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Tailoring the Model of Creative Ability to Patients with Diabetic Foot Problems

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Declaration

I, Marjolein Maria Jansen, state that this dissertation is my own work. It is being submitted for the degree Masters of Occupational Therapy in the University of Pretoria. It has not been submitted before for any degree or examination at this or any other University.

Signed

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On the ……. Day of ……., 20……

Summary

Motivation is recognised as an important factor in the treatment of any patient.[1,2] Motivation is also recognised as the cornerstone of occupational therapy.[2,3] In recent history there has been an increase in the number of people diagnosed with diabetes and its complications, including diabetic foot complications.[4-8] Motivation has been identified as a factor contributing to the treatment outcomes of a person with diabetic foot complications, and an assessment into the level of motivation is recommended.[6,9-12] A review of the literature in the field revealed that this assessment of motivation has not been sufficiently investigated.

The Model of Creative Ability provides a framework within which to assess motivation and principles with which to treat a client, based on the level of motivation.[1-3] The purpose of this study was thus to investigate whether occupational therapy treatment, tailored to the level of motivation, for patients with diabetic foot complications, has more positive treatment outcomes than occupational therapy that is not tailored.

An experimental pre-test-post-test-design with an experimental and a control group was used to conduct the research. Change in ulcer size and change in quality of life score were the two dependant variables that were measured both pre- and post-test.

Subjects were assessed using the Reintegration to Normal Living Index to obtain a quality of life score. A wound tracing was done to determine the ulcer size, and the Creative Participation Assessment was used to

establish the level of motivation and thus tailor the occupational therapy treatment that the subjects received. Subjects in the experimental group then underwent three months of tailored occupational therapy, whereas subjects in the control group continued to receive occupational therapy as usual for the same time period.

At the end of the three month treatment period, the subjects were reassessed using the same assessments that were used pre-test. These results were then analysed statistically, to determine if a statistically significant difference occurred between the experimental and control groups with regards to the dependant variables.

In spite of the small sample size, the results of the research indicate a positive trend towards occupational therapy treatment that is tailored to a client's level of motivation.

Opsomming

Motivering word herken as ‘n belangrike faktor in die behandeling van enige pasiënt.[1,2] Motivering word ook gereken as ‘n hoeksteen in Arbeidsterapie.[2,3] ‘n Toename in die hoeveelheid mense gediagnoseer met diabetes, insluitend diabetiese voet komplikasies, het plaasgevind in die onlangse verlede. [4-8] Motivering is geïdentifiseer as ‘n bydraende faktor tot die uitkoms van behandeling van persone met diabetiese voet komplikasies. ‘n Bepaling van die vlak van motivering word aanbeveel.[6,9-12] ‘n Oorsig van literatuur in hierdie verband toon dat die ondersoek rondom die bepaling van motivering onvoldoende is.

Die Model van Skeppende Deelname verskaf ‘n raamwerk waarbinne die bepaling van motivering geskied, asook behandelingsbeginsels, na aanleiding van die vlak van motivering.[1-3] Die doel van die studie was dus om ondersoek in te stel of arbeidsterapiebehandeling van pasiënte gegrond op vlakke van motivering, beter behandelingsuitkomste inhou as behandeling wat nie gegrond is op vlakke van motivering nie.

‘n Eksperimentele voor-toets-na-toets ontwerp met ‘n eksperimentele en ‘n kontrole groep was gebruik tydens die navorsing. Verandering in ulkusgrootte en ‘n verandering in die kwaliteit van lewe was die twee afhanklike veranderlikes wat voor- en na-toets gemeet is.

Kandidate is geevalueer deur middel van die “Reintegration to Normal Living Index” om ‘n meting van kwaliteit van lewe te kry. Wondomvang is afgemerk om wondgrootte te bepaal. Skeppende Deelname evaluasie is gebruik om die vlak van motivering te bepaal en om arbeidsterapiebehandeling van kandidate te rig. Kandidate in die eksperimentele groep het daarna drie maande van spesifieke arbeidsterapiebehandeling ontvang, waarteenoor kandidate in die kontrole groep normale arbeidsterapie ontvang het vir dieselfde tydperk.

Aan die einde van die drie maande behandelingstydperk, is herevaluasie van die kandidate gedoen deur middel van dieselfde bepalings wat voor toetsing gebruik is.

Die resultate is statisties geanaliseer om te bepaal of ‘n statisties merkbare verskil voorgekom het tussen die eksperimentele en kontrole groepe met spesifieke betrekking tot die afhanklike veranderlikes.

Ten spyte van die klein steekproef, het die resultate van die navorsing ‘n positiewe neiging aangedui in terme van arbeidsterapiebehandeling wat gerig is na aanleiding van ‘n kliënt se vlak van motivering.

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Table of Contents

List of Tables

List of Figures

Abbreviations Used in Thesis

Term	Abbreviation
Creative Ability	CA
Creative Participation Assessment	CPA
Model of Creative Ability	MCA
Model of Human Occupation	MOHO
Pretoria Academic Hospital	PAH
Reintegration to Normal Living Index	RNLI

Note that the first time one of the above terms is used in a chapter, it will be written out in full, and thereafter the abovementioned abbreviation will be used.

Definition of Key Concepts in the Research

Motivation

"The inner condition of the organism that initiates or directs behaviour towards a goal" De Witt in[13 p5].

Intrinsic Motivation

"A concept in human development that proposes that people develop in response to an inherent need for exploration and activity."[14 p118]

Action – as defined in the Model of Creative Ability

"The exertion of motivation into mental or physical effort, which results in the creation of a tangible or intangible end-product as a result of occupational behaviour" De Witt in[13 p5].

Creative Ability

The ability to present oneself freely, without anxiety, limitations or inhibitions and the preparedness to function on whatever level of competence one is on, and being free from self consciousness.[15]

Creative Participation

The process of being actively involved in all activities concerned with daily living. The concept refers to taking an active, rather than passive role in activities.[1]

Tailored Treatment

For the purposes of this research, tailored treatment has been defined as occupational therapy treatment that has been tailored according to the principles and guidelines provided by the Model of Creative Ability.

Treatment outcomes

In healthcare, an outcome may be defined as post-intervention results or measurements – the observed outcome of an intervention.[16] A treatment outcome is thus the measurement that occurs after a specific treatment has taken place. The researcher acknowledges that there are many treatment outcomes when treating any patient. However, for the purpose of this study, the researcher will focus on two treatment outcomes, namely: percentage of change in size of the ulcer and quality of life (this is discussed further in Chapter 3).

Occupational performance

The "doing" of occupations or the individual's performance of activities, tasks and roles during daily occupations.[1] It is important to note that when used in this context, the term occupation does not refer to employment.

Occupational performance areas

The areas in which occupational performance takes place, namely: personal management, social, work and leisure.[15]

Quality of Life

"Quality of life is defined as a person's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationships to salient features of their environment.[17 p79]

Volition – as defined by the Model of Creative Ability

Du Toit described volition as being central to the theory of creative ability, and as having two components; namely: motivation and action. These two components are intrinsically linked. Motivation governs action, since it is only possible to express motivation in an individual through action.[13]

Chapter 1: Introduction and Background

1.1 Introduction

Throughout the last few decades there has been a concerning increase in the number of people suffering from diabetes, especially Type 2 Diabetes. As a result of this, there has been an increase in the number of people presenting with the complications associated with diabetes. These include both acute and chronic complications such as vascular complications, heart complications, glaucoma, cataracts and diabetic foot problems. Despite advances in technology and in the treatment of diabetes, most experts agree that the diabetic foot remains one of the most challenging problems facing health care workers.[4-8]

The diabetic foot is the leading cause of non-traumatic amputations worldwide and cost to the individual, family and health care systems are large.[18] The diabetic foot is a complex problem, with a multi-factorial origin. Of all diabetics that are diagnosed, between 10 and 15% will require amputation.[7,9,12,19-24] Due to the progressive nature of diabetic foot disease; approximately 50% of these patients will face a second amputation within three years.[7,9,19-22]

The term ‘diabetic foot’ is an umbrella term including all problems that occur in the feet of people suffering with diabetes, as a result of the diabetes. These problems include neuropathy, vascular changes and ulceration.[4-6,12] The diabetic foot is usually treated conservatively, in an attempt to heal the ulcer or compensate for other problems such as

decreased sensation in the feet or impaired mobility. However, when conservative management of the ulcer fails, the outcome is often an amputation. 15% of people suffering with diabetes will develop foot ulcerations in their lifetime, and the diabetic foot accounts for the highest percentage of hospital admissions of the diabetic patient.[7,19-22]

Several studies by Evans and Pinzur, and Tennvall and Apelqvist have found that the diabetic foot condition negatively affects the quality of life of not only the patient, but also the patient's family and caregiver.[20-22,24,25] Research has found that patients suffering with diabetic foot ulcers often have poorer quality of life than people who do not suffer with foot complications. They also tend to have poorer quality of life than patients who have undergone amputation for foot complications. The impact on mobility, ability to socialise and ability to earn an income are the major areas of health related quality of life that are affected by diabetic foot problems.[20-22,25] However, Price has found that if patients suffering with diabetic foot problems are treated at a specialised multidisciplinary foot care clinic, their quality of life improves if they receive education and treatment for their foot problems.[25]

The tragedy of the diabetic foot is that it is one of the most preventable long-term complications of diabetes. Through the use of specialised, multidisciplinary clinics, the rate of foot ulceration and amputation can be decreased by as much as 50%.[9,18,26-28]

The education of a patient on how to care for their feet and prevent further problems has been shown to reduce complications and amputation.[9,10,12,23,24,26,28-31] Much has been written on the education of a diabetic patient, and it has been said to be one of the most important functions of the multidisciplinary foot care team. Authors also agree that the most important role player in the foot care team is the patient himself, who should assist the multidisciplinary team in guiding decision making about his/her treatment.[9,18,26-28]

In order to fully benefit from the multidisciplinary team setting, a patient must possess several important characteristics. Certain authors including Reiber, McDermott and Faris believe that motivation is one of the essential elements that a patient must possess in order to adhere to treatment regimes and follow the advice and education received in the clinic set up.[6,9,10-12]

From the researcher's own clinical experience, the lack of motivation can be clearly seen in a hospital patient who was admitted for burn wounds. Although there were no cognitive impairments, the patient simply lacked the motivation to communicate his basic needs to the nursing staff. As a result the patient was often soiled or unfed. No amount of therapy, encouragement or threatening about possible consequences of non-compliance made any difference to the patient's condition. The patient was simply not motivated and therefore did not comply with any treatment regime.

The same can be seen in an example of a patient attending the diabetic foot clinic. The patient was a smoker and had been diagnosed with diabetic foot ulcers on both her feet. Despite several warnings from the doctor and other members of the team the patient refused to give up smoking, even though she had been made aware of the consequences of continued smoking. Although lack of adherence to health measures and treatment is dependant on a number of factors; literature states that motivation has a role to play.[6,910-12] Partially due to her lack of motivation, the patient also lacked the full insight into her condition and the consequences of her behaviour. Edmonds et al view motivation as just as important as knowledge about foot care when looking at successful treatment outcomes.[10]

It has been speculated that long-standing diabetes may cause cognitive and perceptual impairments, which may affect a patients' motivation and thus the effectiveness of prescribed treatment or education.[32] For these reasons, Reiber and McDermott recommended a psychological evaluation of the patient to gain more insight into possible patient compliance and

motivation thus giving an indication of prognosis and guiding clinical decision making.[6,9]

Despite the recognised role that motivation plays in the successful treatment of a patient, and the recommendation by several authors to assess a patient's level of compliance and motivation, minimal literature could be found on the exact content and execution of such an assessment.

Motivation is seen as a cornerstone of occupational therapy and it is accepted that in order to participate in any activity, including the care of a diabetic foot, a person must be motivated.[2,3] Occupational therapists in South Africa widely use Du Toit's Model of Creative Ability (MCA) to assess and treat motivation. The model provides a means to measure the level of motivation as observed in the actions or behaviours of the person. This model also provides treatment guidelines based on the level of motivation that has been assessed.[1] (The reader is referred to Chapter 2 for a more detailed discussion of the MCA.)

Accurate assessment of motivation is crucial for the occupational therapist. If the level of motivation of a patient is established, it can provide a guideline to professionals in the health care team, about the starting point of treatment as well as appropriate and purposeful activities for patient treatment. Although no research has been conducted to date, it is believed that this model could be used as a predictor of prognosis, that is, the higher the level of motivation, the better the prognosis. This assumption could be very useful in populations where the patient's insight into the condition and the motivation to take care of his or her symptoms are crucial elements (such as with patients suffering from diabetic foot complications).[1,13]

Many occupational therapists, practicing in the South African setting, have the skills and knowledge to assess motivation. By looking at a patient's behaviour and observable level of action, a conclusion can be drawn about the level of motivation: occupational therapists use purposeful and meaningful activities to engage and assess patients and thus observe aspects such as problem solving abilities, understanding of the task, use of tools and materials, interest shown in the activity and decision making. It is

from these observations, that the occupational therapist is able determine a patient's level of motivation. The occupational therapist is thus able to provide treatment tailored according to the level of motivation. The successful treatment of any patient including, a diabetic foot patient depends, partly, on tailoring treatment according to the patient's needs and motivation. Could these skills possessed by occupational therapists not be used in the treatment of patients with diabetic foot complications?

This chapter aims to outline the research performed. The remainder of this chapter focuses on the setting in which the research was performed in order to give the reader a better understanding of how the research was implemented. The research problem is then discussed and the objective, hypothesis and objectives are listed. The scope and limitations of the study are also discussed, and finally the significance of the study is stated.

1.2 Setting

Pretoria Academic Hospital (PAH) is a tertiary level hospital situated in the capital of South Africa. The hospital has approximately 820 beds and is the academic hospital for the University of Pretoria. The hospital is thus involved in the training of various health care professionals in numerous fields, including; medicine, occupational therapy, physiotherapy, nursing and others. Amongst the many out patient services offered at the hospital is a specialised diabetic foot clinic.

The Diabetic Foot Clinic at PAH takes place once a week. Between 10 and 15 patients are consulted and treated each week. Patients are referred to the clinic by various doctors working in PAH and also by certain doctors or clinics in and around the hospital area, including the primary and secondary health services associated with PAH. New patients are booked for the clinic by a nursing sister or administrative clerk. The Diabetic Foot Clinic does not see all the patients with diabetic foot complications that present at PAH: certain patients are seen at the vascular surgery clinic while others are seen at the general surgery clinic, depending on the referring doctors. Other patients choose to follow up at a clinic that is more accessible to

them. Once at the Diabetic Foot Clinic, a patient is seen by the doctor (a general surgeon), in consultation with a wound care sister and the occupational therapist. A physiotherapist is also available on a consultation basis. As the clinic is run at a tertiary level hospital, specialist investigations and access to other specialist doctors, such as neurologists or physicians, is readily available. The team, in consultation with the patient, takes a decision about how best to treat the presenting problem. The patient is then asked to follow up at the clinic as often as is necessary (usually every one to two weeks if an ulcer is present).

As the Diabetic Foot Clinic has access to the services of an occupational therapist, it provided the ideal setting to research the effects of occupational therapy treatment on the patient with diabetic foot complications. This research investigated the effect of tailored occupational therapy treatment on the treatment outcomes of patients with diabetic foot ulcers. In this research the occupational therapy treatment was tailored according to a subject's level of motivation, in an attempt to positively influence treatment outcomes. Treatment outcomes are further discussed and defined in Chapter 3. In the next section of this chapter, the research problem will be discussed in more detail.

1.3 The Research Problem

As discussed earlier; the prevalence of diabetes and its associated complications is increasing worldwide, placing a growing burden on individuals, families and health care facilities.[6,9,31] Patients, who have been diagnosed with diabetic foot problems, frequently end up with an amputation of the foot as a result of failed conservative management. The diagnosis of a diabetic foot in itself can also lead to a lower level of independence and a poorer quality of life, especially when pain is involved; and strict bed rest is recommended as treatment.[6,9,31]

As highlighted earlier, several authors have identified patient motivation as one of the major factors affecting the outcome of treatment of a patient with diabetic foot complications.[6,9,10]

Occupational therapists use Du Toit's MCA to determine level of motivation and then tailor their treatment accordingly.

The question whether the MCA could be used in the treatment of the patients with diabetic foot problems by occupational therapists, to achieve better treatment outcomes and possibly reduce the number of amputations performed due to diabetic foot disease emerged. This resulted in the formulation of an aim.

Aim

The aim of this study was to determine whether tailoring treatment of patients with a diabetic foot ulcer according to Du Toit's MCA, would lead to more positive treatment outcomes than treatment as usual.

This aim was then formulated into the hypothesis and from that the null hypothesis was obtained.

Hypothesis

The hypothesis of this study states that tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will lead to more positive treatment outcomes than treatment as usual.

Null Hypothesis

The null hypothesis states that tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will not lead to more positive treatment outcomes than treatment as usual.

Positive treatment outcomes in this research included percentage change in ulcer size and change in quality of life. The reasons for the choice of these outcomes and their measurement are discussed in Chapter 3.

Two objectives were also drawn up which were explored during this research.

Objectives

- Tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will lead to a larger percentage change in ulcer size (75% reduction with tailored treatment, as opposed to 50% reduction with usual care).

- Tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will lead to at least a two point change in at least one item of the Reintegration to Normal Living Index (RNLI)[a].

These objectives were included and are based on the researcher's expectations of what may have emerged from the research. The expectations are based on the clinical experience of the researcher and the opinions of other members of the team at the Diabetic Foot Clinic. It was expected, that as the size of the ulcer reduced, the patients would experience a better quality of life as they would be able to more easily engage in activities, especially mobility activities. Results from previous research studies done by Wood-Dauphine and Williams were also included in the decision of the expected outcome. Their studies have shown that subjects change by approximately two points over a three month period when assessed for quality of life using the RNLI.[16,33,34]

From retrospective clinic data, it was found that a 50% decrease in ulcer size was occurring with treatment as usual over a three month period. It was thus decided that a further 50% decrease in ulcer size would be seen as significant. For this reason, a 75% change in ulcer size has been viewed as significant change in this research. A further explanation of the use of 75% as a significant change in ulcer size as well as the use of the RNLI as a measure for quality of life follows in Chapter 3, where the measuring instruments are discussed in detail.

[a] The RNLI will be used as the quality of life measurement, and the reader in referred to Chapter 3 for more information as well as Appendix 1 for a copy of the index.

In the following section of this chapter, the scope and limitations of this research are defined.

1.4 Scope and Limitations of the Study

- The focus of the study is the use of the MCA for patients with a diabetic foot ulcer; therefore the study will not focus on the causes and medical management of diabetic foot ulcers.

- There are many complex factors which affect a patient's progress in any therapy. The researcher acknowledges from the start that factors such as socio-economic status, culture, belief system and many others all play a role in a patient's treatment. However, the focus of this study is on motivation and its use with patients with diabetic foot ulcers. The theory of motivation should apply to any patient regardless of other factors, however, demographic data was collected during the research process, and any relevant findings will be presented and discussed.

- The research took place at PAH's, Diabetic Foot Clinic. Subjects in the study were therefore limited to those attending the clinic and to those that had ulcers.

- Generalisability of the results may be limited due to the sample that was used. However, as the disease process is similar in all patients with diabetic foot complications, and motivation is believed to be the cornerstone of occupational therapy treatment, it is believed that with further research, the results can be applied to a larger population.

The final section of this chapter will now discuss the significance of this research study.

1.5 Significance of the Study

The research will focus on the effect of tailored occupational therapy treatment for patients with diabetic foot ulcers. The ultimate aim of the research is to contribute to the reduction of the number of amputations performed as a result of diabetic foot ulcers. The research also aims to investigate the quality of life of patients with diabetic foot ulcers, and to explore whether tailored occupational therapy has any effect on this.

Currently, few guidelines could be found for the occupational therapy treatment of patients with diabetes. Cate, Sikes and Gilbert believe that this lack of guidelines makes treatment ambiguous.[35] If the tailoring of occupational therapy, based on the patient's level of motivation, is found to have positive results, guidelines for treatment of diabetic patients with foot ulcers could be drawn up for occupational therapists. Guidelines for the treatment of patients based on the level of motivation are provided by the MCA. The research however, will provide the opportunity to adapt these general guidelines to a specific patient condition, namely: diabetic foot ulcers. These guidelines could then be further researched and contribute to better, evidence based, occupational therapy.

The MCA is used in South Africa to assess a patient's level of motivation, and to provide guidelines for treatment. While the model is taught to undergraduate students and used in practice, more research urgently needs to be done regarding the clinical application and efficacy of the model.[1,3] The outlined study aims to do such research, and provides an opportunity to investigate the use of the model with a specific group of patients. The research will thus contribute new information to the existing body of knowledge.

This chapter has provided an outline of the research that was performed. Background to the problem was given, explaining the prevalence of diabetic foot complications and the related amputations, as well as the effect of these complications on the quality of life of the affected patient and their family. The importance of motivation was discussed as an element

essential for successful treatment and management of the diabetic foot. The importance of motivation to occupational therapy was then explained as well as the use of Du Toit's MCA as a framework within which to assess and treat motivation. This led to the formation of the hypothesis and objectives, which focus on the effect of tailored occupational therapy treatment on the treatment outcomes of the patient with diabetic foot ulcers.

The scope and limitations of the study were discussed. Lastly the significance of the study was examined, including the possible generation and development of occupational therapy guidelines for the treatment of patients with diabetic foot problems.

The following chapter will review the available literature on the main topics of the research including the diabetic foot, quality of life and motivation. This is done in order to better understand the key concepts of this research, and to highlight the gap in the literature concerning motivation and its effect on the treatment of patients with diabetic foot problems.

Chapter 2: Literature Review

2.1 Introduction

In this chapter, the literature concerning the key topics of the research is reviewed. This is done to illustrate the accepted opinion on certain topics, as well as to highlight any gaps that may exist in the current literature. The review is divided up into several subsections, in order to keep the content manageable and clearly illustrate how certain topics are linked.

