Factors Associated with Diabetic Peripheral Neuropathy and Quality of Life Among Type 2 Diabetes Patients in Saudi Arabia

Awatef Ibraheem

Follow this and additional works at: https://ecommons.luc.edu/luc_diss

Part of the Nursing Commons

Recommended Citation
Ibraheem, Awatef, "Factors Associated with Diabetic Peripheral Neuropathy and Quality of Life Among Type 2 Diabetes Patients in Saudi Arabia" (2020). Dissertations. 3863.
https://ecommons.luc.edu/luc_diss/3863

This Dissertation is brought to you for free and open access by the Theses and Dissertations at Loyola eCommons. It has been accepted for inclusion in Dissertations by an authorized administrator of Loyola eCommons. For more information, please contact ecommons@luc.edu.

This work is licensed under a Creative Commons Attribution-Noncommercial-No Derivative Works 3.0 License.
Copyright © 2020 Awatef Ibraheem
LOYOLA UNIVERSITY CHICAGO

FACTORS ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY AND QUALITY OF LIFE AMONG TYPE 2 DIABETES PATIENTS IN SAUDI ARABIA

A DISSERTATION SUBMITTED TO
THE FACULTY OF THE GRADUATE SCHOOL
IN CANDIDACY FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

PROGRAM IN NURSING

BY
AWATEF B. IBRAHEEM
CHICAGO, IL
DECEMBER 2020
ACKNOWLEDGMENTS

All thanks and acknowledgements are due to ALLAH for providing me with the strength to start, sustain, and complete this doctorate journey. It was not I who did it. It was with His support and enabling that I could accomplish this dissertation research.

Although my name is on this dissertation, it would not have been possible for this journey to come to an end without the love and support of many people.

The first person I would like to acknowledge is Mohammed, my husband. Mohammed, you were my rock and will ever be my everything. This dissertation would not have seen the light if it were not for your encouragement, support, and humor. Your devotion to my success has made me speechless. Your humor in the darkest times when I was on the brink of giving up has truly made my life. You gave up numerous pleasures and necessities to allow me to have an extra hour or two of sleep after a long night. Thank you for making sure we had food ready at the table for the countless times I was not able to. Thank you for constantly finding ways to keep the kids busy and entertained while I finished my work. It was particularly challenging during this pandemic of COVID-19, when we were all stuck at home, to find places to hang at while I finished this work.

This dissertation would not have been possible were it not for Dr. Sue Penckofer’s dedication, support, and mentorship. Thank you for believing in me and constantly pushing me forward. The way you mentored me has shown me what a perfect mentorship is like. You always
replied to my emails, reviewed and returned my work in as little time as humanly possible. You are straightforward, succinct, yet a very kind person. Thank you for every comment you made that improved my writing and made me think deeper. Thank you for showing me how to be an honest and meticulous researcher. I am forever indebted to you. I am honored to be your mentee.

Acknowledgement is also due to the committee members, Dr. Barbara Velsor-Friedrich and Dr. Monique Ridosh, for their continuing support and for being always there to help even when it was just to talk. Your priceless expertise and knowledge have enriched this dissertation. I am grateful and appreciative.

Dr. Cara Joyce has provided me with valuable information on statistical matters. She was absolutely vital in strengthening my approach to data analysis. She answered every question I had no matter how small or trivial.

I would like to acknowledge also my son, Ghassan, who made sure I knew how much he loved me and how proud of me he was. Always passing by as I worked and looking me in the eye and telling me, “You Can Do It Mommy!” Or “Is There Anything I Can Do to Help?”

I would like to acknowledge my mother for pushing me to go abroad and get my higher education and constantly telling me, “We love you so dearly, and that is why we can bear not having you around, so you can better yourself and your future.”

Thanks are also due to the sponsors of my education, Taibah University and the Ministry of Education. This would not have been possible without the financial and the logistic support of yours. So, thank you. Loyola University has provided me with first-hand exposure to a transformative education. The resources and support I received as an international student made everything easier.
Last, I want to recognize my daughters, Nehal and Iman; family and friends. This dissertation has seen the light partly by your encouragement and prayers.
To my father, in memoriam
Seek Knowledge from the Cradle to the Grave

— Prophet Muhammad Peace Be Upon Him
# TABLE OF CONTENTS

**ACKNOWLEDGEMENTS**  iii

**LIST OF TABLES**  xi

**LIST OF FIGURES**  xiii

**LIST OF ABBREVIATIONS**  xiv

**ABSTRACT**  xvi

**CHAPTER ONE: PROBLEM STATEMENT**  1
- Diabetic Peripheral Neuropathy  2
- Factors Associated with DPN  3
- Biologic and Individual Factors  3
- Environmental Factors and DPN  4
- Symptoms of DPN  6
- DPN and Foot Complications  7
- Functional Status and Self-Care  8
- Quality of Life in T2DM with DPN  9
- Purpose  11
- Theoretical Framework  11
- Application of the HRQoL Model to The Study  12
- Specific Aims  15

**CHAPTER TWO: REVIEW OF THE LITERATURE**  17
- Methods  17
- Results  17
- Biologic Factors  19
- Characteristics of the Individual  31
- Symptom Status  33
- DPN and Overall QoL  42
- Self-Care Activities and DPN  47
- Characteristics of the Environment  53
- DPN, Perceived Health, and Overall QoL  62
- Summary and Evaluation of the Evidence  64
- Conclusion  65

**CHAPTER THREE: METHODS**  67
- Design  67
- Setting  68
- Sample  70
- Data Collection  72
- Measurements  73
<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>EDUCATIONAL FLYER FOR PARTICIPANTS</td>
<td>225</td>
</tr>
<tr>
<td>E</td>
<td>THE MINISTRY OF HEALTH IRB APPROVAL</td>
<td>231</td>
</tr>
<tr>
<td>F</td>
<td>CERTIFICATE OF TRANSLATION OF THE CIRS</td>
<td>234</td>
</tr>
<tr>
<td>G</td>
<td>LITERATURE REVIEW TABLES</td>
<td>237</td>
</tr>
<tr>
<td>H</td>
<td>INSTRUMENTS RELIABILITY AND ACCESSIBILITY</td>
<td>245</td>
</tr>
<tr>
<td>I</td>
<td>UNIVARIABLE REGRESSION MODEL</td>
<td>249</td>
</tr>
<tr>
<td></td>
<td>REFERENCE LIST</td>
<td>252</td>
</tr>
<tr>
<td></td>
<td>VITA</td>
<td>275</td>
</tr>
</tbody>
</table>
LIST OF TABLES

Table 1. Number and Percentage of Participants from Each Recruitment Source 87

Table 2. Sample Demographic Characteristics 90

Table 3. Mean Scores and Standard Deviations of Key Variables 92

Table 4. Total Scores of MNSI and S-LANSS 93

Table 5. Description of Neuropathy Symptoms as per the S-LANSS 94

Table 6. Description of Neuropathy Symptoms as per the MNSI Questionnaire 95

Table 7. Numeric Scale of Pain and Degree of Bothersome 96

Table 8. Frequency of DPN Symptoms According to MNSI 2 (not mutually exclusive) 97

Table 9. Severity of DPN Based on Foot Examination 97

Table 10. Mean and Standard Deviation of Neuropathy Symptoms of Males and Females 98

Table 11. Gender-Based Differences in DPN Symptoms Between Groups 98

Table 12. Descriptive Statistics of the SF-12v2 Domains and Composite Scores 100

Table 13. Descriptive Statistics of MOS-SSS 101

Table 14. Description of the SDSCA Subscales 102

Table 15. Mean and Standard Deviation of Foot Care Subscale Individual Items 103

Table 16. Mean and Standard Deviation of CIRS Subscales 104

Table 17. Functional Comorbidity Index Results 105

Table 18. Reliability Assessment of Key Study Instruments 106
Table 19. Bivariate Correlation Among Study Variables 109
Table 20. Correlations Among SF-12v2 Domains and Summary Scale 110
Table 21. Impact of DPN on Foot Care Practices 114
Table 22. Impact of DPN and Foot Care Practices on Health Perception 115
Table 23. Impact of DPN and Foot Care Practices on Physical QoL 116
Table 24. Impact of DPN and Foot Care Practices on Mental QoL 117
Table 25. Impact of Key Variables on DPN (S-LANSS) 118
Table 26. Impact of Key Variables on DPN (MNSI 1) 120
Table 27. Impact of Key Variables on DPN (MNSI 2) 121
Table 28. Comparison of the SF-12v2 Scores Between this Study and Another Study 136
LIST OF FIGURES

Figure 1. Study Conceptualization Using the Revised Wilson and Cleary HRQoL Model 15
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
</tr>
<tr>
<td>CIRS</td>
<td>Chronic Illness Resources Survey</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>DPN</td>
<td>Diabetic peripheral neuropathy</td>
</tr>
<tr>
<td>DSME</td>
<td>Diabetes Self-Management Education and Support</td>
</tr>
<tr>
<td>FBG</td>
<td>Fasting blood glucose</td>
</tr>
<tr>
<td>FCI</td>
<td>Functional Comorbidity Index</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Glycosylated hemoglobin</td>
</tr>
<tr>
<td>IDF</td>
<td>International Diabetes Federation</td>
</tr>
<tr>
<td>MCS</td>
<td>Mental Composite Score</td>
</tr>
<tr>
<td>MNSI</td>
<td>Michigan Neuropathy Screening Instrument</td>
</tr>
<tr>
<td>MODD</td>
<td>Mean of daily differences</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>Medical Outcome Study-Social Support Scale</td>
</tr>
<tr>
<td>MAGE</td>
<td>Mean amplitude of glycemic excursions</td>
</tr>
<tr>
<td>SES</td>
<td>Socioeconomic status</td>
</tr>
<tr>
<td>SDBG</td>
<td>Standard deviation of blood glucose</td>
</tr>
<tr>
<td>SDSCA</td>
<td>Summary of Diabetes Self-Care Activities</td>
</tr>
<tr>
<td>S-LANSS</td>
<td>Self-report Leeds Assessment of Neuropathy Signs and Symptoms</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>PCS</td>
<td>Physical Composite Score</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 diabetes mellitus</td>
</tr>
<tr>
<td>T1DM</td>
<td>Type 1 diabetes mellitus</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Evidence has suggested that diabetic peripheral neuropathy (DPN) is associated with decreased quality of life (QoL) and impaired physical and emotional health. About 82% of the diabetic population in Saudi Arabia show signs of DPN. However, it is under-recognized and undertreated. Further, DPN is linked to several clinical and metabolic risk factors. However, there is minimal evidence from Saudi Arabia on the impact of DPN on the individual’s QoL. The aims of this current study were to (1) examine the impact of DPN symptoms on functioning, health perception, and QoL and (2) explore the biologic and individual factors associated with DPN symptoms. This study was guided by the revised Wilson and Cleary Health-Related Quality of Life (HRQoL) Model and included assessment of the biologic functions, symptom status, functional status, health perception, QoL, and the individual and environmental characteristics. This was a cross-sectional descriptive study conducted at a regional diabetes center in Saudi Arabia. The total sample size was 120 participants with T2DM who reported neuropathy symptoms or had confirmed DPN diagnosis. Data collected included: biologic function (e.g., HbA1c), symptoms of DPN (Michigan Neuropathic Symptom Inventory, Numerical Pain Rating Scale, Short-Leeds Assessment of Neuropathy Signs and Symptoms), functional status (Summary of Diabetes Self-care Activities-foot care subscale), and health perceptions and QoL (the Short Form-12v2). Individual (age and gender) and environmental characteristics (Medical Outcome Study-Social Support Survey and Chronic Illness Resources) were also collected.
Regression analyses identified a significant relationship between DPN symptoms, foot self-care, health perception, and QoL (mental and physical). Thus worse neuropathy symptoms were associated with more foot self-care practice, poorer health perception, mental and physical QoL among the population of people with T2DM living in Saudi Arabia. Furthermore, more neuropathy symptoms were associated with poor glycemic control, presence of comorbidity, being inactive and a male. The findings suggested that in Saudi Arabia, similar to other countries, DPN causes mild to moderate QoL impairment. This study identified factors associated with the development of neuropathy among the persons living in Saudi. These findings have significant implications on nursing care, education, and future research. This study was the first that explored the impact of DPN on QoL among the population of Saudi Arabia.
CHAPTER ONE

PROBLEM STATEMENT

Type 2 diabetes mellitus (T2DM), continues to cause significant global health problems and increased healthcare costs. The number of persons living with diabetes is expected to surpass 600 million by the year 2040. Currently, around 422 million adults are living with T2DM (World Health Organization [WHO], 2018). T2DM is associated with multiple long and short-term complications and detrimental sequelae (American Diabetes Association [ADA], 2018). Long-term complications result from damage to large and small blood vessels and nerve fibers. These complications involve conditions such as retinopathy, nephropathy, and neuropathy and lead to blindness, kidney failure, heart diseases and lower limb amputations (ADA, 2018). The healthcare utilization expenses associated with diabetes mellitus (DM) are among the highest in the world, and complications substantially increase those costs. The cost of care for the person with diabetes who has complications is 70% to 150% higher than that of a person with diabetes who does not have the complication (Li et al., 2013). The expenses of DM management and prevention in 2017 were estimated to be over $727 billion worldwide, 12% of expenditure on adult care (International Diabetes Federation, 2017).

In Saudi Arabia, DM is the second leading cause of death following road traffic accidents (Centers for Disease Control-Global Health, 2016a). T2DM poses a significant health threat in the Middle East. Several studies have suggested that the prevalence of DM is higher in
urban areas and is the highest in the Northern region of Saudi. The prevalence of T2DM in Saudi
has significantly increased over time. In 1982 the percentage of diabetics was about 2.5%, and
by 1997 it rose to 10.1% (Bacchus, 1982; Elhazmi & Warsy, 2000). By the year 2011, the
prevalence of DM had increased to 16.4% (AlNozha, Maatouq, AlMazrou, & AlHarthi 2004).
The prevalence estimates of T2DM in SA are projected to increase to up to 44% by 2022
(AIQwaidhi et al., 2014. Currently the prevalence of T2DM is around 18.5% (International
Diabetes Federation, 2019). These estimates are some of the highest in the world. This rapid
increase in the prevalence of DM can be attributed to the increase of food availability, lack of
physical activity, and cigarette smoking which lead to increase in obesity rates and cardiac risk
factors (AlNozha et al, 2004).

**Diabetic Peripheral Neuropathy**

One of the most debilitating complications of DM is diabetic peripheral neuropathy
(DPN). DPN is “the presence of symptoms or signs of peripheral dysfunction in people with
diabetes after the exclusion of other causes” (Vinik, 2006, p. 301). DPN is the most common
type of diabetic neuropathies and accounts for about 75% of all cases (Pop-Busui et al., 2017). It
is also the most common complication of DM. The prevalence of DPN varies widely mainly due
to different diagnostic criteria. Estimates of the proportion of individuals with T2DM who have
measurable DPN are up to 85% (Vukojevic et al., 2014). In the U.S. the prevalence of DPN
among people living with diabetes is 28% (Hicks & Silven, 2019).

The prevalence of DPN among the Saudis is also variable. While some preliminary data
from western Saudi suggests that DPN prevalence is as high as 79% (Mojaddidi, Aboonq,
AlNozha, Allam, & Fath ElBab, 2011), other cross-sectional studies have concluded that the
prevalence of DPN is lower, representing only 20% of participants (Wang, Bakhutmah, Hu, &
Alzahrani, 2014). This variation is reported in the literature globally and is due to different measurement instruments. The variation is also attributable to underreporting, lack of recognition, and perhaps a lack of assessment by both patients and practitioners (Vinik, Nevoret, Casellini, & Parson, 2013). Unfortunately, these estimates do not reflect the overall population of Saudi as DPN is still not represented in the statistics of the Saudi national database.

Factors Associated with DPN

Biologic and Individual Factors

The development of DPN is multifactorial and involves biologic, environmental, and individual variables (Hebert, Veluchamy, Torrance, & Smith, 2017). There appears to be strong evidence implicating some biologic and individual variables in the development of DPN but not others. For instance, evidence is conclusive that age, glycemic control, and the duration of diabetes are major risk factors in the development of DPN symptoms (ALQuliti 2015; Clair, Cohen, Eichler, Selby, & Rigotti, 2015; Halawa et al., 2010). This evidence includes a few studies found among the Saudis. Both Saudi prospective and retrospective, cross-sectional studies have confirmed that poor glycemic control, age, and the duration of T2DM are among the risk factors for the development of DPN among the Saudis (Mojaddidi et al., 2011; Wang et al., 2014).

There is less consensus, however, concerning the role gender, type of DM treatment (insulin versus oral agents), hyperlipidemia, cigarette smoking, body mass index (BMI), and comorbidities play in DPN. For instance, a couple of studies concluded significant gender differences in the onset of DPN where males had earlier disease onset than females (D’Souza et al., 2015; Won et al., 2012). Meanwhile, a couple of studies did not find a statistically significant
difference between men and women with DPN (Bansal et al., 2014; Javed, Furqan, Zaheer, & Kasuri, 2014).

Comorbid conditions are an essential component in examining DPN symptoms and impact on QoL. Individuals with DPN often have several comorbidities. Those conditions may not necessarily have a causal relationship with DPN. They may instead share the same underlying etiology, in some cases. In other cases, however, the comorbid condition may occur merely by chance and have no association with DPN. However, it is essential to examine various comorbidities, since their association with DPN may impact and often worsen the individual’s symptoms presentation, management approaches and QoL (Valderas, Starfield, Sibbald, Salisbury, & Roland, 2009). Comorbidities include hypertension, cardiovascular diseases, nephropathy, and retinopathy. In the case of microvascular comorbidities (nephropathy and retinopathy), the same underlying etiology seems to share a plausible relationship with DPN. Evidence shows a high prevalence of corneal nerve fiber pathology, the primary etiology of retinopathy, in those with DPN (Bitirgen, Ozkagnici, Malik, & Kerminglu, 2014; Nitoda et al., 2012). Similarly, nephropathy is a frequent condition in the presence of DPN. It was found that persons with nephropathy have more severe symptoms of DPN (AIQuiliti, 2015). Further, there is accumulating evidence linking depressive symptoms and emotional well-being to neuropathic symptoms (Vileikyte et al., 2005).

Environmental Factors and DPN

A patient’s efforts of compliance and adherence to diabetes management practices often require various social and environmental contexts (Miller, & DiMatteo, 2013; Smalls, Gregory, Zoller, & Egede, 2015). The social networks of patients influence their outcomes directly and indirectly by providing a means to cope with an illness and assistance to adhere to their self-care
practices to avoid unfavorable events (Stopford, Winkley, & Ismail, 2013). Social support has been found to improve adherence and enhance glycemic control by promoting patients’ self-esteem, emotional QoL, knowledge, and attitudes towards DM (Borhaninejad et al., 2017; Song, Nam, Park, Shin, & Ku, 2017).

Another determinant of DPN symptoms is healthcare resources. The utilization of healthcare resources plays a paramount role in determining the outcome of many health conditions. It is as equally important as the individual and clinical factors. Healthcare resources include the behaviors and attitudes of the provider and the communication of the providers with patients. Especially in DM management, patient satisfaction and involvement in decision-making have been reported as important predictors of better outcomes (Bezreh, Laws, Taubin, Rifkin, & Wilson, 2012; Young, Azam, Meurer, Hill, & Cui, 2016). Communication with the provider was found to positively and negatively influence patients’ outcomes (Almutairi, 2015; White et al., 2016). Patients reported that trust in care of the providers was a facilitator in DM management (Sohal, Sohal, King-Shier, & Khan, 2015). Meanwhile, hindrances of successful DM management linked to provider-patient communication were fear of being judged and shame surrounding dietary intake (Ritholz, Beverly, Brooks, Abrahmson, & Weinger, 2014). In addition, adherence with the recommended medication was associated with receiving education about the disease and the treatment plan from the healthcare provider (Graumlich et al., 2015; Larkin, Hoffman, Stevens, Douglas, & Bloomgarden, 2015).

Given that DPN is a complication of DM, it seems sensible to hypothesize that the factors involved in the development and progression of diabetes are also associated in the development of DPN. Thus, this study is hypothesizing that social support and healthcare resources are associated with of DPN symptoms and health-related Quality of Life (HRQoL).
Symptoms of DPN

DPN affects the sensory and motor neurons of the peripheral nervous system. It manifests with complete or partial loss of sensation and often with an insidious onset. To most patients, the most distal parts of the body are the first to be affected (glove and stocking patterns). The presence of DPN symptoms varies ranging from 22% to 78.5% in various parts of the world (Pop-Busui et al., 2017; Tesfaye et al., 2010). Most DPN patients have predominantly sensory symptoms like burning, tingling, shooting, or a lancing sensation (Vinik et al., 2013; Vukojevic et al., 2014; Wang et al., 2014). Furthermore, patients may experience negative symptoms which include numbness of the feet and legs with or without complete loss of sensation. Others may experience mainly pain.

Pain is an important aspect of DPN. Given the nature of the disease, some patients report severe pain while others report an absence of pain (AlQuliti, 2015; Pop-Busui et al., 2017; Tesfaye et al., 2010). The prevalence of pain (neuropathic in nature) among those with DPN is about 25% (Pop-Busui et al., 2017). Because symptoms including pain vary greatly among individuals, the clinical diagnosis of DPN can be challenging. Some people have extremely severe symptoms while others have a complete absence of symptoms despite the presence of positive objective findings.

Most studies reporting about DPN in Saudi have been epidemiological (Algeffari, 2018; AlQuliti, 2015; Wang et al., 2014). One Saudi study of 263 persons aged 20 to 70 years old who had diabetes for 5-22 years, reported that 63% of the patients were symptomatic while 37% were asymptomatic (Mojaddidi et al., 2011). Finally, an important and serious sequel of DPN is ataxia, loss of full movement and control of the body parts. In turn, ataxia disposes to unsteadiness, falls and fractures (Vinik et al., 2013).
DPN and Foot Complications

Diabetes foot complications are conditions that involve injury, infection, ulcer, gangrene, and amputation of a toe and/or the lower limb of a diabetic patient. The lifetime risk of foot problems for a diabetic patient is as high as 25% in the US (Tesfaye et al., 2010). This risk is also reported among the Saudi population with DM. A diabetic foot is the most common reason for hospitalization among the Saudis. About 25% of persons who are admitted with diabetes issues have diabetic foot problems (AlKhair Ahmed 2010; Yang et al., 2014). Diabetic foot is defined as the penetration of the full thickness of the epidermis of the foot of a diabetic individual (Abolfotouh, Alhafi, AlGannas, 2011). DPN is a significant risk factor for the development of foot complications related to the absence of protective sensation. It is suggested that numbness of the feet and legs is the primary mechanism by which DPN is leading in time to painless foot ulcers. Other risk factors for foot complications are previous foot ulcers, peripheral vascular disease, and foot deformities which are also common in DPN (Yang et al., 2014). Diabetic foot problems are significantly preventable with early identification, proper screening, and preventative foot care practices. However, once an ulcer has developed, treating and preventing the second incident is challenging as about 70% of ulcers return within five years (Dorresteijn, Kriegsman, Valk, 2010). The prevalence of non-traumatic lower extremity amputation among patients with diabetic foot problems in Saudi is alarming even though the evidence is limited. Diabetic patients have a 10-fold increase in the risk of lower limb amputation. Studies reported that the incidence of amputation is between 19% to 34% for persons in Saudi (AlTawfiq and Johndrow, 2009; Qari et al., 2000). In the U.S. there were about 108,000 lower limb amputations related to DM in 2014 (CDC, 2017a). This leads to emotional
and physical burden on patients which results in decreased QoL, depression, and impaired functioning.

**Functional Status and Self-Care**

Functional status refers to the ability to perform tasks in various aspects of life including physical, social, work, and psychological functions (Ferrans et al., 2005; Wilson & Cleary 1995). DPN patients’ ability to function physically, psychologically, and socially is a primary determinant of their HRQoL. Research evidence indicated that DPN patients have compromised functioning in some day-to-day life roles as a result of their sensory and motor impairments (Dermanovic Dobrota et al., 2014; Riandini et al., 2017; Veresiu et al., 2015; Vukojevic et al., 2014). Patients have reported difficulties with the simplest physical functions like walking, standing, balance, and mobility. The specific aspects of daily life influenced were the overall productivity, recreational activities, work, and chores. Meanwhile, the affected social and psychological functions were related to fear, anxiety, and irritability (Dermanovic Dobrota et al., 2014). Furthermore, patients have also had difficulties with sleep, falling asleep, and not feeling rested upon awakening (Brod Pohlman, Blum, Ramasamy, & Carson, 2015).

To maintain therapeutic glucose levels and to prevent complications, T2DM patients must perform certain practices that are collectively referred to as diabetes self-care management (ADA, 2019). Those practices include behaviors like eating a healthy diet, performing physical activity, and monitoring glucose levels regularly. Diabetes self-care management is complex and involves permanent changes in lifestyle and serious commitment efforts from the patients. Prevention of DPN relies heavily on promoting healthy behaviors to attain glycemic control and to detect symptoms early. Patients’ ability to carry out self-care management practices is part of intact functional status. Foot self-care behaviors are an essential component of self-care in
persons with diabetes. Foot self-care includes behaviors like washing, drying, and inspecting the feet daily. Several factors influence foot self-care behaviors. Positive foot self-care behaviors are associated with an individual’s education level, gender, socioeconomic status (SES), body weight, and positive attitude and awareness of DM (D’Souza et al., 2015). Barriers to effective foot self-care practices include age, physical ability, perceived importance, communication with provider, and social integration (Matricciani & Jones, 2015). Other factors are related to a patient’s environment such as neighborhood violence, availability of healthful foods, aesthetics, and facilities (Smalls, Gregory, Zoller, & Egede, 2015). Research on foot care habits, frequency, and association with DPN symptoms among Saudis with T2DM is scarce (AlOdhayani, Tayel, & Almadi, 2017; Yang et al., 2014) and indicates that most patients lack knowledge related to the importance of foot care and risk factors for diabetic foot. Thus, efforts to carefully examine this vital influence on QoL are needed.

**Quality of Life in T2DM with DPN**

Quality of life (QoL) is a multidimensional concept that has been researched extensively and incorporates all factors that impact an individual’s life. Health-related QoL is the medical outcome variable that is specific to health and treatment predictors of QoL. Considering the confusion and inconsistency as to the distinct meaning and usage of the two terms (Karimi, 2016), in this study, while acknowledging that the theoretical framework that guided the study uses the term HRQoL, the terms QoL will be used in reference to the studies variables and results. However, when referencing other research studies the exact terminology used by the authors will be reported herein. For instance, as applicable, studies used terms such as well-being, HRQoL, overall QoL, health, and QoL. The term HRQoL will only be used when referencing the theoretical model.
Research data from around the globe have shown that QoL in people with DPN can be significantly compromised. The level of impact depends on the severity of symptoms. The effect of DPN symptoms on patients’ lives spans physical, emotional, social health, and functioning (Boyd, Casselini, Vinik, & Vinik, 2011; Bredfeldt, Altschuler, Adams, Portz, & Bayliss, 2015; Hoffman, Sadosky, Dukes, & Avir, 2010; Lyrakos et al., 2013). Patients’ QoL depends on the degree of discomfort and disability imposed by the symptoms. There is a correlation between the number and intensity of symptoms and QoL scores. For instance, people with mild DPN symptoms have mild to moderate impairment of QoL (Vukojevic et al., 2014). Likewise, people with severe symptoms have worsened QoL. On all of the Short Form-36 questionnaire’s dimensions, it was found that patients with painful DPN scored significantly lower, indicating worse QoL than patients without DPN (Dermanovic Dobrota et al., 2014).

Literature on QoL among the Saudis is limited to diabetes and is recent in nature (Alaboudi, Hassali, & Shafie, 2016; AlHayek, Robert, AlSaeed, & AlSaban, 2014; AlShehri, 2014). In a cross-sectional survey, AlShehri (2014) studied a sample of (n=75) T2DM patients using the SF-12 and concluded that patients scored significantly lower than the average population. Married patients had lower QoL compared to non-married patients (AlAboudi et al., 2016). Individual characteristics associated with lower HRQoL were female gender (AlShehri, 2014), poor economic status, the presence of DM complications, and longer duration of DM (AlHayek et al., 2014).

Among the Saudis, current evidence has not approached the study of DPN among individuals with T2DM comprehensively or using a theoretical framework. The current study aims to investigate the impact of DPN on physical and mental QoL guided an existing theoretical
framework that delineates various influencers of symptoms, and consequently their functioning, general health perception, and overall QoL.

**Purpose**

This study examined the degree to which DPN symptoms impeded functioning and QoL of persons with T2DM living in Saudi. Furthermore, the study evaluated the individual and environmental factors that contributed to the DPN symptoms in people with T2DM. The revised HRQoL model (Ferrans et al., 2005; Wilson & Cleary, 1995) was the theoretical framework that guided the study.

**Theoretical Framework**

This current study was guided by the revised Wilson and Cleary HRQoL Model (Ferrans et al., 2005; Wilson & Cleary, 1995). This model was the conceptual basis that guided the understanding of the nature of the relationship among several of the variables that were expected to influence the QoL of DPN patients. The model comprises five levels of factors, each of which plays a significant role in linking clinical variables with HRQoL (see Figure 1). Individual and environmental characteristics play essential roles and directly impact each level. The Wilson and Cleary model has been revised, and the importance of the influence of individual and environment characteristics has been highlighted (Ferrans et al., 2005).

The first factor is the biological/physiological influences. These include cellular and molecular factors, such as laboratory values and diagnoses (Wilson & Cleary, 1995). The second factor in the model is symptom status. Symptom status is a manifestation of biological changes and a shift to the general impact on the human being. The symptoms exhibited by the individual can be physical or psychological. The third factor is functional status, and it is a crucial integration point into the previous factors. Functioning level describes an individual’s ability to
perform physical, social, role, and psychological functions. The fourth factor in the model is the general health perception. It is the patient's own beliefs about their abilities, limitations, and satisfaction with health. The last factor is overall QoL, the endpoint of the model. All the factors should lead into one another and end with the overall QoL.

According to the revised model, individual and environmental characteristics play a role at all levels. Individual factors are related to demographics such as the level of education, age, and gender. Environmental characteristics are geographical, sociological variables, and spiritual values.

**Application of the HRQoL Model to The Study**

**Biologic Functions**

Biologic functions in this reported study of DPN among the Saudi population reflected risk factors and comorbidity. Biological indicators included the level of glycosylated hemoglobin (HbA1c) and cardiovascular risk factors. It also included past and current medical history of chronic diseases like kidney, heart, and eye diseases, peripheral vascular insufficiency, other comorbidities, smoking habits, and prescribed medications. The laboratory values were obtained from patients’ medical records. Information related to medical history were collected using a general health survey and the electronic records data.

**Symptom Status**

The current study assessed symptoms and signs that are commonly seen and reported by patients. They were pain, increased/decreased sensitivity to touch, abnormal tendon reflexes, tingling, and impaired sensation. Symptoms were measured using the Michigan Neuropathic Screening Instrument (MNSI), Numerical Pain Rating Scale, and the Self-report-Leeds Assessment of Neuropathy Signs and Symptoms (S-LANSS).
Functional Status

According to the American Thoracic Society functional status is the ability to perform normal daily activities that are required to meet basic needs and maintain health and well-being (American Thoracic Society, 2007). Functional status in the HRQoL model is defined as the ability to perform particular defined tasks (Wilson & Clear, 1995). Accordingly, in this current study based on the aforementioned definitions, the ability to perform foot self-care practices was considered the indicator of sufficient functional status and was measured using the foot self-care subscale of the Summary of Diabetes Self-Care Activities (SDSCA) instrument. The SDSCA is a 15-item tool that measures a diabetic patient’s level of self-care. The SDSCA was used at least once on an Arabic speaking sample (AlJohani, Kendall, & Snider, 2015).

General Health Perception

General health perception is a subjective description of the degree of satisfaction of living with an illness. For this current study of T2DM Saudis with DPN, health perception was assessed using a single item in the SF-12. The single item asks participants to rate their understanding of their health on a Likert-type scale from poor to excellent (Ware et al., 1996).

Physical and Mental QoL

QoL in this study reflected patient perspectives on their physical, emotional, and social role functioning. The data of the dimensions of the QoL was collected using the SF-12v2 subscales (Ware et al., 1996).

Much attention has been directed toward identifying the risk factors and associated conditions of T2DM and foot ulcers among the Saudis. However, DPN is under-recognized and under-treated. DPN is a significant risk factor for the development of foot ulcers and almost all people with diabetic foot ulcers have DPN. Evaluating the QoL of the Saudis within a
comprehensive theoretical perspective aided in bringing attention to the importance of the patient’s perspective within a treatment plan. It will also guide future research efforts to better target environmental traits that are risk factors for neuropathy symptoms.

**The Characteristics of the Individual and the Environment**

The characteristics of the individual included the participants’ demographics which were age, gender, education level, income/SES, marital status, family history, and type of employment. General health survey measured the individual factors. The characteristics of the environment comprised information about chronic illness resources, communication with healthcare providers, and neighborhood aesthetics (walking facilities and access to healthy foods). These were measured using the brief Chronic Illness Resources Survey (CIRS) (Glasgow, Toobert, Barrera, & Stryker 2005). The CIRS is a self-report measure of the multiple resources needed by chronic illness patients to attain healthful lifestyle behaviors.

Environmental factors about the level of perceived social support were measured by the Medical Outcome Survey-Social Support Questionnaire (MOS-SSS) (Sherbourne & Stewart, 1991). The MOS-SSS is a widely-used measure of the amount of support perceived by patients and assesses the four aspects of support: informational support, tangible support, positive social interaction, and affectionate support.
Specific Aims

The primary aims and hypotheses were:

Aim 1: To examine the impact of DPN symptoms on patients’ functional status (foot care practices), general health perceptions, and overall QoL (physical and mental QoL).

Hypothesis: Individuals with more symptoms have poorer functional status (less foot care practices), negative health perceptions, and poorer physical and mental QoL (overall QoL).

Aim 2: To examine the biological (HbA1c, comorbidity, and cardiovascular risk factors) and individual (age and gender) factors associated with DPN symptoms in persons with T2DM living in Saudi Arabia.
Hypothesis: Longer duration of DM, poor glycemic control, increased age, female gender, presence of hypertension, comorbidity, and dyslipidemia, and lack of physical activity are associated with more DPN symptoms.

In summary, DPN has long been implicated in increased morbidity and mortality, decreased satisfaction with QoL and high healthcare expenditures. There is conclusive evidence on the impact of DPN on QoL globally. However, the effect of symptoms on QoL in the population of Saudi diabetics has not been adequately studied. Furthermore, the association of neuropathy symptoms, biologic functions, characteristics of the individual and the environment, and functional status are less understood. Knowledge of these associations is important to inform culturally sensitive guidance for individuals with T2DM and DPN to mitigate risk factors, maintain health and QoL, and reduce cost of care.

Specific details about the study components are discussed in the following chapters. Chapter 2 details the findings from the literature. Chapter 3 discusses the setting, design, and measurements. Chapters 4 and 5 discuss the results from the current study, study strengths and limitations, and recommendations for future research.
CHAPTER TWO

REVIEW OF THE LITERATURE

The purpose of this chapter is to review the pertinent literature relating to DPN, risk factors, and QoL. This chapter contains a discussion of the literature on the symptoms of DPN among the Saudis and from around the world. This review of the literature presents research findings and synthesizes the current literature on the different factors associated with the symptoms. This chapter also has a review of the most recent literature concerning the impact on the individual’s functioning and QoL.

Methods

A literature search was conducted to examine the evidence on the risk factors of DPN and the impact on QoL. About 120 scientific articles were identified. Databases searched were PubMed, CINAHL, PsychINFO, Scopus, and Google Scholar. The keywords used were type 2 diabetes, neuropathy, peripheral neuropathy, predictors, risk factors, determinants, self-care, social support, quality of life, health-related quality of life, Saudis, and Saudi Arabia. Searches were refined for various combination of these keywords. Search limits included English language, and human subjects.

Results

The literature search yielded a combination of cross-sectional and interventional studies examining the predictors of DPN development, systematic reviews, and narrative reports.
It is worth noting that the terms *diabetic peripheral neuropathy* and *polyneuropathy* were often used interchangeably. Many studies abbreviated DPN as *diabetic peripheral neuropathy*, but some studies used DPN for *diabetic polyneuropathy*. The evidence herein is a mixture of factors related to the development of diabetic neuropathies in general, painful diabetic neuropathy, and diabetic peripheral neuropathy. It is yet to be determined whether diabetic peripheral neuropathy and painful diabetic neuropathy/neuropathic pain in DM are the same condition or two different conditions.

Further, the reviewed studies included mostly people with T2DM. A few studies involved people with type 1 DM (T1DM). The articles listed in the table of studies were selected based on the outcome variables. Some of the research studies in which either DPN or QoL were the main outcome variables were chosen. The table of studies reports sample locations, sample sizes, locations, and designs. Table G1 included only Saudi-based studies. Table G2 included studies that were cross-sectional, and Table G3 contained interventional and systematic review studies that addressed DPN from various parts of the world. Table G4 is supplemental including the most recent articles. The evidence reviewed herein includes some studies that were specific to the Saudi population (AlAboudi et al., 2016; Algeffari, 2018; AlHayek et al., 2013; AlJohani et al., 2015; Almutairi, 2015; AlShehri, 2015; AlQuliti, 2015; Halawa et al., 2010; Y. Hu et al., 2014; Mojaddidi et al., 2011; Sidawi & AlHariri, 2012; Wang et al., 2014). The rest of the evidence comes from South Asia, Far East Asia (Bansal et al., 2014; Hussain et al., 2014; Yang et al., 2015), as well as the United States and European countries (Dermanovic Dobrota et al., 2014; Lyrakos et al., 2013; Yoo et al., 2015) see Appendix G for further information.
Biologic Factors

The involvement of the biologic factors in the development of DPN has been examined in the literature more than any other variable. The biologic variables linked to the development of DPN that have been studied the most are glycemic control, cardiovascular risk factors, and the duration of diabetes; all were implicated in the development of DPN.

Glycemic Control

Glycemic control was determined by either the HbA1c (the percentage of glycated hemoglobin) or the fasting blood glucose (FBG; measured by both mmol/L and mg/dL). However, HbA1c is a better indicator of glycemic control when compared to FBG (American Diabetes Association [ADA], 2018; Mannarino, Tonelli, & Allan, 2013). The elevated glucose levels lead to nerve axonal and microvascular injury (Juster-Swilyk & Smith, 2016). All of the reviewed studies reported an association between DPN and HbA1c (Algeffari, 2018; AlQuliti, 2015; Bansal et al., 2014; Hussain et al., 2014; Khawaja et al., 2018; Lyrakos et al., 2013; Mojaddidi et al., 2011), except for one Saudi-based study (Wang et al., 2014). There was also some evidence implicating glycemic variability, in addition to hyperglycemia, in DPN pathogenesis.

A few studies measured both HbA1c and FBG. For instance, a non-Saudi study assessed the participants HbA1c, FBG, and postprandial glucose (Hussain et al., 2014). All the parameters were significantly higher among those with DPN compared to patients without DPN, $p < .05$. The average FBG for the DPN groups was $147.88 \pm 33.03$ mg/dl. Meanwhile, for those without clinical neuropathy, the FBG was $133 \pm 20.31$ mg/dl. Postprandial glucose was also significantly higher for both groups with DPN ($214.46 \pm 39.31$ mg/dl) compared with those without DPN.
(201 ± 32.89 mg/dl) (Hussain et al., 2014). Similarly, participants’ levels of HbA1c were higher for those with DPN, mean = 7.9% ± 2.19 compared to mean = 6.6% ± 0.98 for those without DPN (Hussain et al., 2014). On the other hand, Algeffari (2018) also measured these same parameters on a sample of (n = 233) Saudis and found a significant association between HbA1c level and painful DPN, odds ratio = 3.1, *p* < .05, but not with the FBG, odds ratio = 1.4, *p* = .401.

One Saudi study concluded that the levels of the HbA1c were not significantly associated with DPN symptoms. This Saudi-based study comprised of mostly T2DM (n = 524 of total 552) reported that the level of HbA1c did not differ significantly between DPN and non-DPN cases. However, there was a difference in the glycemic control in this sample between the DPN and non-DPN groups as evident by the FBG levels. FBG levels of those having DPN was 9.7 mmol/L or 176.5 mg/dL, and 9.4 mmol/L or 169.3 mg/dL for those not having DPN, *p* = 0.002.

It worth noting that the lack of significance of HbA1c levels can possibly be explained by the poor hemoglobin levels of the participants as only 21% of the sample had a near normal hemoglobin level of 13.8 g/dL (Wang et al., 2014). The majority of the participants in the study had hemoglobin of less than 13.8 g/dL indicating a possible iron deficiency anemia. Both normal hemoglobin level and healthy red blood cells are important for a valid HbA1c assessment. HbA1c represents the percentage of hemoglobin that binds to glucose. If the hemoglobin level is decreased, it could affect the levels of the HbA1c. In the case of iron deficiency anemia there are fewer hemoglobin molecules for glucose to bind to and thus the HbA1c reading can be faulty. In a study on the effect of iron deficiency anemia on HbA1c levels’ validity, investigators provided iron supplementation to (n = 50) non-diabetic
participants with iron deficiency anemia. The mean HbA1c level of the anemic patients was 7.4% compared to 5.9% for those with healthy hemoglobin levels ($p < .001$). Following the treatment, the HbA1c levels of the anemic patients dropped to 6.2% ($p < .001$) (Coban, Ozdogan, & Timuragaoglu, 2004). This suggests that normal hemoglobin levels are essential for valid HbA1c testing. Thus, referring to the earlier study by Wang and colleagues, one can speculate that since most patients had lower hemoglobin levels, this might have affected the validity of the conclusion on the association between HbA1c and DPN development (Wang et al., 2015).

Glycemic variability is a relatively new factor in the discussion of DPN development. Glycemic variability refers to the fluctuations in glucose levels in the blood. Studies asserted that with varying levels of glucose in the blood over a period of time, DPN starts to develop and worsen even with normal FBG and HbA1c levels. For instance, in a small study in China (n=90) participants developed DPN even with HbA1c < 7% (Xu et al., 2014). Glycemic variability was measured by the standard deviation of blood glucose (SDBG), the mean of daily differences (MODD), and the mean amplitude of glycemic excursions (MAGE). The study found that DPN patients had greater SDBG (2.8 mmol/L, 50.4 mg/dL) compared with non-DPN patients (2.1 mmol/L, 37.7 mg/dL), $p < .001$. They also had higher MODD (2.2 mmol/L, 39.6 mg/dL) compared with non-DPN patients (1.9 mmol/L, 34.2 mg/dL), $p = .005$. The DPN patients also had higher MAGE (5.8 mmol/L, 104 mg/dL) compared with non-DPN patients (4.5 mmol/L, 81.0 mg/dL), $p < .001$. In this study, authors concluded that glycemic variability was closely associated with DPN in well-controlled T2DM patients (Xu et al., 2014). Another study reached similar conclusions. The study examined (n = 982) T2DM patients. Of the total sample,
about 20% had DPN and they had significantly greater MAGE, MODD and SDBG than those without DPN, $p < .001$ (Y. M. Hu et al., 2018).

**Duration of DM**

As with glycemic control, all of the reviewed studies (but one) on the duration of DM concluded that the longer the individual lives with DM the more severe the DPN symptoms become (AlQuliti, 2015; Halawa et al., 2010; Bansal et al., 2014; Hussain et al., 2014; Khawaja et al., 2018; Lyrakos et al., 2013; Wang et al., 2014). It took a sample of (n = 125) T1DM and T2DM Pakistani patients about nine years to develop DPN (Javed et al., 2014). Participants’ mean age at the diagnosis of DM was 41.6 years and 50.2 years at the onset of DPN.

In a large sample (n = 1,039) of mostly T2DM persons from Saudi Arabia, it was reported that those with painful DPN had a longer duration of DM. The duration of diabetes was defined as < 1 year or > 1 year with an average of 10.2 years for painful DPN patients and 6.5 years for non-painful DPN patients. In addition, they also had higher mean pain scores, using the 10-item Dueluer Pain Questionnaire (DN4), with mean = 10.2 ± 5.8 as opposed to non-painful DPN participants with mean = 6.5 ± 5.0, $p < .001$ (Halawa et al., 2010).

Using nerve conduction velocity tests to quantify DPN symptoms, Hussain et al. (2014) examined a small sample (n = 64) of non-Saudi T2DM patients with DPN. The investigators grouped DPN into those who had a duration of diabetes of less than eight years, and those had had a duration of greater than eight years. They reported a significant difference in the duration of T2DM in both neuropathy groups. Those persons who had diabetes for less than eight years had a lower neuropathy score (3.48 ± 1.77) compared to those having had diabetes more than eight years (13.22 ± 4.46), $p < .05$. Furthermore, those with a longer duration of T2DM had
significantly worse nerve function compared to those with a shorter duration, \((p < .05)\). The study is significant because it is one of the three studies that quantified and compared the number of years with diabetes. The second study (non-Saudi-based), examined the duration of diabetes by differing intervals: less than 5, 6–10, 11–15, and more than 15 years. In this study, the odds of neuropathy for those with a duration of diabetes of more than 15 years was 8.03 (CI 95% 5.96-10.8, \(p < .001\)) compared to those with less than five years (Bansal et al., 2014). The third study, compared the duration of DM between \(\geq 5\) and \(< 10\) years and that of \(\geq 10\) years on a sample of (\(n = 1338\)) patients. The odds of DPN for the duration of DM of \(\geq 5\) and \(< 10\) years was 1.31, \(p = .03\). Meanwhile, the risk of DPN increased to 1.63 with the duration of more than 10 years, \(p < .01\) (Won et al., 2012).

All the above-reviewed evidence had tested the presence of an association between DPN and T2DM duration but not the strength of the association. The only study that reported the strength of the correlation was in a sample of both T1DM (\(n = 39\)) and T2DM (\(n = 224\)) patients from Saudi in which a moderate correlation between the duration of DM and the DPN symptoms \((r = .44)\) was found (Mojaddidi et al., 2011).

Surprisingly, one Saudi study did not conclude that there was an association between T2DM years and DPN development despite using a validated instrument (MNSI) and having a sufficient sample size (\(n = 242\)) (Algeffari et al., 2018). They reported that 35% of the sample had painful DPN. The authors did not elaborate on the lack of significant association between duration of T2DM and DPN or on the deviation from the mainstream literature. However, by examining the sample, it looks comparable to other studies; multi-site, sufficient size, diverse (gender-wise), average age was 56 years, mostly T2DM, and a range of duration of diabetes was
5–10 years. Some of the possible reasons for the negative association between duration of disease and DPN symptoms could be related the study’s power and the measurement tools. Factors affecting the power of a study can be related to sample size, significance level, and the effect size.

**Modifiable Cardiovascular Risk Factors**

Research data as to cardiovascular risk factors role in DPN development are variable. Cardiovascular risk factors include obesity, lipid profile, hypertension, cigarette smoking, and physical activity. The suggested pathogenesis involves small-fiber nerve dysfunction, impaired pain perception, and reflex vasodilation (Papanas & Ziegler, 2015).

**Obesity.** In the reviewed evidence, obesity was determined by the participants’ BMI according to the American Heart Association (Algeffari, 2018; Bansal et al., 2014; Halawa et al., 2010; Khawaja et al., 2018; Mojaddidi et al., 2011; Wang et al., 2014). Only one study reported both the BMI and the weight-height ratio as well as the waist/hip ratio (Hussain et al., 2014).

The Research data of the effect of obesity on DPN have been inconclusive. This association between obesity and DPN has been asserted in the U.S. among the population of > 40 years old. The National Health and Nutrition Examination Survey concluded that a cluster of obesity and two other cardiovascular risk factors (hypertension, hyperglycemia, low HDL, or increased waist circumference) increase the likelihood of neuropathy odds ratio = 2.2, (CI 95%, 1.43–3.39, p < .005) (Ylitalo, Sowers, & Heeringa, 2011).

