Deanship of Graduate Studies
Al-Quds University

The Effect of an Integrated Therapeutic Program of Wounds' Dressing, Debridement and Off-loading Techniques on Diabetic Foot Ulcer: A Retrospective Study

Karam Hatem Albarghouthy

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By
Karam Hatem Albarghouthy

B.Sc. Physiotherapy, Bethlehem University
Bethlehem- Palestine

Supervisor
Dr. Hadeel Halaweh

This thesis was submitted in partial fulfilment of the requirements for the Master's degree in Physiotherapy

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Thesis Approval

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Prepared by: Karam Hatem Albarghouthy

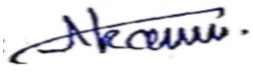
Registration Number: 21812027

Supervisor: Dr. Hadeel Halaweh

Master thesis submitted and accepted date: 15/12/2020

The names and signatures of the examining committee members are as follows:

Head of the committee: Dr. Hadeel Halaweh, Signature: 

Internal Examiner: Dr. Akram Amro, Signature: 

External Examiner: Dr. Mosab Amoudi, Signature: 

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Dedication

I dedicate this dissertation to my parents, Hatem and Fae'da, for their inspiration and encouragement. I also dedicate this dissertation to my wife Abeer, for her unwavering support and to my wonderful kids, AYA, Hatem, Ala'a and Mohammed, my brothers and my sister for being my source of joy and hope for the future.

Declaration

This thesis was submitted in partial fulfilment of the requirement for the Master's degree in physiotherapy.

I declare that the content of this thesis (or any part of the same) has not been submitted for a higher degree to any other university or institution.

Karam Hatem Albarghouthy

Signed: 

Date: 5/11/2020

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Abstract

Background: Diabetes is widely spread in the world, which leads to the occurrence of diabetic foot disease and diabetic foot ulcers (DFUs), which if left untreated may lead to amputate the foot and complications may lead to mortality.

Objective: To examine the effectiveness of an integrated therapeutic program of wounds dressing, debridement treatment, and off-loading therapy on the healing process of DFUs.

Methods: A retrospective study design was used to review and analyze all available medical files (paper hard copy and electronic forms), for the patients who had been referred to the podiatry clinic in the Palestine National center of Non – Communicable Diseases (NCDs) from October 2014 to December 2019.

Results: Data were analyzed using IBM SPSS version 23 software. Data were collected from 192 patients with DFUs, 158 of them had been completed treatment until full healing of the ulcers, About (60.9%) of the patients were male, (98.4%) of them had type II of diabetes, and (82.3 %.) of DFUs were classified as neuropathic, with a mean (5.1cm2) of the size of the ulcer and (1.5 cm) of ulcers depth. 15.6% of the patients had chronic kidney disease. The mean duration of treatment time was (8.7) weeks. There was a positive significant correlation between chronic kidney disease and post ulcer size ($p<0.012$), and a negative significant correlation between duration of using off-loading and pre ulcer size ($p<0.001$), and post ulcer size ($p<0.001$), a positive significant correlation was found between duration of diabetes and pre ulcer size ($p<0.001$), and the number of sessions ($p<0.001$). Also, there is a positive significant correlation between the location of ulcer and type of off-loading device ($p<0.001$). A positive significant correlation was found between the level of hemoglobin bA1c with pre ulcer size ($p<0.001$), and the number of sessions ($p<0.001$),

Conclusions: There was a significant effect of the integrated dressing, debridement treatment, and off-loading therapy on the healing process of DFUs ($p<0.001$). Persistence with treatment, comorbidities mainly kidney diseases, and duration of diabetes are factors of importance related to the healing process of DFUs.

A strong relationship was found in our study between the variables of using off-loading devices and the rest of the other therapeutic measures, which requires the need for physiotherapy to join the treatment team in Palestine. The results of the study will help in opening broad prospects for further studies on DFU disease and its treatment procedures.

Keywords: Off-loading treatment; physiotherapy; podiatry; diabetic foot ulcer healing

الملخص باللغة العربية

تأثير برنامج علاجي متكامل لتقنيات تضميد وتنضير وتفريغ الحمل على قرحة القدم السكرية

إعداد : كرم حاتم اسماعيل البرغوثي

إشراف الدكتورة: هديل حلاوة

ملخص الدراسة :

مقدمة: ينتشر مرض السكري على نطاق واسع في العالم ، مما يؤدي إلى حدوث مرض القدم السكرية وقرحة القدم السكرية ، والتي إذا تُركت دون علاج قد تؤدي إلى بتر القدم وقد تؤدي مضاعفاتها إلى الوفاة.
الهدف: تقييم فعالية برنامج علاجي متكامل لتضميد وتنضير الجروح والعلاج بتفريغ الحمل على عملية التئام قرحة القدم السكرية.
أساليب البحث: تصميم بأثر رجعي للملفات الطبية المتاحة والتقارير الصحية الإلكترونية للمرضى الذين تمت إحالتهم إلى عيادة علاج القدم في المركز الوطني الفلسطيني للأمراض غير المعدية من تشرين الأول ٢٠١٤ إلى كانون الأول ٢٠١٩.
النتائج: تم تحليل جميع البيانات باستخدام برنامج IBM SPSS الإصدار ٢٣. وتم جمع البيانات من ١٩٢ مريضاً مصاباً بقرحة القدم السكرية ،حيث تم استكمال ١٥٨ منهم العلاج حتى الشفاء التام من القرحة ، وكان حوالي (٦٠,٩٪) من المرضى من الذكور ، و (٩٨,٤٪) منهم مصابون بالنوع الثاني من السكري و (٨٢,٣٪) من قرحات القدم السكرية تم تصنيفها على أنها اعتلال عصبي ، بمتوسط (٥,١ سم ^{2}) لحجم القرحة و (١,٥ سم) لعمق القرحة.
وما نسبته ١٥,٦٪ من المرضى يعانون من أمراض الكلى المزمنة. وقد بلغ متوسط مدة العلاج (٨,٧) اسبوع. كان هناك ارتباط معنوي موجب بين أمراض الكلى المزمنة وحجم القرحة ما بعد العلاج ($P < 0.012$) ، وكان هناك ارتباط معنوي سلبي بين مدة استخدام التفريغ وحجم القرحة ما قبل العلاج ($P < 0.001$) وحجم القرحة ما بعد العلاج ($p < 0.001$) ، كما وجد ارتباط معنوي موجب بين مدة مرض السكري وحجم القرحة ما قبل العلاج ($p < 0.001$) ، وعدد الجلسات ($p < 0.001$) ، بالإضافة إلى وجود علاقة ارتباط معنوية موجبة بين موضع القرحة ونوع جهاز التفريغ ($p < 0.001$).، ويوجد ارتباط معنوي موجب بين مستوى الهيموجلوبين bA1c مع حجم القرحة ما قبل العلاج ($p < 0.001$) ، وعدد الجلسات ($p < 0.001$).

الاستنتاجات: نتائج الدراسة ستفتح آفاقًا واسعة لمزيد من الدراسات حول مرض قرحة القدم السكرية وآليات علاجها ، وأفضل علاقة بين المتغيرات في دراستنا كانت بينمدة استخدام احدى تقنيات العلاج الطبيعي وهي تفريغ الحمل واستكمال العلاج مع عملية شفاء قرحة القدم السكرية.

الكلمات الرئيسية: تفريغ الحمل, العلاج الطبيعي , علاج القدم, شفاء قرحة القدم السكرية

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List of Abbreviations

ADA	American Diabetes Association
BMI	Body Mass Index
DFU	Diabetic Foot Ulcer
DHW	Draco Heel wedge
DOD	Duration Of Diabetes
DM	Diabetes Mellitus
ESWT	Extracorporeal Shock Wave Therapy
FDA	Food & Drug Administration
HBOT	Hyperbaric Oxygen Therapy
HbA1c	Glycosylated Hemoglobin
IDDM	Insulin Dependent Diabetes Mellitus
LLLT	Low-Level Laser Therapy
MOH	Ministry of Health
NIDDM	Non - Insulin Dependent Diabetes Mellitus
NCD	Non – Communicable Diseases
PMC	Palestinian Medical Complex
RCT	Randomized Control Trial
SPSS	Statistical Package for the Social Sciences
TCC	Total Contact Casting
UK	United Kingdom
WB	West Bank
WHO	World Health Organization

Chapter One: Introduction

1.1 Background

1.2 Problem Statement

1.3 Study Justification

1.4 Objectives of the Study

1.5 Hypotheses of the Study

1.6 Terminology

Chapter One: Introduction

This is the introductory chapter including study background, problem statement, study justification, objectives, hypotheses and expected outcomes.

1.1 Background

Diabetes Mellitus (DM) is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body can't effectively utilize the insulin it produces. Hyperglycemia, characterized by high blood sugar levels, is a common symptom of uncontrolled diabetes and over time can lead to serious damage to many of the body's vital systems, especially the nerves and blood vessels (World Health Organization, 2018). A person affected with diabetes has a 25% lifetime risk of developing a diabetic foot ulcer (DFU), which may lead to limb amputation in approximately one in six DFU patients (Tchque-Fossuo et al., 2016).

Globally in 2014, 8.5% of adults aged 18 years and older had diabetes. In 2016, diabetes was the direct cause of 1.6 million deaths and in 2012 high blood glucose was the cause of other 2.2 million deaths (World Health Organization, 2018).

The highest prevalence of diabetes among adults was recorded in the Middle East (10.9%) (Kharroubi & Darwish, 2015), diabetes is the fourth leading cause of death in Palestine, with a prevalence of 9.1% in patients aged 20-79 years and it is expected to increase to 20.6% by 2020 (Imam & El Sharif, 2019).

A recent study was published in 2019 quantifying the extent of diabetes mellitus cases in the Ministry of Health (MOH) diabetes clinic. The results included 5671 new cases with a rate of 210.4 per 100,000 populations, distributed to 2.505 cases amongst males and 3,166 amongst females (Ministry of Health, 2019).

Damages to the nerves and blood vessels as complications of DM may cause DFU, which may lead to amputate the foot and complications may lead to mortality (Americ Diabetes Association, 2018). Preventing amputation, decreasing mortality rate due to DFU, and improving the quality of life of the patient can be achieved through early and effective management of the ulcer (Yazdpah, Nasiri, & Adarvishi, 2015).

Preventing the amputation of a diabetic foot is possible via infection-halting treatment. There are several ways to achieve that: antibiotics, debridement (used to remove the necrotic and senescent tissues leading to decreasing bacteria count and healing the wound), dressing, (using collagen components in dressing process may be helpful in the healing process of the wound, and also in skin formation, because its role in creating a biological scaffold matrix, and is a safe method (Park et al., 2016), physiotherapy which is offloading the ulcerate part (Turan, Ertugrul, Lipsky, & Bayraktar, 2015; Yazdanpanah et al., 2015)

Increased pressure on the skin leads to developing an ulcer in the area because it limits blood circulation. Decreasing the pressure will increase blood circulation and improve the health condition of the skin, this method called off-loading (Sicco A Bus, 2016). Many studies (Sicco A Bus, 2016; de Oliveira & Moore, 2015; Elraiyah et al., 2016), indicated that using the off-loading

method in the management of DFU patients has improved the healing process of the wound. Using this technique by the physiotherapist helps in decreasing the risk of recurrence of DFU. In the off-loading method, different devices can be used, such as total contact cast, cast walker and therapeutic shoes, etc. (Sicco A Bus, 2016; de Oliveira & Moore, 2015; Elraiyah et al., 2016; Zheng, Ley, & Hu, 2018).

In the Middle East, a published study in 2019 on the prevalence of type 2 diabetes, it showed that the prevalence of the disease among male is greater than among female in the countries of Bahrain, the Kingdom of Saudi Arabia, the United Arab Emirates and Kuwait, and among female, it was less in Iran and Yemen (Meo et al., 2019).

In Palestine, there are limited resources concerning using off-loading in diabetic foot management. Therefore, this study aims to examine the efficacy of these methods of treating DFUs. The main intention of the researcher is to examine a common management approach and its potential implementation in Palestine for the treatment of DFU. Moreover, a key output of the study will be measured if the off-loading procedure can increase the recovery process of wound ulcers and subsequently reducing amputation risk.

1.2 Problem Statement

In the United States, about 9.3% of 29.1 million diabetic patients have a foot ulcer, which leads to more than 70000 lower-extremity amputations per year, and one-third to one-half of the patients who had major amputations surgeries died within 2 years post the surgery. The adoption of

treatment strategies from various specialities has been developed to reduce the size of these complications that afflict the diabetic community and society in general (Pinzur et al., 2016).

The exacerbation of this problem globally increases the financial burden on the government and the individual alike, and this problem leads to an increase in the number of people dependent on others, which reduces the productivity of the individual and society (World Health Organization, 2018).

In Palestine, 5671 patients with DM were registered in 2019 (Ministry of Health, 2019). These patients may develop complications of (DFU), which may increase the risk of chronic infection, leading to amputation of the ulcerated area, and possibly causing death.

The most used treatment in Palestine for DFU is more limited to conventional treatment that includes dressing and debridement. However, including off-load might be a useful technique for enhancing DFU healing and preventing complications. There is a lack of studies on diabetic foot ulcer management in Palestine, therefore, the aim of this study is to examine the effectiveness of an integrated therapeutic program of wounds dressing, debridement treatment, and off-loading therapy on the healing process of DFUs.

1.3 Study Justification

Due to the large spread of diabetes in the world, which in turn leads to many serious complications that cause damage to many systems in the human body, such as the blood vessels and nervous

system, which leads over time to a dangerous chain that ranges from diabetic foot to DFU to amputation and it may end in death in many patients. Reducing the occurrence of ulcers is the key to preventing this sequence that ends with a painful end.

Based on the evidence (Sicco A Bus, 2016; de Oliveira & Moore, 2015; Elraiyah et al., 2016); using off-loading is considered as an effective intervention in the healing process of the DFU.

In the government medical centers affiliated with the Palestinian Ministry of Health, there is only one center that provides treatment for DFUs, which is the National Center for (NCDs) in the Palestine Medical Complex, as it receives patients from all Palestinian areas, which may make it difficult for patients to access to the center, and they miss the opportunity to complete the treatment or even get it from the ground up.

An integrated therapeutic program of wounds' dressing, debridement, and off-loading techniques may positively contribute to DFU healing among DM patients in Palestine. Studying the effectiveness of the treatment method that is used in the Diabetic Foot Clinic at the National Center for (NCDs) provides decision-makers in the Palestinian Ministry of Health to generalize or modify this method to serve all patients in all Palestinian areas.

The implications of this study are expected to reduce DFU's complications such as amputation and decrease the high cost of treatment which burden individuals and government.

1.4 Objectives of the Study

- To examine the effectiveness of an integrated therapeutic program of wounds dressing, debridement treatment, and off-loading therapy on the healing process of DFUs.
- To determine factors of importance related to the healing process including persistence with treatment, comorbidities and duration of diabetes.

1.5 Hypotheses of the Study

- There is a positive significant effect of the integrated dressing, debridement treatment, and off-loading therapy on the healing process of DFUs,
- Persistence with treatment, comorbidities and duration of diabetes are factors of importance related to the healing process of DFUs.

1.6 Terminology:

Calluses

Develop at increased pressure sites, which progressively thicken, hemorrhage under near than eventually ulcerate.

Charcot-arthropathy

It is characterized by acute inflammation with the collapse of the foot and/or the ankle.

Debridement

It is a method used to remove the necrotic and senescent tissues leading to decreasing bacteria count and healing the wound.

Neuropathy

It is a complication that occurs due to of Diabetes Mellitus, which may lead to loss of feeling and the progression of the disease to the occurrence of ulcers of unknown future in terms of the healing process.

Off-loading therapy

It is a therapeutic technique in which the load on diabetic foot ulcers is discharged using special devices.

Semmes-Weinstein Monofilament

It is a sensory assessment tool.

Medical shoes

It is a type of therapeutic shoes that are designed to distribute pressure on the foot to treat diabetic foot ulcers or not to recur.

Wagner

An international Ulcer classification system to define the calcification of the ulcer, which is necessary for the evaluation process of the ulcer, and consists of 6 grades.

Chapter Two: Literature Review

2.1 Theoretical Studies

2.2 Similar Studies

2.3 Summary

Chapter Two: Literature Review

2.1 Theoretical studies

2.1.1 Diabetes

Diabetes is widely spread in the world, according to WHO about 422 million people are affected by this metabolic disease. The most common type in adults is type 2 diabetes which increasing intensely in all countries and a majority living in low-and middle-income countries (Rozzo, 2020).

