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Exploring a Bio-psychological Intervention for Painful Diabetic Neuropathy

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ABSTRACT

Background:

Painful diabetic neuropathy (PDN) is a major clinical manifestation of diabetes associated with damage to the nerves. The etiology and prognosis of PDN is multi-dimensional, needing a multi-faceted approach for management. The chronic pain associated with PDN is considered a painful crises that involves psychological complications in addition to the mere sensations. A repeated attempt to solve the problem of pain from a biomedical perspective has resulted in a cycle of low health quality of life, sleep disturbance, depression, anxiety and pain catastrophizing. An effective treatment of PDN would require pharmacotherapies supplemented by non-pharmacological approaches like cognitive behavioural therapy (CBT) and hypnosis (HYP).

This study assessed the role of personal beliefs as a coping strategy for PDN, explored the relationship between depression, anxiety, hypertension and PDN, and further evaluated the efficacy of the combined intervention of medication, CBT and HYP for PDN.

The study employed sequential exploratory multiple methods for collecting and analysing both qualitative and quantitative data in three phases. Phase I involved qualitative interviews, phase II applied a cross-sectional descriptive approach, while phase III applied a TAU plus CBT and HYP randomized with TAU plus CBT in the intervention of PDN. Data collection tools for phase I used a demographic questionnaire and semi-structured interview guide to explore participants' personal beliefs and experiences. Data analysis was done through a thematic approach. Data collection tools for phase II comprised the Leeds Assessment of Neuropathic Symptoms and Signs Scale, Medical Outcomes Study Short Form – SF-36, Hospital Anxiety and Depression Scale and the Brief Pain Inventory for Painful Diabetic Peripheral Neuropathy. The data was analysed with Pearson's

Correlation coefficient, Chi-squared Test of Association, Student's *t*-test and Analysis of Variance (ANOVA).

The study found that participants lacked adequate information about their diabetes and PDN condition. It also established that participants use religious activities as a major strategy to cope with PDN. This study also found a strong positive association between depression, anxiety and PDN.

Regarding the relationship between PDN characteristics and quality of life domains, this study established that there is no statistically significant association between eleven pain characteristics, namely throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain on one side, and some quality of life domains such as their physical functioning and their energy fatigue on the other. The study, however, established significant associations between aching pain and emotional well-being on one side and between aching pain and social functioning on the other.

There was also a significant association between burning pain and social functioning, implying that for any PDN patient to be able to function well socially, every form of burning pain should be managed. Similarly, there were significant associations between numbness and role limitations due to emotional problems on one side, and between numbness and emotional well-being, social functioning, pain in general and general health on the other. In this study there was a significant association between miserable pain and role limitation due to physical health, a quality of life characteristic. Thus, as pain reduces, quality of life increases.

The study affirmed that after the introduction of hypnosis (HYP) to the experimental group, there was a statistically significant reduction in pain intensity and interference in the experimental group (TAU + CBT + HYP) compared with the control group (TAU + CBT).

This study, therefore, concludes that patients use personal beliefs as a coping strategy for PDN and that there is a significant relationship between depression, anxiety, quality of life and PDN. There was also a significant improvement after the combined intervention of medication, CBT and HYP for PDN.

DECLARATION

I declare that

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is my own work, that all the sources I have used or quoted have been indicated and acknowledged by means of complete references, and that this work has not been submitted previously in its entirety, or in any part, at any other higher education institution for degree purposes.

……………………………………..

Adzika Agbemenya Vincent

Candidate

Date. 21/07/2021

DEDICATION

This Thesis is affectionately dedicated to my children Philippa, Melchizedek, Jehoshaphat, and Zachariah.

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DEFINITION OF TERMS

Anxiety: Anxiety is distinguished from fear, which is an appropriate cognitive and emotional response to a perceived threat. Anxiety is related to the specific behaviours of fight-or-flight responses, defensive behaviour, or escape.

Depression: Depression, also known as major depressive disorder, is a mood disorder that makes you feel constant sadness or lack of interest in life.

Diabetes Mellitus: Diabetes mellitus refers to a group of diseases that affect how your body uses blood sugar (glucose).

Painful Diabetes Neuropathy: Pain initiated or caused by primate lesion or dysfunction of the peripheral or central nervous system.

Personal Beliefs: A personal belief is something you (or someone else) personally hold to be true. This belief may be based on scientific facts, personal experience, what a person has heard from others (peers, parents, teachers, etc.), or what a person wants to think is true because it is convenient or makes them feel better.

Quality of Life: QoL is the general well-being of individuals and societies, outlining negative and positive features of life. It consists of the expectations of an individual or society for a good life.

KEY WORDS/ PHRASES

Bio-psychological

Cognitive behavioural therapy

Hypnotherapy

Intervention

Painful diabetic neuropathy

Religion/Spiritual

ACRONYMS AND ABBREVIATIONS

ANOVA – Analysis of Variance

CBT – Cognitive behavioural therapy

DM – Diabetes mellitus

DPN – Diabetic peripheral neuropathy

GDM – Gestational diabetes mellitus

HADS – Hospital Anxiety and Depression Scale

HYP – Hypnosis

HBM – Health belief model

IDF – International Diabetes Federation

PDN – Painful diabetic neuropathy

QoL – Quality of life

TAU – Treatment as usual

T1DM – Type 1 diabetes mellitus

T2DM – Type 2 diabetes mellitus

WHO – World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Background

This thesis explores the experience of people living with painful diabetic neuropathy (PDN). It investigates how PDN impacts their lives and how psychological complications such as depression, anxiety, and quality of life (QoL) influence patients with PDN. It further explores the view that for clinicians to help individuals with PDN decrease pain, they can use a combined therapy of medication, Cognitive Behavioural Therapy (CBT) and Hypnotherapy (HYP).

The International Association of the Study of Pain (IASP) defines neuropathic pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage," and is expanded upon by the addition of six key notes and the etymology of the word pain for further valuable context (Merskey & Bogduk, 1994; Treede, 2018; Raja et al., 2020). PDN is "the presence of symptoms and signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes" (Boulton et al., 1998 Kaur, et al., 2011; Rosenberger, et al. 2020).

Diabetes mellitus (DM) is an endocrine disorder characterized by sustained hyperglycaemia (raised blood sugar level) because of loss of insulin secretion and/or impairment of insulin sensitivity at the target tissues (Holt & Hanley, 2012b). The consistent rise in blood glucose concentrations of diabetes culminates in a high blood glucose level (IDF, 2017). According to Norris et al. (2001), the hyperglycaemic nature of DM occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. DM accounts for numerous hospitalizations and mortalities among patients, making it a public health concern needing global urgency (Jiang et al., 2003; Kim, 2007; Bourne et al., 2013; Al-Adsani & Abdulla, 2015).

According to the International Diabetes Federation (IDF) (2017), more than 15.9 million people worldwide have diabetes and this figure is projected to increase by 62% by 2045. The adult population (18 to 99 years) with diabetes is 516 million globally, with an expected rise to 1.1 billion in 2045 (IDF, 2017). Africa is the region with the highest percentage of undiagnosed people, with about 70% of the population not knowing that they have diabetes (IDF, 2017). In Ghana, the highest prevalence of people (20 to 79 years) with diabetes, in the 1,000s was estimated at 140.5–830.3 in 2017 and is projected to increase from 339.8 to –2 026.5 by 2045 (IDF, 2017).

The increasing prevalence, social costs and mortalities combined with DM associated complications emphasizes the importance of effective diabetes care (Hart et al. 1997; Barcelo et al., 2017; Kirigia et al., 2009; Gray et al., 1995; WHO, 1999; WHO, 2017). The complications of DM include both micro-vascular-like neuropathy, nephropathy, retinopathy and atherosclerosis (Tesfaye et al., 1996; Davies et al., 2006; Levterova et al., 2018). Diabetic neuropathies are among the most common long-term complications of diabetes, affecting up to 50% of patients (Boulton & Malik, 2010). Neuropathies in diabetes are classified as those affecting single nerves (mono-neuropathy), those affecting several nerves (mono-neuropathy multiples), or those affective many nerves (polyneuropathy), with the most common form being the distal symmetrical polyneuropathy, affecting sensory more than motor nerves (Forsblom et al., 1998; Abbott et al., 2002).