Among the Saudi population, however, the research findings were inconsistent. One Saudi study with 263 patients concluded that BMI was a significant correlate of DPN ($r^2 = .92$) (Mojaddidi et al., 2011). Meanwhile, three other Saudi studies found that BMI was not a
significant correlate of DPN (Algeffari, 2018; Halawa et al., 2010; Wang et al., 2014). These other studies were with similar or larger samples sizes (n = 242, 549, and 1,039, respectively).

**Lipid profile.** It has been confirmed that the individual’s lipid profile plays a significant role in increasing the odds of neuropathy. However, the type of lipid varies; there is always at least one kind of lipid linked to DPN. Most studies broke down the lipid profile into its components (total cholesterol, triglycerides, low- and high-density lipoprotein (HD, LDL). Other studies reported only whether the sample had dyslipidemia (Algeffari, 2018). One of the suggested mechanisms by which lipids alter the neurons’ function is the change in plasma membranes’ characteristics and the mitochondrial function (Perez-Matos, Morales-Alvarez, Mendivil, 2017; Rumora et al., 2017).

In a six-year follow-up, longitudinal study of T2DM patients (n = 45) from Korea, elevated triglycerides of > 177 mg/dL significantly increased the risk of DPN (odds ratio = 6.13, CI 95% 1.05–35.52, $p = .04$) after adjusting for age and gender (Cho et al., 2014). Another non-Saudi study with a large sample (n = 2,005, T2DM, aged 54 years, 50% were males, and had diabetes for average of 8 years) reported that the lipid profiles of DPN patients were significantly different from those of non-DPN patients, although non-DPN patients had seemingly three higher components of the lipid profile (total cholesterol, LDL, and HDL). Total cholesterol was 179 (mg/dL) for DPN patients compared to 190 (mg/dL) for non-DPN, $p = .006$. The LDL was 92 (mg/dL) for DPN patients compared to 108.1 (mg/dL) for non-DPN, $p < .001$. The HDL was 62.1 (mg/dL) for DPN patients compared to 45.4 (mg/dL) for non-DPN, $p < .001$. Total triglyceride was 163.8 (mg/dL) for DPN patients compared to 174 (mg/dL) for non-DPN, $p < .15$. This study concluded that elevated total cholesterol, elevated LDL, and lower HDL but
not elevated triglycerides were significantly associated with increased risk of DPN. The study also included the presence of dyslipidemia as a variable and concluded that it was associated with risk of DPN, (odds ratio = 0.43, CI 95%, 0.20-0.92), \( p = .03 \) (Bansal et al., 2014). Although the authors did not include dyslipidemia therapy as a variable, they alluded to the fact that participants were treated for dyslipidemia. It was not clear if both DPN and non-DPN cases received dyslipidemia treatment.

On one hand, a study with a smaller sample (\( n = 86 \)) found that lipids (triglycerides, LDL, and very LDL, but total cholesterol) increased in those with DPN, \( p < .05 \) (Cho et al., 2014). On the other hand, Khawaja et al. (2018) took a sample of T2DM patients (\( n = 1,003 \)) and measured the different lipid profile components. They found that LDL and HDL but not the triglycerides to be significantly linked to DPN symptoms. Patients with DPN had an LDL of 102 (mg/dL) compared to 101 (mg/dL) for non-DPN, \( p < .001 \). The HDL was 41.9 (mg/dL) for DPN patients and 39.5 (mg/dL) for non-DPN patients, \( p = .001 \). Finally, a large U.S. prospective cohort study (\( n = 1,992 \)) also found no significant link between lipids (HDL, LDL, and triglycerides) and DPN in those with T2DM (Jaiswal et al., 2017).

Other cardiovascular risk factors linked to DPN are cigarette smoking and hypertension. Both were indecisively related to DPN progression. Evidence was equally supporting and refuting the relationship between DPN and hypertension.

**Hypertension.** Several studies linked elevated blood pressure to DPN. In one large retrospective cohort Taiwanese study (\( n = 37,375 \)) hypertension was found to correlate significantly with DPN, \( p < .001 \). The effect of hypertension as a stand-alone variable and jointly with the levels of the HbA1c was significant. The hazard ratios of DPN for HbA1c level (\( \leq 6.0 \)
to < 10.0), according to a systolic blood pressure of < 130 (mm Hg) and a diastolic blood pressure of < 85 (mm Hg), are between 1.11 (CI 95%, 0.98–1.24) and 1.65 (CI 95%, 1.51–1.81), $p < .001$ (Yang et al., 2015).

In another study, cohorts of individuals T2DM ($n = 258$) and T1DM ($n = 1,734$) were followed for visits in years 1, 2, and 5. The study was called SEARCH for Diabetes Among Youth. The age range of the participants was 14 to 27 years. Data were analyzed separately according to the type of DM. DPN was assessed by the MNSI and was prevalent in 22% of T2DM patients. Elevated blood pressure was not found to be a risk factor for DPN in T2DM patients. However, for the youth with T1DM, hypertension was an independent risk factor for DPN, $p < .001$ (Jaiswal et al. 2017).

In regard to the relationship between hypertension and DPN among the Saudis, two studies found hypertension significantly associated with greater odds of DPN. In one study, T2DM patients had 1.7 the odds (CI 95%, 1.07–2.99, $p = .02$) of developing DPN if hypertensive (Wang et al., 2014). The other study concluded similarly that the odds of DPN increase 2.85 times (CI 95%, 1.57–5.17, $p < .001$) with hypertension (AlQuliti 2015). Two studies did not find a significant relationship (Algeffari, 2018; Mojaddidi et al., 2011). Still another study did not include hypertension in the analysis (Halawa et al., 2010). To conclude, although there is some inconsistency in these studies’ findings, hypertension can be seen as potential risk factor for the development of DPN. In addition, the two studies that found a negative association, as mentioned later, have weaker methodological approaches (Algeffari, 2018; Mojaddidi et al., 2011) than studies that found positive correlation (AlQuliti 2015; Jaiswal 2017; Yang et al., 2015).
Cigarette smoking. The evidence for smoking and DPN is inconclusive. One study found the risk of DPN corresponded to the history of smoking (D’Souza et al., 2015) while others did not support these conclusions (Algeffari, 2018; AlQuliti 2015; Bansal et al., 2014; Halawa et al., 2010; Kisozi et al., 2017; Wang et al., 2014). In a cross-sectional design, D’Souza et al. (2015) found that the risk of DPN was significantly increased with smoking (odds ratio = 5.9, \( p < .001 \)). The study included only people with T2DM. The evidence from Saudi studies did not support the conclusion that smoking is associated with risk of DPN (Algeffari, 2018; AlQuliti 2015; Halawa et al., 2010; Mojaddidi et al., 2011; Wang et al., 2014).

In a systematic review of 38 studies with a large sample (\( n = 33,152 \)), the research data were also inconclusive. The 21 cross-sectional studies in this review reported that smoking was associated significantly with DPN (pooled odds ratio = 1.42, CI 95%, 1.21 –1.65, \( p < .001 \)). However, 10 prospective cohort studies from this same review did not find smoking linked to risk of DPN (Clair et al., 2015).

Physical activity. The level of the individual’s level of activity is seen as a potentially modifiable risk factor. However, attention dedicated to studying physical activity and its impact on DPN progression is limited. Studies claim that regular physical activity could slow the progression of DPN or reduce the severity of symptoms.

In a US pilot study, exercise decreased patients’ perception of pain interference related to DPN (Yoo et al., 2015). Sedentary, middle-aged participants (\( n = 14 \)) engaged in a 16-week aerobic exercise program that entailed a supervised aerobic exercise (cycle ergometers, treadmills, recumbent steppers, and elliptical trainers) three times each week. The sessions progressed from 30 to 50 minutes. There was a significant decline in the mean pain interference
in four out of seven pain interference subscores; walking (4.93 ± 3.03 pre- to 3.29 ± 2.89 post-, \( p = .016 \)), sleep (5.11 ± 3.04 pre- to 3.5 ± 3.03 post-, \( p = .02 \)), relationship with others (3.96 ± 3.53 pre- to 1.29 ± 1.27 post-, \( p = .02 \)), and normal work (5.39 ± 3.32 pre- to 3.79 ± 3.04 post-, \( p = .032 \)). The participants’ overall perception of pain interference also decreased (4.65 ± 2.7 pre- to 2.97 ± 2.22 post-, \( p = .013 \)) following the intervention. However, patients’ perceived pain intensity pre- and post-intervention did not change significantly. Nonetheless, participants reported feeling “less hindered” in some aspects of their lives. This study, however, did not support the relationship between the level of physical activity and DPN development. It rather implied that performing some level of exercise helps to alleviate the level of interference from pain in DPN patients.

A study with a sample from China of 122 T2DM patients of whom 29% were females, 60 years old and had had DPN for 22 months examined the predictors of regular exercise among DPN patients (Pei, Wang, Sun, & Zhang, 2016). This cross-sectional study measured knowledge about DPN and physical activity, physical activity status, physical activity self-efficacy, and DPN symptoms. Knowledge of physical activity and DPN was obtained by a self-designed questionnaire. It had items about beliefs and perceived benefits of performing physical activity, its effect on DPN, and DPN symptoms. DPN was assessed by the MNSI and foot examination.

Physical activity status was obtained by asking about frequency of physical activity per week, the favorite physical activity practice, and the duration of physical activity. Regular physical activity was defined according to the ADA recommendations: at least 150 minutes spread over at least three days per week. Self-efficacy for physical activity was measured using the self-efficacy for exercise, which measures the subjective confidence in one’s ability to carry
out exercise in different situations. A score of zero indicates no confidence and 100 indicates complete confidence. Social support was measured by the Social Support Rating Scale. Participants were grouped into regular physical activity and not-regular physical activity. The study found that half of the patients exercised alone and that walking was their favorite physical activity modality. Most, about 60%, performed regular physical activity. Gender, duration of DPN, exercise self-efficacy, HbA1c, and objective social support were associated with exercise, $p < .001$. Furthermore, patients who performed regular physical activity had DPN for a longer duration (average of 31 months) in comparison to those with not-regular physical activity (average of 8 months), $p < .001$. However, the severity of DPN did not significantly differ between the two groups.

Khawaja and colleagues (2018) examined physical activity and DPN among a sample of patients from Jordan. The level of physical activity was categorized into regular, not regular, and no physical activity. To examine the association between physical activity and other variables, this study conducted two statistical analyses: an independent sample t-test and logistic regression. The t-test model showed a significant difference in physical activity between the DPN and non-DPN groups ($p < .001$) (no mean scores reported). In the logistic regression model, performing regular physical activity (for 30 minutes for 7 days/week) was not found to be associated with lower risk of DPN (odds ratio $= 0.71$ CI 95%, 0.40–1.25, $p = .239$). However, those performing not-regular physical activity (being active 30 minutes for 1–3 days/week) were less likely to have DPN compared to those who were inactive (odds ratio $= 0.51$, CI 95%, 0.35-0.75, $p < .001$). This means that being active even minimally is linked to less risk of DPN. It is interesting in this study’s finding that preforming daily exercise did not decrease the risk of DPN.
the same way did not-daily exercising. Also, what needs to be further investigated is the comparison between the two physically active groups (regular versus not regular).

To conclude on the biologic variables, there is evidence to link HbA1c and duration of diabetes to the risk of developing DPN. Less conclusive evidence exists as to cardiovascular risk factors. This was also verified in a review of all research reports from 1980 to 2015 that examined predictors of DPN in which it was concluded that hyperglycemia and diabetes duration had a robust association with DPN and that weight, smoking, and hypertension had a weak association with DPN (Papanas & Ziegler, 2015).

**Characteristics of the Individual**

The individual risk factors that are linked to DPN are age and gender. Only age was found to be considerably associated with DPN whereas gender had less conclusive evidence.

**Age**

The person’s age has always been one of the few factors that has been consistently linked to the development of DPN both in Saudi and non-Saudi populations (Algeffari, 2018; AlQuliti, 2015; Bansal et al., 2014; D’Souza et al., 2015; Halawa et al., 2010; Khawaja et al., 2018; Mojaddidi et al., 2011; Wang et al., 2014). Studies have shown that for each decade of increase in age there is a worsening of nerve fiber conditions leading to the increased prevalence of DPN. However, the mechanism of action is not fully understood (Papanas & Ziegler, 2015). It is suggested that the natural decline in nerve function due to age consolidates the effect of DPN. A non-Saudi study examined T2DM patients for association of age and DPN. DPN patients mean age was significantly higher than those without DPN (mean = 57.1 vs. 52.5 years,
Age showed increased risk of DPN (odds ratio = 1.02, CI 95%, 1.01-1.03, \( p < .001 \)) (Bansal et al., 2014).

**Gender**

Research studies of the relationship between gender and DPN have been inconsistent. Cross-sectional studies (D'Souze et al., 2015; Gogia & Rao, 2017), including a study from Saudi (Halawa et al., 2010) have concluded that male gender is linked to higher risk of DPN. However, equal evidence from other studies (including Saudi) (Algeffari, 2018; AlQulti, 2015; Bansal et al., 2014; Khawaja et al., 2018; Wang et al., 2014) reported that no relationship exists. For example, Gogia and Rao (2017) studied T2DM patients (n=273) in India, using both the Diabetic Neuropathy Symptoms questionnaire and physical examination measures, concluded that male gender was linked to neuropathy symptoms (\( p = \) not reported).

On the other hand, in a study (non-Saudi) composed of males (n = 57) and females (n = 68) with T1DM and T2DM, the research team aimed to study gender-based differences as they pertain to the frequency of DM, age at diagnosis of DM, age at onset of DPN, and with respect to duration of DM using electrophysiological studies. They found that in diabetic people with DPN there was no significant difference between the mean age (when completing the survey) of males and females. The mean age of females was 51.8 ± 10.04 years and of males 53.29 ± 9.39 years. There was also no difference between the mean age of patients at onset of DPN; the age at onset of DPN was 50.8 7 ± 9.43 years in males and 49.25 ± 10.6 years in females (Javed et l., 2014). A study from Korea concluded otherwise (Won et al., 2012). The study found that DPN was more prevalent in women than men, \( p < .01 \). Female gender increased the odds of DPN 1.26 times, \( p = .02 \).
In one of the earliest studies of gender-based differences, investigators concluded differently from previous study. This retrospective US study examined the records of males (n = 156) and females (n = 220) with T2DM. The study found that the age of males was 63 ± 14.24 years and for females 67 ± 12.61 years at onset of DPN. Males developed DPN about four years earlier than females, \( p = .006 \) (Aaberg, Burch, Hud, & Zacharias, 2008). This study had an ethnically diverse sample with 69% Blacks, 19% Whites, and 1.6% Asians, but the association between ethnicity and the onset of DPN was not significant. When comparing this to the first study (Javed et al 2014), one might speculate that the very different racial make-up of the samples could explain the different findings. In addition to the differing demographics of the samples, there is more than eight years between the data collection of the two studies, which may be a factor. Considering the racially and culturally diverse populations this review has examined and also based on the fact that DPN development involves genetic components, interpreting the lack of significance in the results is complicated.

**Symptom Status**

DPN manifests with complete or partial loss of sensation and often with an insidious onset. To most patients, the most distal parts of the body are the first to be affected (toes and fingertips) (Vinik et al., 2013). The evidence of the symptoms of DPN is challenging to interpret since there is a lack of agreement on standardized measures. Many cross-sectional studies use subjective measures. However, clinical trials use both objective and subjective measures. The only gold standard test for DPN recommended by the ADA is the nerve-conduction velocity test, which has been reported to be objective, repeatable, and sensitive (ADA, 2019). However, the
applicability of the test in clinical practice and in research is limited as it is expensive and unfeasible.

**Neuropathic Pain**

Neuropathic pain is one of the most bothersome symptoms that people with DPN report. The pain can take the form of prickling, burning, sharp stabbing, or deep aching (Hebert et al., 2017). Neuropathic pain in DM is typically bilateral, below knees, nocturnal, not related to exertion, and not caused by other conditions such as vascular disease, arthritis, or sciatica (Vinik et al., 2013). Patients with severe and moderate pain described it as deep pain with a constant background with occasional breakthrough flare-up pain. Meanwhile, people with mild pain reported it as surface pain (Davies, Brophy, Williams, & Taylor, 2006).

There is inconsistency on whether pain is the hallmark feature of DPN, and thus all DPN symptoms should be referred to as painful DPN, or whether pain is one symptom among many others like increased or decreased sensation, numbness, and unsteadiness. This widespread inconsistency is evident in many of the reviewed studies. In many of these studies, the same symptoms are referred to as either painful DPN, simply DPN, or as neuropathic pain in diabetes. For instance, three of the five Saudi studies of DPN used the term painful DPN (Algeffari, 2018; AlQulti, 2015; Halawa et al., 2010).

The other two Saudi studies, despite using the same description and measurement tools for the symptoms, opt to use the term DPN without the word painful (Mojaddidi et al., 2011; Wang et al., 2014). Both Algeffari (2018) and Mojaddidi et al. (2011) used the same instrument, the MNSI, to measure both seemingly same conditions but with different nomenclature (painful DPN versus DPN). Although Mojaddidi et al. (2011) also used physical neurological
examination to evaluate the symptoms, no pain intensity measures were used to evaluate the intensity of symptoms nor to determine the severity of pain. While the MNSI is a good tool to measure the presence and severity of symptoms, it was not designed to measure pain intensity (Herman et al., 2012). Experts recommend that for the diagnosis and assessment of neuropathic pain, all components of pain should be recorded (distribution, quality, severity, associated symptoms, and relieving or exacerbating factors) (Vinik et al., 2013). This is also evident in the international literature. Hebert and colleagues (2017) has described the clinical manifestations associated with DPN as positive symptoms (tingling and itching), negative symptoms (numbness and muscle weakness), and neuropathic pain (burning, and electric shock sensation).

Additional evidence is found from a study reported from a sample of 269 T2DM patients who were aged 67 years in the U.K. The researchers aimed to study the impact of painful DPN. Performing clinical neurological examination allowed for the categorization of patients into painful DPN, non-neuropathic pain, mixed pain, and no pain. Meanwhile, self-report surveys (Toronto Clinical Scoring System) allowed for a determination of the presence and the degree of peripheral neuropathy to be made: no neuropathy, mild, moderate, and severe neuropathy. The diagnosis of painful DPN was made if the pain was bilateral, below the knee, and not caused by other similar conditions. These authors suggested that peripheral neuropathy is a separate symptom from neuropathic pain in that participants’ results were listed as two variables: painful DPN and degree of neuropathy. The odds ratio for having pain for those with mild neuropathy compared with no neuropathy was 3.4 (CI 95%, 1.4–8.0) and the odds ratio for having pain for those with moderate-to-severe neuropathy was 15.6 (CI 95%, 6.8–35.5) (Davies, Brophy,
Williams, & Taylor, 2006). The study concluded that increasing neuropathy severity is associated with an increased risk of developing painful DPN.

Saudi studies have also reported gender differences in neuropathic pain with diabetes (Algeffārī, 2018; Halawa et al., 2010). Halawa et al. (2010) reported that women had a significantly higher prevalence of painful DPN compared to men, 70% and 62%, respectively, \( p = .02 \). Algeffārī (2018) reported a similar finding; women were 66% of the painful DPN group. However, the odds of DPN did not significantly increase with female gender (1.15, CI 95%, 0.63–2.1, \( p = .604 \)).

Furthermore, the pain experience and the cultural beliefs of expressing pain among the Saudis were important considerations for this current study. The religion of Islam, as practiced by the people of Saudi, has distinctive ideology of pain and suffering. Islam views pain as a part of the trials and tribulations of life and so Muslims strive to remain faithful and withstand pain by assenting to the earthly trials. However, Islam does not condemn those who opt to voice their suffering and find relief (Branden & Broeckaert, 2010). Despite this wide belief among Muslims, many still report their pain. Thus there was no reason to believe that assessing pain among T2DM patients in Saudi would be hindered by their religious or cultural viewpoints as there are many research studies on the prevalence and attitudes associated with different types of pain. For instance, a study surveyed 224 Muslim dental practitioners for the prevalence of lower back pain. They found that 90% of the participants reported having musculoskeletal pain with women reporting more shoulder pain than men (AlMohrej, Alshaalan, Albani, Masuad, & Almodainegh, 2016).
Another study also had no issues recruiting patients with different causes of chronic pain. A total of 200 patients, 64% were female, 49 years, and 75% married, completed the survey on the effect of the severity of pain on depressive symptoms. About 50% had severe pain and only 1.5% had mild pain. As to the causes of pain, 33% and 69% had neuropathic pain and spinal problems, respectively. Severe pain, increased age, being married, poor SES, and history of depression were associated with higher risk of depression, \( p < .05 \) (AlMaharbi et al., 2018).

**Sensory Symptoms**

The DPN sensory symptoms involve numbness, paresthesia, hyperesthesia, and tingling. Khawaja et al. (2018) used the MNSI to measure neuropathy symptoms and found that most participants had at least one symptom. Numbness and pain with walking were reported as the most frequent symptoms in 81% and 75% of their patients, respectively. Meanwhile, loss of sensation while walking was the least common and reported by only 9.6%. A Pakistani descriptive study on non-Saudi T1DM and T2DM patients \((n = 800)\), also used the MNSI to measure DPN symptoms. They reported that numbness was the most common symptom at 63%, followed by dry skin/callus at 38% (Qureshi et al., 2017).

However, a study from India \((n = 208)\) also using the MNSI, found that the most common symptom reported by 72% of participants was a feeling of weakness all over most of the time (D’Souza et al., 2015). Generalized weakness is attributed to muscle wasting, a possible consequence of DPN (Vinik et al., 2013). The second most reported symptom was leg pain while walking, reported by 65%. Prickling and numbness came next with 63% and 45%, respectively (D'Souza et al., 2015).
Among the Saudi population, two studies examined the characteristics and the commonly reported DPN symptoms (Algeffari 2018; Halawa et al., 2010). In one study, 1,039 T2DM patients, with a mean age of 51 years, the DPN symptoms reported by the Saudi patients were similar to those seen with other populations. Burning (67.6%), numbness (65%), and tingling (60%) were the most frequently encountered DPN manifestations. Pain that feels like pins and needles (48%), hypoesthesia to touch (34.8%), electric shock (34.5%), and painful cold (27%) were also reported (Halawa et al., 2010. Meanwhile, in another study, T2DM Saudi patients (n = 242) reported burning pain in the legs or feet (91.7%) as well as prickling feelings (79.8%) (Algeffari, 2018).

Some of the earliest research data on symptoms of DPN are from a US population-based study, the National Health Interview Survey (NHIS) (Harris, Eastman, & Cowie, 1993). The NHIS is a cross-sectional, nationwide survey that has been conducted annually since 1957. The 1989 study included T1DM and T2DM American patients 18 years and older (n = 84,572). The study reported that 30% to 40% of the total sample (n = 2,405) had diabetes (n = 5% with T1DM and n = 95% with T2DM). The prevalence of DPN among participants with T2DM was 36% for males and 39.8% for females Twenty-eight percent of the sample reported numbness, 26.8% reported pain or tingling, and 9.8% reported decreased ability to feel hot or cold. Most patients (37%) reported more than one symptom. At the time, data were collected with none of the validated questionnaires that are currently in use. For example, one of the items asked, “During the past three months have you had numbness or loss of feeling in your hands or feet other than from your hands or feet falling asleep?” (Harris et al., 1993).
Similarly, the Rochester Diabetic Neuropathy Study (RDNS) was conducted from 1986 to 1989 with cross-sectional surveys and subsequent longitudinal study in Rochester, Michigan, U.S. This was one of the earliest large-scale, longitudinal studies on the DPN population (n = 64,573), which included patients T2DM (n = 668) (Dyck et al., 1993). The study included not only people with diabetes but also people with multiple causes of neuropathy. Non-diabetic people served as controls. Various types of neuropathy, including DPN, were assessed using a battery of surveys and physical examination measures like the Neuropathy Disability Score, Neuropathy Symptoms Score, Neuropathy Symptoms Profile, nerve conduction studies, and quantitative sensory examinations. In the RDNS, although 48% of the sample had objective evidence of DPN, only about 15% were symptomatic.

**DPN Symptoms, Falls, and Gait Disturbance**

Recent evidence implicates DPN in some health concerns. Muscular and joint weakness and instability due to DPN can cause disruption in the body’s sensorimotor functions (Alam et al., 2017). Impairments of gait attributed to DPN are related to sensory loss, decreased lower extremity strength, and changes in the central nervous system. Those changes have an effect that extends beyond simple, functional impairment. One study looked at DPN, falls, and depression. Vileikyte and colleagues (2005) studied 484 T1DM patients 70% were males, aged 61.8 years with DPN patients from the U.K. and the U.S. who had had diabetes for an average of 17 years and depressive symptoms. The sample included participants with moderate-to-severe DPN symptoms. About 16% had active foot ulcers. The study evaluated DPN and depressive symptoms using validated measures (NeuroQoL and the Hospital Anxiety and Depression Scale). The study found that DPN symptoms and unsteadiness were predictors of depressive
symptoms. The severity of the DPN symptoms explained 39% of the variance in depressive symptoms. The DPN symptom of unsteadiness, alone, accounted for 30% of the variance in the model, \( p < .001 \) (Vileikyte et al., 2005).

Furthermore, DPN patients are at increased risk of falls. Falls in DPN patients occur as a result of a combination of conditions, such as diabetic neuropathic arthropathy, loss of proprioception, and autonomic neuropathy (affecting the cardiovascular system) (Handsaker et al., 2016). Falls in neuropathic patients can also be attributed to muscle weakness and slower movement of legs and feet. These processes lead to vasomotor changes and increased range of motion of joints which lead to instability of the joints. Falls are serious health concerns for people aged 65 and older due to the sustained injuries, recovery process, and burden to the healthcare system (Crews, Yalla, Fleischer, & Wu, 2013). In large-scale studies, muscular quality is found to be significantly lower among DPN patients, which causes impaired gait and repeated falls (Andersen, 2014). These perceived alterations cause patients to have a fear of falling.

A US study had a sample of 34 T2DM patients, average duration of DM of 15 years, average age of 67 years, HbA1c of 7.9%, and males were 44%, investigated patients' (DPN and non-DPN) concerns about falling (Kelly et al., 2013). DPN was assessed using quantitative measures including vibration perception threshold. Meanwhile, fear of falling was assessed via the Falls Efficacy Scale International questionnaire (FES-1), and the gait spatiotemporal assessment was performed with a validated wearable sensor technology (LEGSys). Participants were instructed to walk for 20 minutes in their habitual shoes at their habitual speed, and their balance and stride velocity were monitored. Most DPN patients (n = 28) reported a moderate-to-
high concern about falling, $p < .001$. However, DPN and non-DPN patients had almost the same level of fear of falling. In other words, the mean scores for fear of falling did not differ significantly between DPN and non-DPN patients ($30.2 \pm 11.4$ versus $31.7 \pm 14.9$, $p = .74$). Furthermore, patients with DPN (regardless of severity) demonstrated a 22% longer double-stance phase ($p = .02$), and 44% more steps to reach steady-state walking ($p = .04$) compared to patients without DPN. The severity of DPN positively correlated with gait initiation steps ($r = .4$, $p = .03$) and double-support percentage ($r = .44$, $p = .01$) (Kelly et al., 2013).

Another study found evidence to support the association between DPN and falls. An international study from Bosnia examined postural stability, walking speed, and fear of falling in 48 T2DM patients, aged 35-70 years, and with confirmed DPN. Participants had T2DM an average of 11 years and DPN an average of six years. Assessment of fall risk was performed by objective and subjective measures. The Functional Reach Test (FRT) was used to measure participants’ dynamic balance. The Tinetti Falls Efficacy Scale (Tinetti FES) and the 10-Meter Walk Test (10MWT) were used for the perception of balance and stability and functional mobility. Neuropathy assessment was performed with the MNSI questionnaire and monofilament testing. Participants were categorized into two groups based on history of falls in the past three months: faller ($1 \geq$) and non-faller (zero). There was a significant difference between the two groups in the duration of diabetes and the duration of DPN, $p < .05$. Twenty-eight participants reported falls. Of the 28 participants who reported falls, half ($n = 14$) had one fall, a quarter had two falls ($n = 7$), and another quarter had more than three falls. The absence of protective sensation (monofilament testing) was higher in the faller group compared with the non-faller
group, $p < .05$. In logistic regression analysis, the monofilament score was significantly associated with the probability of falling (odds ratio = 1.37, $p = .007$). The study concluded that the lack of protective sensation is a significant predictor of risk of falls (Bokan-Mirkovic, Skaric-Karanikic, Nejkov, Vukovic, & Cirovic, 2017). There was no similar literature among the Saudis that examined DPN and falls.

**DPN and Overall QoL**

The level of functioning of individuals with DPN varied considerably depending on the degree and severity of symptoms. Functioning includes physical, mental, emotional, and social practices. It also involves patients’ ability to perform self-care behaviors. This section is organized so that the different domains of QoL are listed separately. The review of the studies in each section included the respective subscores of that domain. For example, to discuss the physical functions, the pertinent subscores of the SF-12v2 (physical composite score) were addressed. QoL as a total score as well as the general perception of health were discussed ending with a summary of the impact of DPN symptoms.

**Physical and Mental QoL**

Using the SF-12v2, a study from Greece examined the predictors of QoL in 53 T2DM patients with DPN. The sample included 40 females with mean age of 66 years and duration of DM of 23.5 years. Assessment measures included the MNSI, Depression Anxiety Stress Scale, Multidimensional Fatigue Inventory, Visual Analogue Scale, and the SF-12v2. The study found that DPN patients scored a mean of 34.4 ± 11.5 on the physical composite score (PCS) of the SF-12v2 compared to the normative data of 50 (however, the level of significance is unknown). Moreover, PCS correlated with general fatigue ($r = -.316$), MNSI ($r = -.492$), and total score of
diabetes complications ($r = -.412$), $p < .001$. The study concluded that DPN symptoms, reduced activity, mental fatigue, and poor glycemic control were associated with poor physical functioning (Lyrakos et al., 2013).

Another large, non-Saudi study of mostly T2DM participants ($n = 21,261$) from Romania also confirmed the negative impact of DPN on physical health. In the study, T2DM patients were surveyed using the Norfolk QoL-DN, which assesses DPN symptoms and their effect on QoL. The Norfolk total score range between -4 and 136, with higher scores indicating impairment. The cut off scores are five and 0.5 for the total QoL and physical functioning, respectively. The results show that 65% ($n=13,854$) reported DPN. The total score of the Norfolk QoL-DN for those with DPN was 38.39 versus 13.71 for those without DPN, $p < .001$. The physical-functioning mean score for patients with DPN was 18.8 compared to 7.93 for those without neuropathy, $p < .001$ (Veresiu et al., 2015). The study concluded that DPN patients had lower QoL scores compared to healthy patients. Furthermore, women compared to men had significantly higher scores, indicating worse physical functioning, 17.6 and 14.7, respectively, $p < .001$.

Another recent study came to a similar conclusion. Riandini et al. (2017) concluded that the individual’s functional status mediated the relationship between neuropathy and HRQoL. This non-Saudi study sampled 160 T2DM patients, 42% were female; with Indian and Asian ethnicity; aged 62 years; and with mean duration of T2DM of 13 years to examine the impact of DPN on HRQoL and association of the functional status. Participants were grouped into DPN ($n = 80$) and non-DPN ($n = 80$). This study is noteworthy because of the detailed measurements used for the functional status. Physical-functioning assessment encompassed
biophysical approaches that include muscle strength (dynamometer), range of motion (inclinometer), functional capability (timed up and go, five times sit-to-stand, and functional reach), average body sway velocity, and balance confidence (activities-specific-balance confidence scale). DPN was assessed by the MNSI and using foot physical examination. Individuals’ HRQoL was assessed by the generic measure EQ-5L. Findings indicated that individuals with DPN had significantly lower functional status scores (lower ankle dorsiflexion strength \(p = .068\)), great toe extensor strength \(p = .023\), poorer timed up and go \(p < .001\), and higher body sway velocity \(p = .002\) and lower HRQoL. The study concluded that body sway velocity, five times sit-to-stand, and balance confidence mediated the association between DPN and HRQoL and explained 37.8% of the variance in HRQoL.

Further evidence came from a non-Saudi, Bosnian study of 60 T2DM patients, 50% were male who are aged 56 years, and with duration of DM of 12 years (Vukojevic et al., 2014). The study used nerve conduction studies as a quantifying measure of DPN and the SF-36 to measure HRQoL. Of the total 60 patients, 51 had DPN. The results of the nerve conduction studies of the motor peroneal nerve correlated with physical-functioning domains of the SF-36 \((r = .34, p = .009)\). The scores of the sural nerve testing correlated with the individual’s vitality \((r = .30, p = .013)\). In this study, clinical parameters of the severity of DPN correlated with the SF-36 scores. The study concluded that DPN symptoms caused mild to moderate impact on physical health \((M = 70 \pm 5, p < .05)\) and thus on HRQoL.

Likewise, Dermanovic Doborotah et al. (2014) worked with a sample of T2DM non-Saudi patients \((n=160, \text{aged 62 years and 48\% females})\). The patients were grouped into: painful DPN \((n = 80)\) and non-painful DPN \((n = 80)\). To measure DPN symptoms, objective and
subjective measures were used. QoL was measured by the SF-36 survey and depressive symptoms were measured by the Beck Depression Inventory (BDI). The average score of the BDI was 19.1 for the painful DPN group compared with 9.6 for the non-painful DPN group, \( p < .001 \). The painful DPN group was significantly more depressed compared with the non-painful DPN group. They found that patients with painful DPN had a much lower physical functioning score compared with the general population, mean = 28 and 69, respectively \(( p < .05 \). Compared with those with DPN, the non-painful DPN group had a physical-functioning score mean of 61.9, \( p < .001 \).

Similarly, neuropathy symptoms can impair an individuals’ emotional health. In that same study mentioned earlier, Dermanovic Doborota et al. (2014) examined the components of the mental functions in DPN patients. As with physical health, mental health and mental composite scores were significantly different between the painful DPN and the non-painful DPN groups. The mean mental health score for the painful DPN group was 52.9 compared with 71.9 for the non-painful DPN group, \( p < .001 \). The mean mental composite score for the painful DPN group was 47.8 compared with 55.2 for the non-painful DPN group, \( p < .001 \). This study accounted for the effect of comorbidities on QoL. Comorbidities like sleep disorders and micturition and defecation disorders, angina, and blindness affected multiple subscales of the SF-36 (e.g., physical functioning, general health, and physical role limitations).

**Depression and Mood Changes**

Diabetic patients are, disproportionately, at increased risk of depression. Older adults with T2DM have a two-to-four times higher risk of depression compared with the general population (Roy & Lloyd, 2012). In T2DM patients, depressive symptoms are associated with
the presence of long-term complications, cardiovascular disease, hypertension, poor physical functioning, and increased hospitalization (Papanas & Ziegler, 2015).

Evidence that links depressive symptoms and mood swings to symptoms of DPN is mounting. Although evidence has established that long-term complications of diabetes (DPN) are associated with depressive symptoms, the evidence is less clear regarding the pathophysiology of the two comorbidity conditions (DPN and depressive symptoms) and whether the occurrence of both conditions is interrelated or merely incidental. Nevertheless, the evidence supports the relationship.

As mentioned earlier (in symptoms and falls), Vileikyte and colleagues (2005) studied the impact of having DPN on depressive symptoms. Demographic and other comorbidities accounted for about 3% of the variance in depressive symptoms, \( p < .001 \). When DPN symptoms were added to the model, they accounted for an additional 28%. Pain and unsteadiness were related to higher levels of depression, \( p = .001 \). Furthermore, an important finding that this study identified was the significant relationship between the episodic-unpredictable timeline scale and depressive symptoms. The episodic-unpredictable timeline explains the cognitive representation of DPN symptoms in terms of unpredictability. This positive relationship implies that, possibly, the unpredictable nature of DPN symptoms is what worsens patients’ mood and increases their anxiety and depressive symptoms.

In a Croatian study, patients with mostly T2DM (n = 140 of 160) and DPN symptoms were recruited. They were grouped into painful DPN and non-painful DPN groups. The painful DPN group scored higher on the depression scale BDI (mean = 19.1) compared with the non-painful DPN group (mean = 9.6), \( p < .001 \), indicating more depression (Dermanovic Dobrota et
Also, the painful DPN group scored lower on the emotional role subscale of the SF-36 survey (indicating worse) (mean = 43.4) than the general Croatian population (mean = 72.4) and the non-painful DPN group (mean = 74.2).

A study from Korea came to a similar conclusion in a sample of 200 T2DM with DPN (Kim, Jeong, Mok, Kim, and Lee, 2015). This study assessed DPN symptoms using the MNSI for neuropathy symptoms, and the Brief Pain Inventory (BPI) and Visual Analogue Scale for the severity of pain. The EuroQoL (EQ-5D) was used to measure participants’ QoL. About (n = 82) 41% of the patients had painful DPN. The average pain and worse pain scores were 4.6 and 6.3, respectively, \( p < .001 \). Kim and colleagues found that patients with painful DPN had functional impairment that was significantly substantial across multiple life domains (social, recreational, self-care, relations, and sleep). Of particular importance is that the most reported impairment in the individual’s life was mood stability score. It was reported that about 80% (n = 62) of the total 200 patients had mood swings and emotional instability secondary to painful symptoms.

**Self-Care Activities and DPN**

The evidence on association between self-care activities, DPN, and QoL is multifactorial and complex. In the context of neuropathy, self-care can be viewed as an antecedent. The degree of compliance in performing activities like following a healthful diet or inspecting feet and shoes plays a role in enhancing or limiting the development of DPN. Self-care has a significant impact on the relationship between glycemic control and neuropathy. For instance, an observational study from Pakistan assessed a sample of 400 older adults over 60 years of age with T2DM for the predictors of glycemic control. Forty-six percent were males and had a mean duration of DM of 7 years. Participants responded to a battery of questionnaires (Lawton Instrumental Activities
of Daily Living Scale, Self-care Inventory, Geriatric Depression Scale, and Mini-Nutritional Assessment). Self-care behaviors were found to be strong predictors of glycemic control, adjusted odds ratio = 0.96 (CI 95% 0.95–0.98), \( p < .05 \) (Atif, Saleem, Saghar, Malik, & Ahmed, 2019). This study provides evidence that performing self-care activities affects glycemic control and impacts the individual’s probability of developing DPN symptoms.

On the other hand, symptoms of DPN play a role in the patient's ability to perform self-care behaviors. For instance, if the patient has moderate or severe, painful DPN, he or she may not be able to carry out the routine of cooking healthy meals or performing exercise regularly. However, research to support this important perspective has not become evident as the literature is inconclusive as to the impact of DPN symptoms on the individual’s self-care behaviors. Yet, the individual’s ability to perform proper self-care behaviors depends on physical health (i.e., walking and climbing stairs), mental health (mood, and anxiety), and cognition (memorizing and comprehension).

In the context of the Wilson and Cleary HRQoL model, it can be seen that self-care behaviors are influenced by the characteristics of the individual and the environment. Individual variables such as age, gender, and educational level are associated with readiness and ability to execute self-care behaviors (Wilson & Cleary, 1995; Ferrans et al., 2005). By the same token, social support and healthcare resources are important factors in self-care. Finally, if self-care is seen as a domain of functioning, then it would be influenced by the individual’s physical, social, and emotional health. The interaction among these domains in addition to other variables predicts the overall QoL.
The most important subset of self-care behaviors relevant to the development of DPN is foot self-care. The literature on the association of foot self-care and neuropathy symptoms is scarce since DPN is considered among the complications of DM. Some studies, mainly from Saudi Arabia and the Middle East, examined foot self-care activities in relation to diabetic foot ulcers, omitting that DPN is a significant risk factor for foot problems.

For instance, one study focused on foot self-care practices among T2DM patients (AlOdhayani et al., 2017). A sample of 350 T2DM Saudis, 64% were males, aged 58 years, was surveyed to explore the knowledge and practices of foot self-care. Descriptive statistics were used to address the foot self-care practices. They reported that: 28% of the sample soaked their feet; 41% moisturized their feet; 53% wore socks and shoes regularly; half, 50%, were knowledgeable about diabetes and foot self-care. They also stated that there was a lack of education from health care providers as the majority of the patients obtained knowledge about proper foot care from non-medical sources (magazines and the internet).

Another study of 598 Saudi patients, 95% had T2DM, 62% were males, who had had diabetes for 15 years, examined the predictors of foot complications (Y. Hu et al., 2014). DPN was a predictor rather than an outcome variable. The study found that DPN along with peripheral arterial disease increased the odds of foot complications. Patients with DPN had greater risk of developing foot complications compared with patients without the DPN (odds ratio = 3.2, CI 95%, 1.69–6.1, \(p < .01\)).

One Saudi, descriptive study aimed at exploring knowledge, attitudes, and practices regarding foot care. They surveyed a sample of 74% T2DM patients (n = 229) about their knowledge of foot ulcers and practices of foot self-care and found that more than 60% of the
patients had proper knowledge of the risk factors of diabetic foot and the role diabetes management plays (AlHariri et al., 2017). The most common foot care practice was washing the feet regularly (95%), followed by inspecting feet (85%). The practices least adhered to were wearing stockings, 17%, and trimming nails, 33%. The findings of this study suggest that most patients in the Eastern region of Saudi have satisfactory foot self-care practices.

AlJohani and colleagues (2015) surveyed a Saudi sample (n = 210) T2DM patients, aged 39 years, 50% were female, using the Summary of Diabetes Self-care Activities (SDSCA) to determine the self-care practices (where 1= once a week and 7= every day of the week). Generally, participants showed low-to-moderate levels of self-care with a mean of 3.72. The most followed practice among this sample was taking medications with a mean of 6.2. Meanwhile, foot care varied between participants (3.49 ± 2.37). This suggests that, on average, patients inspected their feet and the inside of the shoes about three times/week, with greater variation implied by the large standard deviation values. Finally, the t-tests (differences in mean scores) of foot care were significant with regard to younger age, female gender, higher income, and positive smoking status, $p < .05$. Younger patients, patients with higher income, and females performed foot care more often than did males, lower income, and older patients (AlJohani et al., 2015). Interestingly, smokers were more compliant with foot care practice compared to non-smokers.

Some studies have also focused on the nature of knowledge and practice of foot self-care among DPN patients. A (non-Saudi) study was conducted to measure the level of foot care knowledge, practices, and DPN symptoms using self-report measures on a sample of (n = 250) individuals who were aged 54 years old and had had DM for 8 years (Saber and Daoud,
To assess DPN, they used the MNSI questionnaire and examination. Assessment of the knowledge and practices was obtained by an 11-part, self-designed questionnaire with possible scores=0–11, a score < 5 indicates poor practice, 6–7 satisfactory practice, 8–11 good practice. The prevalence of DPN among this sample was 31%. The mean knowledge score was 6.1 ± 2.6. As for the subscores for knowledge, 76% had good knowledge about washing feet daily, 73% had good knowledge about inspecting feet daily, and 71% had good knowledge about the importance of socks. The lowest score in knowledge was for wearing slippers at home with 31%. The participants’ practice scores were expectedly lower than their knowledge scores at 5.8 ± 2.1, although no test of significance between the two scores was reported. Almost everybody (95%) washed their feet daily, 62% examined their feet daily, and 61% cut their toenails straight and across. Again, the lowest score of practice was for wearing slippers at home at 23%.

Furthermore, with regard to the type of footwear, about 44% wore round-toe shoes and 33% wore sandals. The majority of patients with low knowledge scores had low practice score too, $p < .001$. In addition, it was found that persons with DPN and high foot care knowledge were 32% compared to persons without DPN and high foot care knowledge which were 61% of the sample. However, there were no significant differences between DPN and non-DPN patients in the foot care practice, $p = .11$ (Saber and Daoud, 2018).

A (non-Saudi) study examined the relationship between foot self-care practices and the development of diabetic foot ulcers among 290 DPN patients. This study was a longitudinal design with baseline, 3-month, and 1-year follow-up periods. Assessment of DPN was performed by the MNSI questionnaire and by foot examination, using the monofilament and vibration tests. The newly developed Diabetes Foot Self-care Behavior Scale (DFSCBS) was used to determine
the frequency of foot care. At baseline, participants lacked sensitivity, as evident by the monofilament testing, but had no existing foot ulcers. By the one-year follow-up, 29% (n = 85) had developed foot ulcers. In the Cox univariate regression analysis, there was a significant difference in the MNSI scores between DPN patients who developed foot ulcers and those who did not. Diabetic foot ulcer patients had a mean score of $2.64 \pm 0.79$ compared with those who did not = $2.34 \pm 0.82$, $p = .009$. The hazards ratio of developing foot ulcers increased by 1.43 times in DPN patients (CI 95%, 1.43, 1.09–1.86, $p = .009$).

Moreover, the two groups (foot ulcers and no foot ulcers) were also significantly different in their foot care practice. Foot care practices were significant predictors of foot ulcers: inspection of bottom of the foot, $p = .002$; inspection between toes, $p = .021$; and moisturization of foot, $p = 0.04$. The predictive power of the foot care practices remained significant after controlling for demographic variables. However, after controlling for both demographic variables and risk factors (including DPN), only moisturizing the foot remained significant (Chin, Liang, Wang, Hsu, & Huang, 2014). This suggests that DPN patients with dry and callused feet are at major risk for developing foot ulcers. Inspecting the foot may not prevent ulcers due to injuries from cracks and fissures, but moisturizing the feet may have an effect. This study is significant because while it does not examine the correlation between foot care practices and DPN development, it does show that having DPN along with improper foot care increases the risk of ulcers and injuries.

Some studies examined the influence of mood symptoms on self-care. Beverly and colleagues (2012) found that depressive symptoms can lead to social withdrawal and compromised self-care practices. They found that T2DM adults (n = 316) with elevated
depressive symptoms were reluctant to discuss their self-care with the provider. Moreover, participants with greater depressive symptoms had less frequent self-care practices \((p = .005)\) and lower QoL \((p = .002)\) (Beverly et al., 2012). These findings suggest that changes in mental health contribute to worse self-care practices.

To conclude, studies (discussed earlier) have focused on measuring the pattern and frequency of performing foot care among T2DM patients (Muhammad-Lutfi, Zaraihah, & Anuar-Ramadan, 2014; Saber & Daoud, 2018). Four studies from Saudi populations examined pattern of foot care regardless of DPN presence (AlHariri et al., 2017; AlJohani et al., 2015; Alodhayani et al., 2017; Y. Hu et al., 2014). There was only one non-Saudi study reviewed herein that included DPN patients and evaluated foot care practices (Chin et al., 2014).

**Characteristics of the Environment**

**Social Support**

The direct examination of the association of social support and DPN is limited. Evidence found discussed ways in which social support impacts people with T2DM by affecting patterns of compliance in self-care, compliance with medication, and diabetes management outcomes. Given that DPN is a complication of uncontrolled DM, this current study hypothesized that this relationship extends to DPN. Social support factors that affected the management of T2DM also extend to affect DPN development.

