ADHERENCE TO WEARING REMOVABLE CAST WALKERS IN PATIENTS WITH DIABETES-RELATED FOOT ULCERS: A MIXED METHODS INVESTIGATION

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Abstract

Background

Diabetes-related foot ulcers (DFUs) are a leading cause of global disability, mortality, and healthcare cost burdens. The most common pathway for developing DFUs is from high foot plantar pressure on the insensate feet of people with peripheral neuropathy. To manage DFUs effectively, offloading the high foot plantar pressure that causes the DFUs is essential to promote healing. Gold standard offloading treatment is provided through non-removable knee-high offloading devices that typically have high costs, are custom-made, require special skills and time to apply, and patients often prefer not to use them as they cannot be removed. Conversely, removable cast walkers (RCWs) are more popular with patients, are typically prefabricated, require limited skills and time to apply, and offload the same amount of high plantar pressure as non-removable devices. However, trials consistently show RCWs are not as effective in healing DFUs, and this is thought to be due to the differences in adherence levels to wearing the different devices. Therefore, methods for improving adherence to wearing RCWs could be crucial to providing more efficient and effective treatment options to heal people with DFUs and reduce the global DFU burden. However, to date, only one study has explored the factors associated with adherence to wearing RCWs in people with DFUs and this study was performed across developed countries.

Aim

The main aim of this research was to investigate the levels of adherence and the factors associated with adherence to wearing RCWs among patients with DFUs.

Methods

Mixed methods (qualitative and quantitative) were utilised in studies in three main diabetic foot referral clinics in Jordan to address this overarching aim. Study 1 had a qualitative design using semi-structured interviews to explore the levels and factors of adherence to wearing RCWs among patients with DFUs. Study 2 tested the test-retest reliability of several diabetes-related foot psychosocial scales that were translated into Arabic (using two forward and backward translations with two

consensus panels) for the purpose of using these in Study 3 of this thesis, including the Foot Care Confidence Scale (FCCS) (1), Foot Care Outcomes Expectations Scale (FCOES) (2), Patient Interpretation of Neuropathy (PIN) scale (3), Neuropathy-specific Quality of Life (NQOL) scale (4), and offloading-related scales (Visual Analogue Scales (VAS) and Likert questions). Study 3 was a cross-sectional observational study that objectively measured adherence to wearing RCWs (using two activity trackers) in patients with DFUs for one week to objectively investigate adherence levels and the associations with these adherence levels with a range of factors, including demographics, medical history, foot, ulcer, treatment, and the aforementioned diabetic foot psychosocial scale factors.

Results

In Study 1, two main themes that described adherence to wearing RCWs among patients with DFUs were identified in the 10 participants interviewed. The first theme described the variation and inconsistency in reporting adherence to wearing RCWs which was represented by three categories: i) the belief of achieving optimal adherence; ii) adherence during indoor activities seemed challenging; iii) RCWs were not worn in some short distances (few indoor steps). The second theme described the factors related to adherence to RCWs which was represented by four categories: i) specific offloading knowledge or beliefs influenced adherence; ii) the impact of the severity of foot disease on adherence outcomes; iii) social support benefited adherence; and iv) logistical issues and physical features of RCWs (the usability of the offloading device)

In Study 2, two consensus panels of experts provided language revision and cultural adaptation of the Arabic translations of the FCCS, FCOES, PIN scales, NQOL scales, and offloading-related scales. The Arabic translated scales were tested with 15 participants, demonstrating reliable internal consistency of all the translated scales (all, Cronbach's alpha >0.75), except the PIN self/practitioner blame and acute ulcer onset items (both, Cronbach's alpha <0.60). Test-retest reliability showed good stability for the FCCS (intraclass correlation coefficient [ICC] = 0.82), FCOES (ICC = 0.79), and NQOL scales (ICC = 0.76–0.90), and between poor-to-good stability for the PIN (ICC = 0.043–0.85) and offloading-related VAS (ICC= 0.43–0.90) and Likert scales (Kappa = 0.34–0.61).

In Study 3, 61 participants were included, with a mean (SD) age of 56 (10) years, 79% were males, and 93% had type 2 diabetes. The mean objective adherence level to wearing the RCWs was 33.6% (16.0) of daily weight-bearing activity, whilst self-reported adherence levels were much higher, at 70.1% (28.8) of daily time and 90.0% (range = 0–100) of daily steps. The factors identified to be independently associated with lower levels of objectively measured adherence to RCWs using a multivariable linear regression model were being male, having a longer duration of diabetes, not having peripheral arterial disease (PAD), and wearing a self-perceived heavier offloading device (all, $p \leq 0.05$).

Conclusions

The main findings of this research significantly contribute to the global understanding of adherence to wearing RCWs in people with DFUs. Collectively, the findings of the mixed method of this thesis show that patients perceived their adherence to wearing their RCW to be much higher in both the qualitative interviews and the quantitative self-reported findings than when measured objectively using activity trackers in the quantitative study. According to the qualitative findings, this may be because patients misperceive that wearing their devices indoors or for short distances is not an important (or included) part of adherence to treatment in this context.

Furthermore, this mixed-methods investigation identified several factors that appear to have a strong relationship with RCW adherence, including gender, the severity of diabetic foot disease (duration of diabetes, PAD), the physical feature of the offloading devices (heaviness), personal knowledge or beliefs (not being aware of the optimal adherence), and the social supports available (the support from clinicians and families).

These factors demonstrate the complexity of understanding offloading adherence, while also providing promising directions for future research aimed at improving RCW adherence, such as patient education on the adherence concept, ensuring RCWs are light in weight, and self-monitoring of adherence. Any improvements in adherence to wearing RCWs in future should be a critical step to enabling more efficient and effective treatment options to heal people with DFUs and reducing the global DFU burden.

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List of Abbreviations

ATL	Arabic Translation
AUD	Australian Dollar
BMI	Body Mass Index
CAD	Coronary Arterial Disease
CI	Confidence Intervals
CVA	Cerebrovascular Accident
DFUs	Diabetes-related Foot Ulcers
DM	Diabetes Mellitus
DN	Diabetic Neuropathy
EBT	English Back-translated
FCCS	Footcare Confidence Scale
FCOES	Footcare Outcomes Expectations Scale
FF	Fitbit Flex
HbA1C	Glycated Haemoglobin (A1c)
HBOT	Hyperbaric Oxygen Therapy
HRQOL	Health-related Quality of Life
ICC	Intraclass Correlation Coefficients
IQR	Inter Quarter Range
iTCC	instance Total Contact Cast
IWGDF	International Working Group on the Diabetic Foot
JD	Jordanian Dinar
JRMC	Jordanian Royal Medical Services
kPa	Kilopascal
LLD	Limb Length Discrepancy

MAPE	Mean Absolute Percent Error
MI	Myocardial Infarction
MMPs	Matrix Metalloproteinases
NCDEG	National Centre for Diabetes, Endocrinology, and Genetics
NPWT	Negative Pressure Wound Therapy
NQOL	Neuropathy-specific Quality of Life
PAD	Peripheral Arterial Disease
PAV	Preliminary Arabic Version
PHH	Prince Hamza Hospital
PIN	Patient Interpretation of Neuropathy
PPP	Peak Plantar Pressure
PS	Peak Shear
PTS	Plantar Tissue Stress
R	Pearson correlation coefficient
RCTs	Randomised Controlled trials
RCW	Removable Cast Walkers
RHO	Spearman
SCT	Social Cognitive Theory
SD	Standard Deviation
SPSS	Statistical Package for Social Sciences
TBI	Toe Brachial Index Pressure
TCC	Total Contact Cast
TL	Translator
2MWT	Two-min Walk Test
UK	United Kingdom
US	United States

USDs	United States Dollars
VAS	Visual Analog Scale
VLUs	Venous Leg Ulcers
WHO	World Health Organization

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Name: Anas Ababneh

Signature: QUT Verified Signature

Date: 23/June/2021

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and Mohmmad, and Zina Alnsour for their support and for caring for my family during this long journey.

Chapter 1: Introduction

The main aim of this research was to investigate adherence to wearing removable cast walkers (RCWs) among patients with diabetes-related foot ulcers (DFUs) using a mixed qualitative and quantitative methods approach. This chapter outlines the background (Section 1.1), definitions (Section 1.2), purpose (Section 1.3), significance (Section 1.4), research questions (Section 1.5), and thesis outline (Section 1.6).

1.1 BACKGROUND

Over the last few decades, diabetes has become a highly prevalent disease with a high morbidity and mortality rate (5, 6). The number of people with diabetes has doubled around the world, particularly in developing countries, making it one of the biggest challenges globally (7). Around 415 million adults have diabetes globally, which is expected to increase to 642 million by 2040 (8).

Diabetes results in hyperglycaemia and prolonged duration of the disease may lead to severe micro and macrovascular complications, including retinopathy, nephropathy, peripheral neuropathy, peripheral arterial disease (PAD) and other complications (5, 9-12). Chronic inflammation is the main cause of diabetes-related microvascular complications, which results from mechanisms such as advanced glycation end products, oxidative stress, and hypoxia (13). The presence of the microvascular complication of neuropathy is associated with loss of protective sensation (sensory neuropathy) and foot deformities (motor neuropathy) (14). Both can increase the mechanical stress to the insensate foot, including peak plantar pressure and shear forces (15, 16). This results in changes in the plantar soft tissue (callus formation), which can lead to further mechanical stress. As a result, tissue trauma can occur, leading to DFUs – one of the most common diabetes complications (17, 18).

DFUs can lead to several negative consequences for both patients and health care systems. First, they are associated with high hospital admission rates (19), which can lead to emotional and economical stress (20). DFUs are also associated with high mortality rates (21-25). Managing these wounds is also associated with high costs in many countries (24, 26-28). Lastly, DFUs can result in serious consequences such as lower limb amputations (29, 30), which can negatively affect the health-related quality of life of those patients (31).

To manage DFUs effectively, evidence-based interventions are recommended by the International Working Group on the Diabetic Foot (IWGDF), including local wound care, control infection, revascularisation, and offloading treatments as appropriate (32-34). Offloading is arguably the most important of these recommended treatments for plantar DFUs (34), which can be achieved to various extents using different offloading modalities such as bed rest, wheelchair use, crutch-assisted gait, total contact cast (TCC), felted foam, half-shoes, therapeutic shoes, custom splints, or RCWs (35).

Offloading treatment is the cornerstone in treating neuropathic plantar ulcers (36). Non-removable knee-high offloading devices, such as TCCs and non-removable walkers (instant TCC), are strongly recommended by the IWGDF as the first treatment of choice for offloading plantar forefoot DFUs supported by high quality evidence (34). Despite such recommendations, TCCs are associated with several drawbacks, such as high treatment costs and application time, in addition to the negative impact on patients' health-related quality of life (HRQL) (37-39). These negatives can be reduced by using removable knee-high offloading devices such as RCWs (37, 40, 41) which have been shown to achieve similar reduced magnitudes of pressure to that of TCCs in gait lab studies (42-44). However, non-adherence to wearing RCWs is an issue; thus, rendering RCWs to be non-removable (instant TCC) by using a fibreglass cast was shown to provide effective offloading (39, 40). However, immobilising the ankle joint in long term offloading (non-removable devices) may impact the health of the limb (45). Additionally, the removability of RCWs is often a more preferable option for patients and clinicians (37, 46). Thus, adopting RCW modality can be promising to address these negatives.

Currently, RCWs are recommended by the IWGDF as a second choice treatment, only when non-removable cast walkers are contraindicated (34). This recommendation is based on several systematic reviews that have reported a significant delay in wound healing in those using RCWs in comparison to those using non-removable knee-high devices (47-49). In instances where patients need to use RCWs, the IWGDF recommends continuous encouragement of patients to adhere to wearing the RCWs as much as possible (34). This recommendation relates to the commonly reported poor adherence to wearing these devices (50-53). Patients have been found to only wear RCWs for the minority or partially of daily activities (52, 54). Although adherence has only been measured in a few studies (52-54), several studies (49-51, 55) have explained the less successful healing outcomes when prescribing RCWs due to poor adherence, highlighting the importance of patients' adherence to wearing RCWs for DFU healing outcomes.

Although poor adherence is implicated in poor healing outcomes, evidence regarding predictors for adherence to wearing their RCWs in people with DFU is limited, restricted to recent research conducted in Western countries. One study in the UK and the US found that factors related to neuropathy (pain, postural instability) and wound size could significantly impact patients' adherence to these devices (52). Two qualitative investigations in Western countries (56, 57) highlighted some adherence barriers related to the usability of RCWs, including the difficulty of wearing these devices and the negative impact on daily life activities. However, there has been no offloading adherence research in other populations, especially from the developing world. Due to this limited evidence, further investigation of the levels and determinants of patients' adherence to wearing RCWs is required.

Patients' adherence to long term treatments is challenging in many chronic conditions (58-61). According to the World Health Organization (WHO) (62), adherence to care can be influenced by several integrated factors, including social, economic, patient-related, health systems, and the chronic condition itself. For instance, patient-related factors such as knowledge, beliefs, or depression have been shown to impact adherence behaviour (63-67). Several studies have shown that patients' confidence in their ability to adhere to the prescribed treatments has also been shown to be a significant factor that may affect treatment outcomes (68-76). This concept has been examined in health studies as self-efficacy (77). Social cognitive theory (SCT) (78) is known as one of the most popular theories in predicting health behaviour, which incorporates most of the previously mentioned factors, including self-efficacy (79). It explains the possible interaction between the patient's environment, personal cognitive factors such as beliefs (outcomes expectations) or self-efficacy, and human behaviour (80). Therefore, adopting SCT to investigate the determinants of RCW adherence can help guide a more comprehensive investigation.

1.2 DEFINITIONS

The major terms are defined here to provide the reader with a better understanding of the field of this research:

- **Diabetic foot ulcer (DFU):** According to the IWGDF, foot ulcers are defined as "break of the skin of the foot that involves as a minimum the epidermis", while DFUs are defined as "foot ulcers in persons with currently or previously diagnosed diabetes mellitus and usually accompanied by neuropathy and/or PAD in the lower extremity" (81 p3).
- **Offloading:** According to the IWGDF, offloading is defined as "the relief of mechanical stress (pressure) from a specific region of the foot" (34 p5). Offloading can be achieved through offloading devices such as TCC or RCW (34).
- **Removable cast walker (RCW):** is an offloading device (prefabricated) used to relieve the plantar pressure (mechanical stress) from a specific area of the foot. As it is removable, this means patients can remove it whenever they want (34). More specifically, according to Crews et al (34 p725) "removable cast walkers typically have rigid struts (or circumferential lattice encasements) that run up the majority of the shank". Ankle-high (the device extends to the ankle) and knee-high (the device extends to the knee) are two common forms of removable cast walkers (34, 43).
- **Adherence to offloading:** According to the IWGDF, adherence to offloading is defined as "the extent to which a person's behaviour corresponds with agreed recommendations for treatment from a healthcare provider, expressed as quantitatively as possible" (34).

1.3 PURPOSE

1.3.1 Aims

This research was conducted in Jordan to improve current understanding of adherence to wearing removable offloading devices (RCWs) among patients with DFUs. This research specifically aimed to:

1. Explore the level of adherence to wearing RCWs among patients with DFUs.

2. Identify the facilitators and barriers to adherence to wearing RCWs among patients with DFUs.
3. Validate the Arabic translation of several psychosocial scales to reliably capture important potential associations with adherence among the Jordanian population.
4. Identify the factors associated with adherence to wearing RCWs among patients with DFUs.

1.4 SIGNIFICANCE

Diabetes is continuously rising and is expected to increase by 50% by 2045 (82). Data from the Global Burden of Disease Study (2016) estimated that around 18.6 million individuals had DFUs and around 2.5 million individuals had diabetes-related major lower limb amputations (83). DFUs are also an epidemic condition among people with diabetes, with a global prevalence of 4.8% (84).

Diabetes-related foot ulcers are a devastating disease with several burdens. DFUs are associated with higher mortality than the pooled mortality of all cancers, which is considered an independent predictor of premature death (85, 86). It also has a significant impact on the quality of patients' lives (87). Management of DFUs is costly. A recent report from England showed that the healthcare expenditure related to the management of chronic and severe DFUs is higher than the cost of lung, prostate, and breast cancers put together (88). Lower limb amputations are one of the most detrimental results related to chronic diabetic ulcers. In Australia, a limb is lost due to DFUs every two hours (89). The situation is not better in developing counties. For example, the reported prevalence of DFUs and the associated amputations among people with diabetes in Jordan is high (5.3% and 1.7%, respectively) (90, 91).

Offloading is one of the most important treatments of DFUs, as supported by high quality evidence according to the recent IWGDF guidelines (34). Implementation of non-removable knee-high offloading devices such as TCCs as the first offloading choice is highly recommended where applicable (34). However, this has not been a common practice in the developed world, including Australia, Europe, and the United States (U.S) (38, 41, 56). Factors related to the long practice time needed to apply, learning application skills, and high cost are the main barriers to adopting TCC as standard treatment (38). For instance, TCC takes around 15.1 minutes to be applied, using 727 Euro of the total cost. In comparison, RCWs can be applied within 10 minutes with much less cost (130 Euro) (40). These drawbacks can be a real challenge against TCC as the gold standard offloading treatment. Recent expert opinion has raised several questions regarding the underuse of TCC as the gold standard offloading treatment and this highlights the need to rethink current standard offloading practices (92).

Fortunately, RCWs have been shown to be an effective alternative offloading device in terms of reducing plantar pressure (37, 43, 44). However, four systematic reviews demonstrated significantly less healing time related to using non-removable offloading devices in comparison with RCWs (47, 48, 93, 94). As mentioned, the removability advantage can be a negative predictor of poor adherence to wearing RCWs, as patients may not always prefer to wear them for all weight-bearing activities, which may impact DFU healing (52-54). Due to this poor uptake of these devices by patients, RCWs are the second recommended choice of offloading treatment, for example, in cases where health care settings do not have the resources to apply TCC. IWGDF experts advise clinicians to focus on patients' engagement with wearing the removable offloading devices due to reported non-adherence (34). However, this issue is not fully understood due to the lack of studies that have measured adherence to offloading (52, 95). To the best of the PhD candidate's knowledge, adherence to offloading has not yet been studied in developing populations. Thus, there is an urgent need for a better understanding of the factors associated with adherence levels to wearing removable offloading devices among patients with DFUs (34, 95). This will help in establishing future interventions that can improve adherence outcomes for wearing removable offloading devices. Consequently, the healing rate of DFUs can increase with fewer complications related to prolonging ulceration. Such improvement may shift the paradigm of offloading practice to be more supportive of the removability feature of the offloading devices, which may subsequently enhance the quality and usability of the currently available offloading devices.

This research aims to fill the current knowledge gap relating to the determinants of adherence to using RCWs among patients with DFUs. More importantly, it aims to investigate adherence to these offloading devices in a different population, that is, Jordanian. Mixed methods were adopted as this is a comprehensive approach to deal with complex research questions (96, 97). SCT was also adopted, as this emphasises the need to investigate different factors that potentially impact patients' adherence to wearing RCWs including psychosocial, physiological, and environmental factors. Thus, this research comprises three main studies (see Figure 1.1), as outlined below:

- Study 1 was a qualitative investigation (using semi-structured interviews) that aimed to explore adherence behaviour to wearing RCWs among patients with DFUs in Jordan. This study describes the level of adherence among the studied population, in addition to providing detailed information on the potential facilitators and barriers of adherence to wearing RCWs. It also led to establishing multiple hypotheses as an inductive guide for the quantitative study (Study 3) of this research.
- Study 2 tested the validity and reliability of the Arabic translation of commonly used psychosocial scales in the field including the Foot Care Confidence Scale (FCCS) (1), Foot Care Outcomes Expectations Scale (FCOES) (2), Patient Interpretation of Neuropathy (PIN) scales (3), and Neuropathy-specific Quality of Life (NQOL) scales (4), and offloading-related scales. These scales were selected to be used in the quantitative investigation (Study 3) according to the inductive guidance from Study 1, adopting the SCT, and reviewing the literature (see Figure 1.1). Therefore, this study determined the validity and reliability of Arabic translated tools, which assisted in testing the psychosocial factors and their impact on offloading management adherence among Jordanian patients. Moreover, these Arabic translated tools will serve researchers in the Arabic region, as it may create opportunities for measuring such factors in the Arabic population in future research.
- Study 3 comprised a quantitative cross-sectional study conducted to investigate the adherence to wearing RCW among Jordanian patients with DFUs. Additionally, this study measured the associations between a combination of physiological, psychosocial, and environmental factors and adherence to wearing RCWs. Adherence was measured objectively, as recommended in previous studies (95, 98), which is a major strength of this study. These results, supported by empirical evidence, aim to contribute to

the current understanding of non-adherence to removable offloading devices.

Research process

- **Literature review:** Searching of RCWs' adherence determinates in electronic databases including PubMed, Ovid MEDLINE, Ovid CINHAL, Embase and the Cochrane Library between January 2000 and Oct 2020.
- **Adapting social cognitive theory:** This theory guided this research. The theory has several constructs that predict human behaviour (adherence) including knowledge, outcome expectations, social structural factors and self-efficacy.

Study 1

A qualitative investigation of the determinates of adherence to wearing RCWs

- Design: Descriptive qualitative Study
- Data collection: Semi-structured interviews (n=10)
- Translation: Back-translation of the interviews
- Data analysis: Content analysis

Study 2

Validating the Arabic translation of the FCCS, FCOES, PIN sub-scales, NQOL sub-scales, and offloading treatment scales

- Design: Translation, validity and reliability
- Translation: Forward and backward translation with two committee consensuses to validate the Arabic translation.
- Reliability:
  - Internal consistency: Cronbach's alpha (n= 15 – 61)
  - Stability: Test-retest (after one week, n=15)

Study 3

Identifying adherence determinants to wearing RCWs (quantitative study)

- Design: Cross-sectional study (n= 61)
- Data collection:
  - Independent variables: FCCS, FCOES, PIN scale, NQOL scale, and offloading treatment scales
  - Measurement of adherence (main outcome): i) self-report of adherence time and steps; ii) objective measurement by attaching two activity trackers for one week.

Data analysis: Multiple linear regression modelling

Figure 1.1: Flowchart of the methods of the conducted research

1.5 RESEARCH QUESTIONS

The research questions addressed in this research are:

1. What is the level of adherence to wearing RCWs of patients with DFUs?
2. What are the barriers or facilitators of DFU patients' adherence to wearing RCWs?
3. Are the translations of the FCCS, FCOES, PIN scale, NQOL scale, and offloading-related scales valid and reliable for the Jordanian population?
4. What is the daily percentage of patients' adherence to wearing RCWs in Jordan?
5. What are the associations between sociodemographic, physiological, and psychosocial factors and patients' adherence to wearing RCWs in patients with DFU?

1.6 THESIS OUTLINE

This thesis consists of eight chapters.

Chapter 1: presents an introductory overview of this research, including background, the significance of the study, and the main purpose of the conducted studies.

Chapter 2: presents a literature review of the burden of DFUs, including the pathophysiology, epidemiology (prevalence, amputations, mortality, cost, and quality of life), and current treatments based on recent literature.

Chapter 3: presents a more comprehensive literature review of the DFU offloading treatment factors associated with, and levels of adherence to using RCWs in people with DFU, before concluding with a review of factors associated with the general treatment adherence in other chronic conditions.

Chapter 4: presents the theoretical framework that guided this research (SCT).

Chapter 5: presents Study 1 (qualitative study), including the methods, results, discussion, and conclusion.

Chapter 6: presents Study 2 (translation and reliability study), including the methods, results, discussion, and conclusion.

Chapter 7: presents Study 3 (cross-sectional study), including the methods, results, discussion, and conclusion.

Chapter 8: presents an overview of the research conclusions, including a discussion of the key findings, contributions, limitations, recommendations, and conclusion.

Chapter 2: Literature Review of Pathophysiology, Burden, and Management of Diabetes-related Foot Ulcers

2.1 PREFACE

This chapter presents the literature review of the pathophysiology, burden, and management of diabetic foot ulcers (DFUs), which is divided into three sections. Section 2.2 includes a review of the pathophysiology of DFUs including neuropathy, foot deformities, and pressure forces. Section 2.3 includes a review of the burden of DFUs including prevalence, incidence, recurrence, amputations, mortality, cost, and quality of life. Section 2.4 includes a review of the management of DFUs including local wound care and adjunctive therapies.

2.2 PATHOPHYSIOLOGY

DFU is a common complication among people with diabetes mellitus (DM) which is a worldwide issue with high morbidity and mortality rates (5, 6, 84, 85). Both type 1 and type 2 DM are characterised by hyperglycaemia due to the insufficiency of insulin secretion, action, or both and this usually leads to microvascular complications such as retinopathy, neuropathy, and nephropathy. Macrovascular complications including cardiovascular disease and peripheral arterial disease (PAD) are also associated with the presence of diabetes (5, 9-12). Chronic inflammation is the main cause of diabetes microvascular complications (13). Advanced glycation end products with other mechanisms such as oxidative stress and hypoxia are strongly associated with the development of microvascular complications of DM (13).

The presence of diabetes complications such as peripheral neuropathy and PAD explains the causal pathway of developing DFUs (17, 99) (Figure 2.1). Neuropathy is one of the microvascular complications of diabetes that can lead to sensory neuropathy (loss of protective sensation) (35, 100-104), motor neuropathy (foot deformities, high plantar pressure) (15, 105-107), and autonomic neuropathy (decrease sweat gland activity) (108, 109). The presence of one or more such neuropathic complications can increase the chance of callus formation (especially in major plantar pressure points), which can frequently traumatise the plantar skin leading to chronic ulceration (DFU) (15, 17, 105-107). Additionally, PAD can sometimes be another devastating factor that increases the risk of non-healing DFUs (110-112).

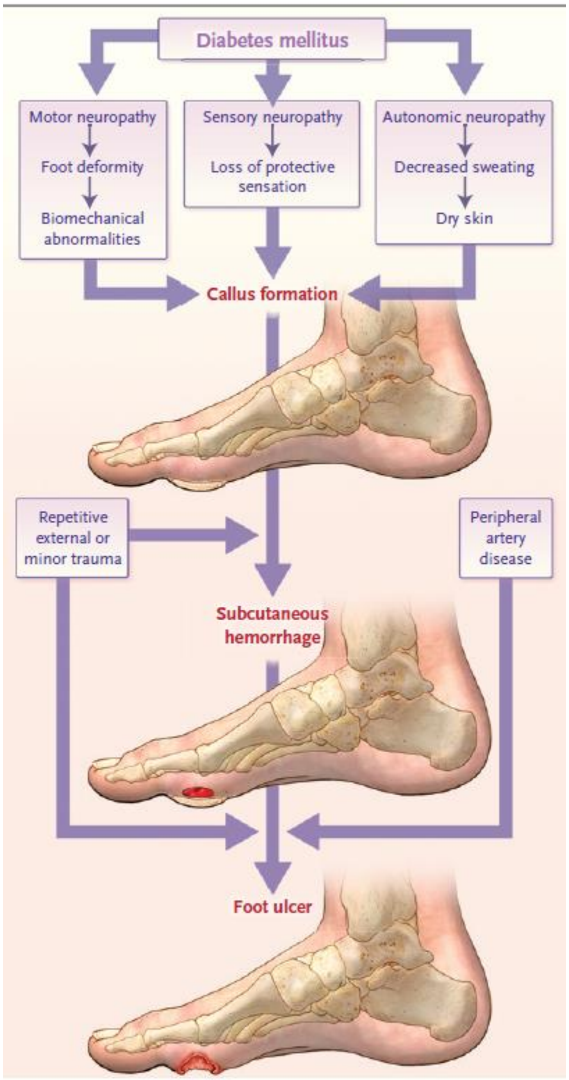

Figure 2.1: The causal pathway of foot ulceration among patients with diabetes

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The literature related to peripheral neuropathy, foot deformities, and plantar pressure is discussed in the following sections.

2.2.1 Neuropathy

As discussed, diabetic neuropathy is a key element of the causal pathway of DFUs (17, 99). The metabolic changes that result from diabetes affect the neural tissue. This is mainly due to the rising of the polyol (sorbitol) pathway activity, oxidative stress, the formation of advanced glycation end products, and pro-inflammatory changes (113). These changes lead to a direct effect on Schwan cells in the neuronal axons and an indirect effect via the nerve vascular supply (113), which consequently affect the neurons' function (13, 113).

Peripheral neuropathy is common among diabetic patients (114). Loss of protective sensation or loss of "gift of pain", which was first described by Dr Paul Brand, as cited in Armstrong et al (17) has been associated with the presence of DFUs (100, 103, 115). Motor neuropathy, which is the involvement of motor nerves, especially in advanced cases of neuropathy, also causes muscle weakness such as weakness of foot muscles (116). The weakness of foot muscles may lead to alteration of foot biomechanics, which increases the amount of plantar pressure and the development of foot ulcers (116). Both sensory and motor neuropathy lead to abnormal plantar pressure accompanied by insecure gait. Hyperkeratosis will gradually develop due to continued elevation in the plantar pressure load, (callus formation) (14) (See Figure 2.1). As a result, a subepidermal haematoma can develop, particularly on metatarsal and heel areas, leading to ulceration (14).

2.2.2 Foot deformities, pressure forces, and ulceration

Foot deformities in the presence of loss of protective sensation are also predictors of developing plantar pressure foot ulcers (16, 107, 117-119). The aetiology behind developing such deformities is still not well understood. Although it is commonly believed that foot deformities can be caused by motor neuropathy, which causes atrophy of the muscles, a systematic review of 17 studies could not confirm this association due to the inability of the implemented designs to establish cause and effect relationships (the majority was cross-sectional) (107).

The presence of foot deformities can significantly raise plantar pressure (119, 120). However, investigating the mechanical forces responsible for developing DFUs is a complex issue (121, 122). Different pressure abnormalities such as peak pressure, pressure-time integral, peak shear, and shear time have been identified among people with diabetic neuropathy. (16, 117, 121, 123-125). A recent review combined all these pressure forces along with activity to propose the concept of accumulated plantar tissue stress (PTS) (126).

For example, peak plantar pressure (PPP) is one of the pressure forces found to be significantly higher under the medial forefoot if a deformity such as a hallux valgus is present (119, 123). A systematic review of 15 studies found that diabetes-related limited ankle joint mobility increased the plantar pressure and the development of DFUs (120). PPP was significantly higher among patients with DFUs than other diabetic patients according to different studies (15, 105, 106, 127). A meta-analysis of eight observational studies that compared the dynamic plantar pressure between diabetic patients who had neuropathy and patients with DFUs found PPP and pressure time integral to be significantly higher in patients with a history of foot ulceration and diabetic peripheral neuropathy compared to those without ulcers (15). However, such findings must be taken with caution due to some heterogeneity between studies. Neuropathy also has a significant impact on PPP and pressure-time integral according to a systematic review (128). In this review, 16 studies consisting of 382 participants who presented in the control group without neuropathy and a case group with neuropathy were examined. The results showed that patients with neuropathy had higher plantar pressure in the rear foot, forefoot, and midfoot. Patients with diabetic neuropathy had elevated plantar pressure with a longer period of stance, which may have led to the destruction of the skin by continuous trauma. Thus, patients with neuropathy had higher levels of dynamic plantar pressure and forefoot pressure which play a significant role in developing plantar ulcers (128).

However, PPP is not the only devastating force, as shear forces have also been shown to be a predictor of DFUs. Yavuz et al (16) measured and compared shear forces between a group with a history of DFUs and a group without any history of DFUs. The sheer pressure was quantified among nine subjects with DFUs (16) and with diabetic neuropathy (DN) without DFUs. Interestingly, despite PPP not being significantly different between the two groups (DFU 738.6 kPa, DN 568 kPa, P = 0.20), the peak shear (PS) (shear force) was significantly higher in the DFU group (DFU 135.3 kPa, DN 86.4 kPa, P = 0.04). This study revealed for the first time that PS can be an important risk factor in the development of DFU, providing new evidence that suggests that PS should be measured with PPP to better predict the risk of developing a DFU (16).

Patients with diabetes have a higher risk of developing foot deformities (107), and these deformities lead to enormous changes in pressure features in this population

(16, 107, 117-119). In addition to the changes in pressure, recent studies have demonstrated some changes in the characteristics of plantar soft tissue among the diabetic population (129, 130). These changes affect the soft tissue, including diabetic tissue stiffness, total elastin, and septal thickness. However, mechanical properties are not a significant predictor of soft tissue changes (129). Another study investigated the mechanical effect on the soft tissue between the ulcerated and non-ulcerated cases (130). Soft tissue thickness and stiffness of the heel pad and sub-metatarsal fat pad were measured using real-time ultrasound electrography. The results indicated that the ulcerated group had a significantly lower heel pad relative stiffness in the left foot. The observed difference in heel pad stiffness between the ulcerated and non-ulcerated feet indicates a possible relationship between changes in the mechanical properties of soft tissue, such as stiffness and ulceration (130). However, according to Naemi et al (130), it is too early to conclude that these observed differences in the properties of soft tissue are the cause or consequence for ulceration.

2.3 BURDEN OF DIABETIC FOOT ULCERS

Diabetes-related lower extremity complications (peripheral neuropathy, foot ulcers, and amputations) have been found to impact 1.8% of the global population (83). Around 2.5 million and 1.1 million individuals with disabilities had DFUs and amputations, respectively, with the global prevalence of DFUs among patients with diabetes around 4.8% (83). Although the prevalence of these ulcers and the associated outcomes have declined in some developed countries such as Denmark and Netherlands (131-134), they are still the main cause of lower-limb amputations in many countries (29, 30). Another reason that DFUs are more devastating is the high recurrence rate, which was noted to be around 22–40% per person-year globally (17, 135). Further, they are associated with a negative impact on patients' health-related quality of life and high mortality rates (136). DFUs are also associated with high treatment costs due to hospitalisation or performance of procedures such as surgical debridement, revascularisation, and amputation (24, 26-28, 137). The following section outlines these DFU burdens in more detail, including prevalence, incidence, recurrence, amputations, mortalities, cost, and quality of life.

2.3.1 Prevalence, incidence, and recurrence

Diabetes-related foot ulcer is a global chronic condition. Data from the Global Burden Disease study estimated around 18.6 million people, with a prevalence of 0.269%, had DFUs in 2016. The prevalence of DFUs is common in the middle-aged population, particularly among males (83). There is a variation of the prevalence of DFUs around the world, with high prevalence reported in the regions of North Africa and Middle East (0.233%), Central Latin America (0.402%), Oceania (0.785%), and Caribbean (0.321%), while it is less reported in developed nations such as Australia (0.134%), Japan (0.180), and Western Europe countries (0.199) (83). Globally, the estimated prevalence in the diabetes targeted population ranged between 4.6–4.8% (83, 84). There are also disparities in the reported diabetes populational prevalence between different countries. The US, Canada, and Belgium have the highest prevalence (13% -16.6%), while Australia, Poland, and South Korea have the lowest prevalence (1.5%-1.7%) (84).

In recent decades, there has been a significant reduction in the incidence of DFUs and the related amputations in some developed European countries (131, 133, 138). For instance, the mean incidence of DFUs in Denmark dropped from 8.1% in 2002 to 2.6% in 2014 (133). Unfortunately, the prevalence of DFUs remains high in developing countries. For example, in Romania, a prevalence of DFUs of 14.85% and amputations of 3.6% was reported (139). Similarly, in Africa, diabetes-related foot disease has been growing in recent decades (140). Studies from hospitals and health centres from Tanzania, Egypt, Ethiopia, Ghana, and Cameroon showed a high prevalence of DFUs (15.3 %, 4.4%, 13%, 11%, 11.8%, respectively) (100, 141-144). In Asia, the situation is no different, countries such as India, Iran, Thailand, Pakistan, and South Korea have shown a prevalence between 7.4%–11.6% (84, 145). In the Middle East, evidence of DFU prevalence is scant, with inadequate quality of the methods used according to a systematic review (146). The prevalence of DFUs was reported as between 4–11% in countries such as Saudi Arabia, Bahrain, and Jordan (146). More specifically, Jordan has an estimated 11,244 people with a DFU, with an overall prevalence of 0.299% in 2016 (83). DFUs are highly prevalent (4.6–5.3%) among people with diabetes according to hospital-based studies (147, 148). Overall, the prevalence of DFUs among patients with diabetes is still high in many countries.

Several factors have been found to increase the prevalence of DFUs, including gender (being male), type two DM, being a smoker, low body mass index (BMI), hypertension, and diabetic retinopathy (84). Duration of DM was also found to be associated with the prevalence of DFUs (100, 149, 150). Similarly, factors including sensory neuropathy, peripheral arterial disease, and foot deformities are associated with the presence of DFUs (100-103). However, there are some modifiable risk factors for DFUs that mainly relate to plantar pressure reduction, such as foot care (callus debridement), preventive footwear, and health education according to a 2020 systematic review (151).

DFUs have a high recurrence rate, with 40% of patients at risk of developing a recurring ulcer after one year, 60% within three years, and 65% within five years. Peripheral neuropathy, foot deformity, plantar pressure, and PAD are well known precipitating factors of DFUs recurrence (17). A recent meta-analysis reported other factors including male gender, smoking habits, and diabetes\ulcers duration (152). Recurrence of DFUs can be prevented through diabetes control, foot care, preventive footwear (reducing plantar pressure), foot skin temperature monitoring, vascular interventions, and adherence enhancement (17).

DFU recurrence could be responsible for high emotional and economic stress (20). For example, in the US, DFUs were shown to increase the risk for emergency department visits, hospitalisation, and new outpatient visits (153). In Australia, despite the significant reduction in the incidence of hospitalisation and amputations among patients with diabetes in recent years, the annual incidence of DFU infections is around (40%) (154, 155), which is responsible for 50% of all non-traumatic lower-limb amputations (156). According to a systematic review of 78 studies between 1980 to 2013, the mean prevalence of DFUs in the hospitalised general population was 4.6% and this was considered a leading cause of all hospitalisations in Australia (103). The average length of hospital stay of DFUs is between 5–38 days (157, 158). Length of hospitalisation can be affected by factors such as the severity of the inflammatory reaction, lack of blood glucose level control (HbA1c), BMI, and major vascular disease such as cerebrovascular accident (CVA) or coronary arterial disease (CAD) at the time of hospital admission (158).

2.3.2 Amputations

Diabetes is a common indicator of higher lower limb amputations (29, 30, 159, 160). The global estimation of diabetes-related amputations was recently reported from the global disease burden data (2016) (83). Around 4.26 million people had minor amputations, with an overall prevalence of 0.061%, and around 2.5 million people had major amputations, with an overall prevalence of 0.037% (83). However, a recent review estimated a decline (up to 85%) of diabetes-related amputations rates in several developed countries in recent decades (134). Similarly, several population studies showed this decline in countries such as Germany, Italy, Spain, and Taiwan (161-166). Interestingly, high amputation rates have been reported in some developed nations. In the Netherlands, according to a nationwide population-based retrospective cohort study between 2007–2011, the annual rate of non-traumatic diabetes-related lower limbs amputations ranged from 4.32–5.28 per 1,000 patients, which is twice that of some Europe countries (167). A comparative cross-sectional study conducted in Spain found that lower extremity amputation rates increased in 2013 compared with 2004 and this was very high compared with reports from developed countries (168).

The incidence of amputations varies in different diabetes-related populations. Indigenous populations in countries such as Australia and New Zealand are noted to have higher amputations than non-Indigenous populations (169-173). This could be due to genetic factors or socioeconomic factors that might prevent patients from receiving early intervention (170). Likewise, there was a variation in the prevalence of amputations related to diabetes between south and north China (2.6% vs 9.7%) (174). The severity of foot problems was found to be significantly higher in north China in addition to cost and risk factors (174). The same was found in Syria, with the incidence of major amputations among patients with diabetes reported as 8% (175) in comparison with a neighbouring country such as Jordan (1.7%), which shares a similar culture, race, and religion (91). The neglect of care for serious diabetic foot outcomes including PAD, infections, or heel ulcers during the Syrian war crisis may explain a large number of amputations in this country (175). Overall, amputation variation between populations can be related to factors such as social, behaviour, culture, race, and health care (132, 176). However, such predictions have to be carefully undertaken due to differences in amputation outcomes (major/minor), and different populations (diabetic/non-diabetic), in addition to the impact of different sociodemographic and commodities (177)

Diabetic foot ulcer infections are considered one of the main risk factors for lower limb amputations (156, 163, 178, 179). Amputations among patients with diabetes have also been associated with different factors such as neuropathy, retinopathy, foot deformities and PAD (91, 115, 165, 167, 180, 181). The presence of other diabetic comorbidities has been reported as a predictor of amputations. In a cohort study of 599 diabetic patients with DFUs, dialysis was found to be a negative predictor of healing and a positive predictor of amputations (182). Similarly, a recent study from Jordan reported chronic kidney disease as a predictor of below-knee amputation (183). Moreover, a retrospective study investigated the incidence of non-traumatic amputations in Spain between 2007–2013(184). Factors such as diabetes, foot ulcers, and previous amputations were associated with minor amputations (184). In addition to the previous factors, other studies have found anemia with haemoglobin < 11 or increased platelets levels were associated with major amputations (21, 185, 186). Finally, poor glycaemic control was also identified as a predictor of amputation in several studies (11, 187-189).

2.3.3 Mortality

Diabetic foot complications such as ulceration, amputations, or Charcot's foot have recently been determined as independent risk factors of premature death (85, 86). A systematic analysis found that the mortality rate of such complications ranged from 29–56.6%, which is higher than the pooled mortality of all cancers (31%) (85). Several studies have shown high related diabetic foot mortality (21-25). The five-year mortality rate among patients with foot gangrene was 71.4% (190). The 4–5 year mortality rate ranged between 16–42.6% among patients with diabetic foot syndrome (22, 191). The mortality rate was 32.8 % for 1 year and 70% for five years in a follow-up study of 140 diabetic patients who underwent major lower limb amputations (192).

In terms of mortality predictors among patients with DFUs, a prospective observational study investigated 10-year mortality rates of 69,992 patients and found that Charcot disease, DFUs under debridement, and lower-limb amputations were strong predictors of mortality (193). According to another retrospective study, other factors such as ischemic heart disease were significantly responsible for 62.5% of premature death among patients with neuropathic foot ulcers (194). Chronic kidney disease and the associated haemodialysis were a risk to mortality among patients with diabetic foot in Australia (195, 196). Further, DFU severity has been shown to predict mortality more than CAD, PAD, or stroke and it should be considered as a fatal warning sign (25, 190). A longitudinal cohort that analysed data from 414,523 people with diabetes in the United Kingdom (UK) did not find a significant association between amputations and the presence of different serious chronic illnesses such as CAD, CVA, or renal disease, while DFU was highlighted as a major cause of death (25). However, two systematic reviews (197, 198) confirmed the previous evidence, finding that the presence of serious comorbidities such as CAD or stroke can increase the risk of death among patients with DFUs.

2.3.4 Cost

The burden of the economic impact of DFUs on both individuals and health systems is high, especially with lost productivity (85). The cost of managing DFUs is the highest among chronic wounds according to a systematic review (2017) (137). To best of the PhD candidate's knowledge, there is no estimation of the global costs of DFUs. However, several studies have reported the national costs of DFUs. For example, diabetic foot complications cost around 580 million pounds in the UK in the period between 2010–2011 and this represented 0.6 % of the National Health Service charges (199). A recent report from the same country (National Health Service) found that length of stay (>8 days) was significantly associated with the high cost of diabetic ulcers and amputations and this was estimated as higher than the total cost of breast, prostate and lung cancers (200). The annual cost of treating DFUs in the US ranged from $9–13 billion USD for both private and public payers. This cost was higher among diabetic patients with DFUs than diabetic patients without DFUs. They had more days of hospital stay, home care, emergency visits, and out patients visits (27). In Canada, in the year 2011, the estimated annual cost of DFUs was around $ 547 million due to the rising DFU prevalence. The acute institutional care (hospitalisations, clinics follow up, and surgical procedures) represented $320.5 million with an additional $125.4 million for home care and $63.1 million for long term care (26). Turkey also had high average costs for treating DFUs. This cost was an economic burden for this country due to several factors including the length of stay, health services and required equipment (28). In Denmark, the average cost of treating DFUs was 4.5 times higher than average cost of the hospitalised medical patients. For instance, the median cost of surgical treatment of DFUs was around 17,970 euro (24). In Jordan, the estimated mean cost of non-traumatic amputation (89.3% of non-traumatic amputations occur in patients with diabetes) is 4904.7USD, with the duration of either admissions or operations found to impact on this cost (201).

However, the high cost of managing DFUs can be significantly reduced if optimal care is implemented instead of usual care. The estimated total saving could reach 2.7 billion AUD over five years, highlighting the importance of applying evidence-based guidelines in daily practice, as this could reduce hospitalisation, infections, and lower extremity amputations (202).

2.3.5 Quality of life

Health-related quality of life (HRQOL) is an important self-report aspect that has been widely investigated among patients with diabetic foot disease (203). Patients with DFUs reported poorer HRQOL than other patients with diabetes (204, 205). A recent meta-analysis of 12 studies found that people with DFUs had poor HRQOL in domains such as physical functioning, role physical, general health, and vitality (87). For example, physical domains include activities such as mobility, self-care, and usual activities (206). Limited physical activity due to ulceration may lead to social isolation, which may influence HRQOL (136, 207). For example, treatment such as offloading is associated with limited mobility and this can negatively affect HRQOL (208). Depression was also found to be a psychological predictor of poorer HRQOL among patients with DFUs (209, 210). Usually, psychosocial determinants including depression and anxiety can develop before and after amputations (31, 206, 210). Other factors such as older age, female gender, being obese, presence of PAD, presence of pain, higher grade on Wagner scale, and longer ulceration were found to be significant predictors of lower HRQL (87, 207, 211).

2.4 DIABETES-RELATED FOOT ULCER MANAGEMENT

Reducing plantar pressure (offloading) is one of the primary recommended treatments to manage DFUs according to the latest International Working Group of Diabetic Foot (IWGDF) guidelines (34). As such, offloading is critically reviewed in the following chapter, while in this chapter, other recommended treatments by the IWGDF are briefly reviewed, including local wound care and adjunctive therapies.

2.4.1 Local wound care

Local wound care can be achieved through wound debridement, moisture balance, and control of the infection and inflammation (212).

2.4.1.1 Debridement

Debridement is an important element in managing DFUs and has several benefits. First, removing the necrotic tissues enables clinicians to assess the wound. Dead tissue is also a good medium for growing bacteria, which can consume a lot of the local resources from the wound such as oxygen and nutrition. Last, keeping hard skin such as callus or hyperkeratosis can work as a physical barrier or increase the plantar pressure, which may prevent keratinocyte migration. As a result, epithelisation may not occur (213, 214). Therefore, theoretically, debridement seems necessary to facilitate wound healing.

However, despite the logical rationale for the role of debridement, the evidence to support its benefits on wound healing is insufficient according to a meta-analysis of five studies, because most clinical trials in this review were not randomised controlled trials (214). However, another meta-analysis of 11 RCTs showed evidence of the efficacy of different types of debridement to accelerate wound healing and reduce amputation (215). According to the IWGDF, debridement is strongly recommended, although clinical evidence that supports different methods of debridement is not strong (216). Debridement can be performed using sharp, mechanical, enzymatic, autolytic, and biological methods (213, 215). The latest IWGDF guidelines strongly recommend sharp debridement in preference to other methods despite the low quality of evidence considering pain or PAD (216).

2.4.1.2 Moist environment

A balanced moist environment is another important element for local wound care (212, 213, 217-219). Moist wound healing was firstly described by George D Winter in 1962 in his in vivo study on young domestic pigs, where he noted that the rate of epithelisation in wounds was faster if they did not develop dry scab (220). Later, another study compared a dry versus a moist environment for wound healing. It was noted that the number of inflammatory cells such as the neutrophils and macrophages decreased under moist conditions (221). Moist wounds were also associated with the rapid rise of fibroblasts and endothelial cells, which are necessary for the proliferative phase in the wound healing process (221). Moist wound healing may also decrease issues such as tissue necrosis and dehydration and accelerate healing through enhancing the angiogenesis quality (222, 223).

Many wound dressing products have been introduced to maintain a moist wound bed such as hydrocolloid, hydrogel, foam, and alginate dressings (224, 225). However, there is no conclusive evidence to support the superiority of any types of dressings such as foams, hydrocolloid, or alginate (216, 225, 226). However, a recent meta-analysis of nine studies supported the effectiveness of hydrogel dressings in reducing the healing time of DFUs compared to other dressings (227). Similarly, another meta-analysis found honey to be an effective dressing to enhance healing of DFUs and reduce bacteria and dead tissue (228). There was a reported risk of bias in the findings of this meta-analysis, as different types of honey were compared, and there was an absence of double-blinding and small sample sizes (228). Overall, the IWGDF strongly recommends that the selection of advanced dressings should be based on providing a moist environment or controlling exudate; however, the potential cost and patient satisfaction should be considered (216).

2.4.1.3 Control infection

Infection is a common problem in chronic wounds, frequently resulting in non-healing and significant patient morbidity and mortality (229). In general, open wounds are colonised with different microorganisms and this leads to infections that can progress from critical colonisation (230). In the case of diabetic foot infections, the IWGDF strongly recommend using antibiotics that have been proven to be effective if clinical signs of infection are present, such as penicillins, cephalosporins, carbapenems, metronidazole (in combination with other antibiotics [s]), clindamycin, linezolid, daptomycin, fluoroquinolones, or vancomycin, but not tigecycline (231).

Local antimicrobial agents can be also used, but not for the aim of healing wounds or treating infections (216, 231). Many antimicrobial agents and cleaning solutions have been widely used in clinical practice such as silver dressings, chlorhexidine, povidone-iodine, hydrogen peroxide, and honey (213, 217, 232, 233). For example, silver products kill microorganisms through different pathways, such as the hydrophobic effect of silver ions (Ag^+) by depleting the fluid and electrolytes from microorganisms which leads to bacterial dehydration and death (234). However, the clinical evidence to recommend using silver dressings in control infection or promote healing of DFUs is absent or not clear according to four systematic reviews (235-238). However, silver dressings can improve patients' HRQOL and reduce treatment costs based on two systematic reviews (238, 239). In general, the IWGDF strongly recommend avoiding using local antimicrobial agents for the aim of accelerating wound healing due to lack of quality evidence (216).

2.4.2 Adjunctive therapies

Adjunctive therapies such as growth factor therapies, matrix metalloproteinases (MMPs) inhibitors, hyperbaric oxygen therapy (HBOT), or negative pressure wound therapy are available advanced treatments to manage DFUs (216). However, there is a lack of definitive evidence to support the wound healing effects of growth factors (240), MMPs (241), or HBOT (242). Overall, the IWGDF weakly recommends growth factors, bioengineered skin products, HBOT (only systematic and with ischemia), and negative pressure wound therapy (cost should be considered) and strongly does not recommend modalities such as electrical stimulation, ultrasound, and shockwaves (216).

2.5 CHAPTER SUMMARY

Diabetes is responsible for the development of microvascular complications such as neuropathy. The absence of the "gift of pain" due to sensory neuropathy is responsible for continuous repetitive injury and developing DFUs. Motor neuropathy may lead to the development of foot deformities. As a result, rising pressure forces significantly affect the plantar of diabetic patients' feet, such as the mean plantar pressure and shear forces. The presence of both sensory and motor neuropathy is responsible for rising plantar pressure forces, which leads to callus formation. As a consequence, the skin may break down and lead to a chronic open wound (i.e. DFU) associated with a high risk for infection and poor healing.

DFUs are an epidemic condition associated with several burdens. Non-traumatic amputations are one of the devastating outcomes of DFUs. High mortality rates have also been reported among people with DFUs. Further, the treatment of DFUs is costly due to hospitalisation or performing surgical procedures. Finally, the HRQOL of patients with DFUs is poor due to the impact of the condition itself.

DFUs can be managed through local wound care including moist environment, debridement, and control infection. However, the causal pathway of developing DFUs explains the associated continuous trauma of the epidermal skin due to the presence of calluses and high plantar pressure that result from both sensory and motor neuropathy. Reducing pressure forces by offloading treatment therefore seems crucial, which is the strongest recommended treatment by the IWGDF. Thus, offloading treatment is critically reviewed in the next chapter.

Chapter 3: Review of Literature on Offloading Treatment and Adherence to Removable Cast Walkers (RCWs)

3.1 BACKGROUND

As discussed in the previous chapter, offloading is essential to managing plantar diabetic foot ulcers (DFUs). This is mainly achieved through redistribution of the pressure away from the wound tissue and typically over a wider contact area of the foot and/or lower leg) (243). Several methods have been used to try and achieve the offloading goal of reducing plantar pressure including bed rest, wheelchair, crutch-assisted gait, total contact cast (TCC), felted foam, half-shoes, therapeutic shoes, custom splints, and removable cast walkers (RCWs) (34, 35). However, high level evidence supports the recommendation of using non-removable knee-high offloading devices (34, 244). For instance, knee-high offloading devices such as TCC or instant TCCs (iTCCs, defined as RCWs rendered non-removable), and RCWs are effective offloading devices for reducing forefoot plantar pressure (244). However, applying RCWs, which is common practice in many countries (245-247), is associated with poor or partial adherence (52, 54) because of the removability feature of these devices (patients may prefer not wearing them continuously) and results in delayed wound healing outcomes as reported by several systematic reviews (48, 49, 94, 244, 248). Therefore, this chapter aims to provide a review of the existing literature on different offloading modalities and their effects on healing DFUs. Adherence to RCWs and other chronic conditions are then reviewed and discussed.

3.2 KNEE-HIGH OFFLOADING DEVICES

Knee-high offloading devices can be prescribed to be non-removable (TCCs or iTCCs) or removable (such as RCWs). However, apart from being removable, RCWs share similar functional characteristics with TCCs, including ankle immobilisation and pressure reduction (43). In contrast to custom-made TCCs, RCWs are prefabricated, easy to apply and allow more frequent inspection of the wound due to their removability. Further, patients can remove them before bathing and sleeping.

However, patients sometimes prefer not to wear them consistently, which gives TCC an advantage through forcing adherence (35, 36, 249). Non-removable knee-high offloading devices are associated with significantly higher healing rates in comparison with removable devices due to enforced adherence and less physical activity (244). Thus, in this section, knee-high offloading devices such as TCC, RCWs, and iTCCs are introduced by describing their action and characteristics, followed by a discussion of their advantages, disadvantages, and clinical effectiveness.

3.2.1 Total Contact Cast

Dr Paul Brand was the first to report the use of TCCs to manage plantar neuropathic foot ulcers in treating patients, as cited in Coleman et al. (250). TCCs have now been found to reduce plantar pressures by 84–92% compared with normal footwear (244, 251-253). The mechanism of the offloading capacity of TCC has been explained by a combination of factors. First, TCC walls bear the load and suspend the foot and this plays a significant role in reducing plantar contact area. Second, using soft cast materials that inlay inside the TCC helps reduce the plantar pressure. Third, using rigid cast materials that extend to the ankle fixes the ankle, which helps in plantar pressure redistribution (254). Lastly, TCC ensures adherence and decreased physical activity because it is not removable (254).

The effectiveness of TCC to promote DFU healing has been demonstrated in many studies, including systematic reviews (48, 49, 94, 244, 248). However, despite the biomechanical characteristics and the clinical efficacy of TCCs in reducing healing time (50, 255-257), it is not always considered the best choice by many clinicians (41, 56, 245-247, 258). TCC was reported in only 2.2% of 221,192 visits from 2007 to 2013 in a retrospective study that extracted data from the US Wound Registry (247). Another survey from the US found that TCC was only used by 1.7 % of foot clinics, despite 55.3% of these clinics considering TCCs to be the gold standard (245). Factors such as the patients' tolerance, preparation time, material costs, and lack of experience were associated with not applying TCC as standard treatment (245). Similarly, another study conducted in 10 different European countries found that TCC was only applied in 13% of patients who needed this treatment due to factors such as high materials costs, technical limitations, and poor patient acceptance (41). Clinicians' lack of awareness or disagreement with the guidelines may also explain this (246, 247, 259). Due to this underuse of TCC, recent expert opinion suggests a re-thinking of considering TCC as a gold standard treatment, with another offloading option such as iTCCs as a possible alternative (92).

Applying TCC in clinical practice is associated with several disadvantages. First, TCC is time-consuming and many health care settings do not have skilled technicians to safely apply TCC (38, 246). Second, improper application can cause skin irritation, or even ulceration in some cases (44). Third, based on expert opinion, TCC and non-removable offloading devices are contraindicated if ulcers have mild-moderate infections or ischemia or when heavy exudate is present (34, 35, 261). Fourth, TCC is not favourable for patients with lower satisfaction (56, 262) as impaired activity, sleeping difficulties, and difficulty in avoiding wetting the cast during bathing are examples of the negative impact of TCC on patients' health-related quality of life (HRQOL) (42, 56, 248). Last, according to Roser et al (45), TCC also may have a significant impact on the health of the knees, hip, and back. The unilateral configuration of TCC has an asymmetrical elevation of the heel that leads to these health issues. TCC can also negatively affect the health of the limb. Total limited mobility of the foot during wound healing treatment by TCC is associated with muscle loss. As a result, gait issues can occur, which raises the forefoot plantar pressure and increases the chance of re-ulceration (45).

However, one prospective study in the US found TCC was a suitable offloading option for patients as it did not show a significant impact on their HRQOL, while wound healing time was the main influence on HRQOL (263). Another study found no difference between TCC and removable offloading devices in terms of satisfaction and comfort (264). More interestingly, TCC was reported as favourable to patients as they believed in the advantage of TCC in comparison with the removable offloading devices in terms of wound healing (248). Therefore, TCC is seen as an effective offloading method to manage DFUs; however, it can be associated with several disadvantages.

3.2.2 Removable Cast Walkers

Due to the disadvantages of TCCs mentioned above, knee-high RCWs can be an effective alternative offloading option to reduce plantar pressure. RCWs provide very similar biomechanical features to that of TCCs, and this is supported by a moderate quality of evidence (43, 44, 244, 251, 253, 265). The mechanism of the RCWs in reducing pressure is not clearly recognised. However, it is believed that the struts in these devices inhibit the movement of the ankle joint, leading to limiting the isolated pockets of high pressure that affect the feet. In addition to the locked ankle and the rocker insole in RCWs, a large portion of the foot keeps contact with a subsequent loading during steps. This combination prevents heel to toe step progression (43).

Although knee-high RCWs are beneficial in reducing forefoot pressure (43, 251, 253, 265, 266), a recent systematic review by the IWGDF (244) found high quality evidence (based on several high-quality systematic reviews) that supports the inferiority of these devices in comparison with non-removable offloading devices in healing DFUs (49, 93, 94, 248, 267). In most of these reviews, improved healing rates associated with non-removable devices were explained by the enforced adherence to these devices. In contrast, one meta-analysis (49) did not show statistical significance between RCWs and non-removable devices in terms of complete wound healing. However, according to Morona et al. (49), non-removable offloading devices are more likely to heal ulcers than removable devices, which demonstrates the importance of patients’ adherence to achieving successful offloading treatment. Therefore, patients’ adherence to wearing RCWs seems to be a very important factor that significantly affects the healing outcomes among patients with DFUs, and as such, clinicians should be aware of their patients’ capabilities to follow this offloading regimen.

3.2.3 Instant Total Contact Cast

Due to the disadvantages of TCCs and the RCW non-adherence, Katz et al (268) suggested a new concept of offloading modality called instant total contact cast (iTCC). In this model, RCWs are wrapped using a single strip of fibreglass casting material to ensure non-removability, which enforces adherence. This new model has been compared with TCCs in several randomised controlled trials (RCTs). Two RCTs (40, 268) showed that iTCCs had the same efficacy of TCCs in terms of healing, supporting the role of patient adherence in previous studies (47, 50, 54, 244). The successful results of iTCC were explained by the non-removability of these devices. iTCCs were also associated with taking less time to apply, were more cost-effective, and considered a favourable offloading option for patients (40). However, when compared with RCWs, two studies found that iTCCs had higher healing proportions than RCWs (51, 249). Patients’ activities were measured in one study (51) showing that the physical activities of patients changed over time during treatment. According to Najafi et al (51), this may be due to poor adherence to wearing RCWs. Thus, these studies confirm the importance of the role of patients' adherence in wearing RCW offloading devices to achieve the best healing results.

3.2.4 The positive outcomes of removable cast walkers

Removable cast walkers have been found to have less successful healing outcomes in managing DFUs in comparison with non-removable offloading devices in the majority of research studies (244). However, a few trials found no difference in healing results between RCWs and non-removable offloading devices (55, 262, 269). Piaggesi et al (262) found that there was no significant difference in healing time for three groups of different offloading modalities in an RCT study where TCCs were compared with RCW and iTCCs in three different groups of 20 patients each for three months. The healing proportions showed no statistical differences at 95%, 90%, 80%, respectively. Similarly, another two RCTs with small sample sizes (< 60) (55, 269) compared RCWs with non-removable fibreglass off-bearing casts in treating DFUs, with no significant difference in terms of wound size reduction and healing time. However, these results are not consistent with the non-removability benefits of TCCs and iTCCs found in previous studies and systematic reviews (40, 50, 54, 249, 268). Piaggesi et al (262) suggested the difference in healing outcomes of their study may be due to the role of clinicians in providing continuous support and explanation of the importance of wearing the devices by patients during treatment, motivating them to achieve better adherence (262). Faglia et al (2010) explained the positive healing results of RCWs and patients' positive adherence to wearing these devices due to the population of this study who had some experience with previous ulcerations or minor amputations. These explanations confirm the suggested critical impact of adherence to wearing RCWs on the healing of DFUs.

In summary, this review found that non-removable offloading devices such as TCCs and iTCCs have the advantage in terms of ulcer healing rates in comparison with RCWs, and this is mainly related to the enforced adherence that these devices provide. This is in line with the IWGDF guidelines considering non-removable offloading devices as the gold standard offloading treatment (34). Making RCWs non-removable has been shown to solve the non-adherence issue (iTCC) (40, 268). However, the removability feature of RCWs can be a preferable option for patients and clinicians (46, 56, 251) making them more commonly used (41, 56, 245-247, 258). Unfortunately, as mentioned, adopting RCWs can be associated with poor adherence, which can significantly impact healing outcomes; thus, it is only the second recommended offloading option by the IWGDF (34). Identifying the levels and determinants of patients' adherence to wearing RCWs seems critical to improving their clinical outcomes to increase the optimal use of RCWs, which may become a potential option as recommended offloading in the future.

3.3 REVIEW OF ADHERENCE TO WEARING REMOVABLE KNEE-HIGH OFFLOADING DEVICES

The issue of patients' poor adherence to wearing RCWs was clearly illustrated in the previous section. This section presents a review of the literature that aims to identify the current knowledge on levels of and factors associated with adherence to wearing RCWs among patients with DFUs. For this review, the concept of RCWS is defined as including removable knee-high offloading devices in general, including custom-made devices (i.e. bivalved TCC) and prefabricated offloading devices (i.e. pre-manufactured RCWs).