Painful diabetic neuropathy (PDN) is a major clinical manifestation of diabetes associated with damage to the nerves (Borissova et al., 2015; Charakchiev et al., 2015). It has a heterogeneous set of clinical or subclinical manifestations affecting the peripheral nervous system (Greene et al., 1990; Greene et al., 1992). In individual patients, PDN has different clinical manifestations as well as pathophysiologic mechanisms at onset and throughout its course (Greene et al., 1990; Greene et al., 1992). A proportion of patients with neuropathy progress to experience a kind of pain termed painful diabetic neuropathy (Boulton et al., 2005). PDN is characterized by diffuse damage to the peripheral nerve fibres with diabetic sensorimotor polyneuropathy (Callaghan et al., 2012). Increased prevalence of DM has stressed the importance of knowing its primary clinical manifestations to establish early diagnosis and management with the possibility of preventing disease progression and its complications (Do Nascimento et al., 2016).

Globally, the overall PDN prevalence among patients with diabetes is high (40.3%) and patients with type 2 diabetes (42.2%) are more often affected than those with type 1 diabetes (29.1%). PDN prevalence increases with age and diabetes duration and is already high (35.0%) following type 2 diabetes diagnosis (Pfannkuche et al., 2020). Major PDN risk factors are "older age" and loss of consciousness due to severe hypoglycaemia episodes among patients with type 1 diabetes as well as "older age" and an adverse cardiovascular-metabolic profile (obesity, hypertension, low HDL-c levels, elevated triglycerides, low physical activity and limited range of motion) among patients with type 2 diabetes (Ugoya et al., 2006; Jarso et al., 2011; Mehra et al., 2014; Ogbera & Ekpebegh, 2014; Liu et al., 2019; Pfannkuche et al., 2020).

Though there is a significant amount of variation in the primary studies on DM regarding the prevalence of PDN in Africa, the overall prevalence of PDN in DM patients in Africa can only be estimated (Shiferaw et al., 2020). In a systematic review and meta-analysis of the prevalence of diabetic peripheral neuropathy (DPN) in Africa, 23 studies, which involved 269 691 participants, were included in the meta-analysis. The overall pooled prevalence of diabetic peripheral neuropathy was 46% (95% CI: 36.21–55.78%) (Shiferaw et al., 2020). Based on the subgroup analysis, the highest prevalence of diabetic peripheral neuropathy in DM patients was reported in West Africa at 49.4%–95% CI: 32.74, 66.06 (Shiferaw et al., 2020). According to Shiferaw et al.

(2020), the overall prevalence of diabetic peripheral neuropathy is relatively high in Africa needing situation-based interventions and preventive strategies, which are specific to each country.

The aetiology and prognosis of PDN is multi-dimensional, needing a multi-faceted approach for management (Castelnuovo et al., 2016; Levterova et al., 2016). Most PDN treatment guidelines recommend a selection of drugs based on patient comorbidities (Levterova et al., 2016; Levterova et al., 2018; Rolim et al., 2017). Despite the large numbers of medications available, most randomized clinical trials (RCTs) conducted so far have yielded unsatisfactory outcomes (Campbell et al., 2012; Tesfaye, Wilhelm, et al., 2013; Demant et al., 2014). Therefore, PDN treatment may require a personalized approach based on pain phenotype and comorbidities (Marchettini et al., 2016; Rolim et al., 2017).

The chronic pain associated with PDN is influenced by both biological and psychological factors (Boulton et al., 2005; Attal et al., 2008; Tesfaye et al., 2011). The affective and evaluative components of pain are often as important as the intensity component, which makes the emotional aspects of pain prominent in individuals with chronic pain (Hansen & Streltzer, 2005). A repeated attempt to solve the problem of pain from a purely biomedical perspective has resulted in a cycle of low health quality of life, sleep disturbance, depression, anxiety, and catastrophizing (Eccleston & Crombez, 2007). Psychological factors have therefore been shown to be associated with the quality of life of patients with PDN. Targeting these factors for treatment can contribute to a reduction in pain (Selvarajah et al., 2014; Pires-Yfantouda & Evangeli, 2012). Magni et al. (1990) and Gallagher and Verma (1999) have documented that there is a high degree of comorbidity between depression and pain. Both Anderson et al. (2001) and Li et al. (2009) found that anxiety, depression, and sleep disturbance are common psychological comorbidities in chronic pain populations (Widerström-Noga et al., 2001). A validation study of the Hospital Anxiety and

Depression Scale (HADS) in different groups of Dutch subjects has also revealed a significant association between chronic pain and both anxiety and depression (Spinhoven et al., 1997).

A study in Nigeria confirms that patients with chronic diseases such as type 2 diabetes mellitus often have a relatively poor QoL, in part because of the cost of care and the impact of the pain on sleep and mood of this condition (Ababio et al., 2017). There is also a comorbidity of depression and anxiety as a result of the stressful negative consequences of living with DM-related pain (Nicholson & Verma, 2004). D'Amato et al. (2016) investigated the effect of depression on diabetic polyneuropathy and found that PDN is a greater determinant of depression than other diabetes-related comorbidities. Similarly, Vileikyte and colleagues found an association between diabetic neuropathy, depressive symptoms and interventions that alleviate depressive symptoms in persons affected by PDN (Vileikyte et al., 2005). Consistent with this body of research, pain researchers often highlight the importance of adopting a holistic approach to chronic pain management, including the need to incorporate interventions to increase psychological flexibility alongside conventional pharmacological treatments to improve emotional distress in PDN (Selvarajah et al., 2014; Pires-Yfantouda & Evangeli, 2012).

An effective treatment for PDN would be pharmacotherapy, supplemented by non-pharmacological approaches like CBT and/or hypnosis (Kirsch et al., 1995; Sturgeon, 2014; Williams, 2011; Jensen et al., 2014). Cognitive behavioural therapy either used alone or alongside pharmacological drugs has proven to have a significant effect on mood, anxiety, depression, and catastrophizing post treatment (Castelnuovo et al., 2016; Chou et al., 2009; Ehde et al., 2014; Williams et al., 2012). However, Ehde et al. (2014) suggest the need to further explore the efficacy of CBT for maximum benefits due to inherent challenges like moderate effect size for practitioners/clinicians (Majeed & Sudak, 2017).

Hypnosis has been shown to have a beneficial effect on pain (Jensen et al., 1991). However, in many cases, the pain returns after a certain period of time following hypnosis (Milling, 2008; Lee & Pyun, 2012). A growing body of evidence indicates that general hypnotisability demonstrates weak and inconsistent associations with hypnotic treatment of chronic pain in the clinical setting (Patterson & Jensen, 2003). An approach to psychotherapy that combines CBT with other approaches – such as hypnosis – may represent the future direction of management of chronic pain with treatment modified for specific circumstances among patients (Thoma et al., 2015; Sveinsdottir et al. 2012).

The influence on health/illness and QoL by culture, religion and personal beliefs has also received attention in psycho-medical research. Personal beliefs have been found to have positive outcomes on health conditions (Jim et al., 2015). Coping has been seen as multi-dimensional and identified religion as a coping mechanism (Jim et al., 2015; Young & Koopsen, 2005; Adzika et al., 2016). McQuillan et al. (2010) observed the relationship between religion and health as complex because religiosity may be associated with beliefs that promote or hinder medical help-seeking. Research can be conducted on both positive and negative effects of personal beliefs, combined with an engagement of religion (Alves et al., 2010). Studies on personal belief and experiences of patients regarding PDN reveal that most patients could recognize their pain and describe pain characteristics, including pain symptoms (Perissinotti & Portnoi, 2016; Selvarajah et al., 2014).

Given these considerations, this study aims to: (1) explore the personal experiences of PDN patients, (2) better understand the role that anxiety and depression play with respect to specific PDN characteristics, (3) investigate the relationship between PDN characteristics and quality of life, and (4) conduct a clinical study on the effect of the combined intervention of pharmacotherapy, CBT and hypnosis among patients with PDN in Ghana.

1.2 Statement of Problem

The chronic pain associated with PDN is considered as painful crises that involve psychological complications in addition to the physical pain (Boulton et al., 2005; Attal et al., 2008; Tesfaye et al., 2011). The affective and evaluative components of pain were often as important as the intensity component, which makes the emotional aspects of pain prominent in individuals with chronic pain (Hansen & Streltzer, 2005). A repeated attempt to solve the problem of pain from a biomedical perspective alone has resulted in a cycle of low health quality of life, sleep disturbance, depression, anxiety, and catastrophizing (Eccleston & Crombez, 2007).