In the effect of social support on T2DM management outcomes, a piece of substantial evidence comes from one of the few, although dated, meta-analysis. Van Dam and colleagues (2005) reviewed randomized controlled trial studies \((n = 6)\) on social support from (1980–2003) with a total of \((n = 712)\) T2DM patients who were aged 60 years old, and had a mean duration of
DM of 9 years. Those studies examined varied forms of social support interventions: support from peer patients in group visits and telephone calls, organized internet peer groups, support from spouses, and support from family and friends in diabetes education—all compared with usual diabetes care or education without social support. The interventions were measured by various means: perceived social support, diabetes support scale, adherence to social support questionnaire for partners, and social involvement and depression scales. The outcome variables examined ranged between biophysical measurements (HbA1c and physical activity level) and physical and emotional well-being and QoL. The review concluded that the effect of the social support was general or specific depending on the source of support. There were a few conclusions. First, support from peers in group sessions, internet-based, and telephone enhanced patients’ lifestyle modifications. Second, support from family and friends participating in diabetes education groups and social support groups had no effect on diabetes control for older men. Third, support from a spouse may have a positive impact on obese women but not on men. Finally, biomedical outcomes only improved in two out of four studies. Also, both positive and negative effects of social support were found. One study in the review reported that men might respond negatively to spouse participation in diabetes education groups (van Dam, 2005).

A recent study from China had a non-Saudi sample of (n = 122) T2DM patients who had DPN for 22 months examined the predictors of regular exercise among DPN patients (Pei, Wang, Sun, & Zhang, 2016). The study aimed to assess the association between social support and patients’ patterns of physical activity. DPN and exercise measurement were discussed earlier in DPN and physical activity. Participants were grouped into regular and non-regular physical activity. Social support was measured by the Social Support Rating Scale-Chinese, which
includes 10 items: subjective support (experience of receiving support and being understood), objective support (visible and practical support), and support availability (the degree of support utilization). Higher scores indicate greater support. The study found that the scores of total social support, subjective, and support availability did not significantly differ between the regular and non-regular physical activity groups, \( p = .179 \). However, the regular physical activity group scored generally higher than the non-regular activity group in the total and subjective social support (means = 38.6 and 22.2 vs. 37.1 and 21.4). This means that DPN patients who exercised regularly did so with help and support from family and friends. Thus, objective social support (actual support) increased the odds of performing regular physical activity 2.1 times (CI 95%, 1.08-4.24, \( p = .029 \)) (Pei et al., 2016). This suggests that receiving support from family and friends predicted a better performance of regular exercise, which was discussed earlier (DPN and physical activity) to slow the progression of DPN.

A recent systematic review has also concluded that social support was associated with self-care practices. The authors evaluated the evidence from 28 studies (\( n = 5,242 \), T1DM and T2DM patients). Social support was significantly associated with self-care in DM patients (\( r = .28, \text{CI 95\%}, .21-.34, p < .001 \)). This association was stronger among T2DM patients compared with T1DM, \( r = .30 \) versus .22 (Song, Nam, Park, Shin, and Ku, 2017).

A study from Iran of an elderly sample examined whether social support was a predictor of self-care. The sample included 374 persons with T2DM, who were 60% female and mean age of 67 years. Self-care was measured using the SDSCA Scale. Social support and self-efficacy were measured by the Perceived Social Support Questionnaire (PSSR) and the Diabetes Management Self-Efficacy Scale. Overall, 67% of the patients had poor diabetes self-care. The
most performed self-care domain was monitoring of blood sugar by 64% of the participants. About half, 55%, had satisfactory foot care practices. Performing physical activity was generally acceptable with 68% of the sample noting regular exercise (Borhaninejad et al., 2017a). In a different publication, on the same sample, the authors examined the association between social support, self-care and self-efficacy. The results of the step-wise hierarchical multiple regression showed that adding social support to the model explained 9.9% of the variance in self-care, \( p < .001 \) (Borhaninejad et al., 2017b).

To conclude, evidence indicated that social support is linked to positive health outcomes for T2DM patients by mediating the relationship between DM and self-care behaviors. Furthermore, evidence showed that social support improves the self-care practices of patients with T2DM, including performing regular physical activity.

**Chronic Illness Resources**

Living with a chronic illness such as diabetes affects the individual in every dimension of life. The integration of chronic disease into existing roles and responsibilities, the need for continuous self-care, diet modification, exercise, and much more is not only exhausting but also requires a tremendous amount of resources. The resources the individual include communication with healthcare providers mainly nurses and physicians, neighborhoods and community conditions.

**Communication with providers.** The interaction with the healthcare provider is an essential element in the management of chronic diseases. It has a significant influence on the patient’s emotional well-being and, thus, has either a negative or positive effect on the patient’s adherence to professional advice. Proper education and technical and behavioral training
empower patients to perform better self-care. Patients often feel overlooked and ignored in the decision-making process. Patients described aspects of favorable relationships with a provider that involves support, collaboration, and encouraging communication strategies outcomes (Bezreh et al., 2012; Young, Azam, Meurer, Hill, & Cui, 2016).

On the negative aspects of communication with providers, a US-based study of Asian-Indians who are first generation US immigrants aimed to explore the patients’ perceptions of the influence of social and healthcare provider support on DM management (Venkatesh & Weatherspoon, 2013). The qualitative study of 30 individuals with T2DM with a duration of DM of 10 years, who were aged 60 years old, and 49% were females, grouped participants according to their HbA1c levels into the acceptable (AC) group with HbA1c < 7% and the unacceptable (UC) group > 7%. Data were collected by in-depth interviews using semi-structured questionnaires with open-ended questions and probes. Regardless of their glycemic control, participants expressed that the provider should have provided clearer communication about the challenges related to their condition. UC HbA1c patients were more likely than AC to report that providers should regularly monitor and follow up with them to achieve target glycemic control. Furthermore, the UC group wished for more attention from providers and more time spent with them (Venkatesh & Weatherspoon, 2013). Considering the cultural differences, patients reported lack of culturally sensitive care regarding dietary counseling. Most patients recognized factors like a disconnect between recommendations and everyday life, lack of support, and inadequate access to the healthcare provider, as in time-limited visits. The expectations of daily glucose monitoring, physical activity, and healthful diet seemed impractical to some patients (Venkatesh & Weatherspoon, 2013).
Poor communication and time constraints may lead to inadequate patient education and less than optimal DM management. For instance, patients often perceive that there is conflicting information about medication, signs and symptoms between the physicians, media sources, and internet which leads to lessened adherence (Carpenter, Elstad, Blalock, & DeVellis, 2014).

Another dimension pertinent to the patient-provider relationship is trust in the provider and healthcare system (Polinski et al., 2014). Lack of trust seem to be also an underlying factor contributing to non-adherence with appointments and medications. Patients with higher mistrust and low health literacy perceived worse communication than did mistrustful patients with higher literacy (White et al., 2016).

Among Saudi patients, the challenges of free-access to healthcare can be a barrier for patients to receive optimal diabetes care. The provision of free services along with the growth in population has led to inadequate numbers of healthcare personnel and decreased patient resources to accommodate growing needs (AlMutairi, 2015). Consistent turnover due to stressful work environments and the employment of expatriates has led to instability and low-health outcomes (AlMalki et al., 2011).

Furthermore, among the Saudis, the patient-provider relationship is influenced by individual characteristics. Patients’ own beliefs, education levels, and ethnic backgrounds have all influenced the dynamic of this relationship (AlAboudi et l., 2016). Due to the differing religious, geographical, and ethnic combination of the Saudi population, people have developed different outlooks and expectations when receiving healthcare services. Some people are generally indifferent; others depend on medications alone to improve diabetes outcomes and to prevent complications. In one study of T2DM patients (n = 75), 77% were male, who had a mean
duration of DM of 12.6 years, and were aged 54 years, researchers explored the association between knowledge, attitudes, and QoL among Saudis with DM (AlAboudi et al., 2016). Data were collected using the Brief Diabetes Knowledge questionnaire and the Attitude Toward Self-care questionnaire. The study found that 77.3% of the participants were afraid of their diabetes, and 40% were depressed and unhappy. Denial and unacceptance influenced 45% of them.

In addition, diabetes knowledge varies among the Saudis depending on the region and the individual (AlMutairi, 2015). Poor knowledge is most apparent with food and medications. The majority of the participants thought that carbohydrates should be removed entirely from the diet. Other participants felt that bitter foods are an alternative to medication and would neutralize hyperglycemia (AlMutairi, 2015). The gap created by improper patient-provider communication has led to suboptimal outcomes, lack of adherence, progressive complications, and ultimately increased healthcare costs.

**Neighborhood conditions and community resources.** Another dimension of diabetes resources involves the general support and empowerment patients can obtain from their environment. This is the broader environment and a potential influencer in living with a chronic illness. Examples of these resources include the neighborhood’s safety, a pleasant environment like sidewalks and parks, access to information in the community, and availability of healthy foods. The evidence on the association between DPN and neighborhood resources is limited. The reviewed studies are based on the established evidence of the impact of neighborhood conditions and community resources on public health with some studies specific to the diabetes population. Again, this evidence is presented to support the hypothesis that factors affecting T2DM extend to being factors affecting DPN (Sidawi & AlHariri, 2012).
One piece of evidence comes from a confirmatory factor analysis on the neighborhood-specific variables that affect health. This US study examined a sample (n = 615, T2DM, aged = 45–64 years, males = 62%, non-Hispanic Black, unemployed = 65%, income < $20,000 = 41%) where the data were collected using a demographic and neighborhood questionnaire, the Medical Outcomes Study Social Support Survey (MOS-SSS), food insecurity, and self-reported Medication Adherence Scale (MAS), and the SDSCA (Smalls, 2015). The measurements for neighborhood characteristics were as follows: aesthetic environment, walking environment, food insecurity, access to healthy foods, and neighborhood problems index. Moreover, participants reported higher scores for social support and social cohesion. The study concluded that neighborhood factors explained the variance in self-care practices. For instance, for medication adherence, 14.2% was explained by food insecurity, and 11.6% was explained by social support. For general diet 20% of variance was explained by social support. For variance in foot self-care, 14.9% was explained by neighborhood activities, and 10.7% was explained by social support. Social cohesion was significantly associated with glycemic control, $p < .05$ (Smalls et al., 2015). This study verified that neighborhood conditions and community characteristics are predictors of diabetes self-care behaviors and health outcomes to varying degrees.

Additional evidence comes from the U.S. in an analysis of data from the Panel Study of Income Dynamics longitudinal study from 1999–2013. This cross-sectional analysis included a community-based sample of older adults (n = 3,240, mean age = 56 years, males= 48%, homeowners = 83%, White = 76%, Black = 18%). Participants were asked to rate their perceptions of their own health using the Self-Rated Health questionnaire. The built environment of the neighborhood was rated based on the availability of health supportive services and
commercial decline in zip codes. Short- and long-term impact of the built environment were measured by single and cumulative typology. On average, participants had fewer than one chronic condition and fewer than one functional limitation. The most common environment was the average density, 41%, followed by low density (census demographic). The commercially declined environment was prevalent in only 3% of the sample. The study findings showed that long-term exposure to neighborhood environments that lack supportive services (physicians, grocery stores, and recreational facilities) and have a negative built environment (liquor stores, pawn shops, and fast food stores) increased the risk of poor self-rated health, $p < .05$. In addition, the built environment influences healthy aging (Spring, 2018).

Among the Saudi population, only one study was found that addressed the impact of a neighborhood’s context on diabetes (Sidawi & AlHariri, 2012). In this study ($n = 30$, T2DM, males = 100%, aged = 45 years, had DM = 12 years), data were collected using questionnaires on performing physical activity, diet, lifestyle habits, and neighborhood conditions. Most of the participants did not have problems with their environments. Nevertheless, participants reported neighborhood conditions that were bothersome: difficulty wandering around within the community, pollutants, noise, noise from traffic, and lack of cleanliness of the neighborhood. The findings, although not significant, showed that the built environment (sidewalks and parks) has a substantial influence on enforcing the adoption of a healthy lifestyle, physical activity, and psychological well-being.

In addition to the built environment, other chronic illness resources included training programs and support systems. The Diabetes Self-Management Education and Support (DSME) is such a service provided for all people with diabetes in the U.S. and is reimbursed by major
health insurance companies like Medicare and Medicaid (Beck et al., 2018). One of the objectives of this program is to help patients develop the critical skills and problem-solving techniques needed to manage their condition and delay or prevent complications. Studies showed that the services provided via the DSME, such as online peer support and electronic health tools, allowed for the implementation of a thorough feedback circle indispensable to enable continuing self-care (Ceriello et al., 2012; Greenwood, Gee, Fatkin, & Peeples, 2017). This service combines multiple factors (social support, community resources, and professional advice) to enable patients to make better health choices.

**DPN, Perceived Health, and Overall QoL**

In the context of neuropathy, QoL has been affected by the severity of symptoms. The overall QoL of patients with DPN is cumulative and is based on the variables mentioned earlier. Based on the accumulating evidence, T2DM individuals living with DPN have decreased overall QoL. The evidence is found in the effect of symptoms on physical, emotional, and social well-being and sleep disorders.

Emphasizing the same earlier reported studies, evidence presented herein is to highlight the impact on overall HRQoL. Veresiu et al. (2015) assessed the QoL of patients (n = 21, 261), of whom 65.2% had neuropathy symptoms. Of those, 22.7% had severe neuropathy symptoms and developed foot ulcers. The total HRQoL score for those with severe DPN, as measured by the Norfolk QoL-DN, was threefold higher than those without DPN (38.39 versus 13.71, p < .001) suggesting worse QoL. Similarly, a study in Greece, discussed earlier, measured the participants’ health perceptions and HRQoL using the SF-12v2 physical and mental composite
scores. The study concluded that DPN symptoms negatively affected the overall perceived HRQoL, and thus patients generally perceived their health as poor (Lyrakos et al., 2013).

Another report that illustrates the effect of DPN on QoL came from a controlled trial that investigated the effect of new DPN investigational drugs, ruboxistaurin, topiramate, versus taking a placebo treatment by measuring nerve-fiber pathways and improvement of QoL dimensions. A sample of 54 T2DM patients with DPN, 20% females and were mostly White was surveyed using the Norfolk QoL-DN to measure QoL. The Neuropathy Total Symptoms Score, Neurological Symptoms Score, Quantitative Sensory Testing, and Neurological Impairment Scores-Lower Limb were used to define and measure DPN symptoms. Participants were randomized equally into three arms (n=18 in each group). Participants received either one of the investigational drugs or a placebo for >18 weeks and completed baseline and posttreatment visits. Changes in neurological functions were significantly higher among the topiramte group compared with the ruboxistaurin group. Both treatment groups improved neurological and QoL scores compared to the placebo group, \( p < .001 \). Total QoL scores improved significantly in both active treatment groups (mean = 9.56 and 12.22, \( p < .001 \) and \( p < .04 \)), compared with (mean = 5.56) for the placebo group (Boyd et al., 2011). The study also found varying degrees of positive correlation between total QoL and DPN subjective and objective measures, \( p < .05 \).

Some evidence of the impact of DPN on QoL comes from interventional studies. Two studies in which patients were treated with either vitamin D\(_3\) (Alam et al., 2017) or vitamins B\(_1\), B\(_6\), and B\(_{12}\) supplements (Hakim et al., 2018) showed patients’ QoL improved secondary to improvement of symptoms. In the case of vitamin B complex, participants received the
supplements for 12 weeks. Their QoL, as measured by the SF-8, improved from the baseline 44 to 51 at visit five, \( p < .001 \). In the vitamin D supplementation study, participants received a single dose of 600,000 international units of vitamin D intramuscularly. The study concluded that participants had improved emotional subscale scores in the NeuroQoL, \( p = .04 \) even though there was no improvement in painful symptoms (Alam et al., 2017).

Another domain of QoL that has been studied and affected by DPN is sleep patterns. In a cross-sectional study from Korea, a sample of 200 patients with T2DM were assessed for impact of DPN on sleep and QoL (Kim, Jeong, Mok, Kim, & Lee, 2015). The degree of sleep disturbance was measured using the MOS-Sleep Scale. Patients with painful DPN had impaired sleep as evidenced by worse scores of sleep adequacy, respiratory problems during sleep, sleep initiation, sleep maintenance, and somnolence.

Studies on Saudis were limited to the effect of DM and foot ulcers on patients’ QoL (AlAboudi et al., 2016; AlHayek et al., 2014; AlShehri, 2014). No evidence was found for the effect of DPN symptoms on QoL among the Saudis. Thus, this finding has provided evidence as to the important need to conduct research in DPN for this population.

**Summary and Evaluation of the Evidence**

The review of the literature confirmed that the strongest factors associated with DPN were age, duration of DM, and HbA1c. A weaker association was found between DPN and gender, BMI, smoking, hypertension, and physical activity. Considering that the evidence reviewed herein is primarily from cross-sectional designs, determining the nature of the association (causal versus incidental) might be limited. Further, the results of the studies differed based on the different measurements of predictors. For instance, in reviewing the effect of
smoking on DPN, some studies defined smoking exposure by “ever smoker” (current or former) and “never smoker”. Other studies compared non-smokers (may include former smoking) to never smokers. Other studies simply had smoking as a variable with no specifying definitions. This wide range of measurement scales considerably affects the validity of the outcome measurements.

Moreover, some studies, like Gogia and Rao (2017), concluded that male gender is associated with the risk of DPN although the level of significance was not reported in the research article. Such weaknesses in the methodology makes the conclusions drawn about the risk factors challenging. It should be noted that poor methodological rigor was observed in some of the Saudi-based studies. One study had discussed the different predictors of DPN and concluded that some variables were correlated to DPN while others were not (Mojaddidi et al., 2011). However, the significance level was not discussed. Also, the authors did not explain which statistical tests were used to test the hypotheses. For instance, the study reports that the HbA1c level was higher among the symptomatic group compared to the non-symptomatic group without discussing whether this difference is significant or not. Also, the study failed to provide the mean scores for each variable. Reporting detailed description of the methods, including statistical tests is imperative and can impact the validity of the study findings and implications.

**Conclusion**

Evidence has been presented herein to support the relationship of DPN symptoms to individual and environmental factors and to impaired QoL. Biologic factors have been identified as risk factors for DPN. Evidence globally has identified several risk factors such as age, duration of diabetes, and glycemic control as the strongest, independent predictors of DPN.
symptoms. However, there was less consensus concerning the roles that gender, hypertension, BMI, and physical activity play in DPN. Research on foot care habits, frequency, and association with DPN symptoms among Saudis with T2DM, albeit scarce, indicated that most patients lack knowledge related to the importance of foot care and that DPN is a risk factor for diabetic foot. What has not been further investigated was the effect of DPN symptoms, considering severity, on QoL among the Saudis with diabetes and neuropathy. Further, the relationship of glycemic control, comorbidity, age, and gender, and DPN need to be examined.

This reported study added to the body of literature in the nursing discipline and the scientific community the association of neuropathy symptoms and individual and environmental risk factors in a comprehensive perspective guided by a theoretical framework. In addition, this reported study made a unique contribution to science and humankind, particularly for those individuals living in Saudi Arabia.
CHAPTER THREE

METHODS

This was an observational study examining the factors associated with DPN symptoms and the impact of symptoms on the QoL. The aims of the study were (1) to examine the impact of DPN symptoms on patients’ functional status (foot care practices), general health perception, and the physical and mental QoL and (2) to examine the biological (HbA1c, comorbidity, and cardiovascular risk factors) and individual (age, gender) factors associated with DPN symptoms in persons with T2DM. This chapter addressed the study design, the setting, the sample, data collection, data analysis, and the protection of human subjects.

Design

This study was non-experimental and utilized a cross-sectional survey to examine the factors associated with DPN symptoms. This study involved obtaining measurements prospectively on a single occasion with no follow-up period. According to Hulley et al. (2013), the cross-sectional design has the advantage of being fast and inexpensive and avoids the issues of adherence and follow-up which are associated with longitudinal studies. This study employed a non-experimental descriptive approach because this design is appropriate for establishing an association before other advanced designs are to be used. Generally, an investigator establishes this association before venturing into a more advanced design (Levin, 2006) especially, when there is a paucity of literature available about a population.
Setting

Background of the Country of Saudi Arabia

The population census. Saudi Arabia is located in the Middle East and is the largest country of the Arabian Peninsula. As of 2017, the population of the country of Saudi Arabia was a little over 32 million people with about 20.5 million people (74.1%) with citizenship. The population is mostly youth and young adults with about 70% of the Saudi population below the age of 35 years. The percentage of people aged > 65 is 2.6% (General Authority for Statistics, 2016). In Saudi, there are 13 administrative regions which represent the entire urban and rural areas. Each region has a capital city that hosts the municipality as well as several smaller governorates.

Housing and living conditions. As of 2010, the number of households stretched to 4.7 million with an average of 6.4 individuals in each household (Abdul Salam, Elsgaey, Khraif, & Almutairi, 2014). Considering the rate of births and the aging population, the number of inhabitants in a single household is expected to continue at the same rate (Ashwan, Abdul Salam, Mouselhy, 2012). Economically, the vast majority of the Saudi people work for the government. The average annual income of Saudis is $54,770 (about 205,387 Saudi Riyals). About 21 million persons in Saudi have an ownership status of their houses, and about 1.3 million persons are renting. The majority of households are apartment units (43%); followed by 29% larger homes (villa); and around 18% are living in traditional (mud or stone-made) houses. The size and type of household reflect the individual’s SES. Accordingly, those who live in apartment units reflect a moderate SES or are middle-class citizens. The housing conditions are standard with blocks, bricks, and concrete as the basic construction materials. The households have accessible amenities and services such as public water, electricity, gas, and sewage networks (General
Authority for Statistics, 2016). The principal means of transportation in the country is cars with an average of 3 cars owned by a household.

**Health and well-being in Saudi.** Many Saudis are living with common metabolic and cardiac conditions such as obesity, coronary artery disease, hyperlipidemia, and heart failure. Besides, other chronic illnesses like hypertension, kidney failure, and peripheral vascular diseases are also prevalent among the Saudis. Further, diabetes is a common health problem among the Saudis. According to the International Diabetes Federation, there were around 4 million cases of DM in Saudi in 2017 (International Diabetes Federation, 2019).

Further, as far as healthcare services, the majority of healthcare services (> 60%) are provided by the Ministry of Health (MoH) free of charge for those with citizenship. Healthcare services include hospitalization, emergency room visits, outpatient visits, medications, home health care, and tertiary care (General Authority for Statistics, 2016). The MoH employs the majority of healthcare personnel working at major referral hospitals, in-patient pharmacies, primary care centers, and rehabilitation facilities. The total number of healthcare workers in primary care centers (nurses, physicians, and pharmacy and laboratory technicians) is 72,473 workers with 19,863 being nurses. There are about 2,325 primary healthcare centers with an average of 150 centers per each administrative region (13 regions). The primary function of those centers is the provision of preventative services, chronic illness care, and as referring facility to advanced specialty centers. The clinics at the primary care centers include well-child clinic, perinatal, dental health, and chronic illnesses clinics. Also, a few centers have health educators’ clinics which are run by nurses.

**Cost of healthcare services.** Since its development in 1950, the MoH has provided full medical care free of charge. The MoH is responsible for planning, formulating the policies and
guidelines, and monitoring the healthcare system in the nation. The centralization of decision-making and the financial demands brought pressure and overwhelmed the MoH. For instance, the expenditure of the national budget on MoH has risen from 2.8% to 6.2% between 1970 and 2009. This budget is more than 29 million Saudi Riyals (about 7.3 million dollars) of the 475 million Saudi Riyals of government’s budget (Saudi Arabia Health Statistical Yearbook, 2009).

Data Collection Site

Data were collected at the Prince Abdul-Aziz bin Majid Diabetes and Endocrinology Center in King Fahad Hospital, Almadinah Region, Saudi Arabia. It is the second largest center of its kind in the country and the referral center for the Almadinah region. The diabetes center is considered the treatment and referral facility for the administrative region and its seven governorates. The population served at the center is the population of Almadinah region, the third largest municipality in the country, about 1.3 million people. The center provides diabetes and endocrinology medical and nursing care which includes a quarterly follow up, DM regimen changes, wound management, and lifestyle and dietary counseling. The center’s physicians provide care for patients upon referral from their primary care physicians. Typically, each patient is followed up regularly every 3 to 6 months. On each follow-up visit, patients undergo biochemical tests that include (HbA1c, lipid profile, kidney and liver functions, and complete blood count) among other diagnostic tests.

Sample

The study used a convenience sampling approach which is a non-probability sampling technique to obtain a representative sample of the DPN population.
Inclusion Criteria

Participants were included in the study if they were men and women who have the diagnosis of T2DM with confirmed diagnosis of DPN or reported experiencing pain, numbness, and tingling sensations. The participants’ age range had to be between 18 and 80 years old. Moreover, participants had to be on diabetes-control regimens, that is, insulin or anti-diabetic medications, regardless of adherence. Participants had to have their most recent HbA1c levels (≤ 6 months) listed in their charts.

Exclusion Criteria

The exclusion criteria included: (1) presence of co-morbid and debilitating illnesses (cancer and end-stage renal disease; blindness, major lower limb amputations, and other causes of neuropathy (chemotherapy-induced neuropathy, fibromyalgia, history of nerve root compression, and spinal stenosis syndromes) that might obscure the assessment of DPN symptoms and worsen QoL; (3) pregnancy; and (3) persons who could not read or write in Arabic.

Sample Size Estimation

In calculating the sample size, the following criteria were applied: the level of significance of \( p < .05 \), a power of 80%, and a medium effect size (.15-.5). Two preliminary sample size analyses were performed based on each aim to obtain the minimum sample size for the study.

To address the first aim (the correlation between symptoms, functioning, and QoL), where linear regression was used, the minimum sample size needed was 80 participants: about 30 participants for each predictor variable + 50 minimum starting size (Wilson, Voorhis, & Morgan, 2007). DPN symptoms predicted the value of functioning, health perception, and QoL.
To address the sample size for aim 2 (the impact of DPN predictors on symptoms), the estimated minimum sample size was 118. This calculation was based on the number of variables=10, significance level of \( p < .05 \), statistical power of 80%, and an effect size of .15 (Soper, 2019). Therefore, the minimum total sample size was 120.

**Data Collection**

**Recruitment Strategies**

This study used several recruitment strategies. Volunteer subjects were recruited via: (1) direct approach at the center; (2) flyers posted at the diabetes center and distributed to the center’s visitors and staff; (3) social media outlets (WhatsApp application); (4) phone calls to potential patients prior to their appointments; and (5) referral from the center’s practitioners. The recruitment flyers included a brief description of the study, inclusion criteria, incentives, the time needed to complete the survey, and the investigator’s contact information. Further discussion on the most effective approach is detailed in Chapter 4.

**The Procedure of Data Collection**

Participants were met at the diabetes center, and the investigator explained the study to them. Also, depending on the means of contact with some participants, the initial meeting was also done through phone calling. When potential participants showed interest in taking part in the study, the investigator discussed means of screening. For some participants, we scheduled an appropriate time to meet at the clinic. For other participants, the investigator performed the screenings over the phone. Interested people were screened using the inclusion/exclusion criteria. The criteria were written in a sheet and patients were asked about each criterion with simple question with a yes or no answer. To make sure patients were able to understand the questionnaires, item 2 of the SF-12v2 was used to verify readability. If the patients read the
question and were able to explain it back to the investigator they were considered for participation. Potential subjects were then consented and handed the questionnaire packets to complete. Depending on their preference, some patients took the packets home and returned it at a later time while some returned using email. Other patients filled out the questionnaires at the center and had their foot examined at the same time. The data collection procedure for the study visit included: (1) self-report questionnaires that took about 30 minutes to complete, and (2) a foot physical exam that lasted for about 10 minutes. The physical exam included inspection of feet, ankle reflex testing, tuning fork, and the monofilament testing. Data collection procedures took place at the diabetes center. A designated room was provided by the administration to ensure patients’ privacy. No data collection involving physical examinations was performed in waiting areas. Since the investigator is not associated with the clinic, temporary access to information in the medical record was provided for the duration of the data collection.

**Measurements**

All self-report questionnaires were collected in Arabic. For the tools that were available in Arabic, the investigator approached the developers and obtained permission to use them. The CIRS was forward and backward translated into Arabic by a group of bilingual academicians for this study. It was also reviewed by an independent certified translation company. See further details about each tool in Appendix H.

**Biologic Functions**

The biologic data collected for the study were the HbA1c, BMI, total cholesterol, HDL, LDL, height, weight, and triglyceride, and list of current medications. These were obtained from the patients’ medical records. The majority of data about biologic functions were within 6 months. There are several cases where some patients’ information dated back close to 6 months.
**HbA1c Levels**

The most recent levels of the HbA1c reflected the average glucose level in the red blood cells on the last two to three months. The HbA1c was obtained from the patients’ medical records. The standard of care at the center’s clinics was in concordance with the ADA recommendations. Patients’ HbA1c levels were obtained by serum blood draw every 3-6 months. Patients are often asked to fast over-night 8 to 12 hours before the tests were performed. Nurses always perform the venipunctures using peripheral veins. Samples were then sent to the main hospital’s laboratory for analysis. Results took about 2-4 days to show in the system. The HbA1c criterion was defined according to the ADA. For a diabetic non-pregnant individual, the HbA1c levels should be kept < 7% (ADA, 2019). The HbA1c levels was used as continuous variable.

**Duration of T2DM**

The survey included a question about the number of years the patients lived with T2DM. This variable was categorical: < 5 years, 5-10 years, 10-15 years, and >15 years.

**BMI**

BMI is the persons’ weight in kilograms divided by the square of height in meters and represented with kg/m². BMI was defined according to the CDC. The normal range is 18.5-25.0 (CDC, 2016b). BMI of 25.1 or more was considered overweight. BMI of >30. 0 is considered obesity. For this study, the BMI was coded as a continuous. Patients data on BMI were obtained from the medical records.

**Lipid Profile**

Patients lipid profile included levels of the total cholesterol, HDL, LDL, and triglyceride. The CDC and the ADA’s criteria were followed to define normal lipids: total cholesterol < 200 mg/dL, LDL < 100 mg/dL, and HDL < 40 mg/dL. For the triglyceride, a value of < 150 is
recommended (CDC, 2017b). The criterion by which to define dyslipidemia in this reported study was if the patient was prescribed lipid-lowering agents. This variable was dichotomous with either yes or no answers.

**Hypertension**

The presence of hypertension was ascertained by the documented diagnosis of hypertension and also by the prescription of blood pressure controlling medication. This was dichotomous variable (yes or no).

**Cigarette Smoking**

Information about smoking history was collected in the general health survey and was coded as current, ever, and never smoker. This was categorical variable.

**Physical Activity**

The possible levels of individual physical activity were as follows: regular physical activity is when a patient performs a moderate intensity workout like fast pace walking, running, and swimming for 30 minutes for 4-7 days per week. Not regular (or some exercise) physical activity was defined by physical activity 1-3 days per week, and no physical activity was when no activity is performed per week. Information about physical activity was collected by two questions one in the general health survey and one as part of the SDSCA exercise subscale. Both variables are identical, however, the analysis included the responses from the general health survey. Physical activity was a categorical variable.

**Diabetes Management Medications**

This variable included the treatment the patient received for DM and included oral agents alone, insulin alone, and a combination of oral agents and insulin. The DM management information were collected as self-report and then verified from the patients’ record.
DPN Management Medications

This variable indicates whether DPN symptoms were managed with medications or not. Including this variable was an important covariate in the analysis of DPN symptoms. This variable was coded as dichotomous (yes or no).

Comorbidity

Comorbidity refers to any other diseases and conditions (besides hypertension and dyslipidemia) that the participants may concurrently have. Comorbidity includes diseases like nephropathy, retinopathy, depression, and cardiovascular disease. To examine the effect of the comorbidities, the Functional Comorbidity Index (FCI) was used. The FCI was specifically developed for use with the general population bearing in mind the importance of measuring functionality rather than mortality. The FCI is one of the few practical comorbidity indices available for clinical and research usage and is the only measure that adjusts for the effect of comorbidity on physical functioning (Groll, Bombardier, & Wright, 2005). The index comprises diseases like visual impairment, osteoporosis, diabetes, and arthritis which have an impact on the physical health and functioning. The FCI is a sum of 18 self-reported conditions including obesity and diabetes. The possible score is 0 to 18; one point is given to every yes answer. A high score indicates greater comorbidity and impairment. Limited information was found about the psychometric evidence of the FCI. Nevertheless, the reliability of the FCI was found on one study that evaluated the tool on acute lung injury patients (n = 421) by correlating it with the SF-36 physical subscale (Fan et al., 2012). The inter-rater reliability score was high at -.91. Unfortunately, there were no Arabic-studies found that used the Arabic version of the measure. The FCI items were coded as yes/no for data collection, however, a total of the items marked “yes” was summed for one FCI total score which was used in the analysis.
Characteristics of the Individual

Characteristics of the individuals included age, gender, marital status, SES, and level of education. These variables were collected using a demographic survey in Arabic. Other noteworthy characteristics of the individuals included family history of DM and physical activity. To learn about family history of DM, participants were asked about any family member with the diagnosis of DM; this response were coded as dichotomous variables.

Characteristics of the Environment

Social Support

Data related to social support was collected using the Medical Outcome Survey- Social Support Survey (MOS-SSS) Arabic. The MOS-SSS is a Likert-type scale that is reliable and valid. It is a widely-used measure of the amount of support perceived by patients and assesses the four aspects of support: informational, tangible, positive social interaction, and affectionate support. Emotional/informational support has questions on empathy, understanding, expressing of feelings, offering advice and guidance (Sherbourne, & Stewart, 1991). Tangible support refers to the availability of support systems for physical needs and medical care assistance. Affectionate support involves love and tenderness. Lastly, positive social interaction concerns the ability of a person to perform recreational activities alongside others. The obtained (raw) scores for each subscale was computed and transformed to calculate the total score. The MOS-SSS has a total score of 100 with higher scores suggesting better social support. The MOS-SSS has been translated into Arabic and psychometrically tested on Arabic sample. The Cronbach’s alpha of the Arabic version was at .78 (Dafallah et al., 2016).
Chronic Illness Resources

The level of support for DM patients was assessed using the Arabic CIRS. The CIRS uses a Likert-type scale and has 22 items in 8 subscales. The CIRS evaluates the different support outlets that enable individuals with chronic diseases to maintain a healthful lifestyle and to perform self-management behaviors (Glasgow et al., 2005). The development of the CIRS was based on the social-ecological and social support theories. The CIRS has items grouped into eight different resources for support: support from healthcare, family and friends, neighborhood, organizational, personal, diet, exercise, and the media. The CIRS has a total mean score for the entire scale that can be calculated based on the number of items in the measure. Also there is a mean score per each subscale as (total score/number of items). The score ranges between 1 and 5 with higher scores indicating better resources. The psychometrics of the CIRS have been tested on a few populations among which is a population of postmenopausal women with T2DM. The reported reliability estimates for the test-retest was .70 and .82 for the Cronbach alpha. The subscales of the CIRS inter-correlate significantly at .17 and .56 (Glasgow et al., 2005). The CIRS was translated into Arabic for the purpose of this current study.

Symptom Status

Three instruments were used to measure DPN symptoms. The MNSI questionnaire (MNSI 1) and examination (MNSI 2) were the first measures used to determine the presence and severity of neuropathy symptoms among patients. The primary investigator performed the physical examination according to the description provided by the authors. The MNSI is used in clinical trials with a focus on diagnosing, intervening, and evaluating outcomes (Feldman et al., 1994; Lyrakos et al., 2013). The MNSI 1 has 15 self-report questions addressing the most
common DPN symptoms (numbness, prickling sensation, temporal nature, and pain). The total possible score is 15, and a score of > 4 is an indicator that someone would test positive for DPN.

The MNSI has been used on Arab populations (Algeffari, 2018; Khawaja, 2018). The psychometric properties of the MNSI have been proven sufficient. The reliability assessment of the MNSI included interrater reliability with an intraclass correlation coefficient of .91. Validity testing included the testing of sensitivity and specificity. Both assessments were low-to-moderate, ranging between 38% and 72%. This reduced sensitivity and specificity are reported to be due to a high published cut-off point of > 7.0. According to some studies, the most sensitive and specific abnormal MNSI questionnaire score was >4 (Herman et al., 2012). Thus, for this study, the score of ≥4 was utilized to determine the severity of the symptoms. Also, for this study, the psychometrics of the MNSI were further tested.

The Leeds Assessment of Neuropathy Signs and Symptoms (LANSS) was the second instrument that was used to collect data on pain and neuropathy symptoms. The study used the S-LANSS which is the self-report version of the LANSS and was developed with the aim of discerning neuropathic from nociceptive pain and provides sensory description of symptoms. The original publication which describes the LANSS uses a clinician’s objective assessment of neuropathy symptoms (Bennett, 2001). However, the S-LANSS is a self-report assessment accounting for subjective report of neuropathy symptoms by the patients which was used in the study (Bennett, 2005). The S-LANSS has a high accuracy rate for neuropathic pain. The measure is a 7-item scale based on grouped sensory descriptions (dysarthria, autonomic, evoked, paroxysmal, and thermal) which are written in a plain language that patients can understand and respond to. This measure asks if patients are experiencing symptoms such as numbness, prickling, warmth of skin, and discomfort when pressures applied. The S-LANSS has been
translated and culturally adapted into Arabic. However, The Arabic version of the S-LANSS was not psychometrically tested (Garoushi, Johnson, & Tashani, 2017).

The numeric pain rating scale which is a numerical 6-item self-report questionnaire was the third instrument used to measure DPN symptoms. The Pain Rating Scale was developed by the British Pain Society. It has several language versions including Arabic. The Pain Rating Scale is reasonably easy to use with five items on the severity of the current and most recent (previous week) pain. Also, there are items on whether the pain is bothersome, and the degree of interference with life (British Pain Society, 2014). The Pain Rating Scale uses a numeric scale where the responses to each item ranges between zero and ten. A score of > 5 suggests moderate-to-severe pain (Ferraz et al., 1990). As numerical data, the scores were averaged to generate a mean score. There were no reports on this measure’s psychometrics. However, as a numerical pain scale, there was established evidence of its validity. For instance, in a group of patients with rheumatoid arthritis, the test-retest reliability was .95 and .96 for literate and illiterate individuals, respectively. Likewise, the validity of the numerical pain scale is adequate. The construct validity was tested on patients with chronic pain of greater than 6 months which ranged between .86 and .95 when correlated with the Visual Analog Scale (Ferraz et al., 1990). Moreover, the numerical pain scale is superior to the Visual Analog Scale because it provides an accurate assessment of pain with measurable data, unlike the visual analog where the results are qualitative and converting them into numeral values is cumbersome. Table H2 details a comparison of the DPN tools and includes the characteristics and the items of each one. Table H3 shows the reliability estimates of each tool as indicated by the Cronbach alpha as reported in the literature.
Physical Examination (MNSI 2)

**Inspection of feet.** The examination of the foot included inspection of the appearance of the foot for deformity and signs of ulceration.

**Semmes-Weinstein Monofilament Test (SWMT).** The SWMT is one of the standard tests and is recommended for diagnosing DPN. The 5.07/10-g SWMT is a thin plastic filament covered by a plastic handle that was applied lightly perpendicular to the skin on several areas to detect the loss of protective sensation (LOPS). The use of the SWMT provides highly sensitive and accurate results compared to other tests of protective sensation (pinprick and light touch). Whether or not a patient senses the touch from the test is an indicator of nerve function. The evaluation was performed on ten sites on each foot as this has been reported to increase the sensitivity and the specificity of the findings, relative to a single site (Singh, Armstrong, & Lipsky, 2005).

**Ankle reflexes and vibration perception.** The assessment of ankle reflex was performed using a queen square reflex hammer. The vibration sensation performed with 128 Hz tuning fork on the great toe unsupported. Physical exam variable was continuous.

**Functional Status, General Health Perception and Overall Quality of Life**

**Diabetes Foot Self-Care Practices**

The frequency of performing foot self-care is an indicator of functional status. Foot self-care practices is a subset of self-care and for this study, data on patients’ self-care behaviors were collected using the self-report, Summary of Diabetes Self-care Activities-Extended (SDSCA) in Arabic. SDSCA is a Likert-type scale and asks about the number of days on the previous week patients performed certain self-care behaviors (0-7 days/week) (Toobert, Hampton, & Glasgow, 2000). A score of zero indicates performing the activity zero day/week and a score of 5 indicates
a frequency of 5 days/week (higher score is better). However, not all items are scored the same way. The extended Arabic-SDSCA has 15 questions covering the five recommended self-care practices for people with DM (diet, exercise, medication taking, foot care, and glucose checking). An example of a question is “How many times per week did you check the inside of your shoes?” The frequency of performing foot self-care is an indicator of functional status. Foot self-care subscale of the SDSCA has five items (checking feet, washing feet, drying between toes, inspecting inside of shoes, & soaking feet). Further details about the foot care subscale can be found in Chapter 4.

The psychometric properties of the SDSCA are found to be adequate. Glasgow et al. (2005) reviewed the results of several studies (five interventional and two observational) that used the measure and concluded that the reliability and the validity of the measure are appropriate. The reliability using inter-item correlation was moderate, $r=.4-.8$. The validity of the measure was tested by correlation with other self-care measures. Its validity was established based on those correlations and on its responsiveness to change. Those correlations were around $r=.58$. The Arabic version has also been psychometrically tested on a population of Saudi diabetics; the Cronbach’s alpha of the tool was at .76 (AlJohani et al., 2015). Appendix H summarizes the reliability estimates of the tools used in this study as reported in the literature.

**Medical Outcome Short-Form-12 Version 2 (SF-12v2)**

The physical and mental composite scores of the SF-12v2 were used to determine the participants’ levels of overall quality of life. Physical and mental QoL were determined by the PCS and MCS, respectively. The SF-12v2 is a widely used generic scale for assessing functional health and well-being. It has been used with a vast array of health conditions and across all age groups. It has been proven to be useful and easy to use with many populations and across
cultures. The scores of the SF-12v2 were used to measure the perceived level of health, including physical, emotional, and role functioning (Ware et al., 1996). The SF-12v2 is a 12-item Likert-type scale that is self-administered. The final scores depend on combining scores, weighing each item, and generating two subscales (mental health and physical health composite scores). The scores are standardized with a mean of 50 and a standard deviation of 10. The SF-12v2 has been used on the Arab population with various conditions and diseases. The SF-12v2 is available in different Arabic dialects (AlShehri, Taha, Bahnassy, & Salah, 2008).

**Data Entry and Cleaning**

After data collection has been completed, the de-identification process took place. Data was entered from the questionnaire booklets into the REDCap software. A detailed discussion on the approach to data entry, cleaning, and information on the missing data can be found in Chapter 4.

**Data Analysis per Aims**

Data analysis using inferential statistical modalities for each aim included:

**Aim 1:** To examine the impact of DPN symptoms on patients’ functional status (foot care practices), general health perception, and physical and mental QoL. The analysis used for this aim was the multiple linear regression. Linear regression is the appropriate statistical analysis because the outcome variable is numerical (Nayak & Hazra, 2011). It is also appropriate because it is a multivariable analysis to test the correlation between one dependent variable (foot care practices subscale, health perception, or QoL) and one or more independent variables (DPN symptoms).

**Aim 2:** To examine the biological (HbA1c, comorbidity, and cardiovascular risk factors) and individual (age and gender) factors associated with DPN symptoms in persons with T2DM.
living in Saudi Arabia. The analysis of this aim was performed using multiple regression. Multiple regression is the appropriate analytical approach for finding an association relationship between one continuous outcome variable and more than one independent variable (Nayak, & Hazra, 2011).

**Human Subjects Protection**

Research on human subjects included face-to-face and telephone screenings, responding to surveys, and a brief physical exam of the feet. The investigator approached all possible participants regardless of their gender, skin color, ethnicity, SES, and educational level. Participants were offered educational handouts about peripheral neuropathy. Also, participants received tote bags and coffee mugs as an appreciation for their time and interest in the study. Participants’ privacy and personal information were protected during the data collection process of this current study. The investigator stored medical records numbers, names, and contact information in a locked cabinet at the diabetes center. During data collection, all questionnaires and biologic values were de-identified for maximum anonymity, and codes were used instead of personal identifiers. Signed consent forms were also stored separately at the investigator’s office. For the electronically accessed data, the investigator ensured safe handling of computer screens while examining patients records to guarantee that there was no access to unneeded information and also that the information was not shared with anyone. Finally, the investigator put significant efforts into ensuring the protection of the completed surveys, informed consents, data storage, and statistical software.

**Risks and Benefits**

While the investigator acknowledges the ethical issues raised by some research, this study carried relatively no risks. However, potential physical, psychological, or social risk were
possible. This study, carried a possible risk of loss of privacy; this risk was addressed earlier.

The investigator made sure that participants were well aware that there were no benefits gained from taking part in this study. This has been explained in full details in the informed consent form that this study was non-experimental, and the purpose was to examine the association between neuropathy symptoms, quality of life, and the specified predictors.
CHAPTER FOUR

RESULTS

This chapter addresses the results from the study. This chapter starts with a description of the sample, data entry, and missing data and ends with the details of the results of the study aims. The purposes of this study were to examine the impact of diabetic peripheral neuropathy (DPN) symptoms on quality of life (QoL) and to explore the factors affecting the development of neuropathy symptoms.

Recruitment Information

Patients were recruited from a regional diabetes center in Saudi Arabia. The main approach of recruitment was the direct approach by talking to patients who had appointments at the center to explain the study and to solicit participation. The total number of patients contacted during the time of data collection was 249 patients. Of these, 8% (n = 20) did not show interest and thus never returned phone calls or declined to discuss the study. Thus, 92% of the participants’ pool (n = 229) was approached for participation. Of those, 36% (n = 83) were unable to participate. About 10% (10.9%, n = 25) refused to participate, and 25.3% (n = 58) were excluded according to the exclusion criteria. Thus, about half of total number of people originally contacted (n = 146) agreed to be interviewed and participate in the study. Of those, 18% (n = 26) did not complete the process; the final sample size was 120 participants.

The most effective methods for recruiting the final sample were directly approaching them in the clinic (58.3%), referrals from clinics (30%), and phone calls (16.6%) (see Table 1).
Table 1. Number and Percentage of Participants from each Recruitment Source

<table>
<thead>
<tr>
<th>Recruitment Source</th>
<th>Approached Patients % (n)</th>
<th>Excluded/Refused/Did not Respond % (n)</th>
<th>Final Sample % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct approach</td>
<td>56.2% (140)</td>
<td>54.2% (70)</td>
<td>58.3% (70)</td>
</tr>
<tr>
<td>Phone calls</td>
<td>28.1% (70)</td>
<td>38.7% (50)</td>
<td>16.6% (20)</td>
</tr>
<tr>
<td>Referrals from clinics</td>
<td>15.6% (39)</td>
<td>6.9% (9)</td>
<td>30% (25)</td>
</tr>
<tr>
<td>Total</td>
<td>100% (249)</td>
<td>100% (129)</td>
<td>100% (120)</td>
</tr>
</tbody>
</table>

**Missing Data**

Missing data were limited to < 7% because all booklets were reviewed upon completion. Participants provided their contact information and agreed to receive a call back for the purpose of querying about missing information. For instance, some participants chose two responses for the same question. In other instances, participants would forget to answer a question or two. Most participants with missing data were called and clarified missing data points. In those cases, the investigator suggested that the participants come to the clinic to complete them. If they refused to or were unable to come, the investigator did read those questions to them on the phone and marked the answers following a strict script according to which she only read the questions and explained the meaning of the Likert-type answers. Moreover, 4.2% (n = 5) of participants were not able to have their feet examined as they opted to complete the booklets at home and then have the exams performed when they returned the booklets. Unfortunately, the investigator was not able to meet with those patients to complete the exams because of scheduling conflicts. There were also a few questions consistently missing on the Chronic Illness Resources Survey (CIRS). These were questions pertaining to access to health care, and, since medical care is provided for all citizens, most patients 87.5% (n = 105) left them blank. The other missing data in the CIRS pertained to the work environment, and, thus, were only applicable to employed
participants. These questions were not applicable to 75.8% (n = 91) of the sample. According to the authors of the instrument, individual subscales can be removed with no impact on the overall scale (Glasgow et al., 2004).