3.3.1 Search strategies

Publications were identified through a search of electronic databases including PubMed, MEDLINE, CINAHL, Embase and the Cochrane Library for studies published in the English language between 1st January 2000 and 1st October 2020. Rudimentary search strings were employed for each database that included a combination of the following keywords: (offloading AND adherence) OR (offloading AND compliance) OR ("removable cast walkers" AND adherence) OR ("removable cast walkers" AND compliance). Eligibility criteria included original studies investigating populations of people with DFUs, interventions that included removable knee-high offloading devices, and outcome measures of adherence levels to wearing them. All human study designs published in English were eligible, except for case reports, narrative reviews, or commentaries. One author (the PhD candidate) screened all titles and abstracts of retrieved studies to determine eligibility based on the study meeting all the above criteria. Any studies identified as potentially meeting all eligibility criteria had their full texts retrieved and reviewed to confirm. Studies were included if they met all criteria after a full-text review. The reference lists of included studies were also hand searched for further potential eligible publications using the above eligibility criteria.

3.3.2 Results

This search yielded 389 records (see Figure 3.1). From these records (titles and abstracts), 10 were duplicates and 376 did not meet the inclusion criteria, leaving only three included studies in this review after assessing the full text. The most frequent reason for exclusion was studies that did not include an outcome measure of adherence to wearing removable knee-high offloading devices. Of the three included studies (see Appendix (1), two were prospective observational studies conducted in the United Kingdom (UK) and/or the United States (US) (52, 54), whilst the other study was an RCT conducted across Germany and the Netherlands (53). All three studies measured the level of adherence (52-54) and only one investigated the factors associated with patients' adherence to wearing RCWs (52).

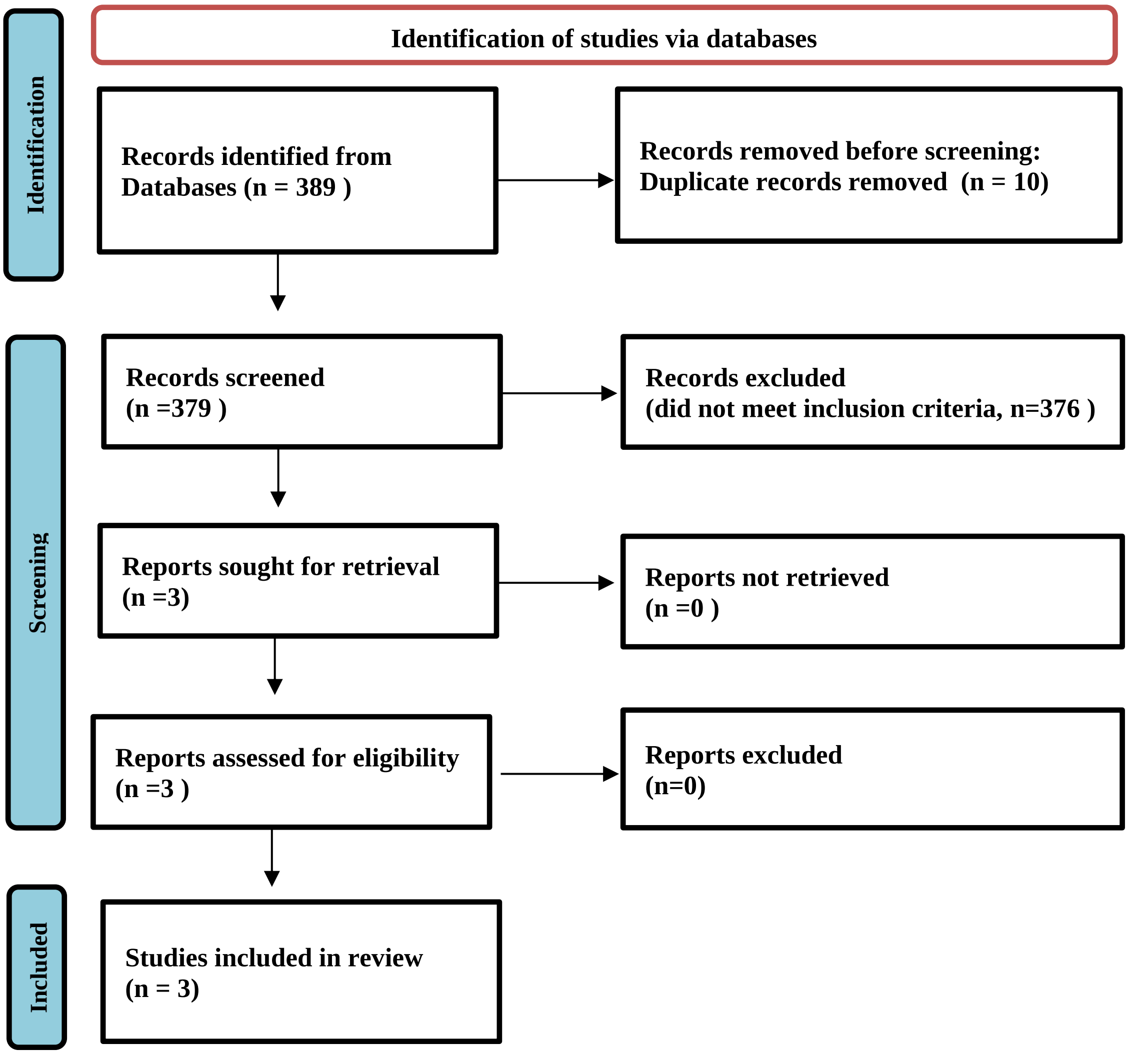

Figure 3.1: Flow chart of the included studies

The first study from Armstrong et al (54) was an observational study investigating the level of adherence to wearing RCWs in 20 participants with superficial plantar DFUs (Grade 1, Stage A; based on the University of Texas Classification (UT)) for seven days (54). Adherence was objectively measured by attaching two accelerometer/pedometers (Biotrainer Pro; IM Systems, Boston, MA) to each participant: one attached to the waist to measure total activity (mean daily steps) and the other attached within the posterior aspect of the offloading device to measure adherent activity (mean daily steps wearing the offloading device). Adherence levels were then determined by calculating the mean daily steps wearing the RCWs, divided by the mean total daily steps measured at the waist. However, this study was associated with risk of bias including the small sample, the non-described source of population, and inclusion criteria that did not represent the diabetic foot population.

The study found that 28% of participants' mean total daily activity were taken when adherent to wearing the RCWs (54). The authors concluded that patients generally do not wear their removable offloading devices, and this may be a reason for the less effective healing outcomes previously identified when using these devices compared to TCCs (54). Measuring adherence objectively was the main strength of this study, while limitations included: i) waist activity monitors being applied by patients, and as such, they may not have worn them at all times to detect total activity and adherence; ii) small sample size; iii) the factors associated with adherence were not measured; and iv) the authors did not clarify whether the RCWs investigated were knee-high or ankle-high or both.

The second study from Crews et al (52) was another observational study investigating the level and predictors of adherence to wearing removable offloading devices in 79 participants (61 of whom were using RCWs and 18 using sandals and other offloading devices) with neuropathic DFUs (Grade 1, 2; Stage A, B; UT) for six weeks. Adherence was objectively measured by attaching two activity monitors (Lifecorder Plus, Suzuken) to each participant: one attached to the hip to measure total activity time and the other attached and concealed to the removable offloading device to measure adherent activity time. Adherence was defined if the offloading device activity monitor reported activity for at least half of each 2-minute epoch period that the hip attached activity monitor reported activity. Activity levels were then determined by the percentage of epochs defined as adherent by the total epochs of activity reported. This study was associated with a risk of bias in terms of the selected population (not including severe DFUs). The selected explanatory variables were also not based on theoretical guidance.

The study found that patients wore their devices for 59 ± 22% of their total daily activity (52). The authors also identified that higher offloading adherence levels were independently predicted by larger DFUs, more severe DFU categories, and more severe neuropathy and neuropathic pain (all, $p<0.05$). Conversely, lower offloading adherence levels were independently predicted by higher postural instability ($p<0.05$). Interestingly, psychosocial factors such as beliefs, personal control, and depression were found not to be predictive of adherence (all, $p>0.05$). Finally, this study identified that faster healing at six weeks was predicted by higher offloading adherence levels and smaller DFUs at baseline ($p<0.05$). The main strength was measuring adherence objectively for six weeks, which helped in predicting determinants of adherence and their impact on DFU healing. The limitations of this study included: i) activity monitors being applied by patients, and as such, patients may not have worn them at all times to detect adherence; ii) using the activity trackers was without validation, as no inter-device reliability or validity supported it (using two activity trackers on both waist and lower limb); iii) whilst most wore RCWs, some wore other removable offloading devices; iv) cognitive factors investigated such as knowledge, beliefs or personal control were tested using scales related to DFUs self-care as no available specific offloading cognitive scales; and v) the relatively small sample size of this study may have resulted in it being underpowered to detect more factors that were independently predictive of adherence to wearing RCWs. The third study from Bus et al (53) was an RCT that randomised 60 participants with neuropathic forefoot DFUs (Grade 1, 2; Stage A; UT) to three different types of removable offloading devices: i) custom-made removable knee high-offloading device (bi-valved TCC); ii) custom-made removable ankle-high offloading device (cast shoe); or iii) pre-fabricated ankle-high offloading device (forefoot offloading shoe). Each participant was followed for 20 weeks and asked to self-report their level of adherence to wearing their offloading devices every 2-week visit after enrolment. The self-report comprised customised Likert questions that simply asked participants if they considered they were >50% adherent or <50% adherent to wearing the device at all times when outdoors/indoors in the previous two weeks. They found that 17.3% of participants in the custom-made removable knee high-offloading device did not adhere (wore the device <50% of all times at each visit) to wearing their offloading device, which was not significantly higher than those in the custom-made removable ankle-high offloading devices (5.2%) and prefabricated ankle-high offloading devices (4.9%) ($p = 0.236$). The limitations of this study included: i) using a customised self-reported measure of adherence without validation; ii) small sample size for those wearing knee-high offloading devices; and iii) the subsequent lack of power to investigate any factors that may predict adherence.

3.3.3 Discussion

This review highlights a knowledge gap in understanding adherence to wearing knee-high offloading devices in people with DFUs. Only three relevant studies (52-54) were identified. However, despite adherence being measured objectively in two studies, all of the included studies are associated with risk of bias as they included only the superficial non-ischaemic and non-infected DFUs which wound healing was a main outcome (there was a need to control infection and ischemia) in two of them (52, 53). This means that current evidence does not represent adherence to offloading for all of the diabetic foot population, especially those with severe complications such as infections and ischemia, and this gap needs to be filled in the future research.

From the literature, identified adherence levels ranged from 28–59% of daily activity time in two studies using objective adherence measures (52, 54) and up to 83% of patients self-reported they were adherent to wearing these devices most of the time in the other trial (53). However, only one of these studies (52) investigated factors that may predict adherence to wearing knee-high offloading devices in this population and found that higher adherence was predicted by those who had factors such as neuropathic pain, larger DFUs, more severe neuropathy, and more severe DFUs and lower adherence in those with postural instability. Importantly, this study also identified that better adherence to wearing RCWs predicted better DFU healing outcomes. Thus, this review highlights the paucity of literature and the need for greater research exploring the predictors of better adherence to wearing knee-high offloading devices in people with DFU to improve DFU offloading care for people with DFU.

Removable knee-high offloading devices have been found to reduce equivalent plantar pressures to that of the gold standard non-removable knee-high offloading devices in people with DFU, as they both possess very similar structural properties (43, 262). However, removable knee-high offloading devices have much poorer healing outcomes than non-removable knee-high offloading devices. The major reason for this poorer healing has been hypothesised to be poor adherence levels to wearing removable knee-high offloading devices among people with DFUs compared to the enforced adherence gained from the same device made non-removable (34, 48). The findings of this review provide some collective evidence to support this hypothesis, suggesting patients do not always wear their prescribed removable knee-high offloading devices for their weight-bearing activity (52, 54) or time (53). In practice, this means that patients choose to go untreated, and in turn, unprotected from the high plantar pressures that significantly impedes their DFU healing for considerable amounts of time (48). Thus, when comparing wearing a knee-high offloading device for 28–59% of the prescribed activity time (52, 54) with wearing the same device 100% of the prescribed activity time as occurs with the same device being made non-removable, it becomes apparent why the outcomes in terms of DFU healing are significantly different (48). However, far fewer patients and clinicians are known to use non-removable knee-high offloading devices in practice compared with the many using the equivalent removable devices (41, 56, 245-247) demonstrating why understanding the factors that influence improved adherence to wearing these removable offloading devices may be critically important to making significant improvements to DFU healing outcomes globally.

Adherence to offloading has recently been defined as “the extent to which a person is adhering to wearing a prescribed offloading intervention while weight-bearing” (126 p873). According to Osterberg and Blaschke (270) to improve patients’ adherence for any treatment the potential factors that act as barriers for such treatment adherence need to first be understood. However, understanding the factors that contribute to patient adherence is not an easy task and has long been considered one of the more complex fields of patient behaviour, particularly among people with chronic disease (58, 59). Whilst the context of the factors that impact on patients’ poor adherence to wearing knee-high offloading devices is certainly not fully understood from the limited evidence found in this review, some previous hypotheses have been proposed to explain the issue of poor adherence to wearing them. Armstrong, Isaac (36) argued that “individuals with diabetes who have lost the gift of pain” may not always appreciate why they need to adhere to the offloading regimen due to their sensory neuropathy that may ‘block’ one of the main physiological factors that seem to improve patients' adherence to treatment for any condition, that of pain. This hypothesis seems to be supported by Crews et al (52), the only study identified by this review to investigate predictors, which found pain and more severe DFU predicted better adherence. However, this study (52) also found contrary findings, with sensory neuropathy predicting higher adherence. This may be because the predictive factor of more severe neuropathy is more likely to be confounded by having more neuropathic pain, but it also may mean that people with more severe sensory loss and other implications on motor control may feel more confident in these devices. However, this remains unexplored and requires further research. In contrast, the same study (52) found that motor neuropathy and the related postural instability were associated with less adherence to wearing the removable knee-high offloading devices, which highlights the conflicting impact of different types of neuropathy on adherence to wearing removable knee-high offloading devices in people with DFUs.

Adherence to wearing removable knee-high offloading devices can also be influenced by several patient-related barriers. According to a survey of Australian podiatrists, these barriers include patient acceptance, quality of life, perceived negative consequences, and some religious and cultural barriers (56). Similarly, a recent qualitative investigation highlighted the difficulty patients have in wearing these devices, which could also be a potential barrier to adhere to wearing them (57).

3.3.4 Strengths and limitations of the review

There are several strengths to this review. The review is unique as it is the first to review the literature specifically investigating adherence predictors to wearing removable knee-high offloading devices in people with DFUs. Whilst identifying limited evidence, it has highlighted some objective evidence for the levels and predictors of adherence that should help facilitate future research and early clinical strategies to enhance adherence to removable knee-high offloading devices and other important diabetes-related foot treatment. There are limitations of this review as the search was only performed by one author; however, the review identified the same publications identified by a recent international diabetic foot guidelines for the same topic (34). Furthermore, no formal quality assessment or data extraction was performed as there were only three included studies, which were thus reviewed individually. Finally, the search strategy only targeted reports published in the English language leaving the possibility of missing the offloading adherence research in other languages.

3.3.5 Conclusions of the review

This review found limited objective evidence on adherence to RCWs. The few conducted studies showed that patients poorly to partly adhere to wearing their removable offloading devices. Only one study found factors such as the severity of neuropathy, neuropathic pain, and postural instability can predict patients' adherence to wearing removable offloading devices. Therefore, future research is required to examine broader factors that may assist understanding and help predict and improve adherence to this pivotal treatment to heal DFU.

3.4 FACTORS INFLUENCING ADHERENCE IN OTHER CHRONIC CONDITIONS

Due to the minimal evidence regarding the predictive factors to wearing RCWs, a broad review of previous studies related to patients' adherence to other treatments in other conditions would be useful and was conducted to develop some theoretical understanding of this health behaviour. Different factors associated with adherence to other similar treatments such as preventative footwear and other chronic conditions have been reported and are addressed below.

3.4.1 Knowledge or beliefs

Lack of knowledge related to understanding care and prevention of DFU is common among patients with DFUs according to a systematic qualitative review (271). However, there is no evidence to support the impact of patients' knowledge or beliefs on adherence to wearing removable knee-high offloading devices (52). The investigation of such cognitive factors has mainly related to patients' perception of DFU onset, consequences, and treatment effectiveness. These findings did not specifically address the relationship between beliefs or knowledge of the importance of wearing knee-high offloading devices or adherence levels, in which this association has been suggested as a potential predictor. Two trials found no significant differences between TCCs and removable knee-high offloading devices in DFU healing and both hypothesised this may have been because of high patient adherence levels to wearing the removable knee-high offloading devices in their knowledgeable patient population, although they did not measure adherence (55, 262) However, a meta-analysis of the effectiveness of patient education to other treatments to prevent DFUs found a lack of evidence to support the impact of enhancing knowledge on improved adherence to other self-care activities (272).

In relation to footwear prescribed to prevent DFUs, which has some physical and treatment similarities to removable knee-high offloading devices, knowledge was also found not to be associated with adherence outcomes (273). Only 28% of the study population wore their footwear more than 80% of the day, despite 90% of patients reporting that wearing the shoes was important or very important (273). However, another study highlighted the possible impact of beliefs on adherence to wearing their prescribed therapeutic footwear in which patients' adherence was found to be higher in those with more severe foot deformities due to the limited wearing options those patients had, or their increased awareness of the benefits of footwear (274).

However, poor patient knowledge or beliefs about treatment were associated with negative adherence in different clinical studies (63, 66, 69, 275-278). An observational study found that factors such as patients' knowledge was associated with improved treatment adherence to compression treatment among patients with venous leg ulcers (VLUs) (279). Similarly, patients' understanding, including knowledge, beliefs, and attitudes about type 2 diabetes, was recognised as the main factor that predicted patients' non-adherence with diabetes medications (275). If patients with diabetes received education, they had better adherence for self-monitoring activity (66). Patients' beliefs about medications have also been found to be a powerful predictor for adherence in other similar chronic conditions (278). According to a prospective cohort study (63), 38% of patients with rheumatoid arthritis reported a lack of belief for the benefits of treatment, which was associated with patients' adherence to the medications (63). A systematic review also showed that stress, patients' beliefs about medications, and patient-doctor disagreement were associated with non-adherence to oral medication for inflammatory bowel disease (276). Therefore, patients' knowledge or beliefs about the significance of wearing RCWs may be a potential predictive factor for adherence outcomes that needs to be tested in future research.

3.4.2 Self-efficacy

Several studies have reported that patients who were not confident or did not believe in their abilities to adhere to the prescribed treatment had lower adherence levels to those treatments (68-73, 76, 280). Personal belief in the ability to accomplish specific behaviour was firstly described by Bandura and Adams (281). This concept has been popularised in different health domains as self-efficacy (77). Self-efficacy can motivate people, especially when they receive feedback on their achievement (281). Self-efficacy is a central concept in self-management (282-284) that can enhance patients' skills of problem-solving and making decisions (285).

In people with DFU, self-efficacy can explain motivation. A recent study showed that patients were more motivated to adhere to self-care activities of DFUs if they were provided objective monitoring feedback on the healing progress of their wounds. (286). According to Bandura and Adams (281), when people are successful in achieving their tasks, they are more motivated (performance achievement). Another recent study found the level of a patients’ self-efficacy is a significant factor that predicts the level of intention to adapt to using wearable technology, such as smart insoles to prevent DFUs and found people who had higher self-efficacy levels related to using this technology had higher acceptance for using that technology (287).

However, in the context of removable knee-high offloading devices, Crews et al (52) did not find a significant association between perceived control, which is quite similar to self-efficacy, and adherence. However, the scales used to measure perceived control in this study were related to general foot and ulceration care. Measuring offloading adherence specific to self-efficacy be can more informative to provide evidence when testing the association between self-efficacy and offloading adherence. A recent expert opinion article suggested a more specific exploration of these psychosocial factors in offloading research (288).

In other chronic conditions, one longitudinal study illustrated that high self-efficacy was significantly associated with a low rate of recurrence of chronic VLU (68). In another study, patients’ compliance for VLUs compression therapy treatment was also affected by self-efficacy (69). Similarly, an RCT found that a self-efficacy intervention improved the healing outcomes among patients with VLUs (280). For example, in type 2 diabetes, higher self-efficacy predicted better outcomes in diet, exercise, blood sugar testing and taking medication due to better self-management behaviour (73). Low self-efficacy was a strong predictor for lower levels of self-care activities for patients with diabetic foot disease in another longitudinal cohort study in Canada (76). According to a narrative review (71), this explained the relationship between self-efficacy and exercise adherence among patients with chronic heart failure, as self-efficacy was the key to changing patients' self-care activities such as exercising (71). Another systematic review found that perceived lack of self-efficacy is one of the psychosocial barriers for achieving adherence to health advice (72). Similarly, self-efficacy was an important psychosocial predictor of adherence to diabetes self-management in another systematic review (289). From the previous studies, there is evidence to support the effect of self-efficacy on adherence to self-care activities in other chronic diseases, which may have the same impact on patients' adherence to RCWs. Wearing these devices in most daily activities may be challenging for patients if they lack the self-efficacy to adhere to wearing them for all daily activities.

3.4.3 Depression

One study (52) showed that depression was not a significant predictor of patients' adherence to wearing removable offloading devices. However, a great deal of clinical evidence has shown the impact of depression on adherence outcomes in different conditions (60, 64, 69, 290-292). One cross-sectional study found that the presence of neuropathy and depression affected the quality of adherence to diabetes self-care related activities (290). Similarly, according to a questionnaire that was administered to 367 patients with both type 1 and type 2 DM, patients with medium or high severity of depression showed significantly less adherence to diary recommendations and oral hyperglycaemic agents than patients with low severity of depression (64). Depression was also associated with poor adherence for compression therapy among patients with VLUs in another study (69). Three meta-analysis studies showed the negative impact of depression on adherence for the treatment of chronic illnesses such as diabetes or the human immunodeficiency viruses (60, 291, 292). A meta-analysis of 12 studies concluded that depression significantly affected patients' adherence to medical treatment, which suggests depression may be a risk factor for poor adherence outcomes (291). Another meta-analysis reported that depression was significantly associated with diabetes treatment non-adherence. Thus, depression may be an important predictor of patients' adherence to RCWs, demonstrating that further investigation is required.

3.4.4 Other possible factors related to adherence to RCWs

Other potential factors have been discussed in the literature and may plausibly affect patients' adherence to wearing their removable offloading devices. These factors mainly relate to the climactic environment of the offloading device itself. For instance, Bus et al (48) highlighted the potential effect of climate on adherence to offloading as it was conducted in developed countries with mild temperature climates. However, in many developing countries climate could be a factor that may affect adherence to treatment (48). According to a survey of Australian podiatrists (56), some patients may have concerns which are related to the climate. Living in hot and humid conditions could interfere with sleep and this may become a barrier for wearing RCWs all the time.

On the other hand, offloading options is one of the potential factors suggested to improve adherence levels (43, 53, 293). Removable knee-high offloading devices did not show any significant difference in DFU healing in comparison with other removable ankle devices despite the difference in pressure reduction capabilities between them in Bus et al. (53) trial. The authors hypothesised that the differences in adherence levels may have been balanced out by the differences in plantar pressure reduction capabilities resulting in similar DFU healing rates, and this was also suggested by IWGDF experts (244). Patients may choose to be more adherent to some types of devices that have less plantar pressure capabilities, and vice versa (53). It was assumed that removable ankle-high devices provide better adherence (43) and this hypothesis is also somewhat supported by the findings from studies that show variation in the size of these devices is associated with different levels of comfort (294) and stability (43), which might affect the level of adherence (53). Thus, clinicians must be aware of the potential impact of different physical features of the offloading device on adherence levels. It is therefore strongly recommended to study adherence levels between different types of offloading devices in future research to further inform clinicians about potential features of offloading treatment that may improve adherence to using the treatment.

Lastly, the appearance of the offloading device may be also a factor. A previous model predicted the possible impact of individual perception of the attractiveness of the prescribed footwear on adherence outcomes (295). In footwear designed for people with diabetes, it has been found that patients' satisfaction for prescribed footwear may not improve their adherence to wearing them. One study showed that despite 92% of participants being satisfied with their shoe's colour and 84% agreeing that the shoes were fit for them, only 22% wore the shoes all the day (296). However, in another study, patients who perceived their footwear as more attractive reported better adherence (274).

3.5 CHAPTER SUMMARY

Managing DFUs by offloading plantar pressure away from the ulcer is supported by strong evidence (35, 48, 244, 260, 297, 298). TCC is the gold standard in offloading due to the biomechanical characteristics and the enforced adherence (244). However, applying TCC in clinical practice has been associated with many difficulties including long application time, need for skilled technicians, and high treatment cost. Moreover, TCC may negatively impact daily life activities such as sleeping or bathing (41, 56, 245, 247, 258). RCWs are the only devices that have shown the same or better offloading properties as TCC to reduce plantar pressure (43, 251, 253, 265, 266). Unfortunately, applying these devices as part of clinical practice can be challenging due to poor adherence, as illustrated in many studies (47, 50, 51, 53, 93, 243, 249, 265, 299). iTCC is another first recommended offloading method by the IWGDF as it demonstrates a balance effective offloading option, it is easy to apply and enforces adherence. However, studying other offloading modalities such as RCWs is also promising and may lead to preferable outcomes for both patients and clinicians. Further, it is a commonly used offloading option and it is the second recommended offloading treatment by the IWGDF (34). As adherence is the main reported issue with using these devices, more research is required.

This review reported the factors that affect adherence to wearing RCWs. It found that factors such as the severity of neuropathy, postural instability, and wound size can predict patients' adherence to wearing removable offloading devices. Due to the limited evidence in understanding adherence to wearing RCWS in people with DFU, studies investigating factors affecting adherence to treatment in other similar conditions were reviewed. Different psychosocial factors have been found to be associated with treatment adherence, including patients' beliefs (63, 66, 69, 275-278), patients' self-efficacy (68-73, 76, 280), and depression (60, 64, 290-292). Therefore, it is suggested that these factors found to influence adherence to other similar conditions should also be factors investigated in future offloading adherence research in people with DFUs.

Chapter 4: Theoretical Framework

4.1 BACKGROUND

As illustrated in the literature review, removable cast walkers (RCWs) are effective offloading devices in reducing the forefoot plantar pressure, which is necessary for shortening the healing time of non-infected, non-ischaemic diabetic foot ulcers (DFUs). However, patients' adherence to wearing these devices is challenging and not well understood. Adopting theories on predicting and explaining health behaviour such as adherence may help. The rationale for using theoretical frameworks in health research is to gain a deep understanding of the various levels of cause and effect relationships and this facilitates guidance and a conceptual roadmap to test these relationships (300).

There are several theories that predict health behaviour that could have been utilised for this research, including the health belief model (HBM), the theory of reasoned action and planned behaviour, social cognitive theory (SCT) and theories of stress and coping (79, 301). However, the HBM, for example, lacks the clinical evidence to support its predictive validity according to meta-analysis of 16 studies (302). Another meta-analysis failed to detect the effectiveness of HBM because only six studies in this review used HBM in its entirety (303). The HBM also does not fully consider the effect of social, environmental and economic factors on behaviour, which makes it less successful in predicting behavioural changes in complex chronic conditions such as smoking or alcohol abuse (79). Theories related to stress and coping are other examples of theories associated with some limitations. They describe the coping of chronic stressors by explicating the physiological relationships involved in stress. However, these theories are associated with some negatives. They are nonspecific re stimuli and stressors and they do not distinguish between cause and effect (disease causing the stress or it is the outcome of stress). There is also an absence of objective measurement of coping (301).

The theory of reasoned action and theory of planned behaviour are popular theories that focus on enhancing motivation (301). Thought plays important role in the decision to engage with behaviour in this theory. However, this theory does not provide a specific explanation or guidance for the behavioural changing (301). Some factors related to personality or cultural factors are not considered in this theory (301). On the other hand, social cognitive theory, which is one of the most popular theories that also focuses on enhancing people's motivation, considers these factors and also describes the relationship between person, environment and behaviour (79). Personal cognitive factors such as self-efficacy are some of the most important elements that have the ability to predict behaviour (281).

Bandura (304) compared the SCT and the theory of planned behaviour by discussing the similarities between them. In the theory of planned behaviour, when the person perceives and recognises the outcomes of the behaviour, the attention of this person toward the behaviour can be produced. Similarly, social cognitive theory has outcome expectations, which also affects attitude. Self-efficacy, which predicts the ability to perform a task, is another important construct that can be compared with perceived control in the theory of planned behaviour. Perceived control is associated with the goals that can be set through the effect of norms in expecting the social outcomes of the given behaviour (304). Bandura (304) argued about the similarities between self-efficacy and perceived control by suggesting this example “I aim to do x and I attended to do x” are the same (304).

Adapting one of the theories that predict patients’ self-efficacy instead of only perceiving the knowledge can be beneficial in predicting patients’ behaviour for offloading treatment. Some studies in the area of preventive foot care (273, 274, 296) found that patients did not show adequate adherence for their preventive footwear despite the fact they had the essential knowledge about the importance of wearing these shoes (273, 274, 296).

Social cognitive theory (79) was chosen to guide the methods and hypothesises of Study 3 of this research due to its ability to explain the interaction between human behaviour (patients’ adherence to wearing RCWs) and personal factors such as self-efficacy, outcome expectations, knowledge and social support (80). Therefore, in this chapter, SCT is first introduced by discussing the most important constructs that affect human behaviour. The adapted conceptual framework is then presented by discussing the main theoretical relationships.

4.2 SOCIAL COGNITIVE THEORY

In the last few decades, SCT has been applied to predict, explain, and change human behaviour in different contexts including clinical psychology, counselling, education, and health (301). This theory describes the relationship between environmental factors, human behaviour, and personal cognitive factors (80). The unique interaction between these three dimensions leads to changing behaviour (301). Social cognitive theory guides examination of health behaviour determinants and strategies for changing behaviour. It explains the interaction between the environment and individuals, particularly their behaviour. Social norms are an example of the effect of environment in changing behaviour and this highlights the importance of this construct in health promotion programs. Personal cognitive factors can also interact with the environment and behaviour (79). Learning by observing, anticipating the values of outcomes, and self-efficacy are the most important personal cognitive factors in social cognitive theory (79).

Social cognitive theory provided the conceptual framework for Study 3 in this research, with several personal cognitive constructs including knowledge, outcome expectations, social structural factors and self-efficacy (see Figure 4.1) (79, 301, 304). Therefore, utilising SCT in this research was essential in providing guidance for testing the psychosocial factors that could impact adherence to wearing RCWs among patients with DFUs in Study 3.

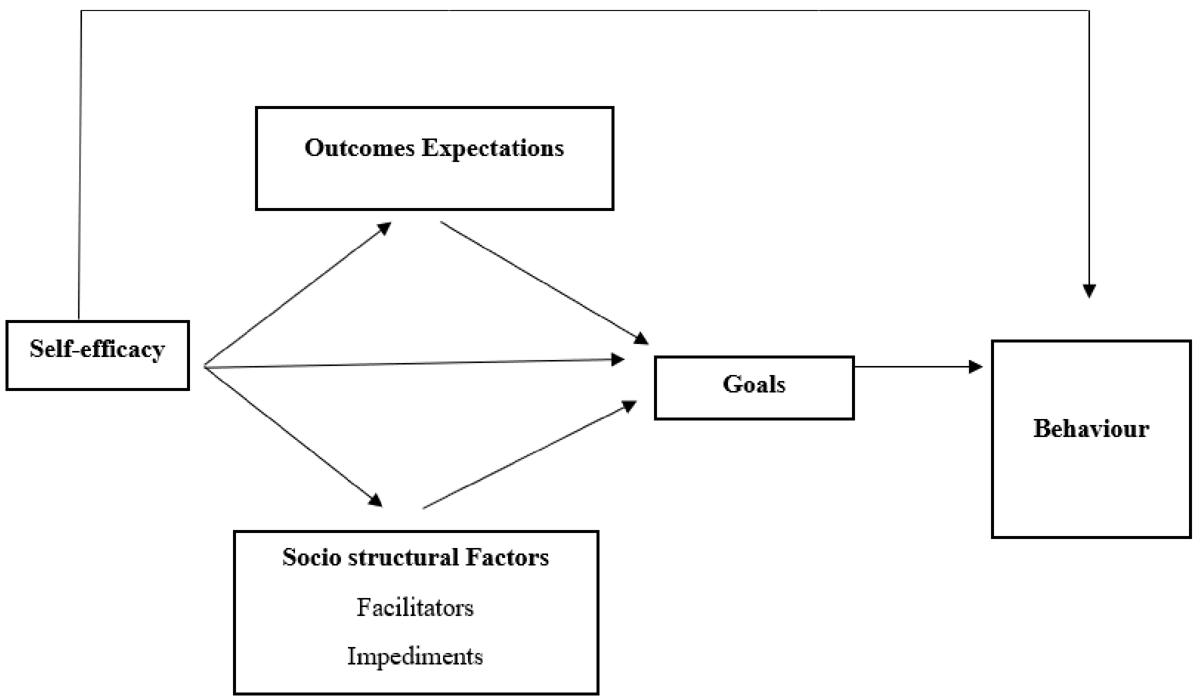

Figure 4.1: The conceptual framework that describes the theoretical relationships (304)

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4.2.1 Self-efficacy

Self-efficacy theory was developed by Albert Bandura and is considered the most significant requirement of behavioural change (78). It was developed from the framework of the social learning theory (80). It discusses people's behaviour depending on their perception of their capabilities (77). The implementation of self-efficacy theory in different psychosocial contexts including anxiety, depression and motivation provides evidence that supports the influence of people's perception of self-efficacy on their motivational and psychosocial functioning (77). Self-efficacy has an important impact in changing the behaviour in different health aspects such as smoking cessation, pain management, weight loss, and adherence to preventive educational health interventions (77). The results of health research illustrate the significance of self-efficacy as an individual cognitive factor which can affect outcomes (77).

Self-efficacy may impact health behaviour in different ways. First, it is associated with self-judgment (77). In this situation, behavioural choices can be controlled by self-judgment such as reducing alcohol and smoking or increasing exercise performance. It also has an impact on the level of effort to achieve certain tasks (77). In addition, it improves the amount of persistence in facing the challenge and can decrease anxiety levels. Many clinical studies have shown that higher perceived self-efficacy reduces stress associated with different medical interventions, such as gastro-endoscopic examination or cardiac catheterisation or debridement of burns (77). Finally, as discussed in the previous chapter, self-efficacy is the core of self-management (282-284). Studies into different chronic conditions have shown significant relationships with patients' behaviours or the clinical outcomes for patients (68-76).

Self-efficacy beliefs can assist to control human functioning by cognition, motivation, feelings, and decision making (305). Peoples' belief in their effectiveness can affect their coping strategies in different situations. Self-efficacy also affects behavioural choices. Individuals try to avoid threatening situations because they think that these challenges exceed their coping skills. However, they become involved in changing behavioural activities if they self-judge that they can handle the situation (78). Another benefit of self-efficacy expectations is detecting how much energy people will expend in facing obstacles and how long they keep dealing with these challenges (78). According to Bandura's experiments, the level of self-efficacy showed high accuracy in expecting behavioural change (281).

Increased self-efficacy can be achieved through either observational learning or participatory learning. These methods of learning increase the skills and knowledge that are essential to building self-confidence and self-efficacy (79). Simplifying the complicated behaviour, persuasion, and reassurance using demonstration from credible models and reducing stress can also enhance self-efficacy (301).

In summary, self-efficacy is one of the most important personal cognitive factors that affects the integration between person, environment, and behaviour according to SCT (79).

Although self-efficacy is one of the most important constructs in SCT (79), other constructs can interact with self-efficacy to change a person's behaviour and these are addressed below.

4.2.2 Knowledge and outcome expectations

Individuals' knowledge may affect their self-efficacy, as well as their health behaviour. Patients' knowledge of the benefits and risks in health can affect their behaviour. When patients do not recognise the reason for changing the behaviour, the possibility of change will decrease (304). However, most people need additional self-influences to enhance their abilities to deal with a new lifestyle (304). On the other hand, outcome expectations is another important factor that can affect human behaviour. Although self-efficacy interventions can successfully change human behaviour in different situations, experiments have shown individuals who are phobic about performing tasks show a variation because of the different expected adverse consequences from changing the behaviour (306). Before Bandura introduced self-efficacy as an important concept in SCT, outcome expectations were one of the main concepts that he discussed for enhancing motivation (306). According to Rosenstock et al (307) outcome expectations are the individual estimations of the expected outcomes from performing a given behaviour, which is quite similar to the "perceived benefits" construct in the health belief model (307). People realise the values that result from changing their habits when personal goals are set, providing further self-incentive to change behaviour (304). Self-efficacy is also associated with expectations (efficacy expectations), which are the individual's belief in his or her ability to successfully achieve the required tasks to get the expected outcomes (307). Efficacy expectations can detect the amount of effort that people perform to face the challenges. The highest level of self-efficacy is associated with higher efforts (78).

However, there is a difference between self-efficacy and outcome expectations. In some situations, outcomes expectations can interact with the role of self-efficacy. Despite people having the essential level of self-efficacy to change their behaviour, their behaviour might not be changed if they recognise serious outcomes of certain behaviour (78). In comparison, in self-efficacy expectations, people give up performing certain tasks if they have fears and negative self-judgment about their coping capabilities in dealing with the task (78).

Self-efficacy may have the largest role in changing behaviour. According to Bandura (306 p392) "the types of outcomes people anticipate depend largely on their judgments of how well they will be able to perform in given situations". However, outcome expectations can be a strong predictor of patients' behaviours in different conditions (308-312). Interestingly, outcome expectations had a greater impact on behavioural change in comparison with self-efficacy in other studies (313, 314). Therefore, according to the clinical evidence that illustrates the significance of this factor (308-314), outcome expectations may have their weight and influence in changing behaviour. The theoretical consideration of outcome expectations during developing and testing health educational programs may be beneficial in detecting its effect on changing behaviour as well as self-efficacy levels.

4.2.3 Socio-structural factors

In addition to knowledge and outcomes expectations, Bandura (304) argued in his theory that perceived facilitators and obstacles are other factors that can affect health behaviour. Some of these barriers can be personal. For example, people give up doing exercise because they have excuses such as work pressure or weather. Thus, the possibility of success in changing the behaviour will be much higher if there are no obstacles. Self-efficacy levels can affect patients' views on these obstacles. Patients with low self-efficacy are more likely to give up and they are more easily to be convinced that they are not able to face the challenges because of these barriers (304).

4.3 CONCEPTUAL FRAMEWORK

Social cognitive theory illustrates the importance of personal cognitive factors in predicting health behaviour, including self-efficacy, outcomes expectations, knowledge, or beliefs. Further, socio-structural impediments and facilitators are other important factors that can interact with health behaviour (304). However, an adapted model by Shortridge-Baggett (315) suggests the importance of including personal characteristics as another influential predictor (see Figure 4.2). Thus, this adapted model describes the interaction of the different psychosocial factors including self-efficacy, outcome expectations, and social support with individuals' behaviour.

In the context of the results from the literature review and the explorative qualitative study (Study 1), adopting this conceptual framework for the following quantitative studies (Studies 2 and 3) of this research was appropriate to address the need to test the possible impact of several personal and socio-structural factors on adherence to wearing RCWs among patients with DFUs. For example, it was hypothesised that the stronger the patients' self-efficacy belief, the more persistent their effort to wear their offloading devices. When patients with DFUs have substantial understanding of their condition (i.e. the causes of DFUs), and expectations of the outcomes that result from adherence to self-care activities, they are more motivated and inclined to adhere to wearing their offloading devices. Furthermore, this conceptual framework highlights the importance of testing other factors that can help patients with DFUs to adhere to wearing RCWs, such as the social support provided from families or caregivers (socio-structural facilitators) or presence of other possible impediments of adherence such as the usability of the RCWs (i.e. heaviness). The qualitative investigation (Study 1) explored these facilitators and impediments in depth for further specific guidance.

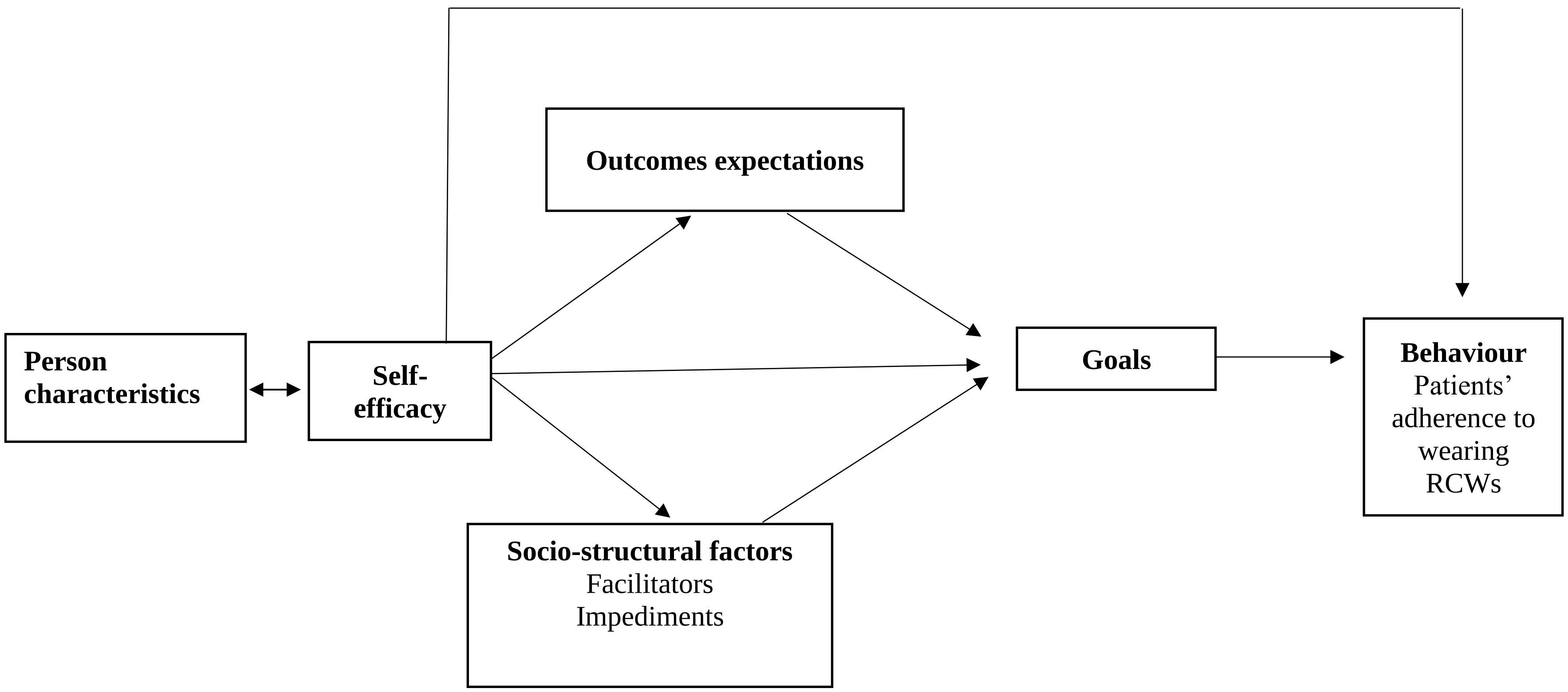

Figure 4.2: The adapted conceptual framework (Shortridge-Baggett and van der Bijl, 1996, Bandura, 2004) that describes the theoretical relationship in Study 3 (304, 315)

4.4 CHAPTER SUMMARY

This chapter described the theoretical framework of SCT, which has been validated through decades of research into explaining and predicting human behaviour. This theory was discussed in detail, including describing the relationships between human behaviour, environment, and personal cognitive factors. This discussion included the vital role of personal cognitive factors such as self-efficacy, knowledge, and outcomes expectations, in addition to the socio-structural factors impacting health behaviour. Finally, this chapter described the adapted conceptual framework (315) used for this research that describes the original theoretical relationships in SCT, in addition to the inclusion of the relationship between personal characteristics and self-efficacy.

Chapter 5: Study 1- A Qualitative Investigation of Adherence to Wearing Removable Cast Walkers: An Exploratory Study

5.1 PREFACE

As discussed in previous chapters, removable cast walkers (RCWs) are successful offloading devices in terms of reducing forefoot plantar pressure. However, the clinical effectiveness of these devices in healing diabetes-related foot ulcers (DFUs) can be negatively affected by patients' poor adherence to wearing them. This study was conducted to explore adherence to wearing RCWs among patients with DFUs. This chapter outlines the background, research questions, methodology (including study design, sample, setting, ethical considerations, procedure, data analysis, and data management), results, discussion, future recommendations, strengths and limitations, and conclusion for Study 1.

5.2 BACKGROUND

Adherence to wearing RCWs among patients with DFUs has previously been investigated by estimating the percentage of adherence time or adherence during weight-bearing activities (52, 316, 317). However, only one longitudinal study has investigated the determinants of adherence to the removable offloading devices, finding factors related to neuropathy (motor neuropathy [postural instability] and painful neuropathy) and wound size predicted removable offloading adherence outcomes (52). Two qualitative studies that specifically explored adherence to self-care activities and offloading found factors related to patients' knowledge, physical features of the offloading devices, gait balance, and patients' motivation as themes that explained barriers to adherence to RCWs (57, 318). To improve understanding of this issue, the qualitative study reported here was conducted to further explore understanding and influences related to adherence to wearing RCWs among patients with DFUs.

5.3 RESEARCH QUESTIONS

1. What is patients' understanding of adherence to wearing RCWs?
2. Which factors influence adherence to wearing RCWs according to patients with DFUs?

5.4 METHODS

5.4.1 Design

This qualitative study adopted a phenomenological approach (319) to explore adherence among patients with DFUs. Information was collected using a semi-structured interview guide during face-to-face interviews.

5.4.2 Settings

- The interviews were conducted in two settings, the first was the diabetic foot clinic at the National Centre for Diabetes, Endocrinology, and Genetics (NCDEG). This centre is one of the largest referral diabetes centres in Jordan and is located on the campus of Jordan University in Amman, the capital city of Jordan.
- The second setting was the diabetic foot clinic at the Jordan University Hospital. This is an educational hospital that is also located on the campus of the University of Jordan in Amman-Jordan.

5.4.3 Participants and sample size

In this qualitative research, a sample of ten participants was recruited to explore adherence to wearing RCWs among patients with DFUs. It has been suggested that a sample of five to 25 individuals can represent the experience of a studied phenomenon of interest (319). According to Sandelowski (320), deciding upon the sample size in qualitative research is relative based on the purpose (i.e. to achieve the variation of a complex phenomenon or developing a theory). A sample of ten participants was found to be adequate for the purpose of this study. Reaching saturation of information regarding the study concepts of interest was another consideration used to decide to end the sampling in this study (321, 322).

Inclusion criteria

- Participants diagnosed with diabetes mellitus (DM) who had a DFU.
- Participants treated using RCWs (knee-high) for their DFUs and who had been wearing RCWs for at least the previous four weeks.

Exclusion criteria

- Participants under 18 years old.
- Participants who were completely immobile (completely bed or wheelchair-bound).
- Participants with a history of cognitive impairment.
- Participants not able to speak or comprehend Arabic.

5.4.4 Ethical considerations

This research was identified as a low-risk project as there was no expected physical, social, psychological, or economic harm for any participant. Ethical approval was obtained from the Office of Research Ethics and Integrity at QUT (ethical approval number: 1800000929), the NCDEG Ethics Committee, and the Jordan University Hospital Ethics Committee (see Appendix 2). Participants were provided with verbal and written information about the study, they then signed a written form to consent and participate (see Appendices 3, 4, 5, 6). The information included the study aim, procedure, and contacts of the PhD candidate, the principal supervisor, and the QUT Research Ethics Office. Participants were informed that the interview could be ceased if they developed any emotional or physical discomfort during the interview. All participants had the flexibility of choosing the time of the interview according to their free time. They were also observed by the interviewer for any level of discomfort and provided with necessary support and friendly communication.

5.4.5 Procedure

The semi-structured interviews were conducted from October 2018 to December 2018 in the identified research settings in Jordan. All of the face-to-face interviews were performed by the PhD candidate during the regular visits of participants to the clinics to receive routine care of their wounds. Participants who met the inclusion criteria were identified by clinicians who worked in the research settings. The PhD candidate asked the potential participants if they were willing to be approached to explain the study.

At the beginning of the interviews, participants were asked to provide information related to relevant sociodemographic variables including age, marital status (married, single, or divorced), total income in Jordanian Dinar (JD), religion (Islam, Christianity, or others), employment status (employed, unemployed, retired, or self-funded), living place (urban, rural), education level (primary school, secondary school, or higher education), and use of walking aids (by stick or frame). They were also asked about health information related to their condition such as type of DM (type 1 or type 2), duration of diabetes (years), the presence of other comorbidities, history of previous ulceration, history of any previous amputation, DFU duration (weeks), and RCW treatment duration (weeks). Other clinical information was collected by the PhD candidate from either clinical inspection of the foot or medical records of the participants. This was mainly to assess DFU location, the presence of amputations or severe foot conditions such as Charcot foot, the presence of osteomyelitis, or lower limb ischemia.

After gathering all the sociodemographic and clinical data, the interviews to investigate participants' level of adherence and the facilitators and barriers to wearing RCWs commenced. The interviews provided optimum privacy for participants to freely answer the questions. The interviews were digitally recorded with the participants' consent.

5.4.6 Interview guide

A framework for the interview guide was developed according to Kallio et al (323), then was reviewed by the supervisors of the PhD candidate. It was then tested on two participants from the research study sites who met the study criteria to test its feasibility.

The interview guide had several open-ended questions that aimed to explore participants' perceptions and understanding of adherence, such as "Tell me about the duration of wearing the offloading boot" or "Tell me about not wearing the offloading boot". The guide also included questions related to different aspects of adherence to RCWs among patients with DFUs, including barriers and facilitators and how the devices affected participants' daily lives. Some sub-questions emerged during the interviews to explore adherence to RCWs in-depth, such as “Tell me exactly about the times when you don’t wear the offloading boot” or “How can this help you to adhere wearing the RCWs?”.

5.4.7 Transcription

The study investigation was based on qualitative data from the participants who were encouraged to talk about their experience in wearing such devices. All data were recorded using a smartphone. All the audio records were transcribed verbatim by the PhD candidate in Arabic.

5.4.8 Translation

As the main language of the transcribed interviews was Arabic, the Arabic transcripts were translated to English to publish the study findings. Translation and back-translation were guided by Chen and Boore (324). First, the transcripts were translated from Arabic to English by the PhD candidate, who is a competent bilingual in those languages and familiar with the culture of the interviewed participants. The English transcripts were then sent to another translator (Jordanian clinician (MD)) for back-translation from English to Arabic. This person is a competent bilingual and familiar with the health and cultural context of this research. This translator was blinded to the original Arabic transcription. The new back-translated Arabic drafts and the original ones were then compared twice by both the PhD candidate and the Jordanian clinician. Any discrepancies including words, phrases, or sentences were re-translated to English then agreed by both translators. Finally, proofreading and editing of the English drafts were undertaken by a professional translator to check any grammar mistakes or inappropriate use of vocabularies. The professional proofreading included a comparison between the translated English transcripts and the original Arabic to address any poor translation, and if necessary, suggesting more appropriate translation.

5.4.9 Data analysis

Content analysis was used as the method of analysis, as guided by Burnard (325). The main aim of the analysis was to produce systematic themes that reflected the content of the transcripts. This involved categorising and coding the interview transcripts and was undertaken by the PhD candidate. First, to be immersed with the content, the transcripts were read carefully several times. Next, open coding was performed using several headings to describe significant statements or meaning units. All codes and meaning units were added to specific software (MS Access) to organise the data and facilitate systematic analysis to then produce categories or themes. Each code had one or more significant statements and some of the significant statements were used for multiple codes. The repeated codes were then deleted and the codes that shared commonality were grouped into categories. Besides, different themes were formulated to connect the categories that shared the same meaning. According to Graneheim and Lundman (326), themes can provide greater interpretation of the data than the description of categories, as they can express the latent content of the text. The PhD candidate was the only person who coded and categorised the content of all the transcripts into main themes or categories.

Trustworthiness is essential to assure reliability, credibility, and generalisability, along with describing how the themes or categories describe the data (326). To assess the trustworthiness of the produced concepts or codes, Elo and Kyngäs (327) advised the need for communication between the co-authors to agree on the labelled data or codes, and categories. The principal supervisor of the PhD candidate independently categorised the codes and the resulting categories. The discrepancies were discussed and agreed upon, with all produced codes and categories then revised and validated with a further supervisor by making a decision and achieving consensus. The main themes/categories were also checked by providing three randomly selected study participants with the final agreed themes/categories and asking those participants if they agreed that the final themes/categories were an accurate reflection of their understanding of the interviews.

5.4.10 Data management

Data are stored in both hard copy data (transcripts) and software data (digital recordings). The hard copy materials for this study are stored in QUT physical storage facilities according to QUT data management policies. Digital data are saved in a QUT Research Data Storage Service or QUT Secure Access U-Drive, which is a cloud service from QUT.

5.5 RESULTS

This section describes the main findings of this study including the characteristics of the population and the resulting themes, including i) adherence to wearing RCWs was reported with variation and inconsistency, and ii) adherence to wearing RCWs was affected by multiple factors. All the themes, categories, and codes are represented in Appendix 24.

5.5.1 Participants' characteristics

Table 5.1 describes the characteristics of the recruited participants. Of the ten participants, seven were male. The ages ranged between 34–62 years. All participants had an active DFU with 12.5 months as the median duration (range = 0.5–60 months). Nine ulcers were in the plantar of midfoot or forefoot. One participant had an ulcer above a trans-metatarsal amputation. One participant had a heel ulcer with osteomyelitis in the calcaneal bone. The median duration of using RCWs was 4.5 months (IQR = 6.5). Eight participants had a history of previous ulceration, six participants had a history of minor amputations and two participants had Charcot deformity. All participants were Muslims and nine were married.

Table 5.1: Participants' characteristics (N=10)

Characteristics	**N (%) or Median (range/IQR)**
Gender	
Male	7 (70%)
Age (years)	54 (34 – 62)
Total income\month (JD)	345 (IQR = 402)
Employment	
Employed	2 (20%)
Unemployed	4 (40%)
Retired	2 (20%)
Self-funded	2 (20%)
Living place	
Urban	8 (80%)
Education	
Primary school	2 (20%)
Secondary school	4 (40%)
Higher education	4 (40%)

Uses walking aid	4 (40%)
Type 2 DM	9 (90%)
Duration of DM (years)	19 (2-35)
Presence of other comorbidities	
Hypertension	5 (50%)
Cardiac disease	1 (10%)
Retinopathy	1 (10%)
History of previous ulceration	8 (80%)
History of previous amputation	6 (60%)
Duration of DFU (months)	12.5 (IQR= 32.5)
RCW duration (months)	4.5 (IQR= 6.5)

IQR: Inter-quarter range; JD: Jordanian Dinar; DM: diabetes miletus; DFU: diabetic foot ulcers; RCW: removable cast walkers

5.5.2 Theme 1: Reporting of adherence was varied and inconsistent

Participants discussed inconsistencies in reporting adherence to wearing RCWs, for both the time wearing the RCWs or the type of activities while wearing RCWs. This theme was represented by three main categories, as outlined below.

5.5.2.1 Category 1: The belief in achieving optimal adherence

This category describes the participants' perceptions of their adherence time to wearing their RCW in response to questions regarding the amount of time they wore their RCW. Most participants believed that they had perfect adherence to wearing their offloading devices when they were asked about their level of adherence.

Mostly adherent, nearly all day. Most participants reported wearing the RCWs for most of the time, with many suggesting this meant around 12 hours of wearing their RCW from when they woke up in the morning until sunset. This may indicate non-adherence is not an overall issue for most of the day time. Some participants reported:

> *The period which I wear the device is from the morning at approximately 10 am until 10:00 pm or 11 PM. [P3]*
>
> *I mean, it's good and perfect (the participant described the device) but only for the day time for a period of 12 hours. Then I go to sleep. It is possible to stay awake with*

some people until 10-11 pm, I mean it is mostly from morning to more than 12 hours, the normal situation is around 12 hours. [P8]

Some non-adherence at night. Some participants also suggested they may not have been adherent all the time, and especially not during the night. This may indicate the difficulty that participants faced to keep wearing the offloading device at night, for example, they reported:

I may adhere to using it around 80%, possibly between 75-80%. [P1]

after evening, after Maghreb (sunset) prayer; I mean most of the days, I used to take the boot off. [P2]

Poor adherence was not common. Only two male participants described that they rarely wore the device each week and sometimes could go up to a month without wearing it.

I only wear it two times a week; when I go to the hospital or if I want to go outside the home, I wear it. I mean there is no specific time but most of the time I do not wear it. I mean I have one or two trips to the hospitals and sometimes I must go to clinics, it is possible to wear it three times. [P7]

No, no. it is possible that I don't wear it for one month. [P9]

Overall, most participants reported that they wore their offloading device most of the time during the day and removed it at night-time, whilst two participants wore the devices only for rare occasions and mainly when outdoors.

5.5.2.2 Category 2: Adherence during indoor activities seemed challenging

Despite participants reporting adherence for most of the day, this category provides a more in-depth exploration of specific activities and occasions that participants did not want to wear their RCWs. Participants reported the vast majority of non-adherence occurred indoors:

Sitting and sleeping. Some participants stated that they preferred not to wear their RCW during some indoor activities, including when they were sitting, sleeping or tired after walking:

I don't wear it during sleeping, having a nap or sitting in the middle of the day. I mean when there is no walking. [P1] *but if I want to relax during the day, I mean if I have nothing to do, I take it off. Then, I wear it back again when I wake up. When I want to sleep at night, I take it off, but I have to keep wearing it. [P4]*

Some participants suggested that using the device during sleeping was challenging as the devices were not comfortable to wear during the day. This may reflect why most participants were not interested in wearing the devices while sleeping:

I can't keep it on and sleep in it, I can't. [P8]

I mean... Ahhh, at the evening time and some afternoon time. For example, sometimes when I am walking, after walking it is annoying. [P5]

Going to the toilet at night. A frequent behaviour of participants regarding the lack of adherence to wearing their devices was going to the toilet at night. Some said:

But if I already wake up and I want to go to the toilet, I don't pay attention to this (wearing the device). [P1]

If I want to enter the toilet at night, it is hard. So, I am forced to walk on the tips of my toes. [P8]

The frequent need to apply or remove the offloading device before and after relaxation or sleeping also affected the adherence of some participants to wearing the offloading device, especially at night. Participants said:

I think that I am able to keep wearing it, but as I told you if I take it off to relax or at night when I want to sleep, of course, I have to walk without it. [P4]

But this was not always the case, as one younger participant (32 years old) did state he was able to wear the device to go to the toilet when he woke up during the night:

My adherence to it was when I sleep, I put it next to my head. If I want to go to the toilet, I would wear it and I enter the toilet wearing it. [P10]

Washing and bathing. Some participants reported that they did not wear the device when bathing or during activities related to religious habits. For example, washing the arms and legs is a part of ablution in Islamic faith among Jordanians and this is a common ritual among Muslims. Two Muslim participants clarified that they did not wear the offloading device during this ritual.

No, (the participant described when they would take the device off) just when I want to take a bath only, during a bath only. [P5]
Just when I want to do ablution, like this I mean. [P3]

Religious beliefs. Interestingly, one participant described that he only wore the offloading device for outdoor activities. He was not interested in wearing the device during activities inside the home due to religious beliefs as walking barefoot inside the home is important for ritual cleanliness. [P7] said:

The carpet!! For the aim of hygiene, I mean we pray in any spot at home, it is only for hygiene, going to the toilet and come [sic] back with the boot is difficult for me.

Overall, participants reported difficulties adhering to wearing their offloading devices during indoor more sedentary activities, such as sitting, sleeping, going to the toilet, washing, bathing, and for religious reasons indoors.

5.5.2.3 Category 3: RCWs were not worn in some short distances (few indoor steps)

This category gives further information regarding which weight-bearing activities were mostly undertaken without wearing RCWs. Non-adherence during these activities was detected after further in-depth questioning, as participants generally thought they had optimal adherence when they wore their RCW for most of the day.

Short distances. Despite the claims in the interviews that the offloading devices were worn most of the time, upon further investigation, most participants admitted not using the offloading devices for weight-bearing activities where they only walked short distances. This suggests that the participants of this study might have overestimated their adherence to wearing their offloading devices. For instance:

Sometimes during walking, I used to walk on my heel without using it, only on my heel. [P1]
Very little steps, this is not a big issue, it does not matter. Two to three meters is not that long. [P3]

Indoors. Most of the weight-bearing activities in which they did not adhere were inside the home, as some participants clearly illustrated:

When the distance is only half a minute, I mean inside the room. But until now I have never been outside the home without using it. [P1]

Just if I want to walk to do a necessary thing, for instance, it takes time when I lace it and stuff like this. Just something important, just I walk without it, only inside the home, I mean not outside, and for a short time. [P4]

A minority were always adherent, regardless of activities. In contrast, two younger participants claimed that they wore the devices for every single step:

(Researcher asked): What about the steps inside the home (were you not wearing the device)? (Participant replied): No, No. (Researcher asked): At all? (Participant replied): At all. [P5]

I mean I have not walked on my foot without the device for two months and a half, not a single step, nothing, I have not stepped on the ground, just only with the device. [P10]

Overall, this theme explains the variation and inconsistencies in participants reports of adherence to wearing RCWs. This was due to the overestimation, as there was misperception regarding optimal adherence. This made capturing actual adherence challenging in this investigation. Adherence was reported with variation including wearing times, indoor activities, and wearing bearing activities. The participants' perceptions of their adherence to wearing RCWs was inconsistent. Most participants believed that they had optimal adherence through wearing their offloading device for most of the day. However, upon further questioning, participants admitted to not adhering to wearing their device during many indoor sedentary activities, in addition to many weight-bearing activities that they perceived would only take a few steps. This suggests that participants generally perceived that they wore their device most of the time, yet, in reality, they removed their device for multiple activities they perceived to be inconsequential, potentially wearing the device for much less time overall then they perceived.

5.5.3 Theme 2: Adherence was a consequence of multiple psychosocial, physiological, and environmental factors

This theme shows that adherence to wearing RCWs in patients with DFUs can result from a combination of psychosocial, physiological, and environmental factors. The four categories the study participants perceived to influence their RCW adherence levels included: personal knowledge or beliefs, the severity of foot disease, social supports, and the usability of the device (Table 5.2). A concept mapping process was also undertaken to help visualise this theme and the interactions between the suggested categories\sub-categories and their collective influence on participants' adherence to wearing RCWs (Figure 5.1).