Psychological interventions for pain management are underutilized, especially in developing countries, due to the unfamiliarity of these treatments, time constraints, and the availability of analgesic medications (Chou et al., 2009). The need to incorporate psychotherapy into the treatment of pain has received increased attention over the last two decades. However, its experimental significance compared to its statistical significance requires further exploration (Jensen, Barber, et al., 2009). The transition from medical intervention to medication and psychotherapy for PDN could potentially improve pain treatment as it involves a holistic approach (Siousioura, 2012).

The use of CBT either alone or alongside medications has aided the treatment of pain to an extent with limited negative side effects (Castelnuovo et al., 2016; Ehde et al., 2014). A Cochrane review indicated that CBT, compared with treatment as usual or wait-list control condition, has reliable beneficial effects. However, the effect of CBT alone on pain and disability was modest and its effects on mood and catastrophizing were moderate (Williams et al., 2012). Ehde et al. (2014) suggested that there is the need to explore the efficacy of CBT further for maximum benefit for patients with chronic pain.

Hypnotherapy has been shown to have a positive effect on pain characteristics and intensity among patients (Jensen et al., 1991; Stoelb et al., 2009). Hypnosis can also be used to enhance other psychological interventions (Spiegel & Bloom, 1983; Jensen et al., 2011; Jensen & Patterson, 2014). A combined intervention that integrates CBT with hypnosis may represent the future direction for the management of chronic pain for specific circumstances and stakeholders (Sveinsdottir et al., 2012).

1.3 Research Questions

The study proposes to address the following research questions in a sample of individuals with PDN from Ghana:

1. What are the experiences of patients with PDN and their use of personal beliefs as coping mechanism?

2. What is the association between socio-demographic variables (i.e., age, sex, marital status, education and occupation) on depression, anxiety, and PDN?

3. Is there a relationship between specific PDN characteristics (i.e., aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, penetrating, nagging, numb, miserable, and unbearable) and specific quality of life domains (i.e., physical functioning, emotional problems, energy fatigue, social functioning, pain, general health, and physical health).

4. Is there a significant difference in the efficacy of the treatment of PDN with medication, CBT and hypnosis compared to medication and CBT in a randomized controlled experiment?

1.4 Hypothesis

The hypothesis for objectives 2–4 were:

Hypothesis 1: There is a significant correlation between socio-demographic characteristics (age, sex, marital status, employment status, and educational background) and depression, anxiety and PDN severity.

Hypothesis 2: There is a significant relationship between specific PDN qualities (aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, penetrating, nagging numb, miserable, and unbearable) and quality of life domains (physical function, psychological function, energy/fatigue, social function, pain, general health, and physical health).

Hypothesis 3: Individuals with PDN who were randomly assigned to receive a treatment program that includes TAU, CBT, and hypnosis will report greater decreases in pain intensity than those assigned to receive TAU and CBT.

1.5 Aim

This study aims to explore the role of personal beliefs as coping strategies for PDN, the relationship between depression, anxiety, and PDN, and further evaluate the efficacy of the combined intervention of medication, CBT, and HYP for PDN.

1.5.1 Specific Objectives

The objectives of the study were to:

Objective 1: Explore the experiences of patients with PDN and their use of personal beliefs as coping mechanism.

Objective 2: Examine the associations between socio-demographic variables (i.e., age, sex, marital status, education, and occupation) and depression, anxiety, and PDN.

Objective 3: Determine the relationship between specific PDN qualities (i.e., aching, throbbing, shooting, stabbing, gnawing, sharp, tender, burning, exhausting, tiring, penetrating, nagging numb, miserable, and unbearable) and quality of life domains (i.e., physical function, psychological, energy/fatigue, social function, pain, general health, and physical health).

Objective 4: Evaluate the relative effects of medication management, CBT and hypnosis compared with medication management and CBT without hypnosis in a randomized controlled experiment.

1.6 Significance of the Study

Despite modern advances in biomedical research on diabetes, behavioural and cognitive factors that contribute to diabetes are important to understand and effectively address the burdens and demands of the disease on individuals with PDN, their families, and society (Hunter, 2016). Thus, there is a need for clinicians in Ghana to have a vested interest in the psycho-medical management and research in diabetes to meet the growing care needs; predicting the fatality of the disease in public health; and prepare for a future economic burden. In an environment where psycho-medical intervention and research of diabetes is limited, the researcher believes that findings of this study will provide evidence for optimizing the current and future care of patients as it attempts to fill the gap in psycho-medical interventions and research of PDN in Ghana.

1.7 Rational of the Study

Pain is a common complaint among patients seeking healthcare, in particular those suffering from diabetic neuropathy. The implications of pain management is clear in healthcare delivery as much as it is for the different types of pain emanating from different conditions. Chronic pain management is obviously different from those of acute pain. Importantly, an understanding of pain managementwould help in not only relieving patients of their pain but in preventing complications of improper pain management. This study builds on the foundation that there exists psychological relationship between different types of main and the modes of treating them respectively. It investigates how painful diabetic neuropathy (PDN) impacts theirlives and how psychological complications such as depression, anxiety, and quality of life (QoL) influence patients with PDN.This therefore explores the view that for clinicians tohelp individuals with PDN decrease pain, they could potentially use a combined therapyof medication, Cognitive Behavioural Therapy (CBT) and Hypnotherapy (HYP). This study closes the gap that the biomedical tratement of PDN so far have yielded unsatisfactory outcomes (Campbell et al., 2012; Tesfaye, Wilhelm, et al., 2013; Demant et al., 2014). Therefore, PDN treatment may require a personalized approach based on pain charateristics and comorbidities such as psychological conditions (Marchettini et al., 2016; Rolim et al., 2017).

1.8 Structure of the Study

The study consists of seven chapters. Chapter one describes the background to the study and states the problem of the research. It also outlines the main aim and specific objectives of the study to its corresponding hypothesis.

Chapter one also addresses the limitation and significance of the study including the ethical considerations of the research.

Chapter two reviews what has already been written in the field of psychology and PDN. The literature cited supports the theoretical argument being made and demonstrates that the author has a grasp of the major ideas and findings that pertain to the topic.

Chapter three provides details of the methodology used so that the study could be replicated. The method section is divided into three phases and includes sub-topics such as research design, sampling, instrument, data collection and procedure, and data analysis.

Chapter four presents the qualitative results of the study, in order by research question, and objectives.

Chapter five presents the quantitative results of the study, in order by research question, and objectives.

Chapter six interprets the results in light of the research questions and discusses them in conjunction with other literature. It discusses the qualitative and quantitative findings of the study.

Chapter Seven draws on the general conclusion, core findings, synthesis of the three phases of the study and final concludes on the limitation of the study.

CHAPTER TWO: CONCEPTUAL FRAMEWORK

2.1 Introduction

This chapter discusses the research literature and the theoretical framework within which this study was conducted. The literature review identifies, evaluates, and synthesises the relevant literature within the field of psychology and pain. It illuminates how knowledge has evolved within the field, highlighting what has already been done, what is generally accepted, what is emerging, and what the current state of thinking on the topic is. The theoretical framework explains the concepts and models used in this study and demonstrates an understanding of theories and concepts that are relevant to explore knowledge in the area of psychology and pain.

2.2 Literature Review

A study of literature relevant to the objectives of this study was conducted with the aim of exploring the relationship between depression, anxiety, and PDN as well as evaluating the individual interventions of medication, CBT, and HYP on PDN over the past decade. The literature review was conducted on the Medline database *via* PubMed, Goggle Scholar and EBSCO host and Cochran Reviews by using the following index terms: "Bio-psychological, Cognitive behavioural therapy, Hypnotherapy, Intervention, Painful diabetic neuropathy and Religion/Spiritual." The literature review primarily analyzed articles from 2003 to 2020 due to high citation index. The study examined titles and abstracts to select the relevant reports. The researcher independently screened the studies that were identified by the literature search and examined the full text of selected studies for compliance with eligibility criteria.

It situates diabetes/PDN within the context of the definition, history, epidemiology, measures, prevalence, risk factors, and comorbidities, including psychological implications such as depression and anxiety. The reviewed literature discussed the personal beliefs and experiences, including the religious/spiritual connection of PDN along with the views of researchers on the diagnosis and treatment options of PDN and the general intervention strategies on PDN. It also provided an opportunity to review of the possibilities of a single treatment of PDN and the need to incorporate a combined intervention of medication, cognitive behavioural therapy, and hypnosis of PDN.