The largest number of missing data was seen with the low density lipoprotein levels as 45% (n = 54) of patients were missing this test despite having had other lipid measures assessed. The center officials verified that for people with no evidenced hyperlipidemia and are not on treatment, only the triglycerides and cholesterol levels were checked quarterly. However, the remainder of indicators of lipid profiles were complete. Finally, there were about 6.6% (n = 8) missing data on the HbA1c. In these cases, patients were being seen at the diabetic foot clinic where they got foot ulcers assessed, dressings changed, or prescription for foot moisturizers filled and did not come to the study site for routine medical visits very often. These patients may have up to a year gap with missing routine medical visit appointments and, thus, did not have up-to-date HbA1c on records.

To utilize the full collected data, missing values were replaced by a single group mean. Data were reviewed and screened manually giving the limited amount of missing data. Although the missing completely at random hypothesis testing was done the decision to impute the missing values was based on manual screening of data (on SPSS and physical booklets) to determine that the missing values occurred completely at random and that they do not follow specific pattern. For instance, the total scores (used in the analysis) of the key variables (MNSI 1, S-LANSS, PCS & MCS had no missing data. MNSI 2 (foot exam) had 4.1% (n = 5) missing data. Thus, the investigator examined the reasons for those missing data by reviewing the missing data manually from the survey and on SPSS. The reasons for the missed data were understood and explained.
Data Entry

As data were being collected, they were de-identified and entered into the Research Electronic Data Capture (REDCap) system, which is a data collection and storage platform. Each participant was given a study identification number. After completing data entry, all records were verified and screened twice to ensure completeness and accuracy. Data were then exported into IBM SPSS Statistics Version 26 for analysis. Data were then screened again, and missing values were identified. Then, the negatively worded questions of the Michigan Neuropathy Screening Instrument (MNSI) and the Summary of Diabetes Self-care Activities (SDSCA) were recoded in SPSS. For instance, items 7 and 13 of the MNSI were reversely phrased and thus had to be recoded. Other computations and transformations that included creating new variables of tools were also conducted.

Characteristics of Overall Sample

The study sample comprised 120 patients with the diagnosis of T2DM and symptoms of DPN. The majority, 67.5% (n = 81), were Native people (those who had always resided the Arabian Peninsula and had no other racial background), who had an average age of 54 years. Seventy percent (n = 84) were married, 70.6% (n = 84) were unemployed/retired, 40.2% (n = 47), had lived with T2DM > 15 years, and about 70% (n = 83) had never smoked. Females made 47% of the sample.

Since falls are an issue in persons with T2DM, this was explored and it was noted that 12.9% (n = 15) of patients reported having fallen within the previous three months. Eleven people (9.2%) reported falling only once. A couple of people (1.7%) said they fell around three times. The most frequent reason for falls was loss of balance, which was reported 40% (n = 6 times) of the time. The demographic characteristics of the sample are described in Table 2.
Table 2. Sample Demographic Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Percentage% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>54.0 (9.4)</td>
<td></td>
</tr>
<tr>
<td>Gender (n=119)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>47.1 (56)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>52.9 (63)</td>
<td></td>
</tr>
<tr>
<td>Race (n=120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native people</td>
<td>67.5 (81)</td>
<td></td>
</tr>
<tr>
<td>North African</td>
<td>10.0 (12)</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>1.7 (2)</td>
<td></td>
</tr>
<tr>
<td>Middle Eastern</td>
<td>4.2 (5)</td>
<td></td>
</tr>
<tr>
<td>South Asian</td>
<td>5.0 (6)</td>
<td></td>
</tr>
<tr>
<td>Multiracial</td>
<td>1.7 (2)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5.8 (7)</td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>4.2 (5)</td>
<td></td>
</tr>
<tr>
<td>Marital status (n=120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>70.0 (84)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>16.7 (20)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>10.8 (13)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>0.8 (1)</td>
<td></td>
</tr>
<tr>
<td>Separated</td>
<td>0.8 (1)</td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>0.8 (1)</td>
<td></td>
</tr>
<tr>
<td>Income (n=120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5,000 SR</td>
<td>49.2 (59)</td>
<td></td>
</tr>
<tr>
<td>5,000-10,999 SR</td>
<td>21.7 (26)</td>
<td></td>
</tr>
<tr>
<td>11,000 – 15,000 SR</td>
<td>10.8 (13)</td>
<td></td>
</tr>
<tr>
<td>&gt; 15,000 SR</td>
<td>6.7 (8)</td>
<td></td>
</tr>
<tr>
<td>Prefer to not answer</td>
<td>11.7 (14)</td>
<td></td>
</tr>
<tr>
<td>Level of Education (n=120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 6th Grade</td>
<td>25.8 (31)</td>
<td></td>
</tr>
<tr>
<td>6th Grade</td>
<td>13.3 (16)</td>
<td></td>
</tr>
<tr>
<td>Intermediate school</td>
<td>20.0 (24)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>8.3 (10)</td>
<td></td>
</tr>
<tr>
<td>Associate degree</td>
<td>5.0 (6)</td>
<td></td>
</tr>
<tr>
<td>Baccalaureate</td>
<td>20.0 (24)</td>
<td></td>
</tr>
<tr>
<td>Higher education</td>
<td>4.2 (5)</td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3.3 (4)</td>
<td></td>
</tr>
<tr>
<td>Employment status (n=119)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed/Retired</td>
<td>70.6 (84)</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>29.4 (35)</td>
<td></td>
</tr>
<tr>
<td>Duration of DM (n=117)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5 years</td>
<td>12.9 (15)</td>
<td></td>
</tr>
<tr>
<td>Age Group</td>
<td>Percentage</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>5-10 years</td>
<td>26.5 (31)</td>
<td></td>
</tr>
<tr>
<td>11-15 years</td>
<td>20.5 (24)</td>
<td></td>
</tr>
<tr>
<td>&gt;15 years</td>
<td>40.2 (47)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relatives with DM (n=115)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80.0 (92)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treated dyslipidemia (n=116)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>62.9 (73)</td>
</tr>
<tr>
<td>No</td>
<td>37.1 (43)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hypertension (n=114)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>51.8 (59)</td>
</tr>
<tr>
<td>No</td>
<td>48.2 (55)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>History CVD (n=116)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>19.0 (22)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Smoking History (n=119)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never smoked</td>
<td>69.7 (83)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>16.0 (19)</td>
</tr>
<tr>
<td>Former smoker</td>
<td>14.3 (17)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exercise for 30 minutes/day: (n=118)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No exercise</td>
<td>54.2 (64)</td>
</tr>
<tr>
<td>Some exercise (1-3 days/week)</td>
<td>27.1 (32)</td>
</tr>
<tr>
<td>Regular exercise (4-7 days/week)</td>
<td>18.6 (22)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T2DM Treatment (n=116)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral agents only</td>
<td>41.4 (48)</td>
</tr>
<tr>
<td>Injections only</td>
<td>55.2 (64)</td>
</tr>
<tr>
<td>Combination Therapy</td>
<td>50.0 (58)</td>
</tr>
</tbody>
</table>

Note: * indicates data obtained from medical records; other data are self-reported

### Data Analysis of Key Study Variables

The key variables used in this study were DPN symptoms (MNSI 1, MNSI 2 and S-LANSS); QoL indicators (general health, foot care, PCS, and MCS); biologic variables (HbA1c, dyslipidemia, comorbidity, level of physical activity, and hypertension); characteristics of the environment (social support and chronic illness resources); and characteristics of the individual (age and gender).

### Biologic Factors

The biologic factors were mostly obtained from the medical record. The most important biologic factor in the study was the HbA1c which was measured in the clinics laboratories quarterly. The average HbA1c level of the sample was 8.89%. The mean levels of lipid profiles
in mg/dL were as follows: triglycerides = 154.2, total cholesterol = 171.7, HDL = 40.6, and LDL = 96.3. These values reflect converted levels since the standard measurement system at the diabetes center was the mmol/L. To perform the conversions, Omni Calculator was used (Omni Calculator sp. z o.o., 2020). Omni Calculator has over 950 different calculators for more than a hundred types of measurement for health, physics, chemistry, and statistics, and many non-science-related values. In addition, the conversions of height and weight, as well as the random glucose sugar were also performed by the website (see Table 3). The variable *treated dyslipidemia* was used instead of the 4 lipid types in the regression models. Information about treated dyslipidemia was obtained from the medical records and it represented the number of people who received lipid lowering agents (see Table 2).
Table 3. Mean Scores and Standard Deviations of Key Variables

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Mean (SD)</th>
<th>Min.</th>
<th>Max.</th>
<th>Lab values conversions</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-Leeds Assessment of Neuropathy Signs and Symptoms</td>
<td>13.2 (6.11)</td>
<td>0</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Michigan Neuropathy Symptoms Inventory</td>
<td>7.6 (2.8)</td>
<td>0</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Average pain during previous week</td>
<td>4.80 (3.09)</td>
<td>0</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>8.89 (1.73)</td>
<td>5.6</td>
<td>12.5</td>
<td></td>
</tr>
<tr>
<td>Random blood sugar (mmol/L)</td>
<td>11.80 (5.20)</td>
<td>4.0</td>
<td>24.6</td>
<td>212.4 (93.6) mg/dL</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.4 (9.65)</td>
<td>140.0</td>
<td>190.0</td>
<td>5.36 (0.31) ft.</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>83.21 (21.68)</td>
<td>41.0</td>
<td>149.0</td>
<td>183.45 (47.79) lbs.</td>
</tr>
<tr>
<td>BMI</td>
<td>30.81 (6.57)</td>
<td>18.7</td>
<td>49.5</td>
<td></td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>1.74 (1.09)</td>
<td>0.25</td>
<td>6.4</td>
<td>154.12 (96.55) mg/dL</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>4.44 (1.35)</td>
<td>1.0</td>
<td>7.9</td>
<td>171.7 (52.2) mg/dL</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>1.05 (0.26)</td>
<td>0.50</td>
<td>1.90</td>
<td>40.6 (10.05) mg/dL</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>2.49 (1.02)</td>
<td>0.40</td>
<td>4.8</td>
<td>96.29 (39.44) mg/dL</td>
</tr>
<tr>
<td>Foot care (SDSCA subscale)</td>
<td>4.74 (1.32)</td>
<td>0.20</td>
<td>7.0</td>
<td></td>
</tr>
<tr>
<td>Functional Comorbidity Index</td>
<td>3.1 (1.49)</td>
<td>1.0</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>Overall social support</td>
<td>70.70 (27.28)</td>
<td>3.95</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>MNSI 2 (foot exam)</td>
<td>3.57 (2.59)</td>
<td>0</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

**DPN Symptoms**

DPN symptoms were measured with three different instruments (MNSI, S-LANSS & Numeric Pain Rating Scale). Both the MNSI and the Self-Report-Leeds Assessment of Neuropathy Signs and Symptoms (S-LANSS) are self-report measures of the neuropathy symptoms that patients experience. MNSI and S-LANSS are both composed of dichotomous items with either “yes” or “no” answers, and the total score is based on the number of “yes” answers that a person selects. For the MNSI, the score represents the presence and the severity of the symptoms. A score between 0 and 4 indicates mild neuropathy, whereas a score of 7 and above (total possible score is 15) is indicative of severe neuropathy (Feldman et al., 1994). For
In this study, the participants had a mean MNSI score of 7.6 ± 2.8, which indicates severe neuropathic symptoms.

On the other hand, on the S-LANSS a higher score, > 12, is suggestive of a neuropathic origin of pain, and a score of < 12 suggests that the pain is likely non-neuropathic. For this study, the participants had a mean S-LANSS score of 13.6 ± 6.11, which suggests that the sample had symptoms caused by neuropathic mechanisms (Bennett, 2001). Table 4 summarizes the descriptive data of the total scores of both measures.

Table 4. Total Scores of MNSI and S-LANSS

<table>
<thead>
<tr>
<th>DPN Measure</th>
<th>Mean (SD)</th>
<th>Median (Mode)</th>
<th>Range</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNSI (n=120)</td>
<td>7.65 (2.86)</td>
<td>8.00 (9.00)</td>
<td>13</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>S-LANSS (n=120)</td>
<td>13.28 (6.11)</td>
<td>14.00 (19.00)</td>
<td>24</td>
<td>0</td>
<td>24</td>
</tr>
</tbody>
</table>

The analysis of the S-LANSS results showed that the symptom most complained about was tingling, pins and needles sensations with a little over 90% (n = 107) of the participants reporting it. The least reported symptom was that of noticing a change in skin color, which was only reported by 19.5% (n = 23) of participants (see Table 5).
Table 5. Description of Neuropathy Symptoms as Per the S-LANSS

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Yes (n)</th>
<th>No (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tingling, pins and needles sensations (Q1)</td>
<td>90.7% (107)</td>
<td>9.3% (11)</td>
</tr>
<tr>
<td>Sudden, unexpected pain (Q4)</td>
<td>80.5% (95)</td>
<td>19.5% (23)</td>
</tr>
<tr>
<td>Skin warmth sensation (Q5)</td>
<td>60.2% (71)</td>
<td>39.8% (47)</td>
</tr>
<tr>
<td>Numbness when pressure applied (Q7)</td>
<td>55.6% (65)</td>
<td>44.4% (52)</td>
</tr>
<tr>
<td>Skin sensitivity (Q3)</td>
<td>52.6% (61)</td>
<td>47.4% (55)</td>
</tr>
<tr>
<td>Discomfort with massage (Q6)</td>
<td>52.1% (61)</td>
<td>47.9% (56)</td>
</tr>
<tr>
<td>Change of skin color (Q2)</td>
<td>19.5% (23)</td>
<td>80.5% (95)</td>
</tr>
</tbody>
</table>

Note: Q(n) signifies the order of the item in the questionnaire.

The MNSI has a similar symptoms inventory and has more descriptors when compared with the S-LANSS. According to the MNSI analysis, the symptoms patients reported most were numbness 80% (n = 96) and tingling, pins and needles 79.7% (n = 94). The least common symptom was the history of amputation with only 7.6% (n = 9) reporting it followed by the loss of temperature sensation 21.7% (n = 27) (see Table 6).
Table 6. Description of Neuropathy Symptoms as Per the MNSI Questionnaire

<table>
<thead>
<tr>
<th>Symptoms Questions</th>
<th>Yes (n)</th>
<th>No (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are your legs or feet numb?</td>
<td>80.0% (96)</td>
<td>20.0% (24)</td>
</tr>
<tr>
<td>Do you have a prickling, pins &amp; needles sensation?</td>
<td>79.7% (94)</td>
<td>20.3% (24)</td>
</tr>
<tr>
<td>Do you feel generalized weakness most of the days?</td>
<td>75.6% (90)</td>
<td>24.4% (29)</td>
</tr>
<tr>
<td>Are your feet too sensitive to touch?</td>
<td>68.9% (82)</td>
<td>31.1% (37)</td>
</tr>
<tr>
<td>Do you ever have any burning pain in your feet or legs?</td>
<td>65.8% (79)</td>
<td>34.2% (41)</td>
</tr>
<tr>
<td>Do the symptoms get worse at night?</td>
<td>65.5% (78)</td>
<td>34.5% (41)</td>
</tr>
<tr>
<td>Do your feet hurt when you walk?</td>
<td>65.0% (78)</td>
<td>35.0% (42)</td>
</tr>
<tr>
<td>Do you get muscle cramps in your legs or feet?</td>
<td>60.0% (72)</td>
<td>40.0% (48)</td>
</tr>
<tr>
<td>Is the skin of your feet so dry that you get fissures?</td>
<td>56.7% (68)</td>
<td>43.3% (52)</td>
</tr>
<tr>
<td>Have you ever had open ulcers in your feet?</td>
<td>33.3% (40)</td>
<td>66.7% (80)</td>
</tr>
<tr>
<td>Do you have pain when bed covers touch you?</td>
<td>32.5% (39)</td>
<td>67.5% (81)</td>
</tr>
<tr>
<td>Has the doctor ever told you that you have DPN?</td>
<td>31.9% (38)</td>
<td>68.1% (81)</td>
</tr>
<tr>
<td>Do you feel your legs when you walk?</td>
<td>24.4% (29)</td>
<td>75.6% (90)</td>
</tr>
<tr>
<td>Can you tell the difference between heat and cold sensation?</td>
<td>21.7% (27)</td>
<td>77.3% (92)</td>
</tr>
<tr>
<td>Have you ever had an amputation?</td>
<td>7.6% (9)</td>
<td>92.4% (110)</td>
</tr>
</tbody>
</table>

Another instrument used was the Numeric Pain Rating Scale (NPRS) to capture aspects of pain, such as intensity and how bothersome, on a scale of 0-10, where 0 is no pain and 10 is the worst pain (British Pain Society, 2014). For this sample, the average pain intensity for the current pain was $3.93 \pm 3.23$. The large standard deviation suggests there was significant variability on this measure as would one expects when assessing level of pain (see Table 7).
Table 7. Numeric Scale of Pain and Degree of Bothersome

<table>
<thead>
<tr>
<th>Pain Scale</th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity (now) (n=120)</td>
<td>3.93 (3.23)</td>
<td>4.00</td>
</tr>
<tr>
<td>Average pain intensity (last week) (n=119)</td>
<td>4.80 (3.09)</td>
<td>5.00</td>
</tr>
<tr>
<td>Degree of bothersome (now) (n=120)</td>
<td>4.38 (3.71)</td>
<td>4.00</td>
</tr>
<tr>
<td>Degree of bothersome (last week) (n=119)</td>
<td>5.13 (3.38)</td>
<td>5.00</td>
</tr>
<tr>
<td>Degree of interference with life (n=118)</td>
<td>4.97 (3.56)</td>
<td>5.00</td>
</tr>
</tbody>
</table>

**Foot examination.** Participants foot exams were performed by the investigator guided by the MNSI 2 directions. It is composed of five items: appearance of feet, presence of ulcers, perception of vibration, ankle reflexes, and the monofilament testing. The assessment of foot appearance and presence of ulcers were performed by inspection. Meanwhile, a 180 Hz tuning fork was used to assess the perception of vibration on the great toe. To elicit ankle tendon reflex response a reflex hammer was used. The investigator followed the MNSI 2 developers detailed description of the methodology of conducting foot examination as detailed in Chapter 3 above. The investigator also received guidance and feedback from the physician overseeing the diabetic foot clinic. The mean foot exam score was $3.57 \pm 2.59$ which shows mild DPN according to the scoring of the test (Feldman et al., 1994). The foot exams of more than two-thirds of participants ($n = 83$) showed abnormal appearance due to structural deformities (e.g., Charcot foot, hammer toe, and overlapping toes), callus, infection, fissure, and non-pitting edema (see Table 8).

Table 8. Frequency of DPN Symptoms According to MNSI 2 (not mutually exclusive)

<table>
<thead>
<tr>
<th>Foot Exam (n=115)</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance of feet</td>
<td></td>
</tr>
<tr>
<td>Normal (both feet)</td>
<td>27.8 (32)</td>
</tr>
<tr>
<td>Abnormal (either foot)</td>
<td>72.2 (83)</td>
</tr>
<tr>
<td>Ulceration</td>
<td></td>
</tr>
<tr>
<td>Absent (both feet)</td>
<td>90.4 (104)</td>
</tr>
<tr>
<td>Present (either feet)</td>
<td>9.6 (11)</td>
</tr>
</tbody>
</table>
Ankle reflex
Present (both feet) 33.0 (38)
Reinforced (either foot) 40.9 (47)
Absent (either foot) 24.3 (28)

Vibration perception
Present (both feet) 32.2 (37)
Decreased (either foot) 47.0 (54)
Absent (either foot) (n=114) 30.7 (35)

Monofilament test (n=114)
Normal (both feet) 57.0 (65)
Reduced (either foot) 24.6 (28)
Absent (either foot) 21.9 (25)

Foot ulceration was evident in 9.6% (n = 11). Also, the majority of participants, 48.7% (n = 56), had mild to moderate neuropathy with total scores of ≤7. Only about one tenth (n = 11) had severe DPN with a score of > 7. Tables 8 and 9 have further information on the clinical findings. Also, during the foot examination sessions several field notes were made that will be referred to in the discussion of implications for nursing in Chapter 5.

Table 9. Severity of DPN Based on Foot Examination

<table>
<thead>
<tr>
<th>Foot Exam Scores/10</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (normal)</td>
<td>13.0 (15)</td>
</tr>
<tr>
<td>≤2 (mild)</td>
<td>28.7 (33)</td>
</tr>
<tr>
<td>&gt;2≤7 (moderate)</td>
<td>48.7 (56)</td>
</tr>
<tr>
<td>7.5-10 (sever)</td>
<td>9.5 (11)</td>
</tr>
</tbody>
</table>

**Gender-Based Differences in Neuropathy Symptoms**

There were no gender differences between the mean symptom scores of DPN. The percentage of males reporting DPN was 53% (n = 63) compared to 47% (n = 56) of females (see Table 10).
Table 10. Mean and Standard Deviation of Neuropathy Symptoms of Males and Females

<table>
<thead>
<tr>
<th>Gender</th>
<th>S-LANSS</th>
<th>MNSI 1</th>
<th>Avg. Pain Last Week</th>
<th>Avg. Current Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13.5 (6.56)</td>
<td>7.69 (2.89)</td>
<td>4.33 (3.07)</td>
<td>3.48 (3.01)</td>
</tr>
<tr>
<td>Female</td>
<td>13.0 (5.67)</td>
<td>7.57 (2.87)</td>
<td>5.33 (3.09)</td>
<td>4.43 (3.45)</td>
</tr>
</tbody>
</table>

Simple student t-test results showed that there was no significant difference in the mean DPN scores between males and females for the S-LANSS, the MNSI, or the average pain, though the average level of pain during last week was trending towards significance, $p = .083$ (see Table 11) and with a larger sample perhaps we may achieve significance.

Table 11. Gender-Based Differences in DPN Symptoms Between Groups

<table>
<thead>
<tr>
<th></th>
<th>F</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-LANSS</td>
<td>0.174</td>
<td>.677</td>
</tr>
<tr>
<td>MNSI</td>
<td>0.057</td>
<td>.811</td>
</tr>
<tr>
<td>Average pain (last week)</td>
<td>3.04</td>
<td>.083</td>
</tr>
<tr>
<td>Average pain (current)</td>
<td>2.58</td>
<td>.111</td>
</tr>
</tbody>
</table>

**Physical and Mental Quality of Life**

Indicators of QoL were measured by the Medical Outcome Study Short Form-12v2. The SF-12v2 comprises of 12 items asking patients about their perception of their health status; degree of symptoms interference in everyday life; and other physical, emotional well-being and functioning-related questions. The scoring was performed using a software provided by Optum Inc. in which the 12 items were combined into eight health domains. The eight health domains (general health, physical functioning, role functioning, bodily pain, role emotional, mental health, role physical, and social functioning) were transformed and combined into to summary scales, the mental composite scores (MCS) and the physical composite scores (PCS). All of the
eight domains were used to score both the PCS and the MCS (Maruish, 2012). To measure the patients level of physical and mental/emotional QoL, the PCS and MCS were used. The mean value of the MCS was 47.29 ± 11.35 and the PCS was 40.21 ± 9.75. The SF-12v2 follows a standardized t-score in which the mean is 50 and the standard deviation is 10. A score below the mean indicates poor health whereas a score above the mean indicates better health (see Table 12).

Meanwhile, the single item of general health was used to assess the patients perceived health. The combination of the two variables represents the overall QoL. Of means of the health domains, patients mean physical role limitations score was the lowest at 39.15 ± 10.43 while the highest mean was for mental health, 49.08 ± 11.18, followed by vitality, 46.20 ± 11.07.

Furthermore, the exploration of the SF-12v2 data showed that few of the domains had a significant difference between the mean and the median, for example, MCS, vitality, mental health, and social functioning. This prompted a skewness assessment to determine the presence of significance level of skewness and, thus, the test for normality of the distribution in the variables was done. Skewness refers to the lack of symmetry in a distribution caused by the presence of extreme scores (outliers). A perfect, normal distribution would have a Fisher-Pearson coefficient of zero, and any symmetric data would have a value of near zero. Generally, the acceptable Fisher-Pearson coefficient of skewness is below 2 for a reasonable degree of skewness (Gravetter et al., 2011). The SF-12v2 domains had Fisher-Pearson coefficients as follows: MCS = -.558, bodily pain = -.318, social functioning = -.536 and mental health = -.410. A positive sign indicates positive skewness (right tail) while a negative sign indicates negative skewness (left tail). Accordingly, those domains showed no significant skewness. As is also noted in the boxplot of the domains, the vitality had four data points that were considered
outliers with a value of 100. The exploration of the mental health domain showed several
data points in the 75th percentile which might have been the cause of some skewness. The social
functioning domain had generally higher values compared to other domains which resulted in
shifting of the mean to the right. The MCS had a few data points in the lower end of the
distribution which resulted in shifting of the mean. However, since these observations were not
significant, the analyses progressed as planned.

Table 12. Descriptive Statistics of the SF-12v2 Domains and Composite Scores

<table>
<thead>
<tr>
<th>Composite Scores</th>
<th>Mean (SD)</th>
<th>Mode</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical composite scores</td>
<td>40.21 (9.75)</td>
<td>30.63*</td>
<td>41.4</td>
<td>16.82</td>
<td>60.45</td>
</tr>
<tr>
<td>Mental composite scores</td>
<td>47.29 (11.35)</td>
<td>46.94</td>
<td>47.0</td>
<td>9.50</td>
<td>68.34</td>
</tr>
<tr>
<td>Domains scores</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitality</td>
<td>46.20 (11.07)</td>
<td>50</td>
<td>50.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Role physical</td>
<td>39.15 (10.43)</td>
<td>50</td>
<td>50.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>40.40 (9.74)</td>
<td>25</td>
<td>50.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>41.42 (11.05)</td>
<td>50</td>
<td>50.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>General health</td>
<td>45.10 (11.03)</td>
<td>60</td>
<td>60.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Role emotional</td>
<td>40.08 (12.20)</td>
<td>100</td>
<td>62.5</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Social functioning</td>
<td>44.34 (12.22)</td>
<td>100</td>
<td>75.0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Mental health</td>
<td>49.08 (11.18)</td>
<td>75</td>
<td>75.0</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>

*Multiple modes existed, the lowest value was reported.

Social Support

The level of perceived social support the patients was measured using the Medical
Outcome Study-Social Support Survey (MOS-SSS). As discussed in Chapter 3, MOS-SSS is a
19-item measure grouped into four subscales. Table 13 below describes the mean and standard
deviation of each subscale and the comparison to published scores (Sherbourne & Stewart,
1991). Each subscale is calculated by adding the scores of individual items and transforming
them into a scale of 0-100, where higher scores suggest better social support. In addition, the
survey has an overall perceived support index that reflects all the items on the scale. Chapter 5 has further discussion on this comparison.

Table 13. Descriptive Statistics of MOS-SSS

<table>
<thead>
<tr>
<th>Overall Support Index (n=119)</th>
<th>Current study</th>
<th>Min.</th>
<th>Max.</th>
<th>Published data (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>70.7 (27.28)</td>
<td>3.95</td>
<td>100</td>
<td>70.1 (24.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subscales</th>
<th>Mean (SD)</th>
<th>Min.</th>
<th>Max.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Informational/Emotional (n=112)</td>
<td>64.50 (31.82)</td>
<td>0.0</td>
<td>100</td>
<td>69.6 (25.5)</td>
</tr>
<tr>
<td>Tangible (n=115)</td>
<td>73.96 (30.26)</td>
<td>0.0</td>
<td>100</td>
<td>69.8 (28.5)</td>
</tr>
<tr>
<td>Affectionate (n=117)</td>
<td>79.20 (29.79)</td>
<td>0.0</td>
<td>100</td>
<td>73.7 (28.3)</td>
</tr>
<tr>
<td>Positive social interaction</td>
<td>74.43 (31.6)</td>
<td>0.0</td>
<td>100</td>
<td>69.8 (26.0)</td>
</tr>
</tbody>
</table>


**Foot Care Practices**

The variable foot care represented a form of the functional status in this study. Self-care practices were assessed using the SDSCA. The SDSCA-Arabic has 15 items under 5 subscales (diet, exercise, medication taking, glucose checking, and foot self-care practices). Each item was scored on a Likert-type scale of 0-7 days/week. Each subscale was calculated by averaging the items within. The foot care subscale has 5 items (see Table 14). Higher scores suggest better self-care practices. For this study, the mean frequency of foot care activities performed by the sample was 4.74 ± 1.32. In other words, the patients performed foot care about 65% of days of the week—see Tables 14 and 15 for further details of the foot care subscale. More discussion on the comparative data can be found in Chapter 5.

It is important to note that items 4 (consuming high fats) and 10 (soaking feet) were reversely phrased and needed to be recoded for the calculations of subscales. It is noteworthy that scoring high in a reversely phrased item in the SDSCA suggests a pattern of un-recommended practice compared to the normally phrased items, in which, higher scores indicate
compliance with the recommended practice of self-care. For instance, having a score of five in *soaking feet* indicates that the patient is practicing foot-soaking five days/week (more frequency = high compliance). Meanwhile, a score of five days/week in *drying feet* item suggests that the patient is following the recommendations. Soaking feet is discouraged for diabetics due to increased risk of dryness, burns, and injuries (American Family Physicians, 2020). For the purposes of descriptive statistics, the authors suggested no re-coding of the reversely phrased items be done (Toobert et al., 2005). Thus, in Table 15, the item *soaking feet* was left as originally scored, though it was recoded in the subscale computations in Table 14.

Table 14. Description of the SDSCA Subscales

<table>
<thead>
<tr>
<th>Subscales</th>
<th>Mean (SD)</th>
<th>% of days/week in this study</th>
<th>Published % of days/week a</th>
<th>% of days/week for the Saudi Population b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet (n=117)</td>
<td>3.69 (1.24)</td>
<td>52.7 ±17.7%</td>
<td>58.25±28.7%</td>
<td>51.42±24.28%</td>
</tr>
<tr>
<td>Exercise (n=120)</td>
<td>2.12 (2.31)</td>
<td>30.3±33.0%</td>
<td>34.3±31.9%</td>
<td>43.14±31.00%</td>
</tr>
<tr>
<td>Blood sugar testing (n=118)</td>
<td>3.52 (2.50)</td>
<td>50.28±35.71%</td>
<td>69.03±4.9%</td>
<td>32.00±27.14%</td>
</tr>
<tr>
<td>Foot care (n=115)</td>
<td>4.74 (1.32)</td>
<td>67.71±14.28%</td>
<td>47.1±21.4%</td>
<td>49.85±33.85%</td>
</tr>
<tr>
<td>Medication (n=118)</td>
<td>6.15 (1.93)</td>
<td>87.85±27.57%</td>
<td>95.0±15.4%</td>
<td>98.42±8.42%</td>
</tr>
</tbody>
</table>

Note: a indicates (Toobert et al., 2005); b indicates (AlJohani et al., 2015)

As can be seen in Table 15, this study mean frequency of soaking feet was 1.39 ± 2.35 suggesting that patients were generally adherent as to not soaking their feet per the ADA (2019) recommendations.
Table 15. Mean and Standard Deviation of Foot Care Subscale Individual Items

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
<th>Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot care subscale</td>
<td>4.74 (1.32)</td>
<td>4.60</td>
<td>5</td>
</tr>
<tr>
<td>Individual items</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checked your feet</td>
<td>3.86 (2.99)</td>
<td>4.00</td>
<td>7</td>
</tr>
<tr>
<td>Checked inside of shoes</td>
<td>3.58 (3.06)</td>
<td>3.50</td>
<td>7</td>
</tr>
<tr>
<td>Washed your feet</td>
<td>6.64 (1.27)</td>
<td>7.00</td>
<td>7</td>
</tr>
<tr>
<td>Soaked your feet*</td>
<td>1.39 (2.35)</td>
<td>7.00</td>
<td>0</td>
</tr>
<tr>
<td>Dried between your toes</td>
<td>3.93 (3.27)</td>
<td>6.00</td>
<td>7</td>
</tr>
</tbody>
</table>

*The original reversely phrased item

**Chronic Illness Resources**

The varying resources a chronic illness patient needs to maintain and promote their health was measured by CIRS which has 22 items grouped into 7 subscales encompassing health care, family and friends, personal factors, neighborhood and community, work environment, media and policy, and the organizational resources. Each subscale has a score of 1-5 with 5 indicating better resources. The media/policy subscale was omitted from the analysis as mentioned earlier since the items were not applicable to the population of Saudi. According to the authors of the instrument, individual subscales can be removed with no impact on the overall scale (Glasgow et al., 2004). Since the CIRS has no total score, calculating a mean score for the entire scale depends on the number of items included, deleted subscales do not impact the total mean score. Comparative data were retrieved from the (Glasgow et al., 2004) to provide a context for our results. Table 16 below describes the mean scores for each subscale of the CIRS. Participants had low to moderate chronic illness resources based on their means scores.
Table 16. Mean and Standard Deviation of CIRS Subscales

<table>
<thead>
<tr>
<th>Subscales</th>
<th>Current Study</th>
<th>Glasgow et al. (2004)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scale mean score</td>
<td>Mean (SD)</td>
<td>Min.</td>
</tr>
<tr>
<td></td>
<td>2.41 (0.68)</td>
<td>1.18</td>
</tr>
<tr>
<td>Health care (n=115)</td>
<td>3.32 (1.21)</td>
<td>1.0</td>
</tr>
<tr>
<td>Family/Friends (n=118)</td>
<td>2.18 (1.12)</td>
<td>1.0</td>
</tr>
<tr>
<td>Personal (n=114)</td>
<td>2.88 (1.25)</td>
<td>1.0</td>
</tr>
<tr>
<td>Neighborhood/Community (n=116)</td>
<td>2.23 (0.97)</td>
<td>1.0</td>
</tr>
<tr>
<td>Organizations (n=114)</td>
<td>1.5 (0.76)</td>
<td>1.0</td>
</tr>
<tr>
<td>Work environment (n=28)</td>
<td>3.04 (1.14)</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**Comorbidity**

The number of illnesses patients had, including T2DM, was assessed by the Functional Comorbidity Index (FCI). The FCI is a “select all that apply” measure and includes 18 conditions that affect the level of functioning of the individual (Groll et al., 2005). It takes into consideration all the different illnesses and was included for the goal of controlling for other comorbidities when predicting QoL (see Table 17). For this study, participants had an average of 3 co-morbid conditions, including diabetes.
Table 17. Functional Comorbidity Index Results

<table>
<thead>
<tr>
<th>Scale</th>
<th>FCI total score (out of 18)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>3.1 (1.49)</td>
</tr>
<tr>
<td></td>
<td>Median (Range)</td>
<td>3 (0-7)</td>
</tr>
<tr>
<td></td>
<td>Individual items</td>
<td>% (n)</td>
</tr>
<tr>
<td></td>
<td>DM</td>
<td>100.0 (120)</td>
</tr>
<tr>
<td></td>
<td>Obesity</td>
<td>50.0 (60)</td>
</tr>
<tr>
<td></td>
<td>Arthritis</td>
<td>40.0 (48)</td>
</tr>
<tr>
<td></td>
<td>Visual impairment</td>
<td>28.3 (34)</td>
</tr>
<tr>
<td></td>
<td>GERD/Upper GI disease</td>
<td>20.8 (25)</td>
</tr>
<tr>
<td></td>
<td>Degenerative disc disease/Lower-back pain</td>
<td>15.0 (18)</td>
</tr>
<tr>
<td></td>
<td>Peripheral vascular disease</td>
<td>10.8 (13)</td>
</tr>
<tr>
<td></td>
<td>Asthma</td>
<td>8.3 (10)</td>
</tr>
<tr>
<td></td>
<td>Angina</td>
<td>8.3 (10)</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>7.5 (9)</td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td>7.5 (9)</td>
</tr>
<tr>
<td></td>
<td>Hearing impairment</td>
<td>5.8 (7)</td>
</tr>
<tr>
<td></td>
<td>Chronic obstructive pulmonary disease</td>
<td>1.7 (2)</td>
</tr>
<tr>
<td></td>
<td>Heart attack</td>
<td>1.7 (2)</td>
</tr>
<tr>
<td></td>
<td>Neurological diseases (Parkinson, MS)</td>
<td>0.8 (1)</td>
</tr>
<tr>
<td></td>
<td>Cerebrovascular accidents (TIA, stroke)</td>
<td>0.8 (1)</td>
</tr>
<tr>
<td></td>
<td>Congestive heart failure</td>
<td>0.8 (1)</td>
</tr>
<tr>
<td></td>
<td>Acute respiratory distress syndrome</td>
<td>0.00 (0)</td>
</tr>
</tbody>
</table>

The Reliability Assessment of the Study Variables

Following the descriptive analysis, the reliability of the measures was assessed. Table 18 describes the estimation of internal consistency by the Cronbach alpha of the key variables. The estimation of internal consistency of DPN measures was low with both MNSI and the S-LANSS: Cronbach alpha = .58 and .65, respectively. This is below the acceptable value of the Cronbach alpha of .7 (Cronbach, 1951). Both the numeric pain score and the MOS-SSS showed stability, with Cronbach alpha of .94 and .95, respectively. The SF-12v2 Arabic version showed stability as well with Cronbach’s alpha of .81 for both composite scores.
The monofilament-testing reliability assessment was performed by the test-retest correlation as indicated by the intraclass correlation coefficient between the right and left foot. Since this study is cross-sectional, it was not possible to perform a test-retest assessment on the same foot; instead the right foot was compared to the left foot by the investigator.

Table 18. Reliability Assessment (Internal Consistency) of Key Study Instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Current Estimations</th>
<th>Published Estimations</th>
<th>No. of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12v2 (MCS &amp; PCS)</td>
<td>.81</td>
<td>.85 and .83</td>
<td>8</td>
</tr>
<tr>
<td>S-LANSS</td>
<td>.58</td>
<td>.76</td>
<td>7</td>
</tr>
<tr>
<td>MNSI</td>
<td>.65</td>
<td>.91</td>
<td>15</td>
</tr>
<tr>
<td>SDSCA foot care</td>
<td>.50</td>
<td>.77</td>
<td>5</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>.95</td>
<td>.78</td>
<td>19</td>
</tr>
<tr>
<td>CIRS</td>
<td>.76</td>
<td>.82</td>
<td>20</td>
</tr>
<tr>
<td>NPRS</td>
<td>.94</td>
<td>.95</td>
<td>6</td>
</tr>
<tr>
<td>Monofilament</td>
<td>ICC=.90</td>
<td>ICC=.92</td>
<td>NA</td>
</tr>
</tbody>
</table>

Note: ICC: interclass correlation coefficient.

**Bivariate Correlations Among Study Variables**

The Pearson correlation (r) was run to detect association between select study variables with a two-tailed significance level of 0.05. The results of the correlations of the main variables showed significance. Neuropathy symptoms as measured by the MNSI 1, MNSI 2, S-LANSS, and the average pain during the previous week correlated significantly with a number of the study variables. QoL (PCS & MCS) also correlated with key variables.

The MNSI correlated significantly with QoL domains, and composite scores. The correlations between MNSI and the subscales were as follows: MCS (r = -.238, p = .007), PCS (r = -.303, p = .007), vitality (VT) (r = -.235, p = .010), role physical (RP) (r = -.211, p = .021), bodily pain (BP) (r = -.460, p < .000), general health (GH) (r = -.322, p < .001), role emotional (RE) (r = -.226, p = .013), mental health (MH) (r = -.308, p < .001), and physical functioning (PF) (r = -.220, p = .016). These correlations, suggest a low-to-moderate negative association
between DPN symptoms and the QoL domains that ranged between -.211 to -.460, were expected. To explain, the reverse association indicates that as the DPN scores increased (worse symptoms), the QoL indicators decreased, suggesting poorer physical and emotional health. For instance, the association of MNSI and MCS is \( r = -.246, p = .007 \). This means that there was weak association in which as DPN symptoms increase, the worse is the patient’s mental health status, as one would expect. The frequency of foot care practices was associated with more DPN symptoms (S-LANSS), poorer health perception, and more illness resources. For further details on correlations see Table 19.

Table 20 describes the association of the health domains of the SF-12v2 with the other outcome variables of the study and among each other. As it appears in the correlation matrix, there were expected positive correlations among the domains and with their respective composite scores. As previously mentioned, PCS is a physical composite score that is made up of varying degrees of contributions from all of the eight domains. This also applies to the make-up of the MCS. These correlations were as expected in direction and strength in that whenever a health domain decreased the respective composite score decreased as well suggesting poorer overall health.

For instance, the overall physical QoL correlated more with the domains physical functioning, role physical, bodily pain, and vitality. Patients with poorer physical functioning who were unable to climb a flight of stairs, were in much pain, and had impaired ability to perform their daily activities would had poorer physical QoL. Meanwhile, patients mental QoL correlated more with the domains mental health, role emotional, and social functioning. So that persons with anxiety and depressive symptoms and decreased social functions had worse mental QoL compared to those who did not. Further discussion on these correlations are Chapter 5.
Table 19. Bivariate Correlation Among Study Variables

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>S-LANSS</th>
<th>MNSI</th>
<th>GH</th>
<th>MNSI 2</th>
<th>PCS</th>
<th>MCS</th>
<th>Foot care</th>
<th>HbA1c</th>
<th>CIRS</th>
<th>MOSS-SS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.017</td>
<td>.031</td>
<td>-0.06</td>
<td>0.257**</td>
<td>-0.195*</td>
<td>0.004</td>
<td>0.056</td>
<td>-0.060</td>
<td>-0.188*</td>
<td>0.257*</td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>1.000</td>
<td>.473**</td>
<td>0.141</td>
<td>0.074</td>
<td>-0.478**</td>
<td>0.424**</td>
<td>0.126</td>
<td>0.131</td>
<td>0.116</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MNSI</td>
<td>1.000</td>
<td>0.326**</td>
<td>0.190*</td>
<td>-0.187</td>
<td>-0.278**</td>
<td>0.150</td>
<td>0.150</td>
<td>0.217*</td>
<td>-0.188*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GH</td>
<td>1.000</td>
<td>0.074</td>
<td>0.525**</td>
<td>-0.316**</td>
<td>-0.243**</td>
<td>0.122</td>
<td>0.259**</td>
<td>-0.211*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MNSI 2</td>
<td>1.000</td>
<td>0.074</td>
<td>0.525**</td>
<td>0.041</td>
<td>0.414</td>
<td>-0.020</td>
<td>-0.259**</td>
<td>-0.211*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCS</td>
<td>1.000</td>
<td>-0.187</td>
<td>-0.187</td>
<td>0.270**</td>
<td>0.083</td>
<td>0.108</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCS</td>
<td>1.000</td>
<td>0.082</td>
<td>-0.092</td>
<td>0.050</td>
<td>0.093</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot care</td>
<td>1.000</td>
<td>0.082</td>
<td>0.082</td>
<td>0.108</td>
<td>0.050</td>
<td>0.050</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>1.000</td>
<td>0.108</td>
<td>0.108</td>
<td>0.108</td>
<td>0.050</td>
<td>0.050</td>
<td>0.108</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIRS</td>
<td>1.000</td>
<td>0.108</td>
<td>0.108</td>
<td>0.108</td>
<td>0.050</td>
<td>0.050</td>
<td>0.108</td>
<td>0.108</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOSS-SS</td>
<td>1.000</td>
<td>0.108</td>
<td>0.108</td>
<td>0.108</td>
<td>0.050</td>
<td>0.050</td>
<td>0.108</td>
<td>0.108</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant correlation at .05 (two tailed); ** Significant correlation at .01 (two tailed); S-LANSS: Self-Report-Leeds Assessment of Neuropathy Sings and Symptoms; MNSI Michigan Neuropathy Symptoms Inventory; PCS: Physical Composite Scores; MCS: Mental Composite Scores; HbA1c: hemoglobin A1c; CIRS: Chronic Illness Resources Survey; MOSS-SSS: Medical Outcome Study-Social Support Survey; GH: General Health.
Table 20. Correlations Among SF-12v2 Domains and Summary Scale

<table>
<thead>
<tr>
<th></th>
<th>PF</th>
<th>RP</th>
<th>BP</th>
<th>GH</th>
<th>VT</th>
<th>MH</th>
<th>RE</th>
<th>SF</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS</td>
<td>.808**</td>
<td>.779**</td>
<td>.627**</td>
<td>.525**</td>
<td>.376**</td>
<td>-.188*</td>
<td>.160</td>
<td>.008</td>
</tr>
<tr>
<td>PF</td>
<td>1</td>
<td>.603**</td>
<td>.464**</td>
<td>.394**</td>
<td>.241**</td>
<td>.202*</td>
<td>312**</td>
<td>.180</td>
</tr>
<tr>
<td>RP</td>
<td>1</td>
<td>.627**</td>
<td>.314**</td>
<td>.349**</td>
<td>.252**</td>
<td>.463**</td>
<td>.217*</td>
<td></td>
</tr>
<tr>
<td>BP</td>
<td>1</td>
<td>.234*</td>
<td>.297**</td>
<td>.348**</td>
<td>.442**</td>
<td>.171</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GH</td>
<td>1</td>
<td>.321**</td>
<td>.262**</td>
<td>-.304**</td>
<td>.225**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCS</td>
<td>.033</td>
<td>.188*</td>
<td>.233*</td>
<td>.246**</td>
<td>.327**</td>
<td>.852**</td>
<td>.760**</td>
<td>.760**</td>
</tr>
<tr>
<td>VT</td>
<td>1</td>
<td>.242**</td>
<td>.105</td>
<td>.156</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MH</td>
<td>1</td>
<td>.577**</td>
<td>.542**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RE</td>
<td>1</td>
<td>.539**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant correlation at .05 (two tailed); ** Significant correlation at .01 (two tailed). PCS: Physical Composite Scores; MCS: Mental Composite Scores; VT: Vitality; RP: Role Physical; SF: Social Functioning; BP: Bodily Pain; GH: General Health; MH: Mental Health; RE: Role Emotional; PF: Physical Functioning.
**Regression Analysis of the Study Aims**

Data were analyzed using multiple regression as it is the appropriate test for the type of variables used and the research questions. Data met the eight assumptions of multiple regression. The first two assumptions were met at the stage of designing the study as the dependent variable was continuously measured and the independent variables were continuous or categorical. The other six assumptions were tested, using the recommended criteria, in SPSS, as a part of the hypotheses testing as they relate to the nature of the data.

The data passed the Durbin-Watson statistic, which checks the assumption of independence of observation. This test affirms that the residuals (errors) of the adjacent observations were not correlated. The data were also established for the assumption of linearity by plotting the studentized residuals against the unstandardized predicted values and the partial regression plots. Moreover, the data met the assumption of homoscedasticity by showing equal error variance along the line of best fit. Assumption six of multicollinearity was also met as determined by the correlation coefficients and tolerance/variance inflation factor values. These tests were met as the correlations among the independent variables were less than $r = .7$, and the tolerance values were greater than 1.0 (Laerd Statistics, 2020).

Outliers were assessed, and we found no values exceeded ± 3 standard deviations. There were also no high-leverage points, nor any highly influential points in the data as assessed by the casewise diagnostics, studentized deleted residuals, and the Cook points. High influential points refer to outlier that greatly affect the regression line and thus bias the conclusions. Finally, the assumption of normality of residuals distribution was also met by the data observed using histograms and the probability P-P plots.
A series of univariable analysis tests were performed to establish the individual predictive patterns between the dependent and independent variables in isolation of the effect of other variables. This was guided by the constructs of the revised HRQoL model by Wilson and Cleary (Ferrans et al., 2005), as discussed in Chapter 3. The results of the univariable analyses can be found in Appendix I, Tables I1 and I2.

**Data Analysis of Aim 1**

Multiple regression models were used to assess the study aims. First, the univariable analysis of the independent variable (DPN) and each dependent variable was run. There were no covariates included in this initial regression model, often referred to as the unadjusted model. Subsequently, a multivariable (adjusted) model was run which adjusts for the covariates that were identified that could impact the outcome variables. For the primary aim, the environmental factors of resources (CIRS) and social support (MOS-SSS) and the individual variables of age and gender were the covariates. The primary aim was: To examine the impact of DPN symptoms on (1) patients’ functioning (foot care practices), (2) general health perception, and (3) overall QoL (PCS and MCS). The hypothesis to be tested was: Individuals with more symptoms have poorer foot care practices, negative health perception, and poorer physical and mental overall QoL.