Table 5.2: Categories of factors influencing adherence to RCWs

Category	Sub-category
Specific offloading knowledge and beliefs influenced adherence	Misbelief that the RCW was not a priority DFU treatment
	Substantial knowledge of the reason for offloading treatment
	Misperception about optimal adherence
	Belief that was difficult to adhere at all times
The impact of the severity of foot disease on adherence outcomes	Foot pain forced participants to wear RCWs
	Loss of sensation had a negative effect on adherence to wearing RCWs
	Postural imbalance related to motor neuropathy (foot deformities) or amputations forced participants to wear RCWs
	Progression of ulcer healing motivated participants to wear RCWs
Social support benefited adherence	Support from health care providers
	Social support from family
	General social support
Logistical issues and physical features of RCWs	Physical features of RCWs
	Satisfaction with the device
	Inability to perform daily life activities

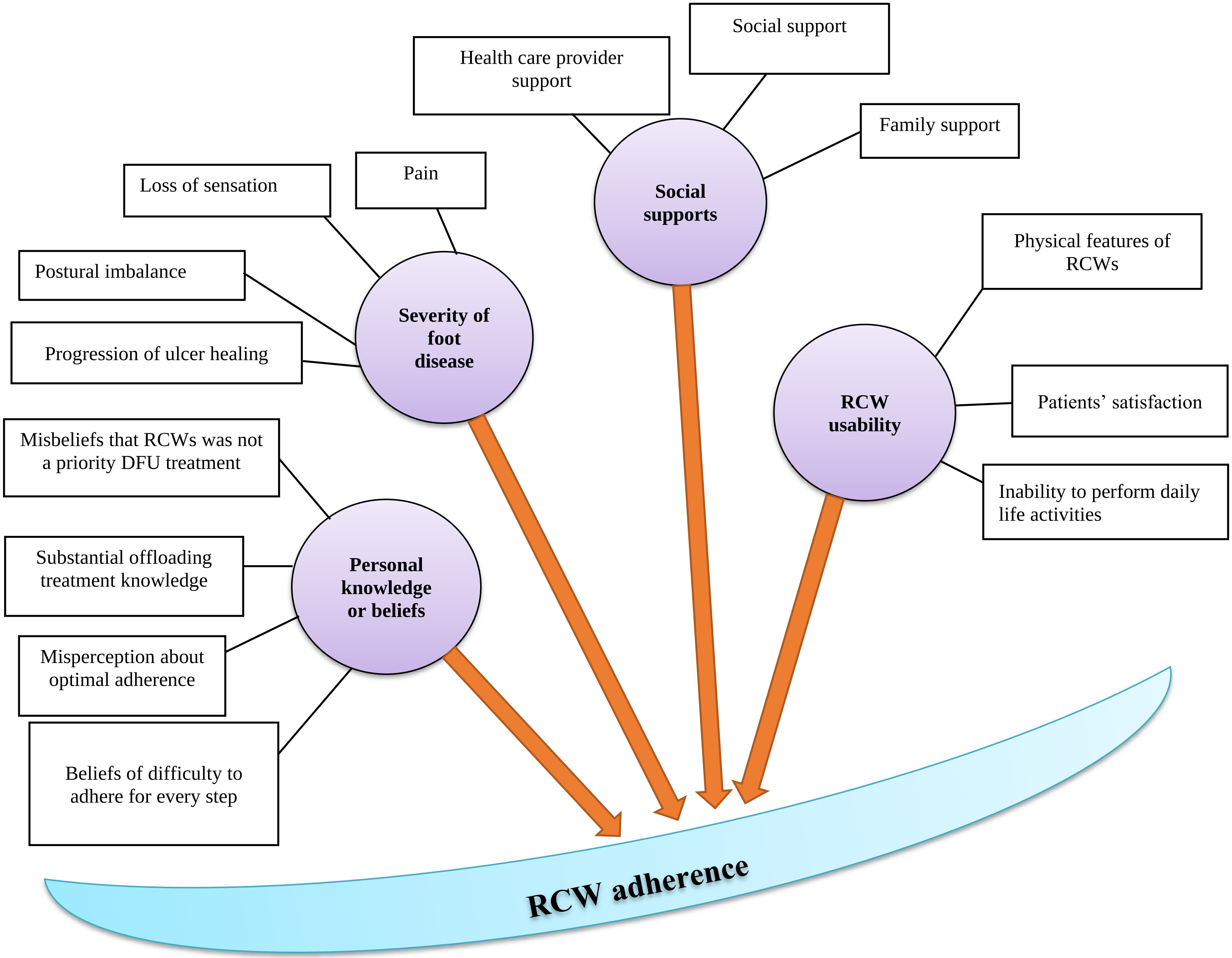

Figure 5.1: Concept mapping of the categories\sub-categories of adherence determinates theme

5.5.3.1 Category 1: Specific offloading knowledge or beliefs influenced adherence

The role of specific knowledge or beliefs on adherence outcomes was subtle. It appeared from the first observation that participants had enough knowledge about the mechanism of offloading and the rationale for using it. However, the potential impact of cognitive beliefs was recognised when they discussed their priorities for managing their DFUs and their adherence to wearing the RCWs.

Misbelief that the RCW was not a priority DFU treatment. It was obvious that offloading treatment was not perceived as a priority to manage DFUs among the study participants. Participants stated that control of diabetes, infections, or even dressings were the most important factors that should be considered to manage their ulcers. This reflects their misbelief regarding the appropriate management of DFUs, which should be based on the evidence-based recommendations. Participants stated:

> *According to my information; it is important to control the food; the individual should control his food and avoid eating sweets or sugar in an uncontrolled manner. Starch, mmm, not doing stuff like this, or anger. [P4]*
> *The antibiotic medication comes in the first. [P5]*
> *The physician, the recommended boot and it is possible that this boot has huge importance. But the physician's role comes before the device, and his treatment is the most important issue in such treatment. [P9]*

One participant also reported a belief that RCW was only for difficult wounds and not needed for every DFU. The participant reported:

> *You just wear it in the cases that need a longer duration of treatment. I mean some ulcers are simple, I mean it is just by one dressing or two, there is no need to wear it, and so I wear normal shoes, as I told you. If the wound, you know, the wound at the beginning has an infection, it needs antibiotics and sometimes injections, in a specific phase I took injections in addition to the boot, all these things facilitate. [P8]*

Substantial offloading treatment knowledge. Although most participants did not consider offloading treatment a priority treatment for their DFU, most demonstrated substantial knowledge regarding the importance of offloading and the benefits of offloading for wound healing and amputation prevention:

Because the wound is located in a place that is affected by high pressure, and it has not been healed without using the boot, waiting for the god, this is the first thing. [P7]

So, it is better than anything (wearing the offloading device) as it helps in many times for cure and wound healing in a shorter time from the expected duration, it shows the results faster. [P8]

Furthermore, all participants were aware of the significant need to reduce the amount of pressure that affected their wounds, as well as being familiar with the mechanism of the offloading treatment:

The device, it is to avoid pressure on the wound as much as possible. [P3]
it is located in a sensitive place and it is on the pressure, I mean as there is weight, it is a pressure. I mean all the toes, if you push, all the pressure affects behind the toes in the high area, all the pressure affects it, it is the region that I have the amputation, in these areas. [P7]

In addition to the good understanding about the need for offloading treatment, participants also had good understanding related to poor DFU outcomes if they failed to use the RCWs, such as increased wound size or developing new wounds or amputations. This also highlights the comprehensive understanding of the reason behind offloading treatment among the study participants. They reported:

Wearing the boot outside the home is better than going outside the home with an amputated leg. [P2]
If you put pressure on the wound without wearing the boot, the wound extends. It will become larger as it is affected by pressure. [P4]

Misperception about optimal adherence (lack of awareness about the importance of wearing the RCWs for every single weight bearing step). Although most participants had substantial knowledge regarding the importance of adhering to wearing their RCWs, they had a misperception about what optimal adherence meant, as mentioned in the previous theme. Many participants did not realise the importance of wearing the device for every weight-bearing step. Some believed that no harm could occur when not wearing the devices for short distances and others believed that wearing RCWs for every step was not necessary. This potentially reflects a misperception regarding what optimal (100%) adherence means to participants. Most stated that they had good adherence, wearing the offloading device for most of the day, while in reality, they had many non-adherent steps. This shows the need for an inclusive definition of the concept of adherence to wearing RCWs, as non-adherence must be evaluated from different aspects such as wearing time or steps. They reported:

> *Very little steps, this is not a big issue, it does not matter. Two to three meters are [sic] not that long. [P3]*
>
> *There are no harms [sic] (walking without the device), but it is better for the individual to wear it. It is better to be wearing it, the more he wears it, the more it reduces the pressure on his foot a lot. [P7]*

Belief that it was difficult to adhere at all times. Several participants stated that wearing RCWs for all weight-bearing activities was difficult. This was possibly due to the strength and physical ability required to wear or take off the RCW at specific times (late nights) when they did not have adequate family support. Some participants stated:

> *Every step at home you mean? Every step, it is too hard, very hard. [P3]*
>
> *Ok, I exploit my full strength if I want to wear it for the toilet then take it off, I need to use my efforts, as I am fear from [sic] falling, I always feel afraid. Because of this, I refuse to go there, then come back, then taking it off in the toilet then I wear it, I can't, I can't, I mean my health does not help me to keep always taking it off and wearing it again. [P6]*
>
> *No, I mean it is around 45%. It's hard for me to wear it and stay at home, it is very hard for me. [P7]*

Yet some of the younger participants, stated that they were confident wearing the devices for all steps, in contrast with the older participants. The younger age of those individuals suggests that they had greater physical strength and perhaps fewer comorbidities, which allowed them to wear or take off the offloading device when required. Participants stated:

> *I think that I am able to keep wearing it, but as I told you if I take it off to relax or at night when I want to sleep, of course, I have to walk without it. [P2]*
>
> *I have applied this for months, I applied it a lot. I am able to apply it, it is not hard but as I told you psychologically. But in terms of ability, I am able, I mean I am able for six months, you can adapt to it. [P5]*
>
> *Of course, I can. For the individual who can't, he does not want to be cured, hahaha, if you don't want to be able, your foot will stay swelling. [P10]*

In summary, participants seemed aware of the role of offloading in healing their wounds but did not prioritise offloading in their DFU treatment regime. They also did not show a great understanding of the meaning of optimal adherence. In other words, they were not aware of the need to wear RCWs for every weight-bearing step. Lastly, many participants, particularly older participants, believed that it was difficult to achieve optimal adherence to RCWs for every step or for activities such as sitting or sleeping.

5.5.3.2 Category 2: The impact of the severity of foot disease on adherence outcomes

This category describes how the severity of diabetes-related foot disease interacted with participants' adherence to wearing their offloading devices. Participants reported several DFD complications such as neuropathic pain, loss of sensation, postural imbalance, and foot ulceration. Each had a unique impact on RCWs adherence outcomes, as shown below.

Pain. Many participants reported that they perceived pain when standing or walking when not wearing their RCW. This pain was usually a result of their diabetic foot disease condition itself (i.e. presence of PAD or DFU infection). They stated that wearing the offloading device relieved the pain in their lower limbs. Thus, the presence of pain was a factor that enforced participants' adherence to wearing their offloading devices. They reported:

> *Also, I will feel pain in my foot when I want to tread on the wound without it (the offloading boot). [P1]*
> *Ahhh, it (RCW) reduces some pain from me, the pressure affects the front side, you know. [P8]*

Loss of sensation. In contrast, a loss of sensation, a symptom of peripheral neuropathy that results from diabetes, which is the main precipitating factor for DFU, seemed to be a potential barrier to wearing their RCW to some participants. The loss of sensation impacted the recognition of one participant regarding the need to wear the offloading device when walking. For example, one male participant suggested:

> *If you walk without it, you will not feel your foot, as you will not recognise this (due to the loss of sensation); thus, you will walk (walking without RCW), you know. [P5]*

Postural imbalance. Some participants stated they were more likely to adhere to wearing the RCWs because they felt they had more balance when standing or walking with the RCW. They highlighted that without the RCW, they felt unbalanced when standing or walking due to the presence of severe foot deformities or forefoot amputations. Thus, this could be an important physiological factor that could be a facilitator of offloading adherence.

A participant with a DFU on a trans-metatarsal amputation site stated:

When I stand on the wound directly, I feel no balance. [P1]

A participant with a Charcot foot deformity stated:

I am not balanced before I wear it, there is no balance at all. After I wore it, thanks to Allah (God in Islamic faith), I noticed an improvement in my body balance. [P6]

(Male participant with Charcot foot deformity) ...I mean, mmm, it (RCW) helps me to walk. [P8]

Progression of ulcer healing. DFU is a major consequence of diabetic foot disease and progress in healing can be another factor to impact adherence to wearing RCWs. The positive progression of DFU healing motivated participants to adhere to wearing the RCW. The good outcomes and prognosis after using the RCW made them believe that the prescribed offloading devices were effective. They stated:

Also, in each dressing, I take a photo for it and I see the progression from better to better. You can see here, this is at the beginning, this is the dressing after, this is the following one also, there is an improvement, this is the after and the after. I used to take photos for each dressing. I saw that there is an improvement and I say, "This means that I have to keep wearing the boot". [P10]

(When poor healing progression can be a barrier) ...when I wear the device, I don't benefit from using it. The wounds are still the same. The pain, the infections still the same. Aaaah, I don't see any progression in it. [P3]

Two participants with DFUs of long durations stated that the offloading treatment was not effective as their DFU had not yet healed. One participant reported that he did not believe the effectiveness of the prescribed RCW despite assurance from clinicians. Similarly, another participant believed that the RCW was not as effective as TCC due to less noticeable healing. Therefore, the progression of DFU healing when using offloading devices impacted these participants' beliefs, motivations, as well as their adherence outcomes.

A participant with a long-standing DFU talking about their RCW treatment stated:

> *In fact, the relevant wounds are open for six years and they are still the same… They say that it cures at 50%. But what I feel, this is not completely true. [P3]*

A participant with a DFU under a rocker bottom Charcot foot deformity stated:

> *When I had the (total contact) cast, the wound healed gradually, I mean it was close to healed. Now, after I re-wore the (RCW) boot, they told me that the wound became larger. I told the nurse here that the wound has become larger, I mean at the beginning it was smaller, so the cast is better than the boot. [P4]*

In summary, the severity of participants' foot disease influenced their adherence, with the main severity factors implicated being pain, loss of sensation from neuropathy, postural imbalance, and the progression of their DFU healing.

5.5.3.3 Category 3: Social support benefited adherence

Participants reported the psychological and physical support provided from the surrounding social environment including health care providers, family, or relatives, was an important factor that helped participants to keep wearing their offloading devices.

Health care providers' support. Many participants reported that they received constant information or advice from clinicians regarding the importance of wearing RCWs. This continuous support from health care providers may have helped to enhance their beliefs and knowledge about the importance of adherence to wearing their offloading devices:

> *Also, doctors and nurses here insist that I have to adhere to wearing the boot…. and it's the cure. It works, 99%, to heal the wound. [P2]*
> *You know, ideally, I should wear it during sleeping as it provides better results as the guys here told me. [P8]*
> *Second, let me tell you that there is a thing which is more important than the device. People who you deal with, guys here, I mean, they have high self-confidence and qualifications. This also has an effect. [P8]*

Family support. Many participants stated that support from family was important. They reported that getting help from a family member helped them to adhere to wearing the RCWs, especially in wearing or taking off the offloading device, as it was a challenge for them without help:

> *As you can see, my son just takes it off for me. I mean, I need help from someone and I am alone at home. If there is someone to help me, it is possible as you say to go with it to the toilet and let someone take it off for me, before doing ablution then wear it again, yes, it is possible, but I don't have anyone at home, all of them have got married. [P6]*
>
> *I can't, If I wake up from sleeping, I want to wear it, I need somebody to help me to dress it as a result of the health condition that results from the foot. If I were in my normal condition, I would wear it and walk. [P8]*

In addition to the potential positive impact on adherence from the physical support provided by family members, participants also reported a positive impact from verbal encouragement and support from their families as well:

> *My daughter always asks me to wear it. My family always insists that I have to wear it to get rid of this thing. [P2]*
>
> *I mean when my wife forces me to wear it, [She says] "You are not allowed to take a step on your foot until you wear it'. [P5]*

General social support. Participants reported that support from other people in their general society or community also had positive impacts:

> *Somebody has to help me if I have specific work. Bring me that, give me this. This is from it, from the device. [P3]*
>
> *I have to hold somebody's hand or call someone to help me, I have to I mean… ahhh, it is very bad. [P5]*

Conversely, some participants also stated that their perceived lack of support from other people sometimes caused them to have a negative impact of their own perceived body image while wearing the RCWs, which could have a corresponding negative impact on them wearing their device:

> *Also, when I walk, I see the kids are staring at it. They see it as foreign stuff and people look at it and they think that both of my legs are amputated are cut, or lost, aaaah, I mean people criticise it a lot. [P3]*

Also, the people when they see me, I feel myself, hmm, I mean my age is 36 years old and when I want to go out in front of people, I feel myself like 70 or 80 years old and this hurts me. [They ask] "Is it ok to hold your hand?", you know, as a man when they ask you to hold your hand, you feel it hard. [P5]

Two participants complained that these incompatibilities led to a change in appearance. One participant said:

It is that with [the] boot your appearance will be different when you wear the boot on this side and sandal on the other side in front of people. I mean I want to get married. I can't go like this!!, I should be healed and improve myself, then I [can] go to the girls' families seeking marriage. [P10]

In summary, social support, both physical and psychological support, and positive and negative from a range of health care providers, family members and their general community seemed to have an impact on participants' level of adherence to wearing their devices.

5.5.3.4 Category 4: Logistical issues and physical features of RCWs (the usability of the offloading device)

This category describes how the usability of the RCWs could negatively influence participants' adherence to wearing them. Using the device was described as a challenging and unpleasant experience by most participants for reasons related to their physical features and the resulting impact on daily activities and health-related quality of life.

Physical features of the RCWs. Several participants complained about the physical features of RCWs being uncomfortable, which impacted on their adherence to wearing them, as described below.

Heaviness. There were many complaints about the heavy weight of RCWs. Consequently, the participants took the devices off, for example, when they were inside the home while sitting or sleeping, and this affected their adherence.

During sitting you feel it is quite heavy. You can say it can be comfortable during sitting if I don't move. [P1]
I mean I can't keep all the weight and hold it from one leg to [the] other and it is uncomfortable for the leg, you know. [P8]

I can bear the wound but not bear the device, I mean the device is good but the heaviness, and as I told you, it affects the leg, which does not allow me to wear it. [P9]

Long devices. Participants reported that the physical length (knee-high) of the device was a barrier against adherence to wearing them. Two participants said:

You feel it long (the device). [P5]
If it is [was] a little shorter, it would be better. [P9]

The length of RCW caused friction between the upper edge of the device and leg. One male participant said:

I mean you see there are two disadvantages, the weight and the leg from the top, Solve it for us. At the bottom is not an issue but from the top [it] is [a] tragedy. [P9]

Difficult to get on. Many participants found RCWs were not easy to put on or take off, especially if they wanted to walk a short distance after relaxation. They stated that they required a lot of effort, strength, support and time to put on and take off the device again. They said:

It needs a lot of effort through putting on or taking off. [P3]
Ok, I exploit my full strength if I want to wear it for the toilet then take it off, I need to use my efforts, as I have a fear of falling, I always feel afraid. Because of this, I refuse to go there, then come back, then taking it off in the toilet, then I wear it, I can't, I can't, I mean my health does not help me to keep always taking it off and wearing it again. [P6]

Pain. Some participants reported pain in their back and legs when using the offloading devices:

I started feeling pain in my flanks (sides) Such pain remains until 2 or 3 PM …. like this. [P2]
If you would like to walk, it causes pain in back and flanks as well, it causes pain. [P5]

Sweating. This was another uncomfortable feeling that was reported by one participant, especially when wearing the RCWs for most of the daytime:

Ok, for example, now, I have a problem that, for instance, it's on from morning to afternoon until I took [sic] it off, there was a lot of sweat from the airbags, you *feel a lot of sweat. This sweating affects the wound. This what was bad for me. [P5]*

Postural imbalance. Several participants complained about the incompatibility between the limb with the device and the other limb with the regular footwear. This was mainly related to the offloading device being higher than their regular footwear, which negatively affected their postural balance and could negatively affect their adherence to wearing RCWs. They reported:

Sometimes, I feel that my leg is heavy, and [I] feel tired because the level of the other leg is slightly lower. I started feeling pain in my flanks. [P2]

the only problem is that it is always long and the nature of walking with it, I mean, it needs balance. It is possible that the individual who does not have a fracture in his foot finds it comfortable. So, when I wear it, I am imbalanced, so I am forced to take off the other shoe to get the balance and the proper stand, then walk. [P8]

Some participants also reported a negative impact of RCWs on the quality of their walking and balance:

I mean when you walk using it and your walk is slow. [P3]

I walk slowly, also it is very long, they have raised it (the struts). Look from here it has risen a lot, and this is a problem. [P9]

Its heaviness makes me subject to falling down. Once I did fall down and suffered a fracture in my arm. [P3]

I mean if I want to go downstairs, just a moment ago, if I was not catching the handrails, I may fall down on my face. [P9]

Some satisfaction with using the device. Despite the mentioned drawbacks of the usability of the RCWs, some participants suggested the devices were excellent to use and they were satisfied with their device experience:

Excellent, excellent, it helps me a lot, I mean, the situation will be better. [P2]

I see it [as] very excellent, thanks, Allah. [P6]

Interestingly, one participant (P6), who had end-stage Charcot foot (rocker bottom deformity) with chronic ulceration, found the RCWs better than regular footwear, as the foot was swollen, and no regular footwear would fit that foot.

The shoes started challenging me, I did not know which shoes I [would] have to wear. No shoe fits my foot, my feet get bigger and swollen, no shoe fits them. I *have been forced to (wear the boot) ..., I am psychologically comfortable, yes, thanks, Allah. [P6]*

However, one participant was not satisfied with the high cost of the RCWs.

The second thing is that the device is costly, very costly for normal people if they want to buy it for 140 dinars (around 280 AUD), I mean it is overpriced and not normal, that's all. [P9]

Other participants indicated that were not satisfied with their experience wearing the RCW, which had created psychological stress for them:

Of course, it has a psychological effect. I feel upset with this thing. [P3]
No, because after a long time you will get bored from it. [P5]

TCC was described as a more practical offloading option. Two participants who had previously used both TCC and RCW for their offloading treatments stated that TCC was a better and more convenient experience.

It is good. But for me, the cast is better than the boot. [P4]
It is more comfortable. The cast is more comfortable. If you want to enter the house, you keep wearing it as a shoe. You can't take it off then wear it again. But for the cast, you can take off the bottom of the casting, which is the cast shoe, you can take it off and walk, I mean it is more comfortable. [P5]

The superior healing effectiveness of TCC in comparison with RCW was another reason for this preference. Another participant stated:

When I had the cast, the wound was healed gradually, I mean it was close to healed. Now, after I re-wore the boot, they told me that the wound became larger. I told the nurse here that the wound has become larger, I mean at the beginning it was smaller, so the cast is better than the boot. [P4]

Performing activities of daily living. Most study participants reported that wearing the RCWs negatively impacted their ability to perform daily life activities:

There are no activities, I gave up going outside. I don't go for some occasions or stuff. [P4]
The life becomes limited with it. You can't go to the toilet because of its heaviness. [P9]

More specifically, wearing RCWs impacted the working abilities of some participants in their routine jobs:

> *You can't work while using it, you can't bend down, and you can't pull some stuff as well. [P3]*
>
> *I used to supervise my business. I only took sick leave in the last several days. I wanted to wear it and go to work, the day I went for an examination, my brother came and took me to the hospital, and after that, I haven't worked. [P7]*
>
> *Also, regarding me, I used to work as a lecturer in the university and my work has stopped because I can't stand on my foot, so the device, I have used it, it obstructs my movement, I always sit up because of it. It pulls me to the chair to always sit up in it. [P9]*

Moreover, wearing RCWs created difficulties when climbing stairs or even going to the bathroom for some of these participants:

> *I wear it in the bathroom during bathing, I elevate my legs. I use a chair to elevate my foot, and in a period, I used to elevate both legs during bathing, but you see how this is uncomfortable if I don't have anyone, I mean if I fall. I mean, thanks to Allah, I can slightly manage myself. [P6]*
>
> *Stairs affect [me] a lot when I go up or down the stairs because both legs are not on the same level. One leg is higher than the other one. So, when I go downstairs, all the pressure affects the knee. This what I have felt that it is harmful regarding the boot. If it is possible to provide a shoe with the same height of the boot, I think it will be good. [P7]*
>
> *Moving in [sic] stairs, going downstairs, you can't, because of its heaviness. I mean its heaviness hits the leg from the upper side. [P9]*

In contrast, two participants reported that wearing the devices helped them to walk and to perform specific daily life activities

> *Yes, I wear it and go outside. In the past when I used to come here before around one month, my brother used to take me by car. He used the wheelchair to bring me here. I mean I came here by a wheelchair and the same when we go back home but now as you see in real. [P1]*
>
> *That is it, I wear it (the RCW) for the reason of walking and to protect the foot bone from extra fractures. This is what makes me wearing it. [P6]*

Whereas others reported that wearing the devices did not alter their activities:

It is normal, I wear it when I am invited to an event or go to the market…, this is normal. [P2]

I get used to, I get used to it and I can work, thanks to Allah, I mean I can serve myself; I do my work even if I stand little and sit little. [P6]

I drive my car while wearing it, and I haven't felt any changes. [P10]

In summary, the usability of these devices was found to influence the participants' perspectives to adhere to wearing their devices, including factors such as the comfort, physical features, impact on balance, satisfaction, and the impact of the devices on daily life activities. All of these factors potentially interacted with each other, affecting participants' daily adherence to wearing RCWs.

5.6 DISCUSSION

This study resulted in two main themes. The first theme described the variation and inconsistency in the reported adherence to wearing RCWs. Despite participants reporting adherence for most of the day, they later admitted non-adherence in sedentary indoors activities and short distances of weight-bearing steps. The second theme explained that adherence seemed to be affected by factors related to personal knowledge or beliefs, the severity of the diabetic foot disease, social support, and the usability of the RCW.

5.6.1 Theme 1: Reporting of adherence was varied and inconsistent

Adherence was presented with inconsistency by the study participants. Most participants initially reported using RCWs for most of the day except during the night when sleeping. Wearing the offloading device for most of the day is in line with a previous quantitative study (n = 60), in which 82.7% of patients self-reported they adhered to wearing knee-high removable devices for more than 50% of the day (53). However, after further discussion, participants in the current study admitted non-adherence in several sedentary indoor activities such as sitting, relaxing, or during personal hygiene and non-adherence in short distances of weight-bearing steps. It seems participants did not understand different aspects of adherence such as wearing time or walking steps as many of them claimed that they perfectly adhered to wearing the device for most of the day. This highlights the importance of considering patients' perception of offloading adherence for both clinical practice and future research.

This theme provided details of non-adherence to wearing RCWs, which has not been mentioned in previous quantitative studies (52-54, 274, 328). Most non-adherence took place indoors, in line with previous studies of adherence to preventive footwear (274). New information showed the specific activities where patients with DFUs were unlikely to wear RCWs, for example, at night, especially when they woke up to go to the toilet. This specific information was not mentioned in previous offloading research. Adherence was mainly measured objectively using activity tracking without any subjective information from patients regarding where they specifically did not adhere to wearing their offloading devices (52, 54).

This theme also showed that investigating non-adherent steps was challenging during the study interviews as participants' perception of adherence was that wearing the device for most of the day could be considered "ideal adherence". However, after a deeper discussion regarding any non-adherent steps, most started to acknowledge they did not always have ideal adherence behaviour. Some participants reported that the number of steps without their RCWs was not that large, only a few meters within indoor space. Clinicians may need to be more specific in the assessment of adherence to offloading devices or preventive footwear through careful assessment of the steps that patients usually walk without any offloading. The need for this specific investigation is mainly related to the potential variation of subjective perception of adherence, as patients in this study showed a misperception about what ideal adherence was, including the aspects of adherence such as wearing time or walking steps. This also highlights the need to identify the perceptions of patients with DFUs regarding adherence to wearing offloading devices or footwear in future research.

In this investigation, participants reported only walking short distances (a few meters) indoors without using the offloading devices. This is in contrast to previous quantitative research that showed much higher non-adherence (40–70%) during weight-bearing activities (52, 54). It is possible that the participants in this study overestimated their adherence to wearing RCWs, as reported previously in other conditions (329, 330). However, factors affecting adherence can be responsible for this difference, including the culture or differences in populations of heterogenicity (331). For this reason, objective measurement of adherence to offloading devices has been reported as stronger than subjective (52, 95, 316). However, future research is required to compare the validity and applicability of using mixed methods for estimating offloading adherence.

5.6.2 Theme 2: Adherence was a consequence of multiple psychosocial, physiological, and environmental factors

The second theme of this qualitative investigation explained a range of potential factors that may interact with DFUs patients' adherence to wearing RCWs, as follows.

5.6.2.1 Specific offloading knowledge or beliefs influenced adherence

Knowledge or beliefs formed a category of factors affecting adherence to wearing RCWs. Personal cognitive factors are important constructs to predict human behaviour in SCT, as supported by much clinical evidence (63, 66, 69, 275-278). Different levels of knowledge related to the prescribed offloading treatment (RCWs) were noticed among participants. Despite their impressive understanding of the mechanism and the benefits of RCWs, it was clear that there was a misperception regarding the optimal adherence to offloading, as mentioned. Participants believed that walking without wearing the RCWs for a few steps might not be harmful. Interestingly, similar findings were also reported in previous qualitative reports that studied offloading and self-care activities in patients with DFUs (57, 318). However, Crews et al (52) found no significant association between beliefs and adherence to RCWs. However, their investigated beliefs were mainly related to DFU onset, consequences, and treatment effectiveness not specifically beliefs related to offloading adherence. Previous observational studies (55, 262) have highlighted the possibility of knowledge\beliefs impacting on adherence to offloading. However, there are contradictory findings regarding the impact of knowledge on adherence outcomes to wearing preventive footwear for instance with minimal evidence (273, 274). Thus, future research with new valid tools for measurement of specific beliefs or knowledge of RCWs, especially measuring perceptions or understanding of offloading adherence, is required, which may lead to more powerful evidence regarding adherence predictors.

The results of this study also highlighted self-efficacy beliefs as a possible predictor of adherence to wearing RCWs. Most participants stated that wearing RCWs for every step or all the time was difficult for them, especially during activities such as sitting or sleeping, and they were not confident about accomplishing such behaviour. Likewise, a previous qualitative investigation (57) reported that adherence to wearing the offloading devices all the time was challenging for patients because of the impact of such devices in performing daily life activities. Personal control of offloading adherence was previously tested with no significant relationship found (52). However, the tool used was related to the personal ability to manage DFUs, while the current study showed low self-efficacy to adhere to wearing RCWs for every step, demonstrating the need for a specific measurement of self-efficacy to offloading or footwear adherence.

5.6.2.2 The impact of the severity of foot disease on adherence outcomes

Physiological consequences related to diabetic foot disease such as pain, postural imbalance, and ulcer healing were reported to impact adherence to wearing RCWs. Pain, especially around the wound area, encouraged some participants to wear their offloading devices as it relieved the degree of pain. A previous longitudinal study (52) showed adherence to RCWs was significantly predicted by the presence of pain related to neuropathy. In another area, pain was found to be a predictor of adherence to anti-pain medications (332). Postural imbalance also enhanced participants adherence to wearing RCWs. This imbalance can result from severe diabetic foot neuropathy or amputation of toes (333-335). However, surprisingly, a previous longitudinal investigation of RCWs' adherence found neuropathic postural instability was associated with poorer adherence to offloading treatment (52). This contradictory finding could be related to the exclusion of advanced diabetic foot disease in Crews et al's (52) study, as there was a need to control for factors that contributed to wound healing. This could decrease the chance to include patients with serious diabetic foot complications where RCWs could help them to walk. This limited inclusion of the less severe DFUs cases could impact the generalisability of the determinants of adherence detected by Crews et al (52). Lastly, the progression of wound healing motivated participants to adhere to wearing RCWs. It has been hypothesised that motivation can be enhanced through visualising the progression of wound healing, which can enhance patients' ability to perform health behaviours such as self-care activities (336, 337). Previous qualitative research has reported that patients' motivation and engagement with self-care activities were enhanced through monitoring the successful healing outcomes of their DFUs (286). Likewise, a case-series study reported the empowerment and the motivation of patients with VLUs to their treatment when they measured the progress of their wound healing (338). Bandura (78) argued that once individuals are involved in the mastery of their success, they are more likely to perform the required tasks, and this was stated as "performance achievement". Thus, engaging patients with the treatment by observing the progression of their wounds seems promising to enhance RCW adherence.

5.6.6.3 Social support benefited adherence

Participants stated the importance of support from clinicians and families. This has been shown to improve adherence outcomes in other chronic conditions such as HIV (339, 340). Further, social support was associated with self-care activities and self-management among people with diabetes (341, 342). However, a recent systematic review showed scant evidence to support education or motivation in enhancing diabetic patients' adherence to preventive footwear (343). The possible impact of the continuous support of clinicians on enhancing RCWs adherence has been highlighted in previous offloading research (51, 262). Edwards et al (344) reported the significant impact of a social model of community care in improving the clinical outcomes of patients with VLUs. Similarly, a review of the literature (345) emphasised the role of clinicians such as nurses in providing health education that can prevent DFUs. Support from family and other individuals was highlighted in this study as helping patients to wear their RCW and to remind and motivate them to adhere to wearing RCWs. This issue was also reported in a previous qualitative investigation from Canada (248) in which diabetic neuropathy in extremities was a barrier to patients' ability to wear or take off the device independently. Family support is recommended to improve adherence to compression therapy among patients with VLUs (346). However, the evidence to confirm the benefits of social support on adherence outcomes is weak according to a previous meta-analysis (347). In this study, the lack of social support impacted participants negatively when wearing offloading devices in outdoor settings as they received negative reactions to the physical appearance of these devices from others. Appearance has been found to impact acceptance and adherence to preventive footwear among patients with diabetes in different developed populations (274, 296, 328, 348). Physically, RCWs are knee-high orthotic devices which have worse appearance than preventive footwear. This highlights the need for social support to help patients in accepting these devices.

5.6.6.4 Logistical issues and physical features of RCWs (the usability of the offloading device)

RCWs were described as uncomfortable devices and this was related to the physical features and the usability of the devices. The heavy weight of RCWs was one of the main reported issues that impacted the level of comfort. According to Crews et al (43) ankle-high RCWs, which have less size and weight, may enhance stability as well as adherence outcomes. This was confirmed by previous findings of one RCT from the Netherlands and Germany in which the knee-high RCW was associated with the lowest adherence self-reports (53). Another previous cross-sectional study reported the impact of the size of the RCW on the level of comfort. Wearing knee-high RCWs was significantly less comfortable than wearing ankle-high RCWs or regular athletic shoes (349). The friction between the upper edge of the knee-high RCW and the underlying skin was also reported as an upsetting experience, demonstrating the need for enhancing the quality of RCW manufacturing to deal with such issues.

Participants also described pain resulting from the use of the RCWs. The incompatibility between the limb with the RCW and the other limb with regular footwear was reported as the possible cause of this pain. This was described previously in older adults as induced limb length discrepancy (LLD), which can lead to musculoskeletal pain (350, 351). A previous expert report discussed the possible impact of wearing RCWs on developing pain knees or low-back due to the related to LLD (352). Pain was a barrier to adherence to physiotherapy according to a previous systematic review (353). A previous study showed that peak plantar pressure increased when the LLD was induced above 20 mm and this can increase the risk of ulceration in the shorter limb (the limb without RCW) (354). This demonstrates the importance of maintenance of limb length balance when prescribing RCWs to enhance walking balance, pain reduction, and balance pressure distribution on both feet.

Despite the reported drawbacks of using RCWs, several participants reflected positive satisfaction, in line with a previous study into using removable offloading devices (264). The removability of prescribed RCWs may lead to satisfaction, as patients can perform some daily activities such as bathing, sleeping, or driving more easily compared to non-removable offloading devices (42, 56, 263). A previous comparative study found that patients' satisfaction with the removable loading devices was significantly higher than the other non-removable offloading modalities (262).

According to Piaggesi et al (262) prescribing RCWs was also significantly less costly than non-removable offloading modalities. However, the current investigation demonstrated that some participants were more satisfied with the total contact cast method for offloading, as casting was described as a better and more convenient experience and that a total contact cast was more effective in healing DFUs. They can also be more practical for walking inside the house because participants usually wear shoes over the cast, so when they enter the house, they can take off the shoes and walk with only the cast, while wearing shoes with RCWs is not possible. Similarly, in a previous qualitative investigation, patients were highly satisfied with the healing results of the total contact cast, which were considered faster than RCWs but their level of satisfaction regarding comfort, mobility, and the cost was less (248). Lavery et al (264) found the removability feature of the prescribed offloading devices was not a significant predictor of patients' satisfaction. In general, treatment satisfaction is a significant predictor of adherence according to a literature review (355). To the best of the PhD candidate's knowledge, the association between satisfaction with RCWs and adherence has not been investigated. However, in diabetic preventive footwear, although Waaijman et al (274) found that patients who perceived their diabetic preventive footwear to be more attractive showed better adherence, a previous investigation (296) reported contrary findings. Some studies of other conditions have also reported that dissatisfaction was associated with less adherence (356-358). A quantitative investigation is required to test the possible relationship between satisfaction of the prescribed RCW and adherence.

Lastly, in this study, RCWs were reported to be useful in performing daily life activities as they helped participants with walking balance, as mentioned previously, which resulted in improving the quality of daily living and performing some daily activities. However, this was not always the case, as some participants complained about the negative impact of RCWs in limiting their daily activity and this could potentially impact their adherence. A negative impact on daily life activities or mobility was also reported in previous qualitative semi-structured survey from Australia (56), in which patients reported that activities such as bathing, sleeping, mobility, or climbing the stairs were negatively affected. Some participants illustrated the negative effect of wearing RCWs in performing their daily routine jobs or outdoor activities (56). Similarly, a previous qualitative investigation from Canada found a moderate impact of RCWs on reducing mobility, such as the heaviness and bulkiness of the devices reducing daily life activity (248). However, there was no significant difference between RCWs and other offloading options such as TCCs regarding the impact on daily life limited mobility (263, 264). None of the previous studies explored the association between performing daily life activities during using the RCWs and adherence, which requires testing in future research.

5.7 RECOMMENDATIONS

As the perception of the optimal adherence to wearing RCWs was not clear for the participants of this study, further investigation of adherence is required in routine practice (i.e. to ask more specific questions about the steps that patients usually walk without any offloading). However, this suggestion needs to be explored in future quantitative research by testing patients' recognition of offloading adherence. This study resulted in several barriers and enablers that can impact adherence to RCWs among people with DFUs and need to be considered. The barriers included: i) lack of knowledge and motivation to wear the offloading device for every weight-bearing step which highlights the need for specific education programs to enhance patients' adherence; and ii) the physical features of the RCWs such as heaviness, size, appearance, and balance are barriers to adherence, which the offloading industry may wish to address by identifying solutions to enhance patients' experiences. Enablers, on the other hand, included: i) increased severity of diabetic foot disease, which interestingly improved adherence, thus, clinicians need to consider the possibility of less adherence if patients have fewer neuropathic symptoms and the need for using non-removable offloading devices as a priority for this population; and ii) social support from families, clinicians, and the community seems beneficial to improve adherence to wearing RCWs.

5.8 STRENGTHS AND LIMITATIONS

This is one of the few qualitative studies in offloading and the first known qualitative study to explore adherence to RCWs. The resulting themes and categories were comprehensive in describing patient perceptions of adherence and factors influencing adherence. Using a qualitative design to explore RCW adherence has identified new details in terms of which times of the day or walking activities where patients avoid wearing RCWs. Further, this study provides new information about adherence to offloading from a different culture than in the available literature. Finally, translation of the transcripts was robust using forward/backward translations.

However, there are some limitations of this study. First, as the design was qualitative, the results should be considered with caution and are unable to be generalised. Second, many of the recruited participants had severe diabetic foot disease (i.e. Charcot foot, or amputations); thus, the results can only be interpreted for this group.

5.9 CHAPTER SUMMARY

This chapter presented a qualitative investigation of adherence to wearing RCWs among patients with DFUs, resulting in two themes. The first theme described inconsistent reporting of adherence, as RCWs were reported to be worn for most of the day; however, participants admitted non-adherence in sedentary activities or weight-bearing steps, especially indoors. This highlights the overestimation of adherence in this study. This qualitative study was also informative in exploring the specific times and activities of non-adherence to wearing RCWs. The second theme described the multiple factors that could affect adherence to RCWs, including factors related to knowledge or beliefs; more specifically, barriers related to the poor understanding of optimal adherence. There was a lack of understanding regarding the importance of wearing the offloading device for every single weight-bearing step, in addition to poor self-efficacy in achieving this task. Physiological factors related to diabetic foot disease, such as pain, postural balance, and wound healing were also found to impact adherence. Finally, social support, in addition to the offloading device usability and its physical features, can be other important factors that affect adherence. Overall, this study highlights the complexity of the determinants of adherence to offloading among patients with DFUs, including the interaction of multiple psychosocial, physiological, and environmental factors.

Chapter 6: Study 2 – Translation Study

6.1 PREFACE

Study 2 aimed to produce a valid and reliable Arabic translation of several diabetes foot-related psychosocial scales including the Foot Care Confidence Scale (FCCS) (1), Foot Care Outcomes Expectations Scale (FCOES) (2), Patient Interpretation of Neuropathy (PIN) scale (3), and Neuropathy-specific Quality of Life (NQOL) scale (4). It also aimed to validate the translation of several offloading treatment questions and visual scales developed\adopted for this research carried out in Jordan. The translated instruments were required to measure different factors that may be associated with adherence to wearing removable cast walkers (RCWs) among Jordanian patients with diabetic foot ulcers (DFUs) in the main study of this research (Study 3).

Producing a valid and reliable Arabic translation of the FCCS, FCOES, PIN, NQOL, and offloading-related scales was undertaken in two phases (validation of translation and testing of reliability). Phase A comprised the translation process, including the research question, selected scales, translation method and translation results. Phase B comprised the reliability study (test-retest) including the research question, study design, selected sample, research setting, ethical considerations, data collection procedure, data analysis, data management, and main results.

6.2 PHASE A: TRANSLATION

6.2.1 Background

As the main study (Study 3) was conducted among Jordanian population who had DFUs, a valid Arabic translation of these scales was essential. More importantly, the Arabic translation of these important scales will help researchers in the Arabic world to investigate different aspects of diabetes-related foot disease that these scales aim to measure. Diabetes is an epidemic disease in most Arab countries and is associated with a rapid increase (359). Similarly, DFUs and lower limb amputations were highly reported in these countries (360). This demonstrates the significant need for further research in this region (361). Thus, having a new valid and reliable Arabic translation of the different popular psychometric scales selected in this study will facilitate new research in the Arabic region.

Cross-cultural translation of psychometric scales is a common practice in healthcare-related research; however, it is important to produce a valid translation (362). This means that the meaning of the original questionnaire should be translated thoroughly so that language differences do not impact understanding of the instrument's content (363).

6.2.2 Aim

This phase aimed to produce a valid cross-cultural translation of several diabetes foot-related psychosocial scales.

6.2.3 Methods

6.2.3.1 Research question

Are the Arabic translations of the FCCS, FCOES, PIN scale, NQOL scale, and offloading-related scales valid for the Jordanian population?

6.2.3.2 Questionnaire

The original English questionnaire comprised of two main sections (see Appendix 19): Section A contained the psychosocial scales: FCCS (1), FCOES (2), PIN scales (3), and NQOL scales (4) (see Table 6.1). These scales aim to measure factors related to diabetes-related foot self-care activities such as footcare confidence (self-efficacy) (FCCS) and footcare outcomes expectations (FCOES). They also measure patients' knowledge about neuropathy and ulceration (PIN) and neuropathy quality of life (NQOL) symptoms (i.e. pain, sensory and motor neuropathy). Section B contained several Likert and visual scales developed by the PhD candidate based on the findings of Study 1 (see Table 6.2). In the field of diabetic foot offloading, there is a lack of robust psychometric scales that measure different aspects related to this treatment. Visual scales have commonly been used in several offloading studies to measure different variables related to using the offloading device among patients with DFUs (262, 349, 364, 365). This includes level of comfort (349, 364, 365), level of activities or the ability perform them level of sleeping (364), level of satisfaction (364, 366), and the likelihood of wearing the offloading device again (364). In this study, these scales were translated into Arabic to explore offloading treatment (RCWs) in the Jordanian population.

Table 6.1: Section A. Validated psychosocial scales incorporated in the study questionnaire

Instrument	Description
FCCS (1)	Consisting of 12 Likert scale items measuring the confidence (used as a substitute measure of self-efficacy) of individuals with diabetes to undertake foot self-care activities. It is a valid and reliable scale (Cronbach's alpha coefficient was 0.92) (1). One item was added to provide a specific measurement of patients' confidence to wear RCWs during all walking steps. It was adapted from one of the original questions of FCCS that addressed diabetic patients' confidence to wear preventive shoes.
FCOES (2)	This is an adapted scale by Nguyen et al (2) from Vileikyte et al (3) comprising 15 items that measure the expectations of diabetic patients regarding the outcomes of footcare. However, a new item (number 16) was added and adapted to measure patients' outcomes expectations of wearing removable offloading devices. The previous testing (2) showed this scale as valid and reliable (content validity index= 0.97, Cronbach's alpha= 0.97).
PIN scales (3)	This instrument measures level of knowledge of the potential causes of diabetic neuropathy and DFUs and includes the following scales: • A scale of four items that measures self/practitioner-blame: (Cronbach's alpha = 0.62, Pearson's r = 0.56). • A scale of four items that measures knowledge of physical causes of foot ulcers: (Cronbach's alpha = 0.77, Pearson's r = 0.52) • Two items (1, 6) of self-blame of the cause of neuropathy and physical causes of foot ulcers: Pearson's r was < 0.40. • A scale of three items that measures knowledge of the duration and time of the onset of DFUs: (Cronbach's alpha = 0.70, Pearson's r = 0.62)
NQOL scales (4)	This instrument measures the frequency (i.e. never – all the time) of neuropathic symptoms including neuropathic pain, loss of sensation, and motor neuropathy and the related bothering feelings (i.e. non- very much bothering). The scales also

examine the effect of these conditions on patients' health-related quality of life. This includes the following subscales:

- A scale of seven items that measure the frequency and the degree of bother of symptoms of painful neuropathy paraesthesia such as burning or throbbing in the feet (Cronbach's alpha = 0.88).
- A scale of three items that measure the frequency and the degree of bother of reduction or loss of sensation in the feet, such as inability to feel temperature and/or objects (Cronbach's alpha = 0.90).
- A scale of three items that measure the frequency and the degree of bother of motor neuropathy symptoms such as weakness in hands or problems in standing or walking balance (Cronbach's alpha = 0.86).

Table 6.2: Section B. Customised questions developed and incorporated in the study questionnaire

Item	**Description**	**Rationale**
Item 1: *This question asks you about your personal beliefs regarding the treatment of diabetic foot ulcers treatment. Please order the items below from 1-6 according to the importance of treatment. (Control diabetes, antibiotics, dressings, offloading, physician role, and others).*	This question asked participants to order different DFUs treatments from 1-6 according to the importance of treatment.	Study 1 described participants' beliefs of treatment priorities for DFUs where offloading treatment was not considered as a priority
Item 2: *How comfortable is the offloading device that you use to treat your ulceration? (0-10).*	This is a visual scale (0–10) created to measure the level of comfort during wearing RCW (i.e. 0 = not at all comfortable, 5 = moderately comfortable, 10 = maximally comfortable).	Visual scales are reliable to measure the level of comfort of footwear (367). This scale has been used previously as a validated scale to measure DFU patients' level of comfort with RCWs or footwear but with no evidence of reliability

		(349, 364, 365)
Item 3: *How well are you able to perform normal daily activities? (0-10).*	This is a visual scale (0–10) created to measure the ability to perform daily life activities during wearing RCWs (i.e. 0 = not at all able, 5 = moderately able, 10 = maximally able).	This scale has been used previously (364) to measure DFU patients' ability to perform daily life activities while wearing RCWs, but with no evidence of reliability.
Item 4: *How much is your activity level altered? (0-10).*	This is a visual scale (0–10) that was created to measure the alteration in activity level during wearing RCWs (i.e. 0 = not at all altered, 5 = moderately altered, 10 = maximally altered).	This scale has previously been used (364) to measure the alteration in activity level during wearing RCWs, but with no evidence of reliability.
Item 5: *How much your sleeping activity is changed? (0-10).*	This is a visual scale (0–10) created to measure changes in sleep activity during using RCWs (i.e. 0 = not at all changed, 5 = moderately changed, 10 = maximally changed).	This scale has previously been used (364) to measure changes in sleeping activity during using RCWs, but with no evidence of reliability.
Item 6: *Overall, how satisfied are you with the offloading device used to treat your ulceration? (0-10).*	This is a visual scale (0–10) created to measure the level of satisfaction during using RCWs (i.e. 0 = not at all satisfied, 5 = moderately satisfied, 10 = maximally satisfied).	This scale has previously been used (262, 364) to measure the level of satisfaction during using RCWs, but with no evidence of reliability.
Item 7: *How much are you likely to wear the prescribed offloading device again? (0-10)*	This is a visual scale (0–10) created to measure the likelihood to wear the prescribed RCW again (i.e. 0 = unlikely, 5 = moderately likely, 10 = maximally likely).	This scale has previously been used (364) to measure the likelihood of wearing the RCWs if it will be prescribed again, but with no evidence of reliability.

Item 8: *How heavy have you found the offloading device to wear? (0-10).*	A visual scale (0–10) was created to measure participants' perception of the heaviness of the device (i.e. 0 = not heavy at all, 5 = moderately heavy, 10 = very heavy).	Study 1 described the heaviness of the RCWs while wearing them. Visual scales are reliable and valid in health research (368).
Item 9: *How much difficulty do you have in putting on the prescribed offloading device? (0-10).*	A visual scale (0–10) was created to measure the difficulty in putting on the device (i.e. 0 = not difficult at all, 5 = moderately difficult, 10 = very difficult).	Study 1 described the difficulty that participants face when putting on the RCW. Visual scales are reliable and valid in health research (368).
Item 10: *How often do family members or somebody help you when you put on and take off the offloading device? (0-10).*	This Likert scale question was created in this research to estimate how often family members support wearing or taking of RCWs.	Study 1 described the impact of social support. Participants claimed that getting help from a family member helped them to adhere to wearing the RCWs especially in wearing or taking off the offloading device, which was a challenge for them.
Item 11: *Please estimate the percentage of the time you wear the offloading device on an average day (excluding sleeping). (0-100%).*	A visual scale (0–100) of the percentage of the time of adherence during the day was adapted to this study. It aimed to measure the participants' self-reported estimation of adherence time to wearing the offloading device	Measuring adherence time to wearing the offloading device is recommended (95, 126). Visual scales were found to be reliable and valid in health research (368). Analog scale of self-report of medication adherence was also found to be valid (369).
Items 12, 13: *How often do you wear the offloading device inside the house (12) or outside the house (13)? (All of*	This is a self-report estimation of adherence time to wearing the offloading device during the day.	Measuring adherence weight-bearing time to wearing the offloading device is recommended (95, 126).

the time, most of the time, some of the time, a little of the time, or none of the time)		These are Likert questions that ask participants to estimate their daily adherence time to wearing the offloading device inside or outside the house. These questions were used in a previous self-report of adherence time to wearing the offloading devices but without validation (53).
Item 14: *Please estimate the percentage of steps you wear the offloading device for on an average day (excluding sleeping). (0-100).*	A visual scale (0–100) was created to measure participants' estimation of adherence to wearing the offloading device (i.e. 0 = not wearing the device at any step, 50%= wearing the device for half of the steps, 100 = Wearing the device for every single step).	Measuring adherence to weight-bearing steps to wearing the offloading device is recommended Visual scales were found reliable and valid (368). Analog scales of self-report of adherence to medication or wearing footwear are also found to be valid (369).
Items 15, 16: *How often do you wear the offloading device inside the house (15) or outside the house (16)? (Every single step, most of the steps, half of the steps, only in a few steps, or not in a single step).*	These are Likert questions that ask participants to estimate their daily adherence steps to wearing the offloading device inside or outside the house.	Same as above (95, 126). This was developed in this research, with no previous validation.
Item 17: *How much do you agree that walking a short distance (i.e. distance up to 5M inside the home) without the offloading device will not be harmful to your wound? (Totally agree, moderately agree,*	This is a Likert question that estimates the belief of the importance to wear the RCW for every step.	Study 1 reflected participants' lack of awareness of the importance to adhere to wearing the RCWs for every step, although they showed adequate knowledge of offloading treatment and adherence.

neither disagree nor agree, disagree, or not agree at all).	

6.2.3.3 Translation model

The translation of psychometric scales is an accepted method to ensure appropriate and valid translation (370-372). Evaluating and adapting cultural acceptance should involve a forward translation, a back-translation, and pilot testing procedure (362). Back-translation is a common method to assure appropriate and valid translation (370-372). The translation procedure was guided by Brislin (373), Jones et al (371), and Sousa and Rojjanasrirat (362). This included having both forward and backward translations with two committees (i.e. each had two translators and clinicians).

A model of translation suggested by Brislin (373) highlighted the importance of having different translations by a team of independent translators. This can lead to a consensus of the most accurate translation. Sousa and Rojjanasrirat (362) also argued about the importance of having two translators; one of whom is ideally aware of the medical language, while the other translator must know about the culture and the differences in language structures of both languages. This should result in covering both the medical and the regular spoken language.

6.2.3.4 Face validity

In both forward and backward translations, a panel of experts judged the validity of the produced translation. Face validity is one of the psychometric essentials to assess if the scale seems to measure the concept of interest (374). The subjective assessment by the two panels' experts was evidence of validation of the translated scales (374).

6.2.3.5 Participants and setting

The translation procedure for the study questionnaire was conducted in Jordan between April–July 2019. This facilitated direct contact with a group of bilingual translators, clinicians, and experts who contributed to all the steps of this translation. Then the translation was tested among Jordanian patients with DFUs. The inclusion criteria details of the study participants are presented in Table 6.3.

Table 6.3: Characteristics of the included participants in the translation process

Forward translation and the first consensus	**Backward translation and the second consensus**	**Pilot testing**
Translator 1 (TL1) was a bilingual clinician with adequate knowledge of health care terminology and the content of the scales.	**Translator 3 (TL3)** had the same characteristics as TL1.	**The five participants** were Arabic native Jordanian patients with DFU who met the inclusion criteria of the main study (i.e., who had DFUs and used RCW offloading treatment). Further, they were competent in Arabic reading and writing skills.
Translator 2 (TL2) was a certified translator familiar with the cultural and the colloquial phrases, and the emotional terms of the scales. However, this translator was not familiar with the medical terminology of the scales.	**Translator 4 (TL4)** had the same characteristics as TL2.	
The independent translator (TL3) was a bilingual person with a high academic degree in English literature.	**Two native English researchers** with high research degrees in the fields of nursing and podiatry.	
Expert in Arabic linguistics with PhD in Arabic literature and synonyms.	**The bilingual experts** were experts in the fields of diabetic foot and nursing and competent in both English and Arabic. They had a high degree in nursing (which was taught in English) and clinical experience of at	

	least two years in the diabetic foot.
	The expert in pain was competent in both English and Arabic and holds a higher degree (PhD taught in English).

6.2.3.6 Procedure

All participants were given information sheets and they then signed a consent form of the study procedure (see Appendix 7-11), The translation procedure is presented in Figure 6.1, and included the following steps:

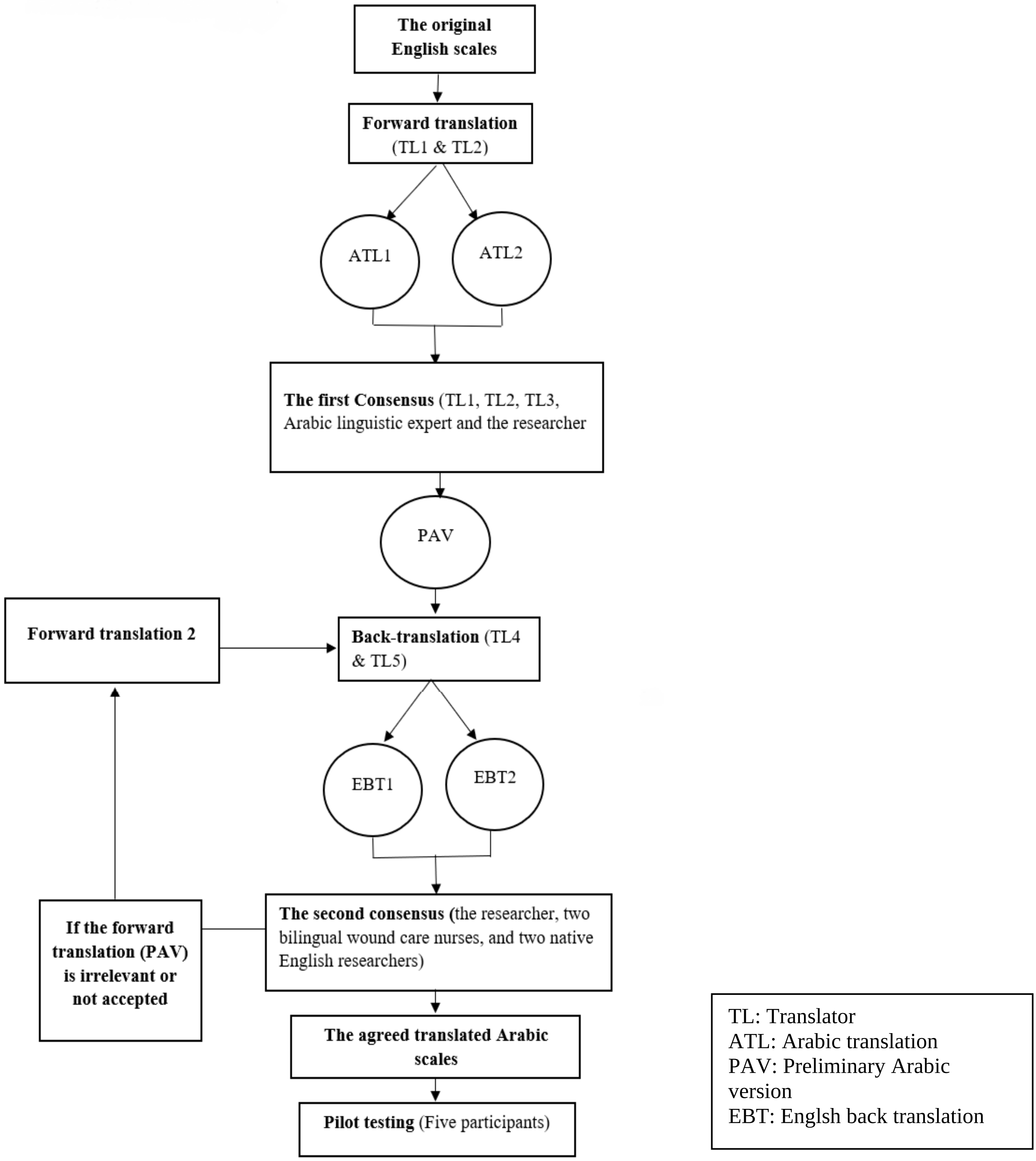

Figure 6.1: The translation process of the study questionnaire

Forward translation

The English scales were sent to two independent English-Arabic bilingual translators (TL1, TL2) to produce two Arabic translation drafts (ATL1 and ATL2) that covered both the medical and regular spoken language. Both TL1 and TL2 were asked to translate the entire questionnaire from English to Arabic within one week then provided the translations to the PhD candidate.

The first consensus process

Both ATL1 and ATL2 were compared to each other, as well as the original English version by an independent translator (bilingual speaker) (TL3). This comparison aimed to check and gain agreement for the translation regarding any ambiguities and discrepancies of meanings of words or sentences. Any non-agreed items, phrases, or words during this comparison were discussed and revised by both translators (TL1, TL2), the PhD candidate and the independent translator (TL3). Both ATL 1 and ATL2 were compared to produce an agreed draft. For discrepancies that related to using Arabic synonyms, the opinion of an expert in Arabic linguistics (PhD) was obtained, which helped the panel of TL1, TL2, and TL3 to agree on the most appropriate use of the Arabic language regarding these synonyms. This expert also reviewed the overall agreed Arabic translation to detect any grammar or spelling mistakes and detect any poor use of the Arabic language. All of the previous steps facilitated in producing a preliminary Arabic version (PAV) of the instrument.

Agreement on the PAV version was obtained from a consensus of a committee that included both TL1, TL2, TL3, the Arabic linguist, and the PhD candidate (facilitator). The PhD candidate facilitated meetings and correspondence between the committee members (TL1, TL2 and TL3) until consensus on the Arabic translation was achieved on all items of the PAV, which was then used to inform the back-translation procedure.

Back-translation

The PAV was translated back into English by another two independent translators (TL4 and TL5) who were blinded to the forward translation procedure and the original English versions of the instrument. At this stage, two English back-translated versions (EBT1 and EBT2) were produced.

The second consensus process

Two native English researchers (in nursing and podiatry) compared two different back-translations (EBT1, EBT2) with the original English version. This included the format, wording, grammatical structure of the sentences, and more importantly, similarity in meaning and relevance. This helped to detect any discrepancies between EB1 and EB2. Both back-translators (TL4 and TL5) discussed these discrepancies through consensus to resolve any disagreements and agreed on one back-translation, which helped the native English researchers to compare one agreed back-translation with the original English version in a second round. Any detected discrepancies between this agreed back-translation and the original questionnaire were discussed and compared with the Arabic translation (PAV) by a panel of bilingual speakers, including the PhD candidate (methodologist) and two bilingual Jordanian wound care nurses to revise any poor translation of PAV. The opinion of bilingual experts outside the panel was also obtained on some occasions. For instance, an expert in pain (PhD) was consulted to translate items related to pain (i.e. shooting or stabbing pain or throbbing). This led to forward translation 2 of these discrepancies, which then was back-translated again (two versions) (see Figure 1). The agreement of this second translation was obtained from the native English researchers (the same researchers who had previously compared EBT1 and EBT2) through a third round of comparison. Any discrepancies that could not be resolved and were not agreed by the native English researchers were justified by the bilingual individuals based on cultural equivalency and language appropriateness.

Final consensus regarding the back-translation including linguistic agreement and cultural equivalence was obtained from all the second consensus panel. The PhD candidate facilitated meetings and correspondence with the bilingual wound care nurses in addition to the continuous contact with the native English researchers by email to obtain the overall agreement.