2.2.1 Definition of Diabetes Mellitus

Diabetes mellitus is a “life-threatening disease that occurs when the pancreas does not secret insulin or when the body cannot effectively use the insulin it produces” (WHO, 2000; 2019). According to the American Diabetes Association (ADA) (2010), DM is a cluster of metabolic conditions aided by hyperglycaemia emanating from inadequacies in insulin discharge, insulin activity, or both. The sustained hyperglycaemia of diabetes is, therefore, linked with lasting impairment, disability, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels (ADA, 2010). It is evident that the central underlying abnormality of DM is the ineffectiveness and/or the nonexistence of the hormone insulin. Insulin is a hormone produced in the pancreas by the islets of Langerhans which regulates the amount of glucose in the blood, becoming essentially the only hormone that can lower blood glucose (ADA, 2010; 2019; IDF, 2017; Ackermann et al., 2011). Numerous pathogenic progressions are involved in the advancement of DM causing autoimmune destruction of the β-cells of the pancreas with consequential insulin paucity to abnormalities that cause resistance to insulin action (Yeh et al., 2012). In a recent classification of DM by the WHO (2019), the long-term specific effects of diabetes include retinopathy, nephropathy, and neuropathy, among other complications, with diabetic patients being at an increased risk of other diseases such as heart, peripheral arterial and cerebrovascular disease, obesity, cataracts, erectile dysfunction, non-alcoholic fatty liver disease, and tuberculosis.

2.2.2 History of Diabetes Mellitus

Evidence from the Ebers Papyrus from 1550 BC showed that DM and its clinical features had been known since ancient times as describing a polyureic state that looks like diabetes. However, Aretaeus of Cappadocia first used the word ‘diabetes’ in the second century AD. Aretaeus suggested a clinical description of the disease, noting the increased urine flow, thirst, and weight loss (Bilous & Donnelly, 2010, p. 5). During the fifth and sixth centuries AD, Sushrut, a Hindu physician, reported the sweet, honey-like taste of urine in polyureic states, enticing insects, especially ants.

The word Diabetes comes from the Greek ‘diabainein’, meaning, "to pass through", relating to the increased urine flow in diabetes patients . In the 18th century, the term diabetes mellitus (honey) was used to differentiate patients with sweet-tasting urine from patients whose urine was tasteless or insipid (Holt & Hanley, 2012a). In the 19th century, a French physiologist, Claude Bernard, discovered that the sugar that was inherent in urine was stored in the liver as glycogen. German pathologist Paul Langerhans first described the histologic structure of the pancreas. Langerhans identified the cells that would later come to be known as the "islets of Langerhans. Later, in 1893, Edouard Laguesse named the cells ‘islets of Langerhans’ and further explained that they were endocrine tissue found in the pancreas, which emits a glucose-lowering hormone. Insulin was discovered in 1921 at the University of Toronto, Canada, through collaboration between a surgeon, Frederick G Banting, and his student intern, Charles H Best. An experiment by Banting and Best involved extracting insulin from a dog and injecting it into another dog to stabilize blood sugar levels. This yielded dividends when the first attempt in a clinical trial to treat diabetes through insulin injection was conducted on a 14-year-old boy, Leonard Thompson, who was treated on 11th January 1922. Insulin therapy has since been developed from using bovine insulin in 1923 to using recombinant DNA techniques to sequence and produce human analogue insulin in the 1980s.

2.2.3 Classification of Diabetes Mellitus

Since 1965 the World Health Organization has occasionally restructured and published guidance on how to classify DM (WHO, 1999). Previously, the World Health Organization (2019) and the

American Diabetes Association (2010) categorized DM as type 1 diabetes including subtypes, type 2 diabetes including subtypes, gestational diabetes mellitus (GDM), and specific types of diabetes due to other causes. However, a new classification of DM by the WHO (2019) recognizes only two main types of DM, namely type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). The new system of classification does not identify subtypes of T1DM and T2DM. It does, however, include new types of diabetes as “hybrid types of diabetes” and “unclassified diabetes” as seen in Table 2.1 (WHO, 2019).

The main goal of this new classification is to provide hands-on control to clinicians for attributing a type of diabetes to patients at the time of diagnosis (WHO, 2019). Other clinical reasons include the suggestion that “the derivatives T1DM and T2DM are less specific with a growing prevalence of obesity at a young age". Most importantly, "developments in molecular genetics have allowed clinicians to identify growing numbers of subtypes of diabetes, with important implications for the choice of treatment in some cases” (WHO, 2019).

Table 2.1: Classification of Diabetes Mellitus

Types of Diabetes	**Brief Description**	**Change from the previous classification**
Type 1 Diabetes	β-cell destruction (mostly immune-mediated) and specific low insulin predicts most common in childhood and early adulthood	Type 1 sub-classes removed
Type 2 Diabetes	Most common type, various degrees of β-cell dysfunction and insulin resistance; commonly associated with overweight and obesity	Type 2 sub-classes removed
Hybrid forms of diabetes		**New type of diabetes**
Slowly evolving, immune-mediated diabetes of adults	Similar to slowly growing type 1 in adults but more often has features of the metabolic syndrome, a single GAD autoantibody and retains a more significant β-cell function	Nomenclature changed – previously referred to as latent autoimmune diabetes of adults (LADA)

Ketosis-prone type 2 diabetes	Presents with ketosis and insulin deficiency but later does not require insulin; frequent episodes of ketosis, not immune-mediated	No Change
Other Specific Types		
Monogenic diabetes- Monogenic defects of β-cell function – Monogenic defects in insulin action	Caused by specific gene mutations, has several clinical manifestations requiring different treatment, some occurring in the neonatal period, others by early adulthood Caused by particular gene mutations; has features of severe insulin resistance without obesity; diabetes develops when β-cells do not compensate for insulin resistance	Updated terminology for specific genetic defects
Diseases of the exocrine pancreas	Various conditions that affect the pancreas can result in	No Change

	hyperglycaemia (trauma, tumour, inflammation, etc.)	
Endocrine disorders	Occurs in diseases with excess secretion of hormones that are insulin antagonists	No Change
Drug- or chemical-induced	Some medicines and chemicals impair insulin secretion or action, and some can destroy β-cells	No Change
Infection-related diabetes	Some viruses have been associated with direct β-cell destruction	No Change
Uncommon specific forms of immune-mediated diabetes	Associated with rare immune-mediated diseases	No Change
Other genetic syndromes sometimes associated with diabetes	Many genetic disorders and chromosomal abnormalities increase the risk of diabetes	No Change
Unclassified Diabetes	Used to describe diabetes that does not fit into other categories. This type should be employed when there is not	No Change

	a clear diagnostic category especially close to the time of diagnosis	
Hyperglycaemia first detected during pregnancy.		
Diabetes mellitus in pregnancy	Type 1 or type 2 diabetes first diagnosed during pregnancy	No change
Gestational diabetes mellitus	Hyperglycaemia below diagnostic thresholds for diabetes in pregnancy	Defined by 2013 diagnostic criteria
Diagnostic criteria for diabetes: fasting plasma glucose ≥ 7.0 mmol/L or 2-hour post-load plasma glucose ≥ 11.1 mmol/L or Hba1c ≥ 48 mmol/moL		
Diagnostic criteria for gestational diabetes: fasting plasma glucose 5.1–6.9 mmol/L or 1-hour post-load plasma glucose ≥ 10.0 mmol/L or 2-hour post-load plasma glucose 8.5–11.0 mmol/L		

The American Diabetes Association (ADA, 2019) “Standards of Medical Care in Diabetes”, however, maintains the following categories as types of diabetes; T1DM, T2DM, gestational diabetes mellitus and specific types of diabetes due to other causes. T1DM causes the destruction of β cells, usually leading to absolute insulin deficiency (ADA, 2010; ADA, 2019). Type 2 DM ranges from predominantly insulin resistant, with relative insulin deficiency, to a predominantly insulin-secretory defect, with or without insulin resistance (ADA, 2010; ADA, 2019). GDM is the type of diabetes diagnosed in the second or third trimester of pregnancy that was not overt diabetes before gestation (ADA, 2010; ADA, 2019). Specific types of diabetes due to other causes include monogenic diabetes syndromes (such as neonatal diabetes) and maturity-onset diabetes of the young, diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced diabetes (ADA, 2010; ADA, 2019).

2.2.4 Clinical Features and Diagnosis of Diabetes Mellitus

Diabetes Mellitus is usually detected by recognizing perpetual hyperglycaemia. However, ascribing a kind of diabetes to an individual frequently relies upon the conditions present at the time of diagnosis. Hence some DM patients do not effectively fit into a solitary type (ADA, 2019). Classification of DM is significant for deciding on treatment. However, some people cannot be categorised as having a specific form of DM at the time of diagnosis (ADA, 2019). The October 2015 symposium by the ADA, the European Association for the Study of Diabetes, and the American Association of Clinical Endocrinologists reiterated that the differentiation of DM should be based on disease pathophysiology, natural history, and prognosis.