First, the impact of DPN on diabetes self-care of the feet (foot care practices) was examined as delineated in the HRQoL model (Figure 1). On univariable analysis, only one of the DPN measures, the S-LANSS, had a relationship with foot care practices (see Appendix I, Table I1). The multivariable model was significant, \( R^2 = .116, F (7, 112) = 2.102, p = .049 \) (see Table 21). The standardized beta coefficient of the S-LANSS was 0.203 meaning that for each point increase in S-LANSS the predicted foot care value increases by 0.203 after holding the other
variables constant, \( p = .050 \). This suggests that more neuropathy symptoms were associated with better foot care practices. The model explains 11.6\% of the relationship between DPN and foot care practices. Although this did not support the hypothesis that more symptoms would be associated with worse self-care, it is logical that as DPN symptoms worsen, persons may be more engaged to participate in better foot care practices, and is discussed in Chapter 5.

Table 21. Impact of DPN on Foot Care Practices

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>( p )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>2.334 (0.955)</td>
<td></td>
</tr>
<tr>
<td>Key Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>0.203 (0.022)</td>
<td>.050</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>0.040 (0.047)</td>
<td>.701</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>0.015 (0.048)</td>
<td>.875</td>
</tr>
<tr>
<td>Covariates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>0.046 (0.013)</td>
<td>.633</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.008 (0.238)</td>
<td>.930</td>
</tr>
<tr>
<td>CIRS</td>
<td>0.183 (0.175)</td>
<td>.050</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.138 (0.005)</td>
<td>.145</td>
</tr>
</tbody>
</table>

\( R^2 = .116 \)
\( n = 120 \)

Note: Standard errors are reported in parentheses

Next, the impact of DPN and foot care on health perception was tested. On the univariable analysis, MNSI 1, S-LANSS, and foot care practices were significantly associated with health perception as noted in Appendix I, Table I1. The multivariable model was significant, \( R^2 = .236, F (8, 111) = 6.244, p < .001 \) (see Table 22). The standardized beta coefficient of the MNSI 1 was -0.240 meaning that for each point increase in MNSI 1, the expected health perception value decreases 0.240 points, after holding the other variables constant \( p = .015 \). The standardized beta coefficient of foot care was 0.218 indicating that for each point increase in the frequency of performing foot care practices the expected health perception increases 0.218 points, after holding the other variables constant \( p = .015 \). Meaning,
the more patients cared for their feet, the better they felt about their health. Fewer neuropathy
symptoms and better foot care practices were associated with positive health perception. The
results of the regression model supported the second part of the hypothesis in which we
hypothesized that DPN and foot care would be associated with health perception. This model
explained 23.6% of the variance in health perception.

Table 22. Impact of DPN and Foot Care Practices on Health Perception

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>40.447 (19.569)</td>
<td></td>
</tr>
<tr>
<td>Key Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.134 (0.442)</td>
<td>.170</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-0.240 (0.944)</td>
<td>.015</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>-0.070 (0.968)</td>
<td>.431</td>
</tr>
<tr>
<td>Foot care</td>
<td>0.218 (1.887)</td>
<td>.015</td>
</tr>
<tr>
<td>Covariates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.046 (0.266)</td>
<td>.605</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.073 (4.744)</td>
<td>.393</td>
</tr>
<tr>
<td>CIRS</td>
<td>0.157 (3.565)</td>
<td>.076</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.176 (0.096)</td>
<td>.051</td>
</tr>
</tbody>
</table>

\[ R^2 = .236 \]

n=120

Note: Standard errors are reported in parentheses

Then, the impact of DPN and foot care on physical QoL (PCS) was examined. On
univariable analysis, all DPN symptoms as measured by MNSI 1, S-LANSS, MNSI 2 were
associated with PCS (see Appendix I, Table I1). The multivariable regression model was
significant, \( R^2 = .282, F (8, 111) = 5.440, p < .001. \) The standardized coefficient of the MNSI 2
was -0.214 meaning that for each point increase in MNSI 2 the expected PCS value decreases by
0.214 points after holding the other variables constant, \( p = .014. \) The standardized beta
coefficient of S-LANSS was -0.182, that is for each point increase in S-LANSS the expected
PCS value decreases by -0.182 points after holding the other variables constant, \( p = .057. \) That is
more neuropathy symptoms was associated with lower physical QoL (see Table 23). This model also supported the primary hypothesis that DPN and foot care practices are associated with poorer physical QoL. This model explained explaining 28.2% of variance in physical QoL.

Table 23. Impact of DPN and Foot Care Practices on Physical QoL

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>46.388 (6.671)</td>
<td></td>
</tr>
<tr>
<td>Key Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.182 (0.151)</td>
<td>.057</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-0.154 (0.322)</td>
<td>.105</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>-0.214 (0.330)</td>
<td>.014</td>
</tr>
<tr>
<td>Foot care</td>
<td>0.076 (0.643)</td>
<td>.375</td>
</tr>
<tr>
<td>Covariates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.098 (0.091)</td>
<td>.259</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.180 (1.617)</td>
<td>.032</td>
</tr>
<tr>
<td>CIRS</td>
<td>0.269 (1.215)</td>
<td>.002</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>-0.006 (0.033)</td>
<td>.941</td>
</tr>
</tbody>
</table>

\[ R^2 = .282 \]
\[ n=120 \]

Note: Standard errors are reported in parentheses

Lastly, the impact of DPN and foot care on the mental QoL (MCS) was examined. On the univariable analysis, MNSI 1 was significantly associated with MCS (see Appendix I, Table I1). The multivariable model was significant, \( R^2 = .259, F (8, 111) = 4.860, p < .001 \). The standardized coefficient of the MNSI 1 was -0.196 suggesting that each point increase in MNSI 1 was associated with 0.196 points decrease in MCS values, after holding the other variables constant, \( p = .044 \) (see Table 24). Thus fewer neuropathy symptoms were associated with better mental health. The results of this model supported the primary hypothesis that DPN was associated with poorer mental QoL. This model explained 25.9% of the variance in mental QoL.
Table 24. Impact of DPN and Foot Care Practices on Mental QoL

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>50.868 (7.880)</td>
<td></td>
</tr>
<tr>
<td>Key Variables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.061 (0.178)</td>
<td>.524</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-0.196 (0.380)</td>
<td>.044</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>0.027 (0.390)</td>
<td>.755</td>
</tr>
<tr>
<td>Foot care</td>
<td>0.034 (0.760)</td>
<td>.698</td>
</tr>
<tr>
<td>Covariates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.117 (0.107)</td>
<td>.185</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.210 (1.910)</td>
<td>.014</td>
</tr>
<tr>
<td>CIRS</td>
<td>-0.039 (-1.436)</td>
<td>.648</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.435 (0.039)</td>
<td>.000</td>
</tr>
</tbody>
</table>

$R^2 = .259$

n=120

Note: Standard errors are reported in parentheses.

**Data Analysis of Aim 2**

The aim of this analysis was to establish a relationship between a number of independent variables and the key outcome variables, the S-LANSS, MNSI 1, and the MNSI 2. The hypothesis to be tested was as follows: Longer duration of T2DM, poor glycemic control, increased age, female gender, presence of hypertension, comorbidity, and dyslipidemia, and lack of physical activity are associated with more DPN symptoms. Similar to approach for the first aim, for each outcome variable a univariable analysis was run with each independent variable to establish a relationship before adjusting for other variables (results are in Appendix I, I2). After running individual analyses for each outcome variable a series of multivariable (adjusted) regression analyses were run to establish relationships between the outcome and the independent variables. The independent variables were HbA1c, age, and comorbidity (FCI), duration of diabetes group with 4 levels (< 5 years, 5-10 years, 11-15 years, & > 15 years). Other variables were treated dichotomously with hypertension (yes = 1, no = 0), treated dyslipidemia (yes = 1,
no = 0), level of exercise (none = 0, not-regular = 1, regular = 2), and gender (female = 1, male = 0).

**Impact of Key Variables on DPN (S-LANSS)**

The S-LANSS entered the regression model as the outcome variable and all other variables were entered as independent variables. The results of the univariable analyses showed that FCI was associated with the S-LANSS scores (see Appendix I, Table I2). However, the multivariable model, was not significant ($F$-value $(9,110) = 1.292, p = .249$). The beta coefficient for both models had FCI as important in contributing to DPN symptoms. The results of this model did not add information to support the hypothesis that DPN was associated with the key variables.

Table 25. Impact of Key Variables on DPN (S-LANSS)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>11.535 (5.075)</td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>0.059 (0.407)</td>
<td>.557</td>
</tr>
<tr>
<td>FCI</td>
<td>0.230 (0.407)</td>
<td>.022</td>
</tr>
<tr>
<td>Hypertension</td>
<td>-0.038 (1.395)</td>
<td>.736</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>-0.087 (0.579)</td>
<td>.391</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>-0.114 (1.539)</td>
<td>.247</td>
</tr>
<tr>
<td>Not-regular</td>
<td>-0.186 (1.376)</td>
<td>.066</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>0.085 (1.242)</td>
<td>.381</td>
</tr>
<tr>
<td>Age</td>
<td>-0.018 (0.068)</td>
<td>.866</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.075 (1.186)</td>
<td>.443</td>
</tr>
</tbody>
</table>

$R^2 = .096$

n=120

**Impact of Key Variables on DPN (MNSI 1)**

Next, the association of key variables with the MNSI 1 was assessed. On the univariable analysis, hypertension, FCI, and not-regular exercise were significant. HbA1c and treated
dyslipidemia were marginally significant (see Appendix I, Table I2). The multivariable model was significant, $R^2 = .266$, $F(9, 110) = 4.421$, $p < .001$ (see Table 26). The standardized beta coefficient of the HbA1c was 0.237 meaning that each point increase in HbA1c was associated with 0.237 points increase in MNSI 1 scores, after holding the other variables constant, $p = .009$. This means that higher HbA1c levels were associated with worse DPN symptoms. The standardized coefficient of the FCI was 0.322 indicating that with each point increase in comorbidity the predicted MNSI 1 value increases 0.322 points, after holding the other variables constant, $p < .001$.

The standardized beta coefficient of performing regular exercise was -0.115 and trending towards significance, $p = .089$. This finding suggests that performing regular exercise may be associated with 0.115 points decrease in the expected MNSI 1 value compared to not performing any physical activity, after holding the other variables constant. The beta standardized coefficient of performing not-regular (some) exercise was -0.183 indicating that performing some exercise was associated with 0.183 points decrease in the expected MNSI 1 value compared to not performing any physical activity, after holding the other variables constant, $p = .044$. Thus expectedly, higher HbA1c levels, more comorbidities, and being less active were associated with worse neuropathy symptoms. The findings of this model supported parts of the secondary hypothesis in which higher HbA1c levels, more comorbidities, and being less active were associated with worse neuropathy symptoms. Gender, age, hypertension, treated dyslipidemia, and the duration of DM were not associated with DPN. This model explained 26.6% of the variance in the MNSI 1.
Table 26. Impact of Key Variables on MNSI 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>3.769 (2.141)</td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>0.237 (0.153)</td>
<td>.009</td>
</tr>
<tr>
<td>FCI</td>
<td>0.322 (0.172)</td>
<td>.000</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.144 (0.589)</td>
<td>.154</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>0.057 (0.244)</td>
<td>.535</td>
</tr>
<tr>
<td>Exercise Regular</td>
<td>-0.115 (0.649)</td>
<td>.089</td>
</tr>
<tr>
<td>Exercise Not-regular</td>
<td>-0.183 (0.580)</td>
<td>.044</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>0.095 (0.524)</td>
<td>.280</td>
</tr>
<tr>
<td>Age</td>
<td>-0.127 (0.029)</td>
<td>.181</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.086 (0.500)</td>
<td>.328</td>
</tr>
</tbody>
</table>

R² = .266
n = 120

Note: Standard errors are reported in parentheses.

Impact of Key Variables on DPN (MNSI 2)

This model included the MNSI 2 as the outcome variable with the selected independent variables. The MNSI 2, as mentioned earlier, is the second part of the MNSI and is a foot examination that was performed by the investigator. The univariable analysis showed that age and gender were significantly associated with MNSI 2. Hypertension and exercise were marginally significant (see Appendix I, Table I2). The multivariable model was significant, R² = .162, F (9, 110) = 2.361, p = .018 (see Table 27). The beta standardized coefficient of performing not-regular (some) exercise was -0.222, meaning that performing some exercise was associated with 0.222 points lower MNSI 2 values compared to not performing any activity, after holding the other variables constant, p = .023. The beta standardized coefficient of treated dyslipidemia was -0.172 indicating that treated dyslipidemia may be associated with 0.172 points lower predicted MNSI 2 values compared to non-treated dyslipidemia, after holding the other variables constant, p = .068. The beta standardized coefficient of age was 0.185 meaning that for
each point increase in age the predicted MNSI 2 value may be increased 0.185 points, after holding the other variables constant \( p = .069 \).

Lastly, the beta standardized coefficient of gender was -0.220 indicating that females had 0.220 points lower MNSI 2 values compared to males, after holding the other variables constant \( p = .020 \). Thus, performing some exercise (compared to no exercise) and female gender were associated with lower foot exam scores. The findings of this model supported parts of the secondary hypothesis in which gender and physical activity were associated with worse neuropathy symptoms. HbA1c, comorbidity, age, hypertension, treated dyslipidemia, and the duration of DM were not associated with DPN. This model explained 16.2% of the variance in foot exam scores.

### Table 27. Impact of Key Variables on MNSI 2

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standardized coefficients</th>
<th>( p )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>1.397 (2.032)</td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>0.005 (0.145)</td>
<td>.959</td>
</tr>
<tr>
<td>FCI</td>
<td>0.041 (.163)</td>
<td>.670</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.010 (0.559)</td>
<td>.927</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>0.099 (0.232)</td>
<td>.310</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>-0.066 (0.616)</td>
<td>.484</td>
</tr>
<tr>
<td>Not-regular</td>
<td>-0.222 (0.551)</td>
<td>.023</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>-0.172 (0.497)</td>
<td>.068</td>
</tr>
<tr>
<td>Age</td>
<td>0.185 (0.027)</td>
<td>.069</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.220 (0.475)</td>
<td>.020</td>
</tr>
</tbody>
</table>

\( R^2 = .162 \)

n=120

Note: Standard errors are reported in parentheses.

### Summary of the Study Aims Findings

Multivariable analyses did support much of the proposed hypotheses. For the primary aim, we hypothesized that more symptoms are associated with poorer foot self-care practices,
health perception and physical and mental QoL. This hypothesis was partially supported. Our findings did support an association between DPN and foot self-care, but not in the direction that we anticipated. As stated previously, DPN was associated with better foot self-care. There were also significant associations between DPN, health perception, physical, and mental QoL as proposed. Those with more DPN symptoms experienced poorer health perception, physical, and mental QoL.

For the secondary aim, findings supported the hypothesis. DPN was associated with HbA1c, comorbidity, physical activity and gender. The results indicated that people with worse DPN symptoms had poor glycemic control, more comorbidity, were sedentary and males.

**Conclusion of the Results Chapter**

This study was descriptive to shed some light on the association of neuropathy symptoms, biologic, environmental factors and quality of life. Through the use of descriptive and inferential statistics, an examination of the relationship amongst the aforementioned variables has been undertaken. The two study aims have been tested and supported. An interpretation of these results as well as the implications of these results are addressed in the next chapter.
CHAPTER FIVE

DISCUSSION

Despite the fact that Diabetic Peripheral Neuropathy (DPN) is getting more attention from researchers and clinicians around the world and in Saudi Arabia, certain aspects, including its impact on patients’ lives, have not been examined sufficiently. The vast majority of research in Saudi has been dedicated to the prevalence of DPN and the different approaches to detect and diagnose the symptoms (AlOdhayani et al., 2017; Halawa et al., 2010; Mojaddidi et al., 2011). Other studies focused on biomedical and physiological factors linked to the development of DPN symptoms (Algeffari, 2018; AlQuliti, 2015; Wang et al., 2014). There has been no published evidence that examined the impact of the symptoms on patients’ health, including the different aspects that represent Quality of Life (QoL). In addition, there has never been a research endeavor that was guided by a comprehensive theoretical framework.

This dissertation study attempted to bridge that gap as it pertains to the Saudi diabetic population by using the revised Wilson and Cleary Health-related Quality of Life (HRQoL) model (Ferrans et al., 2005; Wilson & Cleary, 1995). This model delineates the different factors and influences that affect the individual’s QoL. By focusing on the health-related factors, the model still acknowledges the individual and environmental forces that affect every dimension of QoL in addition to biologic functions, symptom status, functional status, and health perceptions.
This chapter addresses the study results, their relevance to clinical practice, and future research. It also evaluates the study by addressing its strengths and weaknesses and means to delimit them. This study aimed to find association between neuropathy symptoms and QoL in the setting of type 2 diabetes mellitus (T2DM) in Saudi Arabia. It also aimed to examine the factors associated with these symptoms. Based on the review of the literature and supported by the revised Wilson and Cleary’s HRQoL (Ferrans et al., 2005), it was hypothesized that those with symptomatic DPN would have poorer functioning, physical, and emotional QoL, and negative health perceptions. It was also hypothesized that select factors would be associated with more DPN symptoms.

**Characteristics of the Individual**

**Description of the Sample**

The majority of participants 67.5% (n = 81), were Native people (who always resided on the Arabian Peninsula and have no other ethnic background). The average age was 54 years, 70% (n = 84) were married, 70.6% (n = 84) were unemployed/retired, 40.2% (n = 47) had T2DM > 15 years, and about 70% (n = 83) had never smoked. As mentioned in Chapter 3, people who are above the age of 50 make up 30% of the general population and the majority of the people, 70%, are below 35 years. The percentage of people aged > 65 is only 2.6% (General Authority for Statistics, 2016) in Saudi Arabia yet the sample age range of 30 to 74 is consistent with the demographic of the growing T2DM population with DPN. T2DM is becoming more prevalent among young adults between the ages of 18 and 35 years (AlJohani et al., 2015). This current sample’s age is similar to the evidence found in Saudi-based studies on people with T2DM and DPN. Saudi studies reported an average age of patients of 58 & 39 years, respectively (Algeffari, 2018; AlOdhayani et al., 2017). The wide age range of 30-74 in the current study provide an
additional unique contribution of our study. The proportion of individuals who were unemployed or retired is also similar to previously published studies. A Saudi-based study found that 52.4% of individuals with T2DM were unemployed (AlGhamdi et al., 2018).

Gender was almost evenly represented as 54% of the sample was male and 46% was female. Further, the sample was homogenous in terms of race, marital, and employment status as nearly two-thirds of the sample, about 67%, were Native people and were mostly married. These characteristics also reflect the demographics of the Saudi population (General Authority for Statistics, 2017).

Forty-nine percent (n = 59) of the participants had an income of less than 5,000 Saudi riyals per month or 60,000 Saudi riyals (about $16,000) annually. The median income of the Saudi family is between $25,000 and $40,000 annually. The gross national income in Saudi in 2018 was $55,840 compared to $63,690 in the U.S. (World Bank, 2020). Thus, the majority of the patients benefiting from the free health services provided by Ministry of Health (MoH) are low-income people. A Saudi study, in a different region from this study, reported much lower family income and found that 47% of the participants made less than 30,000 Saudi riyals ($9,600) annually (Wang et al., 2014). This difference in reported income speaks to the wide variations of income in Saudi. However, it is important to note that female patients, specifically the housewives, frequently clarified that they do not have any income as their male family member is the source of income in the household. Thus these results might be biased by the fact that some unemployed women may have selected no income due to the fact that in Saudi some people consider the income per the individual not the household as a whole. Further, although no information of the location of residence was collected in this study, most patients reported living in rural areas about 35 miles away from the city.
In terms of education, 39.2% (n=47) were educated at the level of grade 6 or less, while 28.3% (n=34) had intermediate or high school; 25% (n = 30) had some college degree. This span in education level may have affected the patients’ comprehension of the questionnaires and their responses.

An important characteristic of the sample was that 31.7% (n = 38), had a formal diagnosis of DPN as reported by participants that stated their physicians told them they exhibited symptoms of DPN. Of those, 16.6% (n = 20) were prescribed neuropathy-specific medications such as pregabalin and gabapentin. Another portion of the patients, 34.1% (n = 41), received only vitamin B complex to help improve nerve function. The remaining 48.3% (n = 58) participants did not receive any form of relief for their neuropathy symptoms and were not aware of the condition. Thus there is such a large portion of the sample (48.3%) without symptom relief and only one fourth (16.6%, n = 20) of sample who were formally diagnosed were treated appropriately. This highlights an important issue related to the awareness and recognition of DPN symptoms and it suggests that despite the high prevalence of symptoms, proper identification and treatment are still lagging.

Overall, the study characteristics are comparable to other Saudi-based diabetes-related studies. For instance, a study on the risk factors of diabetic foot ulcers had a sample of 598 patients with T2DM who were 38% females, aged 50 years, 39% illiterate, and of which 44% had annual income of less than $16,000 (Hu et al., 2014). Collecting and reporting the racial and ethnic characteristics of the participants is not customary in the Saudi literature. Only one study of a Saudi-based population reported race/ethnicity of the sample. These categories were Middle Eastern, Asian, and Black (Halawa et al., 2010). The ethnicity Middle Eastern, reported in the above study, is inclusive of Native, North African, and Middle Eastern races, which were
reported in this current study. This study used race, and the Halawa et al. (2010) study used the term ethnicity to describe the racial/ethnic background as there are no clear guidelines for describing race in Saudi.

**Biologic Functions**

**HbA1c**

The average HbA1c level of the sample was 8.89%. The sample had poor glycemic control based on the criteria of the American Diabetes Association (ADA). For a diabetic, non-pregnant individual, the HbA1c levels should be kept < 7% (ADA, 2019). Although the HbA1c levels in this dissertation study were higher than most studies, generally, glycemic control is one of the most challenging goals that people with T2DM in Saudi strive to attain (Al-Rubeaan et al., 2015). Thus, this current study’s level of HbA1c was reflective of persons who had diabetes for a long period of time (> 15 years) and consequently had complications. In a non-Saudi study, 86 persons with T2DM with a comparable age range of 53.29 ± 7 years, and gender reported that the HbA1c level was higher for those with DPN, 7.9% ± 2.19% compared to 6.6% ± 0.98% for those without DPN (Hussain et al., 2014). Similarly, another non-Saudi study reported an average HbA1c level of 8.8% in patients with DPN (Bansal et al., 2014). High HbA1c values, however, are often found among the Saudi diabetic population. One study reported that patients with symptomatic DPN had on average an HbA1c level of 10.06% ± 1.91% compared with those who are asymptomatic, 8.58% ± 1.41% (Mojaddidi et al., 2011). In addition, another Saudi study of persons with T2DM (n = 54,670) reported that 15% had a HbA1c level greater than 8% (Al-Rubeaan et al., 2015).
Dyslipidemia

Dyslipidemia is one of the most commonly associated conditions with T2DM. In this current study, dyslipidemia was considered if the participant had a prescribed lipid-lowering medication. As discussed in Chapter 4, about 63% (n = 73) of the sample received lipid-lowering treatments. However, it should be acknowledged that the evidence suggests that these medications can be prescribed even with the absence of the diagnosis of dyslipidemia. According to the American College of Cardiology, dyslipidemia is considered with either elevated triglycerides or low HDL levels (American College of Cardiology, 2019). However, the American Diabetes Association (ADA) guidelines recommend prescribing statins for T2DM patients with or without a history of cardiovascular risk factors and irrespective of dyslipidemia diagnosis. Specifically, the ADA recommends that all T2DM patients (unless exclusion criteria apply) should be treated with varying doses of statins (ADA, 2019). This was based on the evidence that in T2DM, statins may play a role in reducing the all-cause mortality and major vascular events. In this current study, all patients who received treatment were prescribed a type of statins as most Saudi guidelines are consistent with most of the ADA’s recommendations.

In the current study, a variation in the levels of the lipids between participants was found. There was an abnormal lipid profile across the board between those treated for dyslipidemia and those who were not. Those who received statins had lower LDL levels (2.3 ± 1.1 mmol/L, or 88.94 ± 42.54 mg/dL) compared to those who did not (2.8 ± 0.81 mmol/L, or 108.28 ± 31.32 mg/dL) (p = .033). There were also significant differences in mean HDL between those who received statins (1.1 ± 0.28 mmol/L, or 42.54 ± 10.82 mg/dL) and those who did not (0.99 ± 0.23 mmol/L, or 38.28 ± 8.89 mg/dL) (p = .002).
Evidence of the prevalence of dyslipidemia among T2DM patients is significant. In one cross-sectional study from Korea (n = 37,375), around 24% (n = 8,902) of persons with T2DM had dyslipidemia (i.e., elevated triglycerides or low HDL) (Yang et al., 2015). Another cross-sectional study (n = 600) found that based on the lipids profile, 58% of those with T2DM and aged 60.6 years had dyslipidemia (Mejias, & Ramphul, 2018). Most reviewed evidence determined dyslipidemia based on the levels of the lipids profile. However, one study (n = 2,006) did report that there was a difference between the prevalence of dyslipidemia between DPN patients (n = 8) and non-DPN patients (n = 44) (Bansal et al., 2014). The overall prevalence of dyslipidemia in those with DPN in Bansal et al.’s study was low (2.6%) compared with the current study (62.9%).

**Hypertension**

The observed prevalence of hypertension was 52% (n = 59) in the current study. Hypertension was ascertained by data in the medical records, which is based on a formal diagnosis by the treating practitioners. One Saudi-based study of T2DM patients (n = 233) reported that only 7.8% (n = 19) of the Saudi DPN patients had hypertension (Algeffari, 2018) while another Saudi study reported higher numbers with up to 56% of DM patients also having hypertension (AlJabri, Bokhari, & AlJabri, 2018). Other studies reported lower prevalence of hypertension among individuals with T2DM. For instance, a study with a Taiwanese individuals found that 41% of those with T2DM have hypertension concurrently (Yang et al., 2015).

**Comorbidity**

The prevalence of other comorbidities among the participants in the current study was as follows: 50% had obesity (BMI > 30), 40% had degenerative joint diseases, 28.3% had visual impairment, and 20.8% had upper gastrointestinal diseases. These comorbidities are common in
T2DM as well as depression, nephropathy, cardiovascular diseases, and peripheral arterial diseases (Rumora et al., 2018). Other studies reported higher prevalence of comorbidities in individuals with T2DM and DPN. For example, Yang et al. (2015) found 10 comorbidities with a sample of individuals with T2DM (n = 37,375). Also, a Saudi-based study found that individuals with T2DM and DPN have about seven comorbidities, including hypertension, retinopathy, nephropathy, and stroke (AlQuliti, 2015).

**Symptom Status**

Participants in the current study reported multiple DPN symptoms. About 80% of subjects reported the presence of at least one symptom of DPN. As discussed in Chapter 2, DPN symptoms can take the form of neuropathic pain or sensory or motor dysfunction. In the current study, 90% of participants reported numbness most frequently. Numbness has been largely reported in the literature, which suggests that it is one of most common symptoms of DPN. One cross-sectional study examined the risk of developing DPN in patients with T2DM (n = 1,003) and the Michigan Neuropathy Screening Instrument (MNSI) (the same instrument used to measure DPN in this study) was used. They reported that numbness was reported by 81% of the participants (Khawaja et al. 2018). In the current study, both the MNSI and the Self-Report-Leeds Assessment of Neuropathy Signs and Symptoms (S-LANSS) had numbness as the most reported symptom (MNSI 90%) & (S-LANSS 80%). Another study from India (n = 208) which also used the MNSI, reported that 72% of participants stated a feeling of weakness most of the time (D’Souza et al., 2015). In the current study, 75.6% of our participants also reported generalized weakness which ranked third in the symptoms list for DPN in our study.

Another Saudi-based study also concluded similarly that DPN symptoms numbness, tingling, and pain (measured using the self-report Douleur Neuropathique 4) (DN4) were
prevalent in at least half of the sample (n = 1,305) (Halawa et al., 2011). Thus two important conclusions can be made with regard to our results. First, DPN among the population of Saudi Arabia can be symptomatic. Second, despite the fact that MNSI reliability in our sample was at .65, the findings were consistent with previously reported studies. It is important to note, however, that the high prevalence reported in the current study was due to the recruitment of those with confirmed or experienced symptoms of DPN, unlike other studies that included people with or without DPN.

Of concern is that the participants in the current study reported severe symptoms of DPN. Almost fifty-six percent (n = 67) of the participants had more than seven symptoms (a score of ≥ 7 indicates severe DPN when assessed by the MNSI). In addition, about one third of the sample had more than 10 symptoms (n = 34). Thus, in the current study, the ability to study DPN was possible with evidence indicating that more than half of the sample had severe DPN. Additionally, of interest is that even though the DPN measures of S-LANSS and the MNSI had low reliability estimates, they both correlated with pain appropriately such that higher DPN scores, measured with the S-LANSS and MNSI 1, were associated with more pain (r = .433, p < .001 and r = .402, p < .001, respectively).

Characteristics of the Environment

Social Support

The participants completed the Medical Outcome Study-Social Support Survey (MOS-SSS) to measure their perceived social support. The results showed that the sample had an adequate social support as the overall perceived social support index was 70.70 ± 27.28, with a range of 0-100 (higher scores indicate better social support). These data are comparable to the results found in the published literature. Sherbourne and Stewart (1991), had a sample of mostly
women (n = 2987), of whom 69% had chronic diseases (DM, hypertension, depression, and coronary heart diseases). They reported a total MOS-SSS score of 70.1 ± 24.2. Overall (except for informational support), this current study found higher perceived social support with regard to the four subscales. For instance, in tangible support our sample had a score of 73 ± 30.26 compared with 69.8 ± 28.5 reported by Sherbourne & Stewart (1991). This is expected since about 70% of the sample were married. For informational type support, our sample had a mean of 64.5 ± 31.82 while the original study had a mean of 69.6 ± 25.5. This indicated that patients in the current sample may have had either limited social network or less perceived benefit from their existing social network. Perhaps patients did not get the help needed to address some of their concern or received limited recommendations which may have contributed to their lower scores.

The reliability estimates of the MOS-SSS in the current study (.95) was consistent with that previously published (.97). In the current study, however, there was some concern about the understanding of certain questions. Patients constantly inquired about the difference in meaning between items 2 and 3. Item 2 reads, “How often someone gives you information to help you understand a situation?” Item 3 reads, “How often someone gives you good advice about a crisis”. Although the scale is properly translated and culturally adapted, previously, the two statements in Arabic can understandably be misinterpreted. Patients needed help understanding the differences between what constitutes a “situation” versus a “crisis”. There were also questions about items 16, “someone to have a good time with” and 18, “someone to do something enjoyable with.” To most patients, having a good time and doing something enjoyable meant the same thing. The investigator had to provide examples to explain the difference
between the two. Whether these questions asked by participants impacted the study findings is unknown, but are important to consider in future research with this population.

**Chronic Illness Resources**

The support that T2DM patients need to manage their symptoms, maintain their health, and prevent further complications from occurring expands beyond social support. They often need accurate medical information; assistance in maintaining a healthful lifestyle; and support and advocacy from family, friends, and the community at large. This was measured by the Chronic Illness Resources Survey (CIRS). Participants in this current study had a mean chronic illness resources score of $2.41 \pm 0.68$ (score range 1-5) with higher scores suggesting better resources. The current study results were compared to the published means of the CIRS (pre-intervention scores) in persons with T2DM (n = 279) aged 60 years old, of whom 93% were White and with an average comorbidity of 3 conditions (Glasgow et al., 2005). Our patients had a negligibly lower total CIRS scores, $2.41 \pm 0.68$ compared with $2.71 \pm 0.6$ of the Glasgow et al. (2005) sample. However, generally, the participants in both studies reported equal illness resources. The lowest mean for our population was the mean of organizational support, $1.5 \pm 0.76$ versus $1.71 \pm 0.8$. For our population of Saudis with T2DM, most of support in the items in this subscale had extremely limited availability. For instance, the community and organizations did not offer low-cost meetings that supported managing diabetes. Thus, the lower scores may be due to these factors. Also, the country has limited resources for public indoor exercise facilities (Bajamal et al., 2017).
Functional Status

Foot Self-Care

Patients’ level of functioning was represented by the frequency of performing foot self-care. Foot care was measured by the Summary of Diabetes Self-Care Activities (SDSCA) foot-care subscale. The sample had a mean of 4.74 ± 1.32. That is a frequency of performing foot care 67.71 ± 14.28% days/week. Meaning that patients performed foot self-care for the majority of the time/week which indicate a good practice. Other studies had reported lower values compared with this study. The developers of the SDSCA published a review of seven studies that used the scale between 1992 and 2000. The means of each subscale were computed across all studies. The sample was composed of adult individuals who had had DM for a duration of 6.3 to 13.0 years (Toobert et al., 2000). The percentages of days/week for foot care were also examined. For foot care practices, the published mean day/week was 47.1 ± 21.4%, which suggests poorer foot-care practices compared with this current study, which had a mean of 67.7%. The mean foot care subscale for participants in this study was also higher than that published for another Saudi population of 49.85 ± 33.85% (AlJohani et al., 2015). Thus, participants in this current study were performing foot care activities more frequently compared with other published studies. Our sample composed of only symptomatic DPN patients and we found association of DPN and foot care which suggested that more symptoms were associated with more foot care. It is important to note that most of our sample had positive foot care exams indicating neuropathy and this may explain the good foot self-care practices we found.

Additionally, considering the culture of Islam, our patients probably performed well in foot self-care partly because of the daily prayers. Muslims perform prayers five times day and part of getting ready to do so involves washing certain part of the body including face, lower
arms, and feet. Thus, it is most likely that they wash their feet more frequently than other populations. Yet, this frequency of feet washing might have impacted the skin condition of the feet and perhaps contributed to dryness since participants expressed that they do not apply moisturizer afterwards. The foot exams findings indicated that 72.2% had abnormal appearance of feet. Of which, 36.1% (n = 30) had dry, cracked and callused feet. This might have played a role in worsening foot ulcers. These issues will be further discussed as nursing implications.

Finally, the current results compared with those of the larger study of SDSCA across different languages and populations were similar, even though the Cronbach alpha of the foot-care subscale in our sample was low at .50, providing some support that the current study findings are valid.

**Health Perception and Quality-of-Life Indicators**

The SF-12v2 was used to measure the QoL indicators for this study. The participants had, expectedly, lower PCS values compared to MCS, which shows that the impact of DPN is greater on the physical health compared with the mental health (see Table 28).

We compared the MCS and PCS scores of the current study with another study of Saudi patients with T2DM (n = 216) who had diabetes for a mean of 8.6 years, and half were female and had a mean age of 50 years (Al-Shehri, Taha, Bahnassy, & Salah, 2008). They aimed to assess the effect of T2DM on HRQoL by comparing T2DM patients against another 216 healthy people from Saudi. They reported that the sample’s PCS mean score was 41.3 ± 8.9 compared to 47.5 ± 9.5 of the healthy control group. The patients’ MCS mean was 47.8 ± 9.1 compared with 51.5 ± 9.4 of the controls. Thus, the results of the AlShehri et al. (2008) sample is comparable to ours for these QoL scores. In addition, their sample had similar complications (72%), however unfortunately, DPN was not reported among them. This may suggest that this level of
impairment in the QoL among Saudis can be in part a result of having T2DM and its other long-term complications along with DPN. To better account for the effect of DPN a comparative design with T2DM patients without DPN is needed.

Table 28. Comparison of the SF-12v2 Scores Between this Study and Another Saudi Study

<table>
<thead>
<tr>
<th></th>
<th>Current Study</th>
<th>Al-Shehri et al. (2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS</td>
<td>40.21 (9.75)</td>
<td>41.3 (8.9)</td>
</tr>
<tr>
<td>MCS</td>
<td>47.29 (11.35)</td>
<td>47.5 (9.5)</td>
</tr>
</tbody>
</table>

As for the SF-12v2 reliability estimation, the measures’ two composite scores showed high stability as the Cronbach alpha for PCS and MCS was .81. It is important to note that through personal communication with the SF-12v2 scientist at Optum Corporation and also as validated in the *User’s manual for the SF-12v2 Health Survey*, assessing the internal consistency by the means of Cronbach alpha was not recommended nor endorsed. This is mainly because subscales have one or two items and, thus, this would reflect poor correlation between items. However, for the lack of a better indicator and considering many published peer-reviewed papers using this method of testing reliability, the authors of this report, based on a statistician’s recommendations, opted to use the internal consistency to determine the reliability of the SF-12v2. Additionally, a published study on a large group of diabetic individuals (n = 2,214) asserted the reliability of the SF-12v2 via assessing the Cronbach alpha. It reported sufficient internal consistency with MCS and PCS alphas of .83 and .85, respectively (Kathe, Hayes, Bhndari, & Payakachat, 2018). This finding is comparable to the finding of this reported study (.81 for both).
Discussion of Bivariate Association Among Variables

DPN Symptoms

The MNSI correlated negatively with MCS ($r = -.238$, $p = .009$), PCS ($r = -.303$, $p = .001$), and the general health perception domain ($r = -.322$, $p < .001$). These correlations, suggest a low-to-moderate negative association between DPN symptoms and the QoL domains in that as MNSI scores increase, patients’ health perceptions, physical and mental health would decrease, leading to poorer health perceptions, and worse physical and mental health. These correlations were reflected also in the multivariable models, except for MNSI and PCS. More is discussed about this in the primary aim section.

The DPN measures S-LANSS and MSNI were correlated ($r = .473$, $p < .001$), suggesting that the two measures were related so that if subjects scored high on one measure they also scored high on the other scale, adding more credibility to the DPN findings. Other studies have reported either the relationship of DPN using the S-LANSS or the relationship of DPN using the MNSI. Saudi studies most commonly used the MNSI (Algeffari, 2018; Halawa et al., 2010; Mojaddidi et al., 2011). Only one Arabic, non-Saudi study used the S-LANSS (Garoushi et al., 2017). However, no study has examined these two different measures at the same time which makes this study the first to combine these measures of DPN. It worth noting that S-LANSS although correlated significantly with the MNSI in the bivariate assessment which suggests both measures are measuring the concept of DPN, S-LANSS did not show significant association with other variables in the study such as QoL indicators, biologic, and individual factors.

Mental QoL

Social support correlated with mental QoL ($r = .414$, $p = .021$) so that more social support was associated with better mental health suggesting that with better social support
mental health improves (Zhong et al., 2016). Other Saudi investigators reported similarly that lack of social support was associated with worse depressive symptoms in middle aged Saudis (Albalawi, Faraj, Alanazi, & Albalawi, 2019). Also, the bivariate correlation of the current study found an association of mental QoL with comorbidities (FCI) which included obesity, arthritis, visual impairment, lower back pain, and peripheral vascular disease ($r = -.219$, $p = .016$). This indicated that more comorbidity was associated with poorer mental health. This was also found to be consistent with the multivariable model discussed next. Previous research has supported this finding in T2DM individuals living in Saudi (AlHayek, et al., 2014; Bahjiri, Jambi, Alraddadi, Ferns, & Tuomilehto, 2016; Wang et al., 2014). That evidence has indicated that diabetic patients were disproportionately at increased risk of certain mood disorders such as depression (Penckofer et al., 2017). Long-term complications, cardiovascular disease, hypertension, and increased hospitalization were some of the precipitating factors (Papanas & Ziegler, 2015).

**Physical QoL**

Physical QoL correlated, expectedly, negatively with age ($r = -.198$, $p = .032$), indicating that poorer physical health was associated with increasing age which would be consistent with the normal aging in the setting of T2DM (Papanas & Ziegler, 2015). A Saudi-based study, however, did not find the physical QoL to be associated with age (AlHayek et al., 2014). They assessed factors associated with QoL among people with T2DM ($n = 238$), aged 56.4 years, of which 63% were males. The SF-36 was used to assess physical and mental QoL among participants in that study. They concluded that gender, economic status, and DM complications are risk factors for poorer physical health.
Physical QoL also correlated with illness resources ($r = .217, p = .018$), suggesting that more illness resources were associated with better physical health. When patients receive more education and information about caring for their diabetes, their improved physical health reflected better disease control (i.e., better self-care, lower HbA1c, and less pain and fatigue). These current study results are supported in the literature in persons with T2DM (Glasgow et al., 2005; Zhong et al., 2016).

Physical QoL also correlated with social support ($r = -.188, p = .041$) in this current study. The results showed that more social support was associated with poorer physical health. Considering that these associations are not causational, it cannot be suggested that more social support causes poorer health. However, it could be that people with poorer physical health require more support from their social network. An alternative explanation is that people with poorer physical health are less engaged in social activities due to their poor health (Koetsenruijter et al., 2015).

The findings also showed that exercise correlated with physical QoL ($r = .287, p = .001$) suggesting that more exercise is associated with physical benefits. Several non-Saudi studies associated performing regular exercise with better physical health in the setting of diabetes and peripheral neuropathy (Kluding et al., 2014; Riandini et al., 2017). Physical and physiological benefits of exercise include enhancing insulin receptors, promoting weight loss and muscle tone, and mitigating insulin resistance. Significant improvements were found in general fatigue, physical fatigue, and peripheral blood flow with regular exercise (Kluding et al., 2014).
**Discussion of the Study Aims**

**Regression Analysis of Aim 1**

Aim 1 sought to explore the impact of DPN symptoms on the patient’s functional status (foot-care practices), general health perception, and the overall QoL (PCS and MCS scores). It was hypothesized that individuals with more DPN symptoms would have had poorer functional status (fewer foot care practices), a negative health perception, and lower physical and mental health. Most these associations were supported by the study findings. Each will now be addressed with the literature that supports or refutes these results.

**The Impact of DPN Symptoms on Foot Care**

The current study demonstrated that foot care was associated with neuropathy symptoms (S-LANSS), \( p = .05 \). This suggests that as the patients were exhibiting more neuropathy symptoms, it prompted them to perform more self-care behaviors. This seems to be both logical considering the nature of onset of complications of T2DM. It is not unusual that patients start committing themselves to better self-care when they experience the long-term, disease-associated complications (Koetsenruijter et al., 2015). There were no Saudi-based studies found that discussed the association of neuropathy symptoms and foot self-care which makes this study the first to do so. A study of the association of self-care behaviors and the presence of complications concluded that within the first year of T2DM diagnosis, those with diabetes related-complications performed foot self-care practices more frequently compared to with those without complications (\( p < .001 \)). Further, in the presence of complications T2DM patients perceived their condition to be unpredictable and has more consequences (van Puffelen et al., 2015). Additionally, evidence suggested that newly diagnosed patients who do not exhibit complications may perceive their condition differently from those with longer illness duration.
This optimistic perception about living with diabetes could be misleading on the ability to control their condition. It is also not conducive to self-care management given the low emotional impact they experienced and the limited consequences for daily life (Gherman et al., 2011).

The hypothesized relationship between DPN symptoms and foot self-care, however, presented findings that were the opposite of those we had planned. We hypothesized that patients with more symptoms would perform foot care less frequently due to symptoms. This hypothesis was based on the assumption that neuropathy symptoms affect the physical and emotional functions and, if compromised, this will also impact patients’ ability and willingness to care for themselves and manage their diabetes. Foot care in this assumption was considered a form of functioning and, as such, would be affected by the severity and the disability resulted from the symptoms. Individual factors such as fatigue, visual impairments, pain, mental and emotional decline in addition to physical disability would lead to decreased self-care activities in individuals with T2DM (Devarajooh & Chinna, 2017; Sina et al., 2018).

Although this association could be bi-directional the majority of evidence on the association of self-care and diabetes outcomes is often in the direction of self-care impacting the conditions. Evidence to support the impact of diabetes complication on self-care is scarce. A cross-sectional study explored the effect of sleep disturbance on DM patients’ ability to perform self-care management with a convenience sample of 64 patients aged 60 years, 49% of whom were male, 26.5% were White, and had a mean duration of DM of 11.2 years (Zhu et al., 2018). They measured sleep problems with both subjective (Pittsburgh Sleep Quality Index) and objective (ActiGraph) instruments. They concluded that sleep disturbance, diabetes distress, and daytime sleepiness were significant predictors of self-care. Zhu et al. (2017) study showed that
the frequency of self-care can be affected by factors related to the ability to function and problems with sleep could affect the level of functioning.

Another study of a predominantly Black (86.6%) diabetic female patients (76%), assessed the relationship between two other factors that involve self-care, pain and HbA1c levels. The study looked to see if the degree of pain resulted in higher HbA1c levels and if self-care mediated this association (Herbert et al., 2013). They concluded that moderate to severe pain was directly associated with the glycemic control (HbA1c). Although self-care did not significantly mediate the association between pain and HbA1c, those with pain were more likely to eat fat more frequently, exercise less, and have more depressive symptoms when compared to participants without pain (Herbert et al., 2013). Another study focused on barriers of self-care among diabetes patients and was conducted in Denmark (Sina, Graffy, & Simmons, 2018). They found that most patients reported the following barriers to self-care management: physical (comorbidity and treatment side effects) psychological (priorities, health beliefs, lack of time, and lack of motivation), system (lack of personal finance, accessibility to proper care, and lack of close proximity to resources), and psychosocial barriers (lack of support, pressure from others, and family demands) (Sina et al., 2018).

**The Impact of DPN Symptoms on Health Perception, Physical and Mental QoL**

The first aim of the study also addressed the association of neuropathy symptoms, health perception, and physical and mental QoL. We hypothesized a negative relationship between neuropathy symptoms, health perception and physical and mental QoL such that more neuropathy symptoms were associated with negative health perceptions and worse physical and mental QoL. Our findings supported this hypothesis. To our knowledge, this current study is the
first to address the health perception and QoL of T2DM patients with DPN. Other Saudi-based studies addressed QoL and health perception in T2DM only.

**Health perception.** A cross-sectional study is one of the few studies on health perception among the Saudis had a sample of persons with T2DM (n = 383) of which 48.8% were males and were aged 46 years old. About 43% of the sample reported concurrent comorbid conditions. Participants responded to the Illness Perception Questionnaire which had 84 items and addressed various aspects of living with diabetes which included questions on whether they think that their diabetes was temporary or permanent, was a serious condition, its consequences, symptoms control, and the role of treatment in curing the condition (AlGhamdi et al., 2018). The findings indicated that in the Saudi population, a level of acceptance and optimism was expressed by persons with T2DM. For instance, 65.3% believed that diabetes had a major impact on their lives. Eighty percent believed that there was “a lot to do to control symptoms.” On the positive outlook, 72% thought that they had the power to influence their condition. In contrast, in the current study, health perception was assessed using a single item that simply asked participants to rate their health from poor to excellent. This might have been a limitation. However, DPN was the focus of this study and was not in the other study. Thus, the conclusions made from both studies were different. In addition, the focus was more on the level of understanding the way patients feel about their disease and the outcomes of having a chronic condition. Meanwhile, this current study focused on how generally patients rate their health, including having pain, from a scale of poor-to-excellent. A simple question of rating health sufficed the purpose of understanding the overall health perception of current sample.

**Physical and mental QoL.** Literature on the impact of DPN on physical and mental health supported the current study findings. In the current study, DPN was predictive of the
individual’s health perception and QoL (PCS and MCS). The subjective assessment of DPN using the MNSI 1 was predictive of the physical QoL. Meanwhile, the objective assessment of DPN via the MNSI 2 was predictive of the mental QoL. The S-LANSS did not correlate with neither physical nor mental QoL. Other studies have reported similar findings, however none of them have explored these relationships in the Saudi population (Brod et al., 2015; Geelen et al., 2017; Kim et al., 2015; Singh-Franco & Jacobs, 2017; Ziegler et al., 2020). Thus, this is an important contribution of the current study.