Pilot testing

Sousa and Rojjanasrirat (362) suggested the importance of pilot testing the translation on a sample from the target population. For the current study, a pilot test of the agreed Arabic questionnaire was conducted between the 13th and 17th of July 2019. The first five participants who met the inclusion criteria of the main study (i.e., who had DFUs and used RCW offloading treatment) were recruited. Participants were asked to fill out the Arabic questionnaire, and the PhD candidate then offered them a short feedback survey where participants could add their comments (see Appendix 17). This survey included several open questions related to the clarity, understandability, and cultural appropriateness of the Arabic questionnaire. In addition, the PhD candidate estimated the time that the participant took to answer the questionnaire. Overall, this pilot testing helped to establish clarity and feasibility of the Arabic questionnaire in addition to participants' willingness to answer it.

6.2.3.7 Results

The adopted translation model (forward and backward translations with two committee consensus) aimed to produce valid Arabic translation of the study instrument, as discussed in the previous section. Overall, this process resulted in an agreed Arabic translation that maintained the semantic equivalence and cross-cultural adaptation (see Appendix 20).

First, the produced two forward translations resulted in disparities between them. A panel of the first consensus resolved and agreed on these disparities, which resulted in preliminary Arabic version (PAV). The produced two backward translations also resulted in disparities between them, from which an agreed one back translation was then produced. However, when this agreed back-translation was compared with the original English version in the second round of comparison, it resulted in some non-agreed items. A panel of the second consensus resolved and agreed on these items through forward translation 2 then re-back translation (see Figure 6.1). This resulted in several revised items and cross-cultural adaption of other items. Of the 75 items of the translated instrument, 18 items (25%) were revised (Table 6.4), while eight items (11%) were cross-culturally adapted (Table 6.5).

Table 6.4: The resulted revised non-agreed items derived by comparing one agreed back-translation with the original English version

The original words, phrases, or sentences	Back-translation	Committee comments	Revised items
FCCS			
1. Please answer about your CONFIDENCE to do the foot care, NOT if	Please, answer according to your confidence with yourself regarding caring about your	The meaning in the original item is to clarify the difference between	Please answer about your confidence to do the

	you do the foot care.	feet NOT if you take care of them or not	self -confidence and action (do).	foot care, not if you do the foot care
2.	Moderately confident\not confident	Quite confident\ not confident	Moderately confident and quite confident do not convey the same meaning.	Moderately confident\ not confident
3.	I can look at my feet daily to check for cuts	I can check my feet daily for wounds	Cut or fissure is a break in the skin, not truly a wound.	I can inspect my feet daily to check for cuts (cracks) on skin
4.	If I was told to do so, I can wear shoes and socks every time I walk (includes walking indoors).	If I was requested to do that, I can wear shoes and socks whenever I walk (including walking inside the home)	Walking indoors probably covers more than just inside the home.	If I was requested to do that, I can wear shoes and socks every time I walk (including walking indoors)
FCOES				
1.	All statements should be answered	(the original phrase was missed during translation)	The original phrase was written in a small box in the table, which was missed during Arabic translation.	All statements should be answered
2.	Checking inside the shoes before putting them on can prevent foot	Checking inside the shoes when wearing them may prevent the occurrence of foot ulcers.	"Before" and "when" have different meanings. Checking the shoes should be before putting them on not	Checking inside shoes before wearing them can prevent the occurrence

	ulcers from occurring		during wearing them	of foot ulcers.
3.	Immediately informing the diabetic doctor about any changes in my feet (i.e. numbness, muscle cramp, lost or reduce feeling, any lesions, corns, calluses) can prevent foot ulcers from occurring	Telling diabetic doctor directly about changes in feet (numbness, muscle spasm, loss or decrease sensation, any abrasions, callus, or hardness) may prevent the occurrence of foot ulcers.	Directly is different from immediately. In the original instrument "feeling" was used but it was translated to Arabic as a sensation. Despite "sensation" being accepted by the native researchers, bilingual wound nurses suggested a more accurate Arabic translation of the original word "feeling".	Telling diabetes doctors immediately about any changes in my feet (such as numbness, muscle spasm, loss or decreased feeling, any scratches, corns or calluses)
PIN				
1-	Lost or reduced feeling	Loss or decrease of sensation	In the original instrument "feeling" was used but it was translated to Arabic as a sensation. Despite "sensation" being accepted by the native researchers, bilingual wound nurses suggested a more accurate Arabic translation of the original word "feeling".	Loss or decrease in feeling

2- Please indicate how much you agree or disagree with each of the following statements by ticking the appropriate box.	Please point to how much you agree or disagree with each of the following statements by putting (√) in the appropriate square.	The 'point to' is not quite the same meaning as 'indicate' in this instance. Try 'show. You want them to tick or cross on the paper and therefore this is not indicated by point to.	Please indicate how much you agree or disagree with each of the following statements by putting a (√) in the appropriate box.
3- Ill-fitting shoes can cause foot ulcers (open sores)	Improper shoes may cause foot ulcers (opened sores)	Not quite. Ill-fitting specifically refers to the size of the shoe.	Shoes that do not fit the foot can cause foot ulcers (open sores).

NQOL

1- In the past four weeks, how often have you experienced the following symptoms?	In the past four weeks, how many times have you suffered from the following symptoms?	Often refers to 'frequency' not 'many times'.	In the past four weeks, how often have you experienced the following symptoms?
2- Shooting or stabbing pain in your legs or feet	Episodes of severe pain in your legs or feet.	"Shooting" pain refers to strong pain like an electric shock. The stabbing pain is a sharp, deep pain.	Stabbing pain or pain similar to an electric shock in your legs or feet
3- Throbbing in your legs or feet	Shivering in your legs or feet	Throbbing is closer to 'pulsing,' not shivering.	Pulsating pain (comes and goes quickly) in legs or feet

Offloading scales

1-	How comfortable is the offloading device that you use to treat your ulceration?	How comfortable is the offloading device which you are using to heal the ulcers that you have?	Heal and treat have two different meanings.	How comfortable is the offloading device that you use to treat your ulcers?
2-	How often do family members or somebody help you when you put on and take off the offloading device?	To what extent do family members or any other person help you in wearing or taking off the offloading device?	Despite being agreed to by the native researchers, bilingual wound nurses suggested a more accurate Arabic translation to describe how often.	How often do family members or someone help you to wear or remove your offloading device?
3-	Overall, how satisfied are you with the offloading device used to treat your ulceration?	Overall, what is the extent of your satisfaction with the prescribed offloading device which is prescribed to cure the ulcers that you have?	Treat and cure have two different meanings.	Overall, how satisfied are you with the offloading device that is prescribed to treat your ulcers?
4-	The questions (11-16) aim to investigate how often you wear the offloading device in your house and outside your house.	Questions from 11 to 16 aim at checking the time and number of times of wearing the offloading device at home and outside.	Despite the relevance of meaning being agreed to by the native researcher, bilingual wound nurses suggested that often refers to ‘frequency’ not ‘many times’, thus a more accurate Arabic translation was suggested.	Questions from 11 to 16 aim to check how often you wear the offloading device inside and outside the house

5- Please estimate the percentage of the time you wear the offloading device on an average day (excluding sleeping)	Kindly estimate percentage of time for wearing the offloading device during the day (except for sleeping time)	An average day was missing.	Please estimate the time percentage which you wear the offloading device on an average day (except for sleep times).

Table 6.5: Cross-cultural adaptation of some non-agreed items

Original English	**Back-translation**	**Justification to be more appropriate for Arabic use and cultural equiveillance (the PhD candidate and the bilingual wound care nurses' opinions)**
FCCS		
All statements should be answered	All phrases must be answered	Despite the slight difference in meaning between should and must according to the native English researcher, the expression of the Arabic verb is accurate, which reflects both must or should (expressing necessity).
I can call my doctor about problems with my feet.	I can tell my doctor about the problems of my feet	Calling the doctor or clinician is not popular in Arabic culture, especially in Jordan. Patients usually inform or tell clinicians about their needs in the clinic. The verb 'call' could be about access or availability for making an appointment rather than discussing the actual foot pathology in a consultation (This comment was made by one the native experts who agreed with the

		cultural modification of the translation)
FCOES		
Can	may	The literal translation of the verb "can" to Arabic expresses the meaning of the ability. Such translation does not make sense in Arabic especially in the context of the scales. i.e. *Examining feet every day can prevent foot ulcers.* If this sentence is translated literally, it will give this meaning in back-translation. i.e. *Examining feet every day is able to prevent foot ulcers.* This does not make sense for Arabic people and we strongly recommend using an Arabic expression that reflects the probability *(may).*
Seeing the diabetic doctor regularly	Visiting the endocrinologist regularly	The literal translation of seeing the diabetic doctor does not make sense in Arabic culture. The term *"Regular visiting"* is more appropriate.
Offloading scales		
How long do you wear the offloading device inside the house?	How much time do you spend while wearing the device inside the home?	In English, *"how long"* asks about the duration or length. As in the context of the scale, the duration of wearing the offloading device is the aim of the question, the Arabic expression which was used reflects the phrase *"how much time"*

Overall, how satisfied are you with the offloading device used to treat your ulceration?	Generally speaking; what is the extent of your satisfaction for the prescribed offloading	To be clearer, in Arabic we need to add a verb that describes the level of satisfaction such as, *what is the extent.*
How heavy have you found the offloading device to wear?	What is the extent of heaviness did you find in wearing the offloading device?	The same as the above
This question asks you about your beliefs of adherence to wearing the offloading device	This question enquires about your beliefs regarding compliance with wearing the offloading device.	The used Arabic word describes either adherence or compliance which means patients follow-up of treatment. However, the keyword "adherence" has not been evolved in the Arabic language in comparison with English health literature. i.e. "Adherence" has been commonly used instead of compliance.

Pilot testing results

Overall, the recruited participants reported that the Arabic questionnaire was clear, and they faced no difficulties in understanding the content of the questionnaire (see Table 6.6). However, one male participant (P2) stated that the keyword "offloading device" was not clear to him, and after discussion, he suggested adding "offloading boot" or offloading shoe" in brackets. Two participants also missed answering some items. Regarding the visual analog scales (VAS) (0-10) in Section B of the survey, two participants pointed out the numbers above boxes for the given categories. The participant filled the visual scales by choosing the number above the boxes of the given categories. This point was discussed with the PhD candidate supervisors. They agreed to revise the phrase "Circle the number on the line" to "Circle any number on the line". They also suggested separating the boxes that described the scale from the analogue line. The mean required time to fill out the questionnaire was 24 minutes and ranged from 18 to 30 minutes. Overall, based on answering a quick survey (Appendix 17), participants were satisfied with the clarity, understandability of the instrument with no reported issues.

Table 6.6: Pilot testing outcomes of the final agreed Arabic version of the study questionnaire

Code	**Clarity**	**Difficulty in understanding**	**Cultural appropriateness**	**Participant comments**	**Period**	**Researcher comments**
P1*	Clear	No difficulties	Appropriate	No comments	18 Mins	The participant filled the visual scales by choosing the number above the boxes of the given categories
P2	Clear	No difficulties	Appropriate	The keyword "Offloading device" was not clear Offloading boot or shoe was suggested	25 Mins	Around 15 items were missed The participant filled the visual scales by choosing the number above the boxes of the given categories
P3	Clear	No difficulties	Appropriate	No comments	30 Min	No comments

P4	Clear	No difficulties	Appropriate	No comments	26 Min	3 items were missed
P5	Clear	No difficulties	Appropriate	The participant said that this questionnaire is very good and clear which has reminded him of important footcare to do.	20 Min	No comments

* P1-P5: Participants 1-5

6.3 PHASE B: RELIABILITY TESTING

6.3.1 Background

Testing the reliability of a cross-cultural adaptation of translated scales is essential to estimate the consistency of these scales when used across different cultures (375). This is typically performed by conducting internal consistency and stability testing. Internal consistency is one of the most common reliability coefficients, which aims to estimate the homogeneity of the scale items or how well these items measure the same construct (376). On the other hand, stability testing (test-retest reliability) aims to detect the correlation between two scores that usually result from administering the same test by the same persons at two different points of time (377). Thus, these two methods were implemented to test the reliability of the Arabic version of the study instrument.

6.3.2 Aim

This phase aimed to produce a reliable cross-cultural Arabic translation of several diabetes foot-related psychosocial scales.

6.3.3 Research question

- Is the translation of the FCCS, FCOES, PIN scales, NQOL scales, and offloading-related scales reliable for the Jordanian population?

6.3.4 Methods

6.3.4.1 Study design and setting

This study was a cross-sectional design (two visits) to measure the reliability of the Arabic translation of several diabetic foot scales. It was conducted in the Diabetic Foot Clinic at the National Centre for Diabetes, Endocrinology, and Genetics (NCDEG) in Jordan between the period of August and October 2019. Ethical approval was sought from QUT University Human Research Ethics Committee (ethical approval number:1900000418) and Institutional Research Board at the NCDEG.

6.3.4.2 Participants

Two samples of 15 participants were recruited from the NCDEG in Amman, Jordan. The first sample (Sample A) was recruited for the aim of testing the reliability of FCCS, FCOES, NQOLS, and offloading scales. The protocol of Study 3 (the main study) was also tested with this sample. However, another sample of 15 participants (Sample B) was recruited for the aim of testing the reliability of the PIN scales, as the data of this scale were mistakenly collected from Sample A (one of the Likert options was missed).

The inclusion criteria for participants in this study were:

- Age 18 years or more.
- Participants had active DFUs.
- Participants had been using RCW for the treatment of an active DFUs for at least the four previous weeks.
- Participant could speak and understand Arabic, including reading skills.

6.3.4.3 Participant characteristic variables

A large number of characteristic variables were collected from all participants for this study, including socio-demographic, medical history, foot ulcer and treatment variables. Self-reported questionnaires were used to determine socio-demographic, medical history, and treatment variables, except for body mass index (BMI) and HbA1c, which were determined from a review of the participant's medical records or clinical measurement. Furthermore, foot and ulcer variables were determined via clinical examination, except for previous foot ulcer history and ulcer duration, which were self-reported. Table 6.7 displays all variables collected and their definitions.

Table 6.7: Participant characteristic variables and definitions, self-reported unless otherwise indicated*

Variable	Definition
Socio-demographic	
Age	Age in whole years at the time of data collection (378, 379).
Gender	Male or female (378, 380, 381).
Living arrangement	With whom do you live? Living alone, living with family, you are the primary carer for another household member or other living arrangements (279, 382).
Educational level	What is the highest education qualification you have achieved? Primary school, secondary school, undergraduate (bachelor's degree or diploma), or postgraduate (master or doctorate) (73, 378-381).
Employment	What is your current employment status? Employed, unemployed, retired or self-funded (73, 381).
Family income	What is the highest income of your family per month? The monthly income of the family in Jordanian Dinar (JD) (73, 380).
Medical history	
BMI*	Overweight or obese if BMI $\geq$ 25 (383). Weight and height were undertaken from recent medical records or actual measurement on the day of participation if there were no recorded data in the medical files.
Type of diabetes	Self-report of DM type: Which type of diabetes do you have: type 1 or type 2? (73, 378, 379, 384).
Duration of diabetes	Self-report of DM duration in years: How long have you been diagnosed with DM? (73, 378, 379, 384).
HbA1C	Latest test from the medical records (mmol\L) % (52, 73, 378).
Comorbidities	Self-report of other comorbidities. Have you ever been diagnosed with?

	• Renal failure and there is a need for dialysis (should have lasted or likely to last for 6+ months) (378, 379, 384). • Heart failure (should have lasted or likely to last for 6+ months) (378). • Impaired vision (should have lasted or likely to last for 6+ months)(378). • Osteoarthritis (should have lasted or likely to last for 6+ months) (378). • Rheumatoid arthritis (should have lasted or likely to last for 6+ months) (379, 385). • Cerebro-Vascular Accident (CVA) (should have lasted or likely to last for 6+ months) (379, 384, 386). • Dyslipidaemia or high cholesterol (should have lasted or likely to last for 6+ months) (379, 384, 386). • Myocardial infarction (MI) or heart attack (should have lasted or likely to last for 6+ months) (379, 384, 386). • Cancer (should have lasted or likely to last for 6+ months) (379, 385, 387). • Depression (should have lasted or likely to last for 6+ months) (379, 385, 386).
Foot	
Previous ulcer	Self-report of history of previous ulceration: Have you ever had an ulcer that has healed before? (378, 379).
Loss of protective sensation *	A 10 g (5.07 Semmes–Weinstein) monofilament was used as recommended by the International Working Group of Diabetic Foot (IWGDF) guidelines (231, 388). This included testing the three recommended sites (plantar of the big toe, first metatarsal and fifth metatarsal (388). If participants were unable to answer two of the three sites correctly, this indicated the absence of protective sensation; two correct answers indicated the presence of protective sensation (388).
Peripheral arterial disease*	The peripheral arterial disease was defined if the calculations of toe brachial index pressure (TBI) were less than 0.75 (389). The systolic pressure of the big toe was

	measured using a small occlusive cuff on the proximal portion of the great or second toe (390). The indices of the systolic brachial arm pressure and toe pressure were measured to detect TBI.
Minor amputation*	Any resection through or distal to the ankle was clinically examined to detect minor amputations (388).
Major amputation*	Any resection proximal to the ankle will be clinically examined to detect major amputations (388).
Foot deformities *	Inspecting of the following deformities: Hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, pes cavus, pes planus, and residuals of Charcot neuroosteoarthropathy, trauma, amputations, or other foot surgery (378, 388).
Ulcer	
University of Texas (UT) classification*	UT DFUs grades (52, 378, 391) were defined according to the depth of the wound: • Grade 1: superficial ulcers which do not penetrate to tendon, capsule, or bone. • Grade 2: ulcers which penetrate to tendon or capsule. • Grade 3: ulcers which penetrate the joint or bone (391).
DFU infection	Was reported based on clinical diagnosis in the medical records.
Area*	Was estimated by measuring wound diameter (378). Tape measurement has been shown to be valid (392). A two-dimensional technique was used to calculate the surface area by measuring the greatest length and the greatest perpendicular width of the wound. This was measured by using a disposable measuring ruler calibrated in Centimetres (392, 393).
Duration of DFU	Self-report of the duration of DFU: How long have you had this ulcer? duration in weeks? (378).
Duration of offloading	Self-report of the duration of using the current offloading device: How long have you wear\used this offloading device? duration in weeks.

*Clinical examination determined variable

6.3.4.4 Outcomes measures

All items contained in the translated Arabic questionnaire (the subject of Phase A) were tested for test-retest reliability. The Arabic questionnaire comprised five main scales of previously validated instruments that were translated into Arabic, including 13 items for the FCCS (range 1-65), 16 items for the FCOES (range 1-80), 13 items for the PIN scales (range 1-20, except PIN acute ulcer onset with 15 maximum score), 17 items for the NQOL scales (range 1-20), and 17 items (visual scales and nominal Likert items) related to offloading treatment. The supporting citations for the selected scales are presented at the beginning of this chapter (Section A, B; Table 6.1, 2).

6.3.4.5 Procedure

Participants were initially interviewed to collect their self-reported socio-demographic and medical history variables. Participants were then provided with the Arabic questionnaire to complete while waiting in the waiting room before receiving regular care. They were encouraged to ask the PhD candidate if they faced difficulties in understanding any item of the instrument. A clinical examination of the foot and ulcer was conducted by the PhD candidate (a trained wound care nurse consultant) to collect the foot and ulcer variables. The follow-up re-test of the translated Arabic questionnaire was conducted at the participants next ulcer care follow up consultation at the NCDEG. The questionnaire was given to the participants to be filled according to the best of their understanding (week 1). Then, they were advised to complete the same questionnaire again after 1 week – 12 days interval. This was during their regular visits to the NCDEG. Participants were free to withdraw from this study.

6.3.5 Data analysis

Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS, Version 23). Descriptive analyses were used to measure the frequency, mean, median (for not normally distributed), range and standard deviation (SD) as appropriate to the sociodemographic and clinical data of the sample. A Cronbach's alpha coefficient was calculated for each scale to determine the internal consistency. A Cronbach's alpha that ranges between 0.70–0.90 is commonly accepted, which indicates the internal consistency of the scale is reliable (394). The stability (consistency) of test-retesting of the questionnaire was evaluated by calculating intraclass correlation coefficients (ICC, two-way random effect models;

95% CI) for the continuous scales. ICC is a common metric that commonly used to quantify stability which the Pearson product-moment correlation coefficient (Pearson r) is often used to achieve this goal (395). The values of ICC range between 0–1. The strength of agreement of the ICC result was considered excellent if the value ranged above 0.90; good if the value ranged between 0.75–0.90; moderate if the value ranged between 0.50–0.75; and poor if the value was less than 0.50 (396). However, for the nominal (categorical) scales, or questions, Cohen's kappa was used to determine the coefficient of agreement (397, 398), while weighted kappa (quadratic) was used for the items with the ordinal categories (399). The strength of agreement of Kappa results was considered perfect if the value ranged between 0.81–1; substantial if the value ranged between 0.6–0.80; moderate if the value ranged between 0.41–0.60; fair if the value ranged between 0.21–0.40; and slight if the value was less than 0.20 (400).

6.3.6 Data management

Data were collected in both hard copy data and using software data. The hard copy transcripts and data were kept in locked data storage facilities at QUT. However, in compliance with QUT data management processes, while the data were being collected in Jordan, the hard copy surveys were saved at the NCDEG (Amman-Jordan) storage facilities. Then, before travelling back to Australia, the hard copy transcripts were photo scanned as a soft copy and then stored in QUT's U drive to safeguard the data in case of any possibility of luggage loss. Digital data (SPSS data) are saved in a QUT Research Data Storage Service or QUT Secure Access U-Drive, which is a cloud service from QUT.

6.3.7 Ethical considerations

The ethical approval was obtained from the Office of Research Ethics and Integrity at QUT (Ethical approval number: 1800000929) and the Institutional Review Board Committee at the NCDEG. This study was low risk as there were minimal suspected physical, psychological economic or social harms that could influence the recruited participants. Participants were seen during their regular visits to obtain wound care (dressings) at the diabetic foot clinic-NCDEG without any further costs that could be associated with the second visit of data collection (re-test).

A written information sheet was given to participants before they signed the consent form of participation (see Appendix 7-11). It included the study aim, procedure in addition to the contact of the PhD candidate, the principal supervisor, and the QUT Research Ethics Office. Participants were free to withdraw from the study without any consequences that affected their relationship with the clinicians at the NCDEG.

6.3.8 Results

6.3.8.1 Participant characteristics

A sample of 15 participants was recruited. Only one participant did not complete the re-test of the instrument. Of the study population, the mean age was 56.9 (SD 6.7) years, 60% were male, 93% were living with their families, 40% were unemployed and 40% had only a primary school level education (see Table 6.8 for additional details of the socio-demographics of the study population).

The mean duration of DM was 16.2 years (SD 7) and the mean duration of DFU was 19.9 weeks (SD 14). Eight weeks (IQR 45) was the median duration of wearing the RCW (see Table 6.8 for additional health characteristic).

Table 6.8: Characteristics of Study 2 participants, reported as numbers (%), mean (SD) unless otherwise stated* (n=15)

Characteristics		**N**	**Mean (SD)**	**95% Confidence Intervals**
Age (years)		15	56.9 (6.7)	5.3 – 60.6
BMI		15	31.9 (5.7)	28.7 – 35.1
Duration of diabetes (years)		15	15.6 (7)	11.7 – 19.5
HbA1C		14	8 (1.6)	7.1 - 9
Duration of ulcer (Weeks)		15	19.9 (14)	12.1 – 27.7
Characteristics		**N**	**Median (IQR)**	
Family income (Dinar/month)*		12	300 (277.5)	
Ulcer area (CM^2) *		15	1 (2)	
Duration of RCW (weeks)*		15	8 (45)	
Characteristics		**N (%)**		
Males		9 (60)		
Living arrangement	Living alone	1 (6.7)		
	Living with family	14 (93.3)		
Educational level	Primary school	6 (40)		
	Secondary school	4 (26.7)		
	Undergraduate	3 (20)		

	Postgraduate	2 (13.3)
Employment	Employed	1 (6.7)
	Unemployed	6 (40)
	Retired	5 (33.3)
	Self-funded	3 (20)
Type 2 DM		15 (100)
Renal failure		1 (6.7)
Heart failure		2 (13.3)
Impaired vision		10 (66.7)
Hypertension		10 (66.7)
Osteoarthritis		4 (26.7)
Rheumatoid arthritis		1 (6.7)
Dyslipidaemia		7 (46.7)
Myocardial infraction		2 (13.3)
History of previous ulceration		10 (66.7)
Loss of protective sensation		14 (93.3)
PAD		7 (46.6)
Foot deformities		10 (66.7)
Minor amputations		4 (26.7)
Major amputations		0
UT grade	Grade 1	8 (53.3)
	Grade 2	2 (13.3)
	Grade 3	5 (33.3)
DFU infection		8 (53.4)

SD: standard deviation; IQR: inter-quarter range; RCW: removable cast walkers; PAD: peripheral arterial disease; DM: diabetes miletus; UT: University of Texas; DFU: diabetic foot ulcers

6.3.8.2 Reliability results; internal consistency and stability

Footcare confidence scale

The Cronbach's alpha of the FCCS was 0.64. However, this scale had two items, including item 4 (judge if the toenails need to be trimmed by the doctor) and item 5 (trim toenails straight across) that were not correlated with the overall scale in terms of measuring the confidence of doing foot care activities. The analysis showed that if one of these items was deleted, the internal consistency would be acceptable (Cronbach's alpha > 70). Regarding the stability of the test-retest, Table 6.9 shows the weighted Kappa agreement result of each item. The total score of this scale was stable after conducting the test-retest as calculating the ICC using 2-way random effects

(95% CI) showed good agreement (ICC = 082; 95% CI: 0.44–0.94, P = 0.002) (see Table 6.9).

Table 6.9: FCCS; internal, and test-retest reliability of the scale

FCC Item	Cronbach's alpha if item deleted	Corrected item-total correlation	Weighted Kappa	Strength of agreement
1: Protect feet	0.617	0.318	0.50	Moderate
2: Feet daily check	0.586	0.506	0.48	Moderate
3: Drying between toes	0.640	0.190	0.57*	Moderate
4: Judge if toenails need to be trimmed by doctor	0.742	- 0.524	0.15	Slight
5: Trim toenails straight across	0.716	-0.134	0.66*	Substantial
6: Judge to use the pumice	0.583	0.473	0.28	Fair
7: Test water temperature	0.682	-0.059	0.80**	Perfect
8: Wear shoes\ socks	0.576	0.582	0.33	Fair
9: Shop for good shoes	0.548	0.719	0.61*	Substantial
10: Call doctor	0.624	0.515	-0.13	Slight
11: Check inside shoes	0.579	0.545	0.027	Slight
12: Apply lotion	0.566	0.698	0.18	Slight
13: Wearing the offloading device (Adapted item)	0.562	0.579	0.40	Moderate
Internal reliability of the total scale (N=15)	0.644			
Test-retest stability of the total scale (ICC) (N=14)	0.82 (95% CI: 0.44–0.94, P= 0.002) Good agreement			

FCCS: a total score of 13 Likert items (5 points each, range 1-65); ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

Foot care outcomes expectations scale

The Cronbach's alpha of the FCOES was 0.92. Regarding stability, this scale was stable after conducting the test-retest. Table 6.10 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random effects (95%

CI) showed good agreement (ICC = 0.79; 95% CI: 0.36–0.93, P = 0.004) (see Table 6.10).

Table 6.10: FCOES; internal, and test-retest reliability of the scale

FCOES Item	Cronbach's alpha if item deleted	Corrected item-total correlation	Weighted Kappa	Strength of agreement
1: Control blood sugar	0.924	0.178	0.32	Fair
2: Examining feet	0.915	0.658	0.60*	Substantial
3: Checking inside shoes	0.912	0.707	0.33	Fair
4: Washing feet	0.913	0.691	0.51	Moderate
5: Testing water temperature	0.909	0.805	0.61**	Substantial
6: Drying feet	0.917	0.513	0.36	Fair
7: Moisturizing	0.915	0.606	0.85**	Perfect
8: Cutting toenails straight	0.905	0.872	0.23	Fair
9: Wearing proper footwear	0.917	0.643	0.30	Fair
10: Seeing diabetic doctors	0.914	0.649	0.13	Slight
11: Informing diabetic doctors	0.915	0.611	0.23	Fair
12: Avoid walking outside in barefoot	0.910	0.765	0.20	Slight
13: Never using chemicals or blades	0.911	0.780	0.65*	Substantial
14: Avoid putting feet near hot devices	0.916	0.620	0.73**	Substantial
15: Overall footcare	0.914	0.654	0.67**	Substantial
16: Wearing the offloading device (Adapted item)	0.922	0.458	0.69**	Substantial
Internal reliability of the total scale	0.92			
Test-retest stability (ICC) (N=14)	0.79 (95% CI: 0.36 – 0.93, P=0.004) Good agreement			

FCOES: a total score of 16 items (5 points each, range 1-80); ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

Neuropathy quality of life physical symptoms scales (pain, reduced feeling, and diffuse sensory-motor)

The first neuropathy quality of life symptoms scale (NQOL) was related to neuropathic pain. The Cronbach's alpha was 0.95, which was accepted (>0.70). Regarding stability, this scale was stable after conducting test-retesting. Table 6.11 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random effects (95% CI) showed good agreement (ICC = 0.76; 95% CI: 0.26–0.92, P = 0.007) (see Table 6.11).

Table 6.11: NQOL pain scale; internal, and test-retest reliability

NQOL pain scale	**Cronbach's alpha if item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
1: Burning in legs or feet	0.943	0.867	0.59*	Moderate
1: Bothering	0.943	0.932	0.68**	Substantial
2: Excessive heat or cold in legs or feet	0.943	0.884	0.82**	Perfect
2: Bothering	0.945	0845	0.62**	Substantial
3: Pins and needles in legs or feet	0.959	-0.63	0.16	Slight
3: Bothering	0.956	0.018	0.03	Slight
4: Shooting or stabbing pain in legs or feet	0.944	0.849	0.65*	Substantial
4: Bothering	0.945	0.803	0.56	Moderate
5: Throbbing in legs or feet	0.946	0.749	0.19	Slight
5: Bothering	0.943	0.932	0.42	Moderate
6: Sensation in legs or feet make them jump	0.941	0.939	0.30	Fair
6: Bothering	0.945	0.873	0.37	Fair
7: Irritation of skin	0.946	0.762	0.30	Fair
7: Bothering	0.947	0.785	0.28	Fair
Item A: Painful neuropathy and quality of life	0.948	0.750	0.64*	Substantial

Internal reliability of the total scale	0.95
Test-retest stability (ICC) (N=14)	0.76 (95% CI: 0.26 – 0.92, P= 0.007) Good agreement

NQOL (range 1-20): a total score of the mean of neuropathy symptoms scale (number of items, 5 points each) multiplied by the mean of bothering symptoms scale (number of items, 3 points each) then the score of quality of life neuropathy pain scale (1 item, range 1-5) was added (this was also applied for the other NQOL scales below); ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

The second NQOL was related to neuropathic reduced feeling. The Cronbach's alpha was 0.76, which was acceptable (>0.70). Regarding stability, this scale was stable after conducting a test-retest reliability check. Table 6.12 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random effects (95% CI) showed good agreement (ICC = 0.86; 95% CI: 0.5–0.95, P = 0.001) (see Table 6.12).

Table 6.12: NQOL reduced feeling scale; internal, and test-retest reliability

NQOL reduced feeling scale	**Cronbach's Alpha If item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
1: Numbness in feet	0.73	0.549	0.67**	Substantial
1: Bothering	0.74	0.484	0.81**	Perfect
2: Inability to feel difference between hot and cold in feet	0.65	0.808	0.53*	Moderate
2: Bothering	0.69	0.902	0.73**	Substantial
3: Inability to feel objects in feet	0.83	-0.20	0.40	Moderate
3: Bothering	0.72	0.78	0.45*	Moderate
Item B: Reduced feeling and quality of life	0.74	0.50	0.61*	Substantial
Internal reliability of the total scale	0.76			
Test-retest stability (ICC) (N=14)	0.86 (95% CI: 0.5 – 0.95, P< 0.001) Good agreement			

ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

The third NQOL was related to neuropathic diffuse sensory-motor. The Cronbach's alpha was 0.87, which was acceptable (>0.70). Regarding stability, this scale was stable after conducting a test-retest reliability check. Table 6.13 shows the weighted Kappa agreement result of each item. The ICC using 2-way random effects (95% CI) showed excellent agreement (ICC = 0.90; 95% CI: 0.69–0.96, P = 0.00) (see Table 6.13).

Table 6.13: NQOL diffuse sensory-motor scale; internal, and test-retest reliability

NQOL diffuse sensory-motor scale Items	**Cronbach's Alpha If item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
Item 1: Weakness in hands	0.90	0.36	0.67*	Substantial
Item 1: Bothering	0.87	0.68	0.80**	Perfect
Item 2: Problems with balance or unsteadiness while walking	0.84	0.78	0.82**	Perfect
Item 2: Bothering	0.85	0.75	0.67*	Substantial
Item 3: Problems with balance or unsteadiness while standing	0.85	0.75	0.50	Moderate
Item 3: Bothering	0.84	0.83	0.67**	Substantial
Item C: Diffuse sensory-motor and quality of life	0.84	0.79	0.77**	Substantial
Internal reliability of the total scale	0.87			
Test-retest stability (ICC) (N=14)	0.90 (95% CI: 0.69 – 0.96, P< 0.01) Excellent agreement			

ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

Offloading scales

These were several separate visual scales (0–10, or 0–100) that aimed to measure different aspects related to using offloading devices. Stability analysis (test-retest) was conducted to test the reliability of these scales. After calculating the ICC using 2-way random effects (95% CI), two items (ability to do daily activities and difficulty in wearing the offloading device) showed excellent agreement (p<0.01); another two items (level of comfort and wearing the device again) showed good agreement (p<0.01); another four items (alteration in activity, satisfaction, heaviness, and adherence time visual scale) showed moderate agreement (p<0.05); while two items (sleeping activity and adherence steps) showed poor agreement (p>0.05) (see Table 6.14).

Table 6.14: Different visual discrete scales related to offloading device; test-retest reliability (N=14)

Visual scale	**ICC**	**95% CI**	**Strength of agreement**	**P value**
Item 2: Level of comfort (0-10)	0.81	0.4 – 0.94	Good	0.01
Item 3: Ability to do daily activities (0-10)	0.90	0.70 – 0.96	Excellent	0.01
Item 4: Alteration in activity (0-10)	0.64	-0.11 – 0.88	Moderate	0.03
Item 5: Sleeping activity (0-10)	0.43	-0.75 – 0.81	poor	0.15
Item 6: Satisfaction (0-10)	0.67	-0.003 – 0.89	Moderate	0.02
Item 7: Wearing the device again (0-10)	0.77	0.28 – 0.92	Good	0.01
Item 8: Heaviness (0-10)	0.66	-0.034 – 0.89	Moderate	0.02
Item 9: Difficulty in wearing the device (0-10)	0.90	0.70 – 0.97	Excellent	0.01
Item 11: Adherence time visual scale (0-100)	0.52	-0.49 – 0.84	Moderate	0.09
Item 14: Adherence steps visual scale (0-100)	0.092	-2.65 – 0.77	Poor	0.44

ICC: Intraclass Correlation Coefficient; CI: Confidence Interval; ** P<0.01; * P<0.05

The stability of several categorical items related to offloading treatment was also tested (see Table 6.15). Cohen’s Kappa was calculated to measure the agreement between the test-retest responses. One item (adherence time outside the house) was associated with a substantial agreement (Kappa = 0.61, p = 0.00); three items (adherence time outside the house, adherence steps, and offloading beliefs) were associated with a moderate agreement (Kappa = 0.61, 0.55, 0.52, P > 0.05); one item (family support) was associated with a fair agreement (Kappa = 0.34, p = 0.01; and one item (adherence steps inside the house) was associated with a slight agreement (Kappa = 10, p = 0.53).

Table 6.15: Different categorical questions related to offloading device; test-retest reliability (N=14)

Categorical question	**Kappa**	**SE**	**Strength of agreement**	**P-value**
Item 10: Family support (Never, rarely, sometimes, or always)	0.34	0.16	Fair	0.01
Item 12: Adherence time inside the house (A little of the time, some of the time, most of the time, or all of the time)	0.50	0.17	Moderate	0.01
Item 13: Adherence time outside the house (A little of the time, some of the time, most of the time, or all of the time)	0.61	0.16	Substantial	0.01
Item 15: Adherence steps inside the house (A little of the steps, some of the steps, most of the steps, or all of the steps)	0.10	0.19	Slight	0.53
Item 16: Adherence steps outside the house (A little of the steps, some of the steps, most of the steps, or all of the steps)	0.55	0.16	Moderate	0.01
Item 17: Offloading beliefs related to walking without the device may harm (Not agree at all, disagree, neither disagree, or agree, moderately agree, or totally agree)	0.52	0.18	Moderate	0.01

SE: Standard Error

6.3.8.3 Reliability test of Patients' Interpretation of Neuropathy (PIN) scales

This scale was tested using another sample. This was mainly due to an error in collecting the data when testing the previous scales. One of the Likert options (the strongly agree column) was missed, which meant participants only had four options to answer (strongly disagree, disagree, uncertain, agree). Thus, the test-retest was repeated (using the five options the same as the original scale) on another population who had DFUs and experienced offloading treatment. The selected PIN scales were to measure the patients' cognitive variables related to DFUs and neuropathy. This included self/practitioner blame scale, physical causes of DFUs scale, and acute foot ulcer onset scale. The socio-demographic and health information of the participants who answered this scale is presented in Table 6.16.

Table 6.16: Characteristics of PIN scale test-reset participants (N=15)

Characteristics		**N**	**Mean (SD)**	**95% Confidence Intervals**
Age (years)		15	56 (9.57)	50.8 – 61.5
Family income (Dinar/month)		15	570 (258.2)	426.9 - 713
BMI		14	30.5 (6.9)	26.6 – 34.5
Duration of diabetes (years)		15	17 (11.1)	10.7 - 23.2
HbA1C		14	9.1 (2.2)	7.9-10.5
Characteristics		**N (%)**		
Males		10 (66.7)		
Educational level	Primary school	1 (6.7%)		
	Secondary school	7 (46.7%)		
	Undergraduate	7 (46.7%)		
	Postgraduate	0		
Employment	Employed	1 (6.7%)		
	Unemployed	4 (26.7%)		
	Retired	6 (40%)		
	Self-funded	4 (26.7%)		
Type2 DM		14 (93.3%)		

SD: Standard Error; BMI: Body Mass Index; DM: Diabetes Miletus

The first PIN scale was self/practitioner blame (items 2-5). The internal consistency of the total scale was 0.37. Regarding stability, this scale was stable after conducting the test-retest study. Table 6.17 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random (95% CI) showed good agreement 0.85 (95% CI: 0.55–0.95, P = 0.00) (see Table 6.17).

Table 6.17: PIN self/practitioner blame scale; internal, and test-retest reliability of the scale

PIN Self/practitioner blame scale	**Cronbach's Alpha If item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
Item 2: Reduced feeling and poor medical care	0.32	0.186	040	Moderate
Item 3: Reduced feeling and poor self-care	0.63	-0.072	-0.07	Slight
Item 4: Foot ulceration and poor medical care	-0.084	0.49	0.91**	Perfect
Item 5: Foot ulceration and poor self-care	0.20	0.51	0.00	Slight
Internal reliability of the total scale	0.36			
Test-retest stability (ICC) (N=15)	0.85 (95% CI: 0.55 – 0.95, P<0.01) Good agreement			

PIN: a total score of the number of items (5 points each) (this was also applied for the other PIN scales below); ICC: Intraclass Correlation Coefficient; ** P<0.01; * P<0.05

The second PIN scale was the physical causes of DFUs (items 7-10). The internal consistency of the total scale was 0.33. Regarding stability, this scale was stable after conducting a test-retest study. Table 6.18 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random model (95% CI) showed poor agreement 0.43 (95% CI: -0.67 – 0.81, P = 0.14) (see Table 6.18).

Table 6.18: PIN physical causes of DFUs scale; internal, and test-retest reliability of the scale

PIN physical causes of DFUs	**Cronbach's Alpha If item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
Item 7: Changes in foot shape can cause foot ulceration	0.59	-0.243	0.12	Slight
Item 8: Ill-fitting shoes can cause ulceration	0.44	-0.09	0.25	Fair
Item 9: Excessive hard skin can cause foot ulceration	-0.28	0.49	0.14	Slight
Item 10: Dry skin can cause foot ulceration	-0.66	0.63	0.34	Fair
Internal reliability of the total scale	0.33			
Test-retest stability (ICC) (N=15)	0.43 (95% CI: -0.67 – 0.81, P=0.14) Poor agreement			

ICC: Intraclass Correlation Coefficient; ** P<0.01; * P<0.05

The third PIN scale was acute foot ulcer onset (ulceration timeline) (items 11-13). The internal consistency of the total scale was 0.38. Regarding stability, Table 6.19 shows the weighted Kappa agreement result of each item. Calculating the ICC using 2-way random (95% CI) showed poor agreement 0.043 (95% CI: -1.85–0.67, P = 0.46) (see Table 6.19).

Table 6.19: PIN acute foot ulcer onset scale; internal, and test-retest reliability of the scale

PIN Acute foot ulcer onset	**Cronbach's Alpha If item deleted**	**Corrected item-total correlation**	**Weighted Kappa**	**Strength of agreement**
Item 11: Foot ulcers take a long time to develop	0.87	-0.17	0.15	Slight
Item 12: Foot ulcers can develop very fast	-0.13	0.39	0.55*	Moderate

Item 13: Foot ulcers can develop any time	-0.63	0.67	-.21	Slight	ICC:
Internal reliability of the total scale	0.38				
Test-retest stability (ICC) (N=15)	0.043 (95% CI: -1.85– 0.67, P=0.46) Poor agreement				

Intraclass Correlation Coefficient; ** P<0.01; * P<0.05

6.3.8.3 Re-tested reliability of scales using a larger sample size from the main study

Testing the internal consistency of some of the previous scales showed a Cronbach's alpha of <0.70, which is usually not accepted as reliable (394). This included FCCS, PIN physical causes and acute ulcer onset scales. However, the small sample size was not optimal to obtain accepted internal consistency (401). Therefore, the internal consistency of these scales was re-tested using a larger sample size (61 participants from the main study) to show internal consistency evidence. Furthermore, three independent items (Likert and VAS) that aimed to estimate adherence steps to wearing RCWs showed poor stability agreement after test-retest (ICC<0.5). Thus, the stability was retested using a larger sample size (35 participants) as some participants (20 participants) from the main study answered these items two times within a week (test-retest).

The results of the internal consistency (n = 61) were: i) FCCS (Cronbach's alpha = 0.87); ii) PIN self/practitioner blame (0.57); iii) PIN physical causes (Cronbach's alpha = 0.74); and iv) PIN acute ulcer onset (Cronbach's alpha = 0.49). While the results of the test-retest stability were: i) adherence steps visual scale (0-100) (n = 29): moderate agreement; ICC = 0.56 (95% CI: 0.67–0.79, P = 0.02); ii) adherence steps inside the house (n = 33): fair agreement; Kappa= 0.36 (SE: 0.11, P<0.01); iii) adherence steps outside the house (n = 33): moderate agreement; Kappa = 0.45 (SE: 0.11, P<0.01).

6.4 DISCUSSION

This study aimed to develop valid and reliable Arabic translations of different psychometric scales related to diabetes-related foot disease. The process of translation was guided by Brislin (373), Jones et al (371), and Sousa and Rojjanasrirat (362) and aimed to produce two forward and backward translations by recruiting both health and general language independent translators. In this study, there was a debate between the participating translators regarding both forward and backward translation phases. For instance, there were discrepancies by using different Arabic synonyms between the two forward translations. The agreement of one forward translation was challenging as it was obtained after having a revision of third translator and opinion of expert in Arabic language (PhD). Similarly, in back translation, significant time was required to achieve one agreed backtranslation. However, the benefit of this method ensured a rigorous translation (371)

The reliability of the Arabic translation of the study questionnaire (internal consistency and stability) was also tested to ensure its consistency for the Arabic population. The translation and reliability findings are discussed separately for each scale in the following sections.

6.4.1 Footcare Confidence Scale (FCCS)

This is an English scale developed by Sloan (402) with the main aim of measuring self-efficacy for foot self-care activities among patients with diabetes. Self-efficacy related to self-care activities for general diabetes self-management has previously been investigated among Arabic populations (73, 403). However, to the best of the PhD candidate's knowledge, there is no available scale in the Arabic language to test self-efficacy for foot self-care activities. Both forward and backward translations resulted in revising of the translated Arabic FCCS to maintain the rigour of translation. Further, some of the items were modified to meet cultural equivalency. Testing the reliability of the scale showed that the total internal consistency was acceptable (Cronbach's alpha = 0.74), which is in line with the original testing of FCCS (1) where the Cronbach's alpha was 0.92. Similarly, all scale items were inter-correlated (Cronbach's alpha >0.70) in previous Mexican and Vietnamese translations (404, 405). Stability was also promising, as the test-retest at a one-week interval showed an excellent agreement of the overall score (ICC = 0.82, 95% CI: 0.44–0.94, P = 0.002). The stability of FCCS was not tested in the original scale (1) or previous translations (404, 405); thus, this study has filled this gap and demonstrated that FCCS is a reliable instrument. Overall, this study resulted in a reliable Arabic translation of FCCS that can assist researchers in Arabic countries to study self-efficacy to perform foot self-care in future research.

6.4.2 Foot Care Outcomes Expectations Scale (FCOES)

Outcomes expectations have been an important construct in self-efficacy theory, which can influence both individual self-efficacy and outcome behaviour (281). Both forward and backward translations resulted in revising the translated Arabic FCOES to maintain the rigour of translation. Further, there were cross-cultural modifications that resulted in some modification of this scale. The reliability testing resulted in excellent internal consistency (Cronbach's alpha = 0.92). Similarly, the translation stability was reliable (ICC = 0.79, 95% CI: 0.36–0.93, P = 0.004). This is in line with the previous positive internal consistency of translation to Vietnamese (2). Several items of this scale were also adapted from a previous reliable scale (Cronbach's alpha = 0.85, ICC = 0.60) (3). Thus, this scale is reliable for the use in the Arabic population; however, further reliability testing is required to confirm the findings.

6.4.3 Patients' Interpretation of Neuropathy (PIN) scales

These scales have been commonly used to estimate the knowledge or beliefs of patients with diabetes-related neuropathy in terms of understanding the potential causes of DFUs (288). There was no cross-cultural modification of PIN scales; however, some of the Arabic translated items of this scale were revised during back-translation to English. The reliability testing resulted in variable internal consistency between the tested PIN scales. PIN physical causes of DFU had acceptable internal consistency (Cronbach's alpha >0.70), while both PIN self-practitioner blame and acute ulcer onset had Cronbach's alpha <0.70. The original testing of the PIN scales by Vileikyte et al (3) showed similar internal consistency where the PIN physical causes had a Cronbach's alpha of 0.74 and the PIN self-practitioner blame and acute ulcer onset had a Cronbach's alpha of <0.70. However, the previous testing of the reliability of Vietnamese translation (2) showed a Cronbach's alpha >0.70 for both PIN physical causes and acute ulcer onset. Regarding stability (test-retest), the current testing showed poor agreement (ICC<0.5) for both PIN physical causes and acute ulcer onset while PIN self-practitioner blame showed good agreement (ICC = 0.83). In the original testing (3) PIN physical causes, self-practitioner blame, and acute ulcer onset showed ICC of 0.52, 0.56, and, 0.62, respectively. The reliability variation of the tested PIN scales between the current testing and the previous studies may be related to the differences in sample sizes as well as the cultural disparities.

6.4.4 Neuropathy Quality of Life (NQOL) scales

These scales were developed by Vileikyte et al (4) and have 43 valid and reliable items that measure both physical and psychosocial effects of diabetic neuropathy on health-related quality of life. However, in this cross-cultural adaption study, only the NQOL physical symptoms subscales were selected due to previous evidence supporting the possible impact of the neuropathic quality of life physical symptoms on patients' adherence to wearing the removable offloading devices (52). Some of the back-translated items of NQOL physical symptoms scales were revised by both native researchers and Jordanian wound nurses. There was no cross-cultural adaption of any items of this scale in both translation consensuses, where all Jordanian bilingual translators and wounds nurses agreed to the literal translation of the original NQOL to Arabic. In terms of reliability, this study showed excellent internal consistency. The Cronbach's alphas of the three tested NQOL scales (pain, reduced feeling, diffuse sensory motor) were 0.95, 0.76, and 0.87, respectively. These positive internal consistency findings were similar to previous Brazilian and Chinese translations (406, 407). Regarding the stability, the test-retest of the total score of these scales showed excellent agreement, with the intraclass correlation coefficients above 0.76 ($p < 0.05$) of all the scales. To the best of the PhD candidate's knowledge, there was no reported stability testing of the original scale; thus, it is possible that this is a pilot stability testing of NQOL physical symptoms scales.

6.4.5 Offloading-related scales

There was a slight revision of the translation of these scales during the second consensus with no significant cross-cultural adaptation. The stability of the Arabic translation of these scales was tested after conducting test-retests (one-week interval) among the population who were treated by offloading (RCW). The outcomes were stable, with good to excellent agreement in most of the scales. This included a 0–10 level of heaviness scale that was developed in this research. These findings are in line with the reported reliability of visual scales (367, 408, 409). However, there was no previous reliability testing of these scales in different offloading studies (262, 349, 364, 365). For instance, Crews and Candela (349) relied on previous evidence (367) that supports the reliability of visual scales in measuring the level of comfort to using footwear. Thus, based on these test-retest findings, this study provides new evidence of the reliability of visual scales to measure different aspects related to using offloading devices. However, further reliability testing is required to confirm these findings.

Furthermore, other visual and Likert questions were adapted to have some self-report of offloading adherence. Likert questions were used by Bus et al (53) to estimate adherence (wearing) time of the offloading device inside or outside the house but without validity or reliability testing. This question was translated and tested and showed moderate (inside the house) to substantial (outside the house) agreement ($P<0.01$) after conducting test-retest (Kappa analysis). Adherence can be also estimated in other conditions using visual scales, which were found reliable measures (369). A visual scale was adapted by asking participants to estimate the percentage of wearing the offloading device during the day (0–100%). This visual scale showed promising reliability with a moderate agreement (ICC = 0.52). Thus, these findings suggest the potential use of either Likert or visual scales to self-report adherence time to wearing offloading devices in future research.

However, in order to have more robust measures of adherence to offloading, it is recommended to measure both wearing time and weight-bearing steps (95, 126). For this reason, Likert and visual scales were developed for this study to measure patients' estimation of their daily weight-bearing steps while using their offloading devices. The Likert scale offered options (i.e. wearing the offloading device in all the steps, most of the steps, half of the steps, only in a few steps or not in a single step). This question showed variation in stability results between the two Likert items (adherence steps inside and outside the house). Participants provided fair agreement of stability after test-retest of when they estimated walked steps during using the offloading device inside the house (Kappa = 0.36). On the other hand, the stability of the item related to the adhered steps during using the offloading outside the house was moderate (Kappa = 0.45). The results showed that 60% of participants claimed that they wore the offloading in all the steps outside the house, while only 6.7% of them wore the device for all steps inside the house. This might indicate that participants use their offloading devices as a regular shoe that people usually wear when they go outside the house. Thus, it could be easier for patients to estimate the number of offloading steps when they are outside as that is when they usually wear the offloading device. A visual scale (0–100%) was also tested to estimate adherence steps to offloading devices during the day. The results showed moderate agreement between the test-retest (ICC = 0.56, P =

0.02) Thus, self-reporting of adherence steps can be reliable in estimating adherence to wearing the offloading devices. However, validity testing is required as the objective tracking of activities or steps that are undertaken under offloading using activity trackers is the recommended method (410).

6.5 STRENGTH AND LIMITATIONS

This translation study resulted in a valid (consensus agreement) and reliable (test-retest) Arabic psychometric scales in diabetic foot and offloading, and this may influence diabetic foot research in the Arabic region in future research. The process of translation was robust, including creating two drafts of forward and backward translations. This was based on a previous popular model (362), which argued for the importance of having different translators including health and bi-cultural backgrounds to produce a valid translation. In addition, the produced translation was in classical Arabic (formal Arabic), which will facilitate using the scales in different Arabic populations regardless of different dialects.

However, this study should also be read cognisant of some limitations. First, during the second consensus, the two native researchers compared the two back-translation drafts separately instead of each comparing both drafts with the original instrument. This was mainly due to the limited timeline of this research, as these comparisons are usually time-consuming. Despite the cross-cultural validation of translation being robust and relying on the opinion of two wound care nurses, the PhD candidate and pilot testing on five Jordanian patients, the content validity of the translation was not measured; however, it is ideal if it is assessed by a panel of many experts, as then this can produce more robust cross-cultural adaption of the translated scales (411). Second, due to limited resources, the reliability testing was conducted on a small sample size (15 participants) without an optimal sample size calculation, while a larger sample size would be likely to result in more accurate reliability results. Finally, recruiting two samples for testing the reliability of the study scales may add a concern in terms of the comparability between the tested scales, however, this limitation is likely to be minimal as the two samples had the same inclusion criteria and were selected from the same research setting.

6.6 CHAPTER SUMMARY

This chapter discussed the methods and results of a study that aimed to provide a valid Arabic translation of different psychometric scales related to diabetic foot disease among Jordanian population. The scales included the Footcare Confidence Scale (FCCS), the Footcare Outcomes Expectations Scale (FCOES), the Patient Interpretation of Neuropathy (PIN) scales and the Neuropathy-specific Quality of Life (NQOL) scales. It also aimed to validate the Arabic translation of several offloading treatment questions and visual scales that were customised in this thesis to estimate a specific measurement of variables related to offloading treatment.

The translation process resulted in valid Arabic translation, as it involved two stages of forward and backward translations, followed by two main consensuses of two committees that included health experts and certified translators. The reliability testing (internal consistency and stability) showed evidence to support using most of the translated Arabic scales. However, further validity and reliability testing are recommended in future research.

Chapter 7: Study 3 - A Cross-sectional Investigation of Adherence to Wearing Removable Cast Walkers

7.1 PREFACE

The clinical effectiveness of popular offloading devices such as removable cast walkers (RCWs) can be significantly affected by patients' adherence to wearing them. As identified in previous chapters (Chapters 1 and 3), the reason for non-adherence is not yet fully understood due to scarce clinical evidence in this area. However, reviewing the literature regarding adherence to treatments in other chronic conditions (Chapter 3), as well as the qualitative findings in Study 1 (Chapter 5) highlighted the possible impact of multiple physiological and psychosocial factors on adherence to wearing RCWs. Furthermore, adopting social cognitive theory (Chapter 4) confirmed the vital role of personal cognitive factors (self-efficacy, outcome expectations, and knowledge), environmental factors (impediments or facilitators), and personal characteristics (i.e. age, gender) on the outcomes of behaviour (adherence). Thus, the need for quantitative research to test these relationships by investigating the factors associated with adherence to wearing RCWs among patients with diabetic foot ulcers (DFUs) was identified. Therefore, the main study for this research program (Study 3) aimed to investigate the levels of and factors associated with adherence to wearing RCWs among patients with DFUs. This chapter describes the research questions and methodology, including the study design, population sample, research setting, study procedure, measurement tools, ethical considerations, data management, and data analysis. It also presents the study results, discussion, strengths, limitations, and conclusion.

7.2 BACKGROUND

Offloading is essential to managing DFUs, with RCWs commonly used in routine care. Despite RCWs being efficient in reducing plantar pressure, they are the second recommended offloading choice due to patients' poor uptake of using them

(34). Previous research has shown that adherence to wearing these offloading devices can significantly impact DFU healing, demonstrating the importance of studying adherence to wearing offloading devices (52). However, current understanding of offloading adherence is still limited, and this current study contributes to filling this gap. More importantly, previous offloading adherence studies were conducted in Western developed countries (i.e. the US, the UK, and the Netherlands) (52-54, 274), including one study that detected some significant adherence determinants including painful or motor neuropathy (52). Therefore, this was a novel investigation into offloading adherence in a different population (among Jordanians) and a different culture (Middle East). This research aims to provide a better understanding of this behaviour, especially in relation to objective evidence in terms of the levels of and factors associated with adherence to the removable offloading devices.

7.3 RESEARCH QUESTIONS

- What is the level of adherence to wearing RCWs in patients with DFUs?
- What are the factors independently associated with adherence to wearing RCWs in patients with DFUs?

7.4 METHODS

7.4.1 Study design

This study was a multi-centre, cross-sectional design study to identify the levels and associations of adherence to wearing RCWs among patients with DFUs.

7.4.2 Settings

The settings for this study were the three largest diabetes centres in Amman, Jordan, including the National Centre for Diabetes, Endocrinology, and Genetics (NCDEG), Jordanian Royal Medical Services (JRMC), and Prince Hamza Hospital (PHH).

7.4.3 Participants

Inclusion criteria

- Patients with DM.
- Patients who had an active DFU.

- Patients treated with RCWs (knee-high) for their DFU and who had experience using these offloading devices for at least the four previous weeks.
- Patients who attended one of the mentioned diabetic foot clinics.

Exclusion criteria

- Patients unable to mobilise at all (completely bed or wheelchair-bound).
- Patients diagnosed with cognitive impairment.

7.4.4 Sample size

Following consultation with a statistician at QUT, it was anticipated that a sample size of 50–60 participants would be sufficient to fit a multiple linear regression model with an expected five to six independent variables. According to VanVoorhis and Morgan (412), a rule of thumb to detect relationships through correlations or regression can be a sample size of around 50 participants. Harris (413) also suggested that the required number of participants to examine correlation should exceed the number of predictors variables by at least 50. In terms of examining regression using six or more predictors, Harris's formula assumes an absolute minimum of 10 participants per predictor variable. Steven (414) also suggested that for social sciences, 15 participants for each predictor can be sufficient to run a reliable multiple regression which was used in this study.

7.4.5 Independent variable measures and data collection

Table 7.1 outlines the definitions of the collected independent variables in this study. These included sociodemographic, medical history, foot, ulcer, and psychometric variables.

Table 7.1: Summary of the independent variables in Study 3

Variables	Definition
Sociodemographic	Included self-reporting of: • Age: Whole years at the time of data collection (378, 379). • Gender: Male or female (378, 380, 381). • Living arrangement: With whom do you live? Living alone, living with family, you are the primary carer for another household member, or other living arrangements (279, 382).

- Educational level: What is the highest education qualification you have achieved? Primary school, secondary school, undergraduate (bachelor's degree or diploma), or postgraduate (Master or doctorate) (73, 378-381).
- Employment: What is your current employment status? Employed, unemployed, retired or self-funded (73, 381).
- Family income: What is the highest income of your family per month? The monthly income of the family in Jordanian Dinar (JD) (73, 380).

Medical history

- Body mass index (BMI): Overweight or obese if BMI $\geq$ 25 (383). Weight and height were undertaken through the recent reading from medical records or actual measurement in the day of participation if there is no recorded data on medical files.
- Type of diabetes: Self-report of the type of diabetes you have: type 1 or type 2? (73, 378, 379, 384).
- Duration of diabetes: Self-report of DM duration in years: How long have you been diagnosed with DM? (73, 378, 379, 384).
- HbA1C: Latest test from the medical record (mmole\L) % (52, 73, 378).
- Comorbidities: Self-report of other comorbidities. Have you ever been diagnosed with:
  - ➢ Renal failure and there is a need for dialysis (should have lasted or likely to last for 6+ months) (378, 379, 384)
  - ➢ Heart failure (should have lasted or likely to last for 6+ months) (378)
  - ➢ Impaired vision (should have lasted or likely to last for 6+ months) (378)
  - ➢ Osteoarthritis (should have lasted or likely to last for 6+ months) (378)
  - ➢ Rheumatoid arthritis (should have lasted or likely to last for 6+ months) (379, 385)
  - ➢ Cerebro-Vascular Accident (CVA) (should have lasted or likely to last for 6+ months) (379, 384, 386)

- Dyslipidaemia or high cholesterol (should have lasted or likely to last for 6+ months) (379, 384, 386)
- Myocardial infarction (MI) or heart attack (should have lasted or likely to last for 6+ months) (379, 384, 386)
- Cancer (should have lasted or likely to last for 6+ months) (379, 385, 387)
- Depression (should have lasted or likely to last for 6+ months) (379, 385, 386)

- Level of activity: Was estimated by taking the mean of wrist steps for 3–7 days)

Foot	Foot screening was performed to detect the following abnormalities: • Loss of protective sensation: Was defined if participants were unable to feel the 10 g (5.07 Semmes-Weinstein) monofilament in at least two of the three recommended testing sites (plantar of the big toe, first metatarsal and fifth metatarsal) (231, 388). • Peripheral arterial disease (PAD): Was defined if the calculations of toe brachial index pressure (TBI) was less than 0.75 (389). The systolic pressure of the big toe was measured using a small occlusive cuff on the proximal portion of the great or second toe (390). The Indices of the systolic brachial arm pressure and toe pressure was measured to detect TBI. • Minor amputations: Any resection through or distal to the ankle was clinically examined to detect minor amputations (388). • Major amputations: Any resection proximal to the ankle will be clinically examined to detect major amputations (388). • Foot deformities: Inspecting of the following deformities: Hammer toes, mallet toes, claw toes, hallux valgus, prominent metatarsal heads, pes cavus, pes planus, and residuals of Charcot neuroosteoarthropathy, trauma, amputations, or other foot surgery (378, 388).

Ulcer	• University of Texas (UT) classification: Grade 1: no penetration of tendon, capsule or bone, grade 2: tendon or capsule penetration, grade 3: joint or bone penetration (391). • DFU infection: Was reported based on clinical diagnosis in medical records. • Duration of DFU: Self-report of the duration of DFU: How long have you had this ulcer? Duration in weeks? (378). • DFU area: Was estimated by measuring the wound diameter (378). Tape measurement has been shown to be valid (392). A two-dimensional technique to calculate the surface area by measuring the greatest length and the greatest perpendicular width of the wound. This was measured by using a disposable measuring ruler calibrated in centimetres (392, 393).
Psychosocial variables (the questionnaire)	The questionnaire contained: • The Foot Care Confidence Scale (FCCS) (1): This is a valid and popular scale to measure the beliefs of the confidence of the ability to perform the daily foot self-care activities among patients with diabetes. It was developed by Sloan (1) and comprises 13 items with a maximum 65. Study 2 (Chapter 6) resulted in a valid and reliable Arabic translation of this scale (Cronbach's alpha = 0.74; ICC = 0.82. P = 0.002). • Footcare Outcomes Expectations Scale (FCOES) (2): This is an adapted scale by Nguyen (2) to measure the beliefs of patients with diabetes of the expected outcomes from performing daily foot self-care activities. It comprises 16 items with a maximum score of 80. Study 2 (Chapter 6) resulted in a valid and reliable Arabic translation of this scale (Cronbach's alpha = 0.92; ICC = 0.79, P = 0.004). • Patient Interpretation of Neuropathy (PIN) scales (3): Three scales were developed by Vileikyte et al (3) to measure patients' knowledge of the

potential causes of diabetic neuropathy and DFUs including self/practitioner blame scale (4 items, maximum score 20), physical causes of DFUs scale (4 items, maximum score 20), and the duration and time of the onset of DFUs (3 items, maximum score 15). Study 2 (Chapter 6) resulted in a valid Arabic translation of these scales. Testing the reliability of the Arabic PIN scales showed good internal consistency (0.74) of the PIN physical causes of DFU, while the PIN self-practitioner blame and acute ulcer onset had internal consistency of Cronbach's Alpha < 0.70. However, stability testing showed a poor agreement of the PIN scales (ICC = 0.043 – 0.43) except PIN self-practitioner blame which had good agreement (ICC = 0.85, P<0.01).