A serious complication that may be developed is diabetic foot disease that may lead to the episode of DFUs. This may create a critical challenge for governments and societies, in terms of controlling and reducing serious complications that progress to wound infection and then amputates the affected limb which may finally lead to death (Gâv& Bondor, 2020).

2.1.2 Diabetic Foot Ulcer (DFU)

DFU is defined as a thickening; open sore or wound that occurs in the skin of the foot, management of DFU may lead to healing the wound and prevent the complications such as infections, amputation and even death (Gâv& Bondor, 2020).

Globally DFU Prevalence and Mortality Rate

It is estimated that approximately 15-25% of diabetic patients suffer from DFUs, and the total number of DFUs may reach 50 million by 2030, also the total cost of treating is between 300-600 million pounds in Britain, and one billion dollars a year in America (Mahdipour& Sahebkar, 2020).

2.1.3 Diabetic Foot Ulcer (DFU) Evaluation

Diabetes leads, as it was mentioned, to a disorder in the nervous system, which often leads to a defect in the structure and function of the foot such as ulceration, infection, and also gangrene, so it is necessary to evaluate the diabetic foot to know the extent of the patient's exposure to risk factors and thus integrated treatment plan based on the results of the examination (Pérez-Pero, Ruiz-Muñoz, Cuesta-Vargas, & Gónzalez-Sánchez, 2019).

At the initial visit, The patient's condition must be evaluated comprehensively and accurately, evaluation of DFU requires a multidisciplinary foot care team, it should include the patient's medical history, laboratory values, dermatological, musculoskeletal, neurological and vascular status (Jorgetto, Gamba, & Kusahara, 2019), past medical history should include blood glucose values, previous ulcers or amputations, vascular symptoms, surgeries, smoking habit, neuropathic symptoms, renal and retinal vascular changes.

Physical examinations should determine the size, depth, colour and position of the DFU, neuropathy which it is the most common symptom, which is distal neuropathy and may lead to loss of feeling and the progression of the disease to the occurrence of ulcers of unknown future in terms of the healing process. About a third of patients with diabetic neuropathy report pain, tenderness, burning and tingling (Calcutt, 2020), ischemia or neuro-ischemia of the foot, bone exposed, necrosis, infection, and the colour and consistency of exudates.

The musculoskeletal examination should include foot deformities, joint mobility, muscle wasting and presence of calluses, dryness. Dry skin is considered one of the risk factors for DFU formation

and its development, and their percentage in a study conducted in Egypt was approximately 62%, and one of the indicators of the healing of DFUs is the cure of dry skin (Al-Nakeeb, Tarshoby, & Kyrillos, 2020).

Muscle, cartilage, tendons and ligaments function will be altered due to motor neuropathy, which will culminate in a limitation of foot mobility and abnormal walking pattern. Besides physical examination should include common diabetic foot deformities such as claw toes (metatarsophalangeal joint hyperextension with inter-phalangeal flexion), hammer-toes (distal phalangeal extension), prominent metatarsal heads, pes-cavus and Charcot foot arthropathy (Jorgetto et al., 2019).

Calluses develop at increased pressure sites, which progressively thicken, hemorrhage under near than eventually ulcerate. When any callus appears in the vicinity of a foot ulcer, it must be removed quickly by debridement to assess the extent of the foot ulcer and classify it to determine treatment methods (P. R. J. Vas & Edmonds, 2020).

Charcot-arthropathy occurs secondary to neuropathy and most often affects the mid-foot. It is characterized by acute inflammation with the collapse of the foot and/or the ankle. The patient initially sustains unperceived injury but continues to walk until a severe inflammatory process leads to osteopenia, distention of joints, and foot or ankle dislocation. In late stages, the foot develops and ‘rocker bottom’ appearance. Charcot arthropathy in diabetic patients is a more complex entity with higher mortality compared with Charcot arthropathy in non-diabetic patients (Jorgetto et al., 2019).

The neurological evaluation will evaluate by using the protective sensation with the Semmes-Weinstein 10-g monofilament. As for the evaluation of blood vessels, it must include examining the appearance or non-appearance of the pulse in the posterior tibia artery, the femoral, popliteal and dorsal artery. If the pulse is absent, it must be examined by Doppler and ultrasound (Jorgetto et al., 2019).

Among the risk factors that must be paid attention to is the change that occurs in the nails, as they become thick, and measures to reduce these symptoms are to reduce their thickness with debridement and to teach the patient how to maintain and adapt the shoe so that it does not put pressure on the area of the toes (Priyadarshini et al., 2018).

To assess the perception and feeling of pain, clinical practice guidelines recommended a level of evidence And a high grade in a study conducted in 2019 the use of Semmes– Weinstein monofilament as shown in figure (2.1) see (Appendix I), tuning fork or temperature, (The specificity of this monofilament is higher than 80%, while the sensitivity is higher than 95%.) monitoring as it measures superficial sensation, which is a measure of pain and deep sensation that measures the pressure (Pérez-Pero et al., 2019).

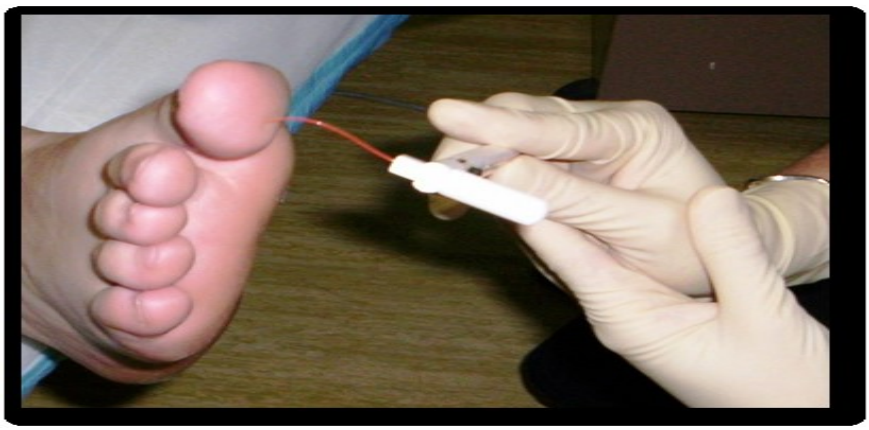

Figure 2.1: Semmes– Weinstein monofilament figure taken from (Snyder, Munter, Houston, Hoch, & Hoch, 2016)**.**

To define the calcification of the ulcer, which is necessary for the evaluation process of the ulcer, the international "Wagner ulcer classification system", which consists of 6 grades as follows see (Farooque et al., 2020).

0: No open lesions; may have deformity or cellulitis.

1: Superficial diabetic ulcer (partial or full-thickness).

2: Ulcer extension to the ligament, tendon, joint capsule, or deep fascia without abscess or Osteomyelitis.

٣: Deep ulcer with abscess, Osteomyelitis, or joint sepsis.

4: Gangrene localized to the portion of the forefoot or heel.

5: Extensive gangrenous involvement of the entire foot.

2.1.4 Management of Diabetic Foot Ulcer (DFU) Therapeutic Program

The treatment of DFUs needs an integrated team of specialists in the medical field, including podiatrists, endocrinologist, vascular surgeons, physiotherapists, etc., and also a need to use an integrated treatment regimen that includes improved blood sugar control, non-surgical debridement. Acute, dressing application, and discharging (Meloni, Izzo, Giurato, Lázaro-Martínez, & Uccioli, 2020).

The management of DFU treatment remains a major challenge for specialists in its treatment, and the International Diabetic Foot Working Group published a literature review on the topic of DFU treatments in 2008, 2012 and 2016 to evaluate existing treatments and consider the possibility of recommending studies. They found that previous studies did not find it necessary to add advanced therapies except for the use of negative pressure technique after surgery, but they also found evidence of the use, including the combined white blood cells, a sucrose-octasulfate dressing, and topical application of some placenta membrane products. In addition to the fibrin patch and platelets, all provided that the best usual care is provided, yet the evaluation of treatments still needs more research (P. Vas et al., 2020).

The time factor is very important in treating DFUs, so the earlier the treatment is started, the more efficient results are obtained, as studies conducted in Canada have shown that patients who received early and continuous treatment achieved better results than those who did not follow their treatment and the recurrence of foot ulcers they have diabetes (Boulton et al., 2018; Roth-Albin et al., 2017).

The average days of healing for a DFU was an average in the United Kingdom, reaching 78 days, while it was high in India by 241 days, while in Kuwait it reached a low average of 52 days(Messenger, Masoetsa, Hussain, Devarajan, & Jahromi, 2018).

2.2 Similar Studies

Studies conducted in many countries in the world recorded that prevalence range of the DFU was about(6.3%), where the largest incidence of it in North America(13%), and the lowest rate was in Oceania (3.0%), the study stated that the incidence rate in Africa (7.2%), which is greater than the rate in Asia (5.5%), besides the lowest rate was in Europe (5.1%) (P. Zhg et al., 2017).

In other studies, the percentage of females with diabetes was 57.5% which is higher than males, but when studying the progression of the disease to the occurrence of DFU was 90%greater among males (Madmoli et al., 2019; Yazdanpanah et al., 2018).

In a study by "The International Diabetes Federation Diabetes Atlas" about the mortality attribution among adults between 20-79 years old diabetes patients according to income groups, results showed that the number of deaths attributable to diabetes was the highest among the middle-income countries, where the death rate per 100,000 population was 92.4; the second-high number was among the low – income countries, the death rate per 100,000 population was 64.1. Finally, the lowest ratio was among the high – income countries, the death rate per 100,000 population was 62.7 (Saeedi et al., 2020).

Regarding DFU prevalence in some Arabic countries, a study which was conducted to assess the prevalence of DFUs in the Arab world showed that the highest prevalence of the disease was in the Kingdom of Saudi Arabia at (19%), followed by Egypt at (6.1%), then Bahrain at (5.9%), Jordan (5.3%), and the lowest percentage was in Iraq (2.7%) (Mairghi et al., 2017).

In Palestine, it was difficult to find a study showing the extent of DFU prevalence, as the report of the Palestinian Ministry of Health and scientific research libraries was searched through the databases sites.

2.2.1 Diabetic Foot Ulcer (DFU) Risk Factors

According to previous studies, it was found that differences in risk factors were recorded from one study to other, but the most common of these factors is the history of a previous foot ulcer or previous amputation, and these results are subject to reasoning because patients who had previous ulceration may be at risk of developing micro vascular or peripheral nervous system impairment (Yazdanpanah et al., 2015, 2018)

A similar study has indicated that diabetic patients with kidney diseases are associated with developing of DFU, as it was found that DFU patients suffer more from the development of foot ulcers to worse and delayed healing process than those who do not have kidney diseases (Yazdpah et al., 2018).

Many of the risk factors for developing a diabetic foot to a DFU such as, the long-time of the duration of diabetes, also, smoking was found as a risk factor for developing diabetic foot into

DFUs, delaying wound healing and peripheral vascular disease is one of the great risk factors for increasing the symptoms and complications of the diabetic foot, such as numbness and vascular dysfunction, and if it is not treated properly, developing consequences that occur in the diabetic foot may lead to amputation (Nongmaithem et al., 2016).

A statistically significant relationship was found between blood sugar and DFUs, while no statistically significant relationship was found between blood sugar level and the amputation, but HbA1clevel in the blood was significantly associated with the occurrence of DFU (Madmoli et al., 2019), and a relationship was found between health education and the rate of amputations, as it was found that the proportion of people, those who are subjected to amputation are less in the educated and health-educated group (Madmoli et al., 2019).

An important risk factor to be considered is the nature of the shoes that a person with diabetic foot disease wears, which plays an important role in forming the risk of occurrence, if the shoe does not guarantee a consistent distribution of pressure at the bottom of the foot, this will increase pressure on more areas than others, especially the anterior region of the foot (Meloni et al., 2020). An important factor to prevent the formation of ulcers is the fit of the shoe to be of the medical type that helps to relieve pressure on the area at the beginning of the ulceration or at the area of the ulceration itself (Madmoli et al., 2019). A literature review study was conducted in 2019 to compare the effectiveness of using custom-made shoes and medical shoes for patients with diabetes in preventing or delaying the occurrence of ulcers using medical shoes, results have shown that the use of medical shoes greatly contributed to preventing the occurrence or recurrence of diabetic foot ulcers (Jorgetto et al., 2019).

2.2.2 Treatment Methods of Diabetic Foot Ulcer (DFU) Therapeutic Program

2.2.2.1 Dressing

A systematic study, which included 43 studies aimed to evaluate the effectiveness and safety of using hydrogel (which provides and maintains a moist environment, adequate gaseous exchange, and thermal insulation in the absence of toxic contaminants, also it protects against secondary infections, inducing tissue regeneration, relieving wound pain, and promoting wound healing quality) in treating wounds, burns, DFUs and dog bites. The results showed that the use of hydrogel dressing is associated with reducing the time of wound healing and also increasing the chances of healing of DFUs and relieving pain at the same time, no statistically significant differences were found in the wounds that were treated with hydrogel compared with those wounds that were not used in the treatment of hydrogel, although it was found that the use of hydrogel is safe and effective for treating wounds (L. Zhg et al., 2019).

In 2018, a multicenter study aimed to evaluate the safety and efficacy of using collagen in DFU treatment, compared with standard therapy, according to Wagner grade II-III calcification, it was found that the intervention group had better outcomes regarding the increase of complete epithelialization than the control group post 4 weeks of the treatment, the authors indicated that using collagen in the dressing of the DFU is a safe and effective procedure (Stupin et al., 2018).

A prospective single-center study which had been conducted between 2011 and 2014 aimed to study the efficient of collagen material in treating DFU. The dressing had been performed for two or three times per week, and the rate of complete ulcer healing had been evaluated to compare the

difference of results between control and intervention groups; the results supported the using of 100% collagen in dressing process because it had better outcomes than not using it (Stupin et al., 2018).

In a similar study, the efficacy of using natural rubber latex of alginate for treating wounds was evaluated, and the results indicated that it helps in tissue formation and thus facilitates tissue adhesion that in turn leads to wound healing. The use of this bandage helps to regulate the secretions necessary for wound healing, in addition to nourishing the wound area has proteins, nutrients, cells and the environment conducive to cell regeneration. However, it must be taken into consideration not to produce excess secretions, and for this, a highly absorbent bandage was developed, and the results of laboratory tests showed that for cell proliferation, the use of this bandage increased the proliferation of fibroblasts (de Barros et al., 2020).

Among the methods of treating DFUs is the use of growth factors and recombinant proteins, and in a systematic review, which was conducted in 2020 by 3 reviewers on 26 studies, which summarized that DFUs leads to a defect in growth factors, which leads to a weakness in the wound healing process. Therefore, the use of factors that help regulate growth factors is necessary, according to FDA it has been found that the use of a platelet-derived growth factor to treat foot ulcers is efficient and safe (Mahdipour & Sahebkar, 2020).

2.2.2.2 Debridement

Wound debridement is one of the necessary therapeutic methods for treating DFUs, and it is the removal of damaged cells, allowing the opportunity for the growth of living tissues, and this process needs an expert in debridement to take into account not to damage the developing living tissues, and debridement is divided into several sections, the most important of which is surgical debridement. and acute debridement, as surgical debridement is often performed in operating rooms, while acute debridement is done in clinics specialized in treating DFUs (Kavitha et al., 2014).

The benefits of ulcer debridement are clear, but there has been some confusion as to the best method. Current diabetic foot ulcer training concentrates mainly on sharp or surgical debridement, largely because it is the fastest method of preparing the wound bed. Speed is a compelling factor, but not the only important one. When co-morbidities, vascular status, level of infection, location of the ulcer and patient preference are also be taken into consideration, practitioners may find another debridement method works better either as the primary treatment option or in tandem with options over time. In some situations, like early-onset ischemia, sharp or mechanical debridement is not just sub-optimal, it's a bad idea

Patients often need additional debridement with each dressing change or for the wound bed to become sub-optimal by the next visit. Though sharp/surgical debridement is the preferred method due to its immediate results, other methods are also valid treatment choices. For example, in areas where district nurses are not permitted to carry out sharp debridement, products that use micro-

fibers instead of a blade to remove debris around the wound are popular (Lázaro Martínez et al., 2019; P. Vas et al., 2020).