T1DM is caused by a pancreatic islet cell destruction of β cell, usually leading to absolute insulin deficiency. T1DM is subdivided into two main types, namely type 1a or autoimmune, in which immune markers such as circulating islet cell antibodies suggest autoimmune destruction of the β cells, and type 1b, or idiopathic, where there is no evidence of autoimmunity. T2DM is caused by a combination of insulin resistance and β cell insulin secretory dysfunction. Current perspectives by many specialist doctors and health practitioners believe that these are symptoms of DM and not the underlying cause (Bruno & Landi, 2011; Goedecke et al., 2009; Okur et al., 2017). However, experts concurred that in both T1DM and T2DM, different hereditary and natural variables can bring about the progressive loss of β-cell mass as well as hyperglycaemia (White, 2014; Inzucchi et al., 2015; Garber et al., 2016). When hyperglycaemia happens, patients with all types of diabetes are in danger of developing similar complications, even though rates of movement may vary (White, 2014; Inzucchi et al., 2015; Mottalib et al. 2016; Garber et al., 2016). These experts further noted that the distinguishing proof of individualized treatments for diabetes would in future require a better portrayal of the numerous ways leading to β-cell death or brokenness (White, 2014; Inzucchi et al., 2015; Mottalib et al. 2016; Garber et al., 2016).

The World Health Organization (WHO) and the American Diabetes Association (ADA, 2019) have used fasting plasma glucose (FPG) to define diabetes. A diagnosis of DM is therefore based on plasma glucose criteria, either the FPG or the 2-h plasma glucose (2-h PG) value after a 75-g oral glucose tolerance test (OGTT) or A1C criteria (1,6). While an FPG, 2-h PG after 75-g OGTT, and A1C are similarly fitting for demonstrative testing, the ADA (2019) claims that it ought to be noted that the tests do not recognize DM in similar people.

2.2.5 Aetiology and Treatment of Diabetes Mellitus

Insulin is the vital hormone that controls the take-up of glucose into most cells from the blood, particularly muscle and fat cells, but not focal sensory system cells. Inadequacy of insulin or insensitivity of its receptor cells assumes a focal job in all types of DM (Rother, 2007). The beginning of clinical malady T1DM begins with the obliteration of β-cells, promoting the onset of the condition. Okur et al. (2017) suggest the following characteristics as describing T1DM as an immune system: The presence of immuno-equipped and embellishment cells in invaded pancreatic islets; a relationship of vulnerability to infection with the class II (resistant reaction) qualities of the real histocompatibility complex (MHC; human leukocyte antigens HLA); and the nearness of islet cell explicit autoantibodies. Changes of T cell intervened immune regulation, specifically in CD4 + T cell compartment, the contribution of monokines and TH1 cells creating interleukins in the illness procedure, reaction to immunotherapy, and the frequent occurrence of other organ specific auto safe ailments in patients or their relatives are among some major clinical appearance of T1DM. Symptoms of type 1 diabetes are polyuria (increase in urination), polydipsia (increase in thirst), slow healing wounds, polyphagia (increase in appetite), extreme tiredness, and sudden weight loss (De Orduña & Brosa, 2016).

Type 2 DM occurs when there is impaired insulin action and failure of the pancreatic β cells to secrete insulin. Type 2 DM is characterized by insulin resistance and β-cell dysfunction, which varies widely among individuals (Jensen et al., 2002). Insulin resistance is frequently well established in individuals with impaired glucose tolerance. It is the presence of β-cell dysfunction that distinguishes those in whom glucose intolerance worsens from those in whom it remains stable (Weyer et al., 1999). Interventions that decrease insulin resistance and preserve or improve β-cell function are likely to be effective in slowing progression from impaired glucose tolerance to diabetes, or even allowing reversion to normal glucose tolerance. Many interventions, such as drugs, weight loss, and physical activity, are thought to improve insulin resistance and might also affect insulin secretion (ADA, 2010; 2019).

Type 2 DM has been associated with social and ecological factors such as being overweight, physical latency, and dietary predispositions (Narayan et al., 2000). For example, it has been known for at least 80 years that a low carbohydrate/high fat intake is associated with poor glucose tolerance and insulin resistance (Himsworth, 1935; Steinberger et al., 1995; Wilcox, 2005; Erasmus et al., 2012; Brundisini et al., 2015). There is currently some controversy over the role of carbohydrates in a healthy diet and most national guidelines recommend that the proportion of energy contributed by carbohydrates should be approximately 50% (SACN, 2015; Macdonald, 2016; Johnson et al., 2013; Sánchez-Lozada et al., 2010). There is an association between diets high in sugars (predominantly sucrose) and risk of disease, and experimental studies have shown that high intakes of fructose (over 100 g/d) can reduce insulin sensitivity, although somewhat lower intakes may affect serum TG (Macdonald, 2016; Jayabalan et al., 2019; WHO, 2019). Narayan et al. (2001) are therefore of the opinion that evidence that a modest way of life can avert type 2 DM promotes DM aversion and well-being advancement. A life-style adjustment could be an effective weapon in the arsenal of anticipating the beginning of DM, which is fundamental to lessen the related expanded danger of morbidity and mortality that may overwhelm medical services frameworks in emerging economies (Thomas et al., 2010).

Gestational diabetes mellitus is commonly characterized as the type of DM presenting during pregnancy (WHO, 1999). GDM is, by description, any degree of glucose intolerance with onset or first recognition during pregnancy (Metzger & Coustan, 1998). During pregnancy, the placenta produces hormones that interfere with the activities of the hormone insulin. In a typical pregnancy, the woman's pancreas, the organ that produces insulin, can make up for this by making extra insulin during pregnancy (Butte, 2000; Homko et al., 2001). According to Buchanan et al. (2000), increasing demands on pancreatic β cells in the presence of impaired pancreatic β-cell compensation for insulin resistance (IR) and leads to GDM. GDM is related to various hazard factors related to insulin opposition such as obesity, ethnicity, and maternal age (Lindsay, 2009).

2.2.6 Painful Diabetic Neuropathy

The most common cause of PDN is diabetes and it affects 20 – 30% of patients with adjuvant complications (Quattrini & Tesfaye, 2003; Tesfaye et al., 2010; Callaghan et al., 2012; Tesfaye et al., 2016; Juster-Switlyk & Smith, 2016). “Painful diabetic peripheral neuropathy, usually arises in an individual with background diabetic peripheral neuropathy (DPN), described as a symmetric sensori-motor polyneuropathy which may affect either small or large sensory fibers, with a predilection for the feet and later, hands, in a stockings and gloves distribution" (Petropoulos et al. 2016: Young et al., 2019).

PDN is "the presence of symptoms and signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes" (Boulton et al., 1998). The aetiology of PDN is complex and is not well understood (Tavakoli & Malik, 2008). Several different hypotheses have been invoked to explain the pathophysiology of PDN. These include a conglomeration of augmented oxidative stress, advanced glycation, polyol accumulation, decreased nitric oxide, and impaired (Na + /K +) - ATPase (Tavakoli et al., 2008).

PDN escalates with the extent of diabetes. However, patients with impaired glucose tolerance develop PDN symptoms and damage to small nerve fibres (Boulton & Malik, 2010). According to Borissova et al. (2015) and Charakchiev et al. (2015), poor glycaemic control is the most important risk factor for PDN and evidence indicates that enhanced glucose regulation prevents the progress of clinical neuropathy in T1DM. However, symptoms of PDN manifest earlier in T2DM than in T1DM. In T2DM, 8% of patients have neuropathy at the time of diagnosis (Partanen et al., 1995), and up to 50% of older type 2 DM patients have evidence of a distal neuropathy (Boulton et al., 2004). Distal neuropathy is a progressive disorder that affects nerve cells in the spinal cord (Dyck et al., 2011; Malik et al., 2011; Albers & Pop-Busui, 2014; Pop-Busui et al., 2017). It results in muscle weakness and affects movement, primarily in the legs, with the initial symptoms of cramps or weakness in the muscles of the big toe and later in the entire foot. (Dyck et al., 2011; Malik et al., 2011; Albers & Pop-Busui, 2014; Pop-Busui et al., 2017).