Consistent with the current study, a study from Greece used the SF-12v2 and the MNSI on a comparatively smaller sample of T2DM patients (n = 64) and concluded that neuropathy, reduced activity, mental fatigue, and elevated glucose level were associated with poorer physical functioning (Lyrakos et al., 2013). The results of the current study demonstrated that both subjective (MNSI 1) and objective (MNSI 2) symptoms were associated with mental and physical QoL and, therefore, the overall QoL. In addition, these researchers reported that neuropathy symptoms were not significantly associated with mental HRQoL as measured by the MCS of the SF-12v2. But they did find that depressive symptoms (Depression Anxiety Stress Scale), coronary artery disease, and treatment for neuropathy were associated with worse mental health. In addition, their sample had significantly lower HRQoL scores compared to the current study: PCS and MCS scores were 34.4 ± 11.5 and 41 ± 13.9 compared to 40.21 ± 9.75 and 47.29 ± 11.35 in our study, respectively. In their study, Greek persons had overall significantly lower physical and mental health compared to the Saudi sample of DPN patients of this study. Although HbA1c in the Greek sample was lower than our sample (7.1 0.8% vs. 8.8%), both samples included persons that had lived with diabetes for a long time. However, the Greek sample had higher BMI (31.8 ± 5.3 vs. 30.81), were older (66.6 ± 9.3 vs. 54.0 ± 9.4 years), and
had a more comorbidities. Interestingly, our Saudi patients had much more severe DPN symptoms compared with the Greek patients. The mean MNSI (questionnaire) for that Greek sample was 2.4 ± 1.4 versus 7.6 ± 2.8 of the current study sample. Noting that although MNSI has a physical exam part, the Greek study did not report using it for DPN assessment. Our study had the advantage of assessing the symptoms not only subjectively, but objectively as well (monofilament, tuning fork, and reflex hammer) using the MNSI’s two parts.

The current study findings were also consistent with a recent systematic review (n = 66 studies) that summarized the accumulated evidence on the influence of DPN on QoL in terms of the direct physical effect of pain, economic factors, sleep, mental health, and treatment regimens. In that review, DPN represented 71% (n = 47) of types of neuropathies (Girach et al., 2019). In this review, QoL was measured by different questionnaires. The most common were the SF-36 and SF-12. A notable study in this review was a cross-sectional study that included 90% with T2DM adults (n = 124 total sample) and examined patient’s perspectives of the impact of DPN on QoL (Singh-Franco & Jacobs, 2017). The sample was 95% female, 53% Black, aged 57 years and 49% who had a diagnosis of DPN. The authors adapted questions from the Painful Diabetic Neuropathy Assessment tool. A total of thirty-one items were used to assess the impact of DPN. QoL as it relates to the ability to perform daily activities, pain severity, and interference with sleep was assessed with 13 items. They reported that those with DPN had lower QoL scores with greater impact on daily activities, higher levels of pain, and more sleep interference compared with non-DPN patients (Singh-Franco & Jacobs, 2017). In the current study, we found that Saudis who have T2DM and DPN symptoms also had poor overall physical QoL and also poorer domains: poor vitality, limitations with physical role, and physical functioning. For instance, patients reported decreased ability to perform daily tasks, such as performing daily chores,
climbing a flight of stairs, and limited ability to perform daily prayers (repetitive moves that require physical mobility). However, the effect of symptoms on sleep was not examined in our study due to overburdening the participants, but is a factor that would be worthy of study in future work for the Saudi population. This is particularly true in light of research that indicates that poor sleep has negative consequences on diabetes and contributes to greater complications (Zhu et al., 2019).

Additionally, an interventional study conducted with a sample of 72 non-Saudi patients with DPN who were aged 65 years. Thirty-nine percent were males and 84% had T2DM, with a mean duration of diabetes of 12.7 years, and an average HbA1c of 7.8% (Agathos et al., 2018). In that study, patients received 600 mg/day of alpha lipoic acid for 40 days for treatment of DPN which was assessed using the Neuropathy Symptoms Score, Subjective Peripheral Neuropathy Screening Questionnaire, and the DN4. QoL was as assessed with a number of tools including the Brief Pain Inventory, Neuropathic Pain Symptom Inventory, Sheehan Disability Scale, and the Patient Global Impression Improvement. Patients reported a reduction in pain severity, interference, work and social life disability, and family life disability scores following supplementation (Agathos et al., 2018). This interventional study supported our finding that QoL is associated with DPN and also that improvement in neuropathy symptoms was associated with improvement in QoL.

Another important supporting piece of evidence of the association of DPN and QoL came from a comparative-design study conducted in Croatia that examined T2DM patients (n = 160), aged 62.3 years, of whom 48% were females, and with a duration of diabetes of 17.5 years. DPN patients were divided into two cohorts based on the presence or absence of pain: painful and non-painful DPN (Dermanovic Doborota et al., 2014). Current pain as well as pain during the
previous month was the inclusion criteria. The study used the S-LANSS, Visual Analogue Scale to measure DPN and the SF-36 to assess QoL. The researchers concluded that painful DPN was associated with lower physical and mental QoL. The S-LANSS, as per the developers, was meant to determine whether or not the pain was neuropathic of origin (Bennett, 2001). The type of questions describes the characteristics of pain resulting from impairments in the function of nerve thus using it in this manner seemed noteworthy. Accordingly, the score of 12 or less suggest that the experienced pain is not neuropathic in nature. Interestingly, Dermanovic Doborota et al. (2014) used the S-LANSS to ascertain pain so that the cutoff score of 12 was used to include patients in the painful group. Their study is important since they used other multiple objective measures to assess DPN which included neurological assessments (muscle strength, proprioception reflexes, monofilament, and vibration).

Furthermore, Dermanovic Doborota et al. (2013) found that the physical QoL of men was higher than women. This is similar to what this study is concluding. In our study, women had lower physical QoL scores compared to men. This can be possibly attributed to the level of education, income, and marital status amongst other factors. In our sample, men had higher education levels than women. The number of persons with ≥ 12 years of education was 35 for men versus 10 for women. The number of women who have less than 6 years of education was 33 compared to 13 for men. Thus, the number of women with fewer years of education was higher compared to men. Furthermore, the chi-square test showed a significant relationship between gender and the level of education, \( p < .001 \). This difference in the level of education could have caused men to have greater awareness and, thus, better self-care management behaviors. Another explanation is related to the physical attributes of men and women. As women are the primary child-bearing party, several physical consequences render them more
vulnerable to lower back pain and impaired mobility (Kirchengast & Haslinger, 2008). Additionally, women showed greater attitude towards care-giving compared to men indicating that women performed more care giving than men (Muhwezi, Okello, & Turiho, 2010)

**Regression Analysis of Aim 2**

This aim sought to examine the complex associations delineated in the HRQoL model (Ferrans et al., 2005). Within this theoretical relationship, the association of the biologic factors (HbA1c, comorbidity, hypertension, level of physical activity, duration of DM, and dyslipidemia) and individual factors (age and gender) with DPN symptoms and QoL was examined. This current study hypothesized that poor glycemic control, hypertension, multiple comorbidity, increased age, female gender, longer duration of diabetes, and less physical activity were associated with more DPN symptoms. The analysis of this aim supported most of these associations.

**The Association of DPN Symptoms and Key Variables**

**Glycemic control.** In this study, poor HbA1c control was associated with more neuropathy symptoms. A similar study among the Middle Easterners with diabetes in Jordan found biologic variables (including glucose levels) associated with DPN. However, HbA1c was not one of them (Khawaja et al., 2018). Others (including Saudi-based) concluded that HbA1c levels were associated with more neuropathy symptoms (Algeffari, 2018; AlQuliti, 2015; Assuncao et al., 2020; Hussain et al., 2014; Mojaddidi et al., 2011). As mentioned in Chapter 2, one Saudi-based study concluded that HbA1c level was not associated with neuropathy (Wang et al., 2014). One possible reason for lack of significance is related to the presence of anemia among that sample as discussed previously. Algeffari (2018) assessed a sample of T2DM Saudi patients (n = 233) who were aged 56.9 years and 63% were females. They compared patients
with DPN with non-DPN patients. DPN was measured by the MNSI questionnaire and physical exam. Glycemic control was measured by the HbA1c. The odds of having DPN was 3 times higher for those with HbA1c > 9% (Algeffari, 2018). In the Algeffari (2018) study, 48% of the sample had an HbA1c of > 9% and 49.5% had a level HbA1c of 7-9%. In the current study, the mean HbA1c was 8.89%. Thus, generally, both Saudi studies samples had a poor glycemic control. Additionally, both samples had dyslipidemia and hypertension. However, our sample had other comorbidities that Algeffari (2018) did not discuss. Another factor that might have impacted the association of the level of HbA1c might be the type of DM treatment. In the current sample, 41.4% were treated with oral hypoglycemic agents and 55.2% received injections (insulin and other agents). In the other Saudi study, most patients (81.5%) received oral agent alone to control their condition. This probably explains the higher levels of HbA1c among their sample, since insulin is superior to oral agents in lowering glucose levels (ADA, 2019). Last, there were more people who had had T2DM for > 5 years in Algeffari’s study (2018) than our sample (27.2% versus 12.9%). Having more people with oral agents alone and with longer DM duration may explain the poor glycemic control in that study.

**Duration of T2DM.** Contrary to most previous findings (Assuncao et al., 2020; Halawa et al., 2010; Bansal et al., 2014; Hussain et al., 2014; Khawaja et al., 2018; Lyrakos et al., 2013; Wang et al., 2014), our results indicated no association of longer duration of diabetes and neuropathy symptoms. This lack of association was possibly related to the measurement of study variables. In the current study, the duration of DM was a categorical variable (< 5 years, 5-10 years, 11-15 years, & >15 years). However, it had also been measured categorically in studies that had the same conclusion (Assuncao et al., 2020; Wang et al., 2014). It was also a categorical variable in studies that found no association (Khawaja et al., 2018; Wang et al., 2014). A Saudi-
based study was conducted with a large sample size (n=1,039) of which 94% were T2DM patients with a mean age of 51 years. Males were 53% of the sample, 60% were Middle Easterner, 22% were Asians, and 8% were Black. The duration of DM was both continuous and categorical scales. They concluded that there was an association of longer duration of DM and worsening of DPN symptoms (Halawa et al., 2010).

It is interesting that in the univariable model of the current study the duration of DM was associated with neuropathy symptoms using the MSNI 1 (p = .042). Yet, the multivariable model showed no significance. Thus the lack of association in our study may be due to the association among the other variables in the multivariable model. A study conducted in Bahrain (a neighboring country) found the duration of DM to be associated with increased risk of DPN (AlMahroos & AlRumi, 2007). DPN was assessed using the modified Neuropathy Symptom Score and the Neuropathy Disability Score. The foot examination included sensation of pain, touch, cold, reflexes, and vibration perception. The sample included a large sample (n = 1477) of which 93% were T2DM. Other characteristics include 57% female, mean age of 57.3 years and a mean duration of DM of 9.5 years. AlMahroos and AlRumi (2007) had several categorical intervals for the duration of DM and a large sample size of each interval category compared to the current sample. For instance, they had more patients (n = 34 and 53, respectively) in the categories (1-5 years) and (16-20 years). The odds of having DPN increased with the increased length of having DM >5 years (p<.001). Thus perhaps with a larger sample size in each DM duration category we could have detected an association in our multivariable model.

Hypertension. We found no association between hypertension and DPN symptoms in the current study. Evidence was inconclusive as several cross-sectional studies, including Saudi-based studies, found no association between DPN and hypertension (Algeffari, 2018; Mojaddidi
et al., 2011). Others (Wang et al., 2014; Yang et al., 2015) concluded an association of DPN with hypertension. A retrospective analysis of a large population-based (n = 37,375) study of persons with T2DM found an association of DPN and hypertension (Yang et al., 2015). However, their sample was older persons (60 years) who were Taiwanese, consumed more alcohol, and had more frequent and serious comorbidities compared to our sample. For example, 7.9% of their patients had coronary artery disease, 2.9% had congestive heart failure, 4.1% had stroke, 2% with cancer, and 9% with chronic hepatitis. In addition, hypertension was measured by assessing the systolic and diastolic blood pressure providing increased accuracy. In our study, hypertension was reported as present or absent. Due to feasibility factors we did not assess the blood pressure which was not documented in the medical records. For all of these reasons, perhaps the association that they reported was more accurate.

Among the Saudis, Wang and colleagues (2014) also concluded that hypertension significantly increased DPN risk 1.79 times compared with normotensive patients, $p = .027$. This Saudi study used foot examination tests like vibration perception, light touch perception, monofilament, and pinprick sensation to assess DPN, similar to the current study. Hypertension was also measured dichotomously. Unlike our study, however, Wang et al. (2014) had two groups: DPN and non-DPN patients. A common theme in both studies that concluded association is that they had included DPN and non-DPN cases for comparison. Due to time limitations, this was not possible for the current study. Interestingly, however, Algeffari (2018) also conducted a study with two groups (DPN and non-DPN) of Saudi T2DM patients (n = 233). They concluded that hypertension did not increase the odds of DPN, $p = .763$. In their study, however, the number of hypertensive patients was low for non-DPN (n = 3) and for DPN (n = 16) groups. Perhaps the small number of hypertension cases obscured its association with DPN.
**Dyslipidemia.** Consistent with some of the previous findings is our finding of the association between DPN symptoms and dyslipidemia (Perez-Matos, Morales-Alvarez, Mendivil, 2017; Rumora et al., 2017). Our data did not suggest that the presence of dyslipidemia was linked to worse neuropathy symptoms. Other studies that measured dyslipidemia by the laboratory values of lipids profiles found an association of DPN and dyslipidemia (Cho et al., 2014; Jaiswal et al., 2017) and also some that included the variable indicating the presence or absence of dyslipidemia (Jaiswal et al., 2017). In our study, we used a dichotomous variable, namely dyslipidemia, based on the taking of lipid lowering medication instead of using the individual components of the lipid profile (HDL, LDL, cholesterol, and triglycerides). This decision was based on previous literature where the association of dyslipidemia and DPN has not been consistent, as studies found one or more of the lipid components (HDL, LDL, triglycerides) associated with DPN but not others. There were no studies that concluded that all the lipid types were associated or not associated with DPN. Although the current study found an association where those who receive treatment had lower foot exam scores and, thus, fewer neuropathy symptoms; many providers prescribe lipid-lowering agents, especially statins, for diabetic patients irrespective of dyslipidemia.

**Physical activity.** Our findings indicated that some exercising (not regularly) was associated with fewer DPN symptoms. Consistent with other research examining cardiovascular risk factors, the association between DPN symptoms and physical activity has been inconclusive. Saudi studies did not include physical activity as a factor when studying DPN. Some previous studies found DPN symptoms to be associated with the level of physical activity. One US based study concluded that performing aerobic exercise for 16 weeks was associated with decreased pain perception among T2DM patients with DPN (Yoo et al., 2015). The researchers conducted a
pilot interventional study where 14 middle aged, sedentary participants underwent aerobic exercise regimen. Patients performed exercise on cycle ergometers, treadmills and elliptical trainers for 50 minutes three time a week for 16 weeks. Also, DPN and pain were measured using the Brief Pain Inventory Short Form for Diabetic Peripheral Neuropathy. They developed questionnaires for the frequency of symptoms, impact of DPN on sleep, general activity, mood, and walking ability. Because of the observational measure of physical activity in that study, they were able to detect the true impact of exercise on DPN.

Another three-arm interventional study came to a similar conclusion of the association of DPN and physical activity. Different types of physical activity training levels were examined for relief of DPN symptoms. In the study, 60 patients with T2DM and DPN, who were aged 54 years old and had an average 11 years with their disease, were assigned randomly to three types of treatment: ball training (using a training ball) (n = 20), Frenkele training (slow repetitious movements to improve coordination) (n = 20), and a control group (no exercise) (n = 20). Patients in the two treatment arms showed improved posture, balance, and reduced instability (all of which is a result of DPN) compared to the no-exercise control group which these authors attributed due to an improvement in DPN (Rojhani-Shirazi, Barzintaj, Salimfard, 2017).

Of the cross-sectional studies, Khawaja et al. (2018) had a sample of 1,003 DPN Middle Eastern Jordanians. Physical activity was an ordinal variable (similar to this study) with regular, not-regular, and no-exercise groups. Khawaja and colleagues’ findings were similar to our findings that performing “exercise irregularly (30 minutes for 1-3 days/week)” was associated with lower likelihood of developing neuropathy symptoms compared to those who were inactive. In that same study, performing “regular activity” was not statistically significantly associated with less neuropathy, \( p = .239 \). In our study, the significance of the slope of the association of
neuropathy and “regular exercise” was also trending towards significance, $p = .089$. Also in our sample, the association of neuropathy and performing exercise “not regularly” was significant, $p = .023$. Thus, similar to Khawaja and colleagues’ study, we found that performing irregular exercise and not regular exercise was associated with less DPN. It seems like the performance of some physical activity may curb the progress of DPN.

This finding in which regular exercise was not significantly associated with DPN is interesting as there are many confounders that may be attributable. First, our sample was smaller in the regular exercise group ($n = 22$) compared to the irregular exercise group ($n = 32$). Although the definition of physical activity was provided to our participants (30 minutes of moderate physical activity daily), there are variations on what constitutes moderate physical activity. For instance, when answering the questions, some individuals may have considered strolling around the house (indoors as well as outdoors) a physical exercise while others considered weight lifting at the gym. Therefore, to accurately measure physical activity using reliable questionnaires and objective measures in the future will ensure better conclusions.

**Age.** In addition to these findings about exercise, our results indicated that age was not associated with neuropathy ($p = .069$). The results showed trending toward significance. As the patients aged, they experienced worse neuropathy symptoms. Evidence around the world on the association of age with neuropathy has been consistently significant (Algeffari, 2018; AlQuliti, 2015; Assuncao et al., 2020; Bansal et al., 2014; D’Souza et al., 2015; Halawa et al., 2010; Khawaja et al., 2018; Mojaddidi et al., 2011; Wang et al., 2014). Some studies suggested that for each decade increase in age, the nerve fiber condition worsens leading up to more neuropathy symptoms (Papanas & Ziegler, 2015). Although in our cross-sectional study we did not meaningfully quantify the impact of age on neuropathy, our findings were trending to indicate
that as patients advance in age they experience worse symptoms. Quantifying the impact of age on DPN can possibly be attained by assessing the age of the person at which symptoms started and possibly compare it to the severity of symptoms. Other advanced quantifying endeavors requires physiologic testing which are not feasible in the interim.

**Gender.** Unlike age, the relationship of gender and neuropathy has not been as consistent. Most evidence suggested either no association (Algeffari, 2018; Bansal et al., 2014; Khawaja et al., 2018; Wang et al., 2014) or that males had worse neuropathy symptoms compared to females (D'Souze et al., 2015; Gogia & Rao, 2017; Halawa et al., 2010). However, a study from Korea concluded that women had higher odds of developing neuropathy compared with men (Won et al., 2012). Yet a recent study from Portugal among a sample of persons with T2DM failed to find an association of neuropathy and gender (Assuncao et al., 2020). Evidence from Saudi was mixed with both an association (Halawa et al., 2010; Mojaddidi et al., 2011) and the lack thereof (Algeffari, 2018; Wang et al., 2014).

In line with some findings, our data indicated that females had lower neuropathy scores compared with males, suggesting that males have a higher tendency to have worse symptoms. However, we theorized that females would have worse neuropathy symptoms compared to males. This assumption was based on the previous studies where it was reported that females had worse symptoms compared with males (Abbott, Malik, van Ross, & Bolton, 2011; Jambart et al., 2011; Won et al., 2012) including a Saudi study (Halawa et al., 2010). This was also supported by some evidence that females have greater pain sensitivity compared to males (Fillingim, King, Ribeiro-Dasilva, Rahim-William, & Riley, 2009).

Our findings, however, only suggested an association of gender and DPN. Yet, it does not indicate that one gender develops the symptoms earlier than the other. Studies have not been
focused on the onset of DPN symptoms making it challenging to study gender differences. Nevertheless, a Saudi study also used the MNSI’s two parts, Diabetic Neuropathy Index, and Diabetic Neuropathy Score to measure the prevalence of DPN symptoms (Mojaddidi et al., 2011). They found that females had higher DPN scores compared with males. Females had a mean of 2.88±4.18 higher than the males 1.77±4.30 (though not statistically significant). In addition, electrophysiological tests were performed by blinded neurologists. The sample included 263 persons with diabetes of which 85% had T2DM. The mean duration of DM was 13.89 ± 8.7 years. The mean age was 51.8 years. That study had higher HbA1c levels compared to ours (9.32% vs. 8.89%), more hypertensive patients (57.8% vs. 51.8%), relatively younger people (51.8 years vs. 54.6 years), and a higher BMI (33.4 vs. 30.8).

Some evidence exists suggesting that the differences in DPN severity between males and females can be attributed to the differences in height since height has also been independently linked to worse neuropathy. Height was implicated for the length-dependent pattern of neuropathy as a measure of nerve fiber length (Hébert et al., 2017). In a population study from Mauritius it was found that each 5 centimeters increase in height was associated with 1.36 times higher risk of DPN ($p < .001$). This study was run between 1987 to 1992. Vibration perception threshold was used to determine the presence of DPN. The sample included 1178 participants, of which n=847 had T2DM and 54% were males. The prevalence of DPN among the sample was 8.3%. DPN and non-DPN patients were compared. Other sample characteristics include a mean height of 157.5 cm, average duration of DM of 5 years, and BMI of 26 (Shaw et al., 1998).

By contrast, an US-based study concluded no significant association of height and DPN (Franklin, Shetterly, Cohen, Baxter, & Hamman, 1998). Franklin and colleagues conducted a comparative design study as well with DPN (n = 77) and non-DPN individuals (n = 277). Sample
characteristics included mean age of 60.1 years, 45.2% male, 62% Hispanic, and an average height of 162.4 cm. DPN was also confirmed by history and physical examination. Among the patients in our study, gender-based differences were notable. Males had statistically significantly higher foot exam scores MNSI 2 (4.0 vs. 3.0, \( p = .048 \)) compared to females, were taller (168.5 cm vs. 157.2 cm, \( p = .032 \)), and weighed more (87.5 kg vs. 78.4 kg, \( p < .001 \)). Interestingly, the BMI was not significantly different between males and females, \( p = .252 \).

DPN is a complex human disease and has a magnitude of environmental factors that render some patients susceptible but not others. There is also evidence that implicates genetic risk factors independently, as well as the interactions between the biologic, environmental, and genetic factors. The different genetic compositions of men and women and also differences between races, ethnicities, and nationalities may play a role in differing conclusions (Rich, 2006). A team of genetics researchers in the UK conducted a population-based Genome-Wide Association Study (GWAS) by analyzing data from previous projects (Meng et al., 2015). The sample was divided into neuropathic and a control group. The researchers compared the means of age and BMI between the cases and the controls. Gender differences were evaluated using chi-square. They excluded ethnically outlying, genetically related, and T1DM individuals. The total analysis included \( n = 2491 \) males and \( n = 1729 \) females. The study found that the narrow-sense heritability of neuropathic pain was 30% among males and 14.7% among females. Further, the study found genetic variations in chromosomes 1 and 8 of the DPN group. Narrow-sense heritability is the measurement of the amount of variation among individuals that is influenced by genetic differences which are passed from parents to descendants. The findings suggest that there is gender-specific influence on DPN in that males had higher heritability than females.
(Meng et al., 2015). They also concluded that gender-specific differences in DPN are complex and might be influenced by the parent of origin, hormones, and chromosome.

**Conclusion of Discussion of Aims**

The findings of this study showed mild QoL impairment in a sample of T2DM Saudi patients due to the presence of DPN symptoms. Physical and mental QoL were both affected by neuropathy symptoms. Interestingly, patients had poorer physical health compared to mental health. Neuropathy symptoms were associated with glycemic control, gender, comorbidity, and exercise. In conclusion, our study provided additional evidence for the association of neuropathy and QoL which has not been addressed in previous Saudi studies. The findings of this study demonstrate the importance of neuropathy screening; above all, it aimed at increasing the awareness of the impact of neuropathy on QoL among Saudis. This study is the first to address the problem of DPN, the common and debilitating chronic complications, and its impact on the QoL among the population of Saudi.

**Study Strengths and Limitations**

**Study Strengths**

The findings of this study are significant as they highlighted the impact of DPN on physical and mental QoL and on the overall QoL for persons with T2DM living in Saudi Arabia. In addition, this study found that DPN symptoms impact the QoL of domains of physical and mental QoL the most. However, the traditional individual and environmental factors such as increased age, comorbidities, and social functions did impact the DPN symptoms. Thus, it is likely that a more sophisticated level of modeling the data with the use of mediation, moderation or structural equation models may allow these relationships to be better understood. Although the
multivariable modeling controls for the covariates, the impact of these various relationships may become more clear with different statistical approaches (Hulley et al, 2013).

Further, the strength of this cross-sectional study comes from the ability to collect data on all of the hypothesized variables at one time, and this has ensured that there were minimal missing data that would have been due to attrition. The amount of missing data was limited to 1.5-5%, which was ensured by reviewing the survey packets upon receiving them.

Although a stronger design would have been to include a control group of persons of the same age and comorbid conditions, such factors as time and cost to the investigator were not possible. This may have contributed to the lack of significance in some of the findings (Hulley et al, 2013). For instance, in our sample we found duration of diabetes, hypertension, and regular exercise were not associated with neuropathy. These findings are contrary to many correlational and interventional studies that used a comparative healthy group which may suggest the benefit of such design. Since a few Saudi-based studies with T2DM also found impairment in QoL, comparing those with DPN with T2DM patients and without DPN would have increased the validity of our findings.

Since the data were collected by a single investigator, the protocol was consistently followed. Another strength of this study was that it ascertained DPN using detailed objective assessment of foot examination. The objective assessment yielded significant results which are more reliable compared to the self-report measures. The objective measure (MNSI 2) correlated to physical QoL in a sample of individuals with T2DM in Saudi which make this study the one and only to do so.

The most important strength of this reported study was several fold. It was the first study in the Loyola University Marcella Niehoff School of Nursing to have collected data onsite in
Saudi Arabia. This was an opportunity to set the foundation for future research to be conducted in a country outside the United States that has diabetes as a major health issue. This is important as nursing broadens the multicultural understanding of concepts as QoL. The opportunity to work with the Loyola IRB as well as the Ministry of Health in Saudi Arabia was a factor that needed consideration when working abroad. The investigator was able to navigate through the process of obtaining approval from the centralized system of MoH which provided an additional learning experience. Then, two other IRB applications were submitted to the regional Directorate of Health and the hospital with which the diabetes center is affiliated. After obtaining those approvals, the application to the Loyola University Health Science’s IRB was submitted. Considering the nature of this research in terms of human subject protections our study was exempt from the review in Loyola University as it carried minimal risk to humans. This strength of the study will be further discussed in the nursing implication on research.

In addition, the learning about an international group of persons who are most affected by T2DM is another major contribution of this study, since the practice of nursing has become immensely influenced by the cultural context. This study provided a gateway into understanding the impact of neuropathy on an ethnic group. There are many cultural variations that direct the Saudis perception and practices of self-care management (Albarqawi, Snethen, AlGanns, & Kelber, 2017). It is common that some individuals in Saudi self-treat and utilize unlicensed, non-medical practitioners for various ailments (ElRefaei, Abduljawad, & Alghamdi, 2014) which might be similar to some understudied groups living in the US. Further, although population census in Saudi does not report statistics on the racial/ethnic make-up of the population, this study collected such data. This element further strengthened this study’s impact. Addressing such a high prevalent health issue by a student at Loyola University School of Nursing would
contributed to cross-cultural research in the U.S. Since Loyola University is in the forefront of social justice, equality and empowerment, this work is a proof of the potentials to work with immigrants and marginalized minorities in the U.S.

Finally, in terms of the measurements, the biologic variables like HbA1c were reliable because they were obtained from a certified and dependable laboratory of the Prince Abdul Aziz Bin Majid Diabetes Center. This asserted the accuracy of the data. Also, the use of reliable measures in this study (SF-12v2, CIRS, and MOS-SSS) would facilitate future comparison efforts of our data against other populations.

**Study Limitations**

The limitations of this study should also be addressed. As the sampling approach was non-probability convenience sampling, this could have led to selection bias. This type of bias arises because only patients experiencing neuropathy symptoms volunteered and participated in the study. However, this study examined an important health problem by examining the association of neuropathy and QoL. Also, the predictive ability of this cross-sectional observational study, unfortunately is limited as such affirmation requires a comparative, longitudinal or experimental design.

This study was powered to achieve the aims of this study, however, by increasing the sample size by setting the parameters for the power to be increased, this may have been better as some variables bordered on approaching statistical significance. The statistical power depends on other factors which are the significance level, type II errors, effects size, and number of independent variables. Additionally, increasing our sample size would have improved the generalizability of the findings as it would include a wider range of the Saudi population.
Further, a concern of the investigators was that the sample represented a large understudied group of individuals who were of the lower income which represented an important factor most likely contributing to the health problems in Saudi (Global Burden of Disease (GBD) 2017 Saudi Arabia Collaborators, 2020; Robert et al., 2017). It was noted that about one-half of the sample were poor and some patients expressed lack of access to fresh produce as a hindrance to improving their diet. Participants living in rural areas are at particular risk of limited access to resources and healthcare services.

Further, a limitation of this study was the exclusion of non-Arabic speaking permanent residents and immigrants living in Saudi. Although the sample included (n = 12, 10%) non-Saudi patients, they spoke and read Arabic fluently. Others were not able to participate due to language barriers. This had further limited the generalizability of the findings. Also, this study might have a narrow operationalization of functional status when measured by the frequency of foot self-care. However, it was important for this study to examine the association of foot self-care and DPN considering the limited research globally and in Saudi.

Finally, a limitation of this study was the recruitment of participants from one clinic versus multiple sites. The sample perhaps would be enriched by participants from a variety of access to healthcare resources.

**Instruments reliability.** In reviewing the tools, the reading levels of the tools ranged from 5th to 6th grade. These readability estimates, however, were calculated for the English versions of the measures. Thus with translations and adaptations of the measures, they may not be 5th and 6th grade level in the Arabic versions. In fact, at the onset of the study it became evident that it was necessary to have each participant read the questions to the investigator to determine their ability to read, and this became an enrollment criteria used for participation. In
addition, as evidenced with some of the reliability estimates, there is room for improvement. It was expected that such variation in participants’ educational level would have impacted their responses to the questions. It is interesting, however, that for instance, the SF-12v2, the MOS-SSS, and the CIRS although were verbose and frequent questions were raised about the meaning of some questions, this did not seem to have affected the reliability of those measures. The SF-12v2, the MOS-SSS, and the CIRS all had acceptable internal consistency of .81, .95, and .76, respectively. A concerning question on the SF-12v2 which reads, “Does your health limit you in…moderate activities such as moving a table, pushing a vacuum, bowling, or playing golf?” A particular patient raised worries of the way participants may have interpreted the questions. This is because of their understanding of the answers presented; yes, limited a lot, yes, limited a little, and no, not limited at all. This participant, although had high school level of education, read the answers in a way that made them miss the double negative of no, not limited at all. Thereafter, this was the criterion question with which participants were asked to read and respond to in order to be enrolled in the study.

Meanwhile, the questions on the DPN measures, the MNSI and the S-LANSS were generally easy to understand. Participants did not have many questions about them, yet there was poor internal consistency for these measures. This poor reliability might be related to the nature of the tools as both have dichotomous questions and are composed of multiple characteristics of DPN and thus items were not related (Waltz et al., 2017). Interestingly the MNSI has mixed reliability estimates in the literature. Overall, it had mixed reports of psychometric assessment in the English version. However, in other languages like the Portuguese it had better estimates (Barbosa, Saavedra, Severo, Maier, & Carvalho, 2017). The Arabic version of the MNSI had an acceptable interclass correlation coefficient of .87 (Mohammed et
al., 2019), which is a better indicator of internal consistency compared to Cronbach alpha. However, limited resources made providing the test twice to the participants not feasible.

Additionally, studies on the MNSI used other estimates for the accuracy and precisions considering the diagnostic usage of the measure. For instance, sensitivity, specificity, negative and positive predictive values are methods commonly used in dichotomously scored items (Waltz et al., 2017). However, due to limited resources, lack of objective measures to compare the findings these tests were not performed. Further, interestingly, the MNSI had mixed evidence with some studies reporting low sensitivity (38 -72%) and specificity (79-99%) depending on the cutoff scores used (Moghtaderi, Bakhshipour, & Rashidi, 2006; Oliveira et al., 2016). This poor sensitivity and specificity is said to be due to a high published cut-off point of > 7.0. Also, notable is the difference between the sensitivity and specificity discrimination of the two parts, questionnaire versus examination. As the examination has higher values that suggest better and accurate diagnosis. Herman et al. (2012) recommended that this cut-off point be reduced to >4.0 for better detecting DPN. Yet, the MNSI is the most widely used measure of DPN, including among the Saudis. Thus we opted to use it for this current study and it produced results consistent with other measures and with the literature from different populations.

Another limitation that has to be acknowledged is that self-report measures were used to collect the data. Patients’ responses might have been influenced by the individual, cultural, and emotional status of the person completing the surveys. Although social desirability may not fully apply to this type of survey, as there were no personal or sensitive questions involved, there is the possibility that patients may not have accurately reported their symptoms of the related impact. Of concern, however, was perhaps the lack of privacy for the participants which may have impacted the ability of the participants to be able to concentrate or feel free to ask questions
due to others in the environment. As will be discussed next, patients are often accompanied by their spouses and adult children which may also impact on the responses that they provide.

**Nursing Implications**

**Nursing and Research in Saudi Arabia**

There are a few reasons that this research study on persons with DPN is directly impacting the discipline of nursing and other healthcare providers equally. This study is one of the few nurse-led accomplishments among the Saudi community. The unique aspect and the focus on the patients’ experience with living with chronic conditions in general and diabetes-related complications in specific has not been a goal for nurses in Saudi. The hope is that this study inspires other nurses and provides them with future opportunity to take part in research designing, data collection, and analysis. The lead investigator of this endeavor was a female which shows that gender was not a hindrance to perform research among Saudis. The sample included both males and females equally and interaction with both has been equally positive. The gender of the investigator has not shown to affect the way participants perceived them neither on their openness to get foot exams performed.

A unique perspective of nursing profession is the interest in grounding phenomena on human behavior and psychological and behavioral theories. As Saudi nurses are venturing in the world of knowledge generation and dissemination, the hope is that we can develop multi-professional team to provide a wider cast at studying the different health phenomena that are unique to the Saudi culture. Since there are not many nurse researchers this study showed that Saudi nurses can be on the forefront of conceptualizing, designing, and articulating a research study.
Diabetes Education

Saudi nurse diabetic educators are actively engaged in the plan of care. Typically, patients meet the diabetes educator when they are newly diagnosed, prescribed diabetes controlling injection, or if they have persistent poor glycemic control (Alshareef et al., 2018). Patients meet the educator monthly, quarterly, or more frequently depending on their educational needs. The diabetic educators provide teaching on diabetes symptoms, glycemic control, physical activity, and injection taking. Teaching about dietary consumption is often provided by the dietitians. Foot self-care education is shared between the physicians and wound nurses (AlMustafa, 2013). However, our results showed some degree of lack of recognition of DPN symptoms by patients. It also suggested that DPN is not adequately recognized, discussed, and assessed by the providers. Thus, these findings should be disseminated and shared on a broader level with physicians, diabetic educators and patients alike. It is also the hope that additional roles can be created where nurses can provide foot screening and teaching patients to reinforce foot self-care practices.

Another alarming finding is the poor glycemic control. The average HbA1c in this study was 8.89% which was higher than most reported evidence from outside of Saudi. Other Saudi studies have also reported similar levels. This highlights the importance of promoting patient education to perhaps increase the awareness that poor glycemic control is linked to the debilitating DM complications (ADA, 2019).

Foot Self-care Management

In this reported study, foot care practices showed that patients were performing good foot care practices amongst the other self-care activities. However, our sample had significant symptoms, chronic pain, and foot infections. Further, our data suggested that patients often
initiate and adhere to self-care after experiencing neuropathy symptoms. This highlights the issue of self-care practices, one of the focal issues with patients with chronic illnesses (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Thus, some creative interventions, with simple understandable language, are needed that target patients in the early stages of the disease to help raise awareness to prevent the incidence of DPN. Furthermore, as discussed above, practicing Muslims wash certain parts of their body including the feet prior to performing the five daily prayers. Although this shows a good practice, washing the feet multiple times a day without proper drying and moisturizing can be further damaging to the feet. This damage can result from excessive dryness (ADA, 2019; Institute for Preventative Foot Health, 2012). Another issue with daily washing is related to foot ulcers. As reported earlier in Chapter 4, about 10% of the sample had active foot ulcers and during foot exams patients with foot ulcers showed concerns of improper foot self-care with regards to washing the foot with the presence of ulcers. This practice shows the need for comprehensive education on diabetic foot care which adds additional cultural implications of this study findings.

**Diabetes Risk Factors**

Additionally, our findings indicated that BMI was higher among younger individuals corresponding to previous research (AlNozha et al., 2015). Considering that the majority of the Saudi population is <35 years, and that T2DM is becoming more prevalent among the youth, this finding is alarming. The trajectory of such statistics is worrying as youth with obesity and weight issues can progress to prediabetes and then diabetes (AlHazzaa, Abahussain, Alsobayel, Qahwaji, & Musaiger, 2011). The combination of obesity, smoking and other metabolic conditions is forming a real threat to the public health of the Saudi population (GBD 2017 Saudi Arabia Collaborators, 2020).
Additionally, the current lifestyle of the Saudis provides further environment that worsens their physical QoL. Overwhelming evidence indicated the gross inactivity among the Saudi children, youth and adults. AlHazzaa (2018) compiled a review on the evidence of factors associated with physical activity in Saudis, however, the evidence was limited about the rural areas in Saudi. They reported that physical inactivity among Saudis ranged from 26% to 85%. Some of the hindrances to exercising reported included extreme weather, lack of social support, limited exercise facilities, cultural barriers, and crowded traffic (AlHazzaa, 2018). Other variations are caused by the span of ages, regional, cultural, and educational variability existed between the Saudis. Although Saudi Arabia is seen as homogenous country that is composed mostly of Native people it still has varying degrees of cultural beliefs that in turn impact the lifestyles and health choices of the people (Saudi Arabian Cultural Mission-Australia, 2020).

Gender related influences were also significant among the Saudis as only about 25% of female adolescent meet the recommendation of 60 minutes of exercise per day (AlHazzaa et al., 2011). A Saudi study reported that female adolescents in particular had low physical activity rates. Some of the factors associated with inactivity among them were self-efficacy, enjoyment of physical activity, and social support (Bajamal et al., 2017). Thus, based on the previous knowledge about the people of Saudi, future nursing research and education should build on and further advance this knowledge. The focus should be on women of adolescence and adult age as they are particularly at risk for metabolic syndromes (AlHazzaa et al., 2011).

Research data indicated that poor diet habits are identified as risk factors for poor glycemic control among the Saudis (AlNozha et al., 2007; AlQwaidhi, Pearce, Critchley, Sobngwi, & O’flaherty, 2014). In our study, patients also performed poorly in their diet self-care practices at 3.6 days/week (52% days of the week). This evidence should alert nurses in clinical
settings to screen those individuals at risk more carefully and educate them accordingly. For instance, being aware that diabetes and obesity are part of the family medical history of a younger patient should be an impetus for the nurse to have different strategies for prevention and early detection. Also, the lifestyle practice by patients is an important history to obtain. Foods like crème cheese spreads are a common light food for breakfast and snacks for Saudis. In this current study patients noted that they mostly eat these sandwiches for dinner thinking that they are a healthy food choice. Other similar misconceptions about food were also noted previously. A research team found that half of their Saudi T2DM sample had misconceptions about what carbohydrate is and the recommended daily serving. Other patients had difficulty refraining from or limiting intake of honey and dates thinking that they would never be harmful as they are seen as holy and sacred foods (Alsaeedi, Elzubair, AlDawood, & Bahnasi, 2002). The study also found that there were contrasting perceptions as to the dietary allowance of those two foods. Most patients thought they should not be consumed at all. Others thought that they were harmless regardless of the quantity.

**Cultural Determinants**

This study, as mentioned earlier, examined the frequency of performing diabetes self-care practices. Although not a main purpose of this study, the findings suggested that, among the self-care subscales, the frequency with which participants performed exercise was lower than many of the published non-Saudi evidence (Toobert et al., 2000). This should call for substantial and creative efforts from nurses to provide education and reinforce knowledge to ensure safe and effective exercise routines tailored to the demographic, cultural, and environmental characteristics of the Saudi population. For instance, since the temperature is high almost year-round, negotiating an alternate indoor simple exercise routine instead of outdoor walking can
help motivate patients more. Although indoor fitness centers and gyms are increasing in popularity including a sex-specific sites, the cost of those memberships make such a basic practice a luxury (AlNozha et al. 2011; AlHazzaa, 2018). Thus, this may not be available to people of limited financial resources. However, indoor exercise should not be limited to for-profit fitness facilities. With some creativity nurses can recommend simple hassle-free routines that patient can do in the comfort of their homes. For instance, to increase the level of physical activity by being aware of alternatives keep them active such as taking the stairs instead of elevators, or walking instead of driving to go the masjid (house of worship). Taking their walks inside of an indoor shopping mall can also be an achievable alternative.

It is not uncommon that the family is involved in the care of the diabetic patient in Saudi. Research on the unique social and cultural system supports that observation as well (Jazieh et al., 2018). This is almost always the case with people over the age of 50 years and when illiterate. Involving the daughter or the son of the patient’s care plan is widely practiced in Saudi Arabia. This prompted studies to explore models in which the family as a whole is centered in the care and decision making (Jazieh et al., 2018). Certain individual characteristics such as age, education, medical condition, and cultural issues allow for a shared decision-making process about their family member’s health. Thus, nurses have an understanding of this element and often provide education to the caregiver/family member. In light of these results, now nurses can actively discuss daily foot self-care with the caregiver. They can be involved in the assessment of their family member’s foot, lotion application, and inspecting of inside shoes.

Some Saudi-based evidence suggested that patients for reasons of education and trust would prefer the traditional physician centered model where physicians lead the decision making process (Qidwai, et al., 2013). However, patients should be empowered and educated to make
informed decision about their health. The practice of actively involving the patient in their own care is still growing in the Saudi health system (Ministry of Health, 2016). Actively engaging patients in the decision making process would improve their commitment to self-care management (Bezreh, Laws, Taubin, Rifkin, & Wilson, 2012; Young, Azam, Meurer, Hill, & Cui, 2016). Together, the patient and the provider should adjust and modify the management plan to better address the patient’s QoL concerns.

**Implications on Diabetes Care**

The expenses of healthcare associated with DM and its complications are among the most significant healthcare expenses around the world (CDC, 2018; ADA, 2019; Sadosky et al., 2015). As an essential part of the workforce of the healthcare system, Saudi nurses are concerned with reducing the costs while maintaining optimal care. Decreasing the costs of DPN management can be attained by early detection through careful screening and following evidence-based guidelines. Using the Saudi National Diabetes Registry database of 62,681 persons, Al-Rubeaan et al. (2015) conducted a large retrospective cohort study and reported that almost all (95%) of those with DM have T2DM. Around 37% of them have diabetic foot ulcers; almost all of them had undergone lower limb amputations. Simple measures like inquiring about pain or decrease of sensation as a part of vital signs assessment can be a key to detecting early signs of neuropathy.

The incidence of complications associated with DPN, such as foot ulcers, would be enormously reduced and so would the costs of care. Currently, the practice of DM care in Saudi indicates that patients receive the basic chronic illness care, including laboratory work ups quarterly, at their primary care physician’s office at the primary care centers. Patients are referred to the diabetes center to receive further care and strict glycemic control if their HbA1c > 9%. Also, patients receive annual ophthalmologic assessment and exam along with kidney function assessment.
These standards of care are the general practice followed by physicians and were developed by the MoH and are in line with the ADA’s guidelines (Alshareef, 2013). However, most of these guidelines are followed, the care provision concerning foot care and exams seems to be a challenging goal to attain (AlMutairi, 2015). Unfortunately, there was no evidence found on the frequency of foot care assessment in the Saudi literature.

The study also examined, though indirectly, the patient’s perceptions about communication with the healthcare providers. Communication with the provider is one of the challenges and hindrances in providing optimal diabetes care in Saudi (AlMalki et al., 2011). In most Saudi clinical settings, diabetes care, in terms of diagnosing and treatment is provided by physicians. Nurses provide vital signs assessment including glucose checking, wound changing, and diabetes education. Diabetes educators receive additional training and certifications beyond their nursing license. As healthcare providers, nurses are directly involved with DM patients, and having real data to support the importance of establishing and maintaining a trusting relationship between provider and patients should enrich their knowledge. It should also promote further efforts at providing optimal education for patients.

**Nursing and Health Disparities**

This study’s limitation of excluding illiterate people raised an issue of health disparity. Literacy is also a pressing issue for nurses who provide education to DM patients. The number of illiterate adults (no formal education) in Saudi is 1,105,338 excluding those under 10 years old; of which 398,322 are older adults. This is about 3.8% of the population (General Authority for Statistics, 2017). Literacy is directly linked to knowledge retention and, thus, application and outcome. Providing education and training to individuals with low health literacy is inevitably
challenging to nurses in Saudi. This is also another application for family-centered care. The family member can assume responsibility of care for the beloved one.

Another excluded group from this study was non-Arab immigrants and permanent residents. According to the General Authority for Statistics (2017) there were about 11 million people, about one-third of the population in Saudi with various forms of immigration status who may not have access to healthcare resources. There is thus a lot of unknown health issues that affect the health and QoL of individuals in Saudi. This problem impacts the overall health and QoL of the entire country. A recent example is the Saudi national response during the pandemic of Corona Virus Disease-2019 (COVID-19) (Reuters, 2020). As stated earlier, the access to free healthcare is, mostly, limited to Saudi individuals. Thus, many of non-Saudis were not able to be tested or treated. This in turn has led to potential health crisis due to the rapid widespread of infection as those individuals were either unaware of the infection or have limited access to healthcare resources due to financial restraints. The country was only able to curb this crisis by a royal decree that allowed everybody including the undocumented to be treated free of charge (Alarabiya Network, 2020). Such situation might extend to many non-communicable diseases in Saudi. Similarly, the lack of access to diabetes resources may disproportionately affect those who are non-citizens which creates some ethical concerns and limit the overall benefits in quality of care.

**Recommendations for Future Research**

This reported study contributed to the existing body of research in Saudi by explaining the symptoms of DPN for persons living with T2DM in Saudi. It is significant that this endeavor helped establish a research basis for the unique cultural and environmental attributes of the region. For the Saudi population, the study of factors associated with DPN in relation to healthcare
resources provided an understanding of the role of the environment in the development and progress of neuropathy. Peripheral neuropathy is a developing area of research in Saudi and in the Middle East. There are plenty of questions to be answered about how DPN develops and ways to prevent it. This study contributed to explaining the symptoms of DPN for persons living in Saudi. It was the first step in creating evidence using approved and culturally adapted measures. Future research could focus on the specific aspects of physical impact of neuropathy. For instance, using multiple measures to assess specific functional attributes is warranted. In this current study, functioning was measured by the frequency of self-care practices. Future studies would use instruments that were developed to measure the different components of functionality such as walking, single-leg stance, and gait measures. Reduced functional status has been attributed to reduction in QoL among DPN individuals. Studies found significant results with some population of T2DM and DPN. For instance, a non-Saudi study used a detailed measurement system to assess functional status. The biological approaches included assessing muscle strength with a dynamometer, the range of motion with an inclinometer, functional capability with tests like the timed up and go and sit-to-stand. Also, the average body velocity and balance confidence were assessed (Riandini et al., 2017). Replicating such a study on the population of T2DM in Saudi would be a remarkable endeavor.