2.2.2.3 Physiotherapy program (Off-loading)

Physiotherapy methods play a role in improving the healing of DFUs, such as Neuromuscular Electrical Stimulation, (Goodall, Lgridge, Le, Davies, & Shalhoub, 2020), low-level laser therapy (LLLT), (Stos, Rocha, Hazime, & Cardoso, 2020), the use of the Extracorporeal shock wave therapy (ESWT) device(Hug et al., 2020).

As a result of the long period of diabetes, bony protrusions appear, which in turn lead to the concentration of pressure in the foot on a small area, and with repeated pressure on this area, specifically when standing and walking, and with a lack of innervation and blood supply, the chance of callus formation increases, which in turn leads to the occurrence of diabetic foot ulceration, so to treat these complications, the conditions of these tissues must be improved by allowing for better blood flow, which increases the chance of cell regeneration and eases infection which is achieved by relieving pressure on these areas, and this goal is achieved by using off-loading devices. (S A Bus & Ulbrecht, 2020).

Results of a systematic review indicated that the most effective method in treating and preventing DFU recurrence is the off-loading method. Several studies in this review have stated that using non-removable long cast is more effective than the removable device, but its cost is high. Other

trial studies in the prevention of the recurrence of DFU showed that off-loading method has a good result than non-using off-loading (Sicco A Bus, 2016).

Another systematic review was conducted in 2015 by Martins de Olivera to compare between different devices of off-loading used in the treatment of DFUs. The compared devices were cast/plaster, cast/surgical, and cast/shoes. The results of the 15 studies enrolled in the review, stated that using the total contact casts is more effective than other devices in improving ulcer healing (de Oliveira & Moore, 2015).

In many studies in the world, there are recommendations for the use of medical shoes as an alternative to pressure relievers, but when reviewing studies comparing the use of medical shoes and pressure-relieving devices, the results showed that the use of pressure-relieving devices recorded much better results than medical shoes, in a recent systematic review study that was conducted between 2014-2018, which included 41 studies, 6 of which were meta-analysis. A comparative study was made between the methods of using different off-loading devices and the extent of their impact on helping to heal DFUs, it was found that some studies support the use of non-removable devices that reach the knee or short fixed ones for the treatment of ankle and mid-foot ulcers and anterior plantar nerve ulcers. On the other hand, some studies support the use of removable devices provided the patient adheres to wearing them and does not support the use of medical shoe (P. Vas et al., 2020).

Evidence suggests that using integrated dressing, debridement and off-loading techniques are useful in enhancing healing of DFU. A systematic review and meta-analysis of off-loading

methods for DFUs included 13 RCT studies with 1605 patients of DFU, the methods of off-loading that been used are, total contact casting, cast walker, therapeutic shoes, and physiotherapy, the results showed that using total contact casting and irremovable cast walkers in the treatment of DFUs lead to complete wound healing, and shortening time to full recovery, reducing amputation, infection, and relapse rates, when compared with participants, used regular footwear (Elraiyah et al., 2016).

2.3 Summary

Dealing with diabetes patients must be subjected to an integrated and organized framework to ensure the best outcomes for prevention and treatment. Diabetics must undergo a comprehensive periodic assessment of the foot to determine the risk factors that may lead to the development of the disease into dangerous scenarios. For this reason, these patients must undergo health education, and raising awareness sessions to recognize the complications and risks of DM. Patients should be advised to visit the diabetes clinic as soon as they notice any strange change in their feet, whether they had previously had a DFU or are suffering from it at present or more importantly they have not had it yet(P. Vas et al., 2020)

One of the important specialists in the treatment of DFU is a podiatrist, who plays a role in evaluating the diabetic foot before and after the occurrence of DFUs, as he/she assesses the risk factors, and works to provide recommendations regarding the appropriate lifestyle to limit the development of the diabetic foot to a DFU. In addition to providing treatment of DFUs such as dressing and debridement(Ntuli, Vincent-Lambert, & Swart, 2018).

Among the members of the diabetic foot care, team and actively participating in the treatment of DFUs is the physiotherapist (PT), the Pts. participate in assessing the foot and providing treatment by various physical therapy interventions such as electrical stimulation by helping the angiogenesis stimulation process (Goodall et al., 2020), Laser therapy which helps in increasing fibroblast proliferation and formation of granulation (Stos et al., 2020), shock wave therapy which can effectively improve the complete cure rate, shorten the healing period of DFUs and significantly reduce treatment ineffectiveness by helping in increasing collagen synthesis (Hug et al., 2020). The most important physiotherapy interventions are the off-loading method, which contributes greatly to the healing of DFUs (Sicco A Bus, 2016; de Oliveira & Moore, 2015; Elraiyah et al., 2016).

Chapter Three: Conceptual Framework

3.1 Conceptual Framework

3.2 Operational Framework

Chapter Three: Conceptual Framework

3.1 Conceptual Framework

This chapter presents the factors that are associated with the conceptual framework components for the integrated therapeutic program for DFU.

The conceptual framework for this study shown in Figure 2 and contains the following variables:

- Patient demographics: (e.g. age at diagnoses, sex, and Address).
- Ulcer etiology: (e.g. neuropathic, ischemic, and neuro-ischemic)
- Ulcer size: (e.g. width, length and depth)
- Location of ulcer: such as big toe, toes, planter area, mid-foot and heel.
- Ulcer shape: (e.g. oval, round and irregular).
- Wagner classification: (e.g. 0= no ulcer, but high-risk foot, 1= superficial full-thickness ulcer, 2= deep ulcer, may involve the tendon, no bone involvement, 3= deep ulcer with bone involvement, Osteomyelitis, 4= localized gangrene e.g. toes and 5= gangrene of whole foot).
- Ulcer assessment exudates: (e.g. amount, colour and consistency).
- Ulcer assessment: (e.g. maceration, edges, epithelization and granulation tissue).
- Outcomes: (e.g. ulcer size, ulcer shape, ulcer calcification).

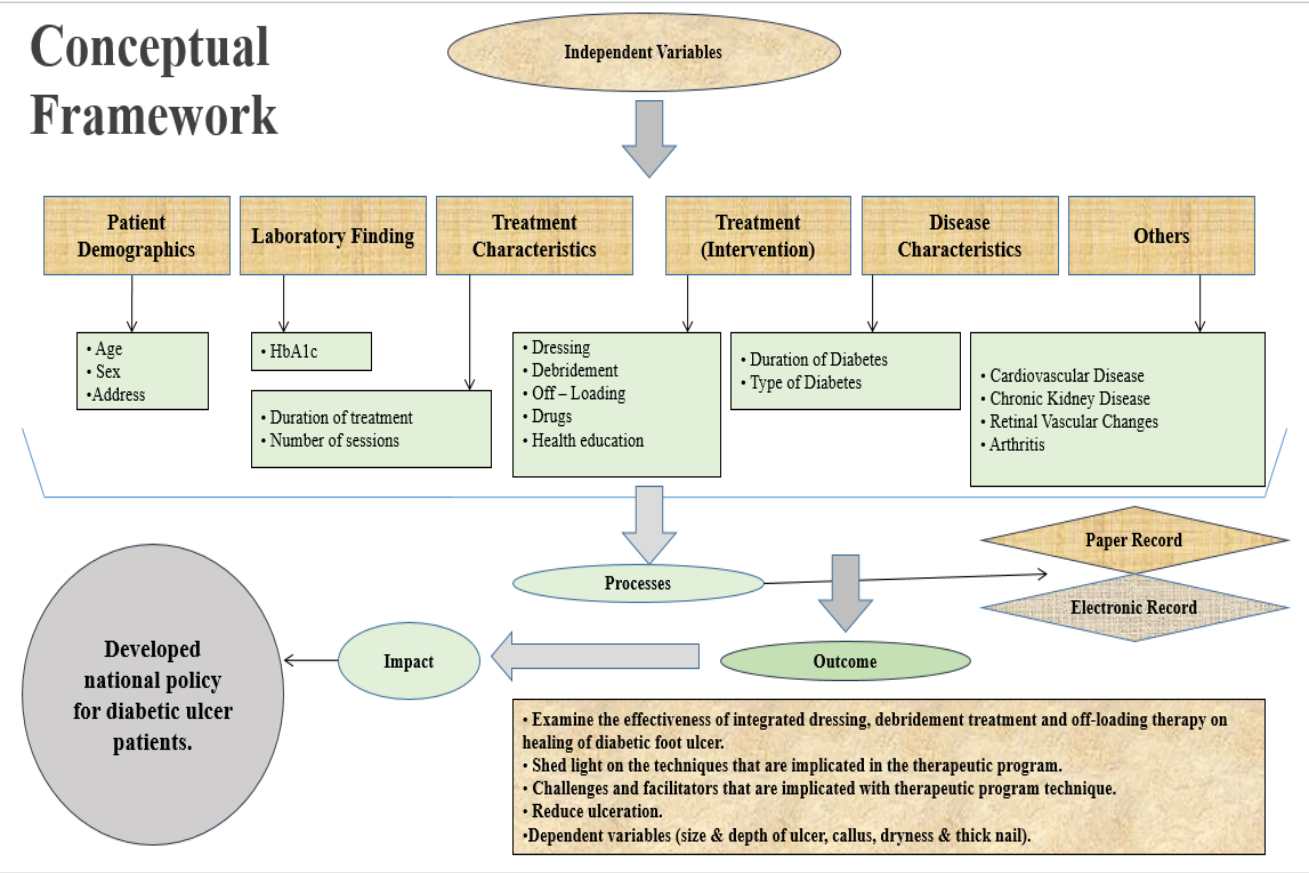

Figure 3.2: Conceptual Framework of the Study

3.2 Operational Framework

Operational definitions must therefore be determined before the collection of data starts when collecting data, assigned staff that is responsible to access the system must have identical understanding, knowledge and skills for retrieving data using same steps. Collecting data is a systematic and consistent procedure that requires well-trained staff to perform the tasks effectively, the same protocol is constructed to be applied by all team members in the same manner. This will help to ensure validity that the data is reliable, and it was conducted through a comprehensive operational definition of terms.

In our study the operational definitions will be as follows:

1. Assess: Measure the level of knowledge about Foot care among diabetic patients.
2. Effectiveness: Outcome of the intervention is measured in terms of numerical scores.
3. Structured teaching program: It is a set of learning activities consists of knowledge regarding foot care among diabetic patients .
4. Knowledge: the information regarding foot Care for diabetic patients.

The conceptual framework includes several independent factors associated with the integrated therapeutic program of DFU, which is divided into patient demographics, laboratory findings and other risk factors. In addition to the process (implementation phase), and ending with the outcomes in terms of healing outcomes of the DFU. These factors were used to build this study's conceptual framework. This chapter is the foundation for analysis in the approaching results as well as the discussion and conclusion.

Chapter Four: Methodology

4.1 Study design

4.2 Study Sample

4.2.1 Sampling Method

4.2.2 Sample Size

4.2.3 Inclusion Criteria

4.2.4 Exclusion Criteria

4.3 Data Collection

4.3.1 Tools of Data Collection

4.3.2 Study Procedures

4.4 Statistical Analysis

4.5 Ethical Consideration

Chapter Four: Methodology

This chapter provides a detailed description of our study methods including the study design, setting, subjects, sample size, data collection methods and measurements, data management, data analysis, and ethical consideration.

4.1 Study design

This study used a retrospective design of the available medical report at National Center for (NCDs) in the Palestine Medical Complex to achieve the aims of the study. The two sources of data were (1) Dataset as paper records from the National Center for (NCDs) in the Palestine Medical Complex and (2) the Dataset as electronic medical records located in Avicenna program.

4.2 Study Sample

The study was conducted in West Bank (WB) in Palestine in the National Center for (NCDs) in the Palestine Medical Complex.

4.2.1 Sampling Methods

All available medical records for patients (between October 2014 and December 2019)who met the inclusion criteria were included in this study, using the dataset from the National Center for (NCDs) and the dataset as electronic medical records located in Avicenna program.

4.2.2 Sample Size

A total of 192 medical papers and electronic records were reviewed since we requested the data for the study from the archives of the National Center for (NCDs), we found 192 files, which are the available files between October 2014 and December 2019. The average taken time for each record (paper and electronic) was 30 min (range 20-40 min).

4.2.3 Inclusion Criteria

- Participants are diagnosed with Diabetes Mellitus (DM) type II.
- Both males and females above 18 years old.
- Complaining of diabetic, and received treatment for DFU at the National Center for (NCDs) between October 2014 and December 2019.

4.2.4 Exclusion Criteria

1. Any paper medical record that not found in the Archive of National Center for (NCDs) at the time of collecting data.
2. Any paper or electronic records before October 2014 or after December 2019.

4.3 Data Collection

Data collection was conducted for review medical report between August 2020 and October 2020 at the National Center for (NCDs) in the West Bank.

The dataset extracted from paper and electronic medical records depends on the objectives of the study and its conceptual framework was classified into three categories. The first is the patient's

demographics, which identifies the diabetic patient's age, gender, address, duration of diabetes. The second category is related to laboratory findings, which are glycosylated hemoglobin (HbA1c), Hemoglobin, which may correlate with Diabetes mellitus severity, and the category three is any additional risk factors such as, History of an acute vascular event, Chronic heart disease, Chronic kidney disease, End-stage renal disease, Retinopathy, Coronary artery revascularization, Peripheral artery revascularization, History of DFU, and History of Osteomyelitis which may delay the healing process of the ulcer.

The independent factors are summarized as follows:

- Age
- Gender
- Address
- Duration of diabetes
- Hemoglobin HbA1c
- Type of diabetes
- Offloading Device such as felt, wedge shoes, Darco Heel wedge (DHW) and Total contact casting (TCC).
- Treatment: such as ulcer dressing, offloading, and debridement.
- Number of sessions
- Duration of treatment
- Health education
- Other diseases such as cardiovascular disease, chronic kidney disease, Retinal vascular changes, and arthritis.

The dependent variables are:

- Size of the ulcer
- Depth of the ulcer
- Dryness
- Callus
- Thick Nail

4.3.1 Tools of Data Collection

Examination of the dataset of reported cases is conducted by reviewing and documenting the data in the National Center for (NCDs) depending on the following used outcome measures.
At baseline, assessment method using an assessment form that is used by the clinic of the DFU treatment, in addition to the following tools:

1. Semmes-Weinstein monofilaments (Rinkel et al., 2018), it is a valid method to examine the Neurological status to determine whether the patient has “protective sensation,” which means determining whether the patient is sensate to the 10-g monofilament. (Appendix I)

2. Vascular assessment: it is important for eventual ulcer healing and is essential in the evaluation of diabetic ulcers. It includes checking: Pedal pulses, the dorsal pedis on the dorsum of the foot, and the posterior tibial pulse behind the medial malleolus, as well as capillary filling time to the digits. (Appendix I)

3. Tape measure for the size of the wound manifestation, it is a tap measurement of cm to measure the length, wide and depth of the wound.
4. Wagner classification (ulcer grade) it is a classification of ulcer of feet in diabetes, it classifies the grades of the ulcers numbering from 0-5 which zero means No ulcer, but high-risk foot bony prominences, callus, claw toe, etc. and 5 means Gangrene of the whole foot(Kumar & Moghadam, 2017). (Appendix I)

4.3.2 Study Procedures

The ethical approval was obtained from Al-Quds University and the Palestinian Ministry of Health to conduct the study. Then, contact was made with officials at the National Center for Non-Communicable Diseases, and all the available paper files for diabetic foot ulcer patients were collected, which included:

1. A demographic and clinical questionnaire was filled by each participant (Appendix I and III)

2. Documentation of the Assessment (Pre- tests) for the participants was performed, which included:
    - Neurological assessment.
    - Vascular assessment.
    - Dermatological assessment.
    - Nail assessment.
    - Musculoskeletal assessment.

- Ulcer assessment, including: (exudates, maceration, edges, epithelization, and granulation tissues).
- Off-loading devices.
- Etiology of the ulcer.
- Size of the ulcer including: (width, length and depth).
- Ulcer shape.
- Wagner calcification (ulcer grade).

With the study's outcomes measure including sensation, blood circulation, and size of the ulcer, which are mentioned in the assessment form (Appendix I and III).