According to Colloca et al. (2017), the burden of continuous neuropathic pain is identified with the unpredictability of neuropathic manifestations, poor outcomes, and difficult treatment choices. Critically, personal health satisfaction is impeded in patients with neuropathic pain attributable to prolonged drug use and visits to the clinic as well as the morbidity from the pain itself and the affecting malady. Colloca et al. (2017) suggest that regardless of the difficulties and gradual progress in the comprehension of the pathophysiology of neuropathic pain, the advancement of new indicative methods and personalized intervention will emphasize the requirement for a multidisciplinary way to deal with the management of neuropathic pain is necessary.

2.2.7 Clinical Manifestation of PDN

The pain associated with PDN is often described as "tingling pain," "numbness," or "increased due to touch as well as burning, electrical, or stabbing with paraesthesia, hyperesthesia, and deep aching" (Backonja & Krause, 2003). While most people experience heightened pain at night (Boulton et al., 2005), PDN typically starts in the feet and lower legs and might likewise include the hands (Vinik et al., 2000). PDN is chronic, dynamic, and ordinarily agonizing, and is unlikely to suddenly cease (Aring et al., 2000). It prominently affects a patient's life, mood, sleep, self-worth, independence, ability to work, and interpersonal relationships (Galer et al., 2000; Vileikyte et al., 2003).

PDN is largely classified based on pathophysiology, clinical features, and neurology intricate, as well as advancement of the disease and covariate risk factors involved as shown in table 2.2 (Boulton et al., 2005; Tesfaye et al., 2010). Thus, it is known that pain transmission in peripheral nerves occurs via the small A-δ and C-nerve fibres (Sorensen et al., 2006). However, the source of pain may be central and peripheral because diabetes affects all levels of the nervous system, from the peripheral nerves to the brain (Tesfaye & Kempler, 2005).

Table 2.2 **Painful Diabetic Neuropathy**

A. Generalized symmetrical polyneuropathies

1. CHRONIC SENSORIMOTOR POLYNEUROPATHY:
    a. SENSORY—THIN FIBRES (C FIBRES)/THICK FIBRES—A Δ AND AB FIBRES
    b. MIXED NERVES
2. ACUTE SENSORY NEUROPATHY (PAINFUL)
3. AUTONOMIC NEUROPATHY—GASTROINTESTINAL TRACT, CARDIOVASCULAR SYSTEM, AND GENITOURINARY SYSTEM

B. Focal and multifocal

- MONO-NEUROPATHIES—CRANIAL NERVE AND PERIPHERAL NERVE
- MULTIPLE MONO-NEUROPATHY—MONO-NEURITIS MULTIPLEX
- FOCAL LIMB/TRUNK INVOLVEMENT—THORACIC, LUMBOSACRAL, AND CERVICAL NEUROPATHY
- COMPRESSION NEUROPATHY: FOR EXAMPLE, CARPAL TUNNEL SYNDROME
- INFLAMMATORY DEMYELINATING NEUROPATHY

The mechanisms that lead to PDN are not entirely understood, even though there is agreement that the harmful impacts of hyperglycaemia speak to a significant factor for the advancement of this difficulty (Dobretsov et al., 2003; Oyibo et al., 2002; Dyck et al., 2011; Malik et al., 2011; Albers & Pop-Busui, 2014; Pop-Busui et al., 2017). Microvascular pathology, causing degeneration and loss of nerve fibres, is an essential contributor to the pathogenesis of human diabetic polyneuropathy (Zychowska et al., 2013). Altered peripheral blood flow in vessels supplying the peripheral nerves can lead to endoneuria hypoxia and damage is attributed to the hyalinization of the vessel walls and increased endoneuria vascular resistance (Nukada, 2014). Endoneuria hypoxia is when blood flow to the arms and legs is decreased or slowed by inflammation, blood clots, or other blood vessel disorders (Lim et al., 2015).

2.2.8 Epidemiology, Pathogenesis, Diagnosis and Treatment of PDN

The study of disease transmission of PDN is inadequately comprehended (Hussain, 2016). This accounts for the varieties in indicative criteria, preferential patient enrolment, and the asymptomatic character of various neuropathies as well as the large number of patients with undiagnosed DM. The prevalence of PDN among patients with type 2 diabetes is 42.2%, while those with type 1 diabetes is 29.1% (Pfannkuche et al., 2020). In one specific study of PDN, more than 50 percent of the participants had distal symmetric sensorimotor polyneuropathy while other neuropathies included median mononeuropathies (25%), autonomic neuropathy (7%), and other neuropathies, including thoracic and lumbar polyradiculopathy and cranial mononeuropathies (3%) (Abbott et al., 2011). PDN leads to minimizing the health-related quality of life in patients with type 2 DM and inflicts an enormous economic drain on patients and the healthcare system (England & Asbury, 2004). Apart from the direct costs involved, PDN can also lead to work absence, change in employment, and disability (Boulton et al., 2005).

In the pathogenesis of PDM, the nerve fibres in the epidermis of the skin are significantly affected, resulting in distortion, twisting, focal swelling or beading, and finally, the disappearance of nerve fibres (Siva, 2019). The reduction in nerve fibres is found even in subjects of impaired glucose tolerance (IGT) and the extent of fibre loss is accounted for among patients with established PDM (Vinik et al., 2003). The nerve fibre loss in the skin is associated with fibre loss in the nerve trunk of the sural nerve, thus in keeping with the presence of clinically evident neuropathy (Boulton et al., 2004).

Experts diagnose PDN as the presence of symptoms and signs of peripheral nerve dysfunction in PDM. Detection of PDN, according to Siva (2019), is only successfully done after exclusion of other causes of neuropathy such as hereditary, traumatic, compressive, metabolic, toxic, nutritional, infectious, immune-mediated, neoplastic, and secondary to other systemic illnesses (Siva, 2019; Tesfaye et al., 2010; Young et al., 1994). Hence, before labelling a patient as a PDN patient, it is mandatory to exclude all other causes of peripheral nerve dysfunction (Greene et al., 1992).

A meta-analysis showed that enhanced glucose control reduces the incidence of clinical neuropathy, although this finding was not statistically significant (Callaghan et al., 2012). The idea of glycaemic control and treatments of cardiovascular hazard components are significant approaches to avoid the movement of neuropathy. According to Chong and Hester (2007), the viability and tolerability of current pharmacotherapy are unsatisfactory. Once the diagnosis of PDN is established, there are two therapeutic approaches: pathogenetic treatments target the underlying pathophysiological processes to prevent nerve fibre loss, and symptomatic treatments aim to alleviate the painful symptoms of PDN to normalize physical and psychological functioning (Javed et al., 2015; Alam, 2020; Moisset et al., 2020).

Researchers have investigated the treatment of PDN in the hope of finding one or more treatments that can relieve a patient’s pain. Classes of drugs and individual agents with the best evidence of effectiveness in treating PDN include antidepressants (duloxetine, venlafaxine, amitriptyline, desipramine), anticonvulsants (pregabalin, gabapentin, carbamazepine, lamotrigine), opioids (oxycodone CR, tramadol) and topical agents (capsaicin, lidocaine). Other drug interventions in PDN management include nonsteroidal anti-inflammatory drugs (NSAIDs), antiepileptic drugs, aldose reductase inhibitors, gamma-linolenic acid, nucleosides and nerve growth factor, but none of them is entirely satisfactory. In a study to compare the efficacy and safety of pregabalin and amitriptyline in alleviating pain associated with DPN in a randomized, double-blind, crossover, active–control, clinical trial with variable dose titration, there were few differences found in efficacy between the two treatments (Bansal et al., 2009). In another study to compare the efficacy and safety of pregabalin, duloxetine, and amitriptyline in reducing neuropathic pain as well as improving the quality of sleep among patients with DPN (Chakrabarty et al., 2016), all three drugs showed similar efficacy in reducing pain in diabetic polyneuropathy as well as improving sleep quality. However, in most low-income countries, amitriptyline, which is relatively inexpensive, may be preferred over the other two in rural financially disadvantaged populations. A large, blind, multi-centric trial is being planned to establish the safety or efficacy of these drugs (Chakrabarty et al., 2016).