The review starts with a look at the history of diabetes and its complications, especially the diabetic foot. The treatment of the diabetic foot is then briefly reviewed, with a focus on the context of the multidisciplinary team and the specialised diabetic foot clinic setup. The specific roles of the various members of the foot care team are also discussed.

The role of occupational therapy in the treatment of chronic diseases, such as diabetes is reviewed. The core of occupational therapy and its quality of life foundation is highlighted, and this is followed by an investigation into the effects of a foot ulcer on the quality of life of people with diabetic foot ulcers.

The importance of patient education and the execution of this education are then reviewed, looking specifically at the role motivation plays in the outcome of patient care and patient education. Lastly the Model of Creative Ability (MCA) is discussed in detail, as a tool with which to assess and treat motivation.

2.2 The History of Diabetes and the Diabetic Foot

Diabetes is one of several diseases known from antiquity, and it can be traced back as far as the second millennium BC, when it is mentioned on the 3rd Dynasty Egyptian papyrus by physician Hesy-Ra.[4,36] In the first century AD, diabetes is described as 'the melting down of flesh and limbs into urine' by Arateus.[36] By the seventeen hundreds, the disease was classified into two forms: diabetes insipidus, in which there is no sugar in the urine, and diabetes mellitus, where sugar is present in the urine (mellitus is the Latin word for honey, referring to its sweetness).[4,36]

In 1885, it was established that the pancreas is involved in diabetes, however, the exact nature of the link between the pancreas and diabetes, was not established until 1900.[4,36] The discovery of Insulin in 1921 drastically changed the prognosis of a previously lethal disease, and death due to coma became a less frequent outcome of diabetes.[4,36] Following this breakthrough, as death due to coma became less common, it was established that deaths from vascular problems, had become more frequent.[4]

Between 1850 and 1870, gangrene and plantar ulcers, were both recognised as a complication of diabetes, and in 1887 Pryce first described the association between foot ulceration, neuropathy and vascular disease.[4] However, the connection between diabetes and symptoms in the limbs had been made as far back as 1798, when it was recognised by John Rollo. He noticed a large percentage of his diabetic patients experienced pain and paraesthesia of the lower limbs, often resulting in an inability to use the

limbs.[4] During this time period, major amputation of a limb for a small area of gangrene was often seen as the only successful treatment.

In the period 1920-1950, arterial disease was also implicated in the formation of foot ulcers. In 1941, the association between retinopathy, neuropathy and nephropathy was described and the suggestion was put forward that the common factor, was the change in the condition of the blood vessels. [4,36]

In recent history, there has been a disturbing rise in the occurrence of diabetes, particularly, Type 2 Diabetes.[5] Worldwide the prevalence of diabetes is rising, and this can be seen particularly in developing countries.[5] Over 90% of people with diabetes have Type 2 Diabetes, which typically affects the older population and is associated with a family history of diabetes, obesity and a sedentary lifestyle.[5,37] In the past, Type 2 Diabetes was referred to as adult onset or non-insulin-dependant diabetes, however this labelling was abandoned for more accurate descriptions; Type 2 Diabetes is thus characterised by insulin resistance and total or partial impairment in insulin secretion.[5,37]

While diabetes can result in many chronic complications, including micro- and macro vascular complications, cardiovascular disease, retinopathy, cataracts and glaucoma[5,8]; the most common complication of diabetes, leading to hospital admission, is diabetic foot disease.[6] The full extent of the diabetic foot problem is currently unclear as the condition is not always uniformly reported.[6] The most commonly described diabetic foot problems include neuropathy, structural changes, foot ulcers and infections.[6] Another reason for the inaccuracy of diabetic foot data is the underreporting of diabetic status on hospital discharge abstracts, and the absence of outpatient data. [6]

Lower extremity diabetic ulcers are identified by the ICD – 10 (International Classification of Diseases) code 250 for diabetes and code 707 for ulcer.[6] It is estimated that 15% of people with diabetes will develop foot ulcers, and that 20% of hospital admissions for diabetics are due to foot ulcers.[7,19-22] Diabetes is one of the most common underlying causes for lower extremity

amputation, and ulceration is the most common single precursor to amputation.[38] Ulceration has been identified as a component in up to 85% of lower extremity amputations.[20-22,38]

Amputations, in turn, have been associated with an increased risk of re-amputation of the same limb, amputation of the other limb, an increased mortality rate in the first three to five years post surgery and increased placement in nursing homes or other care facilities.[38] In total, the prevalence of diabetes in patients undergoing major amputations has been estimated to be as high as 40 to 70%.[28]

Amputations reduce the patient's level of function and independence, and place a large burden on individuals; families and health care systems.[29] Amputations are thus an expensive treatment procedure for all stakeholders involved.[28] Amputation is often viewed by the health care professional as failed conservative management or as the inevitable result of diabetes. Amputation is often viewed by the patient as an end to productive living and the start of long term disability and loss of independent function.[32]

Research has shown that both amputation and ulceration can result in a lower quality of life for both the patient and the caregiver.[25] However, although there is little data on the life experiences of people with diabetic foot problems, several studies have shown that people with ulceration due to diabetic foot complications, have a poorer quality of life than people with diabetes who have undergone amputation.[25]

Studies by Lithner and Apelqvist have shown that preventative care may reduce the number of amputations in patients with a diabetic foot ulcer by as much as 50%.[25] McDermott also acknowledges the advantages in the use of a multidisciplinary team to address foot care and limb salvage.[9]

Knowledge about diabetes has come a long way since Areteus' description of diabetes as 'the melting down of flesh and limbs into urine'. However, despite all this advancement, health care professionals are still challenged to provide effective treatment which prevents chronic symptoms and poor

quality of life. A multidisciplinary team approach in the treatment of the patient with a diabetic foot ulcer has led to a reduction in the number of amputations performed and a reduction in the length of hospital stay.[25,28]

The next section of this chapter explores the multidisciplinary team in more detail, with specific relevance to the diabetic foot problem.

2.3 The Multidisciplinary Team and Management of the Diabetic Foot

Experts agree that no single person can be responsible for every aspect of the prevention and treatment of the patient with a diabetic foot problem; rather in combining the skills of several professionals, including podiatrist, orthotist, nurse and surgeon, the complications related to diabetic foot disease can be reduced.[9,11,12,18,26,28,30]

The multi disciplinary team for the care of a patient with diabetic foot problems is suggested to consist of the following professionals: podiatrist, physician specialised in diabetes, orthotist, nurse and surgeon.[9,28,30] The roles of the various professionals within the multidisciplinary team are described by several authors [9,28,30], and may vary slightly depending on individual clinic set up and access to staff.

The podiatrist is responsible for the routine care of the diabetic foot, including debridement of callus, and care of ulcers. He or she is also responsible for the education of patients and their caregivers and for giving advice on footwear.[9,28,30]

The physician, who has specialised in diabetes, performs the initial assessment of the patient, and diagnoses the diabetic foot condition. He or she is responsible for all aspects of the management of sepsis in the diabetic foot and for ensuring the patients attending the clinic are under good metabolic control.[9,28,30]

The orthotist plays an important role in the provision and manufacture of special footwear to redistribute the weight-bearing forces on the affected foot, and offers technical expertise in shoe wear modification and conservative treatment through the use of insoles. There may be a slight overlap in the roles of the podiatrist and the orthotist, however, this should be clarified at the individual clinic level.[9,28,30]

The nurse has varying roles throughout the clinic; he or she assists with patient assessment, education programmes and foot dressings. Often the nurse is also responsible for the basic nail and skin care of the foot. The surgeon should be available for consultation regarding difficult diagnoses and complex foot problems.[9,30]

The diabetic foot is an intricate and chronic problem, with many contributing factors. While the value of a multidisciplinary foot care team has been well documented[9,11,12,18,28,30] one of the most important role players is the patient himself. Without proper understanding, insight, compliance to treatment and co-operation, effective treatment of the diabetic foot is difficult.[5,6,31]

The role of the physical therapist is also described by McDermott, who states that basic nail and skin care is provided by the physical therapist in certain clinic settings.[9] Physiotherapists and occupational therapists are also consulted when patients need specific intervention with regards to mobility and independence in activities of daily living.

It is the researcher's opinion, after consulting the literature, that while the essential members of the multidisciplinary team are described, the rehabilitation therapist (occupational therapist or physiotherapist) is not usually included in the diabetic foot clinic set up and seems to have been overlooked. However, it is recommended that these professionals be available to the clinic on a consultation basis. The occupational therapist and physiotherapist are often consulted once an amputation has occurred and the patient requires intensive rehabilitation in order to regain independence.

In the next section, the role of the occupational therapist in the treatment of chronic diseases such as diabetes is discussed.

2.4 Occupational Therapy and Chronic Diseases

The benefit of rehabilitation therapists, including occupational therapists, treating people with chronic diseases (including diabetes) has been reported by Rijken and Dekker, Yawn and, Driessen, Dekker, Lankhorst and Van der Zee.[39-41] In chronic diseases, the efficacy of medical treatment is usually limited. An occupational therapist thus shifts the focus from recovery of the disease to maintenance of functional health and reducing the negative consequences of a chronic disease.[39,41,42]

Occupational therapists are often involved in the treatment of patients with diabetes and its complications. However, at the time of the research, no guidelines or protocols could be found for treatment of the persons with diabetes by occupational therapists, possibly making treatment of these patients by the occupational therapist ambiguous.[35] The following databases were searched for guidelines or protocols about the management of diabetes by occupational therapists: Medline, Google Scholar, PubMed, OVID and OTSeeker.

Occupational therapists are often consulted to treat patients once an amputation has occurred, as a result of a diabetic foot problem. The aims of treatment, in such a case, are usually to make the patient as independent as possible, despite the impairment they may now have, to facilitate the patient to return to his previous roles and responsibilities, and to provide education to prevent further injury or amputation.[43] Occupational therapy, therefore, aims to improve a person's ability to function independently despite disease or illness. It aims to assist people to return to purposeful, meaningful activities and thus improve quality of life. This is done through the use of carefully and skilfully selected activities that are both meaningful and useful to the patient.

The next section of this literature review explores the concept of quality of life in more detail, specifically applied to the patient with diabetic foot complications and also in relation to the occupational therapy philosophy.

2.5 Quality of Life

Quality of life is a concept commonly used in health and social research.[17] Medical rehabilitation is built up on a quality of life foundation, emphasizing aspects such as functional, psychological and social restoration.[44] Quality of life provides insight into the global health status, well being and functioning of people.[17,45] There are clear links between occupational therapy philosophy and the concept of quality of life; both have a client centred, holistic approach and are concerned with the roles and functions that give value and meaning to life.[17] Occupational therapists believe that engagement in meaningful and valued occupation gives meaning and worth to people's lives and can be used in therapy to facilitate recovery and promote healing after disease or injury.[17] The term occupation used here does not refer to employment but rather to "All that people need, want, or are obliged to do; what it means to them; and its ever-present potential as an agent of change. It encapsulates doing, being and becoming."[46 p343]. Similarly, the concept of quality of life encapsulates the dimensions of human existence that give meaning to life.[17]

Quality of life is a widely researched concept that has been used by many professions involved in all areas of human function. For this reason, there is much debate about the exact definition of the term 'quality of life'. For the purposes of this research, the researcher has chosen the definition provided the World Health Organisation's Quality of Life Group (1995):

"Quality of life is defined as a person's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health,

psychological state, level of independence, social relationships, and their relationships to salient features of their environment." p1405

In occupational therapy, the overall goals of treatment are almost exclusively focussed on improving quality of life.[17] Several studies have shown that people suffering with diabetic foot complications have a poorer quality of life than their healthy counter parts.[20-22,25] Patients with diabetic foot problems have been found to be significantly more depressed and dissatisfied with their personal lives than people with no history of foot ulcers, or people with lower limb amputations.[20-22,25] People with diabetic foot complications have also been found to have a more negative attitude towards their feet and the related foot care. These negative attitudes may contribute to recurrent ulceration.[25] A diabetic foot ulcer has been shown to not only impact the quality of life of the sufferer, but also of their caregivers. Both caregivers and patients have reported a reduction in social activities, increased family tension, lost time from work and negative effects on general health.[20-22,25]

However, a study in the United Kingdom by Tyrrell, Phillips, Price at al, found that the quality of life of patients suffering with diabetic foot problems improved when they attended a specialised, multidisciplinary diabetic foot clinic and received orthotic interventions.[25]

Attempts to assess the impact of disease and illness and the impact of their treatment on the lives of patients are prevalent in rehabilitation literature.[33] Concepts such as functional status and quality of life are receiving much interest as end points of clinical investigations.[33] Pressure also continues to mount from insurers, employers and clients for rehabilitation staff, including occupational therapists to provide quality, evidence-based therapy.[16] Research into measuring therapy outcomes is thus increasing as can be seen by the increasing amount of articles published on outcomes measures in therapy.[16]

There are many quality of life assessment tools available to health care professionals to assist in determining a patient's quality of life.[16,17] Examples include the Quality of Life Index (QL-INDEX), the Life Satisfaction Questionnaire and the Reintegration to Normal Living Index (RNLI).

The QL-INDEX aims to provide a global measure of quality of life and was developed for use with persons with chronic physical diseases. The index consists of five items and is scored by a therapist or the patient. There was no consultation with an occupational therapist during the development of this index, and for this reason, it was not chosen for use in this research.[16] The Life Satisfaction Questionnaire was developed in consultation with an occupational therapist and aims to measure life satisfaction or happiness as a whole.[16] It was developed for use with the general adult population and consists of nine items examining the client's satisfaction. As the questionnaire was developed for use with a general adult population and not specifically for use with patients with chronic diseases, such as diabetes, it was not suitable for use in this research.

The RNLI was designed to assess the consequences of disease and its treatment on patient's lives.[33] It uses the related concept of reintegration to normal living as a proxy to quality of life, and defines reintegration to normal living as 'the reorganisation of physical, psychological and social characteristics of an individual into a harmonious whole so that one can resume well-adjusted living after an incapacitating illness or trauma'.[33 p492] The concept of reintegration is also closely linked to functional status, if one uses the following definition: Jette defined functional status as 'the normal or characteristic performance of an individual'.[33 p492] Jette then described two dimensions of health status: the physical manifestations of an illness and the functional status. The physical manifestations refer to the disease and the resulting impact on organ systems. The functional status refers to the individual's physical, mental, emotional and social performance. The functional status thus reflects a behavioural and subjective interpretation of health.[33] Dysfunction can thus occur in any of the four areas mentioned and have an effect on the individual's return to normal living patterns.[33]

The RNLI was developed by Wood-Dauphinee and Williams. Although more limited in conceptual focus than a global measure of health, the RNLI assesses the importance of the symptoms of the condition through their effects on daily functioning. [33] The RNLI's content is similar to global quality of life assessments.[33] During the development of the index, several professionals were consulted and among these where occupational therapists, making the index particularly suited for use by an occupational therapist. Patients were also consulted in development and specifically diabetic patients were consulted, thus incorporating a client-centered approach in the development if the index.[33]

What makes this quality of life index unique is the fact that it assesses the consequences of a disease and its treatment on a patient's life. This is done by looking at a patient's level of functioning by examining their perceptions and objective indicators of physical, social and psychological performance.[16] It was originally developed for use with adults suffering with chronic diseases; making it particularly applicable for use with patients with diabetic foot complications.[16]

The RNLI consists of 11 items which are each scored on a 10 point visual analogue scale. The items cover a good range of activities of daily living namely: mobility, self care, family roles, family roles and relationships, presentation of self, coping skills, work, housework, and recreational and social activities. The final score of the RNLI is converted to a score out of 100 for ease of interpretation. The RNLI is easily administered in either interview, or self report format.[16,33,34]

In the case of patients suffering with diabetic foot complications, the ultimate aim of treatment of the specialised multidisciplinary team is to prevent amputation and maintain as high a quality of life as possible. To achieve this, educating the patient to manage and take responsibility for his condition forms an integral part of the treatment regime. Patient education is thus the next topic of this review.

2.6 Patient Education

As previously mentioned, the most important role player in the multidisciplinary team is the patient himself. However for the patient to be an effective member of the team, he should be educated and informed.[5,6,31] Education is an essential function of all those involved in the care of a person with diabetes, and it is found that the more informed a patient is about the possible complications of diabetes, the more he or she can take responsibility for the management of their disease.[11] It has been estimated that between 44 and 85% of lower extremity amputations in patients with diabetes could have been prevented through proper education and preventative care.[7,10] Prevention therefore begins with knowledge about the causes of skin breakdown and the measures to prevent this.[7,10,26,47]

Education of the patient with a diabetic foot condition, and the patient's caregiver (if applicable), should be done regularly and should be tailored to suit the patient's lifestyle, problems and special needs.[9,10,26,47] It is generally agreed that education about the diabetic foot should be thorough and should be repeated regularly in order to ensure compliance and understanding.[9] Diabetic foot care education should include foot hygiene, foot precautions, routine foot and nail care and information regarding shoe and sock wear.[9,10,11,26,30,31,47-49] Information regarding the danger signs of skin breakdown, and possible ulceration, such as warmth, swelling, colour change and pain should also be provided.[10,49]

Education can and should take on several forms and should be tailored to the patient and their caregivers. A variety of techniques of education are available and it has been found that the most effective method is a mixture of reading and learning methods.[10] The written word should be available in brochures and leaflets, and should be backed up by the spoken word. It is important to ensure that there is consistency between all methods of education used by all members of the team.[10] If an ulcer is present, education should expand to include the relevant wound care and dressing information that is necessary for the particular patient.

Even with education, eventual amputation of a diabetic foot still occurs. Patient understanding, insight and motivation have all been listed as key factors in the successful outcome of treatment.[6,9] Edmonds et al view motivation as just as important as knowledge and education about foot care in the successful outcome of treatment.[10]

Faris believes that there are three elements that are essential for the patient to possess in order to adequately care for his or her feet, namely: education, motivation and capacity.[11] Education is the role of the professionals working at a limb salvage clinic. But, motivation is solely the patient's domain. Faris believes that the motivation to comprehend and carry out the instructions given during a consultation is greatest immediately after diagnosis, or following the first episode of infection or ulceration. However, a complacent attitude and decrease in the level of motivation often develops, resulting in deterioration in the standard of care. Lastly, Faris states that the patient must have the physical capacity to care for his or her feet; this includes aspects such as eye sight and joint mobility.[11]

It has been speculated that patients suffering with long-standing diabetes, may present with cognitive and perceptual impairments [32], making successful and lasting education difficult to achieve. In the light of the important role that motivation plays in the outcome of the treatment of a diabetic foot condition, and the possible perceptual and cognitive impairments that patients suffering with long-standing diabetes may have, several authors recommend a psychological evaluation. This evaluation should be executed in order to gain more insight into the patient's level of insight, their possible compliance and their motivation to adhere to prescribed treatment. However, as already mentioned, the researcher could not find more information regarding the specific guidelines or content of this recommended psychological evaluation. The role of the psychologist in the multidisciplinary team caring for people with diabetic foot complications has also not been well documented.

The role of occupational therapy in the treatment of chronic diseases has been discussed. The need for a type of psychological evaluation, based on

motivation, has also been highlighted in the preceding section. The next section thus deals with the role of motivation in occupational therapy. The Model of Creative Ability (MCA) is described as a means with which to assess motivation.

2.7 Motivation and the Model of Creative Ability

Motivation is essential in occupational therapy, and forms the cornerstone of treatment.[2,3] In order to take part in therapy, it is widely agreed that a patient must be motivated.[1,3] Generally two types of motivation are described: intrinsic motivation and extrinsic motivation. Intrinsic motivation comes from within the individual, for example the drive to seek food if one is hungry. Extrinsic motivation however comes from outside the individual from, for example; external factors, such as a reward, which motivates a person to do something.[50] Intrinsic motivation is defined as 'A concept in human development that proposes that people develop in response to an inherent need for exploration and activity.' [14 p118] It is this intrinsic motivation that is referred to in occupational therapy practice.

Intrinsic motivation drives one to have one's basic needs met. Once these needs have been met, intrinsic motivation drives one to achieve higher goals such as self esteem or self actualisation.[51]

Motivation has been widely described in occupational therapy literature, notably by Kielhofner who developed the Model of Human Occupation (MOHO) and by Du Toit who developed the Model of Creative Ability. The MOHO is well documented, while the MCA, although widely used among occupational therapists in South Africa, needs further investigation.[1-3] This literature review will present a brief overview of both models.

2.7.1 Model of Human Occupation

The MOHO is one of the most widely publicised models, and was developed by Kielhofner, Burke and Igi in the 1970's and 1980's. The model is still being refined. The model is based on an 'open system' theory and perceives man as a cyclic system capable of change and development in response to experience. This system has four facets:

- Input: taking in of information
- Throughput: the ability to organise incoming information and formulate a response
- Output: the response to the input in the form of action
- Feedback: the recognition of the consequences of the action or response

Feedback is then accepted back into the cycle as new input. The model proposes that through activity man is thus able to interact with his environment and form responses from the input he receives. He is able to make judgements (throughput) and change his future actions. The model then describes the structure of the throughput facet as hierarchical and made up of three subsystems: volition, habituation and performance.[52]

Volition is the highest subsystem and is composed of values, interests and beliefs. These are seen as the most influential factors in determining priorities and goals, and the driving force which motivates a person to participate in activity.[52] Volition represents the meaning that we make of ourselves acting in the world. It is this volitional meaning which motivates us to choose our occupations.[53]

The three subsystems interact in the throughput stage of the cycle to enable a person to decide whether to participate, to organise patterns of behaviour when participating, and to carry out actions.[52]

The impact of chronic disease on volition can lead to a breakdown in morale. When meaning and purpose in life is diminished, it becomes

difficult or impossible for the individual to make adaptive choices to engage in activities. [54]

2.7.2 Model of Creative Ability

The MCA was being used at the Diabetic Foot Clinic at Pretoria Academic Hospital (PAH); however no research had been done to investigate the value of the use of this model with patients with diabetic foot problems. The use of the model within the clinic was also not standardised.