- Neuropathy-specific Quality of Life (NQOL) scales (4): Three scales of NQOL were developed by Vileikyte et al (4) to measure the frequency (i.e. never-all the time) of neuropathic symptoms (pain, loss of sensation, and motor nerve dysfunction), the related bothering feeling (not at all-very much), and their impact on health-related quality of life. Study 2 (Chapter 6) resulted in a valid Arabic translation of this scale. Testing the reliability of the Arabic NQOLS showed good internal consistency (Cronbach's alpha = 0.76-.95) and excellent agreement, with the ICC ≥ 0.76 (P <0.05) of all the scales.
- Offloading-related scales: These included: i) visual analogue scales (VAS) (range 0-10) of psychosocial variables related to the offloading device including level of comfort (349, 364, 365), the heaviness of the device, level of activities or the ability perform them, level of sleeping (364), level of satisfaction (364, 366), the difficulty of putting on the RCWs, likelihood to wear the offloading device again (364), and estimation of adherence time and steps of wearing the RCW during the day (range 0 -100). ii) Likert questions to examine: the provided

	social support when putting on the offloading device (i.e. rarely or always), the beliefs of the importance of wearing RCW for every weight-bearing step (i.e. the beliefs that walking short distance without the offloading device is not harmful), adherence time and steps of wearing the RCW during the day including inside and outside the house (see Chapter 6, Table 6.2). Study 2 (Chapter 6) resulted in a valid Arabic translation of these scales. Testing the reliability of the Arabic translation of these scales showed moderate to an excellent agreement of all the used VAS (ICC = 0.64–0.90) except alteration of sleeping VAS, which showed poor agreement (ICC = 0.43) while the Likert items related to social support and the beliefs of the importance of adherence showed fair to moderate agreement (Kappa = 0.34–0.50).

7.4.6 Outcome measures

Adherence to wearing RCWs was measured objectively by estimating weight-bearing activities undertaken while using the offloading device (the primary outcome) (95, 98). Activity monitoring using a computerised pedometer or accelerometer has previously been implemented to measure adherence to weight-bearing activities while using an offloading device (52, 54). This method has shown high reliability with diary-record compliance (410). Usually, the proportion of adherence to wearing the offloading device during weight-bearing activities results from calculating the total activity of the offloading device, which can be measured by attaching an activity monitor to the device itself and the total activity by participants by providing them with another activity monitor on the wrist or hip (126). Ideally, two activity sensors have to be synced to compare activities and detect non-adherence activities during different time-stamps, which helps to detect in which hours and activities participants do not adhere (410).

A similar protocol of adherence measurement was implemented in this research using Fitbit Flex© (FF) for seven days (at least three days), which have been shown in previous research to be valid and reliable commercial activity trackers (see Appendix

21). This included attaching FF trackers to the patients' wrists and the posterior or lateral aspect of their RCW to count the number of steps in each 15-minute time-stamp during the measurement period (both trackers were calibrated on the same clock time). A pilot test was conducted to assess the feasibility of the protocol in terms of data management, device usability, battery power, and patients' interactions (see Appendix 22). All timestamps and steps were then entered into Excel spreadsheets to allow the synchronisation between the recorded steps of both trackers for the same time-stamp. Adherence activity was then defined and coded as a unit in which the recorded RCWs steps were more than half of the wrist steps for every single 15-minute time-stamp (52, 410). The overall percentage of adherence activity to wearing RCW was calculated by counting the number of all coded adherence activity units divided by the number of all the recorded activity units (both adherence unites and the wrist activity unites) during the measurement period (3–7 days). Any activity units recorded only by RCWs were excluded. The process of adherence calculation using the activity data is presented in Appendix (23).

Self-report of adherence to wearing RCWs was the secondary outcome, which included reporting adherence time and steps. A Likert question was previously developed by Bus et al (53) to estimate how long patients usually wear an offloading device, including inside or outside the house. This question was translated to Arabic, which was stable during reliability testing (see Chapter 6). Further, a previously valid and reliable visual analog scale (VAS) (0-100) was adapted for this study (369) to estimate the percentage of adherence time to wearing RCWs, which was found to be reliable in Study 2 (see Chapter 6). Adherence to weight-bearing steps was measured through self-report and objective measurement. A Likert question was adapted from Bus et al (53) to estimate how many steps patients usually completed wearing the offloading device, including inside or outside the house. Further, a previously valid and reliable VAS (0-100) (369) was adapted to estimate the percentage of adherence steps to wearing the RCWs, which was found to be a reliable scale in Study 2 (see Chapter 6).

7.4.7 Procedure

This study was conducted between October 2019 and February 2020. The study was advertised through informing the clinicians in these settings about the need for potential participants who met the inclusion criteria of this study. The PhD candidate was available at all of the research settings on different weekdays during regular working hours (8 am–3 pm). Clinicians identified eligible participants, who were then screened by the PhD candidate to ensure they met the inclusion criteria. Eligible participants were invited to participate by the PhD candidate and were then provided with verbal and written information (participant information sheet, see Appendix 12, 13, 14, 15) about the study to consent to participate. Those who voluntarily consented were included as participants of the study.

Consenting participants provided characteristics data, including sociodemographic information, clinical variables (personal health information and clinical foot examination), and completed the study questionnaire. First, the PhD candidate interviewed participants to collect sociodemographic variables in a private room before participants received regular care of their wounds. Next, the PhD candidate then provided participants with the questionnaire to complete in the waiting room before they received their regular wound care. If participants had impaired vision or difficulty in reading or understanding the content, the PhD candidate provided them with assistance to complete the questionnaire. Some participants became weary during answering the questionnaire, so they completed it within more than one visit during their regular wound care follow-up within a maximum of two weeks. The PhD candidate then conducted a clinical examination of the foot and the wound during or after participants receiving their regular wound care at the clinic, which included loss of protective sensation (10 monofilament), peripheral arterial disease (PAD) (TBI), foot deformities, amputations, ulcer size, and ulcer classification. Finally, the PhD candidate provided the participants with the activity trackers (FF) to measure the main outcome of this research. This included calibration of the trackers (entering personal information such as height and weight), attaching the trackers to the offloading devices, and an explanation of the procedure (see Appendix 23). Participants were instructed to wear the wrist trackers for one week. However, the PhD candidate collected the activity trackers from participants within a maximum of two weeks. It is important to mention that participants were not aware of the purpose of the trackers. This information was withheld due to the possibility of participants removing these monitors during data collection and working with their offloading devices without measurement or adhering more to the RCW, which could have led to biased adherence. (410).

To minimise participants' non-compliance of wearing the wrist trackers, the following protocol was implemented. First, FF bands were the trackers of choice as wrist trackers have been found to be worn longer than waist trackers (415). Next, participants were instructed that compliance to wearing the wrist trackers was crucial; however, they were free to withdraw any time if they did not feel confident in complying with wearing the tracker all the time for one week. Participants were then reminded by phone calling or messaging on a daily base to comply with wearing the wrist trackers during the measurement period. As FF trackers are water-resistant, participants did not need to remove them during activities such as hand washing or showering. Participants also did not need to take off the wrist trackers to recharge the batteries during the measurement period. Participants were free to decide which wrist (dominant or non-dominant wrist) they wanted to wear the device on, this was then calibrated in the Fitbit software. Finally, different colour options of the wrist bands were offered to motivate participants (black, cyan, maroon, or pink).

7.5 DATA ANALYSIS

Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS, Version 23). The variables of this study were defined and labelled in SPSS software. A descriptive analysis was used for all study variables. For continuous variables, the mean and standard deviation or median and range were calculated. The frequency, histograms, skewness, kurtosis, and Kolmogorov-Smirnov ($P>0.05$) tests were run for all the continuous variables to detect the normality of the distribution. For categorical variables, frequencies and proportions were calculated.

Bivariate relationships between the primary outcome (objective adherence) and the independent variables were tested. To compare adherence between the categorical variables, independent sample t-tests, or one-way analysis of variance (or non-parametric equivalents for non-normally distributed data) were used. Pearson or Spearman's correlations (r, rho) were used to test the associations between adherence and the other continuous independent variables in addition to testing for any multicollinearities between the independent variables. A scatterplot was also used for each correlation to guide choosing the coefficient test (i.e. choosing Spearman for the nonlinear scatters, not normally distributed). A correlation matrix table was created to organise the conducted coefficients between adherence and the independent variables in addition to detect the multicollinearities between them.

Stepwise multiple linear regression modelling (with backwards eliminations) was used to investigate and predict the independently significant associations between the independent variables and the main dependent variable (objective adherence) and to control for any potential confounding between independent variables. (416). All variables that had $p<0.10$ in bivariate testing were simultaneously entered in the regression model (417). Multicollinearities were tested using Person-Spearman's correlation-coefficients (r, rho). The model was evaluated by checking assumptions such as multicollinearities, residual outliers, normality, and linearity, including collinearity statistics (tolerance, VIF). Residual outliers were also assessed by using Mahal and Cook's distance. Finally, normality and linearity were checked by using normal P-P plot.

7.6 DATA MANAGEMENT

Data were collected in both hard copy and software data. The hard copy transcripts (data collection forms, the questionnaire, and consent forms) were kept in locked data storage facilities at QUT. However, in compliance with QUT data management processes, while the data were being collected in Jordan, the hard copy sheets were saved at the NCDEG (Amman-Jordan) storage facilities.

Before travelling back to Australia, the hard copy data were photo scanned as a soft copy then stored in a secure access QUT drive to safeguard the data in case of any possibility of luggage lost during travelling. Digital data (SPSS data and Fitbit data) are saved in a QUT Research Data Storage Service or QUT Secure Access U-Drive, which is a cloud service. The activity data of the trackers are saved in the Fitbit cloud services and can be accessed as non-identifiable data.

7.7 ETHICAL CONSIDERATIONS

The ethical approval was obtained from the Office of Research Ethics and Integrity at QUT (ethical approval number:1900000418) and the Institutional Review Board Committees at the NCDEG, JRMC, and PHH.

This study was deemed low risk as there were no suspected physical, psychological economic, or social harms that could influence the recruited participants. Participants were seen during their regular visits to obtain wound care without any further costs (i.e. the associated cost with the second visit to return the trackers).

A written information sheet was given to participants before they signed the consent form of participation (see Appendix 12, 13) and included the study aim, procedure, contact of the PhD candidate, the principal supervisor, and the QUT Research Ethics Office.

There was a potential for minor discomfort for participants while participating in this study, as the specific goal of wearing the activity trackers was concealed from the participants. However, this concealing was minimal, as they were told that the aim of using activity trackers was studying the specific behaviour such as activities instead of telling them "measuring adherence". Participants were informed of concealing the main aim of using the activity trackers and told they would know this specific aim after completing the whole study. This was done through the participant information sheet and a debriefing form that showed the percentage of their adherence to wearing the offloading device after the study had finished.

Participants were advised to adhere to wearing the wrist trackers as much as they could. However, they were informed that they were free to remove the trackers for some activities such as sleeping or bathing or if they felt tired or uncomfortable from wearing them. Participants were free to withdraw from the study without any consequences that would affect their relationship with the clinicians at the research settings.

7.8 RESULTS

7.8.1 Participants characteristics

Seventy-two patients were identified as being eligible for this study, and of those, 61 consented to participate. The 11 that did not consent included six who were not interested in participating for no specific reason and five who were unable to return the FF trackers. Of the 61 consenting participants, four had an incomplete measurement of adherence; of these, two had trackers that failed to record any data, one refused to wear the tracker after consenting, and one was hospitalised while recording data.

7.8.2 Demographics and health characteristics

Participants were recruited from three settings in Jordan including 35 participants (57.4%) from the NCDEG, 12 participants (19.7%) from the JRMC, and 14 participants (23%) from the PHH. The mean age of the study population was 55.8 years (SD 10). Most participants were male (78.7%) (see Table 7.2 for additional details of the socio-demographics of the study population).

Table 7.2 also shows the clinical characteristics of the study population. All study participants had DM; 93.4% had type 2. The other collected variables related to DM had the following means: duration of DM (17.4 years, SD 7.3), BMI (30.8, SD 6.2), and HbA1C (8.8 mmol/L, SD 2). The level of activity was demonstrated by the median of the recorded wrist steps (mean steps of 3–7days), which was 2761.7 steps (IQR 2939.7). Several comorbidities were reported, including renal failure (4.9%), heart failure (11.5%), retinopathy (39.3%), hypertension (55.7%), osteoarthritis (13.1%), dyslipidaemia (49.2%), and myocardial infarction (9.8%).

The limb clinical variables are presented in Table 7.2. Of the study population, 67.2% had a history of previous ulceration, 91.8% had a loss of protective sensation, 26.2% had PAD, 73.8% had foot deformities, and 26.2% had minor amputations. All participants had DFUs, with 14.8% of them having ulcers on both feet. The median duration of ulcers was 16 weeks (IQR 27). The median area of ulcers was 1.2 CM^2 (IQR 4). DFU infection was present in 52.5% of the study population. Finally, the median duration of previous use of RCWs was 12 weeks (IQR 28).

Table 7.2: Socio-demographic and clinical characteristics of the study participants (n=61)

Characteristics	**N**	**Mean (SD)**	**95% Confidence Intervals**
Age (years)	61	55.8 (10)	53.2 – 58.4
BMI	59	30.8 (6.2)	29.2 – 32.4
Duration of diabetes (years)	59	17.4 (7.3)	15.5 – 19.4
HbA1C (mmol/L)	58	8.8 (2)	8.3 – 9.4
Characteristics	**N**	**Median (IQR)**	
Family income (JD)	55	400 (400)	
Ulcer area (CM^2)	59	1.2 (4)	
Duration of ulcer (weeks)	61	16 (27)	

Duration of RCW (weeks)	61	12 (28)
Mean daily steps (wrist FF, 3-7days)	57	2778.8 (2977.4)

Characteristics		N (%)
Study site	NCDEG	35 (57.4%)
	JRMC	12 (19.7%)
	PHH	14 (23%)
Male		48 (78.7%)
Living arrangement	Living alone	4 (6.6%)
	With family	56 (91.8%)
	Primary carer for another household member	1 (1.6%)
Educational level	Primary school	13 (21.3%)
	Secondary school	26 (42.6%)
	Undergraduate	19 (31.1%)
	Postgraduate	3 (7.9%)
Employment	Employed	10 (16.4%)
	Unemployed	12 (19.7%)
	Retired	21 (34.4%)
	Self-funded	18 (29.5%)
Type 2 DM		57 (93.4%)
Renal failure		3 (4.9%)
Heart failure		7 (11.5%)
Retinopathy		24 (39.3%)
Hypertension		34 (55.7%)
Osteoarthritis		8 (13.1%)
Rheumatoid arthritis		1 (1.6%)
Dyslipidaemia		30 (49.2%)
Myocardial infraction		6 (9.8%)
History of previous ulceration		41 (67.2%)
Loss of protective sensation		55 (90.1%)
PAD		16 (26.2%)
Foot deformities		45 (73.8%)
Minor amputations		16 (26.2%)
Major amputations		0
UT grade		
	Grade 1	34 (55.7%)

	Grade 2	5 (8.2%)
	Grade 3	22(36.1%)
Ulcer infection		32 (52.5%)

SD: Standard Deviation; BMI: Body Mass Index; IQR: Inter-Quarters Range; JD: Jordanian Dinar; CM: Centimeters; FF: Fitbit Flex©; NCDEG: National Centre for Diabetes, Endocrinology, and Genetics. JRMC: Jordanian Royal Medical City; PHH: Prince Hamzah Hospital; DM: Diabetes Miletus; PAD: Peripheral Arterial Disease; UT: University of Texas

7.8.3 Baseline characteristics of the psychosocial measures

Table 7.3 shows the psychosocial characteristics of the study population. The psychosocial scales of footcare self-efficacy and beliefs in addition to the knowledge of DFU and neuropathy had the following means: FCCS (range 1–65) (48.6, SD 10), FCOES (range 1–80) (67.1, SD 10), and PIN scales (range 1–20) (the mean score was >10, see Table 7.3). The NQOL symptoms scales (range 1–20) had the following means: pain (6.2, SD 3.2), loss of feeling (7.8, SD 5.3), and motor neuropathy (7.3 SD 4.9). All the VAS (0–10) of psychosocial variables related to the offloading device resulted in a median ≥ 5 (range 0–10). Table 7.3 also presents participants' reports of the provided social support when putting on RCWs as well as the beliefs of the importance of wearing RCWs for every weight-bearing step (i.e. walking short distances without the offloading device is not harmful).

Table 7.3: Psychosocial characteristics of the study participants (n=61)

Characteristics	**N**	**Mean (SD)**	**95% Confidence Intervals**
FCCS [1]	61	48.6 (10)	46 – 51.2
FCOES [2]	61	67.1 (10)	64.6 – 69.7
PIN: self / practitioner blame [3]	61	14.8 (3.1)	14 – 15.6
PIN: physical causes of DFU [4]	61	15.9 (2.5)	15.3 – 16.6
PIN: acute ulcer onset [5]	61	11.2 (2)	10.7 – 11.7
NQOL: foot pain [6]	61	6.2 (3.2)	5.4 – 7
NQOL: loss of feeling [7]	61	7.8 (5.3)	6.5 – 9.2
NQOL: motor neuropathy [8]	61	7.3 (4.9)	6 – 8.6
Characteristics	**N**	**Median (Range)**	
Level of comfort (VAS score)	61	5 (0-10)	
Ability of performing daily life activities (VAS score)	60	5 (0-10)	

Alteration in activity level (VAS score)	60	5 (0-10)
Alteration in sleep (VAS score)	58	5 (0-10)
Level of satisfaction (VAS score)	61	6 (0-10)
Re-wearing the offloading device in the future (VAS score)	60	9 (0-10)
Heaviness of the RCW (VAS score)	61	5 (0-10)
The difficulty of putting on the RCW(VAS)	61	5 (0-10)

Characteristics		**N (%)**
Social support[9]	Always	22 (36.1%)
	Usually	8 (13.1%)
	Sometimes	15 (24.6%)
	Rarely	4 (6.6%)
	Never	12 (19.7%)
Offloading beliefs[10]	Totally agree	17 (27.9%)
	Moderately agree	19 (31.1%)
	Neither disagree nor agree	5 (8.2%)
	Disagree	7 (11.5%)
	Not agree at all	12 (19.7%)

SD: Standard Deviation; DFU: Diabetic Foot Ulcer

[1] Footcare confidence scale: a total score of 13 Likert items (5 points each, range 1-65)
[2] Footcare outcomes expectations scale: a total score of 16 items (5 points each, range 1-80)
[3] Patients interpretation of neuropathy (self/practitioner blames): a total score of 4 items (5 points each, range 1-20)
[4] Patients interpretation of neuropathy (physical causes of DFU): a total score of 4 items (5 points each, range 1-20)
[5] Patients interpretation of neuropathy (acute ulcer onset): a total score of 3 items (5 points each, range 1-15)
[6] Neuropathy quality of life pain scale (range 1-20): a total score of the mean of neuropathy pain symptoms scale (7 items, 5 points each) multiply by the mean of bothering symptoms scale (7 items, 3 points each) then the score of quality of life neuropathy pain scale (1 item, range 1-5) was added
[7] Neuropathy quality of life loss of feeling (range 1-20): a total score of the mean neuropathic loss of feeling scale (3 items, 5 points each) multiply by the mean of bothering symptoms scale (3 items, 3 points each) then the score of quality of life loss of feeling scale (1 item, range 1-5) was added
[8] Neuropathy quality of life motor neuropathy scale (range 1-20): a total score of the mean motor neuropathy scale (3 items, 5 points each) multiply by the mean of bothering symptoms scale (3 items, 3 points each) then the score of quality of life motor neuropathy scale (1 item, range 1-5) was added
[9] This is a Likert question to estimate how often participants receive support when putting on the RCW

[10] This is a Likert question that estimates participants' beliefs of the importance of adherence wearing the RCW for every step

7.8.4 Adherence levels

Patients adherence to wearing RCWs (the main outcome variable) was measured using two domains (objective measurement and self-report) (see Table 7.4). First, in relation to objective measurement, participants wore their offloading devices for 33.6% (SD 16.5) of their physical activity (3–7 days). Self-report then resulted in an overall individual estimation of the percentage of the daily adherence time and steps of wearing RCWs. With regards to the VAS (0–100%) for adherence time, participants reported adherence of 70.1% (SD 27.8) of the daily time. However, of using VAS (0–100%) for adherence steps, the participants reported adherence of 90% (range 0–100) of the daily steps. Likert scales were also used to estimate adherence time and steps inside and outside the house. Overall, perfect adherence (all the time and for every step) was higher reported outside the house (78.7%, 82%) in comparison to inside the house (26.2%, 32.8%). (see Table 7.4)

Table 7.4: Characteristics of adherence outcomes (n=61)

Characteristics		**N**	**Mean (SD)**	**95% Confidence Intervals**
Objective adherence activity (%)		57	33.6 (16.5)	29.2 - 38
Self-reported adherence time (%) (VAS)		60	70.1 (27.8)	62.9 – 77.3
Characteristics		**N**	**Median (Range)**	
Self-reported adherence steps (%) (VAS)		57	90 (100)	
Characteristics		**N (%)**		
Self-reported adherence time inside the house	All of the time	16 (26.2%)		
	Most of the time	14 (23%)		
	Some of the time	12 (19.7%)		
	A little of the time	11 (18%)		
	None of the time	8 (13.1%)		
Self-reported adherence time outside the house	All of the time	48 (78.7%)		
	Most of the time	9 (14.8%)		
	Some of the time	0		

	A little of the time	4 (6.6%)
	None of the time	0
Self-reported adherence steps inside the house	Every single step	20 (32.8%)
	Most of the steps	14 (23%)
	Half of the steps	9 (14.8%)
	Only in a few steps	9 (14.8%)
	Not in a single step	8 (13.1%)
Self-reported adherence steps outside the house	Every single step	50 (82%)
	Most of the steps	7 (11.5%)
	Half of the steps	1 (1.6%)
	Only in a few steps	2 (3.3%)
	Not in a single step	0

SD: Standard Deviation; VAS: Visual Analogue Score

Participants reported their adherence to wearing RCWs during weight-bearing steps as 90%, this was the highest reported adherence percentage. In comparison, the objective measurement of adherence to wearing RCW during physical activity (steps) was the lowest (33.6%). (see Figure 7.1).

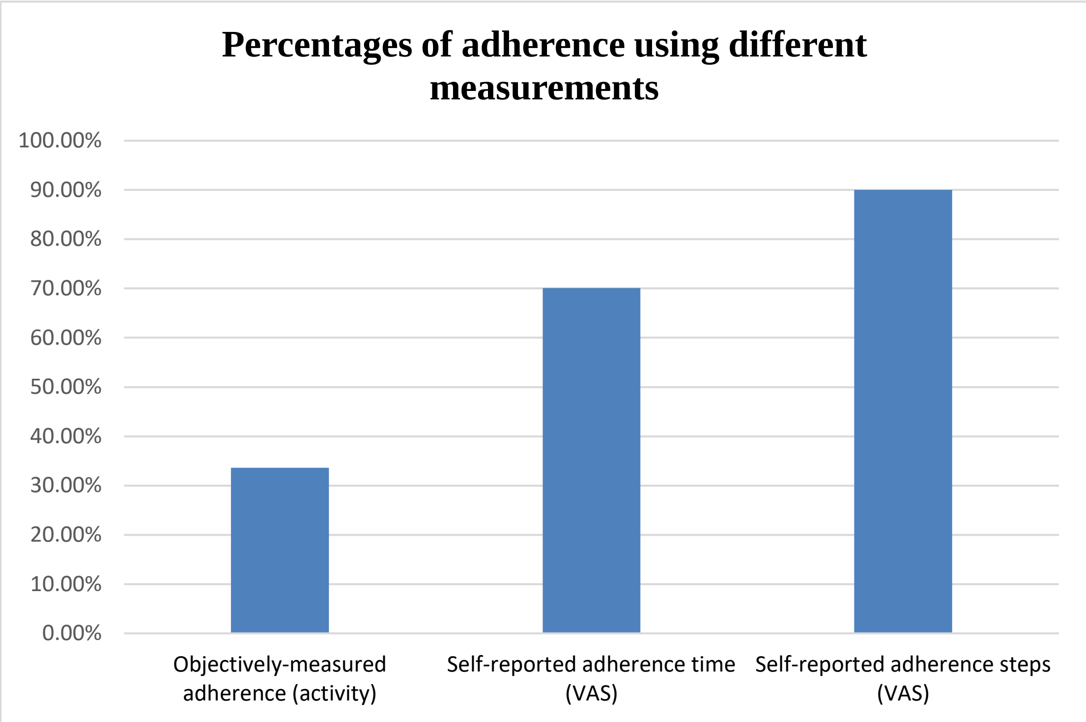

Figure 7.1: Comparison of measures of adherence to RCWs

7.8.5 Bivariate associations between adherence and the study variables

There were no significant associations between the categorical independent variables and objective adherence to RCWs (Table 7.5).

Table 7.5: Relationships between independent variables and objective adherence to RCWs

Independent Variable		**Mean (SD) adherence**	**Test**	**p**
Study site	NCDEG	36.4 (17.2)	F= 2.18	0.12
	JRMC	24.7 (14.5)		
	PHH	34 (14.9)		
Males		31.8 (17)	T= -1.65	0.10
Living arrangement	Living alone	25.3 (17.2)	F= 1.23	0.30
	Living with family	34.5 (16.4)		
	Primary carer for another household member	13.2 (-)		
Educational level	Primary school	42.5 (14.2)	F= 1.57	0.21
	Secondary school	32.1 (15.2)		

Independent Variable		Mean (SD) adherence	Test	p
	Undergraduate	30.2 (19.2)		
	Postgraduate	38.5 (20.5)		
Employment	Employed	38.5 (20.5)	F= 2.14	0.11
	Unemployed	42.6 (11.3)		
	Retired	31.2 (13.5)		
	Self-funded	28.6 (18.6)		
Type2 DM		34 (16.6)	T= -0.67	0.51
Renal failure		39 (13.0)	T= -0.56	0.56
Heart failure		28.9 (15.3)	T= 0.80	0.43
Retinopathy		34.5 (15.8)	T= -0.32	0.75
Hypertension		30.9 (16.8)	T= 1.44	0.16
Osteoarthritis		28.5 (18.7)	T= 0.88	0.38
Dyslipidaemia		30.8 (16.3)	T= 1.26	0.21
Myocardial infarction		44.3 (20.4)	T= -1.70	0.09
History of previous ulceration		30.4 (15.5)	T= 1.95	0.06
Loss of protective sensation		33.4 (16.9)	T= 0.04	0.38
PAD		39.4 (16.7)	T= -1.67	0.10
Foot deformities		33.0 (16.1)	T= 0.43	0.54
Minor amputations		28.2 (15.3)	T= 1.56	0.13
UT grade	Grade 1	30.7 (16.1)	F= 1.67	0.20
	Grade 2	30.6 (15.3)		
	Grade 3	39.0 (16.7)		
Ulcer infection		36.2 (16.5)	T= -1.23	0.22
Social support	Always	34.0 (16.4)	F= 0.21	0.93
	Usually	8.0 (32.8)		
	Sometimes	31.7 (17.8)		
	Rarely	30.2 (23.0)		
	Never	37.3 (17.7)		
Offloading beliefs	Totally agree	40.1 (17.1)	F= 2.11	0.09
	Moderately agree	31.0 (15.6)		
	Neither disagree nor agree	18.5 (17.4)		
	Disagree	39.5 (16.3)		
	Not agree at all	33 (13.7)		

SD: Standard Deviation; NCDEG: National Centre for Diabetes, Endocrinology, and Genetics. JRMC: Jordanian Royal Medical City; PHH: Prince Hamzah Hospital; DM: Diabetes Miletus; PAD: Peripheral Arterial Disease; UT: University of Texas

For the continuous variables, adherence to wearing RCWs had a significant negative correlation with the duration of diabetes (r = -0.34; p = 0.01) and the heaviness of RCW (rho = -0.27; p = 0.04). No significant associations were found between adherence and the total scores of the psychosocial variables such as FCCS, FCOES, PIN scales, NQOL scales, and VAS related to offloading (i.e. level of comfort or heaviness).

7.8.6 Multiple linear regression model

A significant regression model resulted from including the variables that achieved the statistical threshold ($p<0.1$) (duration of diabetes, the heaviness of the RCW, level of comfort, offloading beliefs, gender, and PAD). However, two variables (myocardial infraction and history of previous ulceration) were excluded from the model as they were significantly correlated with PAD and duration of diabetes, respectively, thus there was a risk of multicollinearity.

All variables fitting the criteria above were simultaneously entered into a linear regression model. Backwards elimination of non-significant variables was undertaken one variable at a time, which resulted in deleting two non-significant variables; the level of comfort (p = 0.20) and offloading beliefs (p = 0.27). The final regression model was significant (n = 55, adjusted $R^2 = 0.28$, $p<0.001$), which included four significant variables associated with adherence to RCWs: the duration of diabetes, the heaviness of RCW, gender, and PAD (Table 7.6).

There were no multicollinearities in the model, as all the correlations between the included independent variables were $r<0.70$. The residuals did not exceed the critical value with no impact on the reliability of the model prediction. Furthermore, the scatterplot of the residuals was rectangularly distributed with no systematic pattern or curvilinear located between -3 and 2. Finally, the standardised residuals were distributed on a straight line with no significant deviations from normality.

Table 7.6: Multiple linear regression model: factors associated with adherence to wearing RCWs

	Unstandardised Coefficients		Standardised Coefficients	t	p
	β	SE	β		
Duration of diabetes (years)	-1.003	0.27	-0.44	-3.68	0.001
Heaviness of the RCW (VAS)	-1.53	0.76	-0.23	-2.008	0.050
Gender (male, female)	11.35	4.85	0.28	2.34	0.023
PAD (no, yes)	10.99	4.28	0.30	2.57	0.013

SE: Standard Error; VAS: Visual Analogue Score; PAD: Peripheral Arterial Disease

The multiple linear model (Table 7.6) shows that the duration of diabetes had the strongest association, which was negatively associated with adherence to wearing RCWs ($p = 0.001$, each year of diabetes duration resulted in a 1% decrease of the adjusted mean of adherence). Similarly, the heaviness of the offloading devices was negatively associated with adherence ($p = 0.05$, each increased unit of the reported heaviness resulted in a 1.5% decrease of the adjusted mean of adherence), while being female and having PAD were significantly associated with higher adherence ($p<0.05$, being female or having PAD resulted in around 11% higher adjusted mean of adherence).

7.8.7 Intraclass correlation coefficient (ICC) between subjective and objective adherence

There was a significant correlation between subjective adherence (steps) and objective adherence (physical activity); (ICC = 0.59 95% CI: 0.29–0.76, P = 0.001, moderate agreement).

7.9 DISCUSSION

This study provides new evidence from a previously unexplored population (Jordanians) of the levels and the factors associated with adherence to wearing RCWs. Adherence was poor when was measured objectively (33.6% of the overall recorded physical activity), which is not a surprising outcome. Armstrong et al (54) performed the first objective tracking of adherence to offloading and found that patients with DFUs only adhered to wearing their offloading devices in 28% of their daily activity. This is consistent with the current adherence findings using similar measurements (attaching two activity trackers to count daily steps). However, a more recent investigation of adherence to removable offloading devices using the same instrumentation found higher adherence (59±22%) (52). In Crews et al study (52), around 23% of the removable offloading devices were not RCWs (i.e. they included sandals), while the current study and the previous investigation by Armstrong et al (54) included only RCWs. Using different types of offloading devices can be associated with different adherence levels (43, 349). Preventive footwear was found with the highest known objective adherence to offloading (71%) (274) and offloading shoes (i.e. cast shoe) had higher adherence than knee-high offloading device in another investigation (53). This indicates the need to compare adherence levels between different offloading devices to inform clinicians of the best offloading option that patients can follow.

Another explanation for this offloading adherence variation may be related to cultural disparity or ethnicity between the studied populations (418, 419). For instance, Jordanians with chronic conditions usually have poor adherence outcomes (420, 421). As a part of their culture, they may consider chronic disease such as depression to be a stigma, leading to lack of interest in following the treatment (422, 423). Further, spiritual beliefs related to the Islamic culture can cause Jordanians to believe that "Allah" controls their health outcomes, with no need to adhere to treatment (424, 425). A previous offloading survey also showed ritualistic practices (i.e. washing feet before prayer or walking barefoot inside the house) as a barrier to accepting the offloading device (56). This reveals how the cultural norms of specific populations can impact adherence. Thus, further offloading adherence research is required between different populations and consideration of cultural factors to increase understanding.

It is important to note that despite the similarities between the socio-demographic characteristics (i.e. age, gender, and duration of diabetes) between this study and the previous offloading adherence studies (52-54), the population of this study had more severe DFUs. Previous studies have only included grade 1 or 2 DFUs without infection or ischemia, primarily because there was a need to control the factors that contribute to wound healing, which was a major outcome in two studies (52, 53). However, in the current study, around 36% of participants had grade 3 DFUs (penetrating to bone), 52% of participants had infections, and 26.6% had PAD. Therefore, these findings may provide more generalisable estimation of the overall adherence to wearing RCWs among patients with both complicated and noncomplicated DFUs that typically attend clinics around the world and are recommended in the latest IWGDF to also need knee-high RCW to offload, such as those with DFUs that are moderate to severe infected and/or ischemic (34). Another important difference is that the current study included participants who had been wearing an RCW for at least four weeks, while the duration of wearing the RCW was not mentioned in the previous offloading adherence studies (52, 54). A previous study showed that patients with DFUs who used RCW changed their behaviour significantly after four weeks by being more active and this may indicate a decline in adherence (51). The PhD candidate hypothesised that when the offloading device is newly prescribed for patients, they are more likely to be motivated and adhered to the treatment, but this can be reduced within the time. Thus, the aim was to include an overlap of this potential bias in adherence by recruiting participants after week four of using offloading.

Self-reporting of RCWs adherence was overestimated. Participants reported a median of 90% of adherence during the daily steps undertaken, while their recorded objective adherence was only 33.6%. This is novel evidence that supports the recommendations to use objective methods of measuring offloading adherence (95, 126). Based on this study, researchers and clinicians should be wary of self-reporting as an accurate tool to estimate patients' adherence. However, self-reporting of adherence steps was significantly correlated with objective measurement (ICC = 0.59, moderate agreement). This indicates that self-report can be a predictor of real adherence, despite not being accurate. Patients who reported higher adherence were more likely to have higher actual adherence. This association is an interesting finding, as it shows evidence of the criterion validity of the self-reporting of adherence to wearing RCWs. This reveals that self-reporting of adherence can be a psychometric predictor of objective adherence, requiring further investigation in future research.

Adherence to wearing RCWs was higher in outdoor settings. This study showed that around 80% of participants reported perfect (all the time and for every step) adherence of the offloading device outside the house, while only around 30% reported perfect offloading adherence inside the house. This finding is similar to findings from previous research (53, 273, 274). Importantly, a study on footwear adherence found patients were more active at home (274), highlighting the potentially devastating increased plantar pressure related to higher non-adherence in the home. The qualitative study undertaken as part of this PhD (see Chapter 5) suggested that patients are more likely to wear their offloading device outside the house for religious reasons (cleanliness). However, there is a definite need for more specific investigation of the reasons for not wearing offloading devices inside homes, as well as suggesting interventions to enhance adherence.

Investigating the factors that impact on patients' adherence to wearing their offloading devices is extremely valuable. RCWs are efficient offloading devices and can be a more practical option than the gold standard offloading (TCC) (35, 44). However, there is a need to improve patients' adherence to wearing them. Currently, there are some suggested promising solutions such as motivational interventions (426) or using wearable technology that helps patients to monitor their offloading (427). Nevertheless, it appears too early to argue for any potential intervention without a fuller understanding of the offloading non-adherence dilemma, as only one study has identified some offloading adherence predictors (52). The current study contributes new evidence of the factors associated with adherence to wearing RCWs among patients with DFUs, finding the duration of diabetes and the heaviness of the offloading device to be significantly associated with less adherence, while females or persons with PAD had significantly higher adherence.

The relationship between duration of diabetes and adherence to offloading has previously been investigated (52, 328). According to a systematic review of six studies (328), the duration of diabetes was not a significant factor in adherence to preventive footwear. Likewise, Crews et al (52) found no evidence of the impact of the duration of diabetes on adherence to removable offloading devices. Interestingly, a systematic review of adherence to diabetes medications also found no evidence of the duration of diabetes and adherence (428). Hence, it seems this is the first study to find the duration of diabetes to be associated with offloading adherence. This factor was the strongest ($p = 0.001$, $\beta = -0.44$) in the model; thus, participants with longer duration of diabetes had less objective adherence to wearing RCWs. A previous study from Jordan found a longer duration of diabetes was associated with poorer glycaemic control (429). Longer duration of diabetes can be associated with more complications, which means adherence to several treatments is required. Consequently, adherence to wearing offloading devices can be more challenging. Further, a longer duration of diabetes or more diabetes complications have been associated with depression (430, 431), which is a well-known factor in predicting adherence (60, 291, 292). A previous study showed that patients with diabetic foot disease have significantly higher depression (OR 2.32) than other diabetic patients (431). A study from Jordan found that depression can impact diabetes self-care activities due to the associated poor self-efficacy (403). Despite Crews et al (52) not finding depression to be a predictor of adherence to offloading, robust evidence shows the impact of depression on adherence. Thus, the hypothesis from this study is that patients with longer duration of diabetes may have more complications or higher rates of depression, and this may reduce adherence to wearing RCWs, which needs to be tested in future research.

The heaviness of the RCW was another factor negatively associated with adherence. This is the first study to test this important physical variable using a reliable (stable) visual scale developed for this research, (see Chapter 6). Previous qualitative investigations reported that RCWs were found to be heavy, bulky and awkward to use (248, 318). The qualitative study in this thesis (Chapter 5) also found reports of RCW heaviness causing discomfort, especially when worn during sedentary activities. RCWs (knee-high) are quite heavy (1.4Kg) in comparison with the average shoe (300g); thus, a smaller and lighter offloading device could lead to greater adherence (43). One recent study found ankle-high RCWs were more comfortable, suggesting better adherence outcomes (349), and this was also found in another study (53). Interestingly, the level of comfort was not a significant physical factor related to adherence in this investigation. Using RCWs may result in more comfortable walking, especially for patients who have more severe diabetic foot conditions (i.e. ischemia or minor amputations) (see Chapter 5, qualitative investigation). Overall, this finding shows new information about the importance of considering the physical features of offloading devices, such as heaviness. The orthotics offloading industry may consider this factor to improve their products (i.e. using lighter materials). This also suggests the possibility of considering ankle-high RCWs, especially as they are 20% lighter than knee-high RCWs and this could potentially improve adherence outcomes (43).

This study also found that females reported significantly higher adherence. This is not a surprising finding, as globally females are less likely to have ulcerations or amputations (male-to-female ratio of ulceration and amputation is 1.93 and 1.56, respectively) (83). One explanation is that men are usually committed to the family income, influencing them to engage in heavier work-related activities (432). This can be more devastating among Jordanians, as labour equality is not as common as in the West. The current study sample found that 92% of women were unemployed, in comparison with 2% of men and this may clarify lesser adherence to wearing RCWs among men, particularly outdoors. The qualitative study (see Chapter 5) also showed male participants could not perform their regular jobs using RCWs, which may mean they removed them to remain productive. However, this is in contrast to previous offloading adherence research, which found no evidence of gender differences (52, 328). One explanation may be the lesser gender work disparity in Western countries (433). In other studies on diabetes, a systematic review of medication adherence found little evidence (3\27 studies) of the male gender as a negative factor (428).

Gender can be a factor that impacts the acceptance of the appearance of the offloading device, which can affect adherence outcomes. Previous research from Western countries found females dislike wearing therapeutic footwear, seeing them as unfeminine, massive, and unattractive (433, 434). However, in the current qualitative investigation, only males reported appearance concerns during wearing the RCW. However, as mentioned, Jordanian women are less likely to socialise or have outside jobs, resulting in potentially fewer concerns about appearance. Previous data showed Jordanian women are less interested in body image than Asian or white women (435), which may predict higher acceptance of the appearance of RCWs, resulting in better adherence. Further, the traditional fashion and clothing of the Jordanian females as Muslims may explain more acceptance of the appearance of RCWs, as they usually wear a jilbab (long dress) and hijab, allowing them to hide the knee-high offloading device entirely, while the devices are much more obvious when men wear them due to their Westernised dress. Overall, the association between gender and offloading adherence is an interesting finding that has resulted from this new offloading adherence research from a different culture. This association may relate to the indirect cultural impact on gender behaviour. This demonstrates the complexity of understanding adherence between different cultures, where the outcomes of a specific population cannot be generalised globally.

The results of this study support the role of the severity of diabetic foot disease. Specifically, participants with PAD showed significantly higher adherence to wearing their offloading devices. This is a new finding, as the only previous investigation (52) excluded patients with PAD. The current qualitative study (see Chapter 5) found that participants with more diabetic foot complications (i.e. deformities, pain, amputations, or postural imbalance) needed to wear their offloading devices for better quality and balance walking. Previous evidence (52, 274) showed that more severe diabetic foot conditions (neuropathy, larger and more severe DFUs, foot deformities and foot pain) predicted better adherence to removable offloading devices. One explanation was related to patients' awareness of the severity of their condition (52, 274). This can be applied to the current findings, where patients with more severe PAD presumably perceived a greater impact related to this devastating condition. The qualitative data from the current study also showed that ulcer-related pain during walking is sometimes reduced when wearing the device. As deep, aching and continuous pain could be present in 36.4% of ischemic DFUs (436), it can be hypothesised that patients with PAD are more inclined to wear RCWs to relieve their ischemic pain and this consequence leads to better adherence. As a whole, patients with pain are more likely to adhere to anti-pain medications or treatment according to a longitudinal study (332). Clinicians may need to consider increasing patients' awareness of less severe diabetic conditions to enhance their adherence.

Finally, this study found no significant relationships between adherence and psychosocial factors, including footcare self-efficacy, outcomes expectations, or DFU specific beliefs (PIN). This is in line with the previous offloading adherence investigation (52). However, this may not be conclusive evidence, as the scales used measured cognitive beliefs related to foot self-care activities, not specifically to offloading, due to the lack of available tools. Interestingly, previous qualitative investigations also found patients with DFUs have an inadequate understanding or misperception of what offloading adherence requires (i.e. the importance of wearing the offloading device for every weight-bearing step) (57, 318). Experts in diabetic foot psychosocial research assume that using specific scales related to offloading beliefs or self-efficacy can be more valuable (288). Unfortunately, there are no valid and reliable offloading beliefs or self-efficacy scales to best of the PhD candidate's knowledge. Newly adapted items related to offloading self-efficacy and outcomes expectations were included in the scales for this study; however, this may not have been robust enough, and further work on a valid tool of psychosocial beliefs of offloading is required.

7.10 STRENGTHS AND LIMITATIONS

There are several strengths to this study. First, it is the second specific investigation of offloading (RCW) adherence associates and the first conducted in a developing nation (Jordan). This study was a multi-centre study in Jordan. The investigation was comprehensive and included most of the recommended variables by the IWGDF diabetic foot research standards (378). Furthermore, this research was guided by a theoretical framework (social cognitive theory), which can arguably lead to a more robust investigation of all the relevant psychosocial variables (300). Finally, and most importantly, the main outcome (adherence) was measured objectively, in concordance with the recommended instrumentation to measure offloading adherence (95, 126). This was achieved through using a valid and reliable FF tracker (see Appendix 22).

However, there are some limitations to the methodology used for this study. First, the design was cross-sectional, which can be used to investigate associations but is unable to assign causality (i.e. longitudinal and experimental studies are needed). Second, the adherence activity was only monitored for one week. Patients with DFUs who used offloading devices were found to change their behaviour when observed for long periods, such as four weeks (51). Thus, four weeks of wearing experience was included as an inclusion criterion based on this evidence to minimise such impact. Third, adherence was measured using activity trackers, assuming that participants would wear them all the time. However, the possibility of not recording further RCW non-adherence cannot be ignored if the study participants did not wear the wrist activity tracker for some activities. To reduce such a limitation, the main aim of using the trackers was concealed, as recommended (410). Fourth, there is no evidence of the intra-device reliability of the used trackers (FF) to detect activities (steps) on both wrist and RCWs. This was eliminated by using a validated method previously (410) considering activity as units (active\not active in every 15 time-stamp) not steps. Further, the activity trackers used were not able to measure standing activity, which also needs to be considered (437).

7.11 CHAPTER SUMMARY

This chapter presented the main study, which provided new evidence of the levels and factors associated with adherence to wearing RCWs among patients with

DFUs. Adherence was poor when measured objectively (33.6%); however, it was higher when self-reported (>70%). This is a novel finding in offloading research, demonstrating that patients overestimate their self-reported adherence to wearing RCWs, as hypothesised. Factors such as duration of diabetes and the heaviness of the offloading device were negatively associated with adherence. On the other hand, females and patients with PAD showed higher adherence. This demonstrates the importance of considering sociodemographic and clinical history when prescribing RCWs. Further, the manufacturers of offloading devices may need to evaluate the physical features (i.e. weight) of the offloading devices to improve patients' experiences, which may result in better adherence. Finally, this study showed no significant associations between RCW adherence and cognitive factors such as beliefs or self-efficacy. This highlights the need for multiple solutions rather than only health education or motivational interventions for the aim of enhancing adherence to the removable offloading devices. However, further research using specific validated offloading psychosocial tools is required to confirm this recommendation.

Chapter 8: General Discussion and Conclusion

8.1 INTRODUCTION

This research aimed to examine and provide greater understanding of adherence to wearing removable cast walkers (RCWs) among patients with diabetes-related foot ulcers (DFUs). The research comprised three studies and utilised a mixed methods design to achieve this goal. The first study was a qualitative study to explore adherence to wearing RCWs. More specifically, facilitators and barriers to adherence were explored. This inductive study was critical as it helped guide the main cross-sectional study (Study 3). The second study aimed to produce valid and reliable Arabic translations of previously validated diabetes-related foot scales with a focus on psychosocial aspects. It also tested the reliability of newly developed scales for this research for use in the main study. The third and main study was a quantitative study that examined the levels and factors associated with adherence to wearing RCWs using an objective outcome measure of adherence.

This discussion chapter first summarises the aims and main findings of the three studies. The key findings of the overall research and its contribution to current knowledge are then discussed, including the conceptual framework (the social cognitive theory). The strengths and limitations of the overall research are then presented, followed by future recommendations for clinical practice, health education, and future research. Finally, the main research conclusions are presented.

8.2 SUMMARY OF RESEARCH FINDINGS

The aims and main findings of the studies are summarised in Table 8.1.

Table 8.1: Summary of the aims and main findings of the conducted studies

Study	Aims	Main findings
Study 1: A qualitative investigation of adherence to wearing RCWs	To explore adherence to wearing RCWs including facilitators and barriers of adherence among patients with DFUs	• This study resulted in two main themes that explained adherence to wearing RCWs among patients with DFUs: ➢ Theme 1: Reporting of adherence was varied and inconsistent. Categories included the belief of achieving optimal adherence, adherence during indoor activities seemed challenging, and RCWs were not worn in some short distances (few indoor steps). ➢ Theme 2: Adherence was a consequence of multiple psychosocial, physiological, and environmental factors including specific offloading knowledge or beliefs influenced adherence, the impact of the severity of foot disease on adherence outcomes, social support benefited adherence, and logistical issues and physical features of RCWs (the usability of the offloading device)
Study 2: Validity and reliability of the Arabic translation of several diabetes-related foot psychosocial scales	To produce valid Arabic translations of several psychosocial scales related to neuropathy and diabetes-related foot disease, and in addition to test the reliability of this translation	• This study resulted in a valid and reliable Arabic translation of the following scales: Footcare Confidence Scale (FCCS), Footcare Outcomes Expectations Scale (FCOES), Patient Interpretation of Neuropathy (PIN) scales, and Neuropathy-specific Quality of Life (NQOL) scales, in addition to several offloading treatment questions and visual scales (see Chapter 6, Table 6.2).

Study 3: A quantitative investigation of adherence to wearing RCWs	To identify the levels of and the factors associated with adherence to wearing RCWs among patients with DFUs	• Participants were found to be adherent to wearing RCWs for 33.6% of their weight-bearing activity using objective measures of adherence. However, participants self-reported 90% adherence to wearing RCWs during weight-bearing steps and 70% adherence during the daytime. • Self-reported adherence levels to RCWs differed between inside or outside the house. Eighty percent of participants reported perfect (all the time and for every step) adherence outside the house, while approximately 30% of participants reported perfect offloading adherence inside the house. • This study also identified four factors independently associated with adherence to wearing RCWs, including diabetes duration, heaviness of RCW, being female, and PAD. The duration of diabetes had the strongest association with increased duration negatively associated with lower adherence to wearing RCWs ($p = 0.001$). Similarly, the heaviness of the offloading devices was negatively associated with lower adherence ($p = 0.05$), while being female and having PAD were significantly associated with higher adherence ($p<0.05$).

8.3 DISCUSSION OF KEY FINDINGS

8.3.1 Objective adherence to wearing RCWs was poor

This research found that patients with DFUs adhered to wearing their prescribed RCW for only ~34% of their total weight-bearing activity duration. Activity monitors were used to measure adherence objectively, as recommended (126). This finding suggests that patients have excessive plantar pressures that potentially delay their DFU healing due to poor adherence to wearing RCWs. This poor objective adherence measure provides further evidence that explains the significantly longer healing time of DFUs when RCWs are used in comparison with non-removable offloading devices. These findings also support the latest IWGDF recommendation of not considering RCW as the first recommended offloading option (34).

The poor objective adherence to RCW detected in this study is similar to two previous offloading studies (conducted in the US and UK), which also showed poor to partial objective adherence (28–59%) (52, 54). Studying offloading adherence in other populations (especially developing countries) is pivotal due to the high possibility of clinicians in developing nations considering the use of RCW as a first option to offload DFUs due to the high cost, lack of skilful technicians, and long practice time (41) taking into consideration that non-removable offloading options are not that commonly used, even in developed countries such as Australia, Europe, and the US (38, 41, 56).

The objective measurement of adherence was an important consideration of this research. It was measured by tracking the activity of participants when they wore their offloading devices in concordance with the recommended method (95, 98). Using this protocol to measure the adherence of one specific offloading option (RCW) is important to fill the gap of understanding offloading adherence in different populations as it is the recommended protocol (95, 126). This study was the first to measure offloading adherence objectively in a non-Western country and was successfully implemented among Jordanians using commercial activity trackers (Fitbit Flex©). This could open the way for using the protocol with affordable trackers in different populations to assist in further investigation of offloading adherence issues around the world.

8.3.2 Patients' perception of adherence to wearing RCWs

In addition to the objective measurement of adherence to wearing RCWs, this research contributes evidence to improve understanding of patients' perception of their adherence to wearing RCWs via findings from both the qualitative (Study 1) and self-report scales in the quantitative study (Study 3). In the qualitative study, participants stated that they adhered to wearing their RCWs for most of the day (more than half of the day). These reports are similar to a previous RCT from Netherlands study investigating subjective adherence in this field (53). More specifically, participants reported non-adherence to wearing RCWs during sedentary activities or those activities requiring minimal steps inside the house. It is important to clarify that non-adherence was reported after in-depth questioning, as it seems participants' perceptions of optimal adherence (every weight-bearing step) was not clear, which was also found in previous qualitative research in Australia and the UK (57, 318)

In the quantitative study, participants self-reported their adherence time or steps as very high, including being adherent for 90% of daily steps and 70% of their daily time. Interestingly, these self-reported adherence levels were much higher in comparison to the ~34% found when adherence was measured objectively using activity monitoring. The high subjective self-reported adherence in this research is suggested in the literature to be related to the overestimation, inaccurate memorising of this behaviour (95, 98, 438), or not understanding the importance of adherence to every step as found in Study 1. This is an important finding that provides original evidence of the overestimation of self-reporting offloading adherence and supports the common hypothesis that patients overestimate their adherence levels to wearing RCWs (438). Interestingly, self-reported and objective adherence were significantly correlated, which indicates that self-reporting can be valid to predict higher or lower adherence; however, the estimates are not accurate.

8.3.3 Adherence to wearing RCWs was much better when outdoors

Using mixed methods in this research showed that patients reported much higher adherence when they were in outdoor settings. The qualitative study (Study 1) found that RCWs were not worn for mostly sedentary activities indoors. Furthermore, patients reported not adhering to wearing RCWs during indoor activities they considered involving taking only a few weight-bearing steps. The quantitative study (Study 3) also found participants self-reported they had high levels of perfect adherence (all the time, and for every step) outside the house (78.7%, 82%, respectively), but much lower levels inside the house (26.2%, 32.8%, respectively). These findings are similar to a previous study of offloading and therapeutic footwear (53, 273, 274). The repeated evidence confirms that patients usually have higher adherence outdoors.

8.3.4 Factors that may impact adherence to wearing RCWs

In this research, mixed methods were used to understand adherence to wearing RCWs. Study 1 (the qualitative interviews) explored the factors that can impact adherence as inductive guidance and provided details that helped to explain the quantitative findings. Study 3 provided empirical evidence of the factors independently associated with RCW adherence, finding some important socio-demographic and clinical variables were significantly associated with adherence.

8.3.4.1 Demographics (gender)

Study 3 found female gender was significantly associated with higher adherence to wearing RCWs. However, interestingly, gender disparity in offloading adherence was not found in previous research in developed countries (52, 328). Females had higher offloading adherence than males, and this may be explained by being male commonly being a factor in predicting higher prevalence of diabetes-related foot complications (83, 84). An explanation of this may be the cultural disparity of the studied population. This study is the first investigation in a different culture (middle east) in which females are usually much less involved in regular jobs or social events. However, previous studies found male gender to be a negative predictor of adherence to other self-care activities, according to a systematic review of adherence to diabetes medication (428).

The negative appearance of the prescribed RCWs may explain less adherence among Jordanian males. As Jordanian males are more likely to engage in outdoor activities, adherence to wearing their offloading device can be impacted by the acceptance of the appearance of the offloading device, as well as the possible associated stigma. In the qualitative study, only male participants reported concerns about the appearance of the RCWs. A previous study highlighted that chronic conditions can be a stigma among Jordanians, and this can negatively impact adherence (422, 423). This confirms the complexity of understanding health behaviour in general, and adherence in particular, due to the obvious impact of cultures and demonstrates the need for further offloading adherence research in different populations.

8.3.4.2 The severity of diabetes-related foot disease (duration of diabetes and PAD)

This research found that the severity of diabetes-related foot disease can be a significant predictor of RCW adherence. First, there was a significant association between duration of diabetes and adherence to wearing RCW. However, this association was not detected in previous diabetes-related foot offloading and footwear adherence research (52, 328). A systematic review showed no evidence of the influence of duration of diabetes and adherence to diabetes medication either (428). However, patients with longer duration of diabetes may need to adhere to several treatments and the regimen can be more complex (439). The longer duration of diabetes can also lead to depression, which has been found to strongly affect treatment adherence (60, 291, 292). This new finding demonstrates that factors such as duration of diabetes is an important finding in offloading research in different populations with different sociodemographic profiles and this must be considered in future research.

The qualitative study (Study 1) reported that participants with more severe diabetes-related foot conditions (i.e. minor amputations, or Charcot's foot) reported the need to wear the offloading devices to assist them with improved postural balance, quality of walking, and relieving pain. Study 3 also showed the possible impact of the severity of diabetes-related foot disease on RCW adherence. Participants with PAD had significantly higher adherence to wearing their offloading devices. This is a new finding, as previous investigation into offloading adherence determinants excluded this variable (52). However, other variables related to the severity of diabetes-related foot disease have been associated with or linked with adherence. A previous footwear study found patients with more severe foot deformities had higher adherence (274). Crews et al (52) also found more severe neuropathic pain and more severe and larger DFUs predicted higher adherence. Indeed, patients with more severe foot disease seem to be more amenable to wearing the offloading device and this could be related to the impact of the condition itself or the perceived seriousness of this condition. This highlights the importance of considering different physiological factors when studying adherence in future research.

8.3.4.3 The physical features of the RCW (heaviness)

The physical characteristics of the offloading device (i.e. size) have previously been hypothesised as an adherence predictor (43, 349). The qualitative study (Study 1) reported the importance of physical characteristics of the offloading device such as heaviness, length, and incompatibility with the other limb (using regular shoes). Similarly, previous qualitative research (248, 318) described the bulkiness and heaviness of the RCWs, which impacted walking quality as well as adherence. The heaviness was one of the main themes of one qualitative study, as patients complained of it as a barrier to walking and activities and this may have impacted concordance (318). A VAS of heaviness (0–10) was developed in Study 2 to measure this factor, which has not previously been tested quantitatively. The quantitative study (Study 3) provided new evidence that found the heaviness of the used RCW was significantly associated with adherence. It is possible that due to the heaviness of the devices, patients cannot achieve high-quality walking and performing their daily life activities (318). Therefore, this important finding shows the importance of considering the physical features of offloading devices, particularly the weight, for both clinical practice and future research.

8.3.4.4 The possible role of specific offloading adherence beliefs

In Study 1, participants demonstrated a substantial understanding of the rationale for using RCWs (expected benefits), despite the belief that it was not considered a priority treatment (i.e. patients thought control of diabetes or dressings were more important). However, as mentioned, it seems there was lack of knowledge or understanding regarding the importance of wearing the offloading device for every weight-bearing step and this may have led to non-adhered steps and misunderstanding of ideal adherence levels. This misconception in offloading adherence was reported in previous qualitative research in Australia and the UK (57, 318). The current quantitative study (Study 3) showed no statistical association between adherence and perception of specific offloading beliefs. However, this was tested by using only one Likert question, which established that a comprehensive scale is required for further testing. Crews et al (52) also found no evidence of the impact of personal beliefs about neuropathy and physical causes of ulceration on RCWs adherence; however, the scales were not specifically related to patients' understanding of adherence (i.e. wearing the offloading device for every single step is essential).

Study 1 also reported low self-efficacy of participants in terms of the ability to adhere to wearing the offloading device for every single step; however, specific offloading self-efficacy was not tested in the quantitative study (Study 3) due to the absence of valid scales. Van Natten et al. (57) reported similar qualitative findings, in that wearing the offloading device all the time was considered a difficult task. This highlights the importance of creating a valid offloading specific psychosocial instrument to measure offloading self-efficacy and this has recently been highlighted by diabetes-related foot psychosocial experts (288). This subject is explored in greater detail in the following section.

8.3.5 Valid and reliable Arabic translation of several diabetes-related foot psychometric scales

An important element of this research (Study 2) was translating and testing existing English diabetes-related foot psychosocial scales to determine whether they were reliable in the Arabic language to use in studies such as this thesis. Study 2 found that the Arabic translation of several psychosocial scales related to neuropathy and diabetes-related foot disease was reliable to use for such a purpose, including the Footcare Confidence Scale (FCCS) scale, Footcare Outcomes Expectations Scale (FCOES), Patient Interpretation of Neuropathy (PIN) scales, and Neuropathy-specific Quality of Life (NQOL) scales. In addition, several offloading treatment questions and visual scales were developed\adapted in this research. This finding enables researchers in the Arabic world to use these translated scales to perform further investigations of personal cognitive factors related to diabetes-related foot disease and offloading. This is especially important as diabetes is continuing to rise in this part of the world in line with the devastating diabetes-related foot disease and amputations (359, 360).

8.4 CONTRIBUTION OF RESULTS TO THE CONCEPTUAL FRAMEWORK

Adherence to wearing RCWs was the main outcome of interest of this research. The adopted theoretical framework was important to guide a robust investigation of this health behaviour (300). The importance of implementing conceptual thinking in offloading adherence research was suggested by Jarl (95). Chapter 4 described the adopted conceptual framework, which was based on social cognitive theory (SCT), a validated theory that can explain health behaviour through emphasising the integration of personal and cognitive factors, such as self-efficacy, outcome expectations, social support and environmental factors (impediments or facilitators) (79, 80, 304). An adapted conceptual model (315) based on SCT suggested the importance of including personal characteristics as another influential predictor within the cluster of personal cognitive factors and environmental factors in the framework based on SCT (see Chapter 4). Figure 8.1 shows the results of the testing (Study 3) of the theoretical relationship of the adopted conceptual model.