3. Management methods were documented which included:
    - Drugs, (oral or IV).
    - Debridement using an advanced method such as, (Alginate, Silver, Hydrogel, Growth-factors and Zenume). (Appendix II)
    - Dressing by an expert nurse who is a specialist in DFU treatment, using an advanced method for two sessions per week (Appendix II)
    - An off-loading device by providing the patient with a suitable device for each patient depending on the condition of each ulcer. (Appendix II)
    - Re-assessment was conducted post completing the treatment.

Then the electronic program which is Avicenna had been used to collect other pieces of information as living statues, HbA1c levels an comorbidities.

4. Finally, the data had been managed and analyzed using the SPSS analytic program version 23.

4.4 Statistical Analysis

Data were managed and analyzed using Statistical Package for the Social Sciences (SPSS) 23 (IBM Corporation, 2016), a software package used for statistical analysis for the transformed quantitative data. Descriptive statistics were used to categorize the patients according to age, sex, co-morbidity, ulcer classification and others. Paired sample tests were used to compare the mean value between the pre and post-tests results. Spearman's rank correlation coefficient was used to examine the correlation between the study variables. Statistical significance was set at $P < 0.05$.

4.5 Ethical Consideration

The study approval was obtained from the Research Ethical Committee at Al Quds University, Ref No: 114/REC/2020Appendix IV. After that, approval to use the National Center for (NCDs) Appendix V and Avicenna program was granted by the MOH Appendix VI and Appendix VII. All patients' records were processed anonymously to ensure the patient's confidentiality.

Chapter Five: Results Presentation, Analysis & Discussion

5.1 Results Presentation and Analysis

5.2 Results Discussion

5.3 Study Limitations

Chapter Five: Results Presentation, Analysis & Discussion

This study was conducted using two sources of data were dataset as paper records from the National Center for (NCDs) in the Palestine Medical Complex and the Dataset as electronic medical records located in Avicenna program. Our results depending on dataset review will help us to achieve our aim of the study.

5.1 Results Presentation and Analysis

5.1.1 Descriptive Statistics

A total number of 192 patients were assessed at baseline, the mean age of the participants was 60.2±11.9; about 61% were males, and 59% of the participants living in villages. According to the electronic medical files which are Avicenna, 86% of the patients are alive, a percentage of 98% were typed 2 diabetes, also about 82% of the participants completed their treatment, a percentage of 54% of them had health education. Patients with Cardiovascular disease was recorded of about 35%, and those who had retinal vascular changes about 28%, which it is equal to patients who are free of other diseases, a percentage of 27% had more than one disease. The mean of the duration of diabetes, number of sessions and duration of treatment by weeks of the patients were consecutively 15.3±8.5, 11.5±19, 8.5±15.3, and the mean of Glycosylated hemoglobin (HbA1c) was 8.6±2.1. Clinical characteristics of the participants are illustrated in Table (5.1).

Table 5.1: Demographic and clinical characteristic of the participants (n=192)

Total sample 192	**Frequency (n)**	**Percentage**
Sex		
Male	117	60.9
Female	75	39.1
Living status		
city	73	38.0
village	114	59.4
camp	5	2.6
Mortality		
Still alive	165	85.9
Decease	27	14.1
Type of diabetes		
IDDM/type I	3	1.6
IDDM/type II	121	63.0
NIDDM/type II	68	35.4
Received treatment		
Completed treatment	158	82.3
Didn't complete treatment	34	17.7
Had health education	104	54.2
Morbidity		
Cardiovascular disease	67	34.9
Chronic kidney disease	30	15.6
Retinal vascular changes	54	28.1
Arthritis	46	24
More than one disease	52	27.1
Free of other diseases	54	28.1
No. weeks		
One week	69	35.9
Two weeks	٢٠	10.4
Three weeks	16	8.3
	mean	**standard deviation(±)**
Age	60.2	11.9
Duration of diabetes	15.3	8.5
Glycosylated haemoglobin (HbA1c)	8.6	2.1
Number of sessions	11.5	19
Duration of treatment by weeks	8.5	15.3

The majority of the participants of the ulcer etiology was diagnosed with neuropathic 82%, about 48% of the participant had the ulcers in the toes areas, according to the ulcer shape, the majority of participants had irregular ulcer about 79%, the means of ulcers size and depth were, 5.1±5.4, 1.5±1.3, about 70% of the ulcers was calcified as grade I based on Wagner calcification, as Ulcer characteristics and assessment of the participants are illustrated in Table (5.2).

Table 5.2: Ulcer characteristics and assessment

Total sample 192	**Frequency (n)**	**Percentage**
Ulcer aetiology		
Neuropathic	158	82.3
Ischemic	3	1.6
Nero-ischemic	28	14.6
Others	3	1.6
Wagner calcification		
0	31	16.1
1	132	68.8
2	23	12.0
3	5	2.6
Location of ulcer		
Big toe	50	26.0
Toes	43	22.4
Planter area	50	26.0
Mid-foot	30	15.6
Heel	19	9.9
Ulcer shape		
Oval	5	2.6
Round	15	7.8
Irregular	152	79.2
other	20	10.4
	mean	**standard deviation(±)**
Ulcer area (cm2)	5.1	5.4
Ulcer depth (cm)	1.5	1.3

5.1.2 Univariate and multivariate analysis & Correlations

Statistical tests related to correlations, pre and post-tests were conducted on who had completed the post-test. Out of the 192 patients, a number of 34 participants had been excluded because they did not have the post-test. Correlation and paired sample tests analysis were conducted on 158 patients who completed the treatment program.

Spearman's rho correlations analysis in this study was conducted for related variables, each variable was dealt with separately and its relationship with the other variables was measured based on significant spearman correlation and (*P*-value) was set at 0.05 levels.

As shown in table no (5.3), there is a negative significant correlation ($p<0.001$) between duration of using off-loading and (post ulcer size, post ulcer depth, and the number of sessions). Also, there is a positive significant correlation between the location of ulcer and type of off-loading device, a positive significant correlation has been found between chronic kidney disease and post-tests of ulcer size and depth ($p=0.012$).

Table 5.3: Correlations between variables bivariate analysis (n= 158)

Correlations													
Spearman's rho		post ulcer size, width*length, cm^2	post ulcer Depth cm	Duration of using off-loading	Ulcer Treatment	Ulcer Debridement	Ulcer Offloading Device	Number of sessions	Duration of treatment	Completed treatment	Health education	Ulcer dressing	location of ulcer
Duration of using off-loading	Correlation Coefficient	-.313**	-.313**	1	-.039	.316**	-.180*	-.512**	-.562**	-.313**	-.115	.200*	-.088
	Sig. (2-tailed)	.000	.000		.630	.000	.023	.000	.000	.000	.151	.012	.270
Ulcer Treatment	Correlation Coefficient	-.040	-.040	-.039	1	-.202*	.005	-.040	.057	-.040	-.044	-.176*	-.062
	Sig. (2-tailed)	.616	.616	.630		.011	.949	.620	.478	.616	.582	.027	.436
Ulcer Debridement	Correlation Coefficient	-.072	-.072	.316*	-.202*	1	-.145	-.533**	-.531**	-.072	.049	.624**	.076
	Sig. (2-tailed)	.368	.368	.000	.011		.069	.000	.000	.368	.542	.000	.345
Ulcer assessment Offloading Device	Correlation Coefficient	.114	.114	-.180*	.005	-.145	1	.173*	.072	.114	.052	-.116	.626**
	Sig. (2-tailed)	.155	.155	.023	.949	.069		.030	.370	.155	.516	.145	.000
Number of sessions	Correlation Coefficient	-.042	-.042	-.512**	-.040	-.533**	-.173*	1	.761**	-.042	-.041	.400**	.096
	Sig. (2-tailed)	.600	.600	.000	.620	.000	.030		.000	.600	.608	.000	.230
Duration of treatment	Correlation Coefficient	-.040	-.040	-.562**	.057	-.531**	.072	.761**	1	-.040	-.096	-.404**	-.009
	Sig. (2-tailed)	.617	.617	.000	.478	.000	.370	.000		.617	.231	.000	.912
Completed treatment	Correlation Coefficient	1.000**	1.000**	-.313**	-.040	-.072	.114	-.042	-.040	1	.108	-.048	.158*
	Sig. (2-tailed)	.000	.000	.000	.616	.368	.155	.600	.617		.178	.547	.047
Ulcer dressing	Correlation Coefficient	-.048	-.048	.200*	-.176*	.624**	-.116	.400**	-.404**	-.048	.041	1	.087
	Sig. (2-tailed)	.547	.547	.012	.027	.000	.145	.000	.000	.547	.607		.277
location of ulcer	Correlation Coefficient	.158*	.158*	-.088	-.062	.076	.626**	.096	-.009	.158*	.105	.087	1
	Sig. (2-tailed)	.047	.047	.270	.436	.345	.000	.230	.912	.047	.190	.277	
**. Correlation is significant at the 0.01 level (2-tailed).													
*. Correlation is significant at the 0.05 level (2-tailed).													
Light shading means correlation at 95 % Confidence interval. Grey shading means correlation at 99 % Confidence interval.													

Also, there is a positive significant correlation between chronic kidney disease and post-tests of ulcer size and depth (p=0.012); but there was no correlation between duration of diabetes and post-tests of ulcer size and depth as shown in table no (5.4).

Table 5.4: Correlation between chronic kidney disease and post-test ulcer size and depth

Correlations					
Spearman's rho		Duration of diabetes	Chronic kidney disease	post ulcer size, width*length, cm^2	post ulcer assessment Depth cm
Duration of diabetes	Correlation Coefficient	1	-.090	-.002	-.002
	Sig. (2-tailed)		.260	.985	.985
	N	158	158	158	158
Chronic kidney disease	Correlation Coefficient	-.090	1	.198*	.198*
	Sig. (2-tailed)	.260		.012	.012
	N	158	158	158	158
*. Correlation is significant at the 0.05 level (2-tailed).					
**. Correlation is significant at the 0.01 level (2-tailed).					

Moreover, there is a positive significant correlation between duration of diabetes and pre-tests of ulcer size and depth as a table no (5.5) below.

Table 5.5: Correlation between duration of diabetes and pre-tests of ulcer size and depth

Correlations					
			Duration of diabetes	pre ulcer size, width*length, cm^2	pre ulcer assessment Depth cm
Spearman's rho	Duration of diabetes	Correlation Coefficient	1.000	.167*	.194**
		Sig. (2-tailed)	.	.021	.007
		N	192	192	192
*. Correlation is significant at the 0.05 level (2-tailed).					
**. Correlation is significant at the 0.01 level (2-tailed).					

5.1.3 A curve estimation Regression analysis: has been conducted to predict the effect of duration of diabetes and level of Hemoglobin bA1c, on the ulcer occurrence and the healing period.

There is a positive significant correlation between duration of diabetes and ulcer size, (R=.103), and (P>0.001), as it is shown in figure (5.3), also there is a positive significant correlation between duration of diabetes and number of sessions, (R=.103), and (P>0.001), as it is shown in figure (5.4).

There is a positive significant correlation between hemoglobin bA1c and ulcer size, (R=.121), and (P<0.008), as it is shown in figure (5.5), also there is a positive significant correlation between hemoglobin bA1c and the number of sessions (R=.120), and (P>0.006), as it is in figure (5.6).