As the MCA was being used at the Diabetic Foot Clinic, and it is widely taught and implemented in the South African setting, the researcher decided to use the MCA and not the MOHO in the research. The other reason for the use of the MCA is the urgent need to research this model. Casteleijn and Smit, amongst others, recommend further research into the use of the MCA in an attempt to further develop and refine the model.[1-3,55] The MCA is a unique South African contribution towards occupational therapy; however, if the model is not further researched, and the results published, the model is at risk of perishing and being replaced by more researched and documented theories such as the MOHO.[1-3] The researcher thus hopes that this research will contribute to the body of knowledge about the MCA, in an attempt to make it as well documented and researched as the MOHO.

Du Toit's MCA provides a theoretical framework in which a patient's level of motivation can be determined, based on his/her observable level of action (participation in activities).[8] Du Toit believes that a person goes through different stages of motivation and action throughout life.

Motivation is the inner force that initiates and drives all behaviour, and results in the creation of an end product. The actions which a person displays are observable and express his motivation. Thus it is said that motivation governs action and that action is the manifestation of motivation.[1,2,13] Through assessment of action, a therapist is thus able to

measure the level of motivation. The MCA is a client centred model that was developed for use with a variety of patients.

Du Toit described nine sequential and interdependent levels of motivation with their corresponding levels of action. The levels represent the stages of development or recovery, and growth takes place through exploration, participation and mastery. It is possible to have forward or backward flow between the levels as a person moves through various stages of life, illness or trauma.[1-3,13,35] The nine levels of motivation can be divided into three groups, namely: preparation for constructive action, behaviour and skill development for norm compliancy, and behaviour and skill development for self actualisation.[13] Table I represents the nine levels of motivation and their corresponding levels of action.

Table I: *Summary of the levels of motivation and corresponding levels of action*[13]

Level of Motivation	Level of Action	Description
Group 1: Preparation for Constructive Action		
Tone	Pre-destructive	Motivation is directed at establishing and maintaining a will to live
Self-Differentiation	Destructive	Motivation is directed at establishing and maintaining self-awareness, achieving control over body, and learning basic social behaviours
Self-Differentiation	Incidental Constructive Action	
Group 2: Behaviour and Skill Development for Norm Compliancy		
Self-Presentation	Explorative	Motivation directed towards development of individuality, but also establishing a sense of belonging to a group. Development of basic self concept, exploring ability to influence environment, presentation of self to others and development of basic social skills, and basic elements of productivity

Passive Participation	Experimental	Establishing norms and rules according to which behaviour is acceptable. Motivation becomes more goal-directed, but people struggle to initiate activities independently. Behaviour tends to be passive and erratic. People on this level tend to be followers
Imitative Participation	Imitative	Motivation is directed at following the norms set by society for acceptable behaviour. People actively seek to be part of a group. Motivation is product centred but there is little evidence of initiative and there is reluctance to compete. People at this level are stressed by the unknown and the unfamiliar. People do what is asked of them no less and no more.
Group 3: Behaviour and Skill Development for Self-Actualisation		
Active Participation	Original	Motivation is directed towards improving/changing aspects of activities or behaviour where the person has recognised a problem. Improvement seeks to emphasise individuality
Competitive Participation	Product Centred	Individuals have self confidence and have a realistic cognitive and ideal self. Individuals aim to do better than before or better than others at an activity. Self esteem is adequate enough to tolerate failure.
Contribution	Situation Centred	Individuals able to sublimate own needs for those of others. Concentrates on needs if individuals in own situation/group (situation centred) or concentrates on more global needs of society (society centred)
Competitive Contribution	Society Centred	

If motivation is the driving force behind all action, it stands to reason, that patients with low motivation will have low levels of action. This means that it is difficult for these patients to co-operate with the management of a medical condition, for example, their foot problems. They simply lack the motivation to carry out the instructions, or the insight to understand the importance of a prescribed treatment regime.

If a patient lacks motivation they will often appear non compliant and uncooperative to treatment prescribed by a health care team. Patients with poor motivation are often labelled as “difficult” or “noncompliant”, and are a source of frustration for many health care professionals. However, if motivation can be assessed, this can give the health care team insight into the patient’s condition, compliance to treatment and possible prognosis.

Accurate assessment of motivation is crucial for the occupational therapist. If the level of motivation of a patient is established, it can provide a guideline to professionals in the health care team, about the starting point of treatment as well as appropriate and purposeful activities for patient treatment. It can also be used as a predictor of prognosis.[1,2]

Despite the importance of the assessment of motivation, there appears to be a shortage of research on motivation, specifically research on the accurate assessment of a patient’s level of motivation.

The Creative Participation Assessment (CPA) was developed as a tool to assess motivation, based on the MCA. Once the level of motivation has been determined, this information can be used to guide the health care team in the treatment of a patient and offers valuable information regarding patient compliance to therapy and possible prognosis.

The CPA[b] was developed by Van der Reyden as an assessment for motivation. Creative participation is the term used by Du Toit for the

[b] The CPA has been included as Appendix 3

expression of motivation.[3] The CPA is a one-page tick-off sheet with 12 items that are to be observed and scored on an ordinal scale of 1 to 7. The scale of 1 to 7 represents the seven levels of motivation or creative participation.[3] The validity of the CPA has been established when used with patients suffering from schizophrenia. While validity has not been established for other patient groups, motivation is core to a person's ability to function, and can thus be assessed irrespective of diagnosis. Casteleijn found that the CPA is also a reliable measurement tool when used with patients suffering from schizophrenia (Cronbach's alpha of 0.9960).[1,13]

In order to accurately assess a subject's level of motivation, at least three activities are necessary. The activities should be a mixture of familiar and unfamiliar for the patient.[3,13] The therapist observes the patient's behaviour during the activities and marks off the appropriate comment on the CPA form. The scores are then added up to indicate the patient's level of functioning. The therapist then decides on the phase of the patient's participation. Namely: therapist directed, patient directed or transitional. The reader is referred to Chapter 3 for more detail on the execution of the CPA.

2.8 Summary

The preceding review has given a history of diabetes and, in particular the diabetic foot. The advantages of the multidisciplinary team and the specialised diabetic foot clinic have also been discussed, and consensus was found in the literature, stating that this is the best way to treat the patient suffering with diabetic foot ulcers.[9,11,18,26,28,30]

The role of occupational therapy in the management of chronic diseases was briefly reviewed. In this section, the lack of guidelines for occupational therapists treating patients with diabetes was highlighted, as well as the focus of occupational therapy on the improvement of quality of life. The effect of a foot ulcer on the quality of life of the patient was then discussed in detail, and several research studies have found that people with diabetic

foot ulcers have poorer quality of life than their healthy counterparts.[20-22,25] The RNLI was explored as a proxy to a quality of life assessment.

The importance of preventing diabetic foot complications through patient education was then investigated, and again, consensus was found in the literature about the fact that patient education is a vital role of the foot care team and that motivation is vital for effective patient education.[6,9-11,26,30,31,47,48]

Lastly, motivation and the MCA, developed by Du Toit, were discussed and described in detail, as a tool with which to assess and treat motivation. The CPA was also described.

The preceding review thus clearly highlights the lack of literature and guidelines concerning the occupational therapy treatment of people suffering with diabetes and its complications. It also highlights the importance of motivation in the effective outcome of treatment, and the lack of a way to determine the motivation of a patient.

The next chapter will explain how the research was carried out, looking at the research design, measuring instruments and data collection.

Chapter 3: Methodology

3.1 Introduction

The aim of this chapter is to explain how the researcher carried out the research that was briefly described in Chapter 1. The research design will be discussed in detail. This is followed by an explanation of the population and sampling techniques used. Measuring instruments are then discussed. The data collection plan that was used is illustrated, and data analysis is discussed. Lastly, the ethical issues involved in the research are highlighted.

3.2 Research Design

There are three paradigms or world views which are prominent in social research, namely: positivist social science, interpretive social science and critical social science.[56,57] Most social research is based on the first two paradigms, with positivist social science, being the oldest, most widely used and most prevailing paradigm.[56,57] Positivism broadly defined, is the approach of the natural sciences. It assumes an objective world which science can 'mirror' and it aims to uncover the truth or fact between specified variables.[56] A positivist approach implies that research begins with a cause-effect relationship, and then logically links abstract ideas to precise measures of the social world. The researcher remains detached,

neutral and objective.[57] Research methods of the positivist paradigm include both qualitative and quantitative designs.[56]

A quantitative research design was chosen to test the hypothesis for this research. Quantitative research is an empirical method that is based on hypothesis testing and the measurement of variables within a value-free framework.[58-60] Empiricism is defined as gaining data through the senses that are observable, objective and verifiable. Quantitative research relies on a positivist approach and follows a linear research path.[58-60]

The characteristics of quantitative research include:

- Testing of an hypothesis
- Concepts that are in the form of distinct variables
- Measures that are systematically created before data collection, and that are standardised
- Data that are in the form of numbers from precise measurement
- Theory that is largely causal and deductive
- Procedures that are standard, where replication is possible
- Analysis that is done using statistics, tables, and charts, and by discussing how this information relates to the hypothesis.[60]

The researcher chose to conduct experimental research which, simply stated, means modifying something in a situation and then comparing the outcome to what existed before the modification.[58,59,61] This also requires that the researcher start the experiment with a hypothesis, which has been stated in Chapter 1.

An experiment (such as the research conducted by the researcher) has several characteristics or parts[61]:

1. Manipulation of an independent variable, which is usually the treatment or intervention that the subjects in the study received.
2. Dependent variables which are usually the outcomes of the experiment
3. A pre-test to determine the baseline
4. A post-test to determine change in the dependent variables

5. An experimental group that receives the treatment or independent variable under investigation
6. A control group that does not receive the independent variable or receives a different treatment than the experimental group
7. A sample that is representative of the population being studied
8. Random assignment that gives the subjects of the sample an equal chance to be in either the experimental or control group.

In an experiment, the researcher creates a situation and then modifies it by changing the treatment that is offered (in other words, manipulating the independent variable).[59,61] The dependant variables or the outcomes of the experiment are the physical conditions, social behaviours, attitudes, feelings or beliefs of the subjects that change in response to the treatment. These dependant variables then need to be measured in order to document the effect of the independent variable.[59-61]

In quantitative research, the researcher combines parts of an experiment together into an experimental design. In this case, the researcher chose an experimental pre-test-post-test design with an experimental and control group.[61] The research design thus included the following characteristics of a classical experimental design:

- Manipulation of the independent variable: treatment offered based on the Model of Creative Ability (MCA)
- Dependent variables: percentage change in ulcer size, and change in quality of life
- Random assignment of the subjects into either the experimental or control group
- Pre-test: Assessment of level of motivation using the Creative Participation Assessment (CPA), measurement of ulcer size, and measurement of quality of life using the Reintegration to Normal Living Index (RNLI)
- Post-test: Re-assessment of the level of motivation, measurement of ulcer size, and re-assessment of quality of life
- Control group (received standard treatment, care as usual)
- Experimental group (received tailored treatment) [61]

Pre-test and post-test assessments were administered to both groups. The experimental group received a tailored occupational therapy treatment programme based on the MCA, and the control group received care as usual.[58,59]

The research design thus can be described using notation as follows:

$$O\ X_1\ O$$
$$O\ X_2\ O$$

The use of random stratified assignment (discussed further in section 3.4.3), the manipulation of the independent variable (the occupational therapy treatment offered), and the presence of a control group, meant that any improvement shown could be accredited to the occupational therapy treatment programme (the independent variable), through the use of statistical analysis and finally, possible rejection of the null hypothesis.[58,59,62] Methods to control extraneous variables were implemented and are documented throughout the research. For example, subjects of both genders and all representing ethnicities at the clinic were included in an attempt to obtain a representative sample; demographic data were collected and will be presented in the results chapter. This thus contributed to the internal validity of the research.[58,59]

It was hypothesised that the experimental group would have better treatment outcomes (dependant variables) with tailored occupational therapy (independent variable) than the control group who received care as usual. Clarification and description of the dependant and independent variables thus follows in the next section.

3.3 Variables

3.3.1 Independent Variable

The principles of treatment that are described in the MCA and are based on the level of CA, are used to tailor the occupational therapy treatment thus

making the tailored treatment the independent variable. In order to tailor the MCA (the independent variable) to each subject, the level of CA (motivation) of each subject had to be assessed. This level of motivation was assessed pre test and post test. Although the level was not expected to change drastically in the course of the three month treatment programme; the researcher assessed the level post test in order to monitor and document any changes that did occur. The assessment thereof is hence described in section 3.5.1.

3.3.2 Dependant Variables

The term "Improvement in Treatment Outcomes", as stated in the hypothesis, is rather general, and could mean different things to different people. The researcher acknowledges that there are many additional outcomes in the treatment of a complex condition such as the diabetic foot. For the purposes of this research however, the researcher chose to focus on two outcomes, namely: percentage change in the size of the ulcer and change in the subject's quality of life. These outcomes are the dependant variables for this research. As it is essential that the outcomes of the experiment (the dependant variables) are measured, these outcomes have been operationally defined below.

3.3.2.1 Change in Ulcer size

The ultimate aim of the Diabetic Foot Clinic is to heal any ulcers that may be present, and to prevent new ulcers from forming, thus preventing amputation. The change in the size of the ulcer is thus an important indicator of healing that is taking place. Delmas states that a 20 – 40% reduction in ulcer size after two weeks of treatment is a good indicator of healing at 12 weeks.[27] However, at the Diabetic Foot Clinic, it was established that a 50% decrease was occurring in ulcer size over a period of three months or twelve weeks. The researcher thus chose to use change in ulcer size as one of the outcomes for this research, change in ulcer size was measured using a wound tracing technique. (For the determination of clinically significant changes in ulcer size, the Diabetic Foot Clinic's retrospective data was used in other words: 50% reduction in three months).

3.3.2.2 Quality of Life

The impact of a disease and its treatment on a patient is frequently measured by endpoints such as quality of life.[16,17,44,45] Quality of life is a particularly important concept when therapeutic goals do not include cure, but are focussed rather on controlling the disease process and compensating for impairment, as is the case in the treatment of the a patient with diabetes.[33,40,45] By offering patients tailored treatment based on their level of motivation, it was hoped that the size of the ulcer would decrease and that the patients would have a better understanding of the disease process, its treatment and the possible outcomes. It was expected that this would assist the patient to "resume well adjusted living after an incapacitating illness or trauma" [33 p492] and thus, according to the definition of reintegration to normal living, allow for an improvement in the patient's quality of life. For this reason, change in quality of life was chosen as the second treatment outcome (dependant variable) for this study and was measured using the RNLI.

The operationalisation of the dependant variables into the two measures described above, allowed for the collection of data in the form of numbers from precise measurement, which is a characteristic of quantitative research.[60] The exact measurement of these outcomes is further described in Section 3.5. The researcher used measures (namely wound tracing and the RNLI) that were created before the data collection took place and which were standardised, this is also in keeping with the characteristics of quantitative research.[60]

The next section of this chapter will look at exactly which population was used for the research and how the sampling took place.

3.4 Population and Sample

3.4.1 Population

The target population for this research is all patients suffering with diabetic foot complications who have ulcers as a result of this condition. Stein and Cutler have described a *convenience population,* which is a population that is readily available to the researcher.[63] Using this reasoning, the convenience population for this research was thus all patients attending the Diabetic Foot Clinic at Pretoria Academic Hospital (PAH) who had foot ulcers.

3.4.2 Sample

The sample that was used for this research was a convenience sample by virtue of the fact that the population used was a convenience population. Only patients who agreed to participate in the research by signing the informed consent documents were included in the sample. This thus made the sample a volunteer sample, from a convenient target population. While the researcher acknowledges that the use of a convenience target population may limit the external validity of the results, it should also be noted that by geographically limiting the representativeness of the sample the researcher controls for certain environmental factors which could possibly affect the research.[63] (Patients attending the PAH Diabetic Foot Clinic, thus residing in the PAH catchment area).

Potential subjects were approached to participate in the research during the recruitment phase of the data collection plan. All patients meeting the inclusion and exclusion criteria were approached to participate. Table II shows the inclusion and exclusion criteria that were applied in the research in order to select suitable subjects.

Table II: *Criteria for selection of subjects for sample*

Inclusion criteria	**Exclusion criteria**
Patients attending the PAH Diabetic Foot Clinic	
Patients with diabetic foot ulcerations	Patients with healed ulcers or healed amputations
Patients with new or previously untreated diabetic foot ulcers	Patients with ulcers not related to the complications of diabetes

3.4.3 Assignment

Random assignment is a method for assigning subjects to groups for the purpose of making comparisons. It is a way to divide a collection of cases into two or more groups in order to increase the researcher's confidence that they do not differ in a systematic way. It is a mechanical method and the assignment is automatic.[61,63] Random assignment is thus unbiased as the researcher's desire to confirm a hypothesis does not enter into the selection process.

Once subjects had agreed to participate in the research, they were assessed to determine their level of motivation. Based on the assessed level of motivation, subjects were randomly assigned into either the experimental or the control group. In order to ensure that both groups had a fair representation of all relevant levels of motivation, stratified random assignment was used. Subjects were thus assigned to either the experimental or the control group from within their level of motivation, as described by the MCA.[58,62,63]

Due to the type of subjects used in the research, not all levels of motivation were represented within the sample. For example the first two levels of motivation; tone and self differentiation were not represented in the sample. This however did not negatively influence the research as the researcher attempted to keep the experimental and control groups as homogenous as possible through the use of stratified random assignment.

3.4.4 Sample Size

The sample selection took place over a period of nine months, during which subjects were recruited for the study at each clinic day. Originally the researcher planned the recruitment of subjects over a three month period, but this period was extended in an attempt to obtain more subjects.

From retrospective data of patients seen at the PAH Diabetic Foot Clinic, it was found that the expected reduction in the size of an ulcer is 50% in a three month period, with a standard deviation of 29.3%. For a clinically significant reduction in ulcer size, as a result of tailored occupational therapy treatment to take place, a further 50% reduction in ulcer size (as compared to the pre test ulcer size) was expected. In other words, a 75% reduction was thought to be clinically significant in the experimental group and, a 50% reduction was taking place with the care as usual over a three month period, in the clinic set up.

Under these assumptions, a sample size of 16 subjects per group has power of 90% to detect a difference (improvement) of 25 percentage points between the two groups, with respect to ulcer healing, if testing is one sided at a level of significance of 0.1. A significance level of 90% is often seen as acceptable in the social sciences.[64]

The researcher thus aimed to recruit at least 18 subjects per group. This would ensure that if subjects withdrew from the research, there would be enough remaining subjects to achieve effective research results. Actual sample size will be described in the results section in Chapter 4.

In order to maximise sample size, patients with previous amputations related to diabetes, and new ulcers on the same or contra-lateral limb, were also approached to participate in the research. The conditions of the subjects' feet and any previous amputations were noted.

Once a subject was recruited for the research, the assessment and treatment of the subjects could begin. Subjects were followed up every two weeks in the Diabetic Foot Clinic. In an attempt to retain the subjects for

the period required for the research, the subjects' hospital and transport costs were paid by the researcher.

The next section of this chapter discusses the measuring instruments that were used to record the data for this research.

3.5 Measuring Instruments

The treatment outcomes (dependant variables) of the research have been outlined in preceding sections; this section of the study will now deal with the measuring instruments that were used in order to measure the dependant variables and accurately assess level of Creative Ability (CA) (motivation), ulcer size and quality of life of the subjects in the experimental and control groups.

3.5.1 Level of Creative Ability (Motivation)

To determine a subject's level of CA (motivation), the CPA [c] was used.[2] The CPA was developed by Van der Reyden as an assessment for motivation. It is a one-page tick-off sheet with twelve items that are to be observed and scored on an ordinal scale of 1 to 7.[3]

Creative participation shows us the amount of motivation. Motivation was conceptualised and the following items are included in this theory to operationalise the concept of motivation:

- Handling of tools and materials
- Relating to people
- Handling situations
- Task concept
- Product
- Assistance or supervision needed
- Behaviour
- Norm awareness

[c] Refer to Appendix 3 for a copy of the Creative Participation Assessment

- Anxiety and emotional responses
- Initiation and effort

Casteleijn found that the CPA is a reliable measurement tool for patients suffering from schizophrenia (Cronbach's alpha of 0.9960).[1,2,13] The researcher acknowledges that the validity of the CPA has not been established for use with patients with diabetic foot ulcers; however, as motivation is core to a person's ability to function, it can be assessed irrespective of diagnosis.

The development of creative ability is a life-long process, starting at birth and continuing to old age. It is subject to the same influences and constraints as other aspects of human development. Thus Du Toit described the nine sequential and interdependent levels of motivation which have been discussed in Chapter 2. The level of motivation is not static but varies with the degree that an individual feels secure and with the demands that are placed on him/her. Level of motivation is thus established irrespective of diagnosis or age, and it is possible to have a forward or backward movement through the various levels as a person moves through life and the possible effects of illness or trauma.[1-3,13,35,46]

In order to ensure that the researcher was correctly executing the CPA and thus correctly determining the subject's level of motivation, an expert on the MCA was called in to observe the researcher prior to the commencement of the research. The researcher and the expert then assessed several patients, who were admitted to PAH, as part of the routine assessment. The findings of the assessments were then compared and discussed, thus giving the researcher the opportunity to sharpen her skills in the use of the CPA.

To accurately assess a subject's level of motivation using the CPA, at least three activities are necessary.[13] The researcher thus assessed each subject with the use if a self-care activity, a tea making activity and a table top game. These activities allowed the researcher to observe the subjects in a variety of situations including familiar and unfamiliar activities. This

observation of the subjects' level of action in three different activities allowed for accurate administration of the CPA, and thus accurate assessment of the subject's level of motivation. A description of the activities used follows.

3.5.1.1 Self Care Activity

A simple foot care activity was used to help determine the subject's level of action and thus motivation. Subjects were asked to demonstrate their current foot hygiene routine to the researcher. The subjects were thus required to wash their feet in warm water, dry their feet and apply moisturiser or clip their toe nails according to their foot care routine at home.