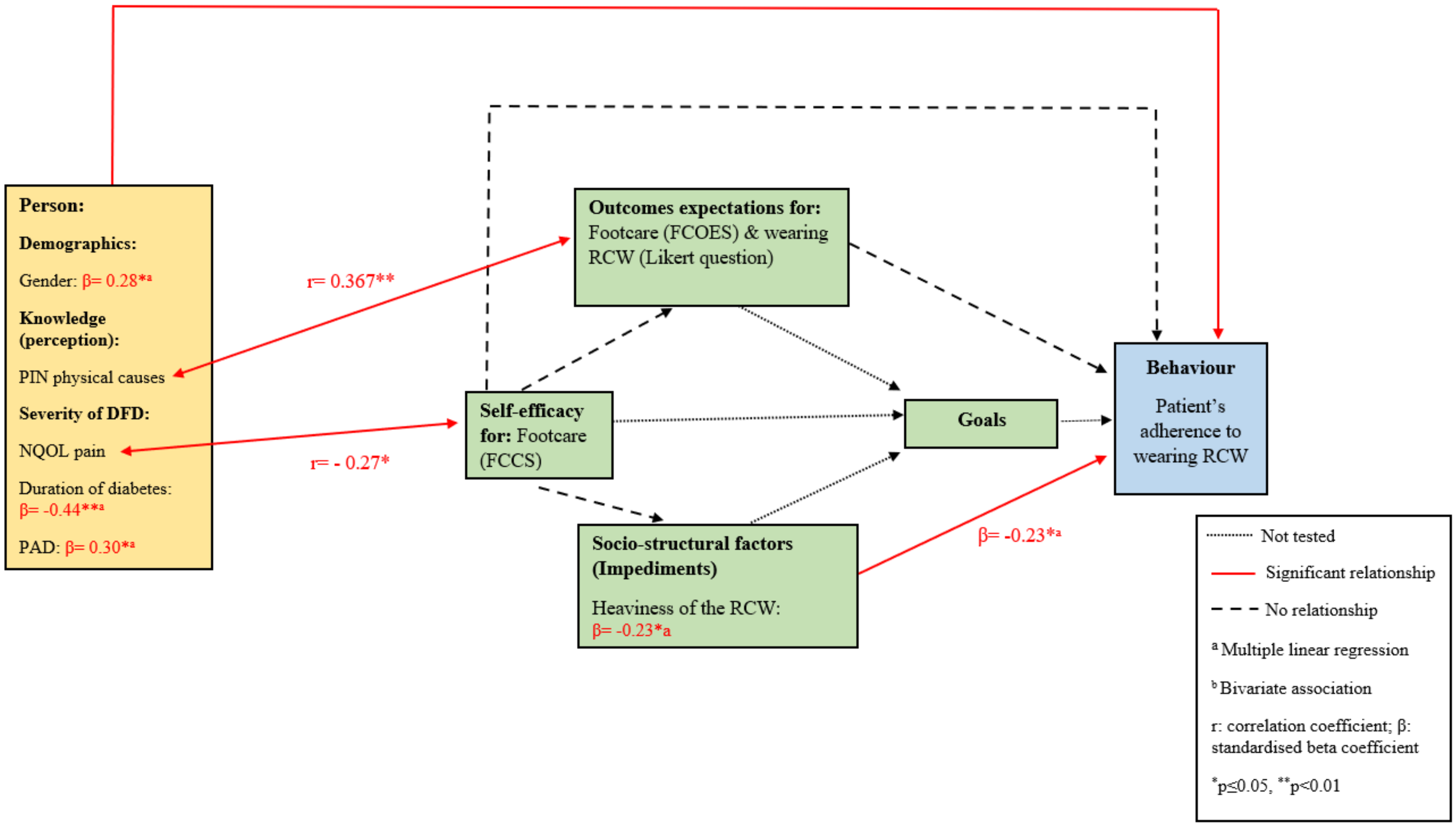

Figure 8.1: The adapted conceptual model based on SCT (315) depicting the study results and theoretical relationships

Study 3 tested the main concepts of the SCT, including the associations between personal cognitive variables such as footcare self-efficacy, footcare outcome expectations, wearing RCW outcome expectations (using Likert items related to offloading beliefs), patients' interpretation of neuropathy (knowledge), and health behaviour (RCW adherence). Surprisingly, there were no significant associations between any of these variables and objectively measured RCW adherence (see Figure 8.1). There are two possible explanations to interpret these results. First, most of the used psychometric scales measured cognitive aspects related to foot-care in general, not specifically to offloading treatment or RCWs. For instance, the FCCS and FCOES measured patients' beliefs of their confidence or the expected outcomes when performing the needed daily life foot self-care activities (i.e. cutting toes nails or removing dry skin) (402, 405). It would be valuable to have valid and reliable comprehensive scales to measure self-efficacy or outcomes expectations that specifically related to offloading adherence among patients with DFUs.

The qualitative investigation showed that patients may not fully recognise the concept of offloading adherence itself. In other words, patients may not understand or believe in the importance of wearing the offloading device for every weight-bearing step to achieve optimal adherence, especially inside the house. Interestingly, very similar findings have been also reported in two other recent qualitative studies in which patients believed walking inside the house without the offloading device was not considered non-adherence (57, 318). Thus, there is consistent qualitative evidence highlighting the importance of understanding the optimal offloading adherence and a specific belief in its effectiveness. This specific belief was tested in the current study using a single Likert question; however, this was not significantly associated with adherence. The question was tested without validation; thus, future research that adopts a valid and robust tool measuring different aspects of this specific belief is required.

This research also found no association between footcare self-efficacy and offloading adherence, although low self-efficacy specifically related to wearing the offloading device for every possible weight-bearing step was obvious in the qualitative study. In his SCT theory, Bandura (440) highlighted that self-efficacy is a task and situational domain (specific self-efficacy) concept, which is a very different construct from general self-efficacy. This indicates the importance of testing the specific self-efficacy related to offloading adherence. Unfortunately, measuring this specific aspect was not possible in the current study because there was no available valid instrument. This emphasises the importance of the recent suggestion of diabetes-related foot experts of having more specific offloading psychosocial scales (288). Therefore, a specific validated offloading self-efficacy scale, outcomes expectations, and beliefs scales that focus on factors related to adherence to offloading devices in different places or situations for more robust testing of the ability of SCT in predicting offloading adherence are required.

The second explanation is that adherence to wearing RCWs in this research may not be related to personal cognitive variables as hypothesised in the conceptual framework. Previous evidence to support the associations between specific beliefs or knowledge and offloading adherence (including footwear) is minimal. A systematic review of the factors affecting footwear adherence did not find consistent evidence of the association between adherence and different beliefs (328). Likewise, the only known offloading adherence determinants study found no evidence of the relationship between personal specific beliefs (patient’s interpretation of neuropathy) or personal control of foot self-care (52) and offloading adherence, although these factors were associated with foot self-care practices in several studies (289, 440-442). It is possible that patients who use RCWs do not have issues understanding or believing in the rationale for using them, as demonstrated in the qualitative findings, in addition to previous qualitative research (57, 318). Thus, it can be assumed that adherence to wearing the offloading device is less complicated in comparison with diabetes self-management, where personal beliefs are influential (289, 439). However, as mentioned, the personal cognitive factors related specifically to offloading need to be tested in future research to explore this assumption.

However, the findings of this research support other constructs of the adopted conceptual model in terms of predicting health behaviour (adherence to wearing RCWs). Socio-structural impediments are proposed as an influential factor on the performance of health behaviour in SCT. According to Bandura (304), behavioural change can be easy if there are no impediments (304). This research found the heaviness of the offloading device was significantly associated with less adherence (see Figure 8.1). Indeed, the weight of the offloading device seemed to be an important impediment against adherence to offloading among patients with DFUs, which was also reported in previous qualitative research (57, 318). Other impediments such as size, appearance, and comfort (43, 274, 328, 349) of the offloading devices have been suggested to impact adherence; thus, further research is required to examine different impediments that can be associated with the use of an offloading device.

Interestingly, the factors related to the characteristics of the person such as gender, duration of diabetes, and history of PAD were significantly associated with RCW adherence in this study, confirming the importance of this theoretical relationship, as included later in the SCT model by Shortridge-Baggett (315). It is important to mention that personal characteristics is a broad construct and future offloading research should consider more specific variables for testing based on the available evidence. Currently, based on the findings of this study and previous research, it seems physiological consequences of diabetes-related foot disease (ulceration, neuropathy, foot deformities and PAD) and health history (age, gender, duration of diabetes, type of diabetes, BMI) are the most evident factors that may affect offloading adherence (52, 274, 328). However, future research into offloading adherence should also consider testing other demographic and health variables related to people by reviewing the recommended standards of diabetic foot research by the IWGDF experts (378). A World Health Organization (WHO) model also suggests that treatment adherence can result from the interaction of five dimensions of factors, including patient factors, therapy factors, condition factors, health system factors, and social and economic factors (61). This reveals the importance of considering these different aspects when studying offloading adherence in future research. However, a limitation of this model is the inability to explain how these factors can interact and impact adherence (95), while the conceptual model from SCT is able to explain these relationships.

It is important to mention that these research findings did not support the association between self-efficacy and outcomes expectations, which is discussed in SCT (307). People are more likely to believe in their ability to successfully perform specific behaviour if they recognise the expected outcomes from this behaviour and this is called efficacy expectations (307). However, according to Bandura (78), if people expect serious outcomes from performing a specific task, this can negatively impact their self-efficacy. The current findings did not show a significant relationship between the expected outcomes from performing foot self-care activities and the self-efficacy to do these activities. A possible explanation is that the FCCS items explore the expected benefits from performing foot self-care, rather than from wearing RCWs, and this might not impact the reported self-efficacy as much as if the expected outcome from performing the behaviour is serious (78).

However, this research supports the theoretical relationship between personal physiological factors and self-efficacy. This research shows that the level of NQOL pain was significantly associated with lower self-efficacy to perform foot self-care activities (see Figure 8.1). The physiological status is a source of self-efficacy information. When people experience a physiological or emotional situation such as depression, anxiety, fatigue, or pain, their estimation of their capabilities can be impacted negatively (443). Indeed, this supported the inclusion of personal characteristics in SCT by Shortridge-Baggett (443).

Another finding was the significant relationship between outcomes expectations related to performing foot self-care activities and knowledge of the causes of DFUs (PIN physical causes) (see Figure 8.1). In SCT, Bandura (304) discussed knowledge and outcomes expectations as one construct, covering understanding the health behaviour and the expected outcomes from performing it, which can lead to behavioural change. However, understanding the chronic condition itself can also impact the expected outcomes from performing the health behaviour related to this condition (304). This research showed that when participants had higher scores for knowledge about the reason for DFUs (the causal pathway of DFUs, i.e. foot deformities can lead to DFUs), their outcome expectations from performing foot care were higher. This study supports the suggested associations by Shortridge-Baggett (443) about how personal characteristics (perception) can interact with the outcome expectations, health behaviour, self-efficacy, and health outcomes.

Overall, the adopted conceptual framework (315) based on SCT seems to be an appropriate framework for identifying associated factors with adherence to wearing RCW (Study 3) including personal characteristics (sociodemographic, health, and physiological factors) in addition to the socio-structural impediments (heaviness of the RCW). However, personal cognitive factors such as beliefs and self-efficacy were not shown to be associated with adherence in this sample, possibly due to the limitation of an absence of specific measuring tools related to offloading; thus, further investigations are required. Therefore, this model is a recommended conceptual framework for future research of adherence to DFUs offloading devices.

8.5 STRENGTHS AND LIMITATIONS

This research contributes to current understanding of adherence to wearing RCWs among patients with DFUs and has several strengths. First, this is one of the first offloading adherence studies and the first from a developing country. Second, mixed-methods were implemented and such study designs arguably resulted in a more comprehensive understanding of complex research questions (96, 97). Third, to the best of the PhD candidate's knowledge, the qualitative study is the first that specifically focused on exploring the level of adherence and the second to investigate the barriers and facilitators of adherence to RCWs (318). Fourth, a conceptual framework based on SCT guided this research on health behaviour (79). Moreover, this research suggested a conceptual model of the relationships between individual and socio-structural factors and adherence, contributing to a future specific conceptual framework for offloading adherence (95). Fifth, a robust Arabic translation of the psychosocial scales using forward and backward translations was undertaken, followed by reliability testing (test-retest). This contributes new Arabic psychosocial scales related to diabetes-related foot disease that can assist researchers in Arabic countries. Sixth, adherence to wearing RCWs was measured objectively by concealing the aim of use of two trackers from participants to avoid bias as recommended (95, 126, 410). This protocol is similar to previous offloading adherence research (52, 54), and allows for future comparisons. Seventh, self-reported measures of adherence to RCWs were also used simultaneously with the objective measurement, leading to original evidence in terms of the accuracy of self-report of offloading adherence. Eighth, in addition to the comprehensive assessment of psychosocial factors, several variables related to the usability of RCWs (i.e. level of comfort and heaviness) were also tested for the first time to the best of PhD candidate's knowledge. Lastly, multiple linear regression was used to identify factors independently associated with adherence after controlling for potential confounders.

However, there are several limitations to this research. First, the sample sizes of the conducted studies were relatively small, and only powered to be able to identify four independent variables without overfitting the model, due to the difficulty of recruiting the required participants within the time constraints of a PhD and using very specific inclusion criteria (i.e. using a knee-high RCW for at least four weeks). However, the study recruited the required numbers of participants according to a sound sample size calculation and was powered to include the four independent associates included in the final model. Second, although the research was multicentre, the findings may not represent all Jordanian people with DFU, as the centres were all located in the capital of Jordan (Amman). Third, this research focused on knee-high offloading devices (i.e. RCWs), which are the most effective and recommended removable offloading interventions; however, there is still a need to explore and compare adherence between different offloading devices (i.e. knee-high or ankle-high RCW or half shoes). Fourth, the design of the main quantitative study was cross-sectional, which was appropriate to establish the associations, but not appropriate to establish causality (predictors of adherence) (95). Further, such a design did not facilitate an investigation of the impact of adherence on DFU healing, which could be very informative (244). Fifth, further validity assessment (i.e. construct validity [factor analysis] or criterion validity) is required for the Arabic translated psychosocial scales for more robust validity. Further, the psychosocial scales used to measure personal cognitive factors were related to diabetes-related foot disease and self-care activities instead of to wearing offloading devices, whereas the availability of specific scales for offloading (i.e. offloading beliefs or self-efficacy) would be useful to test the social cognitive theory to predict offloading adherence. In addition, this research did not investigate all psychosocial factors that might be related to adherence, such as depression, quality of life, or body image, which need to be tested in future research. Lastly, although adherence to wearing RCWs was measured objectively during physical activity, this was only for one week due to the difficulty of long-term observation within the limited timeline of this PhD project. Further, there is no evidence of the inter-device reliability of the trackers used, as they are usually used in different body locations such as wrist and lower limb. This was minimised by considering activity units instead of steps (i.e. being active or not active for a 15-minute time-stamp). However, the possibility of not recording any further non-adherence activity if participants did not wear the wrist trackers and the RCWs could not be excluded, and this was minimised by concealing the real aim of using the activity trackers. The trackers used were also only able to record walking activities, while activities such as standing or sitting or lying were missed.

8.6 KEY RECOMMENDATIONS

These results of this research led to the following recommendations for clinical practice, health education, and future research.

8.6.1 Clinical practice

8.6.1.1 Reenforcing non-removable knee-high offloading devices as the gold standard

This research contributes new evidence from a new population that confirms poor adherence to using RCWs. Research participants only wore RCWs for ~34% of their physical activity, which indicates that high pressures may have affected patients' ulcers due to absence of this offloading for most (~64%) of their recorded activities. The observed poor adherence to wearing RCWs in this research supports the international gold standard offloading recommendation of using non-removable knee-high offloading devices (100% adherence) at the current time to ensure adherence. Non-removable offloading devices such as total contact casts (TCC) or RCWs made irremovable are the gold standard recommended offloading intervention by the latest IWGDF guidelines (34). However, the PhD candidate understands that the lack of skilful clinicians or the required resources are significant barriers to implementing the gold standard non-removable offloading (TCC) in daily routine practice in Jordan. Thus, it is suggested that policymakers in the Jordanian health sectors think about future dissemination strategies to increase awareness about TCC among health care providers, in addition to providing adequate training and financial resources to adopt TCC as a standard offloading treatment in diabetic foot referral clinics in Jordan. Alternatively, the IWGDF suggests the possibility of rendering RCWs to be non-removable (instant TCC) by wrapping the device using a layer of cast or tie-wrap (34). Therefore, the use of iTCC instead of RCWs is also recommended in cases where TCC is not applicable.

8.6.1.2 Consider determinants of RCW adherence

It is important to mention that if non-removable offloading devices cannot be applied due to DFU complications (i.e. infection, ischemia or heavy exudate) or patients' rejection, RCWs can be used as an alternative option. However, as this research found, patients poorly adhered to wearing these offloading devices. Clinicians must therefore consider the factors associated with adherence, as found in this study and the previous research. More attention is required for male patients, who are the majority of DFU population. Similarly, patients who have a long duration of diabetes are more likely to less adhere. Clinicians must be aware of this when prescribing RCWs for those patients considering the challenge of adherence to several treatments with a complex regimen (439).

The heaviness of the offloading device was another factor associated with adherence. Patients reported they did not like to wear these bulky and heavy devices. The offloading industry may consider such an important factor, especially as two previous qualitative studies also reported the same issue (57, 318). Using lighter materials or smaller devices may result in better patient satisfaction and adherence. Currently, ankle-high RCWs are smaller and lighter devices, which are the third recommended offloading option by the IWGDF when TCC or knee-high RCWs are not suitable (34). Although they are less efficient offloading alternative, they may arguably result in better adherence due to the lighter weight and smaller size (43, 349). However, there is no evidence to support the superiority of ankle-high RCWs compared to the knee-high RCWs in terms of adherence outcomes.

8.6.1.3Adopting objective measurement of adherence to wearing RCWs

Assessment of adherence to wearing the prescribed RCW is also important. The qualitative investigation showed a poor understanding of patients of ‘optimal adherence’. Participants reported not adhering to their RCW during various sedentary activities and walking short distances after further questioning. Interestingly, the same specific finding was also reported in two previous qualitative studies (57, 318). Thus, asking about the duration of wearing the device does not seem useful, while focusing on the assessment of adherence during physical activity (non-adherence in specific steps or relative adherence) is much more important (95).

This research found that overestimation of adherence may be expected when assessing patients’ self-reported RCW adherence. This highlights that self-reporting is not accurate when taking the history of offloading adherence. Estimating non-adherence of wearing the offloading device during physical activity is a difficult task for patients with DFU, as this population is usually older with several chronic complications. Thus, clinicians should not rely on self-reporting as a valid measure when assessing offloading adherence. Alternatively, objective measures are recommended.

From the experience of measuring adherence objectively in this research, using commercial activity trackers to measure patients' adherence objectively in routine clinical practice is recommended. Commercial trackers are affordable these days and can be used to assess patients' adherence. However, ethical considerations can be a barrier due to the need to conceal the reason for using the activity trackers when monitoring adherence (410). However, this could be undertaken and discussed with policymakers in health care settings, as it is apparent the expected benefits from implementing objective monitoring of adherence are substantial to justify its use.

8.6.2 Education

8.6.2.1 Specific educational and/or motivational interventions are needed

In terms of educating patients with DFUs who require offloading treatment, despite Study 3 (quantitative) finding no evidence to support the relationships between personal cognitive beliefs (i.e. knowledge or self-efficacy) and adherence, primarily because these specific aspects were not measured robustly in Study 3 due to the absence of the valid tools, health education can be an appropriate intervention. Further, the qualitative study (Study 1) found that patients were not aware of the importance of wearing RCWs for every-weight bearing step, in addition to low self-efficacy to achieve this task. A focus on education regarding the importance of wearing the offloading device for every single step could therefore be a beneficial educational intervention. However, recently suggested self-monitoring solutions using wearable technology (427, 444) also look promising, as patients can be aware of or receive an alarm if any high pressure that impacts the wound is occurring when the offloading device is not worn. However, they would still require education on the importance of the alarms/monitors, and why the alarm is occurring.

8.6.2.2 Education for health care professionals about the importance of adopting non-removable offloading devices

The observed poor adherence to wearing RCWs in this research highlights the need for educating health care professionals about the importance of adopting non-removable offloading devices (i.e. iTCC) as gold standard offloading management. Results from this research suggest non-removable offloading methods such as the iTCC are a possible option for most participants and applying this offloading option may result in more efficient offloading. However, clinicians in Jordan may not be aware of the importance of implementing non-removable offloading as RCWs may not be that effective due to the potential poor adherence. More effort is required to introduce the concept of non-removable offloading treatment by demonstrating the IWGDF offloading guidelines and the supporting evidence. Furthermore, it may be valuable to train health care professionals in implementing protocols for measuring offloading adherence objectively through using activity trackers or other valid technology, as this research found self-reporting was not accurate to evaluate adherence to prescribed offloading. Lastly, clinicians need to be educated on how to assess adherence in addition to the facilitators and barriers of adherence to offloading, as found in this research.

8.6.3 Research

8.6.3.1 Exploring different determinants of adherence to wearing RCWs

As this research investigated the levels and determinants of adherence to wearing RCWs using qualitative and cross-sectional methods, the established causal relationships were limited due to the nature of the study designs. Cohort longitudinal or experimental observations of offloading adherence are now required to establish whether the factors identified from this research are independently associated with adherence, and other factors not tested in this research may also be predictors of adherence to wearing offloading devices (52, 95). Furthermore, investigation of adherence could be guided by a conceptual framework such as SCT, which predicted the factors of adherence in this research or adopting other suggested conceptual frameworks such as the WHO model, which discusses the broad variety of factors that can impact adherence including different dimensions such as patient factors, therapy factors, condition factors, health system factors, and social and economic factors (61).

8.6.3.2 Validating RCWs adherence measurement protocols

Adherence to wearing RCWs during physical activity (weight-bearing steps) was the main outcome in this research. However, using such an outcome measure may not provide the full picture of adherence. Measuring adherence time has been also recommended and this can be done objectively using available valid technology (95, 243). Although this research considered this adherence dimension through self-reporting of the wearing time, such a measurement can be associated with overestimation or inaccuracy (438). Therefore, estimating adherence wearing time in line with adherence during physical activity is also recommended in future research. Moreover, there is also a gap in the validity and reliability of the currently implemented protocols to measure adherence steps when using two activity trackers to compare the overall activity and the offloading device activity. There is a need to test the validity of using the trackers in measuring adherence with a criterion model (i.e. videoing adherence during using the offloading device) (445). Inter-device reliability when using two trackers in different locations (wrist, hip, or lower limb) is also required to implement more reliable protocols of measuring offloading adherence in future research.

8.6.3.3 Understanding offloading adherence in indoor settings

Using mixed methods in this research showed adherence indoors was lower than outdoors. However, this was mainly based on subjective data and a more objective measurement is therefore required for more robust evidence. Further understanding of less adherence indoors could help to create solutions to enhance offloading adherence.

8.6.3.4 Exploring adherence for other offloading devices

Investigating adherence to other offloading devices is also recommended. This research focused on knee-high RCWs. However, other recommended offloading options can be used in routine clinical practice such as ankle-high offloading devices or half shoes (34). These devices are often smaller, lighter, and more comfortable, which may result in better adherence (53, 349). However, future research is required to compare adherence between different offloading devices, and this could guide the clinical practice of selecting efficient offloading devices with more promising adherence outcomes.

8.6.3.5 Exploring RCW adherence in different populations

Although this research contributes new important findings related to offloading adherence, available evidence is still limited. To the best of the PhD candidate’s knowledge, this is the first study in a developing country, as previously conducted research was mainly undertaken in Western countries (43, 53, 54). As discussed previously, adherence is a health behaviour that can be impacted by cultural disparity or ethnicity (418, 419). Thus, there is a significant need to investigate offloading adherence in different populations, as this could assist with further understanding of this pivotal health behaviour.

8.6.3.6 Developing offloading-related cognitive scales

Developing cognitive tools related specifically to offloading is required. Personal cognitive factors such as knowledge, beliefs, self-efficacy, and outcomes expectations have been discussed and hypothesised as an influence on health behaviour (304). This qualitative investigation, in line with previous qualitative findings (57, 318), provides evidence that patients' understanding of adherence for every single weight-bearing step could be an influential belief on their ability to achieve perfect adherence. Therefore, developing tools that can measure such specific offloading beliefs may be beneficial to obtain a more robust investigation of the role of psychosocial factors on offloading adherence.

8.6.3.7 Testing interventions to enhance adherence to RCWs

Lastly, there is a need to develop and test interventions that could enhance offloading adherence. Health education or motivational interventions have been suggested to improve adherence to foot care for the prevention of DFUs and these can be tested to determine whether they improve adherence to offloading management of DFUs (343). Further, there are recent promising smart technologies that afford self-monitoring to offloading through using smart flexible sensors, textile and wearables (i.e. smartphone or watch) that alarm patients when not wearing the device, as well as engaging them to use the prescribed offloading device, potentially resulting in substantial adherence. These technologies require future research to test their effectiveness in promoting offloading adherence (444).

8.7 CONCLUSIONS

This research addressed a significant gap related to the current global understanding of adherence to offloading treatment for DFUs (specifically RCWs). The IWGDF recommends RCWs as a second choice to manage DFUs due to possible poor adherence when prescribing these effective offloading devices. However, evidence is limited in terms of understanding adherence levels and factors associated with adherence levels to wearing RCWs in this population. Thus, a mixed-method research design was used to target a comprehensive investigation of adherence to wearing RCWs among patients with DFUs.

Overall, adherence to wearing RCWs was found to be poor in this research, highlighting the need for adopting non-removable offloading devices (i.e. iTCC), as currently recommended by the IWGDF. This research also provides new evidence of overestimation of adherence to offloading when it is self-reported. Both the qualitative data and patients' self-reported quantitative data described substantial adherence despite the poor objective adherence measured. This indicates that patients with DFUs may not be aware of their level of adherence, while self-monitoring solutions (integrating wearables to enhance adherence) may be promising.

This research also contributes to the current understanding of the factors associated with adherence to RCWs. A theoretical model (SCT) guided this investigation, which has been shown as valid to predict health behaviours. The qualitative investigation highlighted several factors related to adherence including i) specific personal knowledge or beliefs; ii) the severity of diabetes-related foot disease; iii) the social support, and iv) the usability of the RCWs. The quantitative research found adherence to RCWs was negatively associated with duration of diabetes and heaviness of the offloading device. On the other hand, sociodemographic factors such as being female or physiological factors such as having PAD were associated with positive adherence. No significant associations were found between personal beliefs (i.e. beliefs or self-efficacy) and adherence to RCWs. However, this finding was limited due to the lack of testing of specific offloading beliefs, which highlights the need to develop specific offloading psychometric scales in future research.

Lastly, in terms of possible future solutions to improve adherence to wearing RCWs, based on the findings of this research there is a need for: i) testing of specific health education or motivational interventions to enhance offloading adherence, including enhancing patients' offloading knowledge and self-efficacy to achieve the optimal adherence (i.e. every weight-bearing step, indoors and outdoors); ii) development of more usable offloading devices (lighter); and iii) adoption of wearable technology that alarms patients when not wearing the offloading device.

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Appendices

Appendix 1: Studies included in RCWs' adherence review

Study	Year	Country	Population	Population findings	Design	Adherence measurement	Adherence findings	Limitations
Armstrong et al (54)	2003	US	Diabetes with neuropathic DFUs (Grade 1; UT) with no ischemia or infections.	Number: 20 Age: 65 ± 7.6 years Males: 70% DM duration: 12.5 ± 5.2 years	Prospective, observational study	Activity monitoring	Patients adhered to wearing RCW in only 28% of physical activity No investigation of factors associated with adherence	Sample size Adherence determinants were not investigated
Crews et al (52)	2016	US, UK	Type 2 diabetes with neuropathic DFUs (Grade 1,2; Stage A, B; UT). Ulcers with severe ischemia or osteomyelitis were excluded.	Number: 79 Age: 56.5 ± 9.6 years Males: 84% Ethnicity: White 39 (49%), black 13 (17%), Asian 6 (8%)	Prospective, observational, multicentre study	Activity monitoring	Patients adhered to wearing RCW in 59% of physical activity Higher level of neuropathy pain associated with higher adherence	Sample size The study design was not suitable to detect the causality Limited investigation of adherence determinants, used broad scales to

				DM duration:14.1 ± 8.2			(p<0.05), higher neuropathy postural instability associated with less adherence (p<0.01), and larger wounds were associated with higher adherence (p<0.05)	measure different psychological factors related to offloading adherence
Bus et al (53)	2017	Netherlands, Germany	Neuropathic DFUs (Grade 1, 2; Stage A). Ulcers with infection or ischemia were excluded.	Number: Intervention (I) 1:20 I2:20 I3: 20 Age (years): I1: 63.1 ± 9.4 I2: 64.1 ± 13.8 I3: 62.3 ± 11.5 Males: I1: 89% I2: 57% I3: 75% Caucasian ethnicity: I1: 100% I2: 95% I3: 100% Type 2DM: I1: 88%	Randomised controlled trial	Self-reporting	17.3% of participants did not adhere to removable knee high-offloading device (wore the device <50% of all times at each visit No investigation of factors associated with adherence	Sample size Measurement of adherence by Self-reporting is associated with a high level of bias (446, 447) Adherence determinants were not investigated

				I2: 75% I3: 99.5% DM duration: I1: 13.5 ± 9.4 I2: 13.6 ± 9.6 I3: 11.1 ± 8.3				

Appendix 2: Ethical approvals

University Human Research Ethics Committee (UHREC)

HUMAN RESEARCH ETHICS APPROVAL CERTIFICATE

NHMRC Registered Committee Number EC00171

Date of Issue: 10/7/19 (supersedes all previously issued certificates)

Dear Prof Helen Edwards

This approval certificate serves as your written notice that the proposal has met the requirements of the *National Statement on Ethical Conduct in Human Research* and has been approved on that basis. You are therefore authorised to commence activities as outlined in your application, subject to any specific and standard conditions detailed in this document.

Project Details

Category of Approval:	Negligible-Low Risk		
Approved From:	10/07/2019	**Approved Until:**	10/07/2020 (subject to annual reports)
Approval Number:	1900000418		
Project Title:	Identifying adherence determinants to wearing Removable Cast Walkers (RCWs) among patients with Diabetic Foot Ulcers (DFUs)		

Investigator Details

Chief Investigator: Prof Helen Edwards

Other Staff/Students:

Investigator Name	Type	Role
Dr Kathleen Finlayson	Internal	QUT Associate Supervisor
Dr Peter Lazzarini	Internal	QUT Associate Supervisor
Mr Anas Nawwaf Abed Alrohman Ababneh	Student	Doctoral (Research)

Conditions of Approval

Specific Conditions of Approval:

As per This research has been approved by three human research ethics committees in Jordan as the following

1 The institutional review board at the national centre for diabetes endocrinology and genetics Amman Jordan.
2 The institutional committee for the review of research and pharmaceutical studies at Jordan university hospital Amman Jordan.
3 The director of professional training and human resources development at royal medical services Amman Jordan.

Standard Conditions of Approval:

1. Conduct the project in accordance with the principles of the NHMRC National Statement on Ethical Conduct in Human Research 2007, the Australian Code for the Responsible Conduct of Research, any additional specific conditions defined by the UHREC, any associated NHMRC guidelines and regulations, and the provisions of any legislation which is relevant to the project;
2. Obtain UHREC approval for any proposed variation to the project **prior** to implementation (note that major changes may require a different level of review and/or submission of a new application);
3. Obtain any additional approvals or authorisations as required (e.g. from other ethics committees, collaborating institutions, supporting organisations);
4. Maintain research records and data in accordance with MoPP D/2.8 Management of research data.
5. Respond promptly to the requests and instructions of UHREC;
6. Declare all actual, perceived or potential conflicts of interest (NS 5.4);
7. Immediately advise the Office of Research Ethics and Integrity (OREI) of any concerns, complaints or adverse events including (NS 5.5.3):
   - if any unforeseen development or events occur that might affect the continued ethical acceptability of the project;
   - if any complaints are made, or expressions of concern are raised, in relation to the project;
   - if the project needs to be suspended or modified because the risks to participants now outweigh the benefits;

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- o if a participant can no longer be involved because the research may harm them.

8. Report on the progress of the project at least annually, or at intervals determined by UHREC (NS 5.5.5);

If any details within this Approval Certificate are incorrect please advise the Research Ethics Advisory Team immediately.

End of Document

المعهد الوطني للسكري والغدد الصم و الوراثة

NATIONAL INSTITUTE FOR DIABETES ENDOCRINOLOGY & GENETICS

Ref. ______________ الرقم مب/٩/٤٢٦٦

Date ______________ التاريخ ٢٤/١٠/٢٠١٨

Dear Mr Ababneh

Thank you for submitting your application related to the research titled with **"<u>Identifying adherence determinants to Removable Cast Walkers (RCWs) among patients with Diabetic Foot Ulcers (DFUs)</u>"**

The Institutional Review Board (IRB) discussed the detailed protocol of the research above at 23th october 2018 and pleased to inform you that your application was reviewed and approved by the Board with the following recommendation:

- Researcher has to be committed with the research policy adopted in the National Centre.
- Data collected should be used only for research purposes with confidentiality.
- The IRB has the right to request all study approvals from researcher anytime and to possess all study-related documents in the National Centre archive.

Prof. Mohammed El- Khateeb
Vice President
National Center for Diabetes
Endocrinology & Genetics

عمان – الاردن – شارع الملكة رانيا – هاتف ٥٣٤٧٨١٠ / ٥٣٤١٧١٠ – فاكس ٥٣٥٦٦٧٠ – ص.ب ١٣١٦٥ عمان ١١٩٤٢ الأردن
E-mail: ajlouni@ju.edu.jo

مستشفى الجامعة الأردنية

الرقـم :

التاريخ :

Jordan University Hospital

Ref. 10/2018/7459

Date: 3/12/2018

طالب الدكتوراه أنس نواف عبابنه

جامعة كوينزلاند للتكنولوجيا – استراليا

تحية طيبة وبعد ،،

ناقشت لجنة المؤسسية لمراجعة البحوث والدراسات الدوائية (IRB) بجلستها رقم (2018/19) تاريخ 2018/11/27، بحثكم بعنوان :

Identifying adherence determinants to removable cast walkers (RCWs) among patients with diabetic foot ulcers (DFUs)

وبعد المداولة توصي اللجنة ما يلي:

<u>القرار رقم 2018/287:</u>

الموافقة على إجراء البحث المذكور أعلاه شريطة ما يلي :

- الالتزام بسياسة الدراسات الدوائية في المستشفى(Adm po21/3, Adm p032/1).
- الحفاظ على سرية المعلومات وأن لا تستخدم إلا لغايات البحث المقدم.
- يحق للجنة طلب إقرار الموافقات المستنيرة من الباحثين في أي وقت والاطلاع عليها وكذلك يجب الاحتفاظ بها في ملف الدراسة لمدة عامين من تاريخ الموافقة عليها من قبل اللجنة.
- تعتبر هذه الموافقة سارية المفعول لمدة عام من تاريخ صدور القرار.
- تزويد اللجنة بتقرير عن الدراسة بعد ستة أشهر من تاريخ صدور الموافقة.
- إشراك الدكتور أيمن مسمار كمشرف على البحث .

وتفضلـــوا بقبول فائق الاحتـــرام،،،

رئيـس اللجنة المؤسسية لمراجعـة

البحوث والدراسات الدوائيـة (IRB)

الأستـاذ الدكتور شوقـي صالـح

نسخة إلى :

تلفون ٥٣٥٣٤٤٤ – فاكس ٥٣٥٣٣٨٨ – صندوق بريد ١٣٠٤٦ – عمان – الأردن
Tel. 5353444 Fax 5353388 - P.O.Box 13046 - Amman - Jordan

بسم الله الرحمن الرحيم

G. H. Q. Jordan Armed Forces
DIRECTORATE
ROYAL MEDICAL SERVICES
Human Research Ethics Committee
Amman – Jordan

القيادة العامة للقوات المسلحة الأردنية- الجيش العربي
مديريـــــــــــــــة
الخدمـــــــات الطبية الملكيـــــة
لجنة الدراسات واخلاقيات المهنة
عمان – الأردن

Date: 14th Oct, 2019

To: **Queensland University of Technology , BSc. Nursing, MSc Anas N Ababneh .**

I am pleased to inform you that your study proposal entitled:

"Identifying adherence determinants to Removal cast Walkers (RCWs) among patients with Diabetic Foot Ulcers (DFUs)"

Has been approved by the Royal Medical Services Human Research Ethics Committee number (10/2019) on 8/10/2019.

****Please keep the privacy of patient's information & without a financial cost on the Royal Medical Services .***

ROYAL MEDICAL SERVICES
Professional Training Division
Amman - Jordan

Brig. Gen. Dr . Ahmad Al Omari , MD MRCP (UK), FRCP "Edin"
Consultant physician , Diabetologist and Endocrinologist
Director of Professional Training, Rehabilitation and planning
Directorate of the Royal Medical Services

وزارة الصحة
مستشفى الأمير حمزة بن الحسين

الرقم ٢٣/٣٩/٧٤٥٥
التاريخ
الموافق ١٣/١٠/٢٠١٩

Prince Hamzah Hospital مستشفى الامير حمزة

السيد طالب الدكتوراه انس نواف عبابنه
جامعة كوينزلاند للتكنولوجيا -استراليا

تحية طيبة وبعد ،،،

ناقشت لجنة اخلاقيات البحث العلمي (IBR) في جلستها تاريخ 2019/9/24 البحث المعنون ب:

" Identifving adherence determinants to Removable Cast Walders (RCWs) among patients with Diabetec Foot Ulcers (DFUS) " .

وبعد المدواله توصي اللجنة بمايلي مع مراعاة الشروط التاليه :
1- هذه الموافقه سارية المفعول لمدة سنة من تاريخ صدور القرار
2- ضرورة تزويد اللجنة بنتائج البحث حال توفرها
3- مراعاة سياسة البحث العلمي وحفظ سرية المعلومات
4 – عدم نشر البحث دون اخذ موافقه اللجنة
5- اضافة الدكتور هشام الراعوش طبيب القدم والسكري كجزء من الباحثين

وتفضلوا بقبول فائق الإحترام

مدير عام مستشفى الأمير حمزه
الدكتور باسم الزعبي

نسخة:
- مدير دائرة الموارد البشريه
- مقرر اللجنة
- الملف العام .
م.ح
- 2019/10/6

المملكة الأردنية الهاشمية
هاتف ٠٠٩٦٢٦٥٠٥٣٨٣٦ فاكس : ٠٠٩٦٢٦٥٠٥٣٧٩٠ الموقع الإلكتروني www.phh.gov.jo

Appendix 3: Participant information sheet (Study 1)

QUT ihbi Institute of Health and Biomedical Innovation	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT – Interview –**

Identifying adherence determinants to Removable Cast Walkers (RCWs) among patients with Diabetic Foot Ulcers (DFUs)

QUT Ethics Approval Number 1800000929

RESEARCH TEAM

Principal Researcher:	Anas Ababneh, PhD student
Associate Researchers:	Professor Helen Edwards, Principal supervisor
	Dr Kathleen Finlayson, Associate supervisor
	Dr Peter Lazzarini, Associate supervisor
	Faculty of Health, Queensland University of Technology (QUT)
	Professor Nidal Younes, Clinical site supervisor
	Faculty of Medicine, Jordan University

DESCRIPTION

This research project is being undertaken as part of a PhD study for Mr Anas Ababneh.

The purpose of this project is to investigate the determinants of patients' adherence to wearing orthotic boots among patients with diabetic foot ulcers.

You are invited to participate in this research project because you have an active diabetic foot ulcer and you have been using an orthotic boot for at least four weeks.

PARTICIPATION

Your participation will involve an audio recorded interview at the Diabetic Foot Clinic at the National Centre for Diabetes, Endocrinology, and Genetics or the Diabetic Foot Clinic at Jordan University Hospital that will take approximately 30 minutes of your time.

Questions will include:

- Tell me about your experience in wearing RCWs (Removable Cast Walkers).
- What are some facilitators to wearing RCWs?
- What are some barriers to wearing RCWs?

Your participation in this research project is entirely voluntary. If you do agree to participate you can withdraw from the research project without comment or penalty. You can withdraw anytime during the interview. If you withdraw within 2 weeks after your interview, on request any identifiable information already obtained from you will be destroyed. Your decision to participate or not participate will in no way impact upon your current or future relationship with QUT, the National Centre for Diabetes, or Jordan

University Hospital.

EXPECTED BENEFITS

It is expected that this research project will not benefit you directly. However, it may benefit your awareness of the treatment.

RISKS

Your participation in this interview is not expected to have any physical or economic harm. However, there is a minor risk through the interview questions that reflect diabetic foot ulcers and the possible complications and difficulties associated with treatment which may cause discomfort.

There is no research specific counselling offered by the National Centre for Diabetes, however, you can speak with the Psychiatric Clinic at Jordan University Hospital if you develop any discomfort. You are also free to avoid participating in this study if you feel that this discomfort can affect your psychological health.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially unless required by law, or regulatory or monitoring bodies, such as the ethics committee. The names of individual persons are not required in any of the responses.

As the research project involves an audio recording:

- The recording will be destroyed 5 years after the last publication.
- The recording will not be used for any other purpose.
- Only the named researchers will have access to the recording.
- It is possible to participate in the research project without being recorded.

Every effort will be made to ensure that the data you provide cannot be traced back to you in reports, publications, and other forms of presentation. For example, we will only include the relevant part of a quote, we will not use any names, or names will be changed, and/or details such as dates and specific circumstances will be excluded. Nevertheless, while unlikely, it is possible that if you are quoted directly your identity may become known.

Any data collected as part of this research project will be stored securely as per QUT's Management of research data policy.

Please note that non-identifiable data from this research project may be used as comparative data in future research projects or stored on an open access database for secondary analysis.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE RESEARCH PROJECT

If you have any questions or require further information please one of the listed researchers:

Anas Ababneh	anas.ababneh@hdr.qut.edu.au	+9 627 8700 2640
Helen Edwards	h.edwards@qut.edu.au	

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE RESEARCH PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

You may also contact:

- The head of ethics office at the National Centre for Diabetes, Endocrinology, and Genetics, Professor Mohamamd El-Khateeb on + 962-6-534-7810 ext.104 or email mkhateeb@ju.edu.jo.

or

- The head of ethics office at the Jordan University Hospital, Dr Mamoun Ahram on +962-79-556-7779 or email m.ahram@ju.edu.jo

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.

Appendix 4: Arabic version of participant information sheet (Study 1)

QUT ihbi Institute of Health and Biomedical Innovation	**معلومات المشارك لمشروع بحث في جامعة كوينزلاند للتكنولوجيا – نموذج المقابلة –**

تحديد العوامل المرتبطة في التزام مرضى تقرحات القدم السكرية للجبائر القابلة للازالة (أحذية ازالة الضغط)

موافقة اخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1800000929

الباحث الرئيسي : أنس عبابنه (طالب دكتوراه)
الباحثين المشاركين: الاستاذ الدكتور هيلين ادواردز (مشرف رئيسي)
الدكتورة كاثلين فاينالايسون (مشرف مشارك)
الدكتور بيتر لازاريني (مشرف مشارك)
كلية الصحة – جامعة كوينزلاند للتكنولوجيا
الأستاذ الدكتور نضال يونس (مشرف موقع البحث السريري)
كلية الطب- الجامعة الأردنية

الوصف

هذا المشروع البحثي هو جزء من متطلبات الحصول على درجة الدكتوراة للطالب انس عبابنه.
الهدف من هذا البحث هو الاستقصاء عن العوامل المحددة لالتزام مرضى تقرحات القدم السكرية في ارتداء أحذية ازالة الضغط.
تمت دعوتك للمشاركة في مشروع هذه الدراسة حيث لديك قرحة قدم سكرية وتتلقى العلاج الان باستخدام أحذية ازالة الضغط لمدة اربعة اسابيع على الاقل.

المشاركة

تتضمن مشاركتك في هذه الدراسة تسجيل صوتي من خلال مقابلة في عيادة القدم السكري في المركز الوطني للسكري والغدد الصم والوراثة أو عيادة الجراحة (القدم السكري) في مستشفى الجامعة الاردنية حيث تستغرق من وقتك حوالي 30 دقيقة.
تتضمن المقابلة عدة اسئلة منها:

- اخبرني عن تجربتك في ارتداء الجبائر القابلة للازالة.
- ما هي بعض العوامل التي تسهل عليك ارتداء هذه الجبائر؟
- ما هي العوامل التي تعيقك من ارتداء هذه الجبائر؟

مشاركتك في هذا المشروع البحثي تطوعية بشكل كامل، اذا وافقت على المشاركة في هذا البحث يمكنك الانسحاب من المشاركة دون اي ملاحظات او عقوبات. أذا قررت الانسحاب خلال مدة اسبوعين من اجراء المقابلة، بناء على طلبك المعلومات الخاصة بك التي تم جمعها يتم اتلافها فورا. قرارك في المشاركة او عدمها في هذه الدراسة لن تأثر نهائيا على العلاقات الراهنة والمستقبلية مع جامعة كوينزلاند للتكنولوجيا او المركز الوطني للسكري او مستشفى الجامعة الاردنية.

المنفعة المرجوة

لا يتوقع من مشاركتك في هذا البحث حصولك على منفعة مباشرة ولكن اشتراكك في هذه الدراسة قد يزيد من وعيك او معرفتك لطبيعة العلاج باستخدام أحذية ازالة الضغط.

المخاطر

مشاركتك في هذه المقابلة لا يتضمن اي اذى جسدي أو مادي ولكن هنالك احتمال ضئيل من تعرضك لعدم الارتياح قد ينتج عن اسئلة تتعلق بمرض تقرحات القدم السكرية ومضاعفاتها بالاضافة لصعوبات تتعلق بالعلاج الموصوف.
لا يوجد عيادة صحة نفسية في المركز الوطني للسكري ولكن يمكنك استشارة اطباء الصحة النفسية في مستشفى الجامعة الاردنية في حال عانيت من اي ضغوطات نفسية جراء مشاركتك في البحث.
لديك كامل الحرية في تجنب المشاركة في هذه الدراسة في حال وجدت ان هذا الشعور بعدم الارتياح قد يأثر سلبا على صحتك النفسية.

الخصوصية والسرية

جميع المعلومات والردود سوف يتم التعامل معها بسرية تامة ما لم يتطلب القانون أو الهيئات التنظيمية أو المراقبة ، مثل لجنة الأخلاقيات. ليست هناك حاجة لأسماء الأفراد في أي من الردود.

بما أن المشروع البحثي يشمل تسجيل صوتي:
• سيتم إتلاف التسجيل بعد 5 سنوات من النشر الأخير.
• لن يتم استخدام التسجيل لأي غرض آخر.
• سيكون للباحثين المحددين فقط حق الوصول إلى التسجيل.
• من الممكن المشاركة في المشروع البحثي دون تسجيله.

سيتم بذل كل جهد لضمان أن البيانات التي تقدمها لا يمكن تتبعها لك في التقارير والمنشورات وأشكال العرض الأخرى. على سبيل المثال ، سنقوم فقط بتضمين الجزء ذي الصلة من الاقتباس، ولن نستخدم أي أسماء ، أو سيتم تغيير الأسماء ، و / أو سيتم استبعاد تفاصيل مثل التواريخ والظروف الخاصة.

سيتم تخزين أي بيانات يتم جمعها كجزء من هذا المشروع البحثي بشكل آمن وفقًا لإدارة سياسة الأبحاث في جامعة كوينزلاند للتكنولوجيا.

يرجى الملاحظة بأن البيانات غير القابلة للتعريف من هذا المشروع البحثي يمكن استخدامها كبيانات مقارنة في مشاريع البحوث المستقبلية أو المخزنة على قاعدة بيانات مفتوحة للوصول للتحليل الثانوي.

الموافقة على المشاركة

نود أن نطلب منك التوقيع على استمارة موافقة خطية (مرفقة) لتأكيد موافقتك على المشاركة.

أسئلة / مزيد من المعلومات حول مشروع البحث

إذا كان لديك أي أسئلة أو كنت تحتاج إلى مزيد من المعلومات ، فيرجى الاتصال بـ:

أنس عبابنه anas.ababneh@hdr.qut.edu.au +962787002640
هيلين ادواردز h.edwards@qut.edu.au

مخاوف / الشكاوى بشأن اجراء مشروع البحث

تلتزم جامعة كوينزلاند للتكنولوجيا بالبحث عن النزاهة والسلوك الأخلاقي لمشاريع الأبحاث. ومع ذلك ، إذا كانت لديك أي مخاوف أو شكاوى حول السلوك الأخلاقي لمشروع البحث ، فيمكنك الاتصال بفريق الأخلاقيات الاستشاري في جامعة كوينزلاند للتكنولوجيا على الرقم

+61 7 3138 5123
أو البريد الإلكتروني
humanethics@qut.edu.au

لا يرتبط الفريق الاستشاري لأخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا بمشروع البحث ويمكنه أن ييسر حلًا لمخاوفك بطريقة محايدة.
يمكنك أيضا الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم 5347810-6-962 + فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.
أو
- مدير مكتب اخلاقيات البحث العلمي في مستشفى الجامعة الأردنية ، الدكتور مأمون أهرام على الرقم -962+ 79-5567779 او البريد الاكتروني m.ahram@ju.edu.jo.

شكرا لك على المساعدة في هذا المشروع البحثي
يرجى الاحتفاظ بهذه الصفحة لمعلوماتك

Appendix 5: Participant consent form (Study 1)

QUT ihbi Institute of Health and Biomedical Innovation	**CONSENT FORM FOR QUT RESEARCH PROJECT – Interview–**

Identifying adherence determinants to Removable Cast Walkers (RCWs) among patients with Diabetic Foot Ulcers (DFUs)

QUT Ethics Approval Number 1800000929

RESEARCH TEAM

Mr Anas Ababneh	anas.ababneh@hdr.qut.edu.au
Professor Helen Edwards	h.edwards@qut.edu.au
Dr Kathleen Finlayson	k.finlayson@qut.edu.au
Dr Peter Lazzarini	peter.lazzarini@health.qld.gov.au
Professor Nidal Younes	younesnidal@gmail.com

STATEMENT OF CONSENT

By signing below, you are indicating that you:

- Have read and understood the information document regarding this research project.
- Have had any questions answered to your satisfaction.
- Understand that if you have any additional questions you can contact the research team.
- Understand that you are free to withdraw without comment or penalty.
- Understand that if you have concerns about the ethical conduct of the research project you can contact the Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au. You can also contact the head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Prof.Mohamamd El-Khateeb on + 962-6-534-7810 ext. 104 or email mkhateeb@ju.edu.jo or the head of ethics office at the Jordan university hospital, Dr Mamoun Ahram on +962-79-556-7779 or email m.ahram@ju.edu.jo.
- Understand that non-identifiable data from this project may be used as comparative data in future research projects.
- Agree to participate in the research project.

Please tick the relevant box below:

☐ I **agree** for the interview to be audio recorded.
☐ I **do not agree** for the interview to be audio recorded.

Name ____

Signature ____

Date ____

PLEASE RETURN THE SIGNED CONSENT FORM TO THE RESEARCHER.

Appendix 6: Arabic version of participant consent form (Study 1)

QUT ihbi Institute of Health and Biomedical Innovation	**نموذج موافقة للمشاركة في مشروع بحث / جامعة كوينزلاند للتكنولوجيا** **–المقابلة–**

تحديد العوامل المرتبطة في التزام مرضى تقرحات القدم السكرية للجبائر القابلة للإزالة

موافقة أخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1800000929

فريق البحث

أنس عبابنه anas.ababneh@hdr.qut.edu.au
الاستاذ الدكتور هيلين ادواردز h.edwards@qut.edu
الدكتورة كاثلين فاينلايسون k.finlayson@qut.edu.au
الدكتور بيتر لازاريني peter.lazzarini@health.qld.gov.au
الاستاذ الدكتور نضال يونس younesnidal@gmail.com

بيان الموافقة

من خلال توقيعي للنموذج أدناه ، فإني أشير إلى:
• قراءة وفهم وثيقة معلومات المشارك الخاصة بهذا المشروع البحثي.
• إمكانية الاستفسار عن أي أسئلة تتعلق برضاي عن المشاركة في البحث.
• ادرك أنه إذا كان لدي أي أسئلة إضافية ، يمكنني الاتصال بفريق البحث.
• ادرك أنني حر في الانسحاب دون تعليق أو عقوبة.
• ادرك أنه إذا كانت لدي مخاوف بشأن السلوك الأخلاقي لمشروع البحث ، يمكنني الاتصال بفريق أخلاقيات البحوث الاستشارية في جامعة كوينزلاند
على الرقم 61731385123+أو البريد الإلكتروني .humanethics@qut.edu.au
أيضا الاتصال يمكنني الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم 5347810-6-962 + فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.
أو
- مدير مكتب اخلاقيات البحث العلمي في مستشفى الجامعة الأردنية ، الدكتور مأمون أهرام على الرقم-79-962+ 5567779 او البريد الاكتروني m.ahram@ju.edu.jo.

• أدرك أن المشروع البحثي سيتضمن تسجيل صوتي.
• أدرك أن البيانات غير القابلة للتعريف من هذا المشروع يمكن استخدامها كبيانات مقارنة في مشاريع بحث مستقبلية.
• الموافقة على المشاركة في المشروع البحثي.

يرجى وضع علامة في الخانة المناسبة أدناه:
☐ أوافق على أن تكون المقابلة مسجلة صوتيا.
☐ لا أوافق على أن تكون المقابلة مسجلة صوتيا.

الأسم: ____________________

التوقيع: ____________________

التاريخ: ____________________

الرجاء تسليم نموذج الموافقة للباحث

Appendix 7: Participant information sheet of Study 2\Phase A (translation process)

QUT ihbi Institute of Health and Biomedical Innovation	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT – Translation Process –**

Validating the Arabic translation of footcare confidence scale (FCCS), footcare outcomes expectations scale, patient interpretation of neuropathy (PIN) scales, neuropathy-specific quality of life (NQOL) scales, and offloading-related scales

QUT Ethics Approval Number 1800000929

RESEARCH TEAM

Principal Researcher:	Mr. Anas Ababneh, PhD student
Associate Researchers:	Professor Helen Edwards, Principal supervisor Dr Kathleen Finlayson, Associate supervisor Dr Peter Lazzarini, Associate supervisor **Faculty of Health, Queensland University of Technology (QUT)** Professor Nidal Younes, Clinical site supervisor **Faculty of Medicine, Jordan University**

DESCRIPTION

This project is being undertaken as part of PhD study of Anas Ababneh.

The purpose of this research project is to validate the Arabic translation of footcare confidence scale (FCCS), footcare outcomes expectations scale, patient interpretation of neuropathy (PIN) scales, neuropathy-specific quality of life scales (NQOL), and offloading-related scales

The purpose of this stage is to translate the mentioned scales to the Arabic language, besides, to check and gain the agreement of the translated items. This will be through several steps of forward and backward translation.

You are invited to participate in this project because you are one of the following:

- The principal researcher in this project.
- Certified translator.
- Diabetic foot specialist.
- Clinician.
- Diabetic patients who met this inclusion criteria:
  - Arabic native speaker.
  - Who have diabetic foot ulcers.
  - Who are being or have been treated by the offloading boots.
- Native English speakers.

- Bilingual English / Arabic researcher.

PARTICIPATION

The main aim of this stage is to conduct an Arabic translation of the following scales:

- Foot Care Confidence Scale (FCCS) (1): This scale has 12 items that will be used to measure patient confidence in their abilities in doing foot self-care activities. This scale has been chosen to estimate patients' self-efficacy (patients' beliefs of their ability to perform foot self-care activities). However, a new Item (Number 13) has been added and adapted with the original scale to measure patients' self-confidence to wearing removable offloading boots.
- Footcare outcomes expectations scale: It is an adapted subscale from (3) which has 15 items that measure the expectations of diabetic patients regarding the outcomes of footcare. However, a new Item (Number 16) has been added and adapted to measure patients' outcomes expectations to wearing removable offloading devices.
- Patient interpretation of neuropathy (PIN) scales (3): It has 13 items that measure aspects related to physical causes and the onset of diabetic foot ulcers.
- Neuropathy-specific quality of life (NQOL) scales (4): It has 16 items that measure different aspects related to the impact of neuropathy on health-related quality of life including neuropathic pain, loss of sensation, and postural imbalance.
- Offloading adherence scales: these are self-report scales that have been newly developed in this research which have different questions related to the offloading devices such as personal beliefs, devices usability, patients' satisfaction, and social support. Also, reporting adherence to wear these devices is a part of these scales.

After you agree to participate in this study, your involvement in this study includes one of the following tasks (Please follow the ticked one):

☐ ***Forward translation:*** Translating one of the mentioned scales to the Arabic language.

☐ ***A consensus meeting***: Checking and gaining the agreement of the translated items (Please see the attached translation agreement form)

☐ ***Backward translation:*** Conducting a back-translation from Arabic to English

☐ ***Consensus meeting:*** Conducting a comparison between the back-translation and the original items to identify any mistranslation or poor items to send them to back translation. Also, to retranslate and fix any mistranslation. (Please see the attached consensus meeting form)

☐ ***Pilot testing:*** evaluating the clarity of the survey items.

The surveys and the assessment form will be given to you as a hard copy or an attached word file through email. Your comments/opinions will be addressed seriously which can help in revising the content of the translated items of the given surveys. Also, it is more than appreciated, if there are any further aspects or contents that in your opinion should be omitted or added to the surveys.

You can complete the assessment form on the attached word file and return it to us via email: anas.ababneh@hdr.qut.edu.au. We are looking forward to receiving your assessment form during the next couple of weeks.

If you do agree to participate you can stop the survey at any time and withdraw from the project without comment or penalty. Any identifiable information already obtained from you will be destroyed. However, it is advised that once data has been amalgamated into aggregated results it will no longer be possible to withdraw.

Providing your name is not required. However, if you do provide this information, only the research team will have access to the data. No identifiers will be included in any results or publications. You have the right to decline this information. If you are willing to provide this information, it will be stored in accordance with the QUT Code of Conduct for Research (http://www.mopp.qut.edu.au/D/D_02_06.jsp) (please refer to Privacy and Confidentiality below for more details). Your responses will also remain confidential.

Your participation in assessing the questionnaire is entirely voluntary. Your decision to participate or not participate will in no way impact upon your current or future relationship with QUT.

EXPECTED BENEFITS

It is expected that this project will not benefit you directly. However, your expert judgment will contribute to the research team's decisions making regarding the final Arabic version of those surveys which will be used in the main study to identify the associated psychosocial factors with adherence to wearing removable cast walkers offloading devices among patients with diabetic foot ulcers.

RISKS

There are no risks beyond normal day-to-day living associated with your participation in this project. You may feel little discomfort associated with your participation in this research.

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially unless required by law. The names of individual persons are not required in any of the responses.

Any data collected as part of this project will be stored securely as per QUT's Management of research data policy. Please note that non-identifiable data collected in this project may be used as comparative data in future projects.

CONSENT TO PARTICIPATE

The return of the completed survey is accepted as an indication of your consent to participate in this project.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If you have any questions or require further information, please contact one of the listed researchers.

Anas Ababneh	anas.ababneh@hdr.qut.edu.au
Helen Edwards	h.edwards@qut.edu.au
Kathleen Finlayson	k.finlayson@qut.edu.au
Peter Lazzarini	peter.lazzarini@health.qld.gov.au
Nidal Younis	younesnidal@gmail.com

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the project you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email ethicscontact@qut.edu.au or the Research Office of University of Medicine and Pharmacy on +84 8 3855 6284. They are not connected with the research project and can facilitate a resolution to your concern in an impartial manner. You may also contact:

- The head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Prof. Mohamamd El-Khateeb on + 962-6-5347810 ext.104 or email mkhateeb@ju.edu.jo.

  or
- The head of ethics office at the Jordan university hospital, Dr Mamoun Ahram on +962-79-5567779 or email m.ahram@ju.edu.jo

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT. PLEASE KEEP THIS SHEET FOR YOUR

Appendix 8: Participant information sheet of Study 2 \ phase B (reliability testing)

QUT ihbi Institute of Health and Biomedical Innovation	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT** **– Survey (test-retest) –**

Validating the Arabic translation of footcare confidence scale (FCCS), footcare outcomes expectations scale (FCOES), patient interpretation of neuropathy (PIN) scale, neuropathy-specific quality of life (NQOL) scale, and offloading-related scales

QUT Ethics Approval Number 1800000929

RESEARCH TEAM

Principal Researcher:	Mr Anas Ababneh, PhD student
Associate Researchers:	Professor Helen Edwards, Principal supervisor Dr Kathleen Finlayson, Associate supervisor Dr Peter Lazzarini, Associate supervisor **Faculty of Health, Queensland University of Technology (QUT)** Professor Nidal Younes, Clinical site supervisor **Faculty of Medicine, Jordan University**

DESCRIPTION

This research project is being undertaken as part of a PhD study of Anas Ababneh.

The purpose of this research project is to assess the reliability of the Arabic translation of the footcare confidence scale (FCCS), footcare outcomes expectations scale, patient interpretation of neuropathy (PIN) scale, neuropathy-specific quality of life (NQOL) scale, and offloading-related scales.

You are invited to participate in this research project because you have an active diabetic foot ulcer and you have at least 4 weeks of experience in wearing an offloading boot which is important for treating diabetic foot ulcers.

PARTICIPATION

Your participation will be during your regular visit to the diabetic foot clinic at the National Centre for Diabetes, Endocrinology, and Genetics **OR** Jordan University Hospital **OR** the King Hussain Medical Centre.

Your participation includes 2 stages.

Stage 1:

This will be a short interview with you that includes answering several questions related to socio-demographic (i.e. age or occupation) and health information. Also, it includes a clinical examination of your feet and wound including measuring the wound size, assessing your foot sensation using a simple instrument that has a filament, and measuring your arm blood pressure as well as the pressure at your big toe. You will also be asked to complete a survey that has several questions (e.g. asking your agreement (strongly agree, moderately agree, agree, etc...) and some visual scales that you will be asked to rate. It is expected that it will take you about 30 minutes to complete the survey (58 items). The questions will ask about the psychosocial aspects related to your current understanding and practices of your diabetic foot disease and your experience in wearing the offloading boots.

Stage 2

One week after you have completed the first stage, you will be asked to complete the same survey again. This participation will also take place at the diabetic foot clinic at the National Centre for Diabetes, Endocrinology and Genetics, Jordan university hospital, or the King Hussain Medical Centre during your usual visits for wound care.

Your participation in this research project is entirely voluntary. If you agree to participate, you do not have to complete any question(s) you are uncomfortable answering. Your decision to participate or not participate will no way impact upon your current or future relationship with QUT or National Centre for Diabetes, Jordan University Hospital, or King Hussain Medical Centre. If you do agree to participate you can withdraw from the research project during your participation without comment or penalty. Any identifiable information obtained from you will be destroyed as required by the relevant ethics committees.

EXPECTED BENEFITS

It is expected that this research project will not directly benefit you. However, it may benefit your awareness about for treatment and will assist with future care for people with diabetic foot ulcers

RISKS

Your participation in this survey is not expected to have any physical or economic harm. However, as the survey itself reflects diabetic foot ulcers and the possible complications and difficulties associated with treatment, this may cause you some discomfort.

If you do experience any discomfort you can speak with staff at the Jordan University Hospital or King Hussain Medical Centre. You are free to decline to participate in this study if you feel that this discomfort may affect your psychological health.

PRIVACY AND CONFIDENTIALITY

All comments and responses are anonymous and will be treated confidentially unless required by law, or regulatory or monitoring bodies, such as the ethics committee. The names of participants are not required in any of the responses.

Any data collected as part of this research project will be stored securely as per QUT’s Management of Research data policy.

Please note that non-identifiable data from this research project may be used as comparative data in future projects or stored on an open-access database for secondary analysis.

CONSENT TO PARTICPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE RESEARCH PROJECT

If you have any questions or require further information, please contact one of the listed researchers:

Anas Ababneh	anas.ababneh@hdr.qut.edu.au+9 627 8700 2640
Helen Edwards	h.edwards@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE RESEARCH PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

You may also contact:

- The head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Prof.Mohamamd El-Khateeb on + 962-6-5347810 ext.104 or email mkhateeb@ju.edu.jo.

OR

- The head of ethics office at the Jordan university hospital, Dr Mamoun Ahram on +962-79-5567779 or email m.ahram@ju.edu.jo

OR

- The technical training department at King Hussain Medical Centre, Hot complaint line 06-5804-555 or email sco@jrms.jo.

THANK YOU FOR HELPING WITH THIS RESEARCH PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.

Appendix 9: Arabic version of participant information sheet of Study 2 \ phase B (reliability testing)

QUT ihbi Institute of Health and Biomedical Innovation

معلومات المشارك لمشروع بحث في جامعة كوينزلاند للتكنولوجيا
– نموذج الاستبيان (الاختبار واعادة الاختبار) –

التحقق من صحة الترجمة العربية لاستبيان الممارسة المثلى لعلاج ازالة الضغط ومقياس الثقة بالنفس لممارسات العناية الذاتية بالقدم

موافقة اخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1800000929

فريق البحث

الباحث الرئيسي : السيد أنس عبابنه (طالب دكتوراه)
الباحثين المشاركين:الاستاذ الدكتور هيلين ادواردز (مشرف رئيسي)
الدكتورة كاثلين فاينالايسون (مشرف مشارك)
الدكتور بيتر لازاريني (مشرف مشارك)
كلية الصحة – جامعة كوينزلاند للتكنولوجيا
الأستاذ الدكتور نضال يونس (مشرف موقع البحث السريري)
كلية الطب- الجامعة الأردنية

الوصف

هذا المشروع البحثي هو جزء من متطلبات الحصول على درجة الدكتوراة للطالب انس عبابنه.
الهدف من هذا البحث هو اختبار صحة الترجمة العربية لاستبيان الممارسة المثلى لعلاج ازالة الضغط ومقياس الثقة بالنفس لممارسات العناية الذاتية بالقدم
تمت دعوتك للمشاركة في مشروع هذه الدراسة حيث تعاني من قرحة قدم سكرية ولديك خبرة ارتداء احذية ازالة الضغط (الجبائر القابلة للازالة) لمدة اربعة اسابيع على الاقل

المشاركة

تتضمن مشاركتك في هذه الدراسة الاجابة على 63 سؤال في استبيانين والاسئلة عبارة عن اختيار من متعدد. مثال: (أوافق بشدة – اوافق – لا اوافق) حيث تستغرق من وقتك حوالي 30 دقيقة. يتوقع منك ان تقوم بالاجابة على نفس الاستبيان مرتين حيث تكون المرة الثانية بعد اسبوع من تاريخ التحاقك بالدراسة. سوف تكون مشاركتك في عيادة القدم السكري في المركز الوطني للسكري والغدد الصم والوراثة أو عيادة الجراحة - مستشفى الجامعة الاردنية أثناء مراجعة الدورية للعلاج.
الاسئلة تقيس ممارساتك وطريقة تعاملك مع علاج تقرح القدم السكرية وأيضا تجربتك في ارتداء أحذية أزالة الضغط.
مشاركتك في هذا المشروع البحثي تطوعية بشكل كامل، اذا وافقت على المشاركة في هذا البحث لك الحق في عدم الاجابة عن اي سؤال في حال كنت تشعر بعدم الارتياح عن اجابة هذا السؤال. قرارك في المشاركة او عدمها في هذه الدراسة لن تأثر نهائيا على العلاقات الراهنة والمستقبلية مع جامعة كوينزلاند للتكنولوجيا او المركز الوطني للسكري او مستشفى الجامعة الاردنية. إذا وافقت على المشاركة ، فيمكنك الانسحاب من المشروع البحثي أثناء مشاركتك بدون تعليق أو عقوبة.سيتم اتلاف أي معلومات محددة تم الحصول عليها من قبلك.
ستتمكن من مراجعة إجاباتك قبل إرسال وحفظ نسخة من ردودك بعد إرسال الاستبيان.

المنفعة المرجوة

لا يتوقع من مشاركتك في هذا البحث حصولك على منفعة مباشرة ولكن اشتراكك في هذه الدراسة قد يزيد من وعيك او معرفتك لطبيعة العلاج باستخدام جبائر ازالة الضغط.

المخاطر

مشاركتك في هذا الاستبيان لا يتوقع منه أي مخاطر جسدية أو اقتصادية ولكن هنالك احتمال بسيط بان الاستبيان بحد ذاته يحوي بعض الاسئلة التي تتعلق بتقرحات القدم السكرية ومضاعفاتها مما قد يؤدي الى بعض من عدم الارتياح اثناء اجابتك للاستبيان. لا يوجود عيادة صحة نفسية في المركز الوطني للسكري ولكن يمكنك استشارة اطباء الصحة النفسية في مستشفى الجامعة في حال عانيت من اي ضغوطات نفسية جراء مشاركتك في البحث.
لديك كامل الحرية في تجنب المشاركة في هذه الدراسة في حال وجدت ان الشعور بعد الارتياح قد يؤثر سلبا على صحتك النفسية.

الخصوصية والسرية

جميع المعلومات والردود سوف يتم التعامل معها بسرية تامة ما لم يتطلب القانون أو الهيئات التنظيمية أو المراقبة ، مثل لجنة الأخلاقيات. ليست هناك حاجة لأسماء الأفراد في أي من الردود.

سيتم تخزين أي بيانات يتم جمعها كجزء من هذا المشروع البحثي بشكل آمن وفقًا لإدارة سياسة الأبحاث في جامعة كوينزلاند للتكنلوجيا.

يرجى ملاحظة أنه بالامكان استخدام البيانات غير القابلة للتحديد من هذا المشروع البحثي كبيانات مقارنة في مشاريع مستقبلية أو تخزينها في قاعدة بيانات مفتوحة للوصول للتحليل الثانوي.

الموافقة على المشاركة

نود أن نطلب منك التوقيع على استمارة موافقة خطية (مرفقة) لتأكيد موافقتك على المشاركة

أسئلة / مزيد من المعلومات حول مشروع البحث

إذا كان لديك أي أسئلة أو كنت تحتاج إلى مزيد من المعلومات ، فيرجى الاتصال بـ:

أنس عبابنه anas.ababneh@hdr.qut.edu.au +962787002640
هيلين ادواردز h.edwards@qut.edu.au

المخاوف أو الشكاوى بشأن اجراء مشروع البحث

تلتزم جامعة كوينزلاند للتكنولوجيا بالبحث عن النزاهة والسلوك الأخلاقي لمشاريع الأبحاث. ومع ذلك ، إذا كانت لديك أية مخاوف أو شكاوى حول السلوك الأخلاقي لمشروع البحث ، فيمكنك الاتصال بفريق الأخلاقيات الاستشاري في جامعة كوينزلاند للتكنولوجيا على الرقم

+61 7 3138 5123

أو البريد الإلكتروني
humanethics@qut.edu.au

لا يرتبط الفريق الاستشاري لأخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا بمشروع البحث ويمكنه أن ييسر حلًا لمخاوفك بطريقة محايدة.

يمكنك أيضا الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم
  +962-6-5347810 فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.
  أو
- مدير مكتب اخلاقيات البحث العلمي في مستشفى الجامعة الأردنية ، الدكتور مأمون أهرام على الرقم -962+ 79-5567779 او البريد الاكتروني m.ahram@ju.edu.jo.

شكرا لك على المساعدة في هذا المشروع البحثي
يرجى الاحتفاظ بهذه الصفحة لمعلوماتك

Appendix 10: Consent form for Study 2

QUT ihbi Institute of Health and Biomedical Innovation	**CONSENT FORM FOR QUT RESEARCH PROJECT – Translation of surveys –**

Validating the Arabic translation of footcare confidence scale (FCCS), footcare outcomes expectations scale, patient interpretation of neuropathy (PIN) scales, neuropathy-specific quality of life (NQOL) scales, and offloading-related scales

QUT Ethics Approval Number 1800000929

RESEARCH TEAM CONTACTS

Mr Anas Ababneh	anas.ababneh@hdr.qut.edu.au
Prof Helen Edwards	h.edwards@qut.edu.au
Dr Kathleen Finlayson	k.finlayson@qut.edu.au
Dr Peter Lazzarini	peter.lazzarini@health.qld.gov.au
Prof Nidal Younis	younesnidal@gmail.com

STATEMENT OF CONSENT

By signing below, you are indicating that you:

- Have read and understood the information document regarding this project.
- Have had any questions answered to your satisfaction.
- Understand that if you have any additional questions you can contact the research team.
- Understand that you are free to withdraw at any time without comment or penalty.
- Understand that once data has been amalgamated into aggregated results it will no longer be possible to withdraw the data.
- Understand that if you have concerns about the ethical conduct of the project you can contact the Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au or the Research Office of University of Medicine and Pharmacy on +84 8 3855 6284. You can also contact the head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Prof. Mohamamd El-Khateeb on + 962-6-534-7810 ext. 104 or email mkhateeb@ju.edu.jo or the head of ethics office at the Jordan University Hospital, Dr Mamoun Ahram on +962-79-556-7779 or email m.ahram@ju.edu.jo
- Agree to participate in the project.

Participant's Name ______________________________

Participant's Signature ______________________________

Date ______________________________

PLEASE RETURN THE SIGNED CONSENT FORM TO THE RESEARCHER

Appendix 11: Arabic version of the consent form of Study 2

نموذج موافقة للمشاركة في مشروع بحث / جامعة كوينزلاند للتكنولوجيا – ألاختبار واعادة الاختبار –	QUT ihbi Institute of Health and Biomedical Innovation

التحقق من صحة الترجمة العربية لاستبيان الممارسة المثلى لعلاج ازالة الضغط ومقياس الثقة بالنفس لممارسات العناية الذاتية بالقدم (الاختبار وإعادة الاختبار)

موافقة اخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1800000929

فريق البحث

السيد انس عبابنه anas.ababneh@hdr.qut.edu.au
الاستاذ الدكتور هيلين ادواردز h.edwards@qut.edu
الدكتورة كاثلين فاينلايسون k.finlayson@qut.edu.au
الدكتور بيتر لازاريني peter.lazzarini@health.qld.gov.au
الاستاذ الدكتور نضال يونسyounesnidal@gmail.com

بيان الموافقة

من خلال توقيعي للنموذج أدناه ، فإني أشير إلى:

• قراءة وفهم وثيقة معلومات المشارك الخاصة بهذا المشروع البحثي.
• إمكانية الاستفسار عن أي أسئلة تتعلق برضاي عن المشاركة في البحث.
• ادرك أنه إذا كان لدي أي أسئلة إضافية ، يمكنني الاتصال بفريق البحث.
• ادرك أنني حر في الانسحاب دون تعليق أو عقوبة.
• ادرك أنه إذا كانت لدي مخاوف بشأن السلوك الأخلاقي لمشروع البحث ، يمكنني الاتصال بفريق أخلاقيات البحوث الاستشارية في جامعة كوينزلاند
على الرقم 61731385123+أو البريد الإلكتروني humanethics@qut.edu.au

أيضا يمكنني الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم962-6-5347810 فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.
أو
- مدير مكتب اخلاقيات البحث العلمي في مستشفى الجامعة الأردنية ، الدكتور مأمون أهرام على الرقم -79-962+ 5567779 او البريد الاكتروني m.ahram@ju.edu.jo.

• أدرك أن البيانات غير القابلة للتعريف من هذا المشروع يمكن استخدامها كبيانات مقارنة في مشاريع بحث مستقبلية.
• الموافقة على المشاركة في المشروع البحثي.

الأسم: ______________________

التوقيع: ______________________

التاريخ: ______________________

الرجاء تسليم نموذج الموافقة للباحث

Appendix 12: Participant information sheet of Study 3

QUT ihbi Institute of Health and Biomedical Innovation	**PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT -Cross-sectional study-**

Identifying specific behaviour determinants among patients with Diabetic Foot Ulcers (DFUs)

QUT Ethics Approval Number 1900000418

Research team

Principal Researcher:	Mr Anas Ababneh, PhD student
Associate Researchers:	Professor Helen Edwards, Principal supervisor Dr Kathleen Finlayson, Associate supervisor Dr Peter Lazzarini, Associate supervisor **Faculty of Health, Queensland University of Technology (QUT)** Professor Nidal Younes, Clinical site supervisor **Faculty of Medicine, Jordan University**

Why is the study being conducted?

This research project is being undertaken as part of a PhD study of Anas Ababneh.

The purpose of this research project is to investigate the determinants of a specific behaviour of patients with diabetic foot ulcers.

You are invited to participate in this research project because you have an active diabetic foot ulcer and you have 4 weeks experience of using the offloading boot.

What does participation involve?

Your participation will be during your regular visit to the Diabetic Foot Clinic at the National Centre for Diabetes, Endocrinology, and Genetics **OR** the Diabetic Foot Clinic at Prince Hamzah Hospital **OR** the Diabetic Foot Clinic at Jordan University Hospital **OR** the King Hussain Medical Centre.

Your participation includes 3 stages.

Stage 1:

It is a short interview that includes answering several questions related to socio-demographic (i.e. age or marital status) and health information. Also, it includes a clinical exam of your feet and wound including measuring the wound size, assessing the foot sensation by using a simple instrument that has a filament, and measuring your arm blood pressure as well as your big toe.

Stage 2:

You need to answer a survey that has several Likert questions (i.e. strongly agree, moderately agree, agree, etc...). You need around 30 min to answer all the survey (58 items) which has scales related to psychosocial aspects related to your current understanding and practices of your condition (diabetic foot ulcer).

Stage 3:

At this stage, your daily steps will be recorded for one week. The researcher will provide you with two activity trackers. You need to wear one of them (wrist) in all daily steps as much as you can. You are free of not wearing it in activities such as sleeping or bathing. The other activity tracker will be attached with your offloading boot by the researcher. These trackers aim to collect data related to your number of steps for a week to conclude quantitative relationships related to a specific behaviour of patients who have diabetic foot ulcers. But, for the precise goal of using these trackers, you will not be notified until after the completion of data collection for reasons related to research methodology and avoiding bias results.

After one week of steps recording within your next regular visit to change the dressing of your wound, the researcher will receive the trackers from you to download the data. Also, at the same visit, you need to answer a short questionnaire (only 17 questions) related to your behaviour and experience in wearing the offloading boots. Finally, the researcher will tell you about the result of the activity trackers readings and the precise purpose for which it was used.

Your participation in this research project is entirely voluntary. If you agree to participate you do not have to complete any question(s) you are uncomfortable answering. Also, if you find yourself uncomfortable with the idea of wearing the activity trackers without knowing the exact reason, you are free to not participate in this study. Your decision to participate or not participate will no way impact upon your current or future relationship with QUT, the National Centre for Diabetes, Jordan University Hospital, or King Hussain Medical Centre. If you do agree to participate you can withdraw from the research project during your participation without comment or penalty. Any identifiable information already obtained from you will be destroyed. You will be able to review your responses before submitting and save a copy of your responses after submitting the survey.

What are the possible benefits for me if I take part?

It is expected that this research project will not directly benefit you. However, it may benefit your awareness of the offloading treatment. Also, wearing the trackers will increase your awareness of your daily steps, which may help you reduce or increase your daily activities as recommended by your doctor.

Besides, we strongly believe that informing you of the results of this study may enhance your understanding of the prescribed offloading treatment which will reflect positively on the results of your foot ulcer healing.

What are the possible risks for me if I take part?

Your participation in this survey is not expected to have any physical or economic harm.

However, there is a little risk through the survey itself as it reflects diabetic foot ulcers and the possible complications and difficulties associated with treatment which may cause discomfort which also can be present during wearing the activity trackers for one week. Also, you may be inconvenienced by the idea of concealing the specific reason for wearing the activity trackers at the first stage of the study.

There is no research specific counselling offered by the National Centre for Diabetes, however, you can speak with the Psychiatric Clinic at Jordan University Hospital or King Hussain Medical Centre if you develop any discomfort.

You are free to not participate in this study if you feel that this discomfort can affect your psychological health.

What about privacy and confidentiality?

All comments and responses are anonymous and will be treated confidentially unless required by law, or regulatory or monitoring bodies, such as the ethics committee. The names of individual persons are not required in any of the responses.

Any data collected as part of this research project will be stored securely as per QUT's Management of research data policy.

Please note that non-identifiable data from this research project may be used as comparative data in future projects or stored on an open-access database for secondary analysis.

How do I give my consent to participate?

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

What if I have questions about the research project?

If you have any questions or require further information, please one of the listed researchers:

Anas Ababneh anas.ababneh@hdr.qut.edu.au+9 627 8700 2640
Helen Edwards h.edwards@qut.edu.au

What if I have a concern or complaint regarding the conduct of the research project?

QUT is committed to research integrity and the ethical conduct of research projects. If you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au.

You may also contact:

- The head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Professor Mohamamd El-Khateeb on + 962-6-534-7810 extension104 or email mkhateeb@ju.edu.jo.

OR

- Technical training department at King Hussain Medical Centre, Hot complaint line 06-5804-555 or email sco@jrms.jo.

Thank you for helping with this research project. Please keep this sheet for your information

Appendix 13: Arabic version of participant information sheet of Study 3

معلومات المشارك لمشروع بحث في جامعة كوينزلاند للتكنولوجيا
– الدراسة الكمية –

تحديد العوامل المرتبطة بسلوك معين عند مرضى تقرحات القدم السكرية

موافقة اخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1900000418

فريق البحث

الباحث الرئيسي : السيد أنس عبابنة (طالب دكتوراه)
الباحثين المشاركين: الاستاذ الدكتور هيلين ادواردز (مشرف رئيسي)
الدكتورة كاثلين فاينالايسون (مشرف مشارك)
كلية التمريض – جامعة كوينزلاند للتكنولوجيا
الدكتور بيتر لازاريني (مشرف مشارك)
كلية العلوم السريرية – جامعة كوينزلاند للتكنولوجيا
الأستاذ الدكتور نضال يونس (مشرف موقع البحث السريري)
كلية الطب- الجامعة الأردنية

الوصف

هذا المشروع البحثي هو جزء من متطلبات الحصول على درجة الدكتوراه للطالب انس عبابنة.
الهدف من هذا البحث هو الاستقصاء عن العوامل المحددة بسلوك معين لمرضى تقرحات القدم السكرية المتعلق بالجبائر القابلة للإزالة التي تهدف لإزالة الضغط عن تقرحات القدم السكرية .
تمت دعوتك للمشاركة في مشروع هذه الدراسة حيث لديك تقرح قدم سكرية وتتلقى العلاج الان باستخدام هذه الجبائر القابلة للإزالة لمدة أربعة اسابيع على الاقل.

المشاركة

سوف تكون مشاركتك اثناء مراجعاتك الدورية لعيادة القدم السكري في المركز الوطني للسكري والغدد الصم والوراثة أو عيادة الجراحة / مستشفى الأمير حمزة أو عيادة القدم السكري في مستشفى الحسين/ المدينة الطبية.
تتضمن مشاركتك في هذه الدراسة ثلاثة مراحل.
المرحلة الاولى: يقوم الباحث باجراء مقابلة سريعة تشمل عدة اسئلة تتعلق بمعلومات شخصية واجتماعية كالعمر والحالة الاجتماعية. بعد ذلك يقوم الباحث باجراء فحص سريري يتضمن تقييم حالة الجرح ثم فحص الاحساس للأعصاب الطرفية باستخدام اداة بسيطة تحتوي على شعيرة وأخيرا فحص التروية الدموية للاطراف السفلية عن طريق فحص ضغط الدم في الذراع وايضا في ابهام القدم.
المرحلة الثانية: تتضمن الاجابة على استبيان يحوي على العديد من أسئلة اختيار من متعدد (75 سؤال). مثال: (أوافق بشدة – اوافق – لا اوافق – ألخ..) حيث تستغرق من وقتك حوالي 30 دقيقة ، الاسئلة تقيس عدة عوامل نفسية واجتماعية بالاضافة الى قياس عوامل تتعلق بممارساتك وطريقة تعاملك مع وضعك الحالي (تقرح القدم السكرية)
المرحلة الثالثة: في هذه المرحلة سوف يتم تسجيل عدد خطواتك اليومية لمدة أسبوع.سوف يقوم الباحث بتزويدك بعدادات للخطوات عدد 2، احد هذه العدادات سوف تقوم بارتدائه في ساعد اليد ، حيث يطلب منك في هذا البحث بارتداء هذا العداد في جميع خطواتك اليومية قدر المستطاع لكن يمكنك عدم ارتدائه اثناء النوم او الاستحمام. أما العداد الاخر سيقوم الباحث بتثبيته مع الجبيرة القابلة للإزالة (أحذية ازالة الضغط). الهدف من هذه العدادات جمع بيانات تتعلق بعدد خطواتك لمدة أسبوع وذلك لإستنتاج علاقات كمية لها علاقة بسلوك معين للمرضى الذين لديهم تقرحات قدم سكرية ويعالجون باجهزة إزالة الضغط ولكن فيما يتعلق بالهدف الدقيق لهذه العدادات لن يتم إخبارك عنه إلا بعد الإنتهاء من جمع البيانات وذلك لضرورات تتعلق بمنهيجة إجراء البحث وتجنب أي تحيز في نتائج الدراسة.
بعد أسبوع من تسلمك للعددات وفي أقرب مراجعة دورية لك لعمل غيار للجرح في المركز الوطني للسكري او مستشفى الجامعة الاردنية أو مستشفى الحسين/ المدينة الطبية، سيقوم الباحث باستلام العدادات منك لتحميل البيانات. أيضا، في نفس الزيارة سوف يطلب منك الاجابة عن استبيان قصير (فقط 3 أسئلة) تتعلق بسلوك وتجربتك في ارتداء الجبائر القابلة للإزالة. أخيرا سوف يقوم الباحث بإخبارك عن نتيجة قراءة العدادات والهدف الدقيق الذي استخدمت من أجله.

مشاركتك في هذا المشروع البحثي تطوعية بشكل كامل، اذا وافقت على المشاركة في هذا البحث لك الحق في عدم الاجابة عن اي سؤال في الاستبيان في حال كنت تشعر بعدم الارتياح عن اجابة هذا السؤال.أيضا، أذا وجدت نفسك غير مرتاح لفكرة ارتدائك عدادات الخطوات دون معرفة السبب الدقيق لها لك كامل الحرية في عدم المشاركة في هذه الدراسة .
قرارك في المشاركة او عدمها في هذه الدراسة لن تأثر نهائيا على العلاقات الراهنة والمستقبلية مع جامعة كوينزلاند للتكنولوجيا او المركز الوطني للسكري او مستشفى الجامعة الاردنية أو مستشفى الحسين العسكري. إذا وافقت على المشاركة ، فيمكنك الانسحاب من المشروع البحثي أثناء مشاركتك بدون تعليق أو عقوبة.سيتم اتلاف أي معلومات محددة تم الحصول عليها من قبلك.

المنفعة المرجوة

لا يتوقع من مشاركتك في هذا البحث حصولك على منفعة مباشرة ولكن اشتراكك في هذه الدراسة قد يزيد من وعيك او معرفتك لطبيعة العلاج باستخدام جبائر ازالة الضغط. أيضا ارتدائك لعدادات الخطوات سوف يزيد مدى وعيك لخطواتك اليومية مما قد يساعدك في الحد من نشاطاتك اليومية او زيادتها حسب توصيات طبيبك. بالاضافة لذلك، نحن نعتقد بشدة أن إخبارك بنتائج الدراسة بما فيها قراءات عدادات الخطوات سوف يزيد من فهمك لعلاج إزالة الضغط الموصوف لك وبالتالي سوف ينعكس بشكل ايجابي على نتائج التئام تقرح القدم السكرية لديك.

المخاطر

مشاركتك في هذه المقابلة لا يتضمن اي أذى جسدي أو مادي ولكن هنالك احتمال ضئيل من تعرضك لعدم الإرتياح قد ينتج عن أسئلة تتعلق بمرض تقرحات القدم السكرية ومضاعفاتها بالإضافة لعملية رتدائك لعدادات الخطوات بشكل يومي لمدة اسبوع. أيضًا ، قد تكون غير مرتاح لفكرة إخفاء السبب المحدد لارتداء عدادات الخطوات في المرحلة الأولى من الدراسة.

على الرغم من عدم وجود عيادة صحة نفسية في المركز الوطني للسكري ولكن يمكنك استشارة اطباء الصحة النفسية في مستشفى الجامعة او مستشفى الحسين/ المدينة الطبية في حال عانيت من اي ضغوطات نفسية جراء مشاركتك في البحث.لديك كامل الحرية في تجنب المشاركة في هذه الدراسة في حال وجدت أن الشعور بعدم الارتياح قد يأثر سلبا على صحتك العامة.

الخصوصية والسرية

جميع المعلومات والردود سوف يتم التعامل معها بسرية تامة ما لم يتطلب القانون أو الهيئات التنظيمية أو المراقبة ، مثل لجنة الأخلاقيات. ليست هناك حاجة لأسماء الأفراد في أي من الردود.
سيتم بذل كل جهد لضمان أن البيانات التي تقدمها لا يمكن تتبعها لك في التقارير والمنشورات وأشكال العرض الأخرى. على سبيل المثال ، سنقوم فقط بتضمين الجزء ذي الصلة من الاقتباس، ولن نستخدم أي أسماء ، أو سيتم تغيير الأسماء ، و / أو سيتم استبعاد تفاصيل مثل التواريخ والظروف الخاصة. ومع ذلك ، على الرغم من أنه من غير المحتمل ، من الممكن أنه إذا تم اقتباسك مباشرة فقد تصبح هويتك معروفة.
سيتم تخزين أي بيانات يتم جمعها كجزء من هذا المشروع البحثي بشكل آمن وفقًا لإدارة سياسة الأبحاث في جامعة كوينزلاند للتكنلوجيا.

الموافقة على المشاركة

نود أن نطلب منك التوقيع على استمارة موافقة خطية (مرفقة) لتأكيد موافقتك على المشاركة.

أسئلة / مزيد من المعلومات حول مشروع البحث

إذا كان لديك أي أسئلة أو كنت تحتاج إلى مزيد من المعلومات ، فيرجى الاتصال بـ:

السيد أنس عبابنه
anas.ababneh@hdr.qut.edu.au +962787002640
الاستاذ الدكتور هيلين ادواردز h.edwards@qut.edu.au

مخاوف / الشكاوى بشأن اجراء مشروع البحث

تلتزم جامعة كوينزلاند للتكنولوجيا بالبحث عن النزاهة والسلوك الأخلاقي لمشاريع الأبحاث. ومع ذلك ، إذا كانت لديك أية مخاوف أو شكاوى حول السلوك الأخلاقي لمشروع البحث ، فيمكنك الاتصال بفريق الأخلاقيات الاستشاري في جامعة كوينزلاند للتكنولوجيا على الرقم

+61 7 3138 5123

أو البريد الإلكتروني

humanethics@qut.edu.au

لا يرتبط الفريق الاستشاري لأخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا بمشروع البحث ويمكنه أن ييسر حلًا لمخاوفك بطريقة محايدة.

يمكنك أيضا الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم 5347810-6-962 + فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.

أو

- مكتب التدريب الفني، مستشفى الحسين العسكري، خط الشكاوى الساخن 065804555 أو البريد الاكتروني sco@jrms.jo

شكرا لك على المساعدة في هذا المشروع البحثي
يرجى الاحتفاظ بهذه الصفحة لمعلوماتك

Appendix 14: Consent form of Study 3

QUT ihbi Institute of Health and Biomedical Innovation	**CONSENT FORM FOR QUT RESEARCH PROJECT** **-Cross-sectional study-**

Identifying specific behaviour determinants among patients with Diabetic Foot Ulcers (DFUs)

QUT Ethics Approval Number 1900000418

Research team

Mr Anas Ababneh	anas.ababneh@hdr.qut.edu.au
Professor Helen Edwards	h.edwards@qut.edu.au
Dr Kathleen Finlayson	k.finlayson@qut.edu.au
Dr Peter Lazzarini	peter.lazzarini@health.qld.gov.au
Professor Nidal Younes	younesnidal@gmail.com

Statement of consent

By signing below, you are indicating that you:

- Have read and understood the information document regarding this research project.
- Have had any questions answered to your satisfaction.
- Understand that if you have any additional questions you can contact the research team.
- Understand that you are free to withdraw without comment or penalty.
- Understand that if you have concerns about the ethical conduct of the research project you can contact the Research Ethics Advisory Team on +61 7 3138 5123 or email humanethics@qut.edu.au.
- You can also contact the head of ethics office at the National Centre for Diabetes, Endocrinology and Genetics, Professor Mohamamd El-Khateeb on + 962-6-534-7810 extension 104 or email mkhateeb@ju.edu.jo **OR** Technical Training Department at King Hussain Medical Centre, Hot Complaint Line: 06-5804-555 or email sco@jrms.jo .
- Understand that non-identifiable data from this project may be used as comparative data in future research projects.
- Agree to participate in the research project.

Name ______________________________

Signature ______________________________

Date ______________________________

Please return the signed consent form to the researcher

Appendix 15: Arabic version of the consent form of Study 3

نموذج موافقة للمشاركة في مشروع بحث / جامعة كوينزلاند للتكنولوجيا – الدراسة الكمية –

تحديد العوامل المرتبطة بسلوك معين عند مرضى تقرحات القدم السكرية
موافقة اخلاقيات البحث في جامعة كوينزلاند للتكنولوجيا رقم 1900000418

فريق البحث

السيد انس عبابنه anas.ababneh@hdr.qut.edu.au
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الدكتور بيتر لازاريني peter.lazzarini@health.qld.gov.au
الاستاذ الدكتور نضال يونس younesnidal@gmail.com

بيان الموافقة

من خلال توقيعي للنموذج أدناه ، فإني أشير إلى:

- قراءة وفهم وثيقة معلومات المشارك الخاصة بهذا المشروع البحثي.
- إمكانية الاستفسار عن أي أسئلة تتعلق برضاي عن المشاركة في البحث.
- ادرك أنه إذا كان لدي أي أسئلة إضافية ، يمكنني الاتصال بفريق البحث.
- ادرك أنني لدي كامل الحرية في الانسحاب دون تعليق أو عقوبة.
- ادرك أنه إذا كانت لدي مخاوف بشأن السلوك الأخلاقي لمشروع البحث ، يمكنني الاتصال بفريق أخلاقيات البحوث الاستشارية في جامعة كوينزلاند للتكنولوجيا

على الرقم 61731385123+أو البريد الإلكتروني humanethics@qut.edu.au
أيضا الاتصال يمكنني الاتصال بـ:

- مدير مكتب اخلاقيات البحث العلمي في المركز الوطني للسكري والغدد الصم والوراثة ، الدكتور محمد الخطيب على الرقم 962-6-5347810 + فرعي 104 او البريد الاكتروني mkhateeb@ju.edu.jo.
أو
- مكتب التدريب الفني، مستشفى الحسين العسكري، خط الشكاوى الساخن 065804555 أو البريد الاكتروني sco@jrms.jo

الأسم: ______________________________

التوقيع: ______________________________

التاريخ: ______________________________

الرجاء تسليم نموذج الموافقة للباحث

Appendix 16: Data collection form – Study 1

DATE: __________ / __________ / __________

Sociodemographic and health information	
Participant Code No.	
Age:	
Family income (JD):	
Gender:	☐Male ☐Female ☐Other
Marital status:	☐Single ☐Married ☐Widowed ☐Other
Living place:	☐City ☐Rural
Employment:	☐Employed ☐Unemployed ☐Retired ☐Self-funded
Work environment	☐ Office-based ☐Driving ☐Walking ☐Prolong standing
Religion	☐Islam ☐Christianity ☐Other/ Specify…...
Level of education:	☐Illiteracy ☐Primary school ☐Secondary school ☐High education
Carers:	☐Alone ☐Family ☐Primary carer
Do you need a walking aid (e.g. walking stick or frame) to mobilise?	☐Yes ☐No
Smoking:	☐ None ☐ Past ☐ Current
Duration of diabetes:	_____________ Years
Other comorbidities:	☐Renal failure ☐Heart failure ☐Impaired vision ☐Hypertension ☐Other, please specify:_____________
Have you ever had an amputation on either of your feet?	☐Yes ☐No
Have you ever had an ulcer on either of your feet before?	☐Yes ☐No
If yes, which foot or feet were the ulcers on?	☐Right ☐Left ☐Both feet
Diabetic foot ulcer location:	☐Right ☐Left
Diabetic foot ulcer duration:	_____________Weeks or months
Duration of Removable cast walkers prescription:	_____________ Weeks or months

Appendix 17: Pilot testing feedback survey (Study 2- translation phase)

- After reading the questionnaire, have you found any non-cleared items?
- بعد قراءة الاستبيان هل وجدت أي اسئلة غير واضحة؟

- After reading the questionnaire, have you faced any difficulty in understanding the content?
- بعد قراءة الاستبيان هل عانيت من صعوبة في فهم المحتوى؟

- After reading the questionnaire, have you found it appropriate to the Jordanian culture?
- بعد قراءة الاستبيان هل وجدت انه مناسب للثقافة الاردنية؟

- Do you have any comments regarding the given questionnaire?

- هل لديك أي ملاحظات تتعلق بالاستبيان المقدم لك؟

Appendix 18: Data collection form – Study 2 and Study 3

Sociodemographic information	
Participant Code No.	……………................
Research setting	☐ NCDEG ☐ JU ☐ JMC
Age	……………................ years
Gender	☐ Male ☐ Female
Living arrangement	☐ Living alone ☐ Living with family ☐ Primary carer for another household member ☐ Others ………………………………………………………………………
Educational level	☐ Primary school ☐ Secondary school ☐ Undergraduate ☐ Postgraduate ☐ Others ………………………………………………………………………
Employment	☐ Employed ☐ Unemployed ☐ Retired ☐ Self-funded
Family income	……………................ Jordanian Dinar (JD)
Health information	
Person health variables	
Body mass index (BMI)	BMI…………………………… (kg/m2)
Diabetes type	☐ Type 1 ☐ Type 2
Duration of diabetes	……………………………… years
HbA1C	……………………………… (mmole\L) %
Other comorbidities	☐ Renal failure ☐ Heart failure ☐ Impaired vision ☐ Hypertension ☐ Osteoarthritis ☐ Rheumatoid arthritis ☐ CVA ☐ Autoimmune disease ☐ Dyslipidaemia ☐ MI ☐ Cancer ☐ Depression ☐ Other/Please specify………..
Limb health variables	
Previous ulceration	☐ No ☐ Study foot ☐ Non-study foot ☐ Both
Loss of protective sensation	☐ No ☐ Study foot ☐ Non-study foot ☐ Both
PAD	☐ No ☐ Study foot ☐ Non-study foot ☐ Both
Foot deformities	☐ No ☐ Study foot ☐ Non-study foot ☐ Both

Minor amputations	☐No ☐ Study foot ☐ Non-study foot ☐ Both
Major amputations	☐No ☐ Study foot ☐ Non-study foot ☐ Both
Ulcer and offloading variables	
Ulcer location	☐ Right ☐ Left ☐ Both feet
UT ulcer classification	Grade: ………… Stage: ………….
Ulcer area (Length x width)	……………….………….. (mm2)
Diabetic foot ulcer duration	……………….………….. weeks
Offloading device location	☐ Right ☐ Left ☐ Both feet
Duration of offloading treatment	……………….………….. weeks

Appendix 19: Study questionnaire

Section A.

FCCS

After reading each statement, make a check (✓) under the description that best describes how confident you feel about taking care of your feet. There are no right or wrong answers. All statements should be answered. Please answer about your CONFIDENCE to do the foot care, NOT if you do the foot care.

Footcare	**Strongly confident**	**Moderately confident**	**Confident**	**Moderately not confident**	**Strongly not confident**
1- I can protect my feet.					
2- Even without pain/discomfort, I can look at my feet daily to check for cuts, scratches, blisters, redness, or dryness.					
3- After washing my feet, I can dry between my toes.					
4- I can judge when my toenails need to be trimmed by a foot doctor.					
5- I can trim my toenails straight across.					
6- I can figure out when to use a pumice stone to smooth corns and/or calluses on my feet.					
7- I can test the temperature of the water before putting my feet into it.					
8- If I was told to do so, I can wear shoes and socks every time I walk (includes walking indoors).					

9- When I go shopping for new shoes, I can choose shoes that are good for my feet.					
10- I can call my doctor about problems with my feet.					
11- Before putting them on, I can check the insides of my shoes for problems that could harm my feet.					
12- If directed to do so, I can routinely apply lotion to my feet.					
13- If I was told to do so, I can wear my offloading device (Offloading boot\shoes) every time I walk (includes walking indoors).					

FCOES

After reading each statement, make a check (X or ✓) under the description that describes how much you BELIEVE that the following actions can prevent foot ulcers (open sores) from occurring. There is no right or wrong answer.

Statement (All statements should be answered)	**Totally believe**	**Strongly believe**	**believe**	**Strongly not believe**	**Totally not believe**
1- Controlling blood sugar level well can prevent foot ulcers from occurring.					
2- Examining feet every day can prevent foot ulcers from occurring.					
3- Checking inside shoes before putting them on can prevent foot ulcers from occurring.					
4- Washing feet every day can prevent foot ulcers from occurring.					

5- Testing water temperature with hand or elbow before washing feet can prevent foot ulcers from occurring.					
6- Drying feet thoroughly after washing can prevent foot ulcers from occurring.					
7- Putting moisturizing cream on feet can prevent foot ulcers from occurring.					
8- Cutting toenails straight across can prevent foot ulcers from occurring.					
9- Wearing proper footwear can prevent foot ulcers from occurring.					
10- Seeing the diabetic doctors regularly can prevent foot ulcers from occurring.					
11- Immediately informing the diabetic doctors about any changes in my feet (E.g. numb, muscle cramp, lost or reduce feeling, any lesions, corns, calluses) can prevent foot ulcers from occurring.					
12- Never walking outside in barefoot can prevent foot ulcers from occurring.					
13- Never using chemical agents or blades to remove corns on my feet can prevent foot ulcers from occurring.					
14- Never putting my feet near hot devices/ tools/ articles can prevent foot ulcers from occurring.					
15- In overall, I BELIEVE that my routinely foot care can prevent foot ulcers from occurring.					
16- Overall, I BELIEVE that wearing an offloading device (Offloading boot\shoes) can heal foot ulcers.					

PIN scale

The next set of questions is about the likely CAUSE of lost or reduced feeling. Please indicate how much you agree or disagree with **each** of the following statements by ticking the appropriate box.

Item	STRONGLY DISAGREE	DISAGREE	UNCERTAIN	AGREE	STRONGLY AGREE
1- Lost or reduced feeling is inevitable if one has diabetes					
2- Lost or reduced feeling in my feet was caused by poor medical care in the past					
3- Lost or reduced feeling in my feet was caused by not taking good care of my diabetes					
4- Foot ulcers (open sores) are caused by poor medical care					
5- Foot ulcers (open sores) are caused by not taking care of oneself					
6- Foot ulcers (open sores) are inevitable when one has diabetes					
7- Changes in foot shape can					

cause foot ulcers (open sores)					
8- Ill-fitting shoes can cause foot ulcers (open sores)					
9- Excessive hard skin formation (callus) can cause foot ulcers (open sores)					
10- Dry skin on the feet can cause foot ulcers (open sores)					

The next set of questions is about the likely DURATION and the COURSE of lost or reduced feeling in your feet. Please indicate how much you agree or disagree with each of the following statements by ticking the appropriate box.

Item	**STRONGLY DISAGREE**	**DISAGREE**	**UNCERTAIN**	**AGREE**	**STRONGLY AGREE**
11- Foot ulcers (open sores) take a long time to develop					
12- Foot ulcers (open sores) can develop very fast					
13- I can develop a foot ulcer (an open sore) at any time					

NQOL scale

- These questions ask about the effect your FOOT PROBLEMS may have on your daily life and well-being. By foot problems we mean lost or reduced feeling in your extremities, pain, discomfort and/or ulcers (open sores) on your feet and, in some cases unsteadiness while walking or standing.
- Please note that many questions have two parts. Answer every question by ticking one box for each part (tick two boxes per line).
- Please make sure you answer all questions.
- Please concentrate on how you have felt **IN THE PAST 4 WEEKS** for all of the questions.
- There are no right or wrong answers. If you are unsure about how to answer a question, you can ask the person who gave you the questionnaire. Please DO NOT ask a relative or friend to help you.

In the past 4 weeks how often have you experienced the following symptoms?	All the time	Most of the time	Some of the time	Occasionally	Never	**How much bother did this cause you?**		
						Very much	Some bother	None
1. Burning in your legs or feet								
2. Excessive heat or cold in your legs or feet								
3. Pins and needles in your legs or feet								
4. Shooting or stabbing pain in your legs or feet								
5. Throbbing in your legs or feet								
6. Sensations in your legs or feet that make them jump								
7. Irritation of the skin caused by something touching your feet, such as								

bedsheets or socks								

A. Have these **painful symptoms** reduced your quality of life?	Very much	Quite a lot	Somewhat	A little	Not at all

In the past 4 weeks how often have you experienced the following symptoms?	All the time	Most of the time	Some of the time	Occasionally	Never	**How much bother did this cause you?** Very much	Some bother	None
8. Numbness in your feet								
9. Inability to feel the difference between hot and cold with your feet								
10. Inability to feel objects with your feet								

B. Have these **last three symptoms** reduced your quality of life?	Very much	Quite a lot	Somewhat	A little	Not at all

In the past 4 weeks how often have you experienced the following symptoms?	All the time	Most of the time	Some of the time	Occasionally	Never	**How much bother did this cause you?** Very much	Some bother	None
11. Weakness in your hands								
12. Problems with balance or unsteadiness while walking								
13. Problems with balance or unsteadiness while standing								

C. Have these **last three symptoms** reduced your quality of life?	Very much	Quite a lot	Somewhat	A little	Not at all

Section B.

Offloading scales

1. This question asks you about your personal beliefs regarding the treatment of diabetic foot ulcers treatment. Please order the items below from 1-6 according to the **importance of treatment**. Write the numbers in the boxes below where 1 is the most important and 6 is the least important.

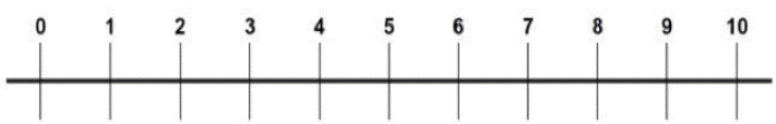
☐ Controlling diabetes (including diet ± Insulin or diabetes medications)
☐ Antibiotics
☐ Wound Dressings
☐ Offloading device (Offloading boot\shoes)
☐ Physician role
☐ Other (please state) ____

The questions (2-10) aim to measure your level of satisfaction regarding your prescribed offloading device (Offloading boot\shoes).

2. How comfortable is the offloading device that you use to treat your ulceration? Circle **<u>any number</u>** **<u>on the line</u>** ranging from 0 to 10, where 0 means the device is not comfortable, 5 moderately comfortable, and 10 means maximally comfortable

0= Not at all comfortable | **5= Moderately comfortable** | **10= Maximally comfortable**

3. How much are you able to perform normal daily activities? Circle **<u>any number</u>** **<u>on the line</u>** ranging from 0 to 10, where 0 means you are not able at all, 5 you are moderately able, and 10 means you are maximally able



0= Not at all able | **5= Moderately able** | **10= Maximally able**

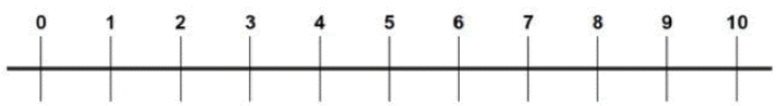
4. How much your activity level is altered?

Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate where you think you are. 0 means your activity level is not altered at all, 5 means your activity level is moderately altered and 10 means your activity level is maximally altered.

0=Not at all altered | **5=Moderately altered** | **10=Maximally** altered

5. How much your sleeping activity is changed?

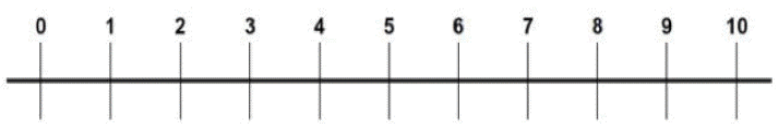
Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate how your sleeping activity has changed after using the offloading device. 0 means your sleeping activity is not changed at all, 5 means your sleeping activity moderately changed and 10 means your sleeping activity maximally changed.



0=Not at all changed | **5=Moderately changed** | **10=Maximally changed**

6. Overall, how satisfied are you with the offloading device used to treat your ulceration?

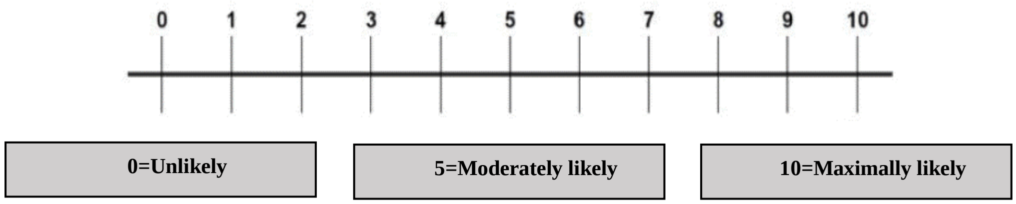
Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate where you think you are. 0 means you were not satisfied, 5 means you were moderately satisfied and 10 means you were maximally satisfied.



0=Not at all satisfied | **5=Moderately satisfied** | **10=Maximally satisfied**

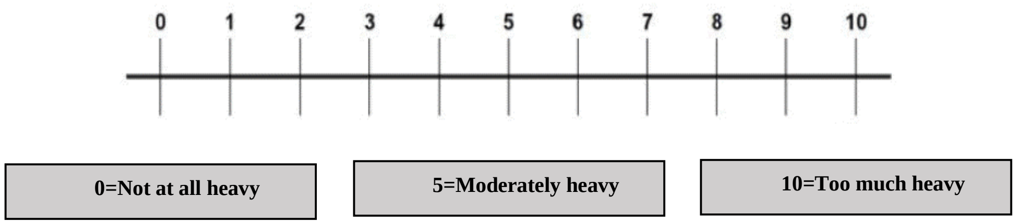
7. How much are you likely to wear the prescribed offloading device again?

Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate the likelihood of your wearing this offloading device again. 0 means wearing the offloading device again is unlikely, 5 means wearing the offloading device again is moderately likely and 10 means wearing the offloading device again is maximally likely.



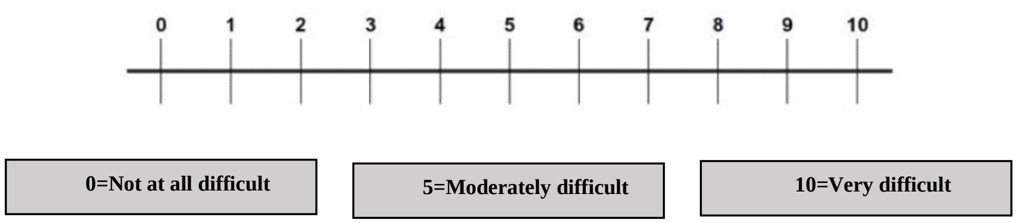
8. How heavy have you found the offloading device to wear?

Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate how heavy you find your device. 0 means the offloading device is not heavy at all, 5 means the offloading device is moderately heavy and 10 means the offloading device is too much heavy.



9. How much difficult do you find putting on the prescribed offloading device?

Circle **<u>any number on the line</u>** ranging from 0 to 10 to indicate your difficulty. 0 means putting on the offloading device is not difficult at all, 5 means putting on the offloading device is moderately difficult and 10 means putting on the offloading device is very difficult.

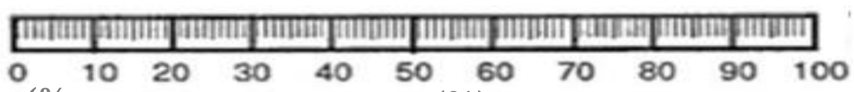


10. This question asks you about the family support that you have during your offloading treatment. How often family members or somebody helps you when you put on and take off the offloading device.

- Always
- Usually
- Sometimes
- Rarely
- Never

The questions (11-16) aim to investigate how often you wear the offloading device (Offloading boot\shoes) in your house and outside your house.

11. Please estimate the percentage of the time you wear the offloading device on an average day (excluding sleeping): Circle **<u>any number on the line</u>** ranging from 0 to 100 to indicate your adherence. 0% means you do not wear the offloading device at any time during the day, 50% means you wear the offloading device half of the day time and 100% means you consistently wear the offloading device all day.



(% (%) (%)

0%=Not wearing the device at any time

50%=Wearing the device for half of the day time

100%=Wearing the device all day

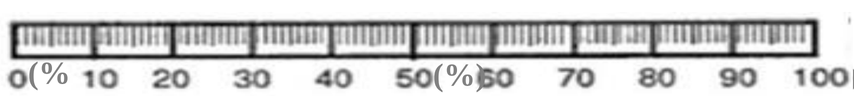
12. How long do you wear the offloading device inside the house?

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

13. How long do you wear the offloading device outside the house?

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

14. Please estimate the percentage of steps you wear the offloading device of all the steps you walk in an average day: Circle **<u>any number on the line</u>** ranging from 0 to 100 to indicate your adherence. 0% means you don't wear the offloading device in any steps, 50% means you wear the offloading device in half of your daily steps and 100% means you consistently wear the offloading device for every single step"



(% (%) (%)

0%=Not wearing the device in any step

50%=Wearing the device in half of daily steps

100%=Wearing the device for every single step

15. How often do you wear the offloading device inside the house? • Every single step • Most of the steps • Half of the steps • Only in a few steps • Not in a single step
16. How often do you wear the offloading device outside the house? • Every single step • Most of the steps • Half of the steps • Only in a few steps • Not in a single step
17. This question asks you about your beliefs of adherence to wearing the offloading device. How much do you agree that walking a short distance (E.g. Distance up to 5M inside the home) **without** the offloading device **will not be harmful** to your wound? • Totally agree • Moderately agree • Neither disagree nor agree • Disagree • Not agree at all

Appendix 20: The final Arabic version of the study questionnaire

القسم الأول

FCCS

بعد قراءة كل عبارة، ضع علامة (√) تحت الوصف الأكثر تعبيرا عن مقدار ما تشعر به من ثقة بنفسك فيما يتعلق في العناية باقدامك. لا توجد هنالك اجابات صحيحة أو خاطئة. كل العبارات يجب ان يتم اجابتها. الرجاء الاجابة عن ثقتك بالقيام بالعناية بالقدم، وليس فيما لو تقوم بالعناية بالقدم.

العناية بالقدم	واثق بقوة	واثق باعتدال	واثق	غير واثق باعتدال	غير واثق بقوة
1. أستطيع ان احمي قدمي .					
2. حتى لو لم اشعر بالالم أو الازعاج ، أستطيع أن أتفقد قدمي بشكل يومي للتحقق من من القُطوع (شقوق) في سطح الجلد أو الخدوش أو الفقاعات أو الاحمرار أو الجفاف.					
3. بعد غسل قدمي، أستطيع أن أجفف ما بين أصابع قدمي.					
4. استطيع ان اقرر عندما تحتاج أظافر قدمي التقليم بواسطة طبيب القدم.					
5. أستطيع تقليم أظافر قدمي بشكل مستقيم.					
6. أستطيع معرفة متى يجب استخدام حجر البرد لتنعيم المسامير اللحمية أو التصلبات في قدمي.					
7. أستطيع تفحص درجة حرارة الماء قبل وضع قدمي فيه.					
8. إذا طُلب مني القيام بذلك ، أستطيع ارتداء احذية وجوارب في كل مرة أمشي فيها (بما في ذلك المشي في الأماكن المغلقة).					
9. عندما اذهب للسوق لشراء أحذية جديدة فانه باستطاعتي اختيار حذاء جيد لقدمي.					
10. أستطيع أن اخبر طبيبي عن المشاكل في قدمي.					
11. قبل ارتداء الحذاء، استطيع التحقق في الأجزاء الداخلية فيه عن المشاكل التي قد تضر قدمي.					
12. إذا طُلب مني القيام بذلك، أستطيع وضع كريم مرطب على قدمي بشكل منتظم.					
13. إذا طُلب مني القيام بذلك ، أستطيع ارتداء جهاز ازالة الضغط (حذاء/ بوت ازالة الضغط) في كل مرة أمشي فيها (بما في ذلك المشي في الأماكن المغلقة).					

FCOES

بعد قراءة كل عبارة ، ضع علامة (√) أسفل الوصف الأكثر ملائمة لمدى اعتقادك أن الإجراءات التالية يمكن أن تمنع تقرحات القدم (القروح المفتوحة) من الحدوث. ليس هناك جواب صحيح أو خاطئ.

العبارات (كل العبارات يجب إجابتها)	أعتقد تماما	أعتقد بقوة	أعتقد	لا أعتقد بقوة	لا أعتقد تماما
1- السيطرة الجيدة على مستوى السكر في الدم يمكن ان تقي من حدوث تقرحات القدم.					
2- فحص القدمين كل يوم يمكن أن يقي من حدوث تقرحات القدم.					
3- تفحُص ما داخل الأحذية قبل ارتدائها يمكن أن يقي من حدوث تقرحات القدم					
4- غسل القدمين كل يوم يمكن أن يقي من حدوث تقرحات القدم .					
5- تفحص حرارة الماء بواسطة اليد أو الكوع قبل غسل القدمين يمكن أن يقي من حدوث تقرحات القدم.					
6- تنشيف القدمين بعناية بعد غسلهما يمكن أن يقي من حدوث تقرحات القدم.					
7- وضع كريم مرطب على القدمين يمكن أن يقي من حدوث تقرحات القدم.					
8- تقليم اظافر القدمين بشكل مستقيم يمكن أن يقي من حدوث تقرحات القدم.					
9- ارتداء حذاء مناسب يمكن أن يقي من حدوث تقرحات القدم.					
10- مراجعة اطباء السكري على نحو منتظم يمكن أن تقي من حدوث تقرحات القدم.					
11- إخبار اطباء السكري فورا عن أي تغيرات في قدمي (مثل: التنميل أو التشنج العضلي أو فقدان / ضعف الشعور أو خدوش أو مسامير لحمية أو تصلبات) يمكن أن يقي من حدوث تقرحات القدم.					
12- عدم المشي خارجا حافي القدمين يمكن أن يقي من حدوث تقرحات القدم.					
13- عدم استخدام المواد الكيميائية أو الشفرات الحادة لإزالة المسامير في قدمي يمكن أن يقي من حدوث تقرحات القدم.					
14- عدم وضع قدمي بالقرب من الأجهزة أو الادوات أو الأشياء الساخنة يمكن أن يقي من حدوث تقرحات القدم.					
15- بالمجمل، أعتقد أن العناية الروتينية بأقدامي يمكن أن تقي من حدوث تقرحات القدم.					
16- بالمجمل ، أعتقد أن إرتداء جهاز ازالة الضغط (حذاء/ بوت ازالة الضغط) يمكن أن يشفي تقرحات القدم.					

PIN scale

الأسئلة التالية تتعلق **بالسبب المحتمل** لفقدان أو انخفاض الشعور في القدمين. يرجى تبيان مدى اتفاقك أو معارضتك لكل من العبارات التالية من خلال وضع إشارة (√) في المربع المناسب.

العبارات	أعارض بقوة	أعارض	غير متأكد	أوافق	أوافق بقوة
1- فقدان الشعور أو انخفاضه أمر لا مفر منه إذا كان الشخص لديه مرض السكري.					
2- ضعف أو فقدان الاحساس في قدمي نتج عن سوء العناية الطبية في الماضي.					
3- ضعف أو فقدان الاحساس في اقدامي نتج عن عدم العناية الجيدة بمرض السكري لدي.					
4- تقرحات القدم (القروح المفتوحة) سببها سوء العناية الطبية.					
5- تقرحات القدم (القروح المفتوحة) سببها سوء العناية الشخصية.					
6- تقرحات القدم (القروح المفتوحة) أمر لا مفر منه عندما يعاني الشخص من مرض السكري.					
7- التغيرات في شكل القدم يمكن أن تسبب تقرحات القدم (القروح المفتوحة).					
8- الأحذية التي لا تتناسب مع القدم يمكن أن تسبب تقرحات القدم (القروح المفتوحة).					
9- التكون الزائد للجلد القاسي (التصلبات الجلدية في القدم) يمكن أن يسبب تقرحات القدم (القروح المفتوحة)					
10- الجلد الناشف في الاقدام يمكن أن يسبب تقرحات القدم (القرح المفتوحة)					

تدور المجموعة التالية من الأسئلة حول المدة أو المسار المرجحين لفقدان أو ضعف الشعور في قدميك. يرجى تبيان مدى اتفاقك أو معارضتك على كل عبارة من العبارات التالية عن طريق وضع علامة (√) في المربع المناسب.

العبارات	أعارض بقوة	أعارض	غير متأكد	أوافق	أوافق بقوة
11- تقرحات القدم (القرح المفتوحة) تحتاج لوقت طويل حتى تتطور.					
12- تقرحات القدم (القرح المفتوحة) يمكن أن تتطور بسرعة.					
13- من الممكن أن تتطور لدي قرحة قدم (قرحة مفتوحة) في أي وقت.					

NQOL scale

- الأسئلة التالية تستقصي عن التأثير المحتمل لمشاكل القدم لديك على حياتك اليومية وصحتك. نعني بمشاكل القدم ضعف أو فقدان الاحساس في اطرافك أو ألم أو عدم ارتياح أو تقرحات (قروح مفتوحة) في اقدامك وفي بعض الحالات عدم التوازن أثناء المشي أو الوقوف.
- يرجى ملاحظة أن العديد من الأسئلة تحتوي على جزئين. أجب عن كل سؤال عن طريق اختيار مربع واحد لكل جزء (ضع علامة √ على المربعين في كل سطر).
- يرجى التأكد من أنك أجبت على جميع الأسئلة.
- يرجى التركيز على مدى شعورك في **الأسابيع الأربعة الماضية** لجميع الأسئلة.
- لا توجد اجابات صحيحة أو خاطئة. إن لم تكن متأكدا حول كيفية الإجابة على السؤال ، يمكنك أن تسأل الشخص الذي قدم لك الاستبيان. من فضلك **لا** تسأل الأقارب أو الأصدقاء لمساعدتك.

في الأسابيع الأربعة الماضية ، كم في العادة عانيت من الأعراض الآتية؟	كل الوقت	معظم الوقت	بعض الوقت	احيانا	ابدا	**كم من العناء تسبب لك من ذلك؟** كثيرا جدا	بعض العناء	لا شيء
1- حرقان في ساقيك أو قدميك								
2- حرارة أو برودة مفرطة في ساقيك أو قدميك								
3- أحساس بالإبر والدبابيس في ساقيك أو قدميك								
4- طعنات ألم أو ألم شبيه بالصعق الكهربائي في ساقيك أو قدميك								
5- ألم نابض (يذهب ويأتي بسرعة) في ساقيك أو قدميك								
6- أحاسيس في ساقيك أو قدميك تجعلهما تقفز								
7- تهيج في الجلد سببه أن شيئا قد يلمس قدميك مثل شرشف السرير أو الجوارب								

أ- هل هذه **الأعراض المؤلمة** قللت من جودة حياتك؟	كثيرا جدا	كثيرا	نوعا ما	قليلا	ابدا

في الأسابيع الأربعة الماضية ، كم في العادة عانيت من الأعراض الآتية؟	كل الوقت	معظم الوقت	بعض الوقت	احيانا	ابدا	**كم من العناء تسبب لك من ذلك؟** كثيرا جدا	بعض العناء	لا شيء
8- خدر في قدميك								
9- عدم القدرة على الإحساس بالفرق بين الساخن والبارد في قدميك								
10- عدم القدرة على الاحساس بالأشياء بقدميك								

ب- هل هذه **الأعراض الثلاثة الاخيرة** قللت من جودة حياتك ؟	كثيرا جدا	كثيرا	نوعا ما	قليلا	ابدا

في الأسابيع الأربعة الماضية ، كم في العادة عانيت من الأعراض الآتية؟	كل الوقت	معظم الوقت	بعض الوقت	احيانا	ابدا	**كم من العناء تسبب لك من ذلك؟** كثيرا جدا	بعض العناء	لا شيء
11- ضعف في يديك								
12- مشاكل في التوازن أو عدم الاستقرار أثناء المشي								

13- مشاكل في التوازن أو عدم الاستقرار أثناء الوقوف								

ت- هل هذه **الأعراض الثلاثة الأخيرة** قللت من جودة حياتك؟	كثيرا جدا	كثيرا	نوعا ما	قليلا	ابدا

القسم الثاني

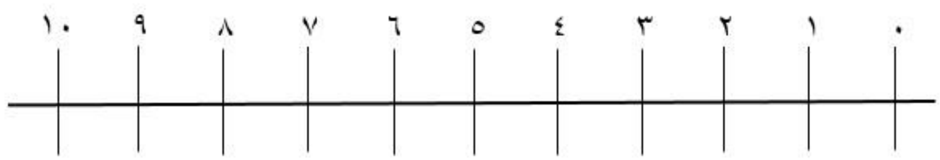
Offloading scales

1- يستفسر هذا السؤال عن معتقداتك الشخصية فيما يتعلق بعلاج تقرحات القدم السكرية. يرجى ترتيب العناصر أدناه من 1-6 حسب أهمية العلاج. يرجى كتابة الرقم في المربعات أدناه حيث يشير الرقم 1 إلى العلاج **الأكثر أهمية** والرقم 6 إلى العلاج **الأقل أهمية**.

- ☐ السيطرة على مرض السكري (بما في ذلك النظام الغذائي ± الأنسولين أو الأدوية السكري)
- ☐ المضادات حيوية
- ☐ الغيارأو ضمادات الجرح
- ☐ جهاز ازالة الضغط (حذاء/ بوت ازالة الضغط)
- ☐ دور الطبيب
- ☐ غير ذلك (يرجى توضيحها)..

تهدف الأسئلة (2 - 10) إلى قياس مستوى رضاك فيما يتعلق بجهاز ازالة الضغط (حذاء/ بوت ازالة الضغط) الموصوف لك.

2- كم هو **مريح جهاز ازالة الضغط** الذي تستخدمه لعلاج التقرح لديك؟
ضع دائرة حول **أي رقم على الخط** أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد انك فيه ، حيث يشير الرقم 0 الى أن الجهاز غير مريح ابدا، ويشيرالرقم 5 الى انه مريح إلى حد ما ، ويشير الرقم 10 الى انه مريح جدا.



صفر=غير مريح ابدا | **5= مريح الى حد ما** | **10= مريح جدا**

3- ما مدى **مقدرتك على القيام بالأنشطة اليومية الاعتيادية** أثناء استخدامك لجهاز ازالة الضغط الموصوف لك؟
ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة الى المستوى الذي تعتقد انك فيه، حيث يشير الرقم 0 الى انك غير قادر ابدا ، ويشير الرقم 5 الى انك قادر الى حد ما ، ويشير الرقم 10 الى انك قادر جدا.