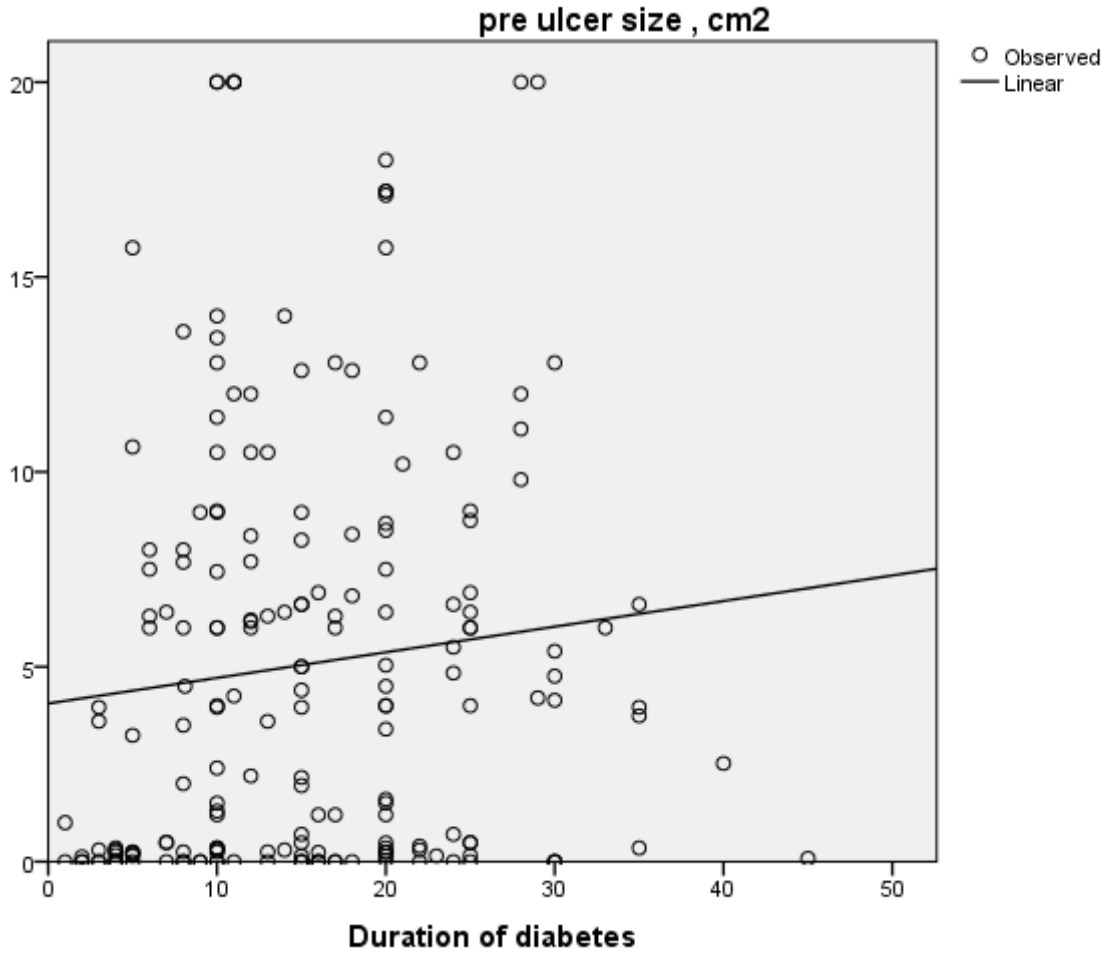

Figure 5.3: Regression analysis between DOD & pre ulcer size

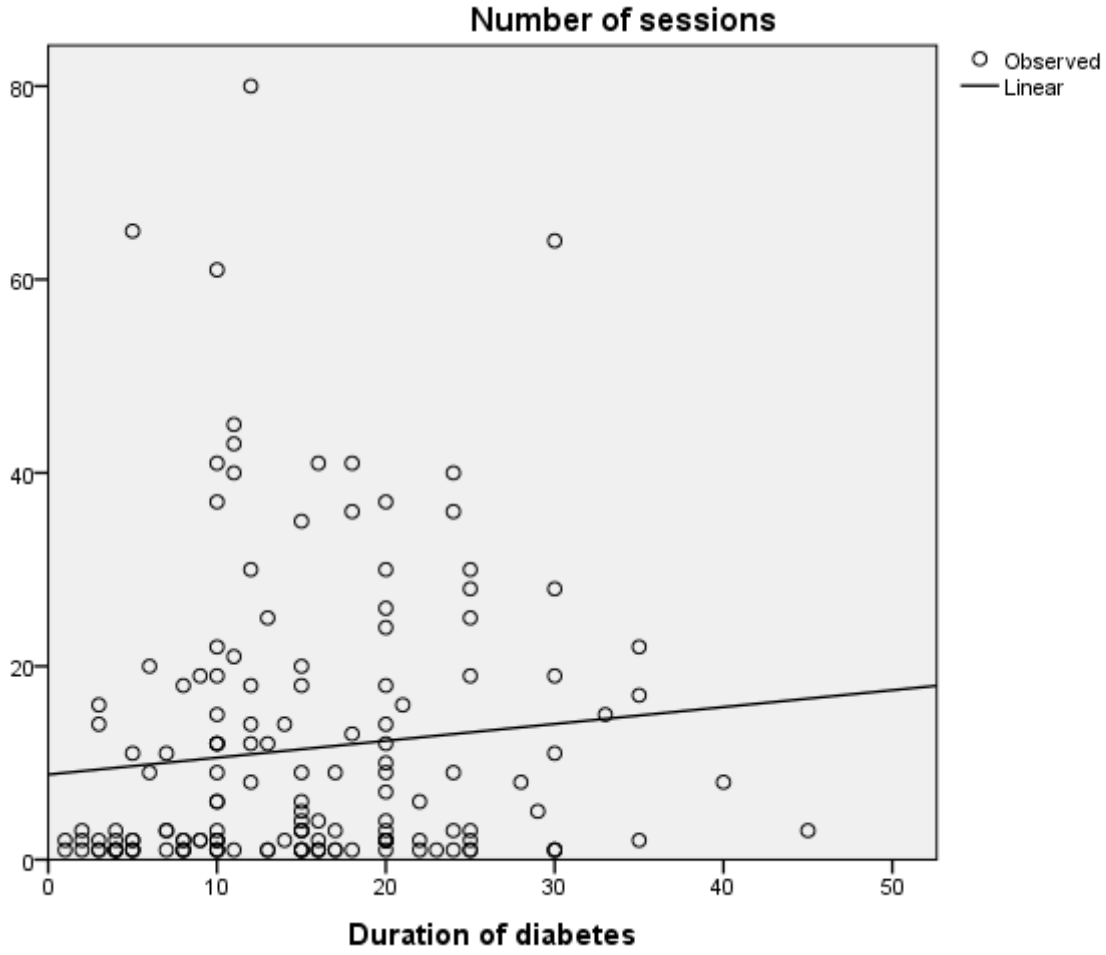

Figure: 5.4: Regression analysis between DOD & Number of sessions

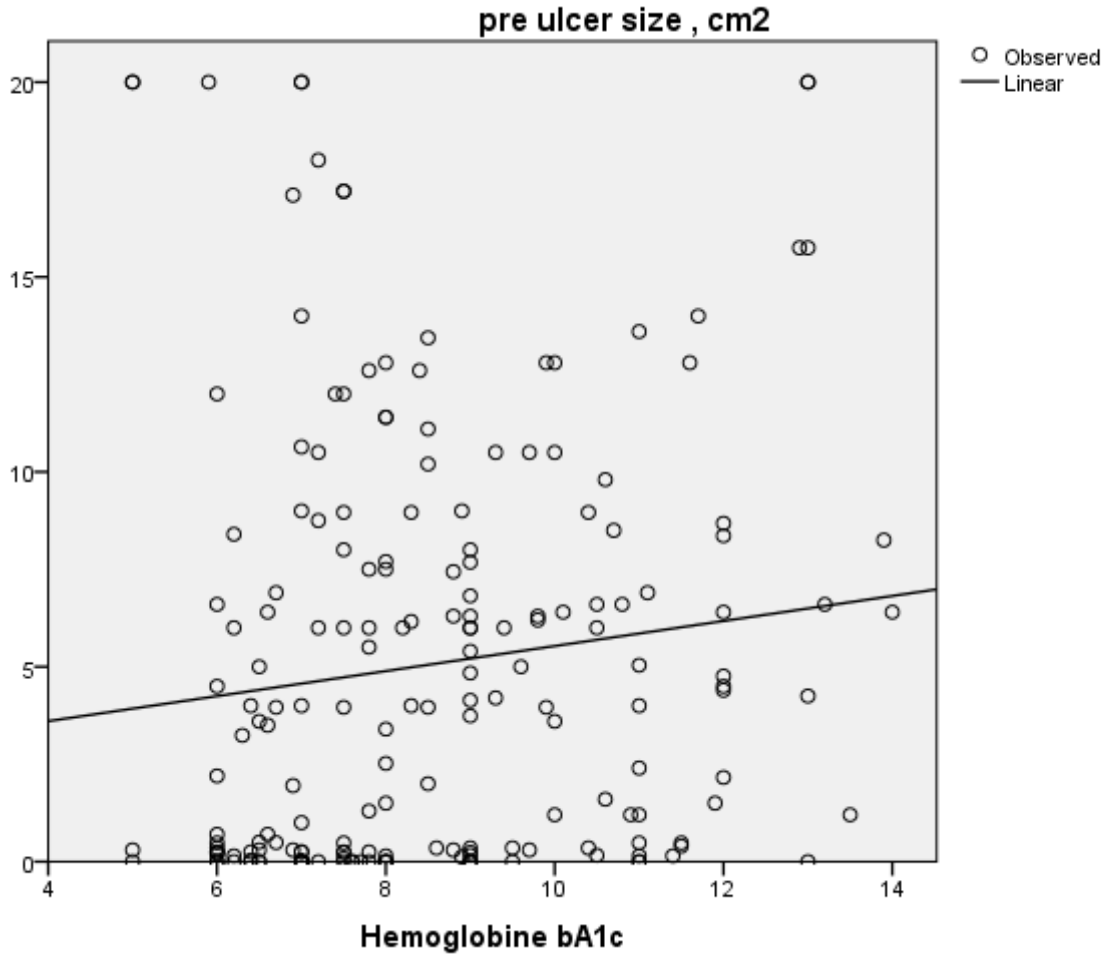

Figure 5.5: Regression analysis between HbA1c & pre ulcer size

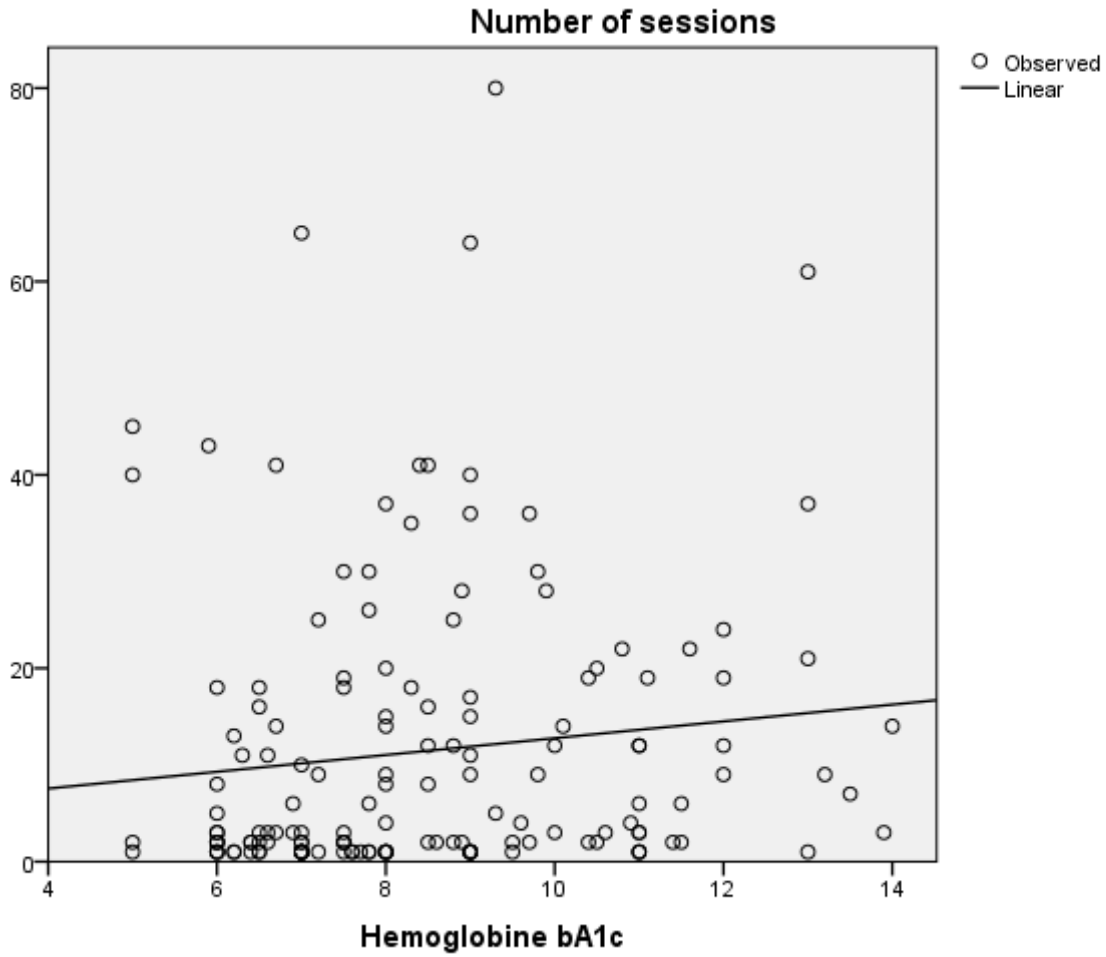

Figure 5.6: Regression analysis between HbA1c & Number of sessions

5.1.4 Paired-Sample T-Test

There is a significant difference between the mean of pre ulcer size$cm^2$is about 4.11 cm^2 post ulcer size $cm^2$is about 0.023 cm^2(p .001) as it is illustrated in table no (5.6), and figure no (5.7).

Table 5.6: Paired-Sample Statistics of pre and post ulcer size, width*length cm2

Paired -Sample Statistics					
	N	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Sig. (2-tailed)**
pre ulcer size, width*length(cm^2)	158	4.1131	5.06324	.40281	0.000
post ulcer size, width*length (cm^2)	158	.0228	.28640	.02278	

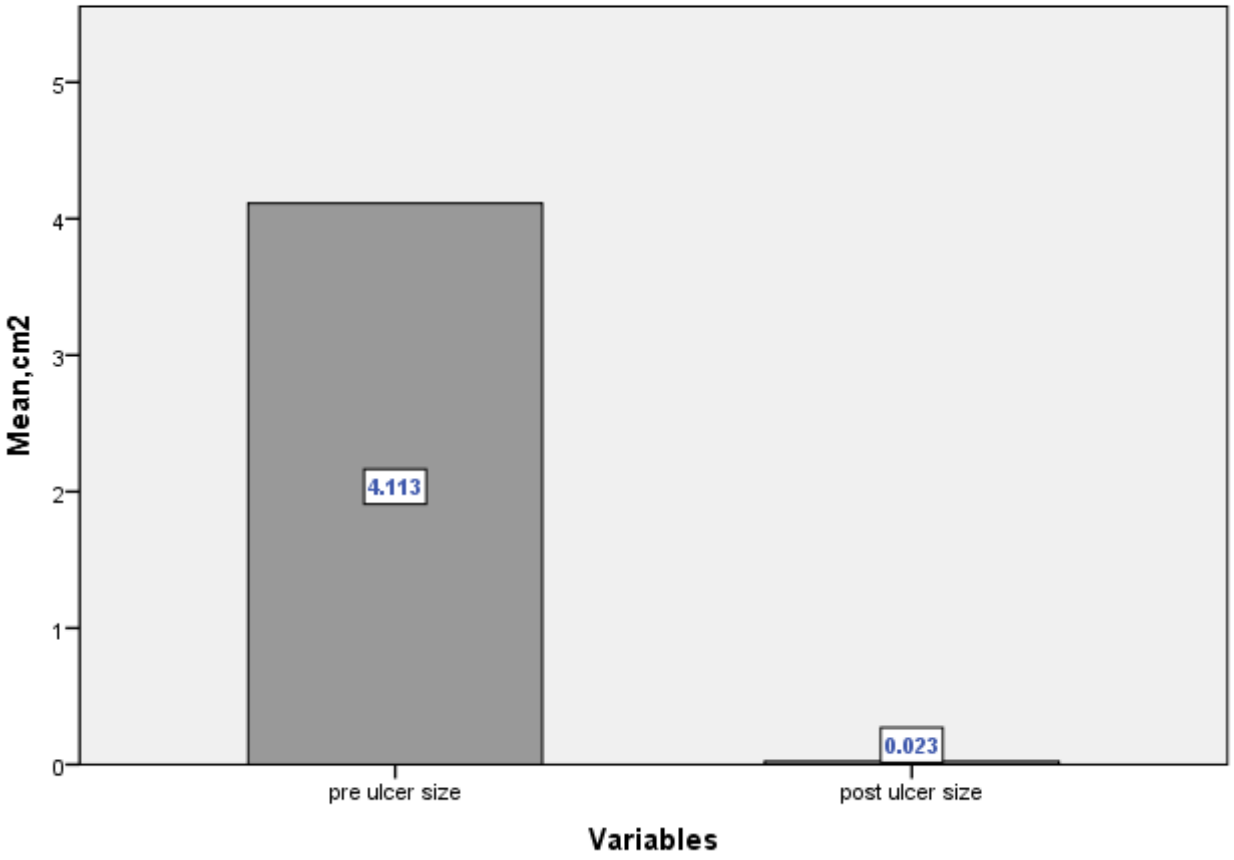

Figure 5.7: Paired sample statistics mean of pre and post ulcer size, width*length cm^2

Also, there is a significant difference between the mean of pre ulcer depth cm is about 1.23 cm post ulcer depth is about 0.011cm , (p<0.001). As it is illustrated in table no (5.7) and figure no (5.8).

Table 5.7: Paired-Sample Statistics of pre and post ulcer assessment depth cm

Paired-Sample Statistics					
	N	Mean	Std. Deviation	Std. Error Mean	**Sig. (2-tailed)**
pre ulcer Depth cm	158	1.2342	1.20407	.09579	0.000
post ulcer Depth cm	158	.0114	.14320	.01139	

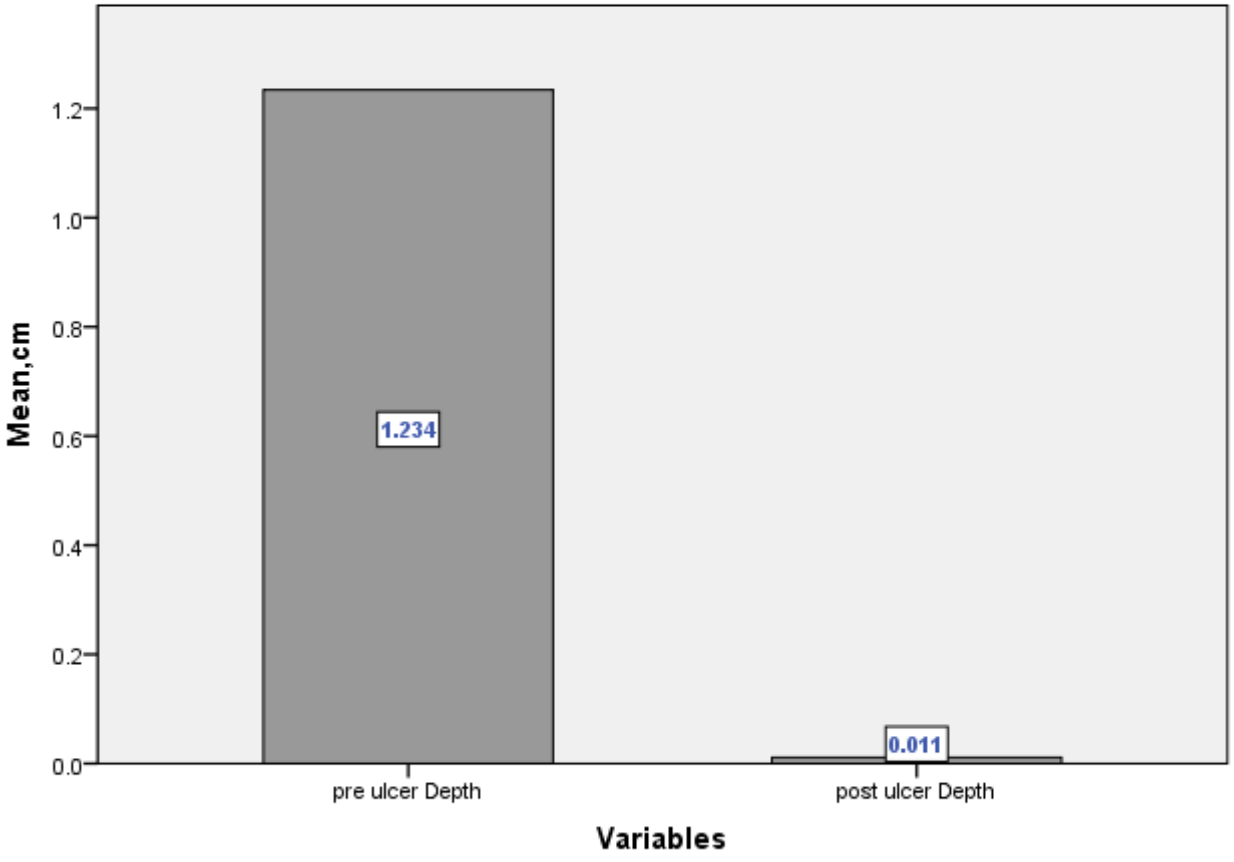

Figure 5.8: Paired sample statistics mean of pre and post ulcer assessment depth cm

In the third dependent variables, there is a significant difference between the mean of pre Dermatological assessment dryness right/left is about (1.1) post Dermatological assessment dryness right/left is about 2($p < 0.001$). As it is illustrated in table no (5.8) and figure no (5.9) below.

Table 5.8: Paired-Sample Statistics of pre and post Dermatological dryness right/ left

Paired-Sample Statistics					
	N	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Sig. (2-tailed)**
pre Dermatological dryness right	158	1.0949	.33459	.02662	0.000
post Dermatological dryness right	158	1.9810	.30851	.02454	
pre Dermatological dryness left	158	1.1582	.36611	.02913	0.000
post Dermatological dryness left	158	1.9747	.15758	.01254	

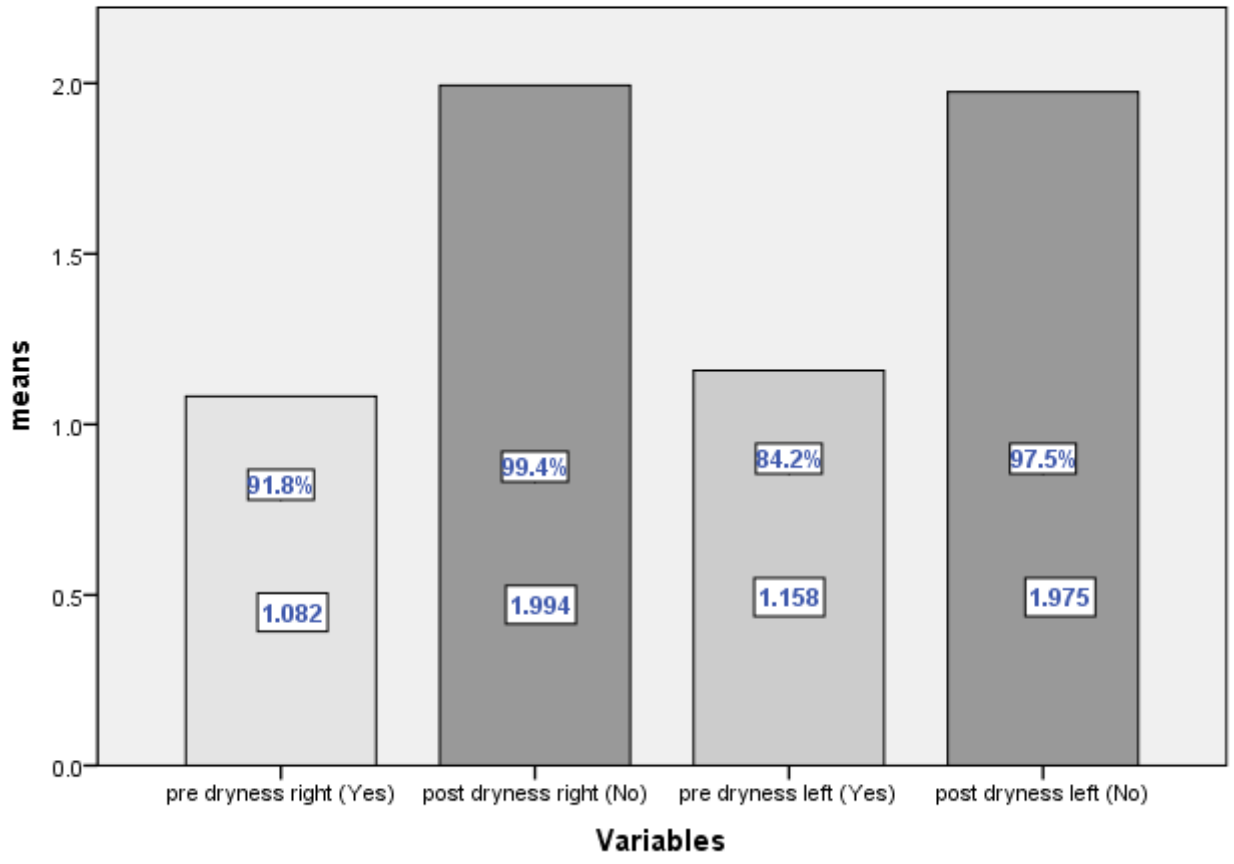

Figure 5.9: Paired sample statistics mean of pre and post dermatological dryness right/ left

Also, in another dependent variable, there is a significant difference between the mean of pre Dermatological assessment callus right/left is about (1.70) (1.62) post Dermatological assessment callus right/left is about (2.02) (1.96) ($p<0.001$). As it is illustrated in table no (5.9) and figure no (5.10).

Table 5.9: Paired-Sample Statistics of pre and post dermatological callus right and left

Paired-Sample Statistics					
	N	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Sig. (2-tailed)**
pre Dermatological callus right	158	1.7025	.48558	.03863	0.000
post Dermatological callus right	158	2.0253	.22430	.01784	
pre Dermatological callus left	158	1.6266	.48525	.03860	0.000
post Dermatological callus left	158	1.9620	.19174	.01525	

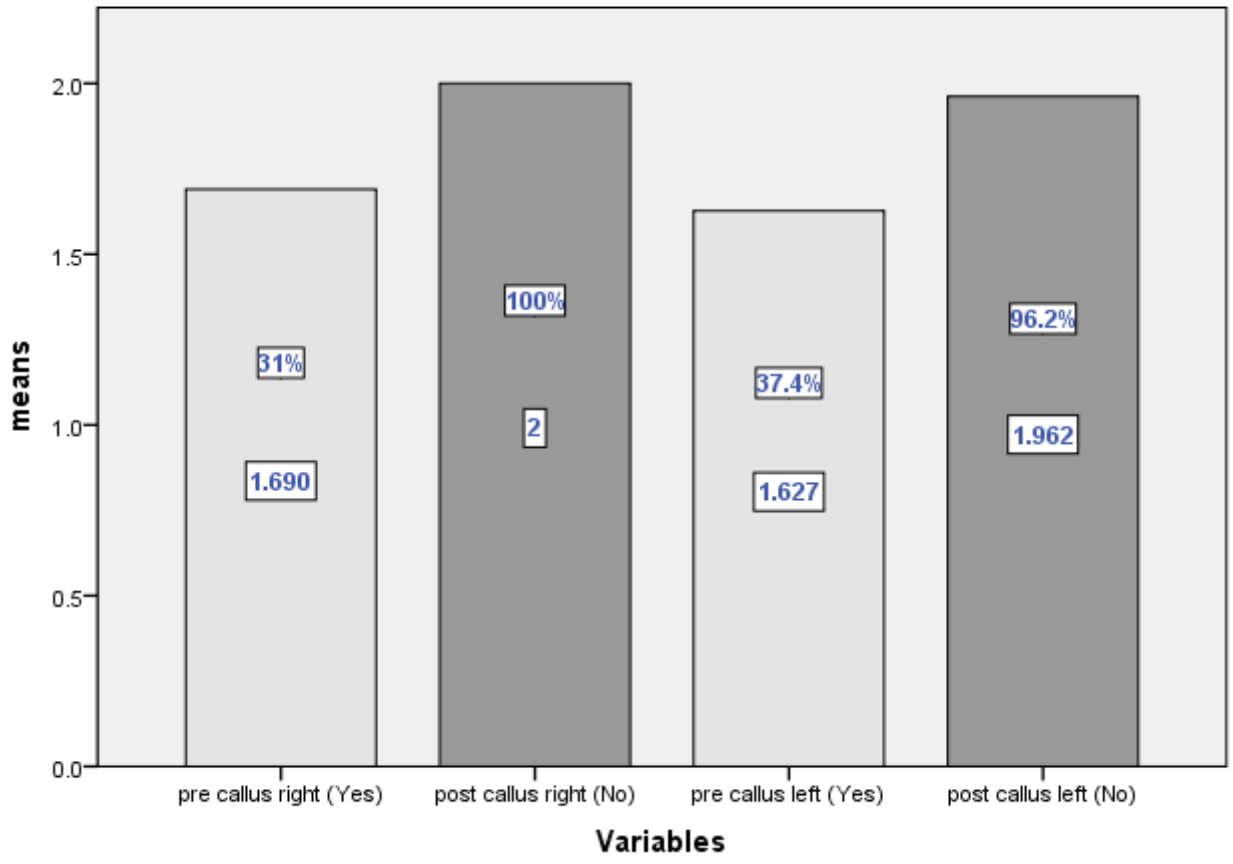

Figure 5.10: Paired sample statistics mean of pre and post dermatological callus right and left

The last dependent variables showed a significant difference between the mean of pre Nail Assessment thick nail is about 1.13 post-Nail Assessment thick nail is about 1.97, ($p<0$ .001) As it is illustrated in table no (5.10) and figure no (5.11).

Table 5.10: Paired-Sample Statistics of pre and post Nail thick nail

Paired-Sample Statistics					
	N	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Sig. (2-tailed)**
pre Nail thick nail	158	1.1392	.34730	.02763	0.000
post Nail thick nail	158	1.9747	.15758	.01254	

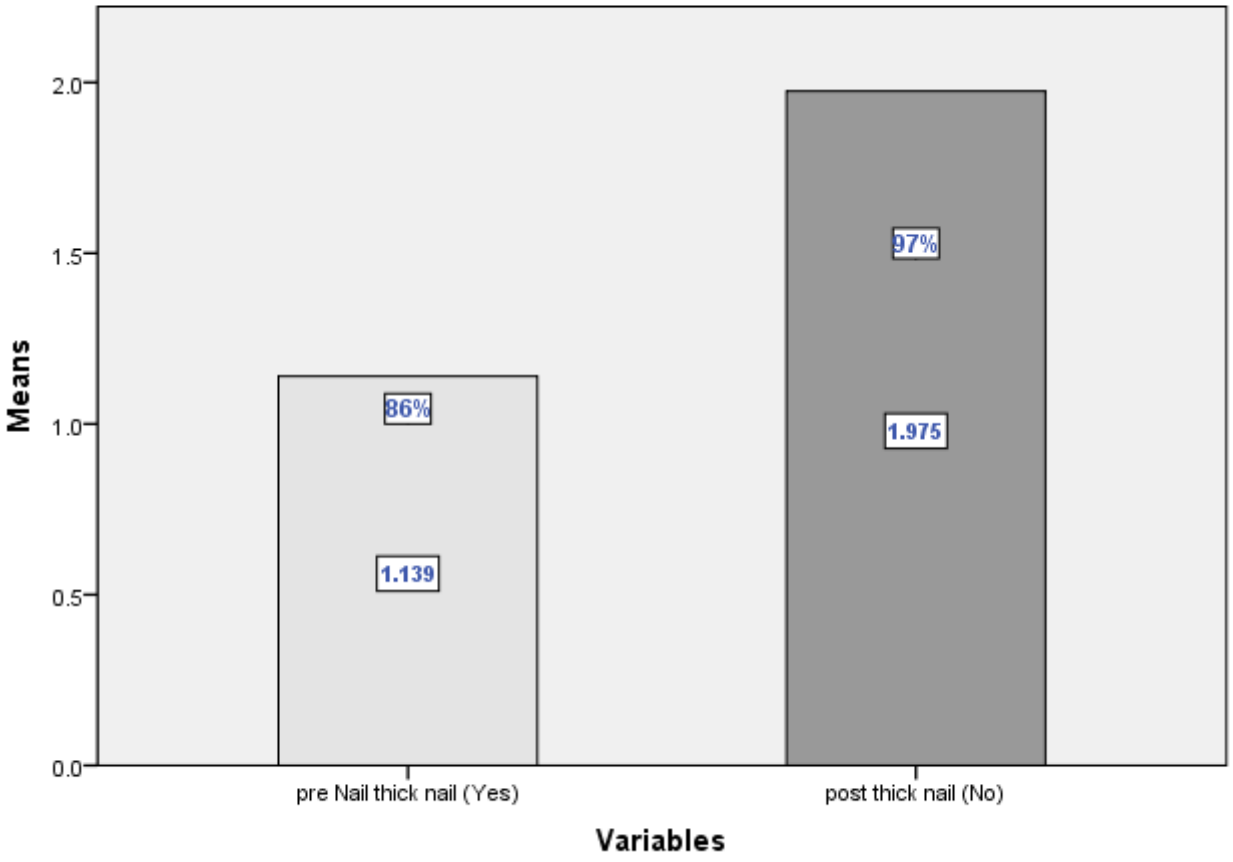

Figure 5.11: Paired sample statistics mean of pre and post Nail Assessment thick nail

5.2 Results Discussion

The main findings regarding the research questions are abstracted, an explanation of how our results confirm or diverge from those of previous researchers was discussed. General conclusions are illustrated based on the results of the study presented in this thesis. Also, the strengths and limitations of this thesis are considered, and recommendations are given for further research. This chapter will contribute to providing policymakers and researchers with recommendations.

According to our knowledge, (when searching about the studied topic in this thesis using relevant keywords of DFU, the search strategy was included searching researches unit in Palestine MOH, and by using the global search databases including PubMed, Scopus, PEDRO, Google scholar and others, no similar studies related to this topic was conducted in Palestine), this is the first study conducted in Palestine, which aimed to study the effectiveness of an integrated treatment program that includes dressing, debridement and offloading on DFUs.

Our study included many variables that we expected to have a correlation and an effect on helping in the occurrence of the disease or an effect on the healing process, such as gender, place of residence, type of diabetes, level of Glycosylated hemoglobin (HbA1c), duration of diabetes DOD and other diseases that patients had been diagnosed with, such as Heart disease, chronic kidney disease, retinopathy and arthritis.

The study also included variables related to the healing process for DFUs, such as the type of treatment provided, the duration of treatment, dressing, and debridement, also the use of offloading devices, ulcer size, depth, location and health education.

Globally in 2014, 8.5% of adults aged 18 years and older had diabetes. In 2016, diabetes was the direct cause of 1.6 million deaths(World Health Organization, 2018).In Palestine, Diabetes is the fourth leading cause of death, with a prevalence of 9.1% in patients aged 20-79 years and it is expected to increase to 20.6% by 2020 (Okuda et al., 2019).

This high rate of diabetes makes it a high-risk disease that affects all societies in the world, and which leads to many complications such as DFUs that can develop into gangrene, leading to amputation, and then increases the risk of death.

In this study, approximately 59.4% of the participants live in villages and the others live in cities and camps, and the vast majority of the participants have type 2 diabetes (98.4%), this percentage is internationally comparable, as it reached nearly 90% with type 2 diabetes (Zheng et al., 2018).

The results in our study indicated that the number of diabetics among females is greater than that of males in Palestine, but the percentage of DFUs were 60.9% higher in males, and this percentage is similar to the proportion in the world based on a study published in 2017, this can be attributed that the spread of DFUs may be greater in males than in females, that the nature of male lifestyle requires more time outside the home, as well as the nature of their work requires placing a greater load on the feet, which is the risk factor for the development of a diabetic foot to a DFU. (P. Zhang et al., 2017).

The percentage of participants in the study who had not been diagnosed with other diseases was 28.1%, and those who had been diagnosed with more than one disease are 27.1%. Our results

indicated that there is a positive statistically significant correlation with chronic kidney disease and the healing process of DFU, and there were no significant correlations recorded between the other diseases (cardiovascular disease, retinal vascular changes and arthritis), and the healing process. this result is similar to a study that was conducted in Kuwait in 2018 (Messenger et al., 2018).

Duration of diabetes (DOD) had a positive correlation with the ulcer's occurring, and time of the healing process (Nongmaithem et al., 2016). However, our results showed a positive significant correlation between DOD and the occurrence of the ulcers pre-test ($p=0.007$) of ulcer size and pre-test ($p=0.021$) of its depth, and the regression analyzing results showed that the increase in the duration of diabetes will increase the like hood of DFU occurrence and time of healing. The reason for this relationship may be between the long periods of diabetes, affecting the rest of the body systems such as the peripheral nervous system and the peripheral vascular system, which may increase the risk of DFU formation, and also the delay in the healing of the ulcer may be related to the same reasons.

The level of HbA1c that ranged from 7.0% to 8.0% during treatment would be more helpful for wound healing in DFU patients than other levels. It seemed that there was no association between baseline HbA1c levels and ulcer healing, but better baseline HbA1c level would benefit wound healing if the HbA1c is maintained between 7.0% and 8.0% during treatment (Xiang et al., 2019), in our study the mean of hemoglobin bA1cis 8.6 %, the results of regression analysis showed that the increase in hemoglobin bA1c will increase the like hood of DFU occurrence and time of

healing, this indicates that controlling the level of hemoglobin bA1c in the blood at a certain level range, helps to reduce the formation of DFUs and reduce the period of healing.

The largest percentage of the participants in our study were suffering from neuropathic peripheral vascular system about 82.2%, neuropathy; the most common symptom is distal neuropathy, which leads to loss of feeling and the progression of the disease to the occurrence of ulcers. About a third of patients with diabetic neuropathy report pain, tenderness, burning and tingling and this percentage is the largest in the world (Calcutt, 2020; Jorgetto et al., 2019). This may be attributed that one of the causes of complications of circulatory diseases is defects in the body's peripheral vascular system, and this disorder leads to the possibility of developing a large DFU.

As for the location of the site of DFU in our study, it was approximately 48% of the ulcers in the toes, and 26% were in the planter area. This can be understood as a lot of people choose completely closed shoes, and their lifestyle required to spend a long time wearing their shoes; this may increase pressure on the front area of the foot more than the other areas and increases the possibility of DFU occurrence in the toes and plantar area (Meloni et al., 2020; Sutkowska, Sutkowski, Sokołowski, Franek, & Dragan, 2019).

The average days of healing for a DFU in the United Kingdom was 78 days, while it was high in India by 241 days, in Kuwait, the average is about 52 days (Messenger et al., 2018). In our study, the results showed that the average recovery time was 8.5weeks, which is equivalent to 59 days, and it is consistent with the results of the study had been conducted in Kuwait(Messenger et al., 2018). This can be attributed that the National Centre of (NCDs) specializing in the treatment of

DFUs does not deal with critical cases in which the size of the ulcer is very large, so the average size of ulceration among the participants in the study was 5.1(cm^2), and the depth of ulceration was 1.5(cm), and about 70% of the ulcers were classified as grade I based on Wagner calcification, indicating that most of the DFU cases do not need a long time to heal, as the results of our study showed that approximately 36% of the participants needed only one week to recover, 10.5% required 2 weeks, and 8.3% required 3 weeks.

In a study conducted in Saudi Arabia, it showed that there is a positive relationship between chronic kidney disease, which is in its final stages, and the possibility of wound healing (Alzahrani, Wang, Alzahrani, & Hu, 2015). While in our study, we found a correlation between chronic kidney disease and the healing of the ulcer (p=012), in the other side, there was no relationship between the other diseases such as heart disease, retinopathy, arthritis, and the degree of healing of a DFU.

Also, there was a negative significant correlation between duration of using off-loading, and the completed healing ulcer, post-test of ulcer size and depth ($p < 0.001$). As one of the conditions for wound healing is to relieve pressure in order to increase the chances of the new tissues' granulation and decrease the infection process which helps to stimulate the healing process, as blood easily reaches the site of the lesion and helps to nourish the tissues around and in the ulceration, and this is the main goal of using off-loading techniques (Elraiyah et al., 2016).

We found a positive significant correlation ($p < 0.001$) between the location of the DFU and the type of off-loading devices that was chosen by the podiatrist at the National Centre of (NCDs), this means that matching the type of off-loading device with the type and location of the ulcer was

appropriate to some extent, but to obtain greater accuracy in choosing the device, it should not be depended on one profession, an integrated treatment team is required, including podiatrist, orthotists, and physiotherapist, to ensure the greatest possible amount of pressure relief on the ulceration to achieve the optimal outcomes (Sicco A Bus, 2016; Elraiyah et al., 2016).

And by comparing between the results and post-test according to the size and depth of the ulcer we obtained in our study, they showed a significant improvement in the size and depth of DFUs pre and post-test (4.11-.022), (1.23-.011) respectively, ($P<0.001$). Various studies worldwide aimed to study the effectiveness of different treatments on healing DFUs, and many of them have shown positive results that have led to partial healing of the ulcer. A study in the UK showed that the application of an integrated treatment program for the treatment of DFUs led to a complete recovery of more than 50% of patients after 12 weeks of treatment, the reason for the delay or non-healing among other patients is due to the large size of the ulcer and other risk factors (Alzahrani et al., 2015). According to the American Diabetes Association (ADA), a recent study in 2018 based on scientific evidence, it indicated that about 25% of patients did not reach full recovery as a result of pathological factors and other complications such as infection, as well as not adhering to treatment regularly, but the recovery time ranged for patients who completed treatment between 4-12 weeks, with an average of 8 weeks (Boulton et al., 2018), and this result is close to the result indicated by our study that showed a significant improvement in the size and depth of DFUs pre and post-test respectively ($P<0.001$).

When analyzing the results of the examination conducted at the National Centre for (NCDs) concerning the dermatological test, which included (hair loss, fissure, dryness, callus, redness,

corn, tineapedis, shiny skin and edema), the most of the cases were suffering from dryness and callus. As a result of the statistical analysis on pre and post-testing, these cases improved by a high rate ($P<0.001$), according to a study had been conducted in Egypt the percentage of dryness skin was approximately 62%, and one of the indicators of the healing of diabetic foot ulcers is the cure of dryness skin (Al-Nakeeb et al., 2020; Jorgetto et al., 2019).

Calluses develop at increased pressure sites, which progressively thicken, hemorrhage underneath and eventually ulcerate. When callus appears in the area of a foot ulcer, it must be removed quickly by debridement to assess the extent of the foot ulcer and classify it to determine treatment methods, following up on removing the callus; it reduces its recurrence, in addition to adapting the shoe so that it is comfortable and appropriate. In this approach of DFUs, it was proved that the treatment of callus greatly helps in healing DFUs (P. R. J. Vas & Edmonds, 2020).

Regarding monitoring risk factors that promoting wounds' healing and limit the development of wounds into worse scenarios; foot care in terms of using appropriate shoes is an important issue to reduce the risk factors of developing DFU. The role of the physiotherapist and the podiatrist is to assess and reevaluate any change that occurs in the nails, as they become thick, and to use procedures to reduce thickness with debridement and to teach the patient how to maintain and adapt the shoe so that it does not put pressure on the area of the toes (Priyadarshini et al., 2018). At the National Centre for (NCDs), the podiatrist would recommend the patient to use suitable shoes, and in our study, all patients who completed the treatment had an inappropriate shoe type, and all patients were required to wear appropriate shoes. The result of our study also showed a remarkable improvement in nail thickness after performing a pre-and post-test ($P<0.001$).

5.3 Study Limitations

A major limitation to this retrospective cross-sectional design is the absence or missing of some important variables related to the studied topic such as smoking habits, BMI, nutrition status, and others which may prevent computing important associations with these variables related to DFU healing process,

It was planned that our study would be prospective, but due to the occurrence of the Corona pandemic, we decided to adopt a retrospective design, which helped us to achieve our study objectives. Future prospective studies are necessary to identify other related important associations.

Another limitation is that the information we obtained were available in paper records format, and part of it was on the patients' electronic program, which consumed a lot of time and effort regarding retrieving data out of paper forms.

Chapter Six: Conclusions & Recommendations

6.1 Conclusions

6.2 Recommendations

Chapter Six: Conclusions & Recommendations

6.1 Conclusions

Based on our results we conclude:

- There was a significant association of the integrated dressing, debridement treatment, and off-loading therapy on the healing process of DFUs ($p<0.001$)
- Persistence with treatment, comorbidities mainly kidney diseases, and duration of diabetes are factors of importance related to the healing process of DFUs.

A strong relationship was found in our study between the variables of using off-loading devices and the rest of the other therapeutic measures, which requires the need for a physiotherapist to join the health care professional team in Palestine. The results of the study will open broad prospects for further studies on DFU disease and its treatment procedures

6.2 Recommendations

1- Disseminating the experience and expertise of the National Center for (NCDs) to all clinics of diabetes of the Palestinian Ministry of Health based on the positive results that our study showed,

2- Adding evaluation forms to the electronic health program that the information of DFU patients is saved electronically.

3- Adding information about important data variables that were not included in the information we obtained, such as smoking, weight and lifestyle.

4- Including physiotherapists in the care and treatment team for DFUs patients, due to the important role that our study demonstrated.

5- Highlighting on the management of DFU, and the role of physiotherapy in both undergraduate and graduate programs at the Palestinian Universities.

6- Conducting follow-up and future studies that may include other therapeutic techniques to enrich the Palestinian and international literature with evidence related to this important topic.

7- Conducting future studies (prospective, RCT and qualitative) that may include risk factors, such as lifestyle, BMI and comorbidities to study its relationship with DFUs occurrence and healing.

8- Conducting future studies on the cost of treating DFUs, to help and motivate decision-makers to develop strategic plans for treating this disease, to reduce the financial burden, whether it is on the government or individuals in Palestine.

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APPENDICES

Appendix I: Assessment Instrument

Appendix II: Treatment Methods

Appendix III: Assessment Form

Appendix IV: Research Ethics Committee

Appendix V: Mission Facilitating Letter NCDs

Appendix VI: Correspondence to the university to the Ministry of Health

Appendix VII: Mission Facilitating Letter MOH

APPENDICES

Appendix I: Assessment Instrument

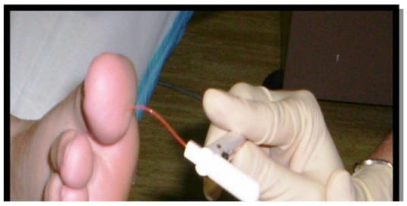
Al – Quds University
College of Graduate Studies
Master Physiotherapy Program

Assessment Instruments
2020

Title of thesis: The Effect of an integrated therapeutic program of wounds' dressing, debridement and off-loading techniques on diabetic foot ulcer

Student's Name: Karam Albarghouthy Supervisor: Dr. Hadeel Halaweh E-mail address: karamph@gmail.com

- **Sensation assessment**



Neurological status can be checked by using the Semmes-Weinstein monofilaments to determine whether the patient has "protective sensation," which means determining whether the patient is sensate to the 10-g monofilament

- Use the (5.07) 10-gram filament to test for "protective sensation"
- Apply the filament perpendicular to the skin`s surface.
- The approach, skin contact and departure of the filament should be 1.5 seconds.
- Apply sufficient force to cause the filament to bend.
- Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- Randomize the selection of test sites and time between successive tests to reduce patient guessing.
- Ask the patient to respond "yes" when the filament is felt and record the response on the diabetic foot.
- Apply the filament along the margin of and not on the ulcer, callus scar or necrotic tissue.
- Have the patient close his/her eyes while the filament test is being performed.

- **Vascular assessment**

Vascular assessment is important for eventual ulcer healing and is essential in the evaluation of diabetic ulcers. Vascular assessment includes checking pedal pulses, the dorsal pedis on the dorsum of the foot, and the posterior tibial pulse behind the medial malleolus, as well as capillary filling time to the digits. The capillary filling time is assessed by pressing on a toe enough to cause the skin to blanch and then counting the seconds for skin colour to return. A capillary filling time > 5 seconds is considered prolonged.

If pedal pulses are no palpable, the patient should be sent to a non-invasive vascular laboratory for further assessment, which may include checking lower extremity arterial pressures by Doppler and recording pulse volume waveforms, The ankle-brachial index is often not helpful because of high pressures resulting from no compressible arteries. However, toe pressures are very useful in determining the healing potential of an ulcer.

- **Assessment of the wound size**

For wound's size, the researcher will use the tap measure for width and length, and swap stick for the depth of the ulcer.

Wagner classification (ulcer Grade)

☐ **0** ☐ **1** ☐ **2** ☐ **3** ☐ **4** ☐ **5**

Wagner ulcer grades

Grade 0: No ulcer, but high-risk foot (bony prominences, callus, claw toe, etc.)
Grade 1: Superficial full-thickness ulcer
Grade 2: Deep ulcer, may involve tendons, no bone involvement
Grade 3: Deep ulcer with bone involvement
Grade 4: Localized gangrene, e.g. toes
Grade 5: Gangrene of whole foot

Appendix II: Treatment Methods

Al – Quds University
College of Graduate Studies
Master Physiotherapy Program

Treatment Methods

2020

Title of thesis: The Effect of an integrated therapeutic program of wounds' dressing, debridement and off-loading techniques on diabetic foot ulcer

Student's Name: Karam Albarghouthy Supervisor: Dr. Hadeel Halaweh E-mail address: karamph@gmail.com

Debridement Method

It will be performed by an expert nurse who is a specialist in wound care Debridement; it is the removal of necrotic tissue to decrease the risk of infection and to promote wound closure. Debridement should remove all necrotic tissue, callus, and foreign bodies down to the level of viable bleeding tissue.

Recommended for diabetic patients "Debridement is essential for the removal of nonviable cells and for healing. Per wound callus must also be removed, as it may contribute to per wound pressure and incomplete wound contraction. Ulcers may also be obscured by the presence of callus.

Debridement is contraindicated in patients with significant vascular compromise, without healing potential, or when they are placed at greater risk. Debridement of dry Escher in the compromised patient may not be necessary.

Special considerations include inadequate blood flow, immunosuppressive therapies, poor nutrition, inadequate diabetes control, and high levels of anticoagulants. Consideration of risk versus benefit must be made in cases where deeper structures, such as tendon, bone, or capsule, may be exposed as a result of debridement. Clean, granulating wounds should not be debrided.

1. Dressing

It will be performed by an expert nurse who is a specialist in wound care, Successful wound management involves the use of:

1. Dressing or agents to control the moisture content.
2. Insulate the wound from its surroundings.
3. Provide an environment that reduces bacterial burden and inflammation without harming the cells involved in the repair process.

The characteristics for optimal wound :

1. Should be free from particulate or toxic contaminants.
2. Should remove excess exudates and toxic components.
3. Should maintain a moist environment at the wound/dressing interface.
4. Should be impermeable to microorganisms, thus protecting against secondary infection.
5. Should be easily removed without trauma.
6. Should Allow gaseous exchange.
7. Should be transparent, or changed frequently, thus allowing monitoring of the wound
8. Should be acceptable to the patient, conformable and occupy a minimum of space in the shoe.
9. Should be cost-effective.

10. Should be available in hospitals and community health care centre.

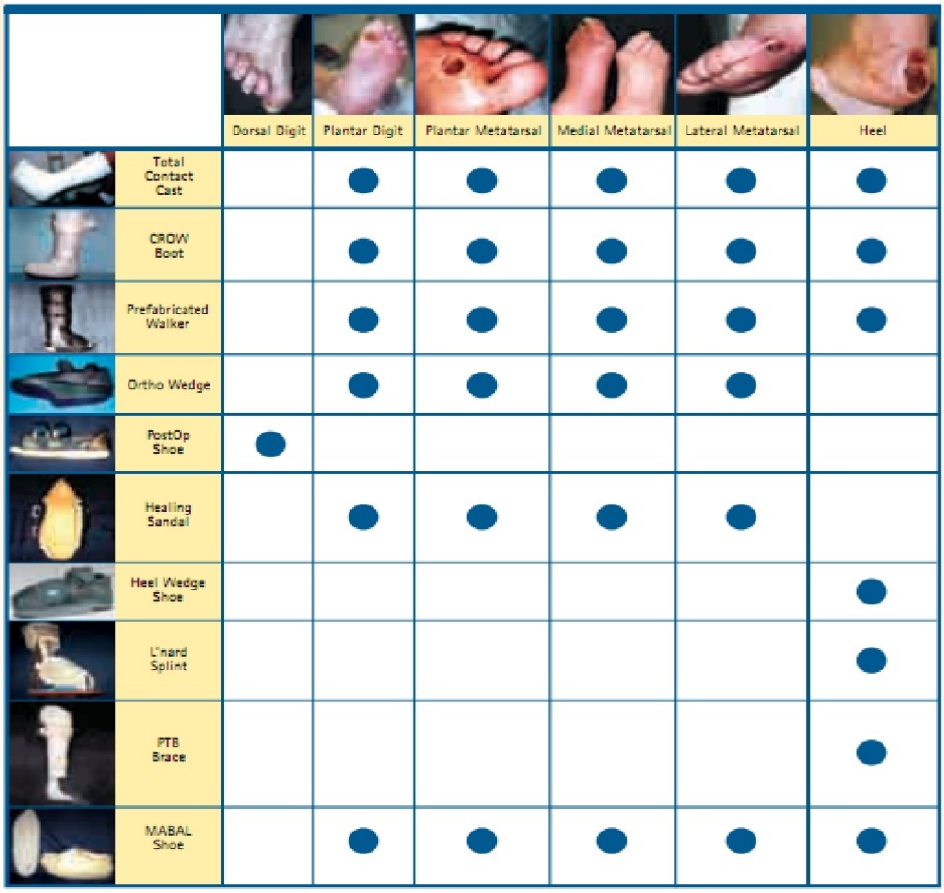
Functional parameters of dressings:

1. The overall goal is to select the appropriate dressing for restoring and maintaining normal wound physiology.
2. To aid in the proper selection of dressing material, an accurate description of the wound characteristics should be obtained.
3. Attention to be given to the color of the wound bed, the size and location of the wound, the wound margins (to identify sinus tracts and undermining), and the characteristics of the exudates (type, amount, color, consistency, odor, and adherence to the wound base).
4. A simple rule may be followed when selecting the appropriate dressing for diabetic plantar foot ulcers.
5. High levels of exudates warrant the choice of a moisture-absorbing material, which may include alginates, foams, collagen-alginate combinations, car boxy-methylcellulose materials, or gauze.
6. Low exudates and desiccated wounds respond well to hydrogels.