2.2.9 Personal Beliefs and Experiences and Diabetes / PDN among Patients

A belief can be defined as trust or acceptance of a thing as true or existing (Thomson, 1995). In epistemology, philosophers use the term "belief" to refer to personal attitudes associated with true or false ideas and concepts (Primmer, 2018). According to Bell et al. (2006), beliefs are sometimes divided into core beliefs (that are actively thought about) and dispositional beliefs (that may be ascribed to someone who has not thought about the issue). Health Psychologists study belief formation and the relationship between beliefs and health/illness actions (Wyer & Albarracin, 2005). “Different representations of belief formation and change have been suggested to address the fact that the responses people have to belief-relevant information are unlikely to be predicted from the objective basis of the information that they can recall at the time their beliefs are reported” (Wyer & Albarracin, 2005). According to Wyer and Albarracin (2005), these responses reflect the number and meaning of the thoughts that people have about the message at the time that they encounter it.

Hohr (2012) explains an experience as the result, the sign, and the reward of interaction between an organism and the environment which, when it is carried to the full, is a transformation of interaction into participation and communication. According to Hohr (2012), the principal and most basic condition of personal experience is that an experience is a result of interaction between an organism and an experienced stimulus in a specific environment (Dewey, 1939). Therefore, a personal belief and experience of diabetes/PDN implies the interaction between patients and their subsequent ongoing, continuous and specific, identifiable experiences regarding their health state.

Studies to examine diabetes/PDN beliefs and personal experiences among diabetic patients have been widely researched by expects in various countries within the illness perception model (Al-Thani, Sathian, & El-Menyar, 2019; Al-Sahouri et al., 2019; Srisanthanakrishnan & Shah, 2016). Although studies in Ghana regarding diabetic experiences are limited, some cases are worth noting. For instance, Kugbey et al. (2017) examined whether type 2 diabetes patients' illness perception and diabetes knowledge significantly predict diabetes self-care practices. Tabong et al., conducted a study in a Ghanaian population to determine risk perception, lifestyle, adherence, and coping strategies of people with diabetes. The study found that respondents believed diabetes was a condition of the aged and rich, and this served as a premorbid risk for diabetes (Tabong et al., 2018). In another study to assess the knowledge and attitude of patients with diabetes and its relationship with self-management practices in government hospitals in the Upper West Region of Ghana, Kpekura et al. (2018) concluded that diabetes patients in the Upper West Region have in-depth knowledge of the disease condition, self-management practices, and a positive attitude. A similar study in the same region by Obirikorang et al. (2016) aimed at determining the knowledge of diabetic complications among DM patients at Sampa Government Hospital, Ghana, and revealed that participants knew the individual complications of DM but lacked in-depth knowledge of the complications. However, there is only one known publication on the burden of peripheral sensory neuropathy (PSN) in DM patients using a validated questionnaire and quantitative sensory test (Yeboah et al., 2016). The study employed a case-control design to measure PSN in 491 DM patients and 330 non-DM controls using the Michigan neuropathy screening instrument and vibration perception threshold. The study concluded that there was a high burden of PSN in diabetes patients in the study sample, using simple, non-invasive screening tools (Yeboah et al., 2016).

Regarding the personal belief and experiences of patients on their PDN state, studies reveal that most patients could recognize their pain and describe pain characteristics, including pain symptoms (Perissinotti & Portnoi, 2016; Selvarajah et al., 2014). In a qualitative study of the perspectives of people living with neuropathic pain, many respondents described the pain they experience as intense, life changing, debilitating, sudden, sharp, stabbing, chronic, intense, and "concentration-stealing". Participants also described the unpredictability associated with their pain symptoms (CDER & FDA, 2017). Discussing the association between pain experience and health outcome, Callin and Bennett (2008) suggest that "patients' beliefs, attitudes, and behaviours influence the outcome and it is important to assess patients' understanding of their pain, the meaning of their pain, and their expectations and goals".

Experts have cited the financial cost and burden on individuals and families of patients suffering from diabetes/PDN in several studies (Hart et al., 1997; ADA, 2010; Barceló et al., 2003; Kirigia et al., 2009; Seuring et al., 2015). Liedgens et al. (2016) observes that diabetes imposes a substantial economic burden on countries of the WHO Regions (Gray et al., 1995; WHO, 2000;

WHO, 2019). According to Moucheraud et al. (2019), the burden of diabetes control leads to the advancement of micro- and macrovascular impediments which further incur additional indirect costs to patients, companies, and society due to absenteeism from work caused by sickness and early retirement. Zhang et al. (2010) add that “people with diabetes have more outpatient visits, use more medications, have a higher probability of being hospitalized and are more likely to require emergency and long-term care than people without the disease”. However, Quaye et al. (2015) argue that the cost of managing diabetes can be used to estimate of the financial problem of the disease in a given area.

In a study to estimate the humanistic and economic burden of painful DPN in Europe, Alleman et al. (2015) argue that the burden from painful DPN appears to be higher with increasing pain severity, which eventually leads to accumulative healthcare costs and work output losses. In a similar study, Schaefer et al. (2015) purport that PDN presents a moderate or severe pain, which has significant associations between pain severity and PDN regarding “related health care resource utilization, productivity, and costs”. Scientists have also indicated that an economic burden, predominantly ancillary expenses, is usually high among PDN patients with severe pain (Berger et al., 2004; Gore et al., 2006; Currie et al., 2010; Dworkin et al., 2010; Stokes et al., 2017; Taylor-Stokes et al., 2011; Sicras-Mainar et al., 2013; Schaefer et al., 2015). While studies to estimate the financial impact of diabetes have received some commendable attention in Africa (Kirigia et al., 2009; Mutyambizi et al., 2018; Moucheraud et al., 2019; Mapa-Tassou et al., 2019; Mercer et al., 2019), an exploration of the economic impact of PDN in Ghana is generally lacking.

2.2.10 Cultural, Religious and Spiritual Considerations of PDN Patients

Culture is difficult to define due to the complexities in its meaning (Avruch, 1998; Lebrón, 2013; Lustig & Koester, 2013). According to Spencer-Oatey (2012), the difficulty in understanding the concept of culture stems from the varied usages of the term. However, most works of literature in the health and social sciences agree with the view of Adler et al. (1997) that:

> Culture consists of patterns, explicit and implicit, of and for behavior acquired and transmitted by symbols. It constitutes the achievements of groups, including an embodiment in artifacts; the essential core of culture consists of traditional, ideas and especially their attached values; culture systems may, on the one hand, be considered as products of action, and on the other, as conditional elements of future action.

Culture, which incorporates the coordinated examples of human conduct, for example, religion language, correspondence, customs, convictions, and qualities, is significant in the well-being framework (Cross et al., 1989; Matsumoto, 1996; Saville-Troike, 1997; Lustig & Koester, 1999; Arredondo, 2013). Hofstede (2001) adds that 'culture is the collective programming of the mind which distinguishes the members of one group or category of people from another'. Hofstede and Minkov (1991) further argues that 'although certain aspects of culture are physically visible, their meaning is invisible, and their cultural meaning lies precisely and only in the way these practices are interpreted by the insiders.'

Riddle (2020), therefore, argues that there is the need to assess the qualitative impact of culture on diabetes/PDN in a group where culture is uniformly distributed among members of the group and the idea imputes cognitive, affective, and behavioural uniformity to all members of the group, especially when there is growing evidence that culture correlates with glycaemic control and pain. For instance, studies indicate that people living with diabetes/PDN will need more than one medication to achieve glycaemic control and pain relief (Riddle, 2020; Pérez et al., 2015; Garber et al., 2016).

While the term religion is a complex concept to understand, William James, in *"The Varieties of Religious Experience*" defines religion as the feelings, acts, and experiences of individual men in their solitude, so far as they apprehend themselves to stand concerning whatever they may consider divine (James, 1958). Generally, religion is a belief in the supernatural power or the Supreme Being and their relationship with nature that surrounds them (Bergunder, 2014). In the opinion of Van Niekerk (2018), “religion is a unified system of beliefs and practices relative to sacred things, that is to say, things set apart and forbidden – beliefs and practices which unite into one single moral community". Religion is an ordered form of beliefs venerating a higher power, usually demonstrated through outward ceremonies of commitment and devotion which uphold the connection between an individual with a higher power (Casarez et al., 2010; Newlin et al., 2008).

From an African point of view, Opoku (1993) defines Africa Traditional religion as “born out of the experience and deep reflection of our African forebearers, which provides answers to the stirring of the human spirit and elaborates on the profundity of the experience of the divine-human encounter based on the resources of Africa’s cultural heritage and insight”. According to Mbiti (1975), to the African, everything in life has to do with religion and it draws its inference from the fact that ‘religion permeates all the departments of life so fully that it is not easy or possible always to isolate it’. Scholars also agree that the African worldview is religious (Bediako, 1995; Mbiti, 1990). In the view of Beyers (2010), the world of the average African is perceived through a religious lens, making every activity and entity have religious significance.