In addition, in future studies efforts should be focused on exploring the impact of DPN on sleep disorders. Among the population of Saudi there is some evidence to suggest sleep problems. Darraj and colleagues (2018) assessed the risk factors of poor quality of sleep among T2DM people and found that it was a prevalent issue with 55% exhibiting symptoms of sleep problems. It was associated with being female, illiterate, having DM >10 years, and having diabetes complications. Another study also studied the pattern of sleep among the Saudis. A team of
researcher found that among 1,369 middle aged Saudis, about 61% reported sleeping disturbance, 18% of whom claiming they have slowed or stopped breathing during sleep (AlTannir et al., 2018).

Future interventional studies could include the impact of physiological and psychological therapy approaches, such as the impact of prescribed physical activity routine on pain perception and QoL. Given the younger population of T2DM Saudi patients, utilizing technology in interventions would create an exciting opportunity for participation.

To provide an enhanced understanding of living with DPN, some qualitative research is also warranted considering the lack of such methodology in the literature of DPN among Saudis with T2DM. There have been no studies examining the understanding of diabetes and its complications among the population of Saudi. Qualitative research is needed to provide deep understanding of the experience of having the diagnosis of DPN. Qualitative data would provide strong evidence and strength to the description of DPN without which the progress to interventional design is deficient.

Other research plans involve studying the perceptions and the attitudes of the practitioners caring for DM patients as understanding the challenges, resources, and approaches of tackling the epidemic of DM from the perspective of healthcare personnel is key for improved outcomes. Again, both qualitative and descriptive quantitative methods are valuable in providing profound understanding of healthcare capacities and limitations. As discussed earlier, the detection and diagnosis of DPN is variable and information is needed on the beliefs and practices of health providers on the frequency of foot care examination and DPN development. It is the hope that such study will increase awareness and enable the scientific community to quantify and measure the variation in DPN management among the Saudis.

As discussed above, in strengths and limitations, the investigator of this study had a first-
hand experience with IRB application both nationally and internationally. Such experience would provide basis for future research collaboration with Marcella Niehoff School of Nursing as nurses are continuing to build knowledge jointly across the globe. Such endeavor would recognize the need for nurses to respond to cross-cultural influences on health phenomena and other global health needs. The cultural influence explored in this study may shed some light to some of the issues some Muslim, Arab minorities living in the US.

Additionally, field observation notes during foot exams indicated that some patients were not adhering to the footwear recommendations and thus were wearing sandals. Those, however, were patients without foot problems. This observation was also previously reported (AlAyed et al., 2019). Those patients are at increased risk of developing foot problems later in their life. It was also noted that patients with foot problems and diabetic foot were adhering to the recommendations of footwear. Most of them wore therapeutic diabetic shoes. The best practice for footwear for diabetic patients is to wear well-fitting shoes with round-toes that is closed from all sides (ADA, 2019). Open footwear like sandals, ill-fitting shoes, and squared-toes are some of the inappropriate footwear for diabetic individuals (van Netten et al., 2020). This observation further proofs the previous research that the presence of complications improves the patients’ self-care practices, discussed earlier. This, however, was not assessed by any instrument. Unfortunately, the SDSCA that was used to measure foot self-care practices does not include questions on footwear. Future research projects should plan to measure this important risk factor of DPN among Saudis, especially that the risk of dryness and callus development increase with wearing sandals (ADA, 2019; AlAyed et al., 2019).

Another research project involves the psychometric testing of the newly translated CIRS. The CIRS has been widely used in the English language. However, to our knowledge, this study
was the first to use the CIRS in Arabic. For the process of translation, the Back-translation approach was used (Waltz et al., 2017). It refers to the use of two translators working independently translating the measure from the primary to the target language. In our study, we used double translators with two persons translating the CIRS from English to Arabic and two different translators to translate it back into English. One of the four translators was a bilingual with English being their first language. The other three translators were Arabic speaking bilinguals. Three of the translators were competent in the Saudi culture. For future research we would field test the measure for clarity and appropriateness. This would provide a great opportunity to utilize such a key measure to be used in research involving the Arabic speaking individuals.

Finally, as discussed in limitations and strengths section, in this current study we excluded those who cannot read and write at the level of 6th grade. Thus future research efforts would utilize designs that allow for interview basis of data collections, since many of excluded individuals in this current study were women and above the age of 45 years. Focusing on the low income, poorly educated Saudis would ensure better understanding of this important group of people. Overall, it is evident that there is an abundance of research that can be conducted in persons with T2DM in Saudi Arabia and the promise for nurses to lead these endeavors is possible.

This study hopes to impark a scholarly discourse and research endeavors on the factors associated with diabetic peripheral neuropathy among the population of people with diabetes in Saudi. This study was the first that explored the association of neuropathy and quality of life among T2DM individuals in Saudi Arabia. This current study, also, was the first study that examined the impact of DPN on QoL using an objective measure. It was also the first to explore the association of foot care and neuropathy.
APPENDIX A

STUDY INFORMATION SHEET (ARABIC AND ENGLISH)
Study Information Sheet

Study Title: Factors Associated with Diabetic Peripheral Neuropathy Symptoms and Quality of Life Among Saudis with Type 2 Diabetes.
The purpose of this study is to see if there is a link between neuropathy symptoms, biological, individual, and environmental factors, and quality of life in adults with type 2 diabetes.
You are invited to participate in the study if:
• You have type 2 diabetes
• You are experiencing pain, tingling, or numbness in your lower legs and feet
• You are between the age of 18 and 80 years
• You are not pregnant
• You are on diabetes treatment (insulin and oral agents)
• Your most recent A1c is obtained within 6 months
• You can read and write in Arabic or English at the level of 6th Grade
If you agree to be in the study,
• You will be asked to complete a booklet of questionnaires. The questions ask about the symptoms, demographics, resources available, social support, and quality of life. It takes approximately 30 minutes to finish the survey.
• You will undergo a brief physical examination including assessment of your feet
• The total time expected for this data collection is about 40 minutes.
If you are interested in taking a part in this study, please contact Awatef Ibraheem on her cell phone.
صفحة معلومات الدراسة

عنوان الدراسة: العوامل المؤثرة على أعراض اعتلال الأعصاب الطرفية لمرضى السكر في السعودية وقياس جودة الحياة.

الهدف من هذه الدراسة هو عمل بحث للتحدي العوامل البيئية، الاجتماعية، وال продукции، والتي تؤثر على تطور مرض اعتلال الأعصاب الطرفية لدى مرضى السكري من النوع الثاني في السعودية. كذلك تهدف هذه الدراسة إلى قياس مستوى جودة نوعية الحياة لدى هؤلاء المرضى.

بإمكانك المشاركة في هذه الدراسة إذا:

- امرأة أو رجل
- لديك سكري من النوع الثاني
- قد تم تشخيصك أو الاشتباك بوجود اعتلال الأعصاب الطرفية، أو كنت تعاني من تمديل، خدر، أو الشعور بوخز كالإبر
- في أغلب الساقين والقدمين
- عمرك بين 30 و 75 سنة
- تتعلق بالأنسولين أو الحبوب
- أخر قراءة نسبة السكر التراكمي ما بين 3 و 6 أشهر
- إذا كنت تكتب ورقا بالعربي أو الإنجليزي.

إذا وافقتي على المشاركة في هذه الدراسة فأنت:

- سوف تقوم بتبني استجابات مختلفة بخصوص الأعراض التي تعريتك وكذلك أسئلة تتعلق ببيانات الشخصية والاجتماعية، والبيئية. تستغرق الإجابة على هذه الأسئلة مدة 30 دقيقة.
- سوف تخضع لفحص مبسط للكشف عن قدميك وعمل اختبار الإحساس في القدمين.
- يستغرق أعمال المشاركة في هذه الدراسة مدة 40 دقيقة.

إذا كنت ترغب بالمشاركة في هذه الدراسة فضل بالتواصل مع الباحث من خلال رقم جوالها، البريد الإلكتروني، أو تتواجد في مراكز السكر.
APPENDIX B

CONSENT FORM (ARABIC AND ENGLISH)
You are invited to participate in a research study:

### Approval of participation in research

<table>
<thead>
<tr>
<th>Title in Arabic</th>
<th>Title in English</th>
</tr>
</thead>
<tbody>
<tr>
<td>العوامل الحيوية، البنية، والفردية المؤثرة على اعراض اعتلال الأطراف العصبية وتأثيره على جودة الحياة لدى مرضى السكري من النوع الثاني في السعودية.</td>
<td>Factors Associated with Diabetic Peripheral Neuropathy Symptoms and Quality of Life Among Saudis with Type 2 Diabetes Mellitus</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awatef Ibraheem, MSN, RN (<a href="mailto:aiabraheem@luc.edu">aiabraheem@luc.edu</a>)</td>
</tr>
<tr>
<td>Under direct supervision of Professor Sue Penckofer (<a href="mailto:spencko@luc.edu">spencko@luc.edu</a>)</td>
</tr>
<tr>
<td>Marcella Niehoff School of Nursing Loyola University Chicago</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicago, Illinois United States of America</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>King Fahad General Hospital-Diabetes Clinic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Data collection period</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>4 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>130 participants</td>
</tr>
</tbody>
</table>

### Introduction
You are being asked to participate in this study because you have type 2 diabetes mellitus and developed a complication known as diabetic peripheral neuropathy. To briefly describe this condition, it develops as a result of longstanding elevated blood glucose level and other underlying changes. The symptoms of this condition that you might be exhibiting varies a lot between individuals but usually are prickling, deep aching, sharp like electrical shock and burning pain.

### Purpose of the research
The purpose of this study is to determine if there is a significant association between blood sugar control, age, duration of diabetes, diabetic neuropathy symptoms, functioning status, and your quality of life.

### Participant selection
This study invites all people with:
• The diagnosis of type 2 diabetes or adult onset diabetes
• Have a confirmed neuropathy diagnosis or experiencing some of the symptoms (prickling, deep aching pain, sharp pain like electrical shock, or burning sensation)
• Between the age of 18 and 80 years
• Not pregnant
• On diabetes management medications such as insulin and oral agents
• The most recent hemoglobin A1c in the record is within 6 months
• Read and write in Arabic or English at the level of 6th Grade

**Voluntary Participation**
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. In case you chose to not participate, all the services you receive at this clinic will continue and nothing will change. You will still be offered the treatment that is routinely offered in this clinic for your case. You may also change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**
If you agree to participate in this study, you will be asked to meet with the investigator for one time. This meeting serves two purposes. First, the investigator will explain the study to you and will obtain your consent to participate. The second purpose of the meeting is to provide you with the survey booklet for you to complete and to perform a physical check-up of your feet. The assessment involves touching your feet with cotton and a plastic object to check sensation. This application should not make you feel any pain.
For the surveys, you will be asked to complete questionnaires about your condition and quality of life and will approximately take around 30 minutes to complete. All the questions are asking about your own point of view. The first three questionnaires are about the condition you have and referred to as diabetic peripheral neuropathy. You will respond to three different surveys about your symptoms.
The second questionnaire is about your perception of your level of energy, limitations, and satisfaction with health and your general well-being. This questionnaire is composed of 12 questions about several aspects of your daily life. Some questions involve how happy you are with your general health, physical, and work-related life.
The third set of questions is about the resources that are available for you to help you manage your condition. You will be asked to answer questions on the resources that you need to manage your diabetes. You should consider your own perception when answering the questions. The fourth set of questions is to assess your social support. For example, it asks about emotional support and support on information needed for diabetes management.
The fifth questionnaire includes questions about your ability and regularity of managing the needs of your diabetes. You will be asked to answer questions on how regular you are checking your glucose level, taking medications, eating healthy, keeping food records, and exercising. There will also be questions about your background and health history: questions on age, gender, education level, income level, and employment. Also, there are questions about your current medical problems and medications you are taking.
Risks
There is relatively no risk of participating in the study. There is a possibility that your shared information gets exposed at any time during data collection or transporting. However, the researcher will do her best to keep your confidentiality.

Benefits
There may not be any benefit for you but your participation is likely to help us find the answer to the research question. The potential benefits of the study are to advance and improve diabetes care.

Reimbursements
Taking part in the study will not cost you anything. If you agree to participate in the study you will be handed a tote bag that contains a mug and an educational flyer about diabetes and nerve damage as an appreciation of your time.

Confidentiality
Your participation in this research study is highly honorable and so every information you share with the researcher will be treated as such. All the information you provide will be kept confidential. All the medical information accessed by the researcher will be treated similarly. The investigator will protect the screen during data collection and will not share the temporary access provided to her with anybody. All survey forms will be stored in a safe place in the investigator’s own home office. Once data collection is finished, the investigator will transport the filled consent forms and survey packets back to the U.S. to be stored at the university’s facilities. Filled forms will also be scanned and stored electronically.

Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice, and all your rights will still be respected.

Questions and Complaints
If you have a question about the study or would like to withdraw, please contact the researcher, Awatef Ibraheem at her email or cell phone number. Acknowledgment of participation in the research: special for the use of participants ....
I understand that I will be free to withdraw at any time. I understand that my information will be treated in strict confidence by the researcher and will not disclose my identity when publishing any results for this study.
The name: ................................................................. .........................
Signature: ................................................................. Date: ...............................................

☐ I am informed that I can keep a copy of this form for myself
☐ I agree to participate in this research study
☐ I do not agree to participate in this research study
الموافقة المستنيرة على المشاركة في بحث علمي
أنت مدعو (6) للمشاركة بحث علمي

<table>
<thead>
<tr>
<th>عنوان البحث</th>
<th>عربى: العوامل المؤثرة على أعراض الاعتنال العصبي وجودة الحياة المعشية لدى مرضى السكري في السعودية</th>
</tr>
</thead>
<tbody>
<tr>
<td>عنوان البحث</td>
<td>إنجليزي: Factors Associated with Diabetic Peripheral Neuropathy Symptoms and Quality of Life Among Saudis with Type 2 Diabetes</td>
</tr>
<tr>
<td>اسم الباحث:</td>
<td>عاطف بكر إبراهيم</td>
</tr>
<tr>
<td>الجواب:</td>
<td>و<a href="mailto:endael07@gmail.com">endael07@gmail.com</a></td>
</tr>
<tr>
<td>البريد الإلكتروني:</td>
<td>@</td>
</tr>
<tr>
<td>المشفى الصحية الحكومية بمنطقة المدينة المنورة إجراء البحث فيها:</td>
<td>ستشفى الملك فهد العام، مركز الأمير عبدالعزيز بن ماجد</td>
</tr>
<tr>
<td>ال جهة المسؤولة عن البحث:</td>
<td>جامعة لوبولا بشيكاغو كلية مارسيلا لينهوف للتمريض وزارة الصحة المدنية العامة</td>
</tr>
<tr>
<td>مدة البحث:</td>
<td>4 شهور</td>
</tr>
<tr>
<td>العدد المتوقع للبحث: (عدد الاستبان)</td>
<td>130 مشارك</td>
</tr>
</tbody>
</table>

**مقدمة**

هذه الدراسة هي بعنوان "العوامل المؤثرة على أعراض الاعتنال العصبي وجودة الحياة المعشية لدى مرضى السكري في السعودية". والمرض من نمذج الوقاية المسبقة هذه هو مصطلح المعلومات التي ستساعدك على أن تقوم أن تكون في هذه الدراسة عام، ولا تتم في طرح أي أسئلة لديك، وأن تقوم هذا النموذج. ليس من الصعب أن نقترح أن يوم مشاركك من عضو، قبل أن تُكلف النموذج، يمكنك أن تستفز، من هذا الدراسة البحثية إلى أي شخص من عناوينه:

إذا واجهتك صعوبة في فهم بعض الكلمات، أرجو أن تطلب مني التوقف لأشرح لك تلك الكلمات. لطفاً، أنتبه لكل التفاصيل ولا تتردد في طرح أي سؤال على. أن تتست مساعدة على المشاركة في هذه الدراسة البحثية، كما يمكنك الانسحاب في أي لحظة خلال المشاركة. وإذا كانت لديك أي أسئلة، فأتمنى أن تقراء لهذا العدد، عند الإجابة على جميع أسئلتك، يمكنك أن تقرر إذا كنت تريد أن تشارك في الدراسة أم لا.

**المرض من الدراسة البحثية**

سبب قيامنا بهذه الدراسة البحثية هو وصف طبيعة أعراض مرض اعتنال الأعصاب الذي قد يواجه المرضى، والذي ينتج عن ارتفاع معدل السكر في الدم. أيضاً الغرض من الدراسة هو دراسة ما إذا كان هناك علاقة بين هذه الأعراض، وعدد من العوامل المؤثرة مثل معدل السكر، العمر، الجنس، الدهون المشبعة، والمواد المتوفرة للعناية بالمرض، وأخيراً، الهدف من هذه الدراسة هو دراسة ما إذا كانت هذه الأعراض تؤثر على جودة المعيشة لديك. أمور مثل إحساس بالتعب، الألم المستمر، عدم القدرة على القيام بالأعمال الروتينية وما إلى ذلك.

**اختيار المشاركين**

تهدف هذه الدراسة إلى استجواب الأفراد من الجنسين الذين يعانون من مرض السكر من النوع الثاني، لديهم أعراض مثل (النوم بالتدريج، ورقة، البدانة في القدم، نوبات، وفقدان الأحاسيس في بعض الأحيان)، أو سبب تشتتهم من قبل الطبيب، مرض اعتنال الأعصاب الطرفية، أعمارهم ما بين 60 سنة، النساء من ليست حامل، ممن يتعاطون أم بالأنسولين أو الديو.
المشاركة تطوعية

إذا وافقت على المشاركة في هذه الدراسة البحثية، فإن المطلوب منك هو أن تقابل الباحثة لمدة واحدة فقط الغرض من هذا اللقاء هو كالتالي: أولاً حتى يتم شرح الدراسة لك بشكل وافي وحتى تقوم بطرح الأسئلة التي تريد ويتم الإجابة عليها. ثانياً، بعد الحصول على الموافقة الخصية للمشاركة في البحث سيتم تقديم الاستمارات لكم للإجابة عليها. وأيضاً سيتم حفظ مختصر للقدام.

ستقوم الباحثة بفحص القدمين وذلك بالنظر إليها. أيضاً سيتم استخدام أدوات قياس الإحساس والالم. سوف لن تقوم بالإحساس بأي نتيجة هذا الحضور. سيتم تصور الباحثة خطبًا بخصوصي، قнят على جلد القدمين قياس الإحساس فيهما. كذلك ستقوم بوخز القدمين بآداء واحدة، ولكن لن تشعر بآلام إذا لم يكن هناك احتكاك للجلد.

بالنسبة للإساتذة ستقوم بالإجابة على عدد 8 أسئلة. هناك ثلاثة من هذه الأسئلة تتعلق بالأعراض التي قد تشعر بها، وهي اجتماع العصب الطرفي. كل واحد منها له غرض مختلف ويساهم في إدراك متعدد من الأعراض. الاستبيان الرابع هو يحدد أعراض ارتك وعبيد ومفاهيم ال저ية، مستوى الطاقة، القوى التي تشعر بها نتيجة انتقال الإسعاد. كذلك ستقوم الاستبان بالسؤال عن مدى تعلق المشاكل السابقة. إذا أدى الاستبان الخامس يتناول أسئلة تتطلب للموازاة الصحية المتعلقة لكل. كذلك هناك أسئلة خاصة بطرق استخدام للموارد الأخرى كالأذى. العمل، المؤسسات المجتمعية.

الاستبان السادس يشكل على مستوى الدعم الاجتماعي الذي تتلقاه والذي له عدة صور. هناك أسئلة عن توفر الدعم العاطفي، الدعم الصحي والملاذ.

الاستبان السابع يطلق على مستوى الرعاية الشخصية التي تقوم بها الطفلة بالسعودي. هذا الاستبان يشمل طريقة وعدد المرات التي تقوم فيها بالقياس السكر، الحمية الغذائية، القبول بالتمارين الرياضية وما إلى ذلك.

الاستبان الأخير هو لجمع بيانات عامة عنك. تشمل أمور مثل العمر، الجنس، المؤهل التعليمي، الوظيفة، والإمراض التي تعاني منها.

كذلك سيتم الوصول إلى مجلتك الطبية للحصول على معلومات الطبية التي تتعلق بالغرض من البحث.

باختصار سيطلب منك بالاحتفال قدم بما يلي:

- قراءة نموذج الموافقة المسبقة ومناقشة وتوقعه.
- إجابة استبان حول معلوماتك الشخصية مثل العمر، الجنس، الحالة الاجتماعية، الدخل، مستوى التعليم.
- إجابة 8 أسئلة حول أعراض انتقال الأعصاب، الدعم الاجتماعي، مدى الرضي عن المعبيشة مع الأعراض، طبيعة ممارسة العناية الشخصية بالقدام، واستخدام الموارد المتوفرة لمرضي السكر وغيرها. ستُفرع الإجابة على جميع الاستبانات لست تتجاوز 30 دقيقة.
- اختيار المطرقة والالتزامات لفحص المعايير العصبية في الأطراف السفلية.
- سيتم مراجعة ملف الطبي من قبل الباحث للحصول على معلومات تتعلق بالأدوية، الأمراض المزمنة الأخرى، ونتائج التحاليل المخبرية.
المخاطر
ليس هناك مخاطر محتملة نتيجة المشاركة في هذه الدراسة. هناك احتمال فقدان البيانات أو تعرضها للضياع. ولكن الباحثة سوف تسعى جاهدة إلى المحافظة على سرية المعلومات وأن ليست مشاركتها إلا مع جامعة لويبلا بشيكاغو ووزارة الصحة بالسعودية (في حال طلب).

المكافآت
مشاركتك قد لا تكون كافية، ولكنها ستسمى على الأرجح في الإجابة عن سؤال الدراسة البحثية. وعلى أي حال، فالمكافآت المرجوة من الدراسة البحثية هي تعزيز وتحسين مستوى رعاية السريري والمضاعفات المتعلقة به. كما أن نتائج الدراسة البحثية قد تساعده على رفع الوعي عن اعراض الاعتلال العصبي ومدى تأثر جودة الحياة نتيجة هذه الاعراض.

التعويضات
لن تكون المشاركة في الدراسة البحثية أي شيء. إذا قررت المشاركة، سيتم منحك حقيبة يد وبداخها معلومات عن الاعراض التي تواجهك.

سرية البيانات
سيتم احتفاظ بسرية البيانات التي يتم جمعها لأغراض هذه الدراسة البحثية. أما معلوماتك الشخصية (مثل اسمك ورقم سجلك الطبي الذي يتم جمعه خلال الدراسة، فسيتم إبعادها ولا يراها أحد غير الباحثين. وسيتم التعرف على كل معلومة شخصية لك عن طريق رقم معين وليس عن طريق اسمك. لن يعرف أحد ما هو رقمك غير الباحثين وستحفظ تلك البيانات مغلقة بفضل ومفتاح، ولن يتم مشاركتها أو إعطائها أحد غير أعضاء فريق البحث ومجالس الجامعة المراجعة والمسؤولون عن جماعة المشاركين من البشر في جامعة لويبلا بشيكاغو وفي وزارة الصحة السعودية. أيضا سيتم حفظ البيانات الإلكترونية (السعودية الوصول إليها) ويستحماية هذه البيانات عن طريق عدد من الوسائط كالمعيار الإزدراوي للوصول.

حق الرفض أو الانسحاب
لست مجبوراً على المشاركة في هذه الدراسة البحثية. لا يمكنني أن أستخدم أي المعلومات التي أنتم فيها في أي وقت وحدها أو مع غيركم. ولكن إذا قررت أن ت оста بالدراسة، فسيتم احترام كافة حقوقك. لن تؤثر أي شكل كان على حقوقك كمريض أو على مستوى أو أخلاقية الحصول على الرعاية الصحية.

الاسئلة والشكاوى
لطرح أسئلة حول حقوقك كمشارك في الأبحاث أو الشكاوى: أتصل بإدارة الصحة/ مديرية الشؤون الصحية. المدينة المنورة

الاستفسارات المتعلقة بالبحث أو في حال الرغبة في الانسحاب، الرجاء التواصل بالباحثة عاطف إبراهيم

قرار بالمشاركة في الدراسة: نتائج للأشخاص الذين لا يستعمل المشاركين

أنا الموقع الجغرافي وبناءً على أعمدة على المشاركة وأدرك تماماً أنني مكلف الحيرة بالانسحاب في أي حالة كما أدركت أنه سيتم التعامل مع المعلومات التي أقدمها بسرية تامة من قبل الباحث وأنه لن يصبح عن

الاسم: __________________________

التوقيع: ________________________

التاريخ: ________________________

تم إلصاقت بالحصول على نسخة من هذا النموذج للاحتفاظ به.

 لأنني أتفق على المشاركة في هذا البحث.

لا أتفق على المشاركة في هذا البحث.
APPENDIX C

SELF-REPORT MEASURES (ARABIC AND ENGLISH)
General Health and Demographic Survey

Please fill out the information below. All the information will remain confidential.

1. Age…… Date of birth……

2. Gender: □ Female □ Male □ Prefer not to answer

3. Race (Saudi from):
   □ Native people □ East Asian (e.g., Malaysia and Indonesia)
   □ North African (Egypt and Morocco) □ African (Black)
   □ Middle Eastern □ South Asian (India and Pakistan) □ Non-Saudi
   □ Prefer not to answer □ More than one race, describe
   □ Other, describe……

4. Marital condition:
   □ Married □ Divorced □ Single □ Widow □ Separated
   □ Prefer not to answer

5. Monthly income (Saudi Riyal):
   □ None □ Less than 5,000 □ 5,000-10,000 □ 10,000-15,000
   □ More than 15,000 □ Prefer not to answer

6. Level of education:
   □ Can read and write Arabic □ Can read and write English □ Less than 6th grade
   □ 6th grade □ 9th grade □ 12th grade □ Associate degree
   □ College degree □ Higher education □ Prefer not to answer

Study ID#: 
7. Employment status:

   Do you work currently? □ Yes □ No □ Prefer not to answer
   (If yes): □ Government □ Private □ Retired □ Self-employed

8. You have diabetes for (which best applies):

   □ Less than 6 months □ Less than 1 year □ Less than 5 years
   □ 5-10 years □ 11-15 years □ More than 15 years

9. Do you have family history of diabetes (type 1 or 2)? □ No □ Yes
   (If yes, who) mother, father, sibling, or child

10. Diabetes Medications:

   1.…….   2.…….   3.…….

   4.…….   5. ….

11. Are you taking any neuropathy medications? □ No □ Yes
    (If yes, please list all)

   1.…….   2.…….   3.…….

12. List all the medications you are currently taking (including the over-the-counter medications)

   1.               …..               2.…….

   4.…….   5. …..               6.…….

   7.…….   8.……..               9.…….

   10.……..

13. Are you a smoker?

   □ Never smoked □ Currently smokes □ Former (smoked in the past but not now)
   If current or former smoker, how many pack(s) per day?
14. How much do you exercise? (at least 30 minutes)

☐ 4-7 days a week ☐ 1-3 days a week ☐ I do not exercise

15. Do you have a history of fall(s)? ☐ Yes ☐ No

(if yes, how many times in the past 3 months)? .........................

16. The circumstances of the fall(s): ☐ Tripped ☐ Legs gave away (knee buckling)

☐ Fainted ☐ Confusion ☐ Poor balance ☐ Foot problems (bunions and hammertoes)

17. Have you ever fallen down because you lost sensation in your feet? ☐ Yes ☐ No

(if yes, how times ........)

18. Have you ever lost sensation while driving? ☐ Yes ☐ No

(if yes, how times ........)

19. Do you have a fear of falling as a result of your symptoms? ☐ Yes ☐ No

(if yes, how times ........)

20. Have you ever been diagnosed for the symptoms of neuropathy? ☐ Yes ☐ No
الصحة العامة والمعلومات الأولية

هذا الاستبيان هو بخصوص تجميع بيانات عن الحالة الصحية والاجتماعية العامة. الرجاء تعبئة هذه الاستمارة علماً بأن جميع المعلومات ستكون سرية.

تاريخ الميلاد: ....

1. العمر: ....

2. الجنس: □ ذكر □ اثناً أفضل عدم الإجابة

3. الأصل العرقي (سعودي من): □ شرق أسيوي (مثل ماليزيا واندونيسيا) □ شمال أفريقيا (مصر، تونس، المغرب)

□ أصل أفريقي (آسيا) □ المشرق العربي (سوريا، العراق، فلسطين) □ جنوب أسي (بلاد الهند، باكستان)

□ غير سعودي

□ أفضل عدم الإجابة

□ متعدد الأصل العرقي، اشرح...

4. الحالة الاجتماعية:

□ مطلق (ة) □ مطلق (ة) □ متزوج (ة) □ عازب (ة) □ أرمل (ة) □ منفصل (غير مطلق)

□ أفضل عدم الإجابة

5. الحالة المادية (الدخل الشهري بالريال):

□ لا يوجد أقل من 0000 □ 0001 - 0005 □ 0006 - 0010 □ أكثر من 0015

□ أفضل عدم الإجابة

6. الحالة التعليمية:

□ يقرأ ويكتب عربي □ أقل من سادس ابتدائي □ ابتدائي □ ثانوي □ متوسط

□ ثاني □ جامعية متوسطة □ جامعي □ دكتوراه □ ماجستير أو الدكتوراه □ يقرأ ويكتب إنجليزي □ أفضل عدم الإجابة

7. هل تعمل حالياً؟ □ نعم □ لا أفضل عدم الإجابة
(في حال الإجابة بنعم)  □ وظيفة حكومية  □ شركة خاصة  □ متقاعد  □ مستقيل

8. انت مريض سكر منذ:

☐ أقل من 6 شهور  ☐ أقل من سنة  ☐ أقل من 5 سنوات  ☐ 5 - 10 سنوات

☐ 11 - 15 سنة  ☐ أكثر من 15 سنة (كم بالتحديد)    

9. هل لديك قريب مصاب بالسكري (النوع الأول أو الثاني)?  □ نعم (من)؟، اب، اخ، طفل...

10. أدوية السكري الموصوفة من قبل الطبيب:

1  2  3  4  5  6  7  8  9  10  11

إنذكر(ي) أي ادوية أخرى تتعاطاه حالياً لم يتم ذكرها مسبقاً (تشمل الموصوفة وغير الموصوفة)

1  2  3  4  5  6  7  8  9  10

11. هل انت مدخن؟  □ لا  □ حاليا  □ سابقا وليس حاليا

في حال الإجابة بنعم: كم عدد السجائر يوميا؟....

12. النشاط البدني هل تمارس الرياضة؟ (بمعدل ثلاثون دقيقة يوميا):

☐ لا  □ 4 أيام في الأسبوع  □ 3 أيام في الأسبوع  

13. هل لديك تاريخ سقوط حديثا (خلال الثلاث شهور الماضية)?
لا (في حال الإجابة بنعم) كم مرة خلال الثلاث الشهر الماضية؟

الظروف المرتبطة بالسقط:
- تعثرت الساقين
- نتائج اعماة
- دوحة
- اختلال التوازن
- مشكلة في القدمين (في الأصابع أو المفاصل)

هل سبق وان سقطت بنتيجة اعراض الاعالت الطرفي العصبي؟ نعم لا

إذا كانت الإجابة بنعم، كم مرة؟

هل سبق وان شُخصت نتيجة اعراض الاعالت العصبي الطرفي؟ نعم لا
ELECTRONIC MEDICAL RECORD VARIABLES

ID# ……………………  Name ……………………  Date ……………………

Date of birth……..   Age……..

Current medical history:

Duration of diabetes ………….. month / years.   Hypertension: Yes □  No □

Dyslipidemia Yes □ No □   Nephropathy: Yes □ No □

Cardiovascular disease: Yes □ No □   Retinopathy: Yes □ No □

Oral agents (OHA): Yes □ No □

(If yes) list: ……………………………

Insulin: Yes □ No □   (If yes) list:

Combination therapy: Insulin+ (OHA) □

Anthropometric measurement (Last reading):

Weight ……..kg   Height……..cm

Waist circumference……cm   Blood pressure……..mmHg

History of tobacco use: Yes □ No □

(if yes): Current smoker:

How many packs/day ____________

Laboratory measurement (Last reading):

HbA1c ……………. %   Fasting blood glucose (FBG) …… mg/dl
Random glucose level (RBG) …………. mg/dl   Vitamin B12 …………… pg/ml
Total Glycerides …………… mg/dl   S.HDL ……………… mg/dl
S.LDL ……………… mg/dl   Total cholesterol ……………… mg/dl
Vitamin D ……….. ng/dl

List of current medications:

1……..   2……..   3……..

4……..   5……..   6……..

7……..   8……..   9……..

10……..
Summary of Diabetes Self-Care Activities Questionnaire

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

**Diet**

1. How many of the last **SEVEN** DAYS have you followed a healthful eating plan?  
   ![Number of Days](0 1 2 3 4 5 6 7)

2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?  
   ![Number of Days](0 1 2 3 4 5 6 7)

3. On how many of the last **SEVEN** DAYS did you eat five or more servings of fruits and vegetables?  
   ![Number of Days](0 1 2 3 4 5 6 7)

4. On how many of the last **SEVEN** DAYS did you eat high-fat foods, such as red meat or full-fat dairy products?  
   ![Number of Days](0 1 2 3 4 5 6 7)

**Physical Activity**

5. On how many of the last **SEVEN** DAYS did you participate in at least 30 minutes of physical activity?  
   *(Total minutes of continuous activity, including walking.)*  
   ![Number of Days](0 1 2 3 4 5 6 7)

6. On how many of the last **SEVEN** DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?  
   ![Number of Days](0 1 2 3 4 5 6 7)

Copyright 2000 Oregon Research Institute, Eugene, Oregon. All rights reserved.
Blood Sugar Testing

7. On how many of the last SEVEN DAYS did you test your blood sugar?  
   Number of Days  
   0  1  2  3  4  5  6  7

8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your healthcare provider?  
   0  1  2  3  4  5  6  7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet?  
   0  1  2  3  4  5  6  7

10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?  
    0  1  2  3  4  5  6  7

Smoking

11. Have you smoked a cigarette, even a puff, in the past SEVEN DAYS?  
    0 No  1 Yes = 11a. How many cigarettes did you smoke on an average day?  
    Number of cigarettes:  
    _____
Additional Items for the Expanded Version of the Summary of Diabetes Self-Care Activities

Self-Care Recommendations

1A. Which of the following has your health-care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? *Please check all that apply.*

- a. Follow a low-fat eating plan
- b. Follow a complex carbohydrate diet
- c. Reduce the number of calories you eat to lose weight
- d. Eat lots of food high in dietary fiber
- e. Eat lots (at least 5 servings per day) of fruits and vegetables
- f. Eat very few sweets (for example, desserts, non-diet sodas, candy bars)
- g. Other (*specify: ____________________________*)
- h. I have not been given any advice about my diet by my health-care team

2A. Which of the following has your health-care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? *Please check all that apply.*

- a. Get low level exercise (such as walking) on a daily basis
- b. Exercise continuously for a least 20 minutes at least 3 times a week
- c. Fit exercise into your daily routine (for example, take stairs instead of elevators, park a block away and walk, etc.)
- d. Engage in a specific amount, type, duration, and level of exercise
- e. Other (*specify: ____________________________*)
- f. I have not been given any advice about exercise by my health-care team
3A. Which of the following has your health-care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply.

- a. Test your blood sugar using a drop of blood from your finger and a color chart
- b. Test your blood sugar using a machine to read the results
- c. Test your urine for sugar
- d. Other (specify: ______________________________________________________________________)
- e. I have not been given any advice about my blood or urine sugar level by my health-care team

4A. Which of the following medications for your diabetes has your doctor prescribed? Please check all that apply.

- a. An insulin shot 1 or 2 times a day
- b. An insulin shot 3 or more times a day
- c. Diabetes pills to control my blood sugar level
- d. Other (specify: ______________________________________________________________________)
- e. I have not been prescribed either insulin or pills for my diabetes

Diet

5A. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?

- 0  1  2  3  4  5  6  7
**Medications**

6A. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?

   0  1  2  3  4  5  6  7

OR

7A. On how many of the last SEVEN DAYS did you take your recommended insulin injections?

   0  1  2  3  4  5  6  7

8A. On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills?

   0  1  2  3  4  5  6  7

**Foot Care**

9A. On how many of the last SEVEN DAYS did you wash your feet?

   0  1  2  3  4  5  6  7

10A. On how many of the last SEVEN DAYS did you soak your feet?

   0  1  2  3  4  5  6  7

11A. On how many of the last SEVEN DAYS did you dry between your toes after washing?

   0  1  2  3  4  5  6  7
Smoking

12A. At your last doctor’s visit, did anyone ask about your smoking status?

- 0 No  1 Yes

13A. If you smoke, at your last doctor’s visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program?

- 0 No  1 Yes  2 Do not smoke

14A. When did you last smoke a cigarette?

- a More than two years ago, or never smoked
- b One to two years ago
- c Four to twelve months ago
- d One to three months ago
- e Within the last month
- f Today
ملخص أنشطة المنايزة الشخصية لمرض السكري

السلام عليكم ورحمة الله وبركاته

أشكرك على المشاركة في هذه الدراسة، وأتمنى أن تكون هذه الأسئلة تساعدك في فهم موضوع هذا البحث. من فضلك كن صادقًا في إجاباتك. في حالة الالتباس، تفضل اختيار الخيار الأول.

Thank you for your participation in this study. We hope that this questionnaire helps you understand the topic of this research. Please be honest in your answers. In case of doubt, select the first option.

الإجابة

الأسئلة الوردة أدناه تهدف إلى معرفة أنشطة المنايزة الشخصية لمرض السكري خلال السبعية أيام الماضية. إذا كنت مريضًا خلال السبعية أيام الماضية، فرجاء الإجابة على الأسئلة بالذكر أو بالأمس. لذا فقد يكون من الأفضل أن تكتب هذا اليوم من الملاحظات في الفترات التي قررت تسجيلها.

قسم النقليات

1. خلال السبعية أيام الماضية، كم عدد الأيام التي ابتعد فيها خطأ؟
2. بالنسبة إلى الشهر الماضي، كم عدد الأيام التي ابتعد فيها الخطأ؟
3. خلال السبعية أيام الماضية، كم عدد الأيام التي أكلت فيها خمسة أو أكثر من الفواكه والخضروات؟
4. خلال السبعية أيام الماضية، كم عدد الأيام التي أكلت فيها طعام يحتوي على دهون عالية مثل الدجاج الحمراء (مثل أحوم المواني)؟

قسم الرياضة

5. خلال السبعية أيام الماضية، كم عدد الأيام التي مارست فيها في النشاطات البدنية لفترات لمدة 30 دقيقة على الأقل (مجموع النقاط الكلية للأنشطة بما فيها المشي)
6. خلال السبعية أيام الماضية، كم عدد الأيام التي مارست فيها في جملة تعني رياضي محدد (السباحة، المشي...). خلال تلك الأيام، تقوم بها في محيط منزلك أو على تقويم جزء من عملك؟

قسم فحص سكر الدم

7. خلال السبعية أيام الماضية، كم عدد الأيام التي فحصت فيها سكر الدم؟
8. خلال السبعية أيام الماضية، كم عدد الأيام التي فحصت فيها سكر الدم؟

النوم حسب العدد المذكور في تعليمات طبيبك؟

الإجابة
قسم العملية بالقدم

7 6 5 4 3 2 1 0

قسم التحضير

7 6 5 4 3 2 1 0

قسم التسجيل

خلايا السبعة أيام الماضية، هل دخلت السبر (المجائر – الشيمة) في الحالة أو نوعيع?

قسم التغذية

أي مما في نصحك الفرق الطبى بمركز الرعاية الصحية (طبيب ممرض، أخصائي التغذية، مثقف السكرى) أن تعمل:

- اتباع جملة غذائية قليلة النسم
- إتباع حمية غذائية من الشروبات المركبة (مثل الأرز والمكرون)
- تقليل عدد السعرات الحرارية التي تأكلها تخفيف الوزن.
- استثمار أطعمة غذائية بالقليل (مثل الغضروفات).
- ج. تأكل كميات من الفواكه والخضروات (على الأقل خمسة يومياً)
- ج. تناول كميات قليلة من الحلوى (مثل حلوى بعد الطعام)
- تناول كميات قليلة من الحلوى (مثل حلوى بعد الطعام)
- تناول كميات قليلة من الحلوى (مثل حلوى بعد الطعام)
- د. أو أفقية أطعمة حول التغذية من قبل فريق رعايتي الصحية

- الممارسة تمارين رياضية بسيطة (مثل المشي)
- بممارسة تمارين مسمرية لمدة 20 دقيقة 3 مرات أسبوعياً
- الممارسة تمارين بالباعة في عادات اليومية (مثل استخدم النجج، بدلاً عن المعنى، أوقف سيارتك بعدًا، ثم أمشي تلك المسافة).
- ج. الأفكار أو عن عدد أو مدة معينة من مستوى التمرين
- ج. أخرى (حدد)
- ج. أخرى (حدد)
- ج. أخرى (حدد)
- ج. أخرى (حدد)
- ج. أخرى (حدد)
- ج. أخرى (حدد)
ما هي الأدوات التي وصفتها لك طبيبك السكري:

- حقن أنسولين مرة إلى مرتين يومياً.
- حقن أنسولين 3 مرات أو أكثر يومياً.
- تحميص سكري لضيющий مستوى سكري الدم.
- شاكره (خاد)
- استماع الفرق رعايتي الصحية.

قسم التغذية

خلال السبعة أيام الماضية، كم عدد الأيام التي تناولت فيها كمية النشويات اليومية خلال اليوم بالنسبة لكمية متساوية من النشويات في الفطور والمساء والعشاء أو من هي وجبات الغداء؟

قسم العلاج

أجب على أحد هذه الأسئلة:

خلال السبعة أيام الماضية، كم عدد الأيام التي أخذت فيها حقن الأنسولين الموسمي باملاخلد اليوم؟

العنية بالقدم

خلال السبعة أيام الماضية، كم عدد الأيام التي ضعفت فيها القدم؟

خلال السبعة أيام الماضية، كم عدد الأيام التي نفعت فيها القدم في الماء؟

خلال السبعة أيام الماضية، كم عدد الأيام التي
ệuحت فيها بين أصابع قدميك بعد الفصل؟

قسم التشخيص

21. عند آخر زيارة لطببك، هل سلتك أحد عما إذا
   □ نعم □ لا
   مدخن؟

22. إذا كنت تدخن، عند آخر زيارة لطببك، هل
   □ نعم □ لا
   نصحك أحد في الأفلاع عن التشخيص أو أشار
   عليك برنامج الأفلاع عن التشخيص؟

23. متى آخر مرة دخنت فيها سجائر:
   □ أكثر من ستين مصد أو لم دخن إطلاقا
   □ بـ، من سنة إلى ستين مصد
   □ ت، من أربعين إلى إليها شهرا، مصد
   □ ث، من شهر إلى ثلاثة أشهر مصد
   □ ج، خلال الشهر الماضي
   □ ح، اليوم
MICHIGAN NEUROPATHY SCREENING INSTRUMENT

A. History (To be completed by the person with diabetes)

Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel. Thank you.

Are you legs and/or feet numb?  □ Yes □ No
Do you ever have any burning pain in your legs and/or feet?  □ Yes □ No
Are your feet too sensitive to touch?  □ Yes □ No
Do you get muscle cramps in your legs and/or feet?  □ Yes □ No
Do you ever have any prickling feelings in your legs or feet?  □ Yes □ No
Does it hurt when the bed covers touch your skin?  □ Yes □ No

When you get into the tub or shower, are you able to tell the hot water from the cold water?

Yes   No

Have you ever had an open sore on your foot?  □ Yes □ No
Has your doctor ever told you that you have diabetic neuropathy?  □ Yes □ No
Do you feel weak all over most of the time?  □ Yes □ No
Are your symptoms worse at night?  □ Yes □ No
Do your legs hurt when you walk?  □ Yes □ No
Are you able to sense your feet when you walk?  □ Yes □ No
Is the skin on your feet so dry that it cracks open?  □ Yes □ No
Have you ever had an amputation?  □ Yes □ No

MNSI, © University of Michigan, 2000
MICHIGAN NEUROPATHY SCREENING INSTRUMENT

استبيان لفحص اعتلال الطرف العصبي

A- التاريخ (تستكمل من قبل شخص يعاني من مرض السكري)

يرجى أخذ بعض الدقائق للإجابة على الأسئلة التالية حول الساقين والقدمين، الإجابة بنعم أو لا على أساس الكيفية التي عادةً ما تشعر بك.

تشعر بك شكرنا.

1) هل تشعر بصدأ في رجليك أو قدميك؟

2) هل تشعر بالماء الساخن (بحرق) في رجليك أو قدميك؟

3) هل قدميك حساستان لأي شيء عند اللمس؟

4) هل تشعر بتشنجات عضليّة في رجليك أو قدميك؟

5) هل تشعر بوخز في قدميك أو رجليك؟

6) هل تشعر بالألل عندما تلامس أغطية السرير جلدك (جسمك)؟

7) هل تستطيع أن تفرق بين الماء الدافئ والبارد عند الاستحمام؟

8) هل أصبت يوما بفترات مفتوحة في قدميك؟

9) هل أخبرك الطبيب يوما من أنك تعاني من الاعتلال العصبي السكري؟

10) هل تشعر بالضعف العام في جسدك معظم الأيام؟

11) هل تزداد أعراض المرض أكثر في الليل؟

12) هل تؤلم رجليك عند المشي؟

13) هل تشعر بقلوب قدميك عند المشي؟

14) هل جلد قدميك جاف لدرجة أن تصاب بشقاق مفتوحة فيها؟

15) هل خضعت يوما إلى عملية بتر في إحدى أطرافك؟

المجموع:..........................
MICHIGAN NEUROPATHY SCREENING INSTRUMENT

B. Physical Assessment (To be completed by health professional)

1. Appearance of Feet
   Right
   a. Normal ☐ 0 Yes ☐ 1 No
   b. If no, check all that apply:
      Deformities ☐
      Dry skin, callus ☐
      Infection ☐
      Fissure ☐
      Other ☐
      Specify: 
   Left
   a. Normal ☐ 0 Yes ☐ 1 No
   b. If no, check all that apply:
      Deformities ☐
      Dry skin, callus ☐
      Infection ☐
      Fissure ☐
      Other ☐
      Specify: 

2. Ulceration
   Right
   Absent ☐ Present ☐
   Left
   Absent ☐ Present ☐

3. Ankle Reflexes
   Right
   Present ☐ 0.5 ☐ 1
   Left
   Present ☐ 0.5 1

4. Vibration
   Perception at Great toe
   Right
   Present ☐ 0.5 ☐ 1
   Left
   Present ☐ 0.5 ☐ 1

5. Monofilament
   Normal ☐ 1 Reduced ☐ 0.5 Absent ☐ 0
   Right
   Normal ☐ 1 Reduced ☐ 0.5 Absent ☐ 0
   Total Score ___________ /10 Points

MNSI, © University of Michigan, 2000
PAIN RATING SCALE
(English)

Title: ........................................ Date: ........................................
First Name: ........................................ Patient number: ........................................
Surname: ........................................ Clinic: ........................................

Please mark the scale below to show how intense your pain is. A zero (0) means no pain, and ten (10) means extreme pain.

How intense is your pain now?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>no pain</td>
<td>extreme pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How intense was your pain on average last week?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>no pain</td>
<td>extreme pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Now please use the same method to describe how distressing your pain is.

How distressing is your pain now?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>not at all distressing</td>
<td>extremely distressing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How distressing was your pain on average last week?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>not at all distressing</td>
<td>extremely distressing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Now please use the same method to describe how much your pain interferes with your normal everyday activities.

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>does not interfere</td>
<td>interferes completely</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you have had treatment for your pain, how much has this relieved (taken away) the pain?

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>no relief</td>
<td>complete relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>9</td>
<td>8</td>
<td>7</td>
<td>6</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>لا يوجد ألم</td>
<td>لا يوجد ألم المتوسط الأسبوع الماضي</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10</th>
<th>9</th>
<th>8</th>
<th>7</th>
<th>6</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>مزعج بشدة</td>
<td>غير مزعج</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10</th>
<th>9</th>
<th>8</th>
<th>7</th>
<th>6</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>لا يوجد ألم المتوسط الأسبوع الماضي</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10</th>
<th>9</th>
<th>8</th>
<th>7</th>
<th>6</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>لا يداخل</td>
<td>لا يداخل</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

لا يوجد شعور من الألم، كيف كان هذا سيرحتك من الألم (ذهب علك الألما؟)

<table>
<thead>
<tr>
<th>100%</th>
<th>90%</th>
<th>80%</th>
<th>70%</th>
<th>60%</th>
<th>50%</th>
<th>40%</th>
<th>30%</th>
<th>20%</th>
<th>10%</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>لازالة</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chronic Illness Resources Survey (CIRS)

The following questions ask about a variety of different resources that people may use to manage their illness. For each item, select the number that best indicates your experience over the *past 6 months*.

<table>
<thead>
<tr>
<th>Over the past 6 months, to what extent:</th>
<th>Not at all</th>
<th>A little</th>
<th>A moderate amount</th>
<th>Quite a bit</th>
<th>A great deal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Has your doctor involved you as an equal partner in making decisions about illness management strategies and goals? (HC)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Has your doctor or other health care advisor listened carefully to what you had to say about your illness? (HC)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Has your doctor or other health care provider thoroughly explained the results of tests you had done (e.g., cholesterol, blood pressure, or other laboratory tests)? (HC)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Have family or friends exercised with you? (FF,E)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Have you shared healthy low-fat recipes with friends or family members? (FF,D)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Family or friends bought food or prepared food for you that were especially healthy or recommended? (FF,D)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. Have you focused on the things you did well to manage your illness instead of those you did not? (P)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. Have you thought about or reviewed how you were doing in accomplishing your disease management goals? (P)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. Have you arranged your schedule so that you could more easily do the things you needed to do for your illness? (P)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Have you walked or exercised outdoors in your neighborhood? (N,E)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. Have you walked or done other exercise activities with neighbors? (N,E)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Over the past 6 months, to what extent:</td>
<td>Not at all</td>
<td>A little</td>
<td>A moderate amount</td>
<td>Quite a bit</td>
<td>A great deal</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------</td>
<td>---------</td>
<td>------------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>12. Have you eaten at a restaurant that offered a variety of tasty, low-fat food choices? (N,D)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>13. Have you gone to parks for picnics, walks, or other outings? (N)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>14. Have you read articles in newspapers or magazines about people who were successfully managing a chronic illness? (M)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>15. Have you had health insurance that covered most of the costs of your medical needs including medicine? (MP)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>16. Have you seen billboards or other advertisements that encouraged not smoking, low-fat eating, or regular exercise? (MP)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>17. Have you attended free or low-cost meetings (for example, Weight Watchers, church groups, hospital programs) that supported you in managing your illness? (O)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>18. Have you volunteered your time for local organizations or causes? (O)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>19. Have you attended wellness programs or fitness facilities? (O)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>20. Have you had a flexible work schedule that you could adjust to meet your needs? (Leave blank if you don’t work.) (W)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>21. Has your workplace had rules or policies that made it easier for you to manage your illness (such as no smoking rules or time off work to exercise)? (Leave blank if you don’t work.) (W)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
<tr>
<td>22. Have you had control over your job in terms of making decisions and setting priorities? (Leave blank if you don’t work.) (W)</td>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

HC = Health Care; FF = Friends/Family; D = Dietary; P = Personal; N = Neighborhood; E = Exercise; MP = Media/Policy; O = Organizational; W = Work or Volunteer Subscales. Use mean of contributing items to create scales.
APPENDIX

THE S-LANSS PAIN SCORE

Leeds Assessment of Neuropathic Symptoms and Signs (self-complete)

NAME______________________________________ DATE____________________

• This questionnaire can tell us about the type of pain that you may be experiencing. This can help in deciding how best to treat it.

• Please draw on the diagram below where you feel your pain. If you have pain in more than one area, only shade in the one main area where your worst pain is.

• On the scale below, please indicate how bad your pain (that you have shown on the above diagram) has been in the last week where: '0' means no pain and '10' means pain as severe as it could be.

NONE 0 1 2 3 4 5 6 7 8 9 10 SEVERE PAIN

• On the other side of the page are 7 questions about your pain (the one in the diagram).

• Think about how your pain that you showed in the diagram has felt over the last week. Please circle the descriptions that best match your pain. These descriptions may, or may not, match your pain no matter how severe it feels.

• Only circle the responses that describe your pain. Please turn over.
**S-LANSS**

1. In the area where you have pain, do you also have 'pins and needles', tingling or prickling sensations?
   
   a) NO – I don’t get these sensations (0)
   
   b) YES – I get these sensations often (5)

2. Does the painful area change colour (perhaps looks mottled or more red) when the pain is particularly bad?
   
   a) NO – The pain does not affect the colour of my skin (0)
   
   b) YES – I have noticed that the pain does make my skin look different from normal (5)

3. Does your pain make the affected skin abnormally sensitive to touch? Getting unpleasant sensations or pain when lightly stroking the skin might describe this.
   
   a) NO – The pain does not make my skin in that area abnormally sensitive to touch (0)
   
   b) YES – My skin in that area is particularly sensitive to touch (3)

4. Does your pain come on suddenly and in bursts for no apparent reason when you are completely still? Words like ‘electric shocks’, jumping and bursting might describe this.
   
   a) NO – My pain doesn’t really feel like this (0)
   
   b) YES – I get these sensations often (2)

5. In the area where you have pain, does your skin feel unusually hot like a burning pain?
   
   a) NO – I don’t have burning pain (0)
   
   b) YES – I get burning pain often (1)

6. Gently rub the painful area with your index finger and then rub a non-painful area (for example, an area of skin further away or on the opposite side from the painful area). How does this rubbing feel in the painful area?
   
   a) The painful area feels no different from the non-painful area (0)
   
   b) I feel discomfort, like pins and needles, tingling or burning in the painful area that is different from the non-painful area (5)

7. Gently press on the painful area with your finger tip then gently press in the same way onto a non-painful area (the same non-painful area that you chose in the last question). How does this feel in the painful area?
   
   a) The painful area does not feel different from the non-painful area (0)
   
   b) I feel numbness or tenderness in the painful area that is different from the non-painful area (3)

**Scoring:** a score of 12 or more suggests pain of predominantly neuropathic origin
تقييم ليدز للأعراض والعلامات ذات النشأة العصبية (مذكى الإكمال)
الاسم: 
التاريخ: 

- هذا الاستبان يمكن أن يساعد في معرفة نوع الألم الذي تصاب به، ويمكن أن يساعد في تحديد أفضل علاج.
- الرجاء تحديد مكان شعورك بالألم على الرسم أسفله. إذا كنت تشعر بالألم في أكثر من مكان ظل المكان الرئيسي الذي تشعر فيه بالألم.

- على النقيض المبين أعلاه، تحديد درجة الألم خلال الأسبوع الماضي، والذي تم تحديده في الرسم أعلاه.

حيث أن 0 لا يوجد ألم و 10 ألم شديد.
لا يوجد ألم 0 1 2 3 4 5 6 7 8 9 10 ألم شديد.

- في الصفحة التالية توجد سبع أسئلة عن ألمك (الذي بيته في الشكل).
- أذكر كيف كان شعورك بالألم الذي حدثه بالشكل في الأسبوع الماضي. ضع علامة على الأوراق المناسبة لألمك هذا.
- الأعراض قد تتعلق أو لا تتعلق بألمك بعض الظلال عن شدته.
- فقط ضع دائرة على الإجابة التي تصف ألمك. الرجاء أغلب الصفحة.
The FCI is a measure of the effect of comorbidity on physical functioning.

Choose all conditions that apply:

□ Arthritis (Rheumatoid and Osteoarthritis
Osteoporosis)
□ Asthma
□ Chronic Obstructive Pulmonary Disease, □ Acute Respiratory Distress Syndrome, or emphysema
□ Angina
□ Congestive heart failure
□ Heart attack (myocardial infarct)
□ Neurological disease (multiple sclerosis or Parkinson’s’)
□ Stroke or transient ischemic attack
□ Peripheral vascular disease
□ Diabetes (type 1 and 2)
□ Upper gastrointestinal disease (ulcer, hernia, reflux)
□ Depression
□ Anxiety or Panic Disorders
□ Visual impairment (cataracts, glaucoma, macular degeneration)
□ Hearing impairment (very hard of hearing, even with hearing aids)
□ Degenerative disc disease (back disease, spinal stenosis, or severe chronic back pain)
□ Obesity and or BMI >30

Total score:
Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an □ in the one box that best describes your answer.

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>□1</td>
<td>□2</td>
<td>□3</td>
<td>□4</td>
<td>□5</td>
</tr>
</tbody>
</table>

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   □ Yes, limited a lot
   □ Yes, limited a little
   □ No, not limited at all

   a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   □1 □2 □3

   b Climbing several flights of stairs
   □1 □2 □3

SF-12® Health Survey © 1994, 2002 by QualityMetric Incorporated and Medical Outcomes Trust. All Rights Reserved.
SF-12® a registered trademark of Medical Outcomes Trust.
(SF12v2 Standard, US Version 2.0)
3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

- Accomplished less than you would like ........................................... □ 1 .... □ 2 .... □ 3 .... □ 4 .... □ 5
- Were limited in the kind of work or other activities ........................................... □ 1 .... □ 2 .... □ 3 .... □ 4 .... □ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

- Accomplished less than you would like ........................................... □ 1 .... □ 2 .... □ 3 .... □ 4 .... □ 5
- Did work or other activities less carefully than usual ........................................... □ 1 .... □ 2 .... □ 3 .... □ 4 .... □ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little bit</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>
6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

a. Have you felt calm and peaceful? □ □ □ □ □

b. Did you have a lot of energy? □ □ □ □ □

c. Have you felt downhearted and depressed? □ □ □ □ □

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
<tr>
<td>□ □ □ □ □</td>
<td>□ □ □ □ □</td>
<td>□ □ □ □ □</td>
<td>□ □ □ □ □</td>
<td>□ □ □ □ □</td>
</tr>
</tbody>
</table>

Thank you for completing these questions!
حالتك الصحية العامة

يستفسر هذا الاستبيان عن وجهة نظرك في صحتك. هذه المعلومات سوف تساعد على تتبع ما تشعر به ومدى قدرتك على أداء نشاطتك المعتمدة. نشكرك على الإجابة عن هذه الأسئلة.

لكل سؤال من الأسئلة التالية يرجى وضع علامة في المربع الخاص بالإجابة التي تصف بشكل أفضل ما تشعر به.

1. بشكل عام، هل تعتبر أن صحتك:

<table>
<thead>
<tr>
<th>متزئة</th>
<th>جيدة جداً</th>
<th>جيدة</th>
<th>لا بأس بها</th>
<th>ضعيفة</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

2. الأسئلة التالية تدور حول النشاطات التي قد تقوم بها أثناء يوم عادي. هل صحتك الآن تحدد من قدرتك على القيام بالأنشطة التالية؟ إذا كان كذلك، فإلى أي حد؟

<table>
<thead>
<tr>
<th>لا بل تشعرها كثيراً</th>
<th>تشعرها قليلاً</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

- النشاطات المتعددة مثل تحريك طالبة أو دفع مكنسة كهربائية، أو لعب البولينغ أو اللمبرتيد
- صعود النزول لعدة طوابق
3. خلال الأسابيع الأربعة الماضية، كم من الوقت حصلت معي أي من المشاكل التالية خلال تأدية عملك أو نشاطاتك اليومية العادية الأخرى كنتيجة لصحتك الجسدية؟

<table>
<thead>
<tr>
<th>كل الوقت</th>
<th>معظم الوقت</th>
<th>بعض الوقت</th>
<th>قليل من الوقت</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

أ. أنجزت أقل مما كنت ترغب...

ب. كنت محدودا في نوع العمل أو النشاطات الأخرى...

4. خلال الأسابيع الأربعة الماضية، كم من الوقت حصلت معي أي من المشاكل التالية خلال تأدية عملك أو نشاطاتك اليومية العادية الأخرى كنتيجة لمشاكل عاطفية (مثل شعورك بالاكتئاب أو القلق)؟

<table>
<thead>
<tr>
<th>كل الوقت</th>
<th>معظم الوقت</th>
<th>بعض الوقت</th>
<th>قليل من الوقت</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

أ. أنجزت أقل مما كنت ترغب...

ب. أديت العمل أو النشاطات الأخرى...

ب. اعتمد أكثر من المعتاد...

5. خلال الأسابيع الأربعة الماضية، إلى أي مدى تعرضك للألم مع عملك العادي (بما في ذلك عملك خارج المنزل والعامل المنزلي)؟

<table>
<thead>
<tr>
<th>لم يتعثر أبداً</th>
<th>تعارض بشكل قليل</th>
<th>تعارض بشكل متوسط</th>
<th>تعارض بشكل كبير</th>
<th>تعارض بشكل كبير جداً</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>
6. هذه الأسئلة تدور حول ما تشعر به وكيف سارت الأمور معك خلال الأسابيع الأخيرة الماضية. الرجاء إعطاء إجابة واحدة عن كل سؤال بحيث تكون الأقرب لما كنت تشعر به. كم من الوقت خلال الأسابيع الأخيرة الماضية...

<table>
<thead>
<tr>
<th>كل الوقت</th>
<th>معظم الوقت</th>
<th>بعض الوقت</th>
<th>قليل من الوقت</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

أ - هل أحسنت في الحموضة والطمعانية؟
ب - هل كانت لديك مشاعر كيبرة؟
ج - هل أحسست بالحزن والاكتئاب؟

7. خلال الأسابيع الأخيرة الماضية، كم من الوقت تضايقك صحتك الجسدية أو مشاكلك العاطفية مع نشاطاتك الاجتماعية (مثل زيارة الأصدقاء والأقارب، الخ...)؟

<table>
<thead>
<tr>
<th>كل الوقت</th>
<th>معظم الوقت</th>
<th>بعض الوقت</th>
<th>قليل من الوقت</th>
</tr>
</thead>
<tbody>
<tr>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

شكرًا على الإجابة عن هذه الأسئلة!
The Medical Outcome Study-Social Support Survey

Table 2. Individual items of the eight-item mMOS-SS and 19-item MOS-SS

<table>
<thead>
<tr>
<th>Number</th>
<th>Question</th>
<th>mMOS-SS</th>
<th>MOS-SS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>If you needed it, how often is someone available...</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 2</td>
<td>to help you if you were confined to bed?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 3</td>
<td>to take you to the doctor if you need it?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 4</td>
<td>to prepare your meals if you are unable to do it yourself?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 5</td>
<td>to help with daily chores if you were sick?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 6</td>
<td>to have a good time with?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 7</td>
<td>to turn to for suggestions about how to deal with a personal problem?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 8</td>
<td>who understands your problems?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 9</td>
<td>to love and make you feel wanted?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Item 10</td>
<td>you can count on to listen to you when you need talk?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 11</td>
<td>to give you good advice about a crisis?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 12</td>
<td>who shows you love and affection?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 13</td>
<td>to give you information to help you understand a situation?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 14</td>
<td>to confide in or talk to about yourself or your problems?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 15</td>
<td>who hugs you?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 16</td>
<td>to get together with for relaxation?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 17</td>
<td>whose advice you really want?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 18</td>
<td>to do things with to help you get your mind off things?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 19</td>
<td>to share your most private worries and fears with?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Item 20</td>
<td>to do something enjoyable with?</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Subscales

| Subscale 1 | Emotional/informational: Items 6, 7, 9, 10, 12, 13, 16, 18 | X       |
| Subscale 2 | Tangible*: Items 1–4                                        | X       |
| Subscale 3 | Affectionate: Items 8, 11, 14                                | X       |
| Subscale 4 | Positive social interaction: Items 5, 15, 19                | X       |
| Subscale 5 | Instrumental*: Items 1–4                                    | X       |
| Subscale 6 | Emotional: Items 5–8                                        | X       |

Abbreviations: mMOS-SS, modified Medical Outcomes Study Social Support Survey; MOS-SS, Medical Outcomes Study Social Support Survey.

* Tangible support and Instrumental support are synonyms [22], subscale labels were chosen by original authors [24,27].
القيام بمسح الدعم الاجتماعي (MOS social support questionnaire)

يتعلق بعض الناس أحبابهم بالناس الآخرين الرفقة أو المساعدة أو أي أнолог أخرى من الدعم. كم من المرات يكون أي من الأنواع الثلاثة من الدعم متاحة لك إذا احتاجت لها؟ أرسم دائرة حول رقم واحد من كل خط.

<table>
<thead>
<tr>
<th>الدعم العاطفي (أعلامي)</th>
<th>الدعم الملموس</th>
<th>الشعور بالحب والإلهة</th>
<th>التفاعل الاجتماعي الإيجابي</th>
<th>بند إضافي</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>5 4 3 2 1</td>
</tr>
</tbody>
</table>
APPENDIX D
EDUCATIONAL FLYER FOR PARTICIPANTS
Nerve damage caused by high blood sugar levels in the body from diabetes is also called diabetic neuropathy. Most people with diabetes will develop some nerve damage, especially as they get older and have diabetes for many years.

Nerve problems are more common if you have diabetes and:
- Have problems controlling your blood sugar
- Are overweight
- Have high blood pressure
- Have high cholesterol

Types of Nerve Damage
There are several types of nerve damage that can occur with diabetes, but the two more common types are:
- Peripheral neuropathy that often causes pain or loss of feeling in the toes, feet, legs, hands and arms. Most often the feet and legs are affected before the hands and arms.
- Autonomic neuropathy that causes changes in digestion of food, bowel and bladder function and sexual response. It can also affect the nerves that control the heart and blood vessels, lungs and eyes. This type is also linked to something called hypoglycemia unawareness, which happens when you no longer have warning signs of low blood sugar levels.
Prevent Nerve Damage

Keep your blood sugar in a normal range. Work with your doctor and diabetes care team to learn how to manage your blood sugar levels.

As part of your care, your doctor should do a foot exam every year to check if you have any sign of loss of feeling in your toes or feet.

Daily Foot Care

Check your feet every day for any open skin, sores or red spots. You may have a sore spot and not feel it because of the nerve damage. If you find skin problems, talk to your doctor.

- Clean your feet each day with warm water and mild soap. Do not soak your feet. Dry your feet well with a soft towel. Be sure to dry between your toes.
- Check your feet and toes for cuts, scrapes, blisters, red spots, sores or other problems. Be sure to check the top, bottom and sides of your feet. Check under and around each toe. You may need to use a mirror or get someone to help you check the bottom of your feet.
- Apply a moisturizing lotion to the skin of your feet, but avoid lotion between the toes.
- Use a pumice stone gently to smooth calluses or corns after a shower. Never cut or shave off calluses or corns.
- When toe nails get long, cut the nails straight across and file with an emery board to smooth any rough edges.
- Wear clean, dry socks that fit comfortably.
• Wear shoes or slippers to protect your feet. You should never go barefoot. Wear shoes that fit well and offer good support. Be sure to check inside your shoes before putting them on to make sure there are no objects in them and there are no tears, rough spots or sharp edges.

Signs of Nerve Damage
Signs will vary based on the nerves that are affected. Some people have no signs at all. Some signs may get worse over time and some people report the signs are worse at night. Signs may include:
• Numbness, tingling, loss of feeling or pain in the toes, feet, legs or fingers, hands and arms
• Muscle loss in the feet or hands
• Nausea and vomiting or problems with indigestion
• Diarrhea or constipation
• Problems with urine flow or control
• Dizziness or fainting when standing or sitting up that causes a drop in blood pressure called orthostatic hypotension
• Weakness
• Erectile dysfunction in men or vaginal dryness in women
• Heart rate changes

If you have any of these signs, visit your doctor for a physical exam.
Your Care

Testing
Your doctor will examine you and ask you questions about any signs you have. Tests may be ordered such as:

- Nerve conduction study or electromyography (EMG) that uses electrical signals to check nerves.
- Ultrasound that uses sound waves to check organs such as your bladder or stomach.

Treatment of Your Nerve Damage
Treatment depends on the type of nerve damage you have and may include:

- Pain control with medicines, physical therapy or other treatments.
- Medicines to treat diarrhea or constipation.
- Eating small amounts of food every few hours, and limiting fats and fiber for indigestion problems.
- Physical therapy to help with coordination issues.
- If you have foot problems, talk to your doctor about seeing a foot doctor called a podiatrist. The nerves that go to the feet are often affected by diabetic neuropathy.
  - Loss of feeling may mean you do not feel a sore or blister.
  - Circulation problems may add to the risk of infection and slow healing in the feet.
Managing Your Diabetes

You also need to manage your diabetes as ordered by your doctor to keep your blood sugar levels in a normal range and prevent further nerve damage:

- Check your blood sugar often.
- Take your diabetes medicines as directed.
- Follow your meal plan.
- Exercise each day.
- Do daily foot care to protect your feet.

Talk to your doctor or nurse if you have any questions or concerns.


Unless otherwise stated, user may print or download information from www.healthinfotranslations.org for personal, non-commercial use only. The medical information found on this website should not be used in place of a consultation with your doctor or other health care provider. You should always seek the advice of your doctor or other qualified health care provider before you start or stop any treatment or with any symptoms you may have about a medical condition. This Ohio State University Wexner Medical Center, Mount Carmel Health System, OhioHealth and Nationwide Children’s Hospital are not responsible for injuries or damages you may incur as a result of your altering medical treatment or your failure to obtain treatment.
APPENDIX E

THE MINISTRY OF HEALTH IRB APPROVAL
Institutional Review Board, General Directorate of Health Affairs in Madinah

To: Awaaf Ibraheem

This is to certify that Institutional Review Board (IRB), General Directorate of Health Affairs in Madinah has reviewed all the submitted updated and amended documents from the ethical point of view and has approved your study titled: "Factors Associated with Diabetic Peripheral Neuropathy symptoms and quality of life among Saudis with Type 2 diabetes"

The committee is fully compliant with the conditions and principles of good clinical practice. The committee is constituted in accordance with the WHO and ICH-GCP guidelines and works according to written Standard Operating Procedures.

The IRB recommended granting permission of approval to conduct the project along the following terms:

1. If there are any future amendments, they must be approved prior to implementation unless they are intended to reduce risk.
2. Monitoring the project may be subject to an audit or any other form of monitoring by the EEC.
3. All unanticipated or serious adverse events must be reported to the EEC within 5 days or according to the protocol.
4. Inform the IRB prior to making prospective changes to the study procedure.
5. Upon the study completion, the PI is expected to submit a final report at the end of the study.

Please note that this approval is valid for one year commencing from the date of this letter.

Head of IRB Committee
Dr. Abdulla Al-Adabhi

IRB 318
DATE 05-11-1440
Institutional Review Board King Fahad Hospital – Medina

TO : Dr. Awatif Ibraheem

This is to certify that departure research committee King Fahad Hospital – Medina Al Munawarch has reviewed all submitted updated and amended documents from the ethical point of view your study (ADCARE) titled: Factory Associated with Diabetic Peripheral Neuropathy Symptoms and Quality of Life among Saudi With Type 2 Diabetes Mellitus.

All the updated documents received by the committee below have been reviewed and approved.

The committee is fully compliant with the conditions and principles of good clinical practice, the committee is constituted in accordance with the WHO and ICH – GCP guidelines and works according to written standard operating procedures.

Below are the list of IRB members that reviewed and approved the above mentioned documents, kindly to know that only those IRB members who are independent of the investigator and sponsor vote / provide opinion on trial related matter:

Dr. Abeer Al-Harbi Head Of Committee
Dr. Ghassan Al-Sisi Member
Dr. Ahmed Al-Hejaili Member
Dr. Kawther Basheer Member
Dr. Fadwa Al-Dolfi Member

The REC recommended granting permission of approval to conduct the project along the following terms:

1- If there are any further amendments, they must be approved prior to implementation unless they are intended to reduce risk.
2- Monitoring: the project may be subject to an audit or any other form of monitoring by REC.
3- All unanticipated or serious adverse events must be reported to the REC within 5 days or according to the protocol.
4- Inform the IRB prior to making prospective changes to the study procedure.
5- Upon the study completion, the PI is expected to submit a final report at the end of the study.

Please note that this approval is valid for any year commencing from the date of this letter.

Head Of IRB Committee
King Fahad Hospital
Dr. Abeer Al-Harbi

Medical Director
Dr. Badr Al-Hosein

www.moh.gov.sa | ® 937 | ® SaudiMOH | ® MOHPortal | ® SaudiMOH | ® Saudi_Moh
APPENDIX F

CERTIFICATE OF TRANSLATION OF THE CIRS
أعذر الرم الذي يعتبر عند تحريكه داخل المست الأسمر الماضية.

<table>
<thead>
<tr>
<th>مسألة متميزة</th>
<th>لا على الاطلاق</th>
<th>لا على الاطلاق</th>
<th>لا على الاطلاق</th>
<th>لا على الاطلاق</th>
<th>لا على الاطلاق</th>
</tr>
</thead>
<tbody>
<tr>
<td>هل قادر مثلك على تقديم مساعدة عند خروج الرم؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم أطباق في القارئ؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>هل قادر مثلك على تقديم خدمات في المطالبة؟</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
1. هل قمت بالكامل في ملازم وموفر عدد من الحيوانات؟
2. هل دخلت إلى المدارس العامة للتعليمبذل، المتطلبات، أو للخبراء؟
3. هل قمت بتعبئة أي مقاطع في الورق أو الصحف عن
4. هل قمت بتعبئة أي مقاطع في النظرات العامة عن
5. هل تعلم نفسك عن بعض الملاحظات، أو
6. هل تعلم نفسك عن بعض الملاحظات، أو
7. هل تعلم نفسك عن بعض الملاحظات، أو
8. هل تعلم نفسك عن بعض الملاحظات، أو
9. هل تعلم نفسك عن بعض الملاحظات، أو
10. هل تعلم نفسك عن بعض الملاحظات، أو
11. هل تعلم نفسك عن بعض الملاحظات، أو
12. هل تعلم نفسك عن بعض الملاحظات، أو
13. هل تعلم نفسك عن بعض الملاحظات، أو
14. هل تعلم نفسك عن بعض الملاحظات، أو
15. هل تعلم نفسك عن بعض الملاحظات، أو
16. هل تعلم نفسك عن بعض الملاحظات، أو
17. هل تعلم نفسك عن بعض الملاحظات، أو
18. هل تعلم نفسك عن بعض الملاحظات، أو
19. هل تعلم نفسك عن بعض الملاحظات، أو
20. هل تعلم نفسك عن بعض الملاحظات، أو
21. هل تعلم نفسك عن بعض الملاحظات، أو
22. هل تعلم نفسك عن بعض الملاحظات، أو
23. هل تعلم نفسك عن بعض الملاحظات، أو
24. هل تعلم نفسك عن بعض الملاحظات، أو
25. هل تعلم نفسك عن بعض الملاحظات، أو
...
APPENDIX G

LITERATURE REVIEW TABLES
Table G1. Saudi-based cross-sectional studies on risk factors of DPN and QoL

<table>
<thead>
<tr>
<th>Author (s)</th>
<th>Sample</th>
<th>Variable (s) Studied</th>
</tr>
</thead>
</table>
| AlAboudi et al. (2016) | n=75, T2DM, males =77%, duration of DM=12.6±8.4 yrs., no demographic data.  | DV: QoL  
Knowledge about DM, attitudes.                                                |
| Algeffari (2018)     | n=233, T1DM n= 9, age=56.9 yrs., no demographic data.                  | DV; painful DPN  
IVs: HbA1c, FBG, comorbidity, compliance, age, gender, BP, BMI, smoking, & duration of DM. |
| Alharirri et al. (2017) | n=229, males=54%, T2DM=74%, aged=51 yrs.                              | Knowledge about foot ulcers and practices of foot-care.                                |
| Alhayek et al. (2013) | n=283, T2DM, age=56 yrs., males=63%, no demographic data.               | DV: QoL  
IV: age, gender, HbA1c, BMI, DM complications.                                    |
| Alodhayani et al. (2017) | n=350, males=64%, T2DM, aged=58 years, no demographic data.              | Knowledge and practices of foot-care.                                                |
| ALQuilti (2015)      | n=198, T2DM, males=37%, aged=52 yrs., duration of DM=10. 5 yrs. (no further demographic data). | DV: painful DPN  
IVs: age, gender, HTN, smoking, years DM, macrovascular and microvascular complications, glycaemia, & insulin use. |
| Mojaddidi et al. (2011) | n=263, T1DM=39, T2DM=224.                                             | DV: DPN  
IV: age, duration of DM, smoking, HbA1c, & gender.                               |
| Halawa et al. (2010) | n=1039, T2DM=94%, aged=52 yrs., males=53%, Middle Eastern=60%, Asian=22%, Black= 8%. | DV: painful DPN  
IV: age, gender, BMI, duration of DM, smoking, & race.                           |
| Hu et al. (2014)     | n=598, females=38%, aged=50 yrs., illiterate=39%, low income=44%.       | DV: foot ulcers  
IV: age, gender, BMI, income status, HTN, biomarkers, & duration of DM.         |
<table>
<thead>
<tr>
<th>Author (s)</th>
<th>Sample</th>
<th>Variable (s) Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang et al. (2014)</td>
<td>n=552, T2DM, age=53.2 yrs., males=62%</td>
<td>DV: DPN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IV: age, gender, HbA1c, BMI, lipid profile, HTN, education level, inflammatory markers.</td>
</tr>
</tbody>
</table>

Table G2. Non-experimental studies on risk factors of DPN and QoL (Other countries)

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Aim</th>
<th>Sample</th>
<th>Variable(s) Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bansal et al. (2014)</td>
<td>Prevalence, compare groups, risk factors; sex-specific differences</td>
<td>n=1637, T2DM, age 52 yrs.</td>
<td>DV: DPN IVs: demographics, years w DM, cardiovascular risk factors, alcohol, &amp; macrovascular.</td>
</tr>
<tr>
<td>Dyck et al. (1993)</td>
<td>The prevalence of DPN symptoms and severity assessment</td>
<td>n=64,573, T2DM=663, males= aged=47 yrs., White=99%</td>
<td>DV: DPN</td>
</tr>
<tr>
<td>Javed et al. (2014)</td>
<td>Assess gender-based differences</td>
<td>n=125, T1DM=10% and T2DM, n= 57 males, n=68 females (equal sample size assumed)</td>
<td>DV: DPN IV: gender, age, duration of DM, duration of DPN.</td>
</tr>
<tr>
<td>Pei et al. (2106)</td>
<td>Assess the effect of regular exercise on DPN</td>
<td>n=122, T2DM, females=29%, aged=60 yrs., had DPN for=22 months.</td>
<td>DV: DPN IV: Exercise frequency.</td>
</tr>
<tr>
<td>Qureshi et al. (2017)</td>
<td>Predictors of severity of DPN symptoms</td>
<td>n= 800, T2DM=80%.</td>
<td>DV: DPN IVs:</td>
</tr>
<tr>
<td>Riandhini et al. (2017)</td>
<td>Examine differences in QoL between</td>
<td>n=160, T2DM, (n=80, DPN), (n=80 non-</td>
<td>DV: QoL IV: DPN</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Aim</td>
<td>Sample</td>
<td>Variable(s) Studied</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Veresi et al. (2015)</td>
<td>Screen undiagnosed DPN Romanian people w/ Norfolk QoL</td>
<td>n= 21,261, T1DM=10%, T2DM=90%, males=9,503, women=10,086 (no further details).</td>
<td>DV: QoL IV: DPN symptoms severity</td>
</tr>
<tr>
<td>Xu et al. (2014)</td>
<td>Examine relationship between DPN and Glycemic variability</td>
<td>n=90, T2DM, aged=59.2 yrs. female=50%</td>
<td>DV: DPN IVs: glycemic variability, BMI, HbA1c, blood glucose standard deviation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Design</th>
<th>Aim(s)</th>
<th>Sample</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boyd et al. (2011)</td>
<td>Randomized trial</td>
<td>Compare effect of two drugs</td>
<td>n=54, T2DM; Age=35–75, Women=11, Men=33, HbA1c=7.0%</td>
<td>DV: QoL, IV: DPN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Topeiramate vs. Ruboxistaurin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clair et al. (2015)</td>
<td>Systematic review</td>
<td>Review evidence on smoking and DPN</td>
<td>n=38 studies, total n==33,152, T2DM, males=50%</td>
<td>DV: DPN, IVs: cigarette smoking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Papanas &amp; Ziegler (2015)</td>
<td>Topical review</td>
<td>Review of risk factors and comorbidities of DPN.</td>
<td>n=159, T2DM w DPN</td>
<td>DV: DPN, IVs: Clinical, individual factors, depression, cognitive dysfunction, HTN, &amp; PVD.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoo et al. (2015)</td>
<td>Interventional</td>
<td>Effect of exercise on painful DPN symptoms.</td>
<td>n=14, T2DM, w painful DPN, age=57 yrs., females=</td>
<td>DV: painful DPN, IVs: regular exercise</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Design</th>
<th>Aim</th>
<th>Sample</th>
<th>Variable (s) Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agathos et al. (2018)</td>
<td>RCT</td>
<td>Effect of alpha lipoic acid treatment on symptoms</td>
<td>(n=72, T2DM=84%, aged=65 yrs., males=39%, &amp; duration of DM=13 yrs.)</td>
<td>DV: DPN symptoms &amp; QoL IV: supplementation of alpha lipoic acid</td>
</tr>
<tr>
<td>Assuncao et al., 2020</td>
<td>Observational</td>
<td>Demographic and clinical factors associated with DPN</td>
<td>(n=359, T2DM, DPN, males=54.8%, &amp; aged &gt;65 yrs.=70%)</td>
<td>DV: DPN symptoms IVs: HbA1c, gender, age, &amp; duration of DM</td>
</tr>
<tr>
<td>Ausili et al. (2017)</td>
<td>Observational</td>
<td>Description of self-care, clinical factors and QoL</td>
<td>(n=302, T2DM, males=53.6%, aged=68 yrs., duration of DM=10 yrs., with DM complications)</td>
<td>DV: self-care, QoL IV: HbA1c, comorbidity, smoking, gender, age, &amp; BMI.</td>
</tr>
<tr>
<td>Girach et al. (2019)</td>
<td>Systematic review</td>
<td>Review on DPN &amp; QoL</td>
<td>(n=60, DPN=71.2%)</td>
<td>DV: QoL IV: peripheral neuropathy</td>
</tr>
<tr>
<td>Kathe et al. (2018)</td>
<td>Observational</td>
<td>Assessment of SF-12 reliability and validity</td>
<td>(n=2214, aged 58.2 yrs., T2DM, duration of DM=9 yrs., females=51%, White=61%, Black=15%, &amp; Hispanic=16%)</td>
<td>Internal consistency, test-retest reliability, construct, criterion, &amp; concurrent validity.</td>
</tr>
<tr>
<td>Markle-Reid et al. (2018)</td>
<td>Interventional</td>
<td>Impact of community program intervention on QoL</td>
<td>(n=159, T2DM, aged=74 yrs., females=45%, with comorbidity)</td>
<td>DV: QoL IV: self-management intervention</td>
</tr>
</tbody>
</table>

RCT: Randomized controlled trials.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Type of Study</th>
<th>Participants</th>
<th>DV</th>
<th>IVs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mejias &amp; Ramphul (2018)</td>
<td>Observational</td>
<td>Prevalence and risk factors of peripheral artery diseases</td>
<td>(n=600, T2DM, males=50%, aged=60.6 yrs., Hispanic=80%, Black=12%)</td>
<td>PAD</td>
<td>DPN, foot ulcers, non-traumatic amputation, race, smoking, hypertension, hyperlipidemia</td>
</tr>
<tr>
<td>Singh-Franco &amp; Jacobs (2017)</td>
<td>Observational</td>
<td>Patient perspective on DPN</td>
<td>(n=124, T1DM, T2DM, DPN, aged=57.2 yrs., females=58.9%, Black=53.2, &amp; White=25.8%)</td>
<td>QoL</td>
<td>DPN, Duration of DM, number of DPN symptoms, activity of daily living, DPN treatment</td>
</tr>
<tr>
<td>van Laake-Geelen (2019)</td>
<td>Systematic</td>
<td>Review on combination of physical and psychological therapy of DPN</td>
<td>(n=8 randomized control trials, T1DM, T2DM, participants aged&gt;18 yrs., DPN)</td>
<td>QoL</td>
<td>Physical activity, psychological therapy</td>
</tr>
<tr>
<td>Venkataraman et al. (2019)</td>
<td>RCT</td>
<td>Effect of structured strength on QoL</td>
<td>(n=143, aged=62 yrs., females=56%, South Asian=77%, duration of DM=15.3 yrs., DPN)</td>
<td>QoL</td>
<td>Physical mobility, muscle strength, &amp; range of motion</td>
</tr>
<tr>
<td>Zeigler et al. (2018)</td>
<td>Observational</td>
<td>Prevalence &amp; risk factors of DPN</td>
<td>(n=1850, T2DM=51%, no DM=42%, males=44.7%, aged=65.7 yrs.)</td>
<td>DPN</td>
<td>Peripheral arterial disease, gender, age, BMI</td>
</tr>
</tbody>
</table>
APPENDIX H

INSTRUMENTS RELIABILITY AND ACCESSIBILITY
<table>
<thead>
<tr>
<th>Instrument</th>
<th>Permission needed</th>
<th>Website</th>
<th>Arabic version/validated</th>
<th>Psychometric Evidence</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michigan Neuropathy Symptoms Inventory Leeds</td>
<td>No</td>
<td>University of Michigan</td>
<td>No validation</td>
<td>Acceptable reliability and validity</td>
<td>Free</td>
</tr>
<tr>
<td>Assessment of Neuropathy Signs and Symptoms</td>
<td>Yes-obtained</td>
<td>Personal communication with authors</td>
<td>No validation</td>
<td>Acceptable reliability and validity</td>
<td>Free</td>
</tr>
<tr>
<td>Numeric Pain Rating Scale Chronic Illness Resources Survey</td>
<td>No</td>
<td>Yes, British Pain Society</td>
<td>No validation</td>
<td>Yes</td>
<td>Free</td>
</tr>
<tr>
<td>MOS-Social Support Survey</td>
<td>Yes</td>
<td>RAND</td>
<td>Yes</td>
<td>Acceptable reliability and validity</td>
<td>Free</td>
</tr>
<tr>
<td>SF-12v2</td>
<td>Yes-obtained</td>
<td>Optum</td>
<td>Yes</td>
<td>Acceptable reliability and validity</td>
<td>Free for students</td>
</tr>
<tr>
<td>Summary of DM Activities Monofilament</td>
<td>Yes-obtained</td>
<td>ORI.org</td>
<td>Yes</td>
<td>Acceptable reliability and validity</td>
<td>$$</td>
</tr>
<tr>
<td>Monofilament</td>
<td>NA</td>
<td>Amazon</td>
<td>NA</td>
<td>Yes</td>
<td>$$</td>
</tr>
</tbody>
</table>
Table H2. Comparison of MNSI, S-LANSS and Numerical Pain Rating Scale of DPN

<table>
<thead>
<tr>
<th>Symptoms/Variables</th>
<th>S-LANSS</th>
<th>MNSI</th>
<th>Pain Rating scale</th>
</tr>
</thead>
<tbody>
<tr>
<td># items</td>
<td>5 questions; 2 exam items</td>
<td>15 questions; 3 exam items</td>
<td>6 questions</td>
</tr>
<tr>
<td>Symptoms/Variables</td>
<td>Dysesthesia</td>
<td>Numbness</td>
<td>Current pain</td>
</tr>
<tr>
<td></td>
<td>Autonomic</td>
<td>Burning</td>
<td>Severity</td>
</tr>
<tr>
<td></td>
<td>Evoked</td>
<td>Sensitivity</td>
<td>Last week</td>
</tr>
<tr>
<td></td>
<td>Paroxysmal</td>
<td>Cramps</td>
<td>Severity</td>
</tr>
<tr>
<td></td>
<td>Thermal</td>
<td>Prickling</td>
<td>Treatment helped</td>
</tr>
<tr>
<td></td>
<td>Allodynia</td>
<td>Hyperensitivity</td>
<td>Mood disability</td>
</tr>
<tr>
<td>Tender/numb</td>
<td>Heat cold feeling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 part</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
</tr>
<tr>
<td>Cotton and pin-prick</td>
<td></td>
<td>Appearance</td>
<td></td>
</tr>
<tr>
<td>Ulceration</td>
<td></td>
<td>Reflexes</td>
<td></td>
</tr>
<tr>
<td>SWMT</td>
<td></td>
<td>Vibration</td>
<td></td>
</tr>
<tr>
<td>Arabic validity</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Table H3. Reliability Estimates of the Study Tools as Reported in the Literature

<table>
<thead>
<tr>
<th>Tool</th>
<th>Cronbach Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michigan Neuropathy Symptoms Inventory</td>
<td>.91</td>
</tr>
<tr>
<td>Short-Leeds Assessment of Neuropathy Signs and Symptoms</td>
<td>.76</td>
</tr>
<tr>
<td>Pain Rating Scale</td>
<td>.95-.96</td>
</tr>
<tr>
<td>Chronic Illness Resources Survey</td>
<td>.82</td>
</tr>
<tr>
<td>MOS-Social Support Survey-Arabic</td>
<td>.78</td>
</tr>
<tr>
<td>SF-12v2-Arabic</td>
<td>.79-.80</td>
</tr>
<tr>
<td>Summary of Diabetes Self-care Activities-Arabic</td>
<td>.76</td>
</tr>
<tr>
<td>Monofilament (SWMT)*</td>
<td>.92</td>
</tr>
<tr>
<td>Functional Comorbidity Index</td>
<td>.91</td>
</tr>
</tbody>
</table>

*Interclass correlation coefficient
APPENDIX I

UNIVARIABLE REGRESSION MODEL
Table II. Univariable Coefficients of Aim 1

<table>
<thead>
<tr>
<th></th>
<th>Coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Foot care</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>0.057</td>
<td>.006</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>0.052</td>
<td>.231</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>0.025</td>
<td>.605</td>
</tr>
<tr>
<td>Age</td>
<td>0.007</td>
<td>.580</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>-0.002</td>
<td>.993</td>
</tr>
<tr>
<td>CIRS</td>
<td>0.350</td>
<td>.045</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.009</td>
<td>.041</td>
</tr>
<tr>
<td><strong>Health perception</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.809</td>
<td>.025</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-3.122</td>
<td>.001</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>-1.231</td>
<td>.212</td>
</tr>
<tr>
<td>Foot care</td>
<td>4.599</td>
<td>.018</td>
</tr>
<tr>
<td>Age</td>
<td>-0.140</td>
<td>.609</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>-1.181</td>
<td>.818</td>
</tr>
<tr>
<td>CIRS</td>
<td>10.349</td>
<td>.005</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.225</td>
<td>.025</td>
</tr>
<tr>
<td><strong>PCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.394</td>
<td>.007</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-1.032</td>
<td>.001</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>-1.045</td>
<td>.003</td>
</tr>
<tr>
<td>Foot care</td>
<td>0.366</td>
<td>.598</td>
</tr>
<tr>
<td>Age</td>
<td>-0.200</td>
<td>.036</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>-2.164</td>
<td>.229</td>
</tr>
<tr>
<td>CIRS</td>
<td>4.724</td>
<td>.000</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>-0.013</td>
<td>.711</td>
</tr>
<tr>
<td><strong>MCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S-LANSS</td>
<td>-0.171</td>
<td>.327</td>
</tr>
<tr>
<td>MNSI 1</td>
<td>-0.942</td>
<td>.009</td>
</tr>
<tr>
<td>MNSI 2</td>
<td>0.177</td>
<td>.665</td>
</tr>
<tr>
<td>Foot care</td>
<td>0.587</td>
<td>.466</td>
</tr>
<tr>
<td>Age</td>
<td>0.005</td>
<td>.967</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>-3.548</td>
<td>.089</td>
</tr>
<tr>
<td>CIRS</td>
<td>0.718</td>
<td>.640</td>
</tr>
<tr>
<td>MOS-SSS</td>
<td>0.176</td>
<td>.000</td>
</tr>
</tbody>
</table>
Table I2. Univariable Coefficients of Aim 2

<table>
<thead>
<tr>
<th></th>
<th>Coefficients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-LANSS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>-0.027</td>
<td>.935</td>
</tr>
<tr>
<td>FCI</td>
<td>0.898</td>
<td>.016</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.976</td>
<td>.392</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>-0.117</td>
<td>.820</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>-0.737</td>
<td>.612</td>
</tr>
<tr>
<td>Not-regular</td>
<td>-2.176</td>
<td>.085</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>1.431</td>
<td>.217</td>
</tr>
<tr>
<td>Age</td>
<td>0.011</td>
<td>.851</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.472</td>
<td>.677</td>
</tr>
<tr>
<td><strong>MNSI 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>0.300</td>
<td>.057</td>
</tr>
<tr>
<td>FCI</td>
<td>0.654</td>
<td>.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.512</td>
<td>.005</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>0.499</td>
<td>.042</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>-0.852</td>
<td>.209</td>
</tr>
<tr>
<td>Not-regular</td>
<td>-1.227</td>
<td>.037</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>1.012</td>
<td>.067</td>
</tr>
<tr>
<td>Age</td>
<td>0.009</td>
<td>.742</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.127</td>
<td>.811</td>
</tr>
<tr>
<td><strong>MNSI 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>-0.031</td>
<td>.833</td>
</tr>
<tr>
<td>FCI</td>
<td>0.080</td>
<td>.624</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.849</td>
<td>.086</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>0.394</td>
<td>.070</td>
</tr>
<tr>
<td>Exercise</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>-0.432</td>
<td>.066</td>
</tr>
<tr>
<td>Not-regular</td>
<td>-1.205</td>
<td>.027</td>
</tr>
<tr>
<td>Treated Dyslipidemia</td>
<td>-0.243</td>
<td>.639</td>
</tr>
<tr>
<td>Age</td>
<td>0.072</td>
<td>.006</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>-0.962</td>
<td>.048</td>
</tr>
</tbody>
</table>


based path analysis. Nursing Research, 66(6), 473-482. https://doi.org/10.1097/NNR.0000000000000244


of Chr1p35.1 (ZSCAN20-TLR12P) and Chr8p23.1 (HMGB1P46) with diabetic neuropathic pain. *Ebiomeditcine, 2*(10), 1386-1393. https://doi.org/10.1016/j.ebiom.2015.08.001


Awatef Ibraheem was born and raised in AlMadinah, Saudi Arabia. Before attending Loyola University Chicago, she attended King Abdul-Aziz University, Jeddah, Saudi Arabia, where she earned a Bachelor of Science in Nursing, with Highest Distinction, in 2006. From 2012 to 2014, Dr. Ibraheem went to the University of Illinois in Chicago for a Master of Science in Nursing. In 2014 she earned her master’s degree as an Adult Gerontology Primary Care Nurse Practitioner. She started her PhD program at Loyola in 2015. While in the program, she worked as a part-time faculty at Marcella Niehoff School of Nursing of Loyola University teaching clinical to undergraduate nursing students. She is a member of the Midwest Nursing Research Society and has been inducted into Sigma Theta Tau. Dr. Ibraheem holds a position as a Clinical Instructor in the Applied School of Medical Sciences of Taibah University, Yanbu, Saudi Arabia.