2. Offload

It will be performed by an expert of physiotherapy as followed:
The easiest way to decrease force overtime is to decelerate the foot onto the ground and shorten the time the foot is on the ground. However, most patients with DFUs have significant neuropathy and they strike the ground more rapidly than those without neuropathy. For a device to be effective in decreasing the rate and absorbing the force, it must extend above the ankle.
The literature supports the following devices as having reproducible ability to heal wounds: cast walkers (e.g., DH Pressure Relief Walker, Bledsoe Conformer Diabetic Boot, Three-D Dura Steppers [3-D], CAM Walkers), Charcot Restraint Orthotic Walkers (CROW)/total contact brace, patellar tendon bearing (PTB) braces, ankle-foot or theses (AFOs) in shoes, and regular or instant total contact casting (TCC). These methods work because they decelerate the foot onto the ground, and decrease weight bearing if they are used for walking. See Figure 10 for examples of off-loading devices the key to effective off-loading is to have an ankle brace that is fixed to the foot bed. [5]

Figure 2. Off-loading options



Adapted from reference 84 with permission.
CROW=Charcot Restraint Orthotic Walker; PTB=patellar tendon bearing.

Appendix III: Assessment Form

Al – Quds University
College of Graduate Studies
Master Physiotherapy Program

Assessment Form
2020

Title of thesis: The Effect of an integrated therapeutic program of wounds' dressing, debridement and off-loading techniques on diabetic foot ulcer

Student's Name: Karam Albarghouthy Supervisor: Dr. Hadeel Halaweh E-mail address: karamph@gmail.com

Palestinian Authority
Ministry of Health
National Center For NCD

السلطة الوطنية الفلسطينية
وزارة الصحة
المركز الوطني للأمراض غير السارية

Diabetic foot Clenic / عيادة القدم السكرية

الاسم:..... تاريخ الميلاد:..... الجنس:..... الحالة الاجتماعية:.....
العنوان:..... الهوية:..... رقم التأمين:.....
تلفون:..... رقم الملف:..... الطبيب المحول:.....

General Assessment

Duration of Diabetes : ..... HbA1c : .....

Type of Diabetes : .....

☐ IDDM/ Type I ☐ IDDM/ Type II ☐ NIDDM/ Type II

Wt.....Kg Ht.....cm BMI.....

Neurological Assessment

☐ Do your feet ever feel numb

☐ Do your feet ever tingle as if electricity were traveling into your foot

☐ Do your feet ever burn

Modality	Right Foot	Left foot
Monofilmant (10 GM) (out of 5 sites) (Semmes-Weinstein Monofilmant)	 / 5	 / 5
Vibration neurothesiometer	≥ 25 < 25	≥ 25 < 25

Vascular Assessment

Right Foot		Left foot
☐ Present ☐ Absent ☐ Present ☐ Absent	Dorsalis Pedal Pulse	☐ Present ☐ Absent ☐ Present ☐ Absent
	Posterior Tibial Pulse	
	Toe Presure	
	Ankle Brachial Index	
	Toe Brachial Index	

Dermatological Assessment

Right Foot				Left foot		
W☐	H☐	C☐	Temperature	W☐	H☐	C☐
☐ Yes	☐ No		Hair loss	☐ Yes	☐ No	
☐ Yes	☐ No		Fissure	☐ Yes	☐ No	
☐ Yes	☐ No		Dryness	☐ Yes	☐ No	
☐ Yes	☐ No		Callus	☐ Yes	☐ No	
☐ Yes	☐ No		Redness	☐ Yes	☐ No	
☐ Yes	☐ No		Corn	☐ Yes	☐ No	
☐ Yes	☐ No		Tinea Pedis	☐ Yes	☐ No	
☐ Yes	☐ No		Shiny Skin	☐ Yes	☐ No	
☐ Yes	☐ No		Edema	☐ Yes	☐ No	

Nail Assessment

Thick nail	☐ Yes ☐ No
Long nail	☐ Yes ☐ No
Involuted nail	☐ Yes ☐ No
Infected nail	☐ Yes ☐ No
In growing toe nail	☐ Yes ☐ No
Subungual haematoma	☐ Yes ☐ No

Musculoskeletal Assessment

Right Foot			Left foot		
☐ Yes	☐ No	Hammer / Claw toes	☐ Yes	☐ No	
☐ Yes	☐ No	Bunions	☐ Yes	☐ No	
☐ Yes	☐ No	Planus	☐ Yes	☐ No	
☐ Yes	☐ No	Cavus	☐ Yes	☐ No	
☐ Yes	☐ No	Charcot Foot	☐ Yes	☐ No	
☐ Yes	☐ No	Amputation	☐ Yes	☐ No	

Amputation site ☐Big toe ☐Foot ☐Ankle ☐Below knee ☐Above knee

Others : .....

Footwear

Style	Good	Poor
Condition	Good	Poor
it	Good	Poor

te : .....

.....

.....

ıe : .....

Signature : .....

Palestinian Authority
Ministry of Health
National Center For NCD

السلطة الوطنية الفلسطينية
وزارة الصحة
المركز الوطني للأمراض غير السارية

Diabetic foot Clinic / عيادة القدم السكرية
Follow up sheet / ورقة متابعه

الاسم : ..... تاريخ الميلاد : ..... الجنس : ..... الحاله الجتماعيه : .....
العنوان : ..... الهوية : ..... رقم التأمين : .....
تلفون : ..... رقم الملف : ..... الطبيب الأول : .....

Ulcer Assessment

Exudates

Amount	☐ None	☐ Scant	☐ Moderate	☐ Large
Color	☐ Serous	☐ Serosanguineous	☐ Sanguineous	
Consistency	☐ Thick	☐ Purulent	☐ Milky	

Maceration

☐ Present	☐ Not Present

Edges

☐ Attached	☐ Not Attached

Epithelization

☐ Present	☐ Not Present

Granulation Tissue ☐ present ☐ not present

☐ Algenate	☐ Silver	☐ Hydro gel	☐ Growth factor

Others : .....

Offloading Device

☐ None	☐ Felt	☐ Wedge shoes	☐ DHW	☐ TCC

Treatment

☐ None	☐ Oral Antibiotic	☐ I.V. Antibiotic

المركز الوطني للأمراض غير السارية

Note : .....

.....

.....

Name : .....

Signature : .....

Ulcer Etiology

◯Neuropathic ◯Ischemic ◯Nuroischemic ◯Other

Anatomical Aocation :

Leg ◯ Right ◯ Left

Foot ◯ Right ◯ Left

Size

◯Cm Width ◯Cm Lenght ◯Cm Depth

Shape

◯Oval ◯Round ◯Irregular ◯Other

Wagner classification (Ulcer Grade)

◯0 ◯1 ◯2 ◯3 ◯4 ◯5

Signature : .....

المركز الوطني للامراض غير السارية

Wagner Ulcer Grades Grade 0 : no ulcer, but high risk foot (bony prominences, callus, claw toe,etc.).

Grade 1 : Superficial full-thickness ulser

Grade 2 : Deep Ulcer, may involve tendons, no bone involvement

Grade 3 : Deep Ulcer with bone involvement, osteomyelitis

Grade 4 : Localized gangrene, e.g.toes.

Grade 5 : Gangrene of whole foot.

Appendix IV: Research Ethics Committee

Al-Quds University
Jerusalem
Deanship of Scientific Research

بسم الله الرحمن الرحيم

جامعة القدس
القدس
عمادة البحث العلمي

Research Ethics Committee
Committee's Decision Letter

Date: 23 March 2020
Ref No: 114/REC/2020

Dears Dr. Hadeel Halaweh, Mr. Karam Hatem Albarghouthy, Mr. Rasheed Adel Tayem, Dr. Thaer Ibrahim Radwan

Thank you for submitting your application for research ethics approval. After reviewing your application entitled **"The Effect of a suggested integrated therapeutic program of wounds' dressing, debridement and off-loading techniques on diabetic foot ulcer ".** The Research Ethics Committee confirms that your application is in accordance with the research ethics guidelines at Al-Quds University.

We would appreciate receiving a copy of your final research report/ publication. Thank you again and wish you a productive research that serves the best interests of your subjects.

PS: This letter will be valid for two years.

Nuha El Sharif, PhD
Research Ethics Committee Chair

Cc. Prof. Imad Abu Kishek - President
Cc. Members of the committee
Cc. file

Abu-Dies, Jerusalem P.O.Box 20002
Tel-Fax: #970-02-2791293
research@admin.alquds.edu
أبوديس، القدس ص.ب. 20002
تلفاكس: #970-02-2791293

Appendix V: Mission Facilitating Letter NCDs

29-07-'20 14:35 FROM-

T-768 P0001/0002 F-621

State of Palestine
Ministry of Health - Nablus
General Directorate of Education in Health

دولة فلسطين
وزارة الصحة- نابلس
الإدارة العامة للتعليم الصحي

Ref:
Date:

الرقم: ع ت/ ٧٣٣/ ٢٠٢٠
التاريخ: ٢٩/٧/٢٠٢٠

الأخ مدير عام الادارة العامة للرعاية الصحية الأولية المحترم،،،

تحية واحترام،،،

الموضوع: تسهيل مهمة بحث

لاحقا لموافقة معالي وزيرة الصحة، يرجى التكرم بتسهيل مهمة طالب ماجستير العلاج الطبيعي: كرم حاتم برغوثي، جامعة القدس، لاجراء بحث بعنوان: " فاعلية برنامج علاجي متكامل لتقنيات تضميد وتنضير الجروح وتفريغ الحمل على قرحة القدم السكرية"، باشراف د. [illegible] ديل حلاوة، والتطبيقات العلاجية سيتم اجراؤها باشراف أخصائي أمراض السكري د. ثائر رضوان، وذلك في:

- المركز الوطني للأمراض الغير معدية

والذي يستهدف علاج مرضى السكري من النوع الثاني والذين يعانون من قرحة القدم السكرية.

حيث ان الباحث سيلتزم بمعايير البحث العلمي والحفاظ على سرية المعلومات.

وتقبلوا فائق الاحترام،،،

د. أمل ابو عواد
مدير عام التعليم الصحي

علم
الدكتور معاذ عاروري
مدير المركز الوطني للأمراض المعدية

نسخة: مشرفة الدراسة المحترمة/ جامعة القدس

P.O .Box: 14
Tel.:09-2333901

ص.ب. 14
تلفون: 09-2333901

Appendix VI: Correspondence to the university to the Ministry of Health

Al-Quds University

Faculty of Health Professions

Physiotherapy & Rehabilitation Dep.

Jerusalem - Abu Dies

جامعة القدس

كلية المهن الصحية

دائرة العلاج الطبيعي والتأهيل

القدس – أبو ديس

16/06/2020

حضرة الدكتورة أمل أبو عوض المحترمة
مديرة عام دائرة التعليم الصحي/ وزارة الصحة الفلسطينية

تحية طيبة وبعد,

الموضوع : تسهيل مهمة طالب الدراسات العليا (ماجستيرعلاج طبيعي) كرم حاتم البرغوثي

تهديكم دائرة العلاج الطبيعي والتاهيل في جامعة القدس تحياتها وترجو من حضرتكم التكرم بالموافقة على اجراء دراسة بحثية بعنوان:

(فاعلية برنامج علاجي متكامل لتقنيات تضميد وتنضيرالجروح وتفريغ الحِمل على قرحة القدم السكرية)

(Effectiveness of an integrated therapeutic program of wounds' dressing, debridement and off-loading techniques on diabetic foot ulcer)

حيث سيقوم الاستاذ كرم حاتم البرغوثي وهو طالب دراسات عليا (ماجستيرعلاج طبيعي) بإجراء دراسة حول فاعلية البرنامج العلاجي الذي يتم اتباعه في المركز الوطني للامراض الغير معدية , والذي يستهدف علاج مرضى السكري من النوع الثاني والذين يعانون من قرحة القدم السكرية .

وستكون الدراسة تحت اشراف الدكتورة هديل حلاوة/ منسقة برنامج الماجستير في جامعة القدس , والتطبيقات العلاجية سيتم اجراؤها بإشراف اخصائي أمراض السكري الدكتور ثائر رضوان والممرض رشيد تيم وهو حاصل على ماجستير في علاج القدم السكرية وهو ايضا رئيس قسم علاج القدم السكرية في المركز , والباحث اختصاصي العلاج الطبيعي كرم البرغوثي وهو رئيس اقسام العلاج الطبيعي في الادارة العامة للخدمات الطبية المساندة في وزارة الصحة.
مع الاشارة أن الفترة المتوقعة لإجراء الدراسة 2020/7/1-2020/11/30

مع جزيل الشكروالتقدير

مرفق:
- **Research proposal and related documents**
- **موافقة لجنة أخلاقيات البحث العلمي في جامعة القدس**

د. هديل حلاوة
منسقة برنامج الماجستير
دائرة العلاج الطبيعي والتأهيل
جامعة القدس

Tel. + 02 2799753 - +02 2791243 **E-Mail:** **البريد الإلكتروني:** **تلفون: 02 2791243 -+ 02 2799753 +**
Fax. 02+2796110 **hhalaweh@staff.alquds.edu** **فاكس: 02+2796110**
Mobile: 0599349554

Appendix VII: Mission Facilitating Letter MOH

State of Palestine
Ministry of Health - Nablus
General Directorate of Education in Health

دولة فلسطين
وزارة الصحة– نابلس
الإدارة العامة للتعليم الصحي

Ref.: ....
Date: ....

الرقم: ١٦٢/٧٣٣/٢٠٢٠
التاريخ: ٢٩/١١/٢٠٢٠

الأخ مدير عام الادارة العامة للرعاية الصحية الأولية المحترم،،،

تحية واحترام...

<u>الموضوع: تسهيل مهمة بحث</u>

لاحقا لموافقة معالي وزيرة الصحة، يرجى التكرم بتسهيل مهمة طالب ماجستير العلاج الطبيعي: **كرم حاتم برغوثي، جامعة القدس**، لاجراء بحث بعنوان: " **فاعلية برنامج علاجي متكامل لتقنيات تضميد وتنضير الجروح وتفريغ الحمل على قرحة القدم السكرية**"، باشراف د. هديل حلاوة، والتطبيقات العلاجية سيتم اجراؤها باشراف أخصائي أمراض السكري د. ثائر رضوان، و د. المرضى رشيد يتم اشراف قسم علاج القدم السكري في المركز وذلك في:

- **المركز الوطني للأمراض الغير معدية**

والذي يستهدف علاج مرضى السكري من النوع الثاني والذين يعانون من قرحة القدم السكرية.

حيث ان الباحث سيلتزم بمعايير البحث العلمي والحفاظ على سرية المعلومات.

وتقبلوا فائق الاحترام...

د. أمل ابو عوض
مدير عام التعليم الصحي

دولة فلسطين وزارة الصحة
الإدارة العامة للتعليم الصحي

نسخة: مشرفة الدراسة المحترمة/ جامعة القدس

P.O .Box: 14
Tel.:09-2333901

ص.ب. 14
تلفون: 09-2333901