The study of the relationship between religion and health has grown substantially in the past decade (Lee & Newberg, 2005; Jawaid, 2014; Koenig et al., 2012; Chatters, 2000). There is a large amount of evidence indicating that religion plays an imperative role in many people's lives and that this has an influence on their health (Lee & Newberg, 2005; Jawaid, 2014; Koenig et al., 2012).

Closely related to the term religion is the word spirituality, which is used as a synonym and most times used interchangeably with religion (Love, 2002; Nash, 2001). Dyson et al. (1998) contend that one of the major interferences in defining spirituality is its connection with religion. According to Ammerman (2013), spirituality is an expansive idea with space for viewpoints. It incorporates a feeling of association with an option that could be greater than ourselves and typically includes a quest for meaning in life (Beck & Walters, 1977; Helminiak, 1998; Newberg et al., 2001; Lynch et al., 2012).

Unantenne et al. (2013) define spirituality as “being related to the ideas of transcendence, meaning, hope and cohesion”. According to Wainwright (1987), spirituality is “existence before God and amid the created world”. However, Darvyri et al. (2018) claim “spirituality is different from religiosity as it refers to the notion of coherence and life’s purpose and is independent of faith in a certain religion”. Jafari, Özhan Dedeoğlu, et al. (2014) argue that religion works as an establishment for spirituality and that certain people might be spiritual depending on their understanding of encounters, even though they are not supporters of a specific religion (Lynch et al., 2012).

Religion and spirituality can be significant factors in handling the difficulties of emotive care and glycaemic control among patients (Esteghamati et al., 2008; Namageyo-Funa et al., 2015; Rivera-Hernandez, 2016). Both small and large expository research on the association between religion/spirituality and diabetes has shown insightful influence on the daily life of patients (Newlin, 2003; Newlin et al., 2008; Park, 2007; Cattich & Knudson-Martin, 2009; Devlin et al., 2006; Gupta & Anandarajah, 2014; Underwood & Teresi, 2002; Amadi et al., 2016).

Koenig et al. (2012) confirmed that church attendance, religious practices, and spiritual beliefs might improve health and generally be beneficial for individuals with chronic illness. Regarding specific faith practices, medical research has closed the gap in the relationship between faith practices and diabetes (Rivera-Hernandez, 2016; Newlin et al., 2008). In a similar study, Dehning et al. (2013) assessed the impact of patients’ depth of religious adherence on their outlook towards diabetes and treatment. A 15-question questionnaire to assess the self-reported level of basic practices of the Christian faith, sense of personal well-being, and attitude toward diabetic treatment was distributed to consenting patients with diabetes attending a hospital. The study, involving 299 patients, concluded that the more adherent a patient was to faith-based activities or demonstrated knowledge of basic dogma, the greater their sense of well-being ($p < 0.001$), suggesting that Christian religion/spirituality may be a positive coping mechanism for diabetic patients (Dehning et al., 2013). Chew et al. (2011) also conducted a study in a mixed population of Christians and Moslems to determine the relationships between religiosity, religions, and glycaemic control of type 2 diabetes mellitus (T2DM). The study concluded that those with higher religiosity among the Muslim population had significantly better glycaemic control, and patients who had church-going religions had better glycaemic control compared with those of other religions. According to Lundberg and Thrakul (2013), Buddhist and Muslim women have self-management capabilities that are often related to their religions.

Strawbridge et al. (1997) contend that Christian religious practices such as prayer, reading scriptures, singing hymns, and giving testimonies, has been regarded as a significant part of illness management orientations among diabetes patients. In a correlation, cross-sectional study with 150 type 2 diabetes patients, Shamsalinia et al. (2016) concluded that there was a significant positive relationship between positive religious coping and social support. Shamsalinia et al. (2016) added that positive religious coping, married life, and social support significantly affected glycaemic control. Some patients also believe that God can help their health struggle and attending church meetings seem to have an improving effect while prayer appears to alleviate the patients' malady (How et al., 2011; Polzer & Miles, 2007). Some patients also claim a relationship with God has an ameliorating effect on their blood sugar control (Heidari et al., 2017; Cattich & Knudson-Martin, 2009; Newlin et al., 2008). To this effect, the Jafari, Farajzadegan, et al. (2014) study argues "that inner peace and stamina protect the diabetic patient from negative emotions and can lead to better management and glycaemic control". Based on the findings presented above, there is enough evidence that religion/spirituality may be an avenue of handling the protracted social and physical frailty emanating from type 2 diabetes mellitus (Rivera-Hernandez, 2015).

Despite the striking positive outcome, some studies have also established that a negative association exists between the level of religiosity/spirituality and health problems (Koenig et al., 2001; Smith et al., 2003; Nelson et al., 2009). Koenig (2009), therefore, cautions that while religious beliefs and practices can represent powerful sources of comfort, hope, and meaning, they are often intricately entangled with neurotic and psychotic disorders, sometimes making it difficult to determine whether they are a resource or a liability. Other studies have also recorded no significant difference between religious activities and diabetes complications. For instance, in a cross-sectional study by Moradali et al. (2016) with 200 elderly type 2 DM patients from 10 rural health centres of Urmia city, North West of Iran, there was no statistically significant difference between spiritual health scores in patients with uncontrolled and controlled blood sugar.

According to all of the above, the religious/spiritual role in the management of diabetes is important. Future studies, therefore, should focus on using interventional programmes including religious/spiritual components to benefit patients (Casarez et al., 2010; Darvyri et al., 2018). This study sets an agenda to explore the importance of religious/spiritual practices among a population where religion is part of daily life and investigates the benefits of incorporating religion/spirituality into the healthcare system in diabetes management (Jawaid, 2014; Koenig et al., 2012).

2.2.11 African Concepts of Health, Disease, and Treatment

According to Oduro et al. (2008), an African concept of health, disease, and treatment, suggests an African way of understanding the world, visible and invisible, including living and non-living things as well as the unseen world, spirits, powers, and diseases. This portrays that the average African interprets daily activities including physical healing to an association with the multiplicity of spirits such as evil forces and ancestors (Magesa, 1997, p. 175; Westerlund, 2006, pp. 91–95). To the average African, health is not just about the proper functioning of bodily organs. Good health for the African consists of mental, physical, spiritual, and emotional stability of oneself, family members, and community; this integrated view of health is based on the African unitary view of reality" (Omonzejele, 2008, p. 120).

White (2015) adds that an African concept of health, disease and treatment is interwoven with cultural and religious beliefs and is all-inclusive in nature. "It does not focus only on the physical condition, but also on the psychological, spiritual and social aspects of individuals, families and communities" (Truter, 2007, p. 57). Craffert (1997) affirms that illness and health care systems in most societies are connected to the culture or worldviews of those societies. Mokgobi (2014), therefore, argues that illness, disease, and healing in an African context are linked to religion/spirituality in order to promote optimal well-being.

Despite the argument for the association between religion and health, Agbiji and Swart (2015) argue that religion has evoked such prominence in most African societies largely because of the limited provision offered by orthodox medical practice. However, cross-cultural research in most parts of Africa revealed that the perception of good or bad health is linked to religion/spirituality (Akpomuvie, 2014; Agbiji & Swart, 2015).

While Clarke and Jennings (2008, p. 1) may argue that modernism has succeeded in distancing religion from the social and political domains in the developed world, Agbiji and Swart's (2015) response is that the potency of such modernism in Africa has not left a lasting imprint on African societies, where religion continues to play an important role in personal and communal life. The claim of Mbiti (1999, p. 1) that "religion permeates all departments of life to such an extent that it is not easy or possible to isolate it in most African societies" also relates to health (Oduro et al., 2008; Akpomuvie, 2014; Agbiji & Swart, 2015; Ajima & Ubana 2018).

According to White (2015), healing in Africa does not separate the natural from the spiritual. Traditional African healing has been in existence for many centuries and claims to relate to God (Yeboah, 2000; Truter, 2007). This causes healers to approach health issues from both spiritual and physical perspectives (Rinne, 2001).

According to the WHO (1976, p. 8),

> Traditional medicine/healing is "the sum total of all knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating a physical, mental or social disequilibrium and which rely exclusively on past experience and observation handed down from generation to generation, verbally or in writing" and "health practices, approaches, knowledge, and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercise, applied singular or in combination, to treat, diagnose and prevent illnesses or maintain well-being".

The services of traditional healers, however, go far beyond the use of herbs for physical illