has gone and the wound size has shrunk. (Pitoon).

I applied toothpaste on her wound (her daughter). It seemed to heal quickly. Currently, it is not dry. There is a lot of pus on it. She was admitted to hospital for dressing the wound every day. (Pete).

Similarly, participants described how family members were often seeking a herbal drink for them for controlling blood glucose levels and improving wound care. "My grandson bought the herb (tea) to

me for reducing the blood sugar levels. I tried to drink it but it doesn't work" (Dan). In some cases participants described the herbal remedies as affective but they also expressed caution in using this method of controlling blood sugar levels.

> *Some neighbours visited me and recommended some herbs. They said the herbs would reduce my blood sugar levels. It works for them. Currently, the neighbour has 110 (mg%) of her blood glucose. The herb looks like grass with small white flowers. Oh! When I first drank it. I urinated a lot and it was painful. (Ban).*

> *Pak Chaing Da (type of herb). This herb gives me complications when I drink it. I get hypoglycaemia after I drink it for two days. Please be careful. (Ban).*

Furthermore, local wisdom influenced participants who had a strong belief in faith healing. This lead to some participants seeking the help of a holy doctor who was considered able to heal through the use of herbs and holy water.

> *If I go to see the doctor and drain the pus the wound would become infected. Then I wouldn't go. I only go to see the holy doctor... I did not do anything. I just drank the holy water then the wound become dry.(Makam).*

The belief in the holy doctor (spiritual healer) is an alternative for people who do not believe in conventional treatments for DFUs. One participant had experienced a wound which was not healing and the doctor planned to amputate his leg. This participant turned to the holy doctor for help. *"I thought the holy doctor may help me. I went to see holy doctor, because the doctor told me to accept amputation. The holy doctor chewed the cumin and put it into the wound... When I went to the primary care unit the nurse told me not to put anything into the wound because it may cause an infection"* (Fang). Consequently, his

wound became infected and the doctor needed to debride his wound to drain the pus. Fang had long-term dressings undertaken in the hospital and the primary care unit. Eventually the infection was cleared and he did not have to have an amputation.

In summary, participants described how modifying their everyday life experiences became difficult when they were diagnosed with a DFU due to old habits being hard to change, uncertainty about the benefits of changing diet and the reality and inconvenience of daily foot ulcer management procedures. Transition and life events had a significant effect on their HRQOL and diabetes control, which in turn affected their wound healing.

Discussion

This study explored the experiences of adults in Northern Thailand who are living with DFUs. The findings contribute to the understanding of the consequences and experiences of DFUs based on their experiences and perceptions. In addition, the findings provide information on the application of evidence-based practices in the Thai context for people living with a DFU. Most of the themes found in this study are common to diabetes populations with a negative and/or positive impact, e.g. limited energy and mobility, cultural impact, spiritual impact, and self-care management.[22-24,38] However, there were themes identified which are unique to the Thai population. All participants described how their old habits were hard to change. Furthermore, the emotional state, lifestyle and belief of local wisdom were key elements experienced by individuals who had poor self-care management practices and poor wound healing.

Living with DFUs

Most participants, particularly people with DFUs, are affected both physically and mentally. Consistent with European studies[39-41], all participants reported low HRQOL which had an impact on their

physical functioning, role emotional, role physical and general health. Similarly, this study found that DFUs cause limitations in energy and mobility, and mental state which had a negative impact on work and everyday activities. The fear of amputation was a significant burden that impacted on people's emotions. Therefore, both physical and mental impacts should be considered when planning care for people with DFUs.

Another challenge for a healthcare provider is providing appropriate advice about diet glycaemic control. Previous eating habits are difficult to change among people with DFUs attempting to manage their blood glucose levels. This is supported by Lundberg and Thrakul[24] who describe diet as challenging to change. Moderation in eating is consistent with following the Buddhism concept of moderation. In this study people with DFUs tried to control their diets by moderating their diet and avoiding prohibited foods. This included not overeating, managing portion sizes, avoiding drinking alcohol and promoting healthy behaviours by reducing the quantity of rice and dessert.

DFUs are widely considered to be a severe complication of diabetes which causes impaired mobility and mortality.[42] In the Thai context, Buddhism is the core principle of Thai beliefs. The Buddhist philosophy can support individuals to adopt coping strategies which can assist lifestyle changes and lead to a calmer way of being. This study found that the coping strategies of "Phlong" and "Thum Jai" were effective among people with DFUs. This may be because it reduced their feelings of stress, worry, and fear. Thus, healthcare providers need to understand the impact of cultural beliefs and cultural backgrounds as a basis for assisting patients to apply these strategies for improving HRQOL.

Managing a DFU

This research has provided insight into the management of DFUs in the Thai context. Surprisingly, there were a large amount of variations in wound care practices identified in this study. Local wisdom and cultural beliefs had an impact on DFU management. Participants' beliefs appeared to impact on their disease and wound healing.[24] This study found that treatment from a holy shaman was associated with chronic wound healing and/ or severe infection. It is noted that the healthcare provider should be aware of a person's spiritual/ cultural beliefs so that they can assist the individual in getting appropriate treatments in conjuction with their beliefs.

This study is a part of a larger piece of research which has explored the HRQOL among Thai adults living with DFUs in Northern Thailand. The results of this qualitative study have explored the lived experiences of people living with and managing their DFUs and the impact this can have on HRQOL.

Limitations

This study involved a small sample of participants in only one province of Thailand. As a result caution should be taken in generalising these findings to other populations. The diversity of partipants (ages, educational levels and treatment of diabetes) made comparisons between participants difficult but this diversity also provided a rich overview of how DFUs impact on HRQOL among Thai adults. Further research should be undertaken to explore the impact of social and cultural norms among people with DFUs and the impact this has on everyday living, wound healing, wound management strategies and HRQOL.

Conclusion and Implications for Nursing Practice

The findings of this study provide additional knowledge for persons working in diabetes clinics who are providing foot care and diabetes management for people with DFUs. Understanding the lived experiences of Thai people with DFU's will assist health care professionals to ensure that cultural and

spiritual beliefs are considered when developing a collaborative plan of care for individuals with DFU's. In addition, this study provides insight into the actual wound management practices used by Thai people who have a DFU. This knowledge can be used to improve education practices and ensure self-care management strategies are understood by people with DFUs who manage their own wound dressings at home. Additional training for health care professionals working in diabetes foot care may be required to improve service delivery to ensure improved outcomes for people with DFUs in Thailand.

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ประสบการณ์ของผู้ที่เป็นแผลเบาหวานที่เท้าที่อาศัยอยู่ในภาคเหนือของประเทศไทย: การศึกษาวิจัยเชิงคุณภาพแบบพรรณนา

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บทคัดย่อ: แผลเบาหวานที่เท้าเป็นหนึ่งในภาวะแทรกซ้อนของโรคเบาหวานชนิดที่ 2 การมีชีวิตอยู่กับแผลเบาหวานที่เท้ามีผลกระทบต่อคุณภาพชีวิตอย่างมีนัยสำคัญ และยังส่งผลกระทบทางลบต่อการใช้ชีวิตประจำวันของผู้ที่เป็นแผลเบาหวานที่เท้า การวิจัยครั้งนี้มีวัตถุประสงค์เพื่อศึกษาประสบการณ์ของผู้ที่เป็นแผลเบาหวานที่เท้าที่อาศัยอยู่ในภาคเหนือของประเทศไทย โดยใช้การศึกษาวิจัยเชิงคุณภาพแบบพรรณนา ผู้เข้าร่วมโครงการวิจัยถูกคัดเลือกจากคลินิกเบาหวานผู้ป่วยนอก และคลินิกเท้าที่โรงพยาบาลระดับตติยภูมิในภาคเหนือ ตั้งแต่เดือนมกราคม ถึงเดือนเมษายน พ.ศ. 2560 ผู้ที่เป็นแผลเบาหวานที่เท้า จำนวน 13 คนถูกสัมภาษณ์เชิงลึกตามแนวคำถามสัมภาษณ์แบบกึ่งโครงสร้าง และวิเคราะห์ข้อมูลโดยใช้กระบวนการวิเคราะห์กระบวนทัศน์ ผลการวิจัยพบว่า ประสบการณ์ของผู้ป่วยเบาหวานชนิดที่ 2 ที่เป็นแผลที่เท้าสามารถจำแนกได้เป็น 2 แบบ คือ 1) การใช้ชีวิตของผู้ที่มีแผลเบาหวานที่เท้า และ 2) การจัดการแผลเบาหวานที่เท้า ผลการวิจัยในครั้งนี้เป็นแหล่งข้อมูลเพื่อให้เกิดความเข้าใจประสบการณ์ของผู้ที่มีแผลเบาหวานที่เท้า แก่ทีมสุขภาพและบุคคลทั่วไป อีกทั้งยังจะเป็นประโยชน์ต่อการจัดการวางแผนการดูแลผู้ที่มีแผลเบาหวานที่เท้าในบริบทของคนไทย การพยาบาลในมิติการป้องกันจึงเป็นเป้าหมายสูงสุดที่ถูกนำมาพิจารณา เพื่อช่วยพัฒนาคุณภาพชีวิตของกลุ่มคนที่เป็นแผลเบาหวานที่เท้า

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