٠ ١ ٢ ٣ ٤ ٥ ٦ ٧ ٨ ٩ ١٠

صفر = غير قادر ابدا | **5= قادر الى حد ما** | **10= قادر جدا**

4- ما مدى **تغير مستوى نشاطك** اثناء استخدامك لجهاز ازالة الضغط الموصوف لك؟
ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة الى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 أن مستوى نشاطك لم يتغير ابدا، ويشير الرقم 5 الى أن مستوى نشاطك قد تغير الى حد ما ويشير الرقم 10 الى ان مستوى نشاطك قد تغير جدا.

٠ ١ ٢ ٣ ٤ ٥ ٦ ٧ ٨ ٩ ١٠

صفر = لم يتغير ابدا | **5= تغير الى حد ما** | **10= تغير جدا**

5- **ما مدى تغير نومك** اثناء استخدامك لجهاز ازالة الضغط الموصوف لك؟ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 الى ان نومك لم يتغير ابدا، ويشير الرقم 5 أن نومك تغير الى حد ما ويشير الرقم 10 أن نومك قد تغير جدا.

٠ ١ ٢ ٣ ٤ ٥ ٦ ٧ ٨ ٩ ١٠

صفر = لم يتغير ابدا | **5= تغير الى حد ما** | **10= تغير جدا**

6- بالمجمل، ما مدى **رضاك عن جهاز ازالة الضغط** الموصوف من اجل علاج التقرحات لديك؟ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 الى أنك غير راضٍ ابدا، ويشير الرقم 5 الى انك راضٍ الى حد ما ويشير الرقم 10 الى أنك راضٍ جدا.

١٠ ٩ ٨ ٧ ٦ ٥ ٤ ٣ ٢ ١ ٠

10= راضٍ جدا | **5= راضٍ الى حد ما** | **صفر=غير راضٍ ابدا**

7- كم من **المرجح أن ترتدي** جهاز ازالة الضغط **في حال تم وصفه مرة اخرى؟**
ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 الى ان ارتداء جهاز ازالة الضغط مرة اخرى غير مرجح ابدا، ويشير الرقم 5 الى ان ارتداء جهاز ازالة الضغط مرة اخرى مرجح الى حد ما ويشير الرقم 10 الى ان ارتداء جهاز ازالة الضغط مرة اخرى مرجح جدا.

١٠ ٩ ٨ ٧ ٦ ٥ ٤ ٣ ٢ ١ ٠

10= مرجح جدا | **5= مرجح الى حد ما** | **صفر= غير مرجح ابدا**

8- ما مدى **الثقل** الذي وجدته في ارتداء جهاز ازالة **الضغط ؟**
ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 الى ان جهاز ازالة الضغط غير ثقيل ابدا، ويشير الرقم 5 الى ان جهاز ازالة الضغط ثقيل إلى حد ما، ويشير الرقم 10 الى ان جهاز ازالة الضغط ثقيل جدا.

١٠ ٩ ٨ ٧ ٦ ٥ ٤ ٣ ٢ ١ ٠

10= ثقيل جدا | **5= ثقيل الى حد ما** | **صفر= غير ثقيل ابدا**

9- ما مدى **الصعوبة** التي وجدتها في **ارتداء جهاز ازالة الضغط** الموصوف لك؟
ضع دائرة حول **أي رقم** على الخط أدناه والذي يتراوح من 0 إلى 10 للإشارة إلى المستوى الذي تعتقد أنك فيه، حيث يشير الرقم 0 الى ان ارتداء أو نزع جهاز ازالة الضغط غير صعب ابدا ، ويشير الرقم 5 الى ان ارتداء أو نزع جهاز ازالة الضغط صعب إلى حد ما، ويشير الرقم 10 الى ان ارتداء أو نزع جهاز ازالة الضغط صعب جدا.

٠ ١ ٢ ٣ ٤ ٥ ٦ ٧ ٨ ٩ ١٠

صفر= غير صعب ابدا | **5= صعب الى حد ما** | **10= صعب جدا**

10- يستفسر هذا السؤال عن **الدعم الأسري** الذي تتلقاه أثناء فترة علاجك بجهاز ازالة الضغط. **كم في العادة يساعدك فيها** أفراد الأسرة أو شخص ما عند **ارتداء** او **نزع** جهاز ازالة الضغط الخاص بك؟

- دائما
- عادة
- بعض الأوقات
- نادرا
- ابدا

تهدف الأسئلة 11-16 إلى التحقق عن كم من الوقت وكم عدد المرات التي ترتدي فيها جهاز ازالة الضغط (حذاء/ بوت ازالة الضغط) في داخل وخارج منزلك.

11- يرجى تخمين **نسبة الوقت** الذي ترتدي فيه جهاز إزالة الضغط في اليوم العادي (ما عدا أوقات النوم).
ضع دائرة حول أي رقم على الخط أدناه والذي يتراوح من 0 إلى 100 للإشارة إلى مقدار التزامك.حيث تشير نسبة 0٪ أنك لا ترتدي جهاز ازالة الضغط في أي وقت خلال اليوم ، و 50٪ تعني أنك ترتدي جهاز ازالة الضغط نصف الوقت في اليوم و 100٪ تعني أنك ترتدي جهاز ازالة الضغط باستمرار طوال اليوم.

%٠ ١٠ ٢٠ ٣٠ ٤٠ %٥٠ ٦٠ ٧٠ ٨٠ ٩٠ %١٠٠

صفر%= لا ارتدي جهاز ازالة الضغط في أي وقت خلال اليوم | **50%= ارتدي جهاز ازالة الضغط نصف الوقت في اليوم** | **100%= ارتدي جهاز ازالة الضغط باستمرار**

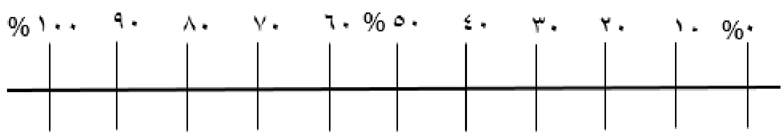
12- كم من **الوقت** ترتدي جهاز ازالة الضغط **داخل** المنزل؟

- كل الوقت
- معظم الوقت
- بعض من الوقت
- القليل من الوقت
- لا شيء من الوقت

13- كم من **الوقت** ترتدي جهاز ازالة الضغط **خارج** المنزل؟

- كل الوقت
- معظم الوقت
- بعض من الوقت
- القليل من الوقت
- لا شيء من الوقت

14- يرجى تخمين **نسبة الخطوات** التي ترتدي فيها جهازازالة الضغط في اليوم العادي (ما عدا النوم).
ضع دائرة حول **أي رقم** على الخط أدناه والذي يترأوح من 0 إلى 100 للإشارة إلى مقدار التزامك، حيث حيث تشير نسبة 0٪ أنك لا ترتدي جهاز ازالة الضغط في أي خطوة خلال اليوم ، و 50٪ تعني أنك ترتدي جهاز ازالة الضغط نصف الخطوات في اليوم و 100٪ تعني أنك ترتدي جهاز ازالة الضغط في كل خطوة طوال اليوم.



صفر= لا ارتدي جهاز ازالة الضغط في أي خطوة خلال اليوم

50%= ارتدي جهاز ازالة الضغط في نصف الخطوات خلال

100%= ارتدي جهاز ازالة الضغط في كل خطوة ممكنة

15- كم في العادة ترتدي جهاز ازالة الضغط **داخل** المنزل؟

- في كل خطوة
- في معظم الخطوات
- في نصف الخطوات
- فقط في بضع خطوات
- ولا حتى خطوة واحدة

16- كم في العادة ترتدي جهاز ازالة الضغط **خارج** المنزل؟

- في كل خطوة
- في معظم الخطوات
- في نصف الخطوات
- فقط في بضع خطوات
- ولا حتى خطوة واحدة

17- يستفسر هذا السؤال عن معتقداتك حول الالتزام بارتداء جهاز إزالة الضغط. إلى أي مدى توافق على أن المشي لمسافة قصيرة (على سبيل المثال مسافة تصل إلى 5 أمتار داخل المنزل) بدون جهاز ازالة الضغط لن يكون ضارًا بجرحك.

- أوافق تماما
- أوافق باعتدال
- لا أوافق ولا اعارض (محايد)
- أعارض
- أعارض بشدة

Appendix 21: Summary of the validity and reliability of Fitbit Flex© (FF)

Study	Population	Method	Validity	Reliability
Diaz et al (448)	23 healthy participants	Two FF were fitted on both the right and left wrists during four activities of walking on a treadmill (slow, moderate, brisk, paces, and jogging) Validity was assessed by comparing the recorded steps of the FF with the observed steps Reliability was assessed by a comparison between both wrist trackers	Wrist steps by using FF were strongly correlated with the observed steps which was 0.77–0.85 The mean difference between the counted steps and the observed ranged 2.9-26.3 steps	Inter-device correlation of the recorded steps between right and left FF was 0.90
Smith et al (449)	32 participants using lower limbs prosthetics	FF were fitted on both right and left wrists of individuals who were using lower limb prosthetics and who walked in an indoor flat surface (140M) Validity was assessed by comparing the recorded steps of the left wrist with the observed steps Reliability was assessed by a	There was moderate agreement between the left FF and the actual steps; (ICC = 0.843, 95% CI [0.683–0.923]) Error was 8.3% (19.4± 22.3 steps)	The agreement between both wrists using FF was low (ICC < 0.8) but no significant difference (p=0.007)

Study	Population	Method	Validity	Reliability
		comparison between FF trackers in both wrists		
Nelson et al (450)	30 healthy participants	FF were fitted on the non-dominant wrist of participants during different activities (sedentary, household, walking, and ambulatory) Validity was assessed by comparing the recorded steps of FF with the observed steps as well as a criterion model (Omron HJ-113) Mean absolute percent error (MAPE) was also calculated No reliability testing	In comparison with observed steps (during walking), FF significantly underestimated steps by 7% (P = 0.034) In comparison with Omron HJ-113 (during walking), FF significantly overestimated steps (P>00.1) MAPE (walking steps) in comparison with the observed steps was 8%	-
An et al (451)	35 healthy participants	FF were fitted on the left wrist of participants during walking on a treadmill, overground, and 24 hours monitoring Validity was assessed by comparing the recorded steps of FF with the observed steps (treadmill & overground) as	Correlations were: - Treadmill, r=0.8, p<0.01 (2-talied) - Overground, r=0.8, p<0.01 (2-talied) - 24-hour, r=0.9, p<0.01 (2-talied)	-

Study	Population	Method	Validity	Reliability
		well as a criterion model (New Lifestyle-NL-1000 Series) for 24 hours monitoring MAPE was calculated No reliability testing	MAPEs (Speed=2.5 mph) were: - 6.2% (Treadmill) - 8% (Over-ground)	
Burton et al (452)	31 older community-dwelling adults (≥65 years)	Validity and reliability were checked in the lab through two-min-walk-test (2MWT, 2 tests) and free-living environment (14 days) In the lab, validity was assessed by comparing the recorded steps of FF with the observed steps In the living environment, validity was assessed by comparing FF with a criterion model (GENEactiv, wrist-worn) Reliability was assessed by: - Test-retest reliability: comparing 2MWT (1) with 2MWT (2) - Inter-device reliability	Intraclass correlations (ICC,95%CI) was used: - Criterion validity of steps (FF VS Observed) was high in both 2MWT1, and 2MWT2 at 0.77 (95%CI: 0.57–0.88) and 0.76 (95%CI: 0.53–0.88) respectively - Criterion validity of distance, steps (FF) and moderate-to-vigorous physical activity (GENEactiv), there was good agreement; Spearman Rho= 0.78 for the free-living environment	Test-retest reliability of using the same FF between 2MWT (1) and 2MWT (2) was excellent, which ICC of using two FF in two tests was 0.79, 0.87 (95%CI: 0.57-0.90, 0.73-0.94) - FF (blue), 2MWT (1): 198 (30.9) - FF (blue), 2MWT (2): 195 (28.8) Mean difference: 2.87 (95%CI: -6.26, 12) Mean proportional difference -FF (black), 2MWT (1): 196 (23.9) - FF (black), 2MWT (2): 198 (26.5) Mean difference: -2.13 (95%CI: -8.46,4.2)

Study	Population	Method	Validity	Reliability
				Inter-device reliability by comparing two FF (blue, black) in 2MWT (1) was excellent, which ICC = 0.88 (0.75, 0.94) In 2MWT (1): FF (blue): 198 (30.9) FF (black): 196 (23.9) Mean difference was 2.5 (95% CI: -4.2,9.2)
Alharbi et al (453)	48 cardiac patients	Validity was assessed by comparing the recorded steps of FF with the with a criterion model (Actigraph GT3X, waist-worn) in four days of monitoring	Steps counts of FF were significantly correlated with Actigraph GT3X; r = 0.95, p=0.01	-
Sushames et al (454)	25 healthy adults	Validity was assessed by comparing the recorded steps of FF with the observed steps (lab) and a criterion model (Actigraph GT3X+, waist-worn (free-living) Reliability was assessed by test-retest	Intraclass correlations (ICC,95%CI) was used: - Criterion validity of steps (FF VS Observed in lab): ICC was poor (r=0.1-0.3) - Criterion validity of steps (FF VS Actigraph in free-living): ICC was high (r = 0.5–1.0)	Mean steps of FF in test 1= 588.1 (21.8) Mean steps of FF in test 2= 583.1 (17.3) The mean absolute difference in steps of FF (test 1 & 2) ranged from 71.9 for walking to 83.1 for incline walking. The mean proportions of these differences were

Study	Population	Method	Validity	Reliability
				13.6% (95%CI 4.6–22.6) for walking and 12.3% (95%CI 7.8–16.9) for incline walking FF had a moderate correlation for the walking activity during test-retest (ICC = 0.57, 95%CI: -0.02,0.82, p = 0.028)
Kooiman et al (455)	33 healthy adults for lab setting and 56 for free-living condition	FF were fitted on the non-dominant wrist Validity was assessed by a comparing the recorded steps of FF with a criterion model (Optogait system for lab and ActivePAL for free-living condition) Reliability was assessed by test-retest (treadmill walking)	MAPE was used to test validity: - Criterion validity of steps (FF VS Optogait in lab): ICC= 0.22 (p<0.05, 95%CI=-0.08%-0.5), MAPE of FF was 5.7% - Criterion validity of steps (FF VS ActivePAL) in free-living condition: - ICC=0.96% (p<0.01, MAPE of FF was 3.7%, 95%CI=0.94%-0.98%)	FF had good reliability; ICC=0.81 (p<0.01, 95%CI =0.64%-0.91%)

Appendix 22: Adherence measurement protocol (pilot test)

Background: Adherence to wearing RCWs was mainly measured objectively by counting the amount of weight-bearing activity (steps) while wearing the offloading device for seven days. This was through using commercial activity trackers (Fitbit Flex© (FF)).

Aim: To pilot test the protocol of measuring adherence to wearing RCWs among patients with DFUs. This included testing the feasibility of using these devices in terms of data management, device usability, battery power, and patients' interaction.

Date: 3 – 15 September 2019.

Sample: Two participants, who had DFUs and used RCWs, were recruited.

Measurement tool: Two activity trackers (FF).

Procedure:

- The FF trackers were calibrated by the PhD candidate including entering the participants' personal information (gender, height, and weight) in the software.
- The first activity tracker was worn on the wrist using a band. The second tracker was attached to the offloading device by using strong adhesive dressing (Curafix \ LR) (see Figure 1,2).
- Participants were instructed to adhere to wearing the wrist bands all the time including bathing or sleeping. However, they were free to remove them during sleeping if they become uncomfortable.
- All the instructions regarding the study protocol were provided to participants in a written information sheet that had the contacts of the PhD candidate.
- Participants were advised to call the PhD candidate anytime if they needed help.
- Participants were reminded by phone calling or messaging on a daily basis to wear the wrist band.
- The main aim of using the trackers was concealed from participants, then the PhD candidate revealed the aim and explained it after the study finished.
- Participants returned the FF trackers during their regular wound care visits (After at least 7 days of observation).

- The FF trackers saved data for 28 days then data were uploaded to Fitbit cloud storage. The PhD candidate downloaded the data from the Fitbit software (dashboard) (456). Every tracker has its own Fitbit account and code and each participant had two Fitbit codes. All the data (non-identifiable) were saved on Fitbit cloud servers and the PhD candidate can access the data by using the Fitbit accounts.

Case 1 (Code: 4D)

- Age: 58 years
- Gender: Male
- Date of measurement: 3 of Sep - 11 of Sep 2019


Figure 1: Attaching FF trackers on the offloading device and the wrist of Participant 4D (NCDEG)

Pilot results:

- The FF trackers successfully recorded the participant's steps on both wrist and the offloading device with no issues.
- The battery life was good as after 7 days of observation more than 30% of the remaining battery was present.
- The data was accessed with no reported issues.

- The participant was comfortable during using the wrist band tracker with no reported issues.

Case 2 (Code: 1A)

- Age: 58 years
- Gender: Male
- Period of measurement: 9 of Sep - 15 of Sep 2019

Figure 2: Attaching FF trackers on the offloading device and the wrist of participant 1A (NCDEG)

Pilot results:

- The FF trackers successfully recorded the participant's steps on both wrist and the offloading device with no issues.
- The battery life was good as after 7 days of observation, there was more than 25% of the remaining battery in both trackers.
- The data were as recorded with no reported issues.
- The participant was comfortable using the wrist band tracker with no reported issues.

Appendix 23: Adherence data and calculations

- The recorded steps during each 15-minutes time-stamp for each tracker were checked on each recorded activity in the Fitbit dashboard (see Figure 1).

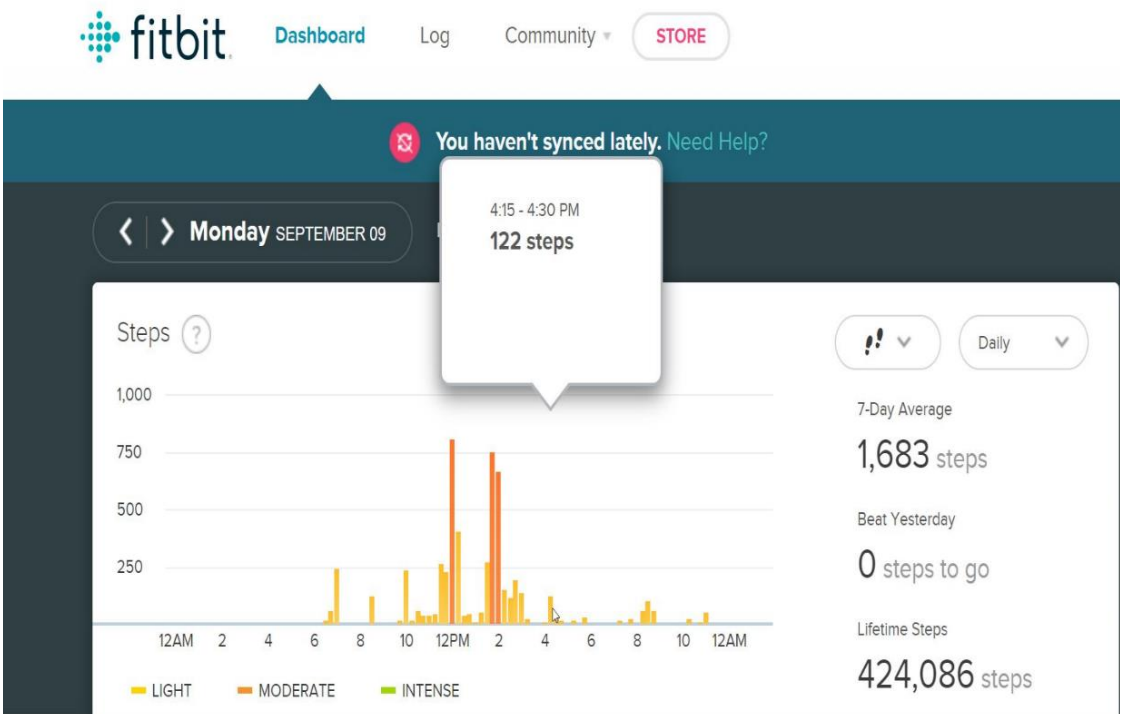


Figure 1: Fitbit dashboard shows the wrist recorded steps at 4:15-4:30 time-stamp of participant 4D on 09 Sep 2019

- All the step data for each 15-minute time-stamp for both trackers were entered manually into Excel spreadsheets during the recorded period (3-7days) for all participants (see Figure2).
- Activity units (cells) were coded as adherent (coloured in green) if the number of RCW steps was more than half of the number of wrist steps (see Figure2).
- Activity units (cells) were coded as non-adherent (coloured in yellow) if the number of RCW steps was less than half of the number of wrist steps (see Figure2).
- Activity units (cells) were coded as missing adherence data (coloured in orange) if the RCW steps were only recorded without any wrist steps recording (see Figure2).

1															
2	Participant 50	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7	
3	Time-stamp	Wrist steps	RCW steps	Wrist steps	RCW steps	Wrist steps	RCW steps	Wrist steps	RCW steps	Wrist steps	RCW steps	Wrist steps	RCW steps	Wrist steps	RCW steps
4	12:00 - 12:15 AM							87	4	16	10	9		26	
5	12:15 - 12:30			4		8	15	65	48	57				42	
6	12:30 - 12:45				19	32	25	48	70	103	9			47	
7	12:45 - 1:00			58		111		79	94	287				57	55
8	1:00 - 1:15			111		69		230						105	
9	1:15 - 1:30			46						10				49	256
10	1:30 - 1:45					95		5		22		17		386	11
11	1:45 - 2:00					82						6		77	
12	2:00 - 2:15			6				9		33				81	
13	2:15 - 2:30			13								27		145	
14	2:30 - 2:45			13				47				4	24	99	
15	2:45 - 3:00							15		21		19		88	
16	3:00 - 3:15							101				164		46	
17	3:15 - 3:30					33		38				84			
18	3:30 - 3:45					96				37				68	
19	3:45 - 4:00									66		47		20	
20	4:00 - 4:15											36			
21	4:15 - 4:30		10					91		7		24		27	
22	4:30 - 4:45	9	18												
23	4:45 - 5:00					168						16		73	
24	5:00 - 5:15														
25	5:15 - 5:30														
26	5:30 - 5:45					14		8				16			
27	5:45 - 6:00							22							
28	6:00 - 6: 15														
29	6:15 - 6:30														
30	6:30 - 6:45							157							

Figure 2: The coded time-stamped based on adherence activity (green: adherence, yellow: non-adherence, orange: missing-adherence)

- The overall percentage of adherence to wearing RCWs during an activity during the measurement period (3-7 days) was calculated by counting all the green cells (adherence units) divided by all the activity units (wrist activity; green and yellow) (see Figure 3).
- Orange cells (missing-adherence units) were excluded from calculating adherence.
- The coloured cells were counted using the “get colour count” function in Excel (see Figure 3).

B111

	A	B	C	D	E	F	G	H	I
80	7:00 - 7:15			25	40	69	14	81	208
81	7:15 - 7:30			88	29	162	290	15	
82	7:30-7:45					32	22	6	
83	7:45 - 8:00			6		83	59	27	
84	8:00 - 8:15					88	34		
85	8:15 - 8:30			55	27	25	15	9	32
86	8:30 - 8:45			36	29	5			7
87	8:45 - 9:00			78	155	29	14	34	52
88	9:00-9:15					67		19	44
89	9:15 - 9:30					166		67	69
90	9:30-9:45			91	147	312	123		
91	9:45 - 10:00					72			
92	10:00 - 10:15			70	94	173			
93	10:15 - 10:30					111	32		7
94	10:30-10:45			8		35	19	90	63
95	10:45-11:00			9		8		124	79
96	11:00 - 11:15			4				28	
97	11:15 - 11:30			11		54	16		
98	11:30-11:45			7	38				
99	11:45-12:00 AM					18	37	41	24
100									
101									
102	Adherence act	192							
103	Nonadherence act	210							
104	Overall activity	402							
105	Adherence (%)	47.80%							

Figure 3: Calculation of adherence percentage: adherence % = adherence activity (green units; if RCW> 0.5Wrist) / Overall activity by wrist (green and yellow units)

Appendix 24: Themes, categories, and codes of Study 1

Theme 1: Reporting of adherence was varied and inconsistent.	
Category	**Transcript**
Category 1: The belief of achieving optimal adherence	*... The period, which I wear the device is from the morning at approximately 10 am until 10:00 pm or 11 PM... [P3C]*
	…If I want to sit all day, I prefer to wear it. Let's suppose that after a while I need to stand and walk to do something, instead of always keep removing or bracing it, I shall be wearing it, you know... [4D]
	... which means wearing it for 12 hours and at 1 o'clock I take it off... [P6]
	... I mean it's good and perfect **(the participant described the device)** *but only for the daytime for a period of 12 hours. Then I go to sleep. It is possible to stay waking up with some people until 10-11 pm, I mean it is mostly from morning to more than 12 hours, the normal situation is around 12 hours... [Pt8H]*
	…but wearing it all the time, honestly, No… [P1]
	…I may adhere using it around 80%, possibly between 75-80%... [P1]
	…after evening, after Maghreb **(sunset)** *prayer; I mean most of the days, I used to take the boot off... [P2]*
	… Do you mean the times? that I don't wear it? No, there is no specific time, only the time that I told you when I feel it uncomfortable... [P5]
	…I mean, I wear it outside. When I leave home, I wear it. I adhere, for example, wearing it four to five hours, but inside the home, I don't wear it, No… [P7]
	… I only wear it 2 times in a week; when I go to the hospital or if I want to go outside home, I wear it. I mean there is no specific time but most of the time I do not wear it. I mean I have one or two trips to the hospitals and sometimes I must go to clinics, it is possible to wear it three times… [P7]
	…In most times I don't wear it. I don't wear it because it has some negative issues... [P9]
	…No, no. it is possible that I don't wear it for a period of one month... [P9]
Category 2: Adherence during indoor activities seemed challenging	*… I don't wear it during sleeping, having have a nap or sitting in the mid of the day. I mean when there is no walking… [P1]*
	…. of course, when I sleep (not wearing it) …. [P3]
	…but if I want to relax during the day, I mean if I have nothing to do, I take it off. Then, I wear it back again when I wake up. When I want to sleep at night, I take it off, but I have to keep wearing it… [P4]
	… Mostly, I take it off when I go to sleep… [P6]
	…I was when I sleep, I put it next to my head. When I wake up, I put it on quickly. I mean within two months and a half I haven't stepped on the ground without it… [P10]
	…I can't keep it on and sleep in it, I can't… [P8]
	…I mean... Ahhh at evening time and some afternoon time. For example, sometimes when I am walking, after walking it is annoying… [P5]
	…I think that I am able to keep wearing it but as I told you if I take it off to relax or at night when I want to sleep, of course, I have to walk without it… [P4]
	…my adherence to it was when I sleep, I put it next to my head. If I want to go to the toilet, I wear it and I enter the toilet with wearing it… [Pt10J]
	…. but if I already wake up and I want to go to the toilet, I don't pay attention to this **(wearing the device)** *…. [P1]*
	…If I want to go to the bathroom, I do not wear it… [P3]
	…If I take it off, you can say at 1 or 12:30 PM, I mean, I take it off at 12 PM, because I have diabetes, I may go to toilet one or two times only, but I wear it at morning… [P6]
	…If I want to enter the toilet at night, it is hard. So, I am forced to walk on the tips of, my toes… [P8]
	…I think that I am able to keep wearing it but as I told you if I take it off to relax or at night when I want to sleep, of course, I have to walk without it… [P4]
	my adherence to it was when I sleep, I put it next to my head. If I want to go to the toilet, I wear it and I enter the toilet wearing it… [P10]

	…No, just when I want to take bath only, during bath only… [P5]
	…Just when I want to do ablution, like this I mean…[P3]
	…When I open my eyes, I go to do ablution then I wear it for all day until I sleep… [P6]
	…I have a yard at home, I have trees. when I go outside for trees, I wear it for outside but inside home, it is difficult…[P7]
	…I mean, I wear it outside. When I leave home, I wear it. I adhere, for example, wearing it four to five hours, but inside the home, I don't wear it, No…[P7]
	…I cannot wear it inside the home, it is difficult. I mean… My need for a toilet is continuous, I go to the toilet a lot. Basically, the source of problems is obesity. I mean overweight forces me to go to the toilet a lot…[P7]
	…I wear it only when I go out of the home, but inside home, No… [P7]
	…The carpet!! For the aim of hygiene, I mean we pray in any spot at home, it is only for hygiene, going to the toilet and come back with the boot is difficult for me…[P7]
Category 3: RCWs were not worn in some short distances (few indoor steps)	*…Sometimes during walking, I used to walk on my heel without using it, only on my heel… [P1]*
	…Very little steps, this is not a big issue, it does not matter. 2 - 3 meters is not that long… [P3]
	…Walking without it? they are few steps… …Without it, not a lot… [P4]
	…I mean, sometimes, for example, when I am at bedroom or I am lying, I might go and open the room door, like this, open or close the room door. You can say within the room borders… [P1]
	…When the distance is only half a minute, I mean inside the room. But until now I have never been outside the home without using it… [P1]
	…Just if I want to walk to do a necessary thing, for instance, it takes time when I lace it and stuff like this. Just something important, Just I walk without it, only inside the home, I mean not outside, and for short time… [P4]
	…Nothing, I mean they are few steps, in our living room from 2-3 meter, only, from the room to the kitchen and to the bathroom, only… [P4]
	…. but If I already wake up and I want to go to the toilet, I don't pay attention to this **(wearing the device)** *…. [P1]*
	Researcher: When do these steps happen? Participant: when I want to enter the bathroom [P3]
	…If I take it off, you can say at 1 or 12:30 PM, I mean, I take it off at 12 PM, because I have diabetes, I may go to toilet one or two times only, but I wear it at morning… [P6]
	…It is nothing. I have my own toilet, which is few steps away from here… [P6]
	…If I want to enter the toilet at night, it is hard. So, I am forced to walk on the tips of, my toes… [P8]
	…I do not wear it when I enter the toilet for a distance of 6-7 meters… [P8]
	Researcher: what about the steps inside the home? Participant: No, No. Researcher: at all? Participant: at all. [P5]
	…I mean I have not walked on my foot without the device for two months and a half, not a single step, nothing, I have not stepped on the ground just only with the device... [P10]
	…. when I sleep, I put it next to my head. When I wake up I wear it quickly. I mean within two months and a half I haven't stepped on the ground without it…[P10]

Theme 2: Adherence was a consequence of multiple psychosocial, physiological, and environmental factors

Category	Sub-category	Transcript
Category 1: Specific offloading knowledge and beliefs	Misbeliefs that RCWs was not a priority DFU treatment	*…the first thing is to control diabetes… [P1]*
		…hmmm as I told you, I will advise him to control diabetes and not neglect his foot… [P1]
		…according to my information; it is important to control the food; the individual should control his food and avoid eating sweets or

influence adherence		*sugar in an uncontrolled manner. Starch, mmm, not doing stuff like this, or anger… [P4]*
		…I advise him to control his food in the first thing… [P4]
		…the first thing is that the diabetic wound does not need sugar to eat. The individual should follow the diet, and persons who are obese should lose weight, this is a fundamental condition, I mean the normal person whose weight suits his height, his diet is normal, but the obese guy eats more and thus his blood sugar will increase, that's normal. Either hypertension or diabetes affects his health, and this is the probable reason why the wound takes a long time to heal.... because of his increased weight I mean…. [P7]
		…according to my information; it is important to control the food; the individual should control his food and avoid eating sweets or sugar in an uncontrolled manner. Starch, mmm, not doing stuff like this, or anger… [P4]
		…The antibiotic medication comes in the first… [P5]
		…Care is in the first demand… [P8]
		…the physician, the recommended boot and it is possible that this boot has huge importance. But the physician role comes before the device, and his treatment is the most important issue in such treatment… [P9]
		…Treatment is represented by the care that I have received here which is gel substance, silver substance… [P10]
		…you just wear it in the cases that need a longer duration of treatment. I mean some ulcers are simple, I mean it is just by one dressing or two, there is no need to wear it, and so I wear normal shoes as I told you. If the wound, you know the wound at the beginning has an infection, it needs antibiotics and sometimes injections, in specific phase I took injections in addition to the boot, all these things facilitate… [P8]
	Substantial knowledge of the reason of offloading treatment	*…I think as I have a wound and amputation, this boot can slightly help to heal the wound… [P1]*
		…Patients should adhere to wearing it, to help in wound closure… [P1]
		…I think the wound itself will be affected as its healing mmm will not be fast… [P1]
		…Now, the second thing is offloading, I feel that I was walking on air, so this helps to heal the wound… [P5]
		…because the wound is located in a place that is affected by high pressure, and it has not been healed without using the boot, waiting for the god, this is the first thing… [P7]
		…It holds despite the boot is not working. If I stand in the air and I don't take steps, it is not the matter, I mean, from my experience, this could be a direct cause. If the boot works probably, it blows the air, it possibly has healed faster than this… [P7]
		…because the wound is located in a place that is affected by high pressure, and it has not been healed without using the boot, waiting for the god, this is the first thing… [P7]
		… So, it is better than anything as it helps in many times for cure and wound healing in a shorter time from the expected duration, it shows the results faster… [P8] *…because I want to be cured* **(the reason for wearing the device)**, *I mean I feel that my foot is being destroyed slowly, I mean, I wished to see this one like this. I have been 10 months and this one is swollen, it was when I sleep and during wakeup in the morning, it was a little venting… [P 10]*
		…ahhh, I wanted it to improve **(the reason for wearing the device)** *… [P 10]*

		…Secondly, aeehh, my body weight when I stand, or walk will not be concentrated on the foot directly as my wound starts to open like what the rustics always say. So, the pressure shall always be distributed… [P1]
		…it also mmm support the foot little bit, support it, so when you are walking… [P1]
		…the first thing is relieving the pressure. The boot works to relieve the pressure from my big toe aeeeeh…[P2]
		…it works to lighten the surface pressure on the wound… [P2]
		…The device, it is to avoid pressure on the wound as much as possible… [P3]
		…The first thing that to do, mmmm, removing the pressure that falls on the wound… [P4]
		…The benefits are removing the pressure, it looks like an Airbags… [P5]
		…The first thing is to have some rest. Secondly, stay at my home, because this will reduce the pressure on the wound…[P6]
		…because it reduces the pressure and I also have an extra weight which is increasing more. It is increasing from insulin. With the extra weight, when I push my foot the ulcers will open more. This boot reduces the pressure on feet significantly. This is what makes me wear it most of the time… [P6]
		…it is located in a sensitive place and it is on the pressure, I mean as there is weight, it is a pressure. I mean all the toes, if you push, all the pressure affects behind the toes in the high area, all the pressure affects it, it is the region that I have the amputation, in these areas… [P7]
		…I find the boot appropriate to wear. I mean I wear it as it protects me from many things because I have extra weight more than the normal limit and there is a pressure on the foot that results from fracture… [P8]
		…The device is good, but I mean let me say that it takes away the pressure from the wound but at the same time it has negatives… [P9]
		…the device? Because it does not put pressure on the wound, I mean the pressure is focused on the columns, on right and left sides, in addition to reducing the movement. Also, the sponge from the bottom, which prevents treading on the wound… [P10]
		…they will amputate my whole foot…. this means another amputation will be done, but this time it shall be larger, compared to the first one… [P2]
		…Wearing the boot outside the home is better than going outside the home with amputated leg... [P2]
		…In fact, this is what I believe in. Going outside with the boot is safer than leaving the house with an amputated leg. This encourages me a lot… [P2] *…It is possible that the wound dilates and also may open again and become infected… for sure… [P3]*
		…It is possible that new ulcers can emerge… [P3]
		…If you pressure the wound without wearing the boot, the wound extends. It will become larger as it is affected by pressure… [P4]
		…the wound will be worsened instead of getting better… [P5]
		…It is possible that I will not walk at all and these ulcers might increase if I don't adhere to it… [P6]
		…aaah, its healing is poor. possibly, it is from the weight, I put all the blame on the weight… [P7]
		…the foot kept swollen. If I don't treat it, I mean it will be cut… [P10]

		…The device is not effective but, in all cases, wearing the device is much better than otherwise… [P3]
		…I don't see a lot of benefits because the device is heavy and tiring… [P3]
		…According to my experience, I don't find it as an effective issue… [P3]
		when I wear the device, I don't benefit from using it. The wounds are still the same. The pain, the infections still the same. Aaaah, I don't see any progression in it… [P3]
		…They say that it cures at 50%. But what I feel, this is not completely true… [P3]
	Misperception of meaning of optimal adherence	*…If I wear it to go and open the door then come back to my bed and remove it (the offloading device), it affects me psychologically and it does not worth… [P1]*
		…very little steps, this is not a big issue, it does not matter. 2 - 3 meters are not that long… [P3]
		…I am telling you I wear it just for necessity. I mean sometimes, when I need to go quickly to the toilet, so I want to walk quickly, you know, so I don't wear it. I wear regular stuff that does not put pressure on the wound, I walk on the heel backward, like this. It is a very short time; it is not a lot that I don't use it… [P4]
		…it is nothing. I have my own toilet, which is few steps away from here… *…No, No, it is a short time, that I walk without it. Not a little. My sons see me, they don't see me at all without it… [P6]*
		…there are no harms, but it is better for the individual to wear it. It is better to be wearing it, the more he wears it, the more it reduces the pressure on his foot a lot… [P7]
		…. No, no, I don't find it necessary… [P8] **(wearing the device for every step is not necessary according to the participant)**
		…when I find myself, I mean in a condition with a foot infection, or wound, at this time I have to wear it. I mean when it is necessary, not always… [P9]
		…let's say that the wound, I mean my wound does not bleed a lot, it produces a white sticky substance, this is what my wound produce, so I always wear normal shoes, or I always stay in bed or the couch but elevating my leg and the boot, this device, I don't wear it… [P9] *…walking, walking. I mean let me be honest with you, I walk only for the necessary trips (walking without the device) … [P9]*
		…Patients should adhere to wearing it, to help in wound closure… [P1]
		…Wearing boot and psychological comfort; is what I feel, adherence to boot and psychological comfort (the factors that heal the wound) … [P2]
		…The major Factor related to wound healing is for sure, wearing the device… [P3]
		…You know, ideally, I should wear it during sleeping as it provides better results as the guys here told me… [P8]
		…but as the boot, I can adapt it easily. It is normal because I am not the only person who wears it, but there more, that are in need to wear it, which is very necessary… [P8]
		…100% I will be cured **(if adherence is perfect)***, I will be cured but it may need a period of months and this is unbearable… [P9]*
		…If I have not adhered it, I haven't been cured now… [P10]
	The belief of difficulty to	*…but complete adherence means wearing it all day, mmmm, It may be hard for me… [P1]*
		…it's very hard to apply… [P3]

	adhere to wearing RCWs for every step	*…every step at home you mean? Every step, it is too hard, very hard… [P3]*
		…ok, I exploit my full strength if I want to wear it for the toilet then take it off, I need to use my efforts, as I am fear from falling, I always feel afraid. Because of this, I refuse to go there then come back then taking it off in the toilet then I wear it, I can't, I can't, I mean my health does not help me to keep always taking it off and wearing it again… [P6]
		…I have told you if I have somebody at home such as a daughter, it is possible to wear it then go to the toilet, take it off for ablution then she; puts it on for me but wearing it and taking off it by myself, it is difficult… [P6]
		…I have to say it is difficult, it is hard in every step… [P6]
		…No, I mean it is around 45%. It's hard for me to wear it and stay at home, it is very hard for me… [P7]
		…I have a yard at home, I have trees, when I go outside for trees I wear it for outside but inside the home, it is difficult…[P7]
		…I cannot wear it inside the home, it is difficult. I mean, my need for a toilet is continuous, I go to the toilet a lot. Basically, the source of problems is obesity. I mean overweight force me to go to the toilet a lot… [P7]
		…I can't because diabetic patient goes a lot to the toilet, so I can't adhere to the boot inside home…[P7]
		…I can't keep it and sleep in it, I can't… [P8]
		…I can't, If I wake up from sleeping, I want to wear it, I need somebody to help me to dress it as a result of the health condition that results from the foot. If I were in my normal condition, I would wear it and walk… [P8]
		…but because of its heaviness, I can't go on with it, I mean it is possible that sometimes this last for months… [P9]
		…but in the current situation, the degree of difficulty is high but if it changes I may wear it forever, I don't care. It does not matter for me at that time, the difference is in its effectiveness… [P9]
		…I can, yes. But sometimes I skip, hahhaah… [P2]
		…yes, yes, yes!!!... [P2] **(participant's answer for the ability to wear the RCW for every step)**
		…I think that I am able to keep wearing it but as I told you if I take it off to relax or at night when I want to sleep, of course I have to walk without it… [P2]
		…Yes, I am able to apply it, why not, it is beneficial for me to do anything that can help…[P2]
		…I have applied this for months, I applied it a lot. I am able to apply it, it is not hard but as I told you psychologically. But in terms of ability, I am able, I mean I am able for six months, you can adapt to it… [P5]
		…Off course, I can. For the individual who can't, he does not want to be cured, hahaha, if you don't want to be able, your foot will be stay swelling… [P10]
Category 2: The impact of the severity of foot disease on adherence outcomes	Foot pain forced participants to wear RCWs	*…Also, I will feel pain in my foot when I want to tread the wound without it (The offloading boot) … [P1]*
		…yes, back then **(before using RCW)** *there was a pain and it pecks as the rulers say… [P1]*
		…when I walk without it, it works to bite on the wound. Yes, the wound… [P4]
		…I will not have benefit if I don't wear it or the cast. I don't get the benefit because the pain will occur, I have pain here in this joint. It is also fragile. I mean it supports the foot, you know… [P4]

		…ahhh it **(RCW)** *reduces some pain from me, the pressure affects the front side, you know… [P8]*
	Loss of sensation affected adherence to wearing RCWs	*…If you walk without it, you will not feel your foot as you will not recognize this, thus you will walk* **(walking without the offloading boot)***, you know…[P5]*
	Postural imbalance related to motor neuropathy (foot deformities) or amputations forced participants to wear RCWs	*…when I stand on the wound directly, I feel no balance… [P1]*
		…when I walk on my heel, I feel that I am not balanced, I couldn't maintain my balance during walking on my heels, even for only a few steps… [P1]
		…I am not balanced before I wear it, there is no balance at all. After I wore it, thanks for Allah **(God in Islamic faith)***, I noticed an improvement in my body balance… [P6]*
		…I am telling you that I am not balanced which means if I walk a short distance without it, I may fall… [P6]
		…you will not have to worry much as pressure will affect the foot. This means, mainly, more comfortable, with the boot during walking… [P1]
		… I think mostly the benefit of this boot is for walking as I can take a step in my foot comfortably… [P1]
		…the main reason that I wear it is that I feel comfortable in my foot during wearing it and walking… [P1]
		…your confidence in walking increases… [P1]
		…The most important thing is I become able to go to the bathroom. I couldn't do it, I need two people catching me and walking on one limb by rising the other limb, I was unable to reach the bathroom. Thanks, Allah… [P1]
		…the first thing is that I am able to walk, I become able to walk. Before wearing it, there was no balance at all, if I want to bend my back forward, I fall down, I want somebody to help me, or I may stabilize myself on the wall, chair or any stuff before wearing it… [P6]
		…that is it, I wear it for the reason of walking and to protect the foot bone from extra fractures. This is what makes me wearing it… [P6]
		…from the day that they told me your foot was... Ahhhh, it needs surgery, I had an operation and after two months of the operation, I had from the middle of the bottom of the foot, it has become like this. I walk and I had no balance, I went to the doctor who did the operation and I told him I have no balance,I mean I fall, what can I do, he told me do you have a boot? you need a boot, you can find it in our pharmacy and you need to buy it, then I bought it… [P6]
		…it is very hard to walk these few steps, I hold myself on the door, on the wall, on the chair, on like this… [P6]
		…I am telling you that I become comfortable when I wear it. Thanks, Allah, I have become able to walk. It is possible that some people say, what is walking? What is walking? Walking is the best grace, the grace of walking for humanity… [P6]
		…Nothing negative. Everything is positive, thanks, Allah. The first time I wore it, my husband was surprised how I just walk directly, he said you look like a deer. I told him thanks Allah, from the first time I wore it I was comfortable… [P6]
		…I mean mmm, it helps me to walk… [P8]
		…When I go outside home, I feel wearing the device is more comfortable than wearing shoes or sandal. I feel the device more comfortable for me when I wear it… [P2]

		…So, they offload the pressure on the wound via wearing this boot and you shall walk better with it… [P4]
		…I can walk, and I can move with it. But without it, I can't move, and I get tired If I walk two steps… [P4]
		…it enables me to walk… [P3]
		…Sometimes, I feel that my leg is heavy, and feel tired because the level of the other leg is slightly lower. I started feeling pain in my flanks… [P2]
		… also, that boot was slightly bigger than this then gradually I used to accustom it. This one, I was not wearing it, it's good, thanks, Allah… [P6]
		…Stairs affect a lot when I go up or down the stairs because both legs are not on the same level. One leg is higher than the other one. So, when I go downstairs, all the pressure affects the knee. This what I have felt that it is harmful regarding the boot. If it is possible to provide a shoe with the same height of the boot, I think it will be good… [P7]
		… the only problem is that it is always long and the nature of walking with it, I mean it needs balance. It is possible that the individual who does not have a fracture in his foot finds it comfortable. So, when I wear it, I am imbalanced, so I am forced to take off the other shoe to get the balance and the proper stand then walk… [P8]
	Progression of ulcer healing motivated participants to wear RCWs	*…In fact, the relevant wounds are opened for six years and they are still the same… [P3]*
		…The wounds on my foot should have been healed a long time since… [P3]
		…They say that it cures at 50%. But what I feel, this is not completely true… [P3]
		…When I had the cast, the wound was healed gradually, I mean it was close to healed. Now, after I re-wore the boot, they told me that the wound became larger. I told the nurse here that the wound has become larger, I mean at the beginning it was smaller, so the cast is better than the boot… [P4]
		…Just if I want to walk to do the necessary thing (wearing the RCWs), for instance, it takes time when I lace it and stuff like this. Just something important, Just I walk without it, only inside the home, I mean not outside, and for short time…[P4]
		when I wear the device, I don't benefit from using it. The wounds are still the same. The pain, the infections still the same. Aaaah, I don't see any progression in it… [P3]
		…Also, in each dressing, I take a photo for it and I see the progression from better to better. You can see here, this is at the beginning, this is the dressing after, this is the following one also, there is an improvement, this is the after and the after. I used to take photos for each dressing. I saw that there is an improvement and I say, "this means that I have to keep wearing the boot… [P10]
Category 3: Social support benefited adherence	Support from health care providers	*…look, in the beginning, the doctor or nurses here recommended it for me. Firstly, according to their experience, it is practical stuff for the wound, so they recommended it… [P1]*
		…They told me to wear the boot from when you wake up from bed until I go to sleep… [P2]
		…Also, doctors and nurses here insist that I have to adhere to wearing the boot…. aaaand it's the cure. It works, 99%, to heal the wound…[P2]
		…They say that it cures at 50%. But what I feel, this is not completely true… [P3]
		…You know, ideally, I should wear it during sleeping as it provides better results as the guys here told me… [P8]

		…With this device, I refused the idea of the device at all, but they told me if you want to be cured you must adhere it. So, this device is… thanks, Allah… [P10]
		…I advise him **(Any person who have DFU)** *to control his food in the first thing, also to come to this center; diabetes center, because their available treatments are good. I mean, after I came here, the wound size decreased, it is not like before. It is much better… [P4]*
		…Second, let me tell you that there is a thing which is more important than the device. People who you deal with, guys here, I mean, they have high self-confidence and qualifications. This also has an effect… [P8]
		…thanks Allah, 100% compared to Al Karak **(City in the south of Jordan)**. *I went to doctors in Al Karak, they told me it is cured, it is cured, good, good. But it was not good and was not cured until I came here, thanks to Allah, the improvement is now 100%... [P10]*
	Social support from family	*…my daughters help me in wearing the boot… [P2]*
		Researcher: Ok what are the things that facilitate you in wearing it? *Participant: …When someone helps you to dress it* **(The offloading device)***, and when someone forces you to dress it… [P5]* **(Facilitators to wear the device)**
		…As you can see, my son just takes it off for me. I mean I need help from someone and I am alone at home. If there is someone to help me, it is possible as you say to go with it to the toilet and let someone take it off for me, before doing ablution then wear it again, yes, it is possible, but I don't have anyone at home, all of them have got married… [P6]
		…I have told you if I have somebody at home such as a daughter, it is possible to wear it then go to the toilet, take it off for ablution then she; puts it on for me but wearing it and taking off it by myself, it is difficult…[P6]
		…I can't, If I wake up from sleeping, I want to wear it, I need somebody to help me to dress it as a result of the health condition that results from the foot. If I were in my normal condition, I would wear it and walk… [P8]
		…I need somebody to help me dress, mean for example here the cleaning worker helps me, this is my issue. But, if the condition of my foot is normal, I can easily take it off, but my problem that I need help to dress it, because I can't bend forward… [P8]
		… my daughter always asks me to wear it. My family always insist that I have to wear it to get rid of this thing… [P2]
		…I mean when my wife forces me to wear it, "you are not allowed to take a step on your foot until you wear it'… [P5]
		…Somebody has to help me if I have specific work. Bring me that, give me this. This is from it, from the device… [P3]
		..I have to hold somebody's hand or call someone to help me, I have to I mean… ahhh, it is very bad… [P5]
	General social support	*…Also, when I walk, I see the kids are staring it. They see it as foreign stuff and people look at it and they think that my both legs are amputated are cut, or lost, aaaah I mean people criticise it a lot… [P3]*
		…Psychologically, in front of kids, your psychology like this… [P5]
		…Also, the people when they see me, I feel myself, hmm, I mean my age is 36 years old and when I want to go out in front of people, I feel myself like 70 or 80 years old and this hurts me. "is it ok to hold your hand?", you know, as a man when they ask you to hold your hand, you feel it hard… [P5]

		…it is that with boot your appearance will be different when you wear the boot in this side and sandal on the other side in front of people. I mean I want to get married. I go like this!!, I should be healed and improve myself then I go to the girls' families seeking marriage… [P10]
Category 4: Logistical issues and physical features of RCWs (the usability of the offloading device)	Physical features of RCWs	*…during sitting you feel it is quite heavy. You can say it can be comfortable during sitting if I don't move… [Pt1A]*
		…You can't be fully relaxing when using it… [P1]
		…it is slightly annoying to be used inside the home… [P3]
		…I cannot feel comfortable like a normal person. The normal is better… [P4]
		…when you want to sleep, for example, it prickles the other leg, like this… [P5]
		…it is possible to prickle the other leg, or punches the one sitting next to you… [P5]
		…All the time, for example, I have an uncomfortable feeling because you are bracing it by saying that the pressure annoys you. I need to take it off, then put it back again, I mean in all times. One-step gets you backward… [P5]
		…I mean I can't keep all the weight and hold it from one leg to other and it is uncomfortable for the leg, you know… [P8]
		…I feel tired from it, I think it is enough to feel more tiredness. For example, I do the housework while I am wearing it. It works to make me feel tired… [P2]
		…the device is not easy, it's tiring, so much tiring…[P3]
		…setting also while wearing it is tiring……, everything is tiring… [P3]
		…that I don't wear it because it is tiring… [P3]
		…what I feel that sometimes it bothers me, I feel tired once I wear it…[P3]
		…I don't have the desire to wear it works to let you feel tired; it is very tiring and annoying…[P3]
		…because it is annoying and tiring. It's very annoying…[P3]
		…it is tiring, I can't, I can't, I mean I always take it off and put my leg on the couch, it is more relaxing for me… [P9]
		…I started feeling pain in my flanks. Such pain remains 2 or 3 PM …. like this… [P2]
		…You see…. sometimes it causes pain in my leg… [P3]
		…yes, there is. Now, if walk in it, it pangs me but not too much… [P4]
		…If you would like to walk, it causes pain in back and flanks as well, it causes pain… [P5]
		…The flanks pain as I told you, the pain of this **(this pain results from wearing the device)** *… [P5]*
		…I mean I have pain in my foot from this boot because of the weight and stairs… [P7]
		…Ok, for example, now, I have a problem that for instance, it's from morning to afternoon until I took it off, there was a lot of sweat from the airbags, you feel a lot of sweat. This sweating affects the wound. This what was bad for me… [P5]
		…if I want to move my leg like this I feel it heavy… [P1]
		…but if I want to move I feel my leg is heavy… [P1]
		…Sometimes, I feel that my leg is heavy… [P2]
		…it is a heavy burden as I feel it as a foreign object, like this… [P2]
		…I don't see a lot of benefits because the device is heavy and tiring… [P3]
		…Also, it is heavy, very heavy… [P3]

		…Out of negatives trends is the weight, it is so heavy that is why the individual gives up wearing it… [P9]
		…but because of its heaviness, I can't go on with it, I mean it is possible that sometimes this last for months… [P9]
		…Moving in stairs, going downstairs, you can't, because of its heaviness. I mean its heaviness hits the leg from upper side… [P9]
		…I can bear the wound but not bearing the device, I mean the device is good but the heaviness and, as I told you, it affects the leg, which does not allow me to wear it… [P9]
		…you feel it long **(the device)** *… [P5]*
		…If it is a little shorter, it would be better… [P9]
		…ahhh the third thing is its edges on the upper part which hits the leg during walking. I mean it should be like cotton, to protect the leg because the trouser alone may not protect it. The trouser is thin and with the hit of the device can hit the leg during walking. Once the leg moves, it will hit from front and back… [P9]
		…This should be considered; when I want to walk forward, the hitting comes from the upper part. I repeat and ensure, it is in the upper region. You see this upper region is a tragedy. It prevents the progression of the foot… [P9]
		…I mean, they have to reduce its weight and solve the problem in the top, these are the negatives. If they are solved, I will be happy to wear it… [P9]
		…I mean you see there are two disadvantages, the weight and the leg from the top, Solve it for us. In the bottom is not an issue but from the top is tragedy… [P9]
		…If I wear it to go and open the door then come back to my bed and remove it, it affects me psychologically because it does not worth… [P1]
		… sometimes, I wake up at 7:30. my daughters help me in wearing the boot… [P2]
		…it needs a lot of efforts through putting on or taking off… [P3]
		…each time it needs lacing and I can't wear it. It's slightly annoying… [P3]
		…it is not easy to wear. I have diabetes and I go to the toilet a lot like this, so to wear it each time is a burden for me… [P3]
		…Just if I want to walk to do necessary thing, for instance, it takes time when I lace it and stuff like this. Just something important, just I walk without it, only inside the home, I mean not outside, and for short time…. [P4]
		…All the time, for example, I have an uncomfortable feeling because you are bracing it by saying that the pressure annoys you. I need to take it off, then put it back again, I mean in all times. One-step gets you backward… [P5]
		…ok, I exploit my full strength if I want to wear it for the toilet then take it off, I need to use my efforts, as I have fear from falling, I always feel afraid. Because of this, I refuse to go there then come back then taking it off in the toilet then I wear it, I can't, I can't, I mean my health does not help me to keep always taking it off and wearing it again… [P6] *…I have told you if I have somebody at home such as a daughter, it is possible to wear it then go to the toilet, take it off for ablution then she; puts it on for me but wearing it and taking off it by myself, it is difficult… [P6]*
		…I can't, If I wake up from sleeping, I want to wear it, I need somebody to help me to dress it as a result of the health condition that results from the foot. If I were in my normal condition, I would wear it and walk… [P8]

		I need somebody to help me dress, mean for example here the cleaning worker helps me, this is my issue. But, if the condition of my foot is normal, I can easily take it off, but my problem that I need help to dress it, because I can't bend forward… [P8]
		…if I want to move my leg like this I feel it heavy… [P1]
		…it is that with boot your appearance will be different when you wear the boot in this side and sandal on the other side in front of people. I mean I want to get married. I can't go like this!!, I should be healed and improve myself, then I go to the girls' families seeking marriage… [P10]
		…I mean when you walk by using it and your walk is slow… [P3]
		…Wearing it when I walk is little tiring… [P3]
		…Ahhh, for example, it is stiff, you know, the step-like., I mean it affects the walking as I told you… [P5]
		…I walk slowly also it is very long, they have raised it. Look from here it has risen a lot and this is a problem… [P9]
		…its heaviness makes me subject to falling down. Once I did fall down and suffered a fracture in my arm… [P3]
		…I become cautious when I walk because you may take a step on something slippery because the bottom is like iron… [P4]
		…I mean if I want to go downstairs, just a moment ago, if I was not catching the handrails, I may fall down on my face… [P9]
		…it is that with boot your appearance will be different when you wear the boot in this side and sandal on the other side in front of people. I mean I want to get married. I can't go like this!!, I should be healed and improve myself, then I go to the girls' families seeking marriage… [P10]
	Participants' satisfaction of using RCWs	*…Excellent, excellent, it helps me a lot, I mean, the situation will be better… [P2]*
		…I see it very excellent, thanks, Allah… [P6]
		…I have no complaint… [P6]
		…I have used to it and I have found it good, good what I have found. It is better than without it… [P6]
		…This is good, I mean for anyone who has wound in his foot from the bottom, the device is excellent… [P7]
		…the boot is very excellent, I mean it is very good… [P7]
		…it is excellent, excellent experience, fast in cure and thanks, Allah… [P8]
		…The Shoes started challenging me, I did not know which shoes I have to wear. No shoe fit my foot, my feet get bigger and swollen, no shoe fit them. I have been forced to …, I am psychological comfortable, yes, thanks, Allah… [P6]
		…I became bored… [P2B]
		…Of course, it has a psychological effect. I feel upset from this thing… [P3]
		…what I have to say, in the beginning, I was upset, and I was not optimistic… [P6]
		…No because after a long time you will get bored from it… [P5]
		…Getting bored from it, because it annoys you (the reason for not wearing the device in all steps when the participant was asked) … [P5]
		…There should be something better than it, like this kind, like this device but lighter… [P3]
		…because from here the boot is completely made by iron and other things I do not realize it, yes like these things. It is not like before when I was normal. It mostly will affect me, either with the boot or cast. It changes the life little bit… [P4]
		…The second thing is that it should be of a light type that has the same design but lighter… [P9]

		…so it should be softer, I have fears because it injures my foot from the top… [P9]
		…I mean, they have to reduce its weight and solve the problem in the top, these are the negatives. If they are solved, I will be happy to wear it… [P9]
		…if this boot was good. It is good but as I told you without the negatives that we talked, it will be great. I mean solve these two issues. The weight and the edge from the top… [P9]
		…If they are able to make it like a half and fix a sponge form the top… [P9]
		…it must that I can find a light one, I mean, ahhh, I don't know where it is made in Australia or here, the important issue is to eliminate the negatives and make it positive otherwise it is good. But there is something regarding manufacturing that here sometimes it gets away, they put this here to get away for a reason… [P9]
		…But I have told you we have negatives. But within specific improvement for it, the patient is cured faster, and the things become better for all people… [P9]
		…I can bear the wound but not bearing the device, I mean the device is good but the heaviness and, as I told you, it affects the leg, which does not allow me to wear it… [P9]
		…but I have not found any benefit from it for me. I mean, some people benefited a lot from it, I mean a lot of sick people benefited, but I did not… [P5]
		…The second thing is that the device is costly, very costly for normal people if they want to buy it for 140 dinars **(280 AUD)**, *I mean it is overpriced and not normal, that's all… [P9]*
		…It is good. But for me, the cast is better than the boot… [P4]
		…it is more comfortable. The cast is more comfortable. If you want to enter the home, you keep wearing it as a shoe. You can't take it off then wear it again. But for the cast, you can take off the bottom of the Casting which is the cast shoe, you can take it off and walk, I mean it is more comfortable… [P5]
	Using RCW negatively impacted performing daily life activities	*…To be honest, it has affected me as I told you, now I have become more boldly to go outside the home. Now, if I have a trip, I can go… [P1]*
		…yes, I wear it and go outside. In the past when I used to come here before around one month, my brother used to take me by car. He used the wheelchair to bring me here. I mean I came here by a wheelchair and the same when we go back home but now as you see in real… [P1]
		…that is it, I wear it for the reason of walking and to protect the foot bone from extra fractures. This is what makes me wearing it… [P6]
		… it is normal, I wear it when I am invited to an event or go to the market…, this is normal… [P2]
		…if I am invited to an event, I wear it and go. I wear it when I go shopping. Everything is normal… [P2]
		…Sometimes I face comments from somebody "how you can wear it outside your home? how can you walk while wearing it? Do you feel shy while wearing it?"No, no, I don't feel shy with it… [P2]
		…I get used to, I get used to it and I can work, thanks to Allah, I mean I can serve myself, I do my work even if I stand little and sit little… [P6]
		…I mean my life is so normal and there is no effect. I mean I go to social events with my foot, it is a normal condition, the necessity requires this, I mean it does not affect my psychological statutes. I

		take things easily. I mean the situation is normal, it is Allah's judgment, we say thanks, Allah… [P8]
		…During the day I wear it even if I enter the toilet, I shall wear it, through the midday for pray, you know I can just wipe it, I am wearing it normally and I enter the toilet easily, I mean I enter the toilet. Now, when I go for bathing, I put the cover, a bag for protection, and I do my bathing easily. I have a shower and I have holders in the bathroom, I do my bathing in a comfortable way… [P8]
		…It has not affected at all. I always go to the market and come back as it is normal, and I returned back to my work and I drive, and I go and come back… [P10]
		…I drive my car while wearing it, and I haven't felt any changes… [P10]
		…You know because it makes my moving hard. With its weight, you can't be free… [P1]
		…Its movement is not fast… [P3]
		…there are no activities, I gave up going outside. I don't go for some occasions or stuff… [P4]
		…I walk in it some steps but not a lot. I don't go too far places… [P4]
		…The life becomes limited with it. You can't go to the toilet because of its heaviness… [P9]
		…Also, regarding me, I used to work as a lecturer in the university and my work has stopped because I can't stand on my foot so the device, I have used it, it obstructs my movement, I always sit up because of it. It pull me to the chair to always sit up in it… [P9]
		…you can't work while using it, you can't bend down, and you can't pull some stuff as well… [P3]
		…Also, the work is hard… [P5]
		…I used to supervise my business. I only took sick leave in the last several days. I wanted to wear it and go to work, the day I went for an examination, my brother came and took me to the hospital, and after that, I haven't worked… [P7]
		…it's very bad whether you go up or down the stairs. I have to use the lift…[P5]
		…Stairs affect a lot when I go up or down the stairs because both legs are on the same level. One leg is higher than the other one. So, when I go downstairs, all the pressure affects the knee. This what I have felt that it is harmful regarding the boot. If it is possible to provide a shoe with the same height of the boot, I think it will be good… [P7]
		…Moving in stairs, going downstairs, you can't, because of its heaviness. I mean its heaviness hits the leg from upper side… [P9]
		…I mean If I want to go downstairs, just a moment ago, if I was not catching the handrails, I may fall down on my face… [P9]
		…. I wear it in the bathroom during bathing, I elevate my legs. I use a chair to elevate my foot and in a period of time I used to elevate both legs during bathing, but you see how this is uncomfortable if I don't have anyone, I mean if I fall. I mean, thanks to Allah, I can slightly manage myself…[P6]