This activity allowed to researcher to assess the subject's self-care abilities, as well as aspects such as tool and material handling and task concept.[1,13,15]

All the necessary tools and materials were available for subjects to use. In cases where assistance was required, this was noted, and the subject's ability to have the assistance arranged was observed. If a subject was able to arrange that a family member/caregiver assist him/her in foot care and was able to guide and instruct the family member/caregiver in how to do this, the subject was marked higher on the checklist. If however, the subject was unaware of the foot care procedure and relied on a family member/caregiver to implement this with little or no awareness of the process or reason for foot care, the subject was marked lower on the checklist.

In all cases, only the unaffected foot was washed, as the affected foot had open wounds and was thus bandaged. In several cases, the subjects had above or below knee amputations of the unaffected foot and were thus unable to demonstrate their foot care routine. In these cases, subjects were asked to describe their routine in detail and then demonstrate it on their affected foot without removal of the dressings.

3.5.1.2 Tea Making Activity

In this activity, subjects were given verbal instructions to make themselves a cup of tea or coffee. All the necessary tools and materials were laid out on a counter in front of the subject. The tea/coffee was then consumed during the interview and collection of demographic data that followed. This activity allowed the researcher to observe aspects such as the subjects' handling of the situation, task concept, quality of the end product, norm awareness and effort exerted.[1,13,15] Tea making is a commonly used activity in occupational therapy, both for assessment and treatment purposes.[65]

3.5.1.3 Table Top Game

This activity required that the subject complete an educational game entitled 'Logic Link'. The game can be compared to completing a puzzle of geometrical shapes. The CPA requires an unfamiliar activity to be used to fully assess a subject's level of motivation; Logic Link provided such an activity. The game allowed to researcher to observe the subjects in an unfamiliar setting that required problem solving skills. Aspects such as frustration tolerance and emotional responses were also observed.[1,13,15]

3.5.2 Measurement of Treatment Outcomes

As already discussed, the treatment outcomes, for the purposes of this research were limited to the change in ulcer size and the change in the subjects' quality of life. It is important to accurately measure these outcomes, and the researcher decided on the following measurement instruments.

3.5.2.1 Wound Tracing

The ultimate goal of the Diabetic Foot Clinic is to heal any ulcers that patients may present with. The rate of wound healing in a diabetic patient is often significantly impaired [9], making measuring of healing difficult and often frustrating for the patient and health care professionals. It is therefore important to have an accurate measurement of the size of an ulcer in order to determine if any wound healing has taken place.

To obtain an accurate measurement of the size of the subjects' ulcers, the ulcers' perimeter measurement was taken. This was done by placing a piece of clear sterile plastic sheeting over the ulcer and then tracing around the border of the ulcer. Using a sheet of carbon paper, the "image" of the ulcer was then transferred onto paper, and the plastic sheeting and carbon paper discarded. A grid was then placed over the "image" of the ulcer and the exact size of the ulcer was calculated in square millimetres.[66]

It has been found that wound tracing yields more reproducible results than simply measuring the length and width of the ulcer.[66] This method also allowed for easy comparison of the ulcer size at different stages of treatment/healing, by simply comparing one image to another image of the same ulcer at a different point in time. Using this method, the percentage change in ulcer size was calculated, and used as a treatment outcome.

3.5.2.2 Reintegration to Normal Living Index (RNLI) [d]

Quality of life is an important aspect of care, particularly when dealing with a disease that cannot be cured, but where treatment focuses more on controlling the disease process and compensating for loss of function. The RNLI was developed by Wood-Dauphinee and Williams as a proxy to quality of life. Although more limited in conceptual focus, the RNLI's content is similar to global quality of life assessments.[33] Reintegration is closely linked to functional performance, one of the key aspects of occupational therapy.

During the development of the index, several professional groups were consulted and among these where occupational therapists, making the index particularly suited for use by an occupational therapist. Patients with chronic conditions were also consulted in the index's development and specifically diabetic patients were consulted.[33]

The RNLI consists of 11 items which are each scored on a 10 point visual analogue scale. The items cover mobility, self care, family roles, family

[d] The RNLI has been included as Appendix 1 and 2. Both the English and the Afrikaans versions of the index have been included

roles and relationships, presentation of self, coping skills, work, housework, and recreational and social activities. The final score of the RNLI is converted to a score out of 100 for ease of interpretation. The RNLI is easily administered in either interview, or self report format.[16,33,34]

The RNLI has been found to have adequate inter-rater reliability for significant others and patients (r=0.62), (inter-rater reliability for health professional and patient is lower (r=0.39)) [33,34] and high internal consistency (Chronbach's alpha above 0.90). [33,34] Content validity is also present. These results were established for patients with chronic conditions such as cancer, myocardial infarcts and diabetes.[34]

Thus the RNLI was chosen as the measuring tool with which to measure quality of life. In order to ensure that subjects understood what the RNLI was asking and how to complete it, the index was translated into the subject's mother tongue. Screening of potential subjects revealed that the most prevalent first language was Afrikaans. The RNLI was thus translated from English into Afrikaans by a person whose first language is Afrikaans, but who is also fluent in English. In order to ensure accuracy of the translation, the RNLI was then translated back into English by a person whose first language is English.

The preceding section has described the measurement instruments in detail. The following section will now deal with exactly how the data was collected and how the research was executed.

3.6 Data Collection

Once ethical clearance was obtained from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria (ethical clearance number: S105/2006); data collection commenced in March 2007.

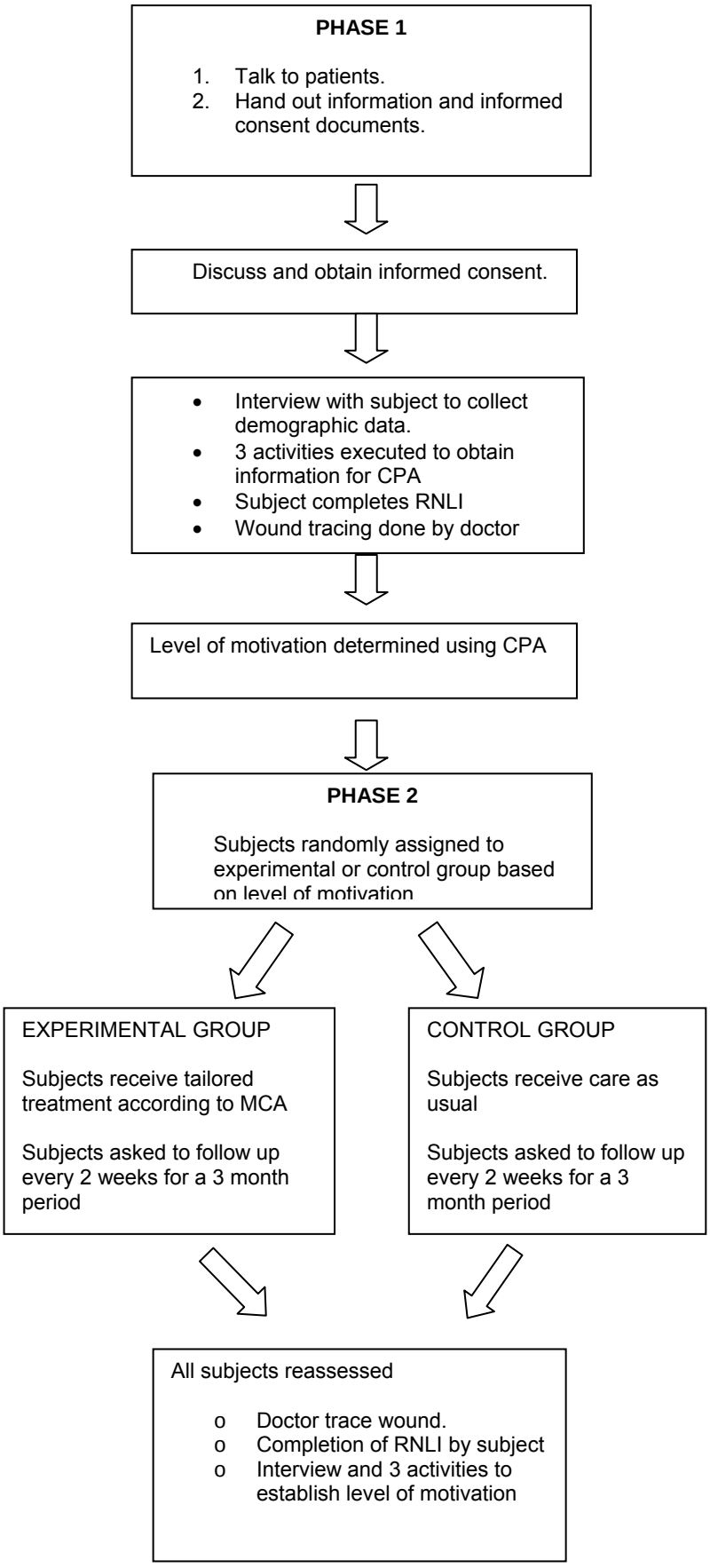
3.6.1 Pilot Study

The data collection started with a pilot study, where four subjects were recruited. Two subjects were placed in the experimental group and two in the control group. The aim of this pilot study was to serve as a trial run for the full data collection phase and thus give the researcher a chance to identify any possible problems. The pilot study also gave the researcher a chance to trial run the activities used in the CPA. The results from the subjects of the pilot study have been included in the results chapter, as minimal changes were made to the data collection process between the pilot study and the full data collection.

3.6.2 Data Collection Procedure

Data collection continued over a period of 12 months. Figure 1 is a diagrammatic representation of the data collection process that was followed by the researcher.

Figure 1 Data collection process



The first phase of the data collection process lasted approximately nine months, and during this time subjects were recruited for the research from the Diabetic Foot Clinic at PAH.

While the patients waited to see the doctor, information booklets and informed consent documents were handed out to potential subjects[e]. When the patient was called in to see the doctor, any questions were answered by the researcher, and informed consent was obtained where appropriate. The doctor then completed a wound tracing of the subject's ulcers. The doctor was asked to complete the wound tracing in order to help eliminate researcher bias. The doctor was unaware of which subjects were in the experimental and control groups, and the same doctor completed the tracing throughout the research.

Once the subject had been attended to by the doctor and the nursing staff, he/she was seen by the researcher. The subject was asked to make him/herself a cup of tea/coffee, as the first of the three activities needed for the CPA. An interview was then conducted with the subject in order to obtain demographic information, background history and information regarding current foot care practices[f]. The subject was then asked to complete the self-care activity and the game in order for the researcher to complete the CPA. Lastly the subject was asked to complete the RNLI.

Once the initial assessment was complete, the subjects were randomly assigned to either the experimental or the control group. This was done using the stratified random assignment as discussed in Section 3.4.3. Subjects were then booked for a follow up clinic visit in two weeks time.

Treatment of the subjects by the occupational therapist (the researcher) started at the next clinic visit, two weeks after the initial assessment. Recruitment of new subjects continued, while the treatment of subjects already recruited started. The two phases of data collection were thus run in a parallel fashion, in order to maximize time and to avoid the risk of

[e] Refer to Appendix 4 and 5 for the informed consent documents
[f] Refer to Appendix 6 for the Interview Guide

"losing" subjects while they waited for the recruitment process to be completed.

A three month period of treatment was chosen by the researcher as this was the period of time in which significant ulcer healing (50% decrease in ulcer size) could be seen, based on retrospective data from the PAH's Diabetic Foot Clinic.

The subjects in the experimental group received the tailored occupational therapy treatment, while subjects in the control group continued to receive care as usual. The researcher thus treated both the experimental and the control group. This made the researcher a constant variable, and thus only the type of treatment received by subjects changed.

At the time of the research, care as usual consisted of:

- Handing the patient a written exercise programme and explaining it to them.
- Educating the patient about foot care using a pamphlet
- Assessing the use of assistive devices and modifying this if necessary.
- Ordering any necessary assistive devices.
- Reinforcing treatment prescribed by the doctor and other team members.

The tailored occupational therapy treatment consisted of similar information and activities. However it was presented to the patient based on their level of motivation using the principles prescribed in the MCA. The information given to the subjects was planned beforehand and a different topic was covered in each session. The topics were:

- Education regarding what is a 'diabetic foot' and how the ulcer developed
- Education about and execution of correct foot hygiene and nail care
- Education about correct shoe wear and compensation for loss of sensation

- Adaptation to daily routine at home/work and discussion about mobility difficulties

Note that the topic sometimes ran over more than one session, or had to be switched with another topic depending on the patient's needs at the time[g].

Patients were also engaged in activities that were relevant to the clinic set up, these thus included mobility exercises and activities, basic foot and nail care as necessary and basic activities of daily living and mobility.

In order to ensure that an accurate and effective treatment programme was drawn up, an expert in the MCA was consulted for assistance and guidance. Table III shows an example of the principles used when treating a subject in the experimental group whose level of motivation was found to be "self presentation".

[g] The reader is referred to Appendix 7 for a copy of the treatment programme for the experimental group.

***Table III**: An example of the principles used when treating subjects.*

Level of action: (determined by CPA)	**Explorative**
Corresponding level of motivation:	**Self presentation**
Principles of treatment according to MCA	
Patient Handling Principles [13,15]	• Therapist should be encouraging and supportive as patients at this level often feel insecure. • Patient individuality should be emphasized by: asking patient for his opinion and ideas and acting on these if practical, sharing patient's achievements with others eg. team members, encouraging patient to take responsibility. • Occupational therapist should facilitate communication between the patient and others.
Structuring Principles for Treatment [13,15]	• Treatment should be carried out in an area in which the patient feels secure, and patients should be orientated to new environments. • Treatment sessions should be approximately 45min long, but this will depend on the patient's endurance. • Treatment areas should be well organised to give patient a sense of security.
Treatment Presentation Principles [13,15]	• Instructions should make the patient aware of the steps to be followed in order to complete the task. • Demonstration should be used with discretion, so as not to reduce exploration. • Emphasis must be placed on the patient's involvement in the activity.

All subjects were asked to return to the Diabetic Foot Clinic on a two weekly basis for their treatment by the foot care team. The costs of the subject's registration at the hospital and their transport costs to and from the hospital were covered by the researcher for the three month research period. This was done to help ensure compliance to the treatment programme. When the subjects attended the clinic, they were seen by all the members of the team and thus received their medication and dressings; this also helped to contribute to compliance.

It is important to note that during the research process, subjects continued to receive treatment from the other members of the foot care team. All other team members were blinded as to which subjects were in the experimental group and could thus not influence results.

After the three month period, the subjects were all reassessed for the post-test assessment. The doctor completed another wound tracing in order to calculate the percentage change in ulcer size after three months of treatment. The subjects again completed the RNLI to monitor their quality of life. Lastly, the subjects were reassessed with the CPA in order to determine their level of motivation. The three activities used for the CPA were the same three activities that were used in the pre-test assessment.

Once data collection was complete for all subjects, data analysis could begin.

3.7 Data Analysis

This section of the chapter will investigate how the data that was collected was analysed.

The data generated from the research, took on several different forms. Table IV summarises the types of data that were obtained from the data collection process. This data was then used in statistical analysis to determine if rejection of the null hypothesis was possible.

Table IV *Types of data collected*

Source of data	Type of data
Demographic data	Nominal data
Creative Participation Assessment	Ordinal data
Reintegration to Normal Living Index	Ordinal data
Wound tracing	Ratio data

Data summary employed descriptive statistics, for example: mean, median, range and frequencies. In the results chapter, the sample is described in terms of experimental and control groups, and similarities and differences are highlighted. The aim of this description is to give the reader good insight into the composition of the sample.[58,67]

The data collected from the CPA, the RNLI and the wound tracing is presented according to experimental and control groups, thus allowing for easy comparison between the two groups.

Inferential statistics were used in this data analysis. Inferential statistics allow one to take the results of a research study such as this one and decide whether or not they are likely to occur in the target population. Inferential statistics also give an indication of the chance of the results occurring. Tests for inferential statistics can be divided into three groups [67]:

- Those that attempt to establish whether the difference between two sets of scores is significant.
- Those that examine two sets of scores and determine the strength of association between them.
- Those that compare more than two sets of scores to find the extent to which they vary among one another.

When using tests for significant difference, the tests assist the researcher in deciding whether the changes in the pre test and post test scores are the result of the experimental treatment or chance. These tests allow for comparison of results from the sample with that which was hypothesised as normally occurring in the target population.[67]

In the case of this research, the test was used with a directional hypothesis as only improvement was expected in the post test results (percentage change in ulcer size and RNLI score). Significance testing is based on the laws of probability and answers the question "what is the probability that this change occurred as a result of the events of the research study, and what is the probability that the change occurred anyway?" [67] As stated earlier, the researcher decided that the level of probability that would be significant for this research study was 0.1. This implies that there is a ten in a 100 (10%) chance that the change occurred as a result of chance and a 90 in a 100 (90%) chance that the change occurred as a result of the experimental treatment, in other words $p<0.1$. The use of a 0.1 significance level is acceptable in social science research.[64]

In this research study, the researcher wished to explore more than two variables in the same study: change in ulcer size and change in RNLI score, of the experimental and control group. For this reason, the researcher required a test that could compare more than two variables, and the ANCOVA (analysis of covariance) test was chosen. The ANOVA (analysis of variance) is a statistical technique that that can compare the mean scores of three or more groups. The ANCOVA is a similar test, but also controls for the initial differences between groups.[67] In other words, if the pre-test scores indicate that the dependant variables (ulcer size and RNLI score in this case), are substantially different for the groups due to extraneous variables such as age and sex, an ANCOVA can take this into account by treating the extraneous variables as covariates and removing their effects from the data.[67] This was particularly useful in this research study where the dependant variables varied greatly due to factors such as severity of the diabetic foot condition (Refer to Table VIII, Chapter 4 for pre-test scores).

In order to ascertain whether the tailored programme had resulted in more positive treatment outcomes, the primary efficacy variables (percentage change in size of ulcer and RNLI score) were thus analysed using an analysis of covariance (ANCOVA) with the baseline ulcer size as covariate. A similar analysis was performed for the RNLI scores. The SAS software programme was used to perform this data analysis.

For analysis of the first objective, the researcher did not use inferential statistics; rather descriptive statistics were used to compare the difference in average percentage change in ulcer size between pre test and post test results of the experimental and control groups.

The analysis of the second objective again made use of descriptive statistics to determine whether or not a two point increase on at least one item of the RNLI occurred in the experimental group as a result of tailored occupational therapy as compared with the control group who received care as usual.

Now that the data collection and data analysis have been discussed, it is important that the ethical implications and precautions of working with human subjects be investigated. The next section looks in detail at the ethical considerations of the research.

3.8 Ethical Considerations

The researcher applied for ethical clearance from the University of Pretoria, Faculty of Health Sciences Research Ethics Committee. Clearance was granted on the 29th of August 2006, and the research was registered under the following number: s105/2006.

As the researcher worked with human subjects, it was imperative that the ethical principles were adhered to. These include:

- **Beneficence**
  Subjects partaking in the research were free from harm and were not exploited. The treatment that was given to the subjects by the occupational therapist was of minimal risk, and thus the risk-benefit ratio was in the researcher's favour.
- **Respect for human dignity**
  Participation in the research was voluntary and subjects had the right to withdraw from the research at any time without detriment to their treatment at the Diabetic Foot Clinic.

- **Justice**

  Treatment that was offered to the control group continued unchanged from the treatment that was being offered at the clinic prior to the start of the research, this thus ensured that no subject was denied occupational therapy treatment. Patients who did not participate in the research also continued to receive therapy.

Informed consent was obtained from each subject prior to the start of the research. The informed consent documents provided a thorough explanation of the purpose and process of the research to potential subjects. In order to ensure that all subjects fully understood the implications of committing to the research, the informed consent documents were available in English and Afrikaans. Subjects were also given the contact number of the researcher so that they could establish contact at any time during the research process, should they feel this was necessary. The researcher was also available in person to explain the informed consent documents to potential subjects.

It was made clear to the subjects that their confidentiality would be guaranteed throughout the research process. Due to the close interaction between the researcher and the subjects, anonymity could not be established, however subjects were assured that any publication or presentation arising from the research would ensure their anonymity.

Subjects will also be given feedback about the outcomes of the research, once the research study is fully complete and the researcher has received feedback. A report will be compiled for the subjects, explaining the results of the research. This report will be given to subjects at their next clinic visit, or, if this is not possible, the report will be mailed to them.

In order to help eliminate researcher bias within the data collection process, all treatment was written out in the form of guidelines, for the experimental and the control groups. The aim of this was to ensure that the researcher did not unknowingly askew the results of the research by spending more time on certain subjects. When the pre- and post-test assessments were

carried out, the other members of the foot care team such as the doctor, assisted with the assessment, again in an attempt to limit researcher bias.

Although subjects were asked to follow up at two weekly intervals, they were also clearly instructed that if complications arose, they should come back to the clinic immediately or report to the casualty department. This was in keeping with clinic protocol.

The researcher plans to publish the results of the research in relevant journals (South African Journal of Occupational Therapy), thus ensuring dissemination of results. Other team members will also be given feedback about the results, thus potentially improving the care offered at the PAH Diabetic Foot Clinic.

This chapter has provided an overview of the methodology used in the research. The sample and population were discussed and this was followed by an illustration of the data collection process that was followed by the researcher. The chapter also discussed how the collected data was analysed. Lastly, the important ethical issues surrounding the research and data collection were highlighted. The next chapter deals with the results of the data collection.

Chapter 4: Results

4.1 Introduction

The preceding chapters have dealt with the introduction to this research, a review of the most relevant literature, and an explanation of the methodology that has been applied in this research. The following chapters will deal with the results of the research. Chapter 4 starts with a sample profile in order to give the reader a thorough understanding of the make-up of the sample. This is followed by the presentation of the results and then statistical analysis is presented in relation to the hypothesis and objectives. The chapter is concluded with interpretations of the main findings.

The hypothesis and objectives are stated here for ease of reading.

4.1.1 Hypothesis

The hypothesis of this study states that tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's Model of Creative Ability (MCA) will lead to more positive treatment outcomes.

The main hypothesis above was subdivided into two objectives:

4.1.2 Objectives

- Tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will lead to a larger percentage change in ulcer size (75% reduction with tailored treatment, as opposed to 50% reduction with usual care).

- Tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA will lead to at least a two point change in at least one item of the Reintegration to Normal Living Index (RNLI).

4.2 Sample Profile

The sample that was recruited for this research study consisted of 16 subjects in total. As stated in Chapter 3, subjects meeting the inclusion criteria were approached to participate in the research while waiting to be seen by the doctor. No subject that was approached to participate declined to do so. Selected subjects were then randomly assigned to experimental and control groups using the procedure documented in Chapter 3.

The experimental group consisted of seven subjects and the control group of nine subjects. During the course of the data collection, four subjects defaulted on their treatment and two underwent amputation due to the severity of the ulcers. The experimental group finally consisted of six subjects and the control group of four subjects. Thus the final sample size is ten subjects. Table V shows the original and final experimental and control groups.

***Table V**: Experimental and control groups*

Experimental Group		**Control Group**	
Subject	**Outcome**	**Subject**	**Outcome**
1	Completed treatment	8	Amputation
2	Completed treatment	9	Completed treatment
3	Defaulted	10	Defaulted
4	Completed treatment	11	Defaulted
5	Completed treatment	12	Completed treatment
6	Completed treatment	13	Defaulted
7	Completed treatment	14	Completed treatment
		15	Amputation
		16	Completed treatment
Total subjects completed treatment: 6		**Total subjects completed treatment:** 4	

The original sample size was calculated as 16 subjects per group. Chapter 3 discussed how this sample size was calculated, and as stated there, it was found from retrospective clinic data that the expected reduction in ulcer size in a three month period is 50%, with a standard deviation of 29.3%. Thus it was determined that for a clinically significant improvement in ulcer size to take place, as a result of tailored occupational therapy, a further 50% reduction in ulcer size was expected. That meant that a 75% reduction in ulcer size was considered to be clinically significant for the experimental group. Using these assumptions, the sample of 16 subjects per group (thus 32 subjects in total), would have a power of 90% to detect a difference (improvement/deterioration) of 25 percentage points between the two groups. As the researcher expected only one sided change (improvement) with regard to ulcer size, one sided testing was used with a significance level of 0.1.

The actual sample size is much smaller than the planned sample size of 16 subjects per group and therefore 32 subjects is total. There are several reasons for the much smaller sample size and this issue is further discussed in Chapter 5, Section 5.2.4.

The researcher aimed to keep the experimental and control groups as homogenous as possible, in an attempt to control for extraneous variables. Table VI shows the constitution of the final groups with regards to age and gender.

Table VI: *Constitution of groups*

	Experimental	**Control**
Age Range	63 – 75 years	48 – 81 years
Mean Age	67.8 years	57.7 years
Number of Females	2	0
Number of Males	4	4

For the purposes of this research, it was most important that the groups be kept as homogenous as possible with regards to the subjects' levels of motivation. As planned, the subjects were assessed for level of motivation, at the pre-test stage. Using this level of motivation, the subjects were then assigned to either the experimental or control group, thus using random stratified assignment, as described in Chapter 3. Table VII shows the levels of motivation that were represented in the experimental and control groups.

Table VII *Levels of motivation in the research sample*

Experimental Group		Control Group	
Subject	**Pre-test Level of Motivation**	**Subject**	**Pre-test Level of Motivation**
1	Passive participation, therapist directed	8	Passive participation, therapist directed
2	Imitative participation, patient directed	9	Passive participation, patient directed
3	Imitative participation, patient directed	10	Passive participation, patient directed
4	Passive participation, transitional	11	Imitative participation, patient directed
5	Imitative participation, therapist directed	12	Imitative participation, patient directed
6	Passive participation, patient directed	13	Passive participation, transitional
7	Imitative participation, patient directed	14	Self presentation, transitional
		15	Passive participation, patient directed
		16	Imitative participation, patient directed

Indicates that subject either defaulted or underwent amputation.

The preceding section has given the reader an in-depth insight into the composition and characteristics of the sample. The next section will describe and summarise the main results obtained from the research.

4.3 Presentation of Results

This section presents the main results of the research study, which were analysed in order to determine whether or not rejection of the null hypothesis was possible. Table VIII summarises the results of the research.

Table VIII: *Results of research*

Experimental Group										
Subject	Pre test ulcer size (mm^2)	Post test ulcer size (mm^2)	% change in ulcer size **	Mean & standard deviation: percentage change in ulcer size	Pre test RNLI score (%)	Post test RNLI score (%)	% change in RNLI score	Mean & standard deviation: change in RNLI score	Pre test level of motivation ***	Post test level of motivation ***
1	68	12	82.4	Mean = 88.1 SD = 14.9	77	77.3	0.4	Mean = 2.5 SD = 8.6	Passive participation, TD	Imitative participation, TD
2	222	0	100		72	86.4	20		Imitative participation, TD	Imitative participation, PD
3*	652				72.7		-		Imitative participation, PD	
4	752	318	57.7		52.7	55.5	5.3		Passive participation, PD	Passive participation, T
5	168	16	90.4		100	99	-1		Imitative participation, T	Imitative participation, T
6	276	8	97.1		73	71	-2.7		Passive participation, PD	Passive participation, T
7	380	0	100		85	79	-7		Imitative participation, PD	Imitative participation, PD
Control Group										
8*	206			Mean = 63.2 SD = 23.3	49		-	Mean = 15.6 SD = 28.0	Passive participation, TD	
9	190	42	77.9		72	69	-4.1		Passive participation, PD	Passive participation, PD
10*	104				58.2		-		Passive participation, PD	
11*	510				83.6		-		Imitative participation, PD	
12	382	20	94.5		80	92	15		Imitative participation, PD	Imitative participation, T
13*	244				82.7		-		Passive participation, T	
14	56	32	42.9		51	46	-9.8		Self presentation, T	Self presentation, T
15*	204				44.5		-		Passive participation, PD	
16	106	64	39.6		58	93.6	61.4		Imitative participation, PD	Imitative participation, PD

* The above subjects either defaulted on their treatment during the course of the research, or underwent amputations due to the severity of the ulcer. Subjects 8 and 15 underwent amputations, while subjects 3, 10, 11 and 13 defaulted.

**These figures have been rounded off to one decimal place for ease of reading and presentation, however the full figure was used in all analysis performed.

*** TD = Therapist Directed Phase; PD = Patient Directed Phase; T = Transitional Phase

As can be seen from Table VIII all subjects who completed the research underwent a reduction in ulcer size, as expected. From the retrospective data that was collected a 50% reduction in ulcer size was expected with treatment as usual, and a 75% reduction was expected for the experimental group over the three month period. Thus one-sided testing could be performed as change was in one direction (positive) only.

The results of the quality of life measure (RNLI score) were not as consistent, and five of the ten subjects had lower quality of life scores post test than pre test. This is not what the researcher expected to find, as an overall increase in quality of life was expected. Analyses of the RNLI have addressed the property of sensitivity to change over time.[33,34] These results indicate that two thirds of clients will change by at least two points on at least two items over a three month period. Within individual patients, the direction of change was consistent, but they may have improved in some areas while worsening in others.[33,34]

In terms of the levels of motivation, five out of ten subjects had progressed in the levels after the treatment. The remaining five subjects' levels of motivation remained unchanged. This is in keeping with the expectations on which the research design was based. The MCA describes how occupational performance develops along a continuum from egocentricity to contribution to society. This development starts at birth and continues throughout life. Development is usually progressive, but need not always be so. Development is not always consistent and may occur in spurts with long periods of consolidation in between.[13] Regression is also possible. The results of the research thus fall within the expectations based on the MCA.

This section has presented the results of the research and has very briefly discussed some of the conclusions. The next section discusses the results in more detail, and looks at the statistical analysis of the data.

4.4 Statistical Analysis of Results

Using the data obtained from the research, statistical analysis was performed, in order to ascertain whether there is a statistically significant difference between the experimental and control groups. The SAS software programme was used to perform the analysis. The outcome of this analysis determined whether or not the null hypothesis could be rejected and thus whether or not, tailored occupational therapy contributes to more positive treatment outcomes for patients with diabetic foot ulcers.

Comparing the experimental and control groups, with respect to percentage change (reduction) in the area of the ulcer(s) adjusted for baseline (pre treatment), the groups were not statistically significantly different (ANCOVA; p=0.1451(p significant at <0.1); 88.1% versus 63.2%). In view of the small sample size, this analysis was repeated using a nonparametric ANCOVA and a similar result followed (p=0.1684)[h].

However, when the absolute change in ulcer size was considered (using a nonparametric ANCOVA), and adjusted for the baseline area, the experimental group did significantly better than the control group (p=0.0236). Note that in the latter, use was made of ranks and mean ranks and thus the actual change was not reflected.

With respect to the quality of life score, obtained from the RNLI, adjusted for baseline, groups did not differ significantly (ANCOVA; p=0.4829; 2.4 versus 9.3).

One possible reason for this result is Subject 16's post test RNLI score. His post test score differs from his pre test score by 35.6 points. In such a small group (four subjects) such an extreme change can affect the results of the entire group, thus possibly affecting statistically significant results.

As can be seen from the above analysis, the ability to infer findings from the sample to the population is limited largely due to the small sample size

[h] The reader is referred to Appendix 8 for the analysis of the raw data.

of this research study and the resultant limitations in data analysis. As a profession, occupational therapy has often been confronted with the challenge to confirm or establish the best therapeutic medium. A practice that is rapidly increasing as the demand for best evidence based practice increases.[68,69] The effects of a small sample size and an in depth discussion of the research methodology follows in Chapter 5.

4.5 Interpretation of Results in Relation to Hypotheses

This section of the chapter will now look more closely at the relevance of these results to the hypothesis and the objectives. Note that in Chapter 1 the formulation of the hypothesis from the aim and objective was illustrated.

4.5.1 Rejection of the null hypothesis

From the statistical analysis that has been performed on the raw data, it is not possible to reject the null hypothesis at the 90% confidence level, as there was no statistically significant difference detected. This is the case with both measures of positive treatment outcomes, namely: percentage change in ulcer size and change in quality of life score. However, if the data is analysed using a nonparametric analysis of covariance, a statistically significant difference is found with regard to absolute change in ulcer size.

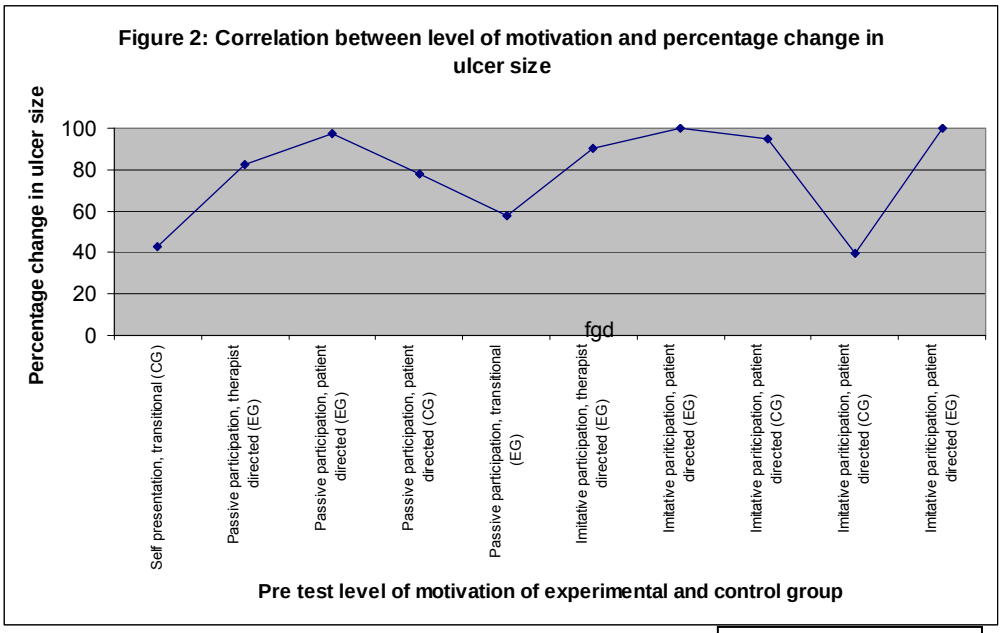
As non parametric data do not meet strict statistical criteria, substantial differences must be found between two sets of scores before those differences are considered meaningful. Bailey states that nonparametric statistics should often be used in health science research (such as this research) as pathological human conditions are being studied. The variables of illness are frequently not distributed normally in the target population. She also acknowledges the difficulty in locating the necessary subjects with the required pathology and the resultant small sample size.[67]

The research thus indicates that there is a trend to more positive outcomes for the experimental group than the control group. This is only the case for the change in ulcer size, and does not apply to the quality of life measurement. However further conclusions, regarding the tailored treatment, can not be drawn from the data largely due to the small sample size. The next chapter will discuss recommendations and suggestions in more detail, with regards to reproducing this research.

4.5.2 Objectives

The first objective stated that the tailored occupational therapy treatment will result in a larger percentage change in ulcer size than the care as usual. From the analysis that has been done, the statistical significance of the results has been discussed, with regard to change in ulcer size. However, when expressed in percentage change in ulcer size per group, the following can be noted: the average percentage reduction in ulcer size for the experimental group was 88.1% and for the control group was 63.2%.

Figure 2 shows the correlation between the subjects' pre test level of motivation and their percentage change in ulcer size. Prior to commencing the research, the researcher felt that it was possible that the higher the level of motivation, the better the prognosis (wound healing) of the subject. Figure 2 shows that there is no clear correlation between these two factors.



EG = Experimental Group
CG = Control Group

The second objective states that tailoring the occupational therapy treatment of the patients with a diabetic foot ulcer according to the MCA will lead to at least a two point change in at least one item of the RNLI. Table IX shows the pre test and post test RNLI scores for the individual items. Changes of two or more points have been highlighted. Although not all subjects achieved an overall increase in the total RNLI score between pre test and post test assessment, the majority of subjects (9 out of 10) did achieve an increase in at least one item. Eight of the ten subjects experienced a two point increase on more than one item. This is in keeping with the research that has been done on the RNLI which found that 66% of clients will change by at least two points on at least two items over a three month period.[33,34]

All subjects showed a decrease in certain items of the RNLI. This is also in keeping with previous research done on the RNLI which found that within the individual patient, improvement may be seen in some areas while worsening is seen in other areas.[33,34]

It should be noted however, that there was no marked difference between the experimental and control group when looking at this objective. Rather, it appears that the changes in RNLI score occurred as a result of a factor independent of the occupational therapy treatment that was offered. As

previously stated, not all subjects showed an overall increase in RNLI score, and thus the assumption that quality of life improves as the size of the ulcer decreases cannot be made.

It is interesting to note that when a change of two or more points occurred for an individual item on the RNLI, it occurred more often in the first five questions. The first five question of the index deal with mobility and personal management issues, whereas the last six questions deal with more psychological and social issues. This could possibly indicate that the programme offered at the Diabetic Foot Clinic has an impact on the quality of life of the personal management and mobility areas of a subject's life.

Table IX: *Pre test and post test RNLI scores for individual items.*

		Item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Subject													
1	Pre test		10	8	10	1	1	10	9	9	9	9	9
	Post test		5	6	10	8	5	5	6	10	10	10	10
2	Pre test		10	1	1	10	5	6	8	9	10	10	10
	Post test		10	8	10	10	5	5	8	9	10	10	10
4	Pre test		8	2	2	6	1	8	2	8	8	8	5
	Post test		9	2	8	7	3	8	2	8	2	9	3
5	Pre test		10	10	10	10	10	10	10	10	10	10	10
	Post test		9	10	10	10	10	10	10	10	10	10	10
6	Pre test		10	5	5	7	8	7	8	5	9	9	8
	Post test		8	7	7	9	8	5	5	7	7	8	8
7	Pre test		7	5	10	10	10	8	8	10	8	8	10
	Post test		7	7	10	10	10	5	5	9	7	8	9
9	Pre test		10	7	2	8	6	8	8	10	6	6	8
	Post test		9	9	6	8	3	8	6	9	8	5	5
12	Pre test		8	3	8	10	10	1	10	10	8	10	10
	Post test		10	10	10	10	10	10	1	10	10	10	10
14	Pre test		5	5	5	8	4	1	5	8	5	5	5
	Post test		5	3	4	8	1	1	7	6	7	8	1
16	Pre test		5	1	5	6	2	4	3	9	9	10	10
	Post test		10	10	10	10	10	7	6	10	10	10	10

Note that subjects 3, 8, 10, 11, 13 and 15 either defaulted on treatment or underwent an amputation due to the severity of the ulcer and did thus not complete the three month treatment period.

4.6 Summary

This chapter has illustrated the results of this research study in detail. The chapter commenced with a sample profile in which the constitution of the sample and the experimental and control groups was discussed. An explanation of the relatively small sample size was briefly given. The sample profile explained that out of the 16 subjects that were recruited, only ten completed the three month treatment period.

The sample profile was then followed by the presentation of the research results. All of the subjects showed a decrease in ulcer size at the end of the three month period. The quality of life measurement however, was not as uniform, and several subjects showed a decrease in RNLI score, despite an improvement in the condition of the ulcer. In terms of the subjects' levels of motivation, five out of the ten subjects showed an improvement in their level of motivation, the remaining five subjects' levels remained unchanged.

A discussion of the results then followed and the statistical analysis that was performed was explained in detail. From this analysis, it was established that the results did not allow for rejection of the null hypothesis as there was no significant difference when comparing the ulcer size or the quality of life between the experimental and control groups. The results however, did indicate a positive trend when comparing the absolute change in ulcer size between the two groups, using non parametric data analysis. This section briefly justified the use of the small sample size and discussed the usefulness of research such as this, where positive trends are identified, in motivating for research projects with larger sample sizes which will allow for more in depth statistical analysis. Lastly this chapter looked at the results of the research in relation to the hypothesis and the objectives.

Conclusions and recommendations derived from this research are given in the next chapter, as well as more detailed discussions of the results.

Chapter 5: Discussion and Recommendations

5.1 Introduction

The preceding chapters in this research study have given the reader an introduction to the research problem and then reviewed the literature relevant to the fields of occupational therapy, the diabetic foot, quality of life and motivation. The previous chapters dealt with the proposed research plan, methodology and the results of the research that was executed.

The aim of this final chapter is to draw together all the research findings and summarise the salient points. This chapter will also look at the larger significance of the research and includes suggestions and recommendations for further research in the field of occupational therapy and the Model of Creative Ability (MCA).

5.2 Discussion

5.2.1 Synopsis Thus Far

Chapter 4 has presented the findings of the research in relation to the hypothesis and objectives that were set out at the beginning of the study. The researcher wished to explore the benefits of tailored occupational therapy, using the MCA, when applied to people suffering from diabetic foot ulcers.

The MCA was chosen by the researcher, as it is widely used and taught in the South African context, but requires further research.[1,3] It is also one of only two models that address the importance of motivation when treating patients.[1,3] The other model that addresses motivation is the Model of Human Occupation (MOHO), developed by Kielhofner. This model is also widely used, and has been well researched. Thus the researcher chose to investigate the use of the MCA and contribute to a gap in the field as this is the lesser researched model. The MCA provides a framework within which to assess the level of motivation of a patient and then provides principles to guide treatment of the patient based on his/her level of motivation.[1,3,13]

Motivation has been acknowledged as a vital aspect in the treatment of any patient and has been identified as one of the factors contributing to the eventual result of treatment. Motivation is been recognised as an important aspect in the treatment of a patient with diabetic foot complications.[10,11] For these reasons the researcher felt that it was appropriate to tailor occupational therapy treatment of clients with diabetic foot ulcers using the MCA for this research.

The research study was thus set up to determine whether tailored occupational therapy led to more positive treatment outcomes for patients with diabetic foot complications. Positive treatment outcomes were defined as a reduction in the area of the ulcer and change the quality of life of the subject. The reason for this choice of treatment outcomes and their measuring instruments has been discussed in detail in Chapter 3.

The methodology of the research made use of an experimental and a control group in order to compare the effects of tailored occupational therapy. A three month treatment period was planned during which time the subjects would receive either tailored occupational therapy treatment, or care as usual. Subjects were assigned to the experimental or control group using random stratified assignment after their pre test level of motivation had been assessed. Despite attempts to keep the experimental and control groups homogenous with regards to the level of motivation, the researcher acknowledges that the final groups were different. It should however be

noted that at the time of assignment into groups and the start of the research, the groups were fairly homogenous. The differences occurred through the drop out of subjects and were exacerbated by the small sample size. The issues related to small sample size are further discussed later in this chapter.

Sixteen subjects were recruited in total and ten of these subjects completed the three month treatment programme and underwent post test assessment. The data that was captured during this time was then analysed in order to determine whether rejection of the null hypothesis was possible. Chapter 4 discussed the data analysis that was done in detail.

In summary, it was found that rejection of the null hypothesis is not possible as there is not a statistically significant difference between the experimental and control groups when examining pre test and post test ulcer size and change in quality of life scores. However the data analysis did reveal a trend that indicates that tailored occupational therapy improves treatment outcomes, when the data was analysed using a non-parametric analysis of covariance, for the absolute change in ulcer size as opposed to the percentage change in ulcer size. With this analysis, a significant difference was found at a p value of 0.0236.

The researcher also set out to examine two objectives which dealt with ulcer size and quality of life. Although rejection of the null hypothesis is not possible, the objectives add valuable information to the research that was conducted.

5.2.2 Ulcer Size

In terms of the objectives that were considered; the first objective stated that tailoring the occupational therapy treatment of patients with a diabetic foot ulcer according to Du Toit's MCA would lead to at least a 75% reduction in ulcer size as compared to the 50% reduction in ulcer size that was already occurring as a result of usual care.

From the data, it was found that the control group experienced a 63.2% average reduction in ulcer size, and the experimental group experienced an average reduction of 88.1%. In other words, the experimental group improved on average 24.9% more than the control group did. This result indicates that there is a trend which shows that patients who are treated using tailored occupational therapy according the MCA show more positive treatment outcomes when considering percentage reduction in ulcer size.

5.2.3 Quality of Life

The second objective stated that the tailored occupational therapy treatment would lead to at least a two point increase in at least one item of the quality of life measurement tool (the Reintegration to Normal Living Index). The results showed that nine of the ten subjects experienced an increase of at least two points on at least one item of the RNLI. Eight out of the ten subjects experienced a change of two points on two or more items. No marked differences were found between the experimental and the control group, and overall change in quality of life scores fluctuated greatly.

The researcher thus, did not obtain the expected results with regards to quality of life. This may be an indication of the fact that quality of life is a complex, multidimensional concept and is influenced by a myriad of factors, most of which are beyond the scope of the research study.

A study by Brod concluded that the quality of life of patients with diabetic foot ulcers is greatly influenced by physical, social and psychological impairments and disabilities. However, it is not clear which specific areas of quality of life are the most affected by diabetic foot ulcers.[20] Price states that although diminished quality of life is thought to be a consequence of diabetic foot ulceration, little is known of the human costs involved or of the impact of this condition on everyday living.[25]

When looking at quality of life, it is important to remember that quality of life is a very broad term that encompasses more than merely health status. The more narrow term ‘health related quality of life’ is perhaps a more

suitable term when looking at the effect of health and illness on quality of life. Health related quality of life, is seen as a subset of overall quality of life.[45] Thus the effect of a change in a person's health status may have an effect on health related quality of life, but not necessarily on overall quality of life. The improvement of the subjects' diabetic foot conditions may not have been directly reflected in the RNLI as this is a tool to measure overall quality of life, and not merely health related quality of life.

The results that have been discussed in this section were all influenced by the size of the sample that was used. The next section of this chapter will look in more detail at the effects of a small sample size on research findings.

5.2.4 The Dilemma of Small Samples and Why Less Can be More

Chapter 4 discussed briefly the limitations that were experienced in this research, as a result of the small sample size that was used. With regards to the results of this study; the actual difference, although not statistically significant, in adjusted mean percentage change, was observed as 88.1% versus 63.2%, in other words, a 24.9% improvement between the experimental and the control group, which the study set out to detect. This result, along with the significant result for the adjusted absolute change suggests that tailored occupational therapy is more effective than therapy that does not cater for the level of motivation of a client. However, this needs to be confirmed in a larger study, with at least 16 subjects per group in the event of one-sided testing and 32 subjects per group in the event of two-sided testing. In view of the results from this study it is clear that one-sided testing will be sufficient, as only improvement has been detected in all subjects.

The reasons for the small sample size used in this research are numerous. The reader is referred back to Chapter 3 where the initial plan for data collection and subject recruitment is laid out and explained in detail. From the analysis that was done at that stage, it was determined that a sample

size of 32 subjects in total would have 90% power to detect a change of 25 percentage points, with regards to change in ulcer size. In the plan for data collection, three months was thus initially allocated to the recruitment of subjects.

Once the research was underway, it became apparent that this would not be enough time to recruit the required 32 subjects, and for this reason, the data collection and recruitment phase was extended to nine months. In this time a total of 16 subjects were recruited. All subjects who were approached to participate in the research did so, and no-one declined to take part. Thus the sample that was used was an all inclusive sample. Even so, these 16 subjects were much less than the expected number of 32 subjects, which was originally considered a realistic figure.

Of the 16 subjects that were recruited, only ten completed the three month treatment period. The reasons that six subjects did not complete the research were discussed in Chapter 4.

It is the researcher's opinion that several factors combined to give the resultant small sample size. One of the possible reasons for this is that in the time between the planning and the execution of this research, Pretoria Academic Hospital (PAH), and thus the Diabetic Foot Clinic, moved to new premises. This resulted in the creation of a new hospital, Tshwane District Hospital, which is located in the old PAH premises.

With this move, PAH officially became a level three or tertiary level hospital, and Tshwane District Hospital became its official step down facility or level two hospital. This had an impact on the Diabetic Foot Clinic and it appeared that many of the patients that would have been previously referred to the clinic were now referred to and treated at Tshwane District Hospital.

The patients that were referred to the clinic at PAH tended to have conditions that were more severe in nature and warranted tertiary level treatment. This made many of the new patients seen at the clinic, that were originally thought suited for participation in the research, unsuitable, as the

severity of their diabetic foot condition made them candidates for hospital admission and possible amputation and not for out patient treatment as required for this research.

The researcher did investigate the possibility of conducting the research at Tshwane District Hospital as well as at PAH however, Tshwane District Hospital did not have a diabetic foot clinic at the time of this research, and all patients with diabetic foot complications were seen at a general outpatient clinic. This thus made the set up unsuitable for the research, as a large focus of the Diabetic Foot Clinic at PAH is the multidisciplinary team approach, as discussed in Chapter 2.

If patients from Tshwane District Hospital had been included in this research, there would be too many extraneous factors contributing to the treatment outcomes, and this would jeopardise the research findings. Extraneous factors include the lack of an organised diabetic foot clinic, with patients, or potential subjects being seen at a general outpatient clinic without preset times or dates. The staff attending to patients at the outpatient clinic, on average lacked the specialist skills that are available at the PAH Diabetic Foot Clinic namely: a surgeon, a wound care sister and an orthotist. Thus it was decided that it would be unsuitable to conduct this research at Tshwane District Hospital.

The Diabetic Foot Clinic at PAH, also treats a number of patients who no longer have ulcers, but attend the clinic for monitoring and follow up purposes only. These patients may have conditions such as amputations or ulcers as a result of varicose veins, and were thus not suited to participate in the research as they did not meet the inclusion criteria.

Several authors acknowledge the difficulty of obtaining a large sample when working with human subjects, and state that clinical research needs to remain both flexible and applicable to the field of study.[68,70] Traditional research opinion tends to favour research designs that use large sample sizes and employ randomised control trails as the methodology of choice. In an article by Harbour and Miller as well as Bell et al, the levels of evidence are discussed: meta-analysis and randomised control trials using

adequate sample sizes, top the list. [71,72] Much emphasis has been placed on the importance of large sample sizes and the inclusion of control groups in all fields of study including occupational therapy.

Petersen however, brings another perspective to the table, and argues that small populations are important to study.[73] People suffering from a specific disease or complication, will be a small group from which to get a sample for research purposes. This is the case with people suffering from diabetic foot complications. However, this group is nonetheless important to study. Although this research studies a small population, it has provided data which would otherwise not have been available. In a field where there is little research or literature available, such as the field of the application of the MCA, research with small samples, contributes to the existing knowledge on the subject.

Occupational therapy has explored several research methods and designs in order to identify those that best suit the issues in the profession.[68] Yerxa believed that quantitative and qualitative research should not coexist in occupational therapy. She contended that the experimental method did not represent the patient's reality because it excluded the patient's subjective experience and natural environment.

However other occupational therapy researchers believed that a mixture of qualitative and quantitative research is not only possible, but also desirable.[68] Much valuable information has been gained in the field of occupational therapy from qualitative research; however the demand for measurable 'proof' of occupational therapy's worth is ever increasing, thus creating a need for quantitative and experimental research. If occupational therapy is to remain a viable profession, the value thereof must be substantiated, using a variety of methodologies.

As a result of the pressure to prove the worth of the profession, the types of research pursued by occupational therapists have evolved, and the 1970s and 1980s were characterised by an increase in the studies using experimental and quasi-experimental designs.[68] However, even advocates

of rigorous experimental methodologies, such as Ottenbacher, have admitted the need for flexibility and relevance in clinical research.[68]

Limitations with sample size have long been problematic for researches in the field of occupational therapy and Ottenbacher and York recognise the practical problems with traditional research designs, stating that many potential investigators cannot assemble a large group of patients and then randomly assign them to experimental and control groups. This is particularly true when the population of interest consists of heterogeneous, widely distributed individuals.[70]

Bennett and Bennett found that due to the highly individualised nature of occupational therapy treatments and the heterogeneity of the client groups, randomised control trials may not always be the most appropriate methodology for use in occupational therapy. They state that many questions concerning the effectiveness of occupational therapy treatments are more suited to quasi experimental or single case experimental designs.[69]

Although randomised control trials require relatively large sample sizes, small sample sizes such as the sample size in this research study, can reveal significant insights into the research problem and emerging trends like the ones identified in this study are useful for future research. Randomised control trials with small samples may not provide Level One evidence according to the levels of evidence, but can provide Level Two evidence, which remains valuable when proving the worth of a treatment or intervention, as in this research.[71,72] The impact of this research and recommendations for possible further research are discussed at the end of this chapter.

For experimental designs that compare groups, the greater the control of similar characteristics, the greater the tolerance of smaller sample sizes.[73] One way to improve the validity of a small sample study is to document any characteristics that may be of interest. As social research is seldom conducted in a laboratory setting, control of all factors is not always possible. It is thus important to mention the circumstances surrounding

data collection as well as the circumstances of the participant's lives in general.[73] In other words, the assumptions of inferential statistics will not be violated if: the only qualitative differences between the groups are in the variables mentioned in the hypothesis, if all other possible explanations of research results are negligible (rival hypotheses), and if the samples are quantitatively similar (equivalent size and distribution) in make up between the experimental and control group.[73] Lenth stated that sample size, while being an important issue in research, is only one aspect of the quality of a study design, and attention should be paid to ensuring that the rest of the study is meticulous and rigorous.[74]

Several measures were implemented in this research in order to ensure rigor. The methodology and efforts at rigor have been discussed in Chapter 2, but include measures such as:

- Blinding other team members at the Diabetic Foot Clinic about which group subjects had been assigned to.
- Using measuring instruments that have been found to be both reliable and valid (Reintegration to Normal Living Index (RNLI), Creative Participation Assessment (CPA) and wound tracing).
- Making sure that the same doctor completed the wound tracings on all the subjects both pre- and post test.
- Having the researcher treat both the experimental and control groups limited inter rater bias.
- All treatment sessions were documented and planned according to the principles of the MCA before treatment commenced.

From the information that has been gathered regarding the importance of sample size, it is the researcher's opinion that although the small sample size used in this research limited inferences that could be made to the general population, the research has nonetheless provided important information in the filed of the MCA and occupational therapy. Thus highlighting the importance and role of research using small samples in the contribution to the filed of study. The literature has also helped to provide evidence that research with small samples can be convincing and is important to conduct.

This section of the chapter has dealt in depth with many of the issues arising from the research, most notably the sample size. The next section, will now examine the results of the research, in relation to the literature that was reviewed.

5.3 Interpretation of Results with a View to Literature

Chapter 2 of this research study reviewed the literature concerning the key topics of the interest. As with Chapter 2, this section will be split into several subsections in order to aid clarity when reviewing the results of the research with regards to the literature.

5.3.1 Diabetes, the Diabetic Foot and the Multidisciplinary Team

In recent history, there has been a disturbing rise in the occurrence of diabetes and its complications. Type 2 Diabetes affects over 90% of people suffering with diabetes and is associated with several contributing factors. There are many chronic complications that can arise as a result of Type 2 Diabetes, but the most common complication leading to hospital admission is diabetic foot disease.[5,6,8] Diabetic foot disease includes complications such as neuropathy, structural changes, foot ulcers and infections.[19]

The literature states that it is estimated that 15% of people with diabetes will develop foot ulcers in the course of their lives.[19-22] Diabetes is also one of the most common causes for lower extremity amputation, usually preceded by ulceration.[38] Ulceration
has been identified as a component in up to 85% of lower extremity amputations.[20-22,38] Overall, the prevalence of diabetes in patients undergoing major amputation has been estimated to be as high as 40 to 70%.[28]

Amputation is thus often the end result of ulceration. The effect of an amputation on the patient as well as the patient's family or caregivers has also been documented, and an amputation is often viewed by the patient as an end to productive living and the start of disability.[32] Thus the effects of ulceration and amputation should not be taken lightly, and both conditions have an impact on a patient's quality of life.[25]

Several studies have shown that preventative care may reduce the number of amputations in patients with diabetic foot complications. A multidisciplinary team approach in the treatment of diabetic foot complications has also proved to be effective in reducing the length of hospital stay.[25,28]

The literature thus clearly recognises the severity and occurrence of diabetic foot complications. With the increasing prevalence of diabetes and its complications, especially in developing countries such as South Africa [5], all attempts should be made to treat patients as effectively and efficiently as possibly and thus limit potential disability and its associated repercussions.

While the results of this research could not reject the null hypothesis, a positive trend was identified in the experimental group, thus suggesting that occupational therapy treatment tailored according to a client's level of motivation may have more positive outcomes than treatment which is not tailored. As already suggested, this research study should be conducted with a larger sample size in order to verify and determine the accuracy of these results. With the increasing number of people suffering from diabetes and it complications, the researcher feels that any approach that may lead to more positive treatment outcomes and prevent further disability and impairment is worth investigation and examination.

The MCA allows occupational therapy to make a unique contribution to a multi disciplinary team setting. While motivation has regularly been identified as playing an important role in the treatment outcomes of a patient with diabetic foot complications, there is little literature available on topic.[9-11] The MCA thus equips an occupational therapist to make a

contribution in a recognised field, where currently there is little information available.

Motivation is an important factor for people suffering from chronic disease and the next section takes a closer look at the role of occupational therapy in the assessment and treatment of people with chronic diseases.

5.3.2 Occupational Therapy and Chronic Diseases

Chronic diseases, including diabetes have benefited from treatment by therapists such as occupational therapists.[39-41] When a patient is diagnosed with a chronic disease and has received optimal medical management, the focus of treatment usually shifts from recovery to maintenance of health and functional status and thus the minimisation of the potentially limiting consequences of the disease.[39,41,42]

There is little literature available on the exact role of the occupational therapist in the treatment of patients suffering from diabetes or its consequences, and, at the time of this research, no protocols or guidelines could be found to direct treatment. However, this research has indicated that occupational therapists in the South African setting possess a unique knowledge of the MCA. This tool provides a way in which to assess an important factor in the treatment of a patient: motivation; and then tailor treatment accordingly. In a field where currently no protocol or guidelines exist, the MCA and its accompanying guidelines could make a valuable contribution to facilitating therapists who are currently operating without guidance, and thus increase good, evidence based therapy.

Occupational therapists could provide a valuable service which may contribute to the eventual prevention of amputation and thus disability. The role of the occupational therapist in the treatment of a patient once an amputation has been performed is well documented. Therapy focuses on making the patient as independent as possible and facilitating return to previous roles and responsibilities.[43] However, the same principles of treatment could be used in treating a patient before an amputation is

considered and thus prevent disability. The MCA provides a framework within which to offer this treatment.

The effects of a chronic disease and more specifically diabetic foot complications, on a patient's quality of life have been discussed in Chapter 2. The MCA aims to improve a patient's level of participation in life activities and treatment and this model could thus have an effect on a patient's quality of life.

5.3.3 Occupational Therapy and Quality of Life

Literature agrees that there is an explicit link between the philosophy of occupational therapy and the concept of quality of life. Both are concerned with the roles and functions that give meaning to life, with occupational therapy based on the belief that engagement in meaningful occupation gives significance to people's lives and can be used as a therapeutic tool to facilitate recovery from illness. Quality of life and occupational therapy both have a holistic and client centred approach.[17]

The research that has been conducted did not find any statistically significant results with regards to change in quality of life pre and post treatment. However, the clinical significance of changes to quality of life should not be excluded when looking at statistical significance. Literature states that people suffering with diabetic foot ulcers have a poorer quality of life than people unaffected by the condition.[20-22,25] Research has also found that people suffering with diabetic foot ulcers tend to have poorer quality of life than people who have undergone amputations as a result of diabetic foot ulcers. The negative attitudes that are associated with diabetic foot ulcers, impact on a patient's compliance to treatment and thus possibly on the eventual success of treatment or the recurrence of foot ulcers.[25] The condition of diabetic foot ulcers has been shown to affect not only the quality of life of the patient, but also that of caregivers and family.[20-22,25]

A study by Tyrrell et al found that the quality of life of patients with diabetic foot complications improved when they attended a specialised multi

disciplinary foot care clinic that also offered orthotic interventions.[25] As occupational therapy can offer a unique contribution to the multidisciplinary team setting and there is an explicit link between occupational therapy and quality of life, the researcher feels that occupational therapy can play an important role in contributing to the improvement of quality of life of patients with diabetic foot complications.

Motivation has been sited as a factor that influences quality of life and the outcomes of treatment. The MCA that was used in this research provides a way to operationalise and measure motivation.

5.3.4 Motivation and the Model of Creative Ability

The importance of motivation and its effect on patient compliance and treatment outcomes in the patient with diabetic foot complications has been described by several authors.[6,9-11] The lack of an accurate method to assess motivation has also been highlighted in Chapters 1 and 2. The MCA provides a tool with which motivation can be assessed and then provides guidelines to use in the treatment of patients. The exact nature of the MCA and its guidelines has been discussed in depth in Chapter 2.

The researcher feels that the MCA is a valuable tool with which to assess and treat patients. The CPA which is discussed in detail in Chapter 2 allows for easy assessment of a patient's level of motivation through the use of activities.[1,3] As occupational therapy's philosophy is based on the engagement of a patient in meaningful activities or occupation, the model and the assessment method detailed in the CPA comply with the philosophy of the practice. The researcher believes that occupational therapists should thus be able to easily use the CPA to determine the level of motivation of a patient. The CPA allows for the use of any activity, thus it is easily adaptable to any therapeutic setting within which an occupational therapist may practice.

Within each level of motivation, the MCA describes three phases namely: the therapist directed phase, the patient directed phase and the transitional

phase. The use of these three phases within each level of motivation allows a therapist to monitor small but nonetheless important progress or regress thus making the assessment of the level of motivation more accurate.

It is also the researcher's experience that as the familiarity and experience with the MCA increases, the level of motivation is more easily and rapidly determined by the therapist. The researcher feels that as a therapist becomes more familiar with the application of the model, smaller changes and deviations in the levels of motivation are easier to recognise and interpret. This thus means that although the CPA requires the observation of a patient's participation in three activities, the assessment of the level of motivation does not necessarily have to be time consuming.

The application of the MCA and the CPA has largely been described for use with children and patients suffering from psychiatric diagnoses.[1-3,13,55] However, after the completion of this research, it is the researcher's opinion that the MCA and the CPA can be applied to patients with a physical diagnosis as well. As already stated, the concept of motivation and its assessment is universal regardless of age or diagnosis. Thus the use of the MCA and the CPA merely requires the use of a therapist's clinical reasoning skills in the application of appropriate and suitable assessment and treatment activities.

The preceding section has dealt with the results of the research with a view to the literature. From the research that was conducted, several suggestions and recommendations arose, and these are the focus of the next section.

5.4 Recommendations and Suggestions

Research sets out to answer a question, however, as it often the case, research also generates other questions and ideas. This section of the chapter will thus address recommendations and suggestions that the researcher feels are important outcomes of the research that was

conducted. Several of these suggestions and recommendations come from the difficulties and challenges that the researcher experienced firsthand.

The most obvious of these is the sample size difficulties that have been discussed in preceding sections. For this reason, the recommendation is that this research be repeated with a larger sample of at least 16 subjects per group. In view of the results that were obtained from this research, one-sided testing will be sufficient for future research. The importance of repeating the research should not be underestimated. The research that was conducted indicated a positive trend in the outcomes when tailoring treatment using the MCA. Casteleijn and Smith have also recommended further research into the MCA as it is a unique South African contribution to occupational therapy. However, if it is not further researched, the model is at risk of disappearing and being replaced by better documented theories.[1-3]

While the researcher recommends repeating the research with a larger sample size in order to produce more reliable data, the practicality of this remains difficult. The fact that statistical procedures are so sensitive to sample size exacerbates the difficulties that researchers face when a small sample size becomes the reality of research. Petersen encourages interest in small data sets. She states that there is considerable need for further studies and innovations to help researchers achieve accuracy with more accessible formulas. Although the development of innovations to achieve accuracy with small samples is well beyond the scope of this study, it may be considered for future studies and research towards higher degrees.[73]

Should the research be repeated with a larger sample; a number of aspects of the methodology could also be altered. The fact that the researcher treated both the experimental and control groups in this research did contribute to the rigor of the research. However, the use of two, trained researchers to treat the experimental and control groups separately should also be investigated. This method would allow for more time to be spent with each patient, and would help to eliminate any researcher bias regarding the outcomes of the treatment.

The use of photography to contribute to recording information about the ulcer should also be investigated. The use of wound tracing versus photography is discussed in the next section of this chapter.

In future research, it should be considered that the search for specialised diabetic foot clinics be extended to other provinces within South Africa. Thus the sample will be drawn from a larger population and will be more representative of the general population. This will also allow for a larger sample to be used in the research.

The literature review that was performed identified a gap that was not addressed in this research. The role of occupational therapy in the treatment of patients suffering from chronic diseases needs to be further researched and clarified. This is particularly true in the preventative stage of treatment where education and information play an important role. In the South African setting where high patient loads and few experienced staff are an unfortunate reality, aspects such as prevention of chronic illness and its complications, and promotion of a healthy lifestyle are often abandoned in favour of more pressing demands such as the treatment of clients already suffering from the consequences of chronic illness. Research has shown the positive effects of prevention and promotion programmes with regards to the diabetic foot [7,10,20], and the unique role of the occupational therapist has been briefly described. Further research into this role and the contribution that occupational therapy can make to the prevention of the complications of chronic diseases such as diabetes is thus recommended.

No matter how carefully research is planned and prepared, it seldom runs exactly as planned; the last section of this final chapter consists of an evaluation of this research which will be useful should future research be considered.

5.5 Evaluation of the Research

This section of the final chapter deals with an evaluation of the research that was conducted. It gives the researcher a chance to critically evaluate not only the results of the research, but also the research process. This may thus help future researchers avoid the same stumbling blocks and difficulties and thus streamline the research process.

5.5.1 Measurement Techniques and Planned Treatment

Chapter 3 dealt with the measurement instruments that were used in detail. After the completion of the data collection, the researcher is more easily able to objectively evaluate the measurement instruments with regard with suitability for this research.

5.5.1.1 Wound Tracing

There is a trend to use photography to capture the size and severity of a wound or ulcer. The researcher opted against this method, as accurate wound photography is challenging and the actual area of the ulcer is difficult to determine from a photograph. Photography of ulcers also potentially invades a subject's right to privacy if the photographs are published.

Wound tracing, as discussed in Chapter 3 provided an easy, cost effective and reliable way to determine the area of an ulcer. The fact that the same doctor did all the wound tracing, increased inter-rater reliability and eliminated any bias the researcher may have had if doing the tracings herself; as the doctor was blind to the assignment of subjects to either experimental or control group.

The use of photography should not be under valued, as photography provides insights into the wound status that wound tracing does not, for example, colour of the wound and depth of the wound. In future research, the use of both wound tracing and wound photography should be

considered as this will allow the researcher to collect more information regarding wound status.

5.5.1.2 Creative Participation Assessment

The CPA was used to assess the level of motivation of the subjects, pre and post treatment. The CPA requires that subjects participate in three activities. This participation is observed by the evaluator (the researcher) in order to determine the level of motivation. The suitability of the three activities that were chosen by the researcher for this research should be evaluated.

The tea-making activity was suitable for most subjects; however, several of the male subjects commented that they never made their own tea/coffee at home and that this was usually done by their wives or caregivers. Thus the tea making activity could not be seen as a familiar activity for all subjects, but did offer valuable insight regardless of the level of familiarity.

The foot care activity, while appropriate to the Diabetic Foot Clinic, was not always practical or easy to carry out. Some of the subjects had undergone lower limb amputations of the now unaffected leg and had an ulcer on the other foot. For hygiene and infection control reasons, foot washing could thus not be done with these subjects. Several subjects also required assistance to care for their feet and stated that they were helped by care givers, children or spouses at home. Any comments such as these were recorded by the researcher. In cases where foot care could not be carried out, the subjects were asked to ‘role play’ their foot care routine and observations were thus made.

The tabletop game proved to be an appropriate activity when looking at unfamiliar activities, however, as some subjects had visual impairments; they struggled to complete the activity independently. Again, any deviations from the original plan were documented by the researcher.

Questions have been raised regarding the use of a standard set of activities to assess the level of motivation. The researcher felt that through

the use of the three chosen activities, subjects of most levels of motivation were catered for. While the tea making activity may have been a low level activity for a subject functioning in the imitative participation level, the table top game posed a challenge. For subjects who struggled with the table top game, the tea making activity presented a familiar and easy activity. The foot care activity was also appropriate to the setting and the aim of the Diabetic Foot Clinic. The CPA requires a variety of activities to assess a subject's level of motivation; activities that are both familiar and unfamiliar to the subject and that pose different challenges. It is the researcher's opinion that the three chosen activities used in the CPA met these criteria.

The subjects' interests are also important in the selection of activities and the participation in therapy. The researcher acknowledges that through the use of three predetermined activities, there was little cognisance taken of the subject's interests and that this may have affected their participation in the activity. It should be noted however that all three activities were short in duration and within the subjects' frames of reference. No subject declined to participate in any of the activities and no subjects expressed boredom. As the activities were used for assessment purposes, the researcher feels the use of predetermined activities is acceptable. During the treatment programme the subjects' interests were taken into account and treatment was tailored accordingly.

It is thus the researcher's opinion that the three activities that were chosen were appropriate for use with the CPA, however the need for relevance and good clinical reasoning skills was demonstrated and this should be noted before any further research is carried out.

5.5.1.3 Planned Treatment

Chapter 3 explained how the researcher planned the treatment and education that the subjects would receive prior to the commencement of the research. This was done to ensure that all subjects in the experimental and control groups received uniform treatment and this thus contributed to rigorous research. However, at times the topic that had been planned was not appropriate. For example; when the researcher planned to cover shoe

wear in a session one of the subjects had just been informed that she was not permitted to wear shoes until her ulcers had healed. This made the planned topic inappropriate and the topic had to be switched with one planned for another week. If the researcher had stuck to the planned topic, the session would have been unsuitable and worthless to the subject. The need for relevance when researching and when educating patients about a topic is again demonstrated.

It should be noted, that patients are not always able to follow up on a two weekly basis as outlined in this study. Several of the subjects that participated in this research study had financial difficulties. While the researcher compensated subjects for travelling expenses, at times subjects struggled to organise the necessary transport to come to the hospital and thus defaulted on the two weekly follow up programme. The importance of good home programmes and information brochures and leaflets should thus not be underestimated, especially when dealing with a population who does not have ready access to medical services or transport.

5.5.2 The Use of the Researcher to Treat Both Experimental and Control Groups

In this research, the researcher was forced to treat both the experimental and control groups as well as patients attending the Diabetic Foot Clinic who were not participating in the research. This was largely due to staff and time limitations in the research setting.

While this method definitely increased inter-rater reliability, the researcher has suggested that in future studies, if the research is repeated with a larger sample size, two occupational therapists be involved in the study. While every effort was made to eliminate researcher bias in this research, through the use of guidelines and spot checks, it may be considered worthwhile to train another therapist in the assessment and treatment procedures required for the research. This would make it possible for one therapist to treat the experimental group, using the guidelines provided in the MCA, while the other therapist takes responsibility for the control group

and continues to offer care as usual. This would make the management of the larger sample easier as the workload would be divided between the two therapists. The practicality of this suggestion however, will have to be carefully investigated especially if the research is conducted in a setting where staff shortages are a reality. The size of the sample will have to be weighed against the workload and available researchers or therapists to conduct the treatment.

5.5.3 Population and Sample

The research setting (PAH's Diabetic Foot Clinic) largely defined the population that was used for this research. While an all inclusive volunteer sample was used, most of the subjects that participated in the research were Caucasian. This is reflective of the population attending the Diabetic Foot Clinic at PAH at the time of the research, but not necessarily reflective of the entire population of people suffering with diabetic foot complications in Gauteng, South Africa or world wide.

The use of other diabetic foot clinics was investigated (at Tshwane District Hospital, Mamelodi Hospital and Mamelodi Clinic), but it was found that these facilities do not offer specialised diabetic foot clinics, but rather run general out patient clinics or general diabetic clinics. It was thus decided that these clinics were not suited for this research, due to the high emphasis that the research has placed on the value of the multi disciplinary foot care team. Any future research should carefully investigate the use of other clinics or centres that offer specialised, multidisciplinary foot care to people with diabetes. If possible the search for such services should be extended beyond the boundaries of the province. This should allow the researcher to access a larger population and thus possibly obtain a more representative sample.

5.5.4 Co-Morbidities

In a condition such as the one studied in this research, the effect of co-morbidities must be recognised. Many of the subjects had co-morbidities either related to diabetes or related to a different pathology. These co-morbidities at times made the assessment and treatment of subjects challenging and plans had to be adapted to accommodate impairments. This again highlights the need for clinical reasoning skills in research as well as the need for flexibility when dealing with human subjects. The co-morbidity most observed in the sample used for this research was visual impairments (either as a result of diabetes, or as the result of another condition). Subjects with visual impairments struggled to complete the RNLI independently due to the small size of the text used in the document. Adaptations thus had to be made and a caregiver was allowed to assist in these cases. Other co-morbidities such as hypertension and obesity were also observed. Therefore it is suggested that in future research studies, researchers should identify possible co-morbidities and have a plan to address any issues that may arise from these co-morbidities beforehand.

5.6 Conclusion

This research study set out to investigate the outcomes of tailored occupational therapy for clients with diabetic foot ulcers. The prevalence of Type 2 Diabetes and its associated complications, including foot ulcers, warranted research into this population. Research into the use of the MCA to tailor occupational therapy was also justified as the model is under-researched and at risk of perishing if further research is not conducted.[2]

The research was conducted at PAH's Diabetic Foot Clinic, which is a specialised, multidisciplinary foot care clinic. The importance of a multidisciplinary team in the management of a complex condition such as the diabetic foot has been well researched and documented.[9,11,12,18,26,28,30]

The treatment outcomes for this research were defined as the percentage change in ulcer size and the change in the subject's quality of life,

measured with the RNLI. The reasoning behind the choice of these outcomes and their measurement has been discussed in detail in preceding sections. The specific design used in this research study was an experimental pre-test-post-test design with an experimental and control group.[61]

The results of this research were not found to be statistically significant with regards to change in quality of life score or percentage change in ulcer size. However, when looking at the absolute change in ulcer size, adjusted for baseline area, the experimental group differed significantly from the control group (p=0.0236). This result indicates the trend to more positive treatment outcomes when using tailored occupational therapy, based on the MCA, as opposed to therapy that has not been tailored to the subject's level of motivation. It is the researcher's opinion that this result, and the trend towards more positive treatment outcomes warrants further research into the use and application of the MCA; more specifically its use with patients with diabetic foot complications or even other physical complications. In the past the MCA has been used mostly in the treatment of children or clients with a psychiatric diagnosis, thus research into this possible different application of the MCA was justified.[1-3,13,55]

The research study addressed the effect of small sample size on the outcomes of a study. It was found that although a small sample may limit the inferences that can be made from the results of the research, it is nonetheless important to conduct rigorous, relevant research with small samples and small populations and thus contribute to the existing body of knowledge.[68,70,73]

The research study also investigated the use of different methodologies in the field of occupational therapy and discussed the perception that large clinical trials with control groups are the favoured research methodology.[68,71-73] Several authors however feel that a mixture of good qualitative and quantitative research is important in the profession of occupational therapy and that the focus should be on research that is both rigorous and relevant to the field of study and the profession.[68,70,73]

In spite of many barriers that hampered the smooth running of this research study, the researcher understands the process of research and has realised that planned research and implemented research are two different aspects of the same process. Nevertheless much was learnt, and the researcher believes that other researchers could learn from this study, and that this study has made a contribution to the field of occupational therapy.

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Appendices:

APPENDIX 1
THE REINTEGRATION TO NORMAL LIVING INDEX

Subject Name: _____ Date: _____

Please complete the following by marking on the scale the number you feels best describes your current abilities.

1. I move around my living quarters as I feel necessary.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

2. I move around my community as I feel necessary.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

3. I am able to take trips out of town as I feel are necessary.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

4. I am comfortable with how my own self care needs (dressing, feeding, toileting bathing) are met.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

5. I spend most of my days occupied in a work activity that is necessary or important to me.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

6. I am able to participate in recreational activities (hobbies, crafts, sports, reading, television, games, computers etc.) as I want to.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

7. I participate in social activities family, friends and/or business acquaintances as is necessary/desirable to me.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

8. I assume a role in my family which meets my needs and those of other family members.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

9. In general, I am comfortable with my social relationships.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

10. In general, I am comfortable with myself when I am in the company of others.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

11. I feel that I can deal with life events as they happen.

1	2	3	4	5	6	7	8	9	10
Does not describe my situation									Fully describes my situation

FOR OFFICIAL USE

Total Score: _____ (sum of points for 11 items)

Adjusted Score: _____ (total score/110) X 100 = _____

APPENDIX 2

DIE HERINTEGRASIE TOT NORMALE LEEFSWYSE INDEX

Naam van Persoon: _____ Datum:_____

Voltooi asseblief die volgende deur die nommer op die skaal te merk wat u huidige vermoëns die beste beskryf.

1. Ek beweeg rond in my blyplek soos nodig.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

2. Ek beweeg rond in my gemeenskap soos nodig.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

3. Ek is instaat om ritte te onderneem soos nodig.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

4. Ek is gemaklik met die wyse waarop my selfversorgings behoeftes (aantrek, voeding, toilet, bad) bevredig word.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

5. Ek is vir die grootste deel van my dag betrokke by ‘n werksaktiwiteit wat nodig of belangrik is vir my.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

6. Ek is instaat om deel te neem aan ontspanningsaktiwiteite (stokperdjies, handwerk, sport, lees, televisie, speletjies, rekenaars ens.) volgens my behoeftes.

1	2	3	4	5	6	7	8	9	10
Beskryf my situasie ten nie									Beskryf my situasie volle

7. Ek neem deel aan sosiale aktiwitiete met familie, vriende en/of besigheids kennisse soos nodig/wenslik.

1	2	3	4	5	6	7	8	9	10
Beskryf my situasie ten nie									Beskryf my situasie volle

8. Ek aanvaar die rol in my gesin wat my behoeftes bevredig en die van my gesinlede.

1	2	3	4	5	6	7	8	9	10
Beskryf my situasie ten nie									Beskryf my situasie volle

9. Ek is oor die algemeen op my gemak in my sosiale verhoudings.

1	2	3	4	5	6	7	8	9	10
Beskryf my situasie ten nie									Beskryf my situasie volle

10. Ek is oor die algemeen op my gemak wanneer ek in die teenwoordigheid van ander is.

1	2	3	4	5	6	7	8	9	10
Beskryf my situasie ten nie									Beskryf my situasie volle

11. Ek voel dat ek lewensvoorvalle kan behartig soos wat dit gebeur.

1	2	3	4	5	6	7	8	9	10
Beskryf nie my my situasie ten nie									Beskryf situasie volle

VIR AMPTELIKE GEBRUIK

Totale telling:_____ (totaal van punte vir 11 items)

Aangepaste telling: _____ (totale telling/110) X 100=_____

APPENDIX 3
THE CREATIVE PARTICIPATION ASSESSMENT (CPA)

Subject Name: _____ Date: _____

	Tone	Self Differentiation	Self Presentation	Passive Participation	Imitative Participation	Active Participation	Competitive Participation
Action	Unplanned undirected	Incidentally constructive or destructive (1-2 step task)	Explorative (3-4 step task)	Product centred (5-7 step task)	Product centred (7-10 step task)	With originality – transcends norms/expectations	Product centred
Volition	Egocentric to maintain existence	Egocentric to differentiate self from others	To present self, unsure	Robust. Directed to attainment of skill	Directed to product, a good product, acceptable behaviour	Directed to improvement of product procedures, etc	Directed to participation with others, to compare & evaluate self in relation to others
Handle tools & materials	Not evident	Only simple, everyday tools eg spoon	Basic tools fro activity participation – poor handling	Appropriate, lack of skill	Good	With initiative	Very good
Relate to people	No awareness	Fleeting awareness	Identification selection, makes contact, tries to communicate, superficial	Communicates	Communicate/ interact	Close interpersonal relationships, intimacy, can assist others, adapt, allowances, consideration	Adapt, allowances, consideration, close interpersonal relationships, can assist others
Handle situations	No awareness of different situations	No awareness/ ability	Stereotypical handling, makes effort but unsure/ timid	Follower, variety of situations, participates in a passive way	Manages a variety of situations, appropriate behaviour	Can evaluate, adapt, adjust according to need, can deal with problems	Can evaluate, adapt, adjust according to need, can deal with problems
Task concept	No task concept, basic concepts	No task concept, basic and elementary concepts	Partial task concept, compound concepts	Total task concept, extended compound (abstract, elementary) concepts	Comprehensive task concept, integrated abstract concepts	Abstract reasoning	Abstract reasoning
Product	None	None	Simple – familiar activities, poor quality product	Product fair quality (aware of expectations)	Product good quality (according to expectations)	Quality – can adapt, modify, exceed expectations, evaluate, upgrade	Quality – can adapt, modify, exceed expectations, evaluate, upgrade
Assistance or supervision needed	Total assistance & supervision (24hr)	Physical assistance & constant supervision	Constant supervision needed for task completion	Regular supervision	Guidance, supervision, regular/new activities, occasional for known activities	Guidance (formal training (own responsibility), help to supervise others	Guidance (formal training (own responsibility), help to supervise others
Behaviour	Bizarre, dis-orientation	Bizarre, little reaction, dis-orientation	At times strange behaviour, hesitant, unsure, willing to try out	Follower, but will participate passively – occasionally strange	Socially acceptable, behaviour generally controlled	Acceptable, shows originality	Socially acceptable/ correct, variety of situations adaptable, plan action, behaviour
Norm awareness	None noted	None noted	Starts to be aware of norms	Norm awareness (aware of expectations)	Norm compliance (do as expected, required standard)	Norm transcendence (do better, more than norm, adapt etc), graded from activities/ situations, variety of situations	
Anxiety & emotional responses	Limited responses	Limited, uncontrolled – basic emotions, comfort/ discomfort shown	Varied, usually low self-esteem & anxiety, poor control	Varied + anxiety, poor control	Full range of emotions, mostly controlled, makes effort	Subtle differences, compassion and increased self-awareness, anxiety used positively	New situations – anxiety, normal emotional responses (anxiety motivator)
Initiation & effort	None noted	Fleeting, minimal effort, not sustained	Effort inconsistent, not maintained. Low frustration tolerance	Varies	As expected/ required, sustained	Consistent & original	Consistent & original
TOTAL							

INSTRUCTION: mark each appropriate block with an X. Add up. The highest total(s) indicates the level(s) on which the patient is functioning.

Final evaluation: Level(s) of creative participation: ☐

Phase: ☐ Therapist Directed ☐ Patient Directed ☐ Transitional

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APPENDIX 4
INFORMED CONSENT DOCUMENTS - ENGLISH
AUTHORISATION TO PARTICIPATE IN A RESEARCH PROJECT

TITLE OF STUDY: Tailoring the Model of Creative Ability to Patients with Diabetic Foot Problems.

Dear Mr. / Mrs. ..... Date …...../…...../…...

1) THE NATURE AND PURPOSE OF THIS STUDY

I understand that I am being asked to participate in a research study. The aim of the study is to look at different ways that an occupational therapist can treat patients suffering from diabetic feet. Occupational therapy that treats patients according to their level of motivation has been effective in other groups of patients. The researcher would like to find out whether this treatment is effective for diabetic foot patients also.

2) EXPLANATION OF PROCEDURES TO BE FOLLOWED.

This study involves answering some questions with regard to your quality of life and diabetic feet, completing a questionnaire, participating in three activities with the researcher and allowing the doctor and the researcher to examine your feet.

The questionnaire you will be asked to complete is a simple 2 page form with 11 questions. Someone will be available to help you, should you need this.

The activities that you will be asked to complete are:

1. A foot care activity involving washing the feet and trimming the toenails.
2. Making tea or coffee with the researcher.
3. Playing a game with the researcher.

The ulcer/s on your foot/feet will be measured; this process involves placing a piece of plastic over the ulcer and tracing it.

While participating in this study your treatment by the doctor and nursing staff will not change. You will be asked to come to the hospital every 2 weeks for a period of 3 months to see the doctor, nursing staff and the researcher. Your transport costs and hospital registration will be paid for the duration of the study only.

3) RISK AND DISCOMFORT INVOLVED.

The only possible risk and discomfort involved is the examination of the ulcer/s on your foot/feet.

4) POSSIBLE BENEFITS OF THIS STUDY.

The study will allow occupational therapists to use better treatment techniques with patients with diabetic feet.

5) I understand that if I do not want to participate in this study, I will still receive standard treatment for my illness.

6) I may at any time withdraw from this study.

7) INFORMATION

If I have any questions concerning this study, I should contact:

Marjolein Jansen Tel: 012 354 2665 or Cell: 082 574 1325

8) CONFIDENTIALITY.

All records obtained whilst in this study will be regarded as confidential. Results will be published or presented in such a fashion that you remain unidentifiable.

9) CONSENT TO PARTICIPATE IN THIS STUDY.

I have read, or had read to me in a language that I understand, the above information before signing this consent form. The content and meaning of this information has been explained to me. I have been given an opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate it will not alter my management in any way. I hereby volunteer to take part in this study.

I have received a signed copy of this informed consent agreement.

.....	.....
Patient / Guardian signature	Date
.....	.....
Person obtaining informed consent	Date
.....	.....
Witness	Date

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VERBAL PATIENT INFORMED CONSENT

(applicable when patients cannot read or write)

I, the undersigned, ……, have read and have explained fully to the patient, named …… and/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the trial in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the study. The patient indicated that he/she understands that he/she will be free to withdraw from the trial at any time for any reason and without jeopardizing his/her treatment.

I hereby certify that the patient has agreed to participate in this trial.

Patient's Name _____
(Please print)

Investigator's Name _____
(Please print)

Investigator's Signature _____ Date _____

Witness's Name _____
(Please print)

Witness's Signature _____ Date _____

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APPENDIX 5
INFORMED CONSENT DOCUMENTS - AFRIKAANS
MAGTIGING OM DEEL TE NEEM AAN 'N NAVOVORSINGS PROJEK

TITEL VAN DIE STUDIE: Aanpasing van die Model van Skeppende Deelname tot die die Pasiënt met Diabetiese Voet Probleme.

Beste Mnr/Mev ……
Datum:……

1. DIE WESE EN DOEL VAN HIERDIE STUDIE

Ek verstaan dat ek versoek word om deel te neem aan 'n navorsing studie. Die doel van die studie is om verskillende maniere waarop 'n arbeidsterapeut 'n pasiënt met 'n diabetiese voet probleem kan behandel, te ondersoek. Arbeidsterapie wat pasiënte volgens hulle vlakke van motivering behandel is effektief met ander groepe pasiënte. Die navorser wil bepaal of hierdie behandeling ook effektief vir pasiënte met 'n diabetiese voet probleem sal wees.

2. VERDUIDELIKING VAN PROSEDURES WAT GEVOLG MOET WORD

Hierdie studie behels die beantwoording van 'n paar vrae oor die kwaliteit van u lewe en diabetiese voet probleem, die invul van 'n vraelys, die deelname aan drie aktiwteite saam met die navorser, en om die dokter en die navorser toe te laat om u voete te ondersoek.

Die vraelys wat u versoek sal word om in te vul is 'n eenvoudige 2 bladsye vorm met 11 vrae. Iemand sal beskikbaar wees om u te help, sou dit nodig wees.

Die aktiwiteite wat u versoek sal word om te voltooi is die volgende:

1. 'n Voetversorgings aktiwiteit wat die was van u voete en die knip van u toonnaels behels.
2. Die maak van tee of koffie saam met die navorser.
3. Die speel van 'n speletjie saam met die navorser.

Die sweer of swere op u voete sal gemeet word; hierdie proses behels die plaas van 'n stukkie plastiek oor die sweer om dit af te teken.

Terwyl u deelneem aan hierdie studie, sal u behandeling deur die dokter en verpleegkundiges nie verander nie. U sal versoek word om elke 2 weke na die hospitaal toe te kom, vir 'n periode van 3 maande, om die dokter, verpleegkundiges en die navorser te sien. U vervoer koste en hospitaal registrasie koste sal vir u betaal word, maar slegs vir die duur van die studie.

3. RISIKOS EN ONGEMAK WAT ONDERVIND MAG WORD

Die enigiste moontlike risiko en ongemak wat u mag ervaar is die ondersoek van die sweer of swere aan u voet/e.

4. MOONTLIKE VOORDELE VAN HIERDIE STUDIE

Die studie sal arbeidsterapeute instaat stel om beter behandlingstegnieke te gebruikvir pasiënte met diabetiese voet probleme.

5. Ek begryp dat as ek nie aan hierdie studie wil deelneem nie, ek nog steeds die standaard behandeling vir my siekte sal ontvang.

6. Ek mag enige tyd onttrek aan die studie.

7. INLIGTING

As ek enige vrae het met betrekking tot hierdie studie, kan ek die volgende persoon kontak:Marjolein Jansen Tel: 012 354 1665 Cell: 082 574 1325

8. VERTROULIKHEID

Enige inligting wat tydens hierdie studie verkry word, sal as vertroulik beskou word. Resultate sal gepubliseer of aangebied word op so ‘n wyse dat u ongeïdentifiseer bly.

9. TOESTEMMING OM DEEL TE NEEM AAN HIERDIE STUDIE

Ek het die bogenoemde inligting gelees, of dit is aan my voorgelees in ‘n taal wat ek verstaan, voordat ek die toestemmingsvorm geteken het. Die inhoud en betekenis van die inligting is aan my verduidelik. Ek het geleentheid gehad om vrae te vra en is tevrede dat dit bevredigend beantwoord is. Ek verstaan dat as ek nie deelneem nie, dit nie my behandeling op enige wyse sal verander nie. Ek bied hiermee vrywillig aan om deel te neem aan hierdie studie.

Ek het ‘n getekende afskrif van hierdie ingeligte toestemmings ooreenkoms gekry.

…….. ……
Pasiënt/voog handtekening Datum

…….. ……
Persoon wat ingeligte toestemming ontvang Datum

…….. ……..
Getuie Datum

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VERBALE INGELIGTE TOESTEMMING VAN DIE PASIËNT
(van toepassing waar pasiënte nie kan lees of skryf nie)

Ek, die ondergetekende, het die pasiënt inligtingsblaadjie, waarop die wyse en doel van die proef wat ek die pasiënt versoek het om aan deel te neem, ten volle aan die pasiënt …….. en/of sy/haar familielid verduidelik.

Die verduideliking wat ek gegee het, meld beide die moontlike risikos en voordele van die studie. Die pasiënt het aangedui dat hy/sy verstaan en dat hy/sy die vryheid het om enige tyd te onttrek uit die proef om watter rede ookal, sonder om sy/haar behandeling in gevaar te stel.

Ek sertifiseer hiermee dat die pasiënt toegestem het om deel te neem aan hierdie proef.

Pasiënt se naam _____

Navorser se naam _____

Navoser se handtekening _____ Datum: _____

Getuie se naam _____

Getuie se handtekening _____ Datum: _____

APPENDIX 6

INTERVIEW GUIDE

This will be used as a guide for the researcher when interviewing the subjects during the initial assessment for level of motivation. The questions are thus broad and mostly open ended, and serve to guide, but not limit the researcher.

Subject's Name: _____

Date of Birth: _____

Contact Details:

Address: _____ Tel (H): _____

_____ Tel (W):_____

_____ Cell: _____

Home Language: _____

Could you tell me a little about where you live and who you live with?

_____

_____

_____

_____

_____

Do you currently have difficulty performing any activities independently? Please explain.

_____

_____

_____

_____

_____

How long have you had diabetes, and how long have your feet been a problem for you?

_____

_____

_____

_____

_____

Do you have any other illnesses? If yes, please explain.

_____

_____

_____

_____

_____

How are you currently caring for your feet?

_____

_____

_____

_____

_____

APPENDIX 7
TREATMENT PROGRAMME FOR THE EXPERIMENTAL GROUP
Motivation: Self Presentation
Action: Explorative Action

Personal Management	Social Ability	Work Ability	Use of Free Time
• Patient learns skills necessary for independent living, but requires structure, encouragement, support and outside organization. • Consolidate basic hygiene skills and care of clothes	• Basic social skills present • Relationships are egocentric and short-lived • Poor stress management skills	• Development of task concept throughout level • Poor decision making especially abstract • Poor rate of work • Poor frustration tolerance	• Development of interests and discrimination of like and dislike • Aware of occupational inadequacy but not how to improve • Poor insight
Treatment Principles			
Handling	**Structuring**	**Presentation**	**Activity Requirements**
• Therapist must be encouraging and supportive • Individuality must be facilitated and emphasised • Allow patient to make decisions and take responsibility for activity • Encourage participation, but don't force • Expectations for behaviour and norms must be made overt	• Patient must feel secure in familiar treatment area • Therapist to prepare and structure activity, patient to execute • Well organized area	• Instructions must make patient aware of process and steps to follow and their order • Patient should be encouraged to evaluate own performance on a concrete level • Avoid use of demonstration as patients tend to model behaviour	• Each step should have between 4 and 7 tasks • Activities should be concrete and simple but not childish • Should challenge patient

Treatment Programme for Patients with Diabetic Foot Problem – Self Presentation

Week 1	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6
• Obtain informed consent • Assess level of CA using CPA • Measure size of ulcer • Complete RNLI	Education regarding what is a diabetic foot and how did the ulcer develop	Recap of treatment 1 Education and execution of correct foot cleaning, washing, inspection and nail care	Recap of treatment 1 & 2 Education about correct shoe wear	Recap of treatment 1, 2 & 3 Education about and practical execution of principles to compensate for loss of sensation	Recap of treatment 1, 2, 3 & 4 Adaptation to daily routine at home and/or work	• Reassessment of level of CA using CPA • Measurement of size of ulcer • Completion of RNLI

- Treatment sessions will last 10 to 15 minutes each in keeping with the current clinic schedule.

Motivation: Passive Participation
Action: Passive Participation

Personal Management	Social Ability	Work Ability	Use of free time
• Interests and experimentation in refined forms of self care develop • Poor prevocational skills influence quality of all work • Survival skills are the main focus • Express want for independence, but need structure and supervision	• Interpersonal activity is directed towards belonging • Assertiveness skills start to develop • Prefer spectator role • Relationships generally egocentric	• Behaviour is more product centred • Difficulty initiating activities, but have desire to complete • External locus of control and poor prevocational skills • Able to deal with obstacles	• Range of interests develop • Will actively participate with others if encouraged/ organised
Treatment Principles			
Handling	**Structuring**	**Presentation**	**Activity requirements**
• Handle with care and understanding • Make aware of norms • Encourage patient to get involved in all steps of activity • Encourage evaluation of participation and activity • Encourage participation even if passive	• Area structured according to patients ability to concentrate • Preparation done by therapist • Accepting atmosphere	• Treatment should be task centred and socio-emotional • Needs instructions in order to monitor progress • Difficulty handling negative feedback therefore focus of properties of activity	• Concrete, experimental and challenging activity • Guaranteed success in activity but with room for improvement • Activity must not require patient to take initiative

Treatment Programme for Patients with Diabetic Foot Problem – Passive Participation

Week 1	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6
• Obtain informed consent • Assess level of CA using CPA • Measure size of ulcer • Complete RNLI	Education regarding what is a diabetic foot and how did the ulcer develop	Recap of treatment 1 Education and execution of correct foot cleaning, washing, inspection and nail care	Recap of treatment 1 & 2 Education about correct shoe wear	Recap of treatment 1, 2 & 3 Education about and practical execution of principles to compensate for loss of sensation	Recap of treatment 1, 2, 3 & 4 Adaptation to daily routine at home and/or work	• Reassessment of level of CA using CPA • Measurement of size of ulcer • Completion of RNLI

- Treatment sessions will last 10 to 15 minutes each in keeping with the current clinic schedule.

Motivation: Imitative Participation
Action: Imitative Participation

Personal Management	Work Ability	Social Ability	Use of Free Time
• Basic hygiene and care of clothes and belongings is consolidated • Develop awareness of fashion and suitability of clothing • Survival skills and skills for independent living are the focus at this stage • Difficulty handling stress associated with being responsible for self	• Performance is goal directed and norm compliant • Able to do what is asked provided that there are no unexpected hitches and problem solving required is minimal • Prevocational skills are good • Vocational skills are developing with training	• Behaviour is directed towards belonging • Communication is efficient and basic social skills are intact • Assertiveness is poor • Function well in familiar settings but struggle with unfamiliar settings • Very susceptible to group pressure • Prefer to follow rather than lead	• Wide variety of interests and recreational skills • Involved in activities that are currently fashionable and done by group members/friends
Treatment Principles			
Handling	**Structuring**	**Presentation**	**Activity Requirements**
• Relationships based on mutual respect and trust, with elements of give and take • Handle firmly with regard to norm compliancy • Expectations must be clearly stated and generalised to other situations • Establish goals and norms together • Be supportive if unable to comply	• Patient should be encouraged to structure own working space • Treatment should happen in groups • Patient given responsibility for attendance	• Activities presented as a whole • Use of verbal and diagrammatic instructions with unfamiliar activities only • Emphasis on purpose and understanding of activities • High level end product should be available for comparison • Encourage critical evaluation of the end product • Present activities in logical fashion, outline method/ technique	• Introduce elements of problem solving • Should challenge patient to use initiative • Allow patient to start showing individuality

Treatment Programme for Patients with Diabetic Foot Problem – Imitative Participation

Week 1	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6
• Obtain informed consent • Assess level of CA using CPA • Measure size of ulcer • Complete RNLI	Education regarding what is a diabetic foot and how did the ulcer develop	Recap of treatment 1 Education and execution of correct foot cleaning, washing, inspection and nail care	Recap of treatment 1 & 2 Education about correct shoe wear	Recap of treatment 1, 2 & 3 Education about and practical execution of principles to compensate for loss of sensation	Recap of treatment 1, 2, 3 & 4 Adaptation to daily routine at home and/or work	• Reassessment of level of CA using CPA • Measurement of size of ulcer • Completion of RNLI

- Treatment sessions will last 10 to 15 minutes each in keeping with the current clinic schedule.

ANCOVA TABLES / RAW DATA ANALYSIS

```
. anova  ulcer_chge grp ulcer_pre, continuous( ulcer_pre)

                    Number of obs =      10     R-squared     =  0.8323
                    Root MSE      = 69.1118     Adj R-squared =  0.7844

               Source |  Partial SS    df       MS           F     Prob > F
              --------+----------------------------------------------------
                Model |  165982.554     2  82991.2771      17.38     0.0019
                      |
                  grp |    1680.214     1    1680.214       0.35     0.5718
            ulcer_pre |  137988.954     1  137988.954      28.89     0.0010
                      |
             Residual |  33435.0457     7   4776.4351
            ----------+----------------------------------------------------
                Total |    199417.6     9  22157.5111

. adjust   ulcer_pre, by( grp)

-------------------------------------------------------------------------------
     Dependent variable: ulcer_chge     Command: anova
  Covariate set to mean: ulcer_pre = 282.5
-------------------------------------------------------------------------------
      grp |         xb
----------+------------
    Exper |    234.095
  Control |    206.198
----------------------
     Key:  xb  =  Linear Prediction

. anova   ulc_ch_r grp  ulc_pre_r, continuous(  ulc_pre_r)

                        Number of obs =      10     R-squared     =  0.9679
                        Root MSE      = .615555     Adj R-squared =  0.9587

               Source |  Partial SS    df       MS           F     Prob > F
              --------+----------------------------------------------------
                Model |  79.8476404     2  39.9238202     105.37     0.0000
                      |
                  grp |  3.14930047     1  3.14930047       8.31     0.0236
             ulc_pre_r |  59.4309737     1  59.4309737     156.85     0.0000
                      |
             Residual |  2.65235964     7   .37890852
            ----------+----------------------------------------------------
                Total |        82.5     9  9.16666667

. adjust  ulc_pre_r, by( grp)

-------------------------------------------------------------------------------
     Dependent variable: ulc_ch_r     Command: anova
  Covariate set to mean: ulc_pre_r = 8.5
-------------------------------------------------------------------------------

----------------------
      grp |         xb
----------+------------
    Exper |    6.30757
  Control |    5.09662
----------------------
     Key:  xb  =  Linear Prediction
```

```
. anova   qol_chge grp

                          Number of obs =      10     R-squared     =  0.1381
                          Root MSE      = 13.4549     Adj R-squared = -0.1082

              Source |  Partial SS    df       MS           F     Prob > F
           ----------+----------------------------------------------------
               Model |  203.050535     2  101.525267       0.56     0.5944
                     |
                 grp |  99.3671131     1  99.3671131       0.55     0.4829
             qol_pre |  30.3299095     1  30.3299095       0.17     0.6945
                     |
            Residual |  1267.23838     7  181.034054
           ----------+----------------------------------------------------
               Total |  1470.28891     9  163.365435

. adjust   qol_pre, by( grp)

--------------------------------------------------------------------------------
     Dependent variable: qol_chge     Command: anova
  Covariate set to mean: qol_pre = 69.4625
--------------------------------------------------------------------------------

----------------------
      grp |         xb
----------+-----------
    Exper |    2.36057
  Control |    9.34421
----------------------
     Key:  xb  =  Linear Prediction


. list  number grp qol_pre qol_post qol_chge

     +-------------------------------------------------+
     | number       grp   qol_pre   qol_post   qol_chge |
     |-------------------------------------------------|
  1. |      7     Exper        85         79         -6 |
  2. |     14   Control        51         46         -5 |
  3. |      9   Control        72         69         -3 |
  4. |      6     Exper        73         71         -2 |
  5. |      5     Exper       100         99         -1 |
     |-------------------------------------------------|
  6. |      1     Exper        77       77.3   .3000031 |
  7. |      4     Exper      52.7       55.5   2.799999 |
  8. |     12   Control        80         92         12 |
  9. |      2     Exper        72       86.4       14.4 |
 10. |     16   Control        58       93.6       35.6 |
     |-------------------------------------------------|
 11. |      3     Exper      72.7          .          . |
 12. |      8   Control        49          .          . |
 13. |     10   Control      58.2          .          . |
 14. |     11   Control      83.6          .          . |
 15. |     13   Control      82.7          .          . |
     |-------------------------------------------------|
 16. |     15   Control      44.5          .          . |
     +-------------------------------------------------+
```

```
. anova    qol_ch_r grp qol_pre_r, continuous( qol_pre_r)

                           Number of obs =      10     R-squared     =  0.0598
                           Root MSE      = 3.32888     Adj R-squared = -0.2089

               Source |  Partial SS    df       MS           F     Prob > F
           -----------+----------------------------------------------------
                Model |  4.92975265     2  2.46487633       0.22     0.8060
                      |
                  grp |  .105750433     1  .105750433       0.01     0.9249
              qol_pre_r |  4.51308598     1  4.51308598       0.41     0.5437
                      |
             Residual |  77.5702473     7  11.0814639
           -----------+----------------------------------------------------
                Total |        82.5     9  9.16666667

. adjust   qol_pre_r, by( grp)

-------------------------------------------------------------------------------
Dependent variable: qol_ch_r     Command: anova
  Covariate set to mean: qol_pre_r = 8.5
-------------------------------------------------------------------------------
----------------------
      grp |         xb
----------+-----------
    Exper |    5.69788
  Control |    5.46565
----------------------
     Key:  xb  =  Linear Prediction

. anova   ulc_perc grp ulcer_pre, continuous( ulcer_pre)

                           Number of obs =      10     R-squared     =  0.2880
                           Root MSE      = 22.3414     Adj R-squared =  0.0846

               Source |  Partial SS    df       MS           F     Prob > F
           -----------+----------------------------------------------------
                Model |  1413.20602     2  706.603011       1.42     0.3046
                      |
                  grp |  1341.55899     1  1341.55899       2.69     0.1451
             ulcer_pre |  12.7964141     1  12.7964141       0.03     0.8773
                      |
             Residual |  3493.95852     7  499.136932
           -----------+----------------------------------------------------
                Total |  4907.16455     9  545.240505

. adjust  ulcer_pre, by( grp)

-------------------------------------------------------------------------------
Dependent variable: ulc_perc     Command: anova
  Covariate set to mean: ulcer_pre = 282.5
-------------------------------------------------------------------------------

----------------------
      grp |         xb
----------+-----------
    Exper |     88.113
  Control |    63.1858
----------------------
     Key:  xb  =  Linear Prediction
```

```
. anova    ulc_perc_r grp ulc_pre_r)

                           Number of obs =      10     R-squared     =  0.4052
                           Root MSE      = 2.63953     Adj R-squared =  0.2353

                Source |  Partial SS    df       MS           F     Prob > F
            -----------+----------------------------------------------------
                 Model |  33.2302685     2  16.6151343       2.38     0.1622
                       |
                   grp |   16.436909     1   16.436909       2.36     0.1684
               ulc_pre_r |  6.56360184     1  6.56360184       0.94     0.3641
                       |
              Residual |  48.7697315     7   6.9671045
            -----------+----------------------------------------------------
                 Total |          82     9  9.11111111

. adjust   ulc_pre_r, by( grp)

-------------------------------------------------------------------------------
     Dependent variable: ulc_perc_r     Command: anova
  Covariate set to mean: ulc_pre_r = 8.5
-------------------------------------------------------------------------------

----------------------
      grp |         xb
----------+-----------
    Exper |      6.714
  Control |    3.94752
----------------------
     Key:  xb  =  Linear Prediction
```

```
. list
```

```
  1. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      1 |     A |   Exper |       68 |      77 |      4A | Not well |       12 |     77.3 |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |       5A |       56 | .3000031 |        3 |        2 |        6 |       11 | 82.35294 |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                             5                                           |
     +-----------------------------------------------------------------------------------------+

     +-----------------------------------------------------------------------------------------+
  2. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      2 |     A |   Exper |      222 |      72 |      5A |   Highly |        0 |     86.4 |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |       5B |      222 |     14.4 |        6 |        9 |        9 |      7.5 |      100 |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                           9.5                                           |
     +-----------------------------------------------------------------------------------------+

     +-----------------------------------------------------------------------------------------+
  3. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      3 |     A |   Exper |      652 |    72.7 |      5B |        . |        . |        . |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |          |        . |        . |        . |       15 |        . |        9 |        . |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                             .                                           |
     +-----------------------------------------------------------------------------------------+

     +-----------------------------------------------------------------------------------------+
  4. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      4 |     A |   Exper |      752 |    52.7 |      4B | Not well |      318 |     55.5 |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |       4C |      434 | 2.799999 |       10 |       16 |        7 |        4 | 57.71276 |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                             3                                           |
     +-----------------------------------------------------------------------------------------+

     +-----------------------------------------------------------------------------------------+
  5. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      5 |     A |   Exper |      168 |     100 |      5C |   Highly |       16 |       99 |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |       5C |      152 |       -1 |        5 |        5 |        5 |       16 | 90.47619 |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                             6                                           |
     +-----------------------------------------------------------------------------------------+

     +-----------------------------------------------------------------------------------------+
  6. | number | group |     grp | ulcer~re | qol_pre | mot_pre | mot_pr~t | ulcer_~t | qol_post |
     |      6 |     A |   Exper |      276 |      73 |      4B | Not well |        8 |       71 |
     |-----------------------------------------------------------------------------------------|
     | mot_post | ulcer~ge | qol_chge | ulc_ch_r | ulc_pr~r | qol_ch_r | qol_pr~r | ulc_perc |
     |       4C |      268 |       -2 |        7 |       11 |        4 |       10 | 97.10145 |
     |-----------------------------------------------------------------------------------------|
     |                                      ulc_pe~r                                           |
     |                                             8                                           |
     +-----------------------------------------------------------------------------------------+
```

7.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
7	A	Exper	380	85	5B	Highly	0	79

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
5B	380	-6	9	12	1	15	100

ulc_pe~r
9.5

8.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
8	B	Control	206	49	4A	.	.	.

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
	.	.	.	8	.	2	.

ulc_pe~r
.

9.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
9	B	Control	190	72	4B	Not well	42	69

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
4B	148	-3	4	6	3	7.5	77.89474

ulc_pe~r
4

10.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
10	B	Control	104	58.2	4B	.	.	.

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
	.	.	.	3	.	6	.

ulc_pe~r
.

11.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
11	B	Control	510	83.6	5B	.	.	.

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
	.	.	.	14	.	14	.

ulc_pe~r
.

12.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
12	B	Control	382	80	5B	Highly	20	92

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
5C	362	12	8	13	8	12	94.7644

ulc_pe~r
7

13.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
13	B	Control	244	82.7	4C	.	.	.

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
	.	.	.	10	.	13	.

ulc_pe~r
.

14.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
14	B	Control	56	51	3C	Not well	32	46

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
3C	24	-5	1	1	2	3	42.85714

ulc_pe~r
2

15.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
15	B	Control	204	44.5	4B	.	.	.

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
	.	.	.	7	.	1	.

ulc_pe~r
.

16.

number	group	grp	ulcer~re	qol_pre	mot_pre	mot_pr~t	ulcer_~t	qol_post
16	B	Control	106	58	5B	Highly	64	93.6

mot_post	ulcer~ge	qol_chge	ulc_ch_r	ulc_pr~r	qol_ch_r	qol_pr~r	ulc_perc
5B	42	35.6	2	4	10	5	39.62264

ulc_pe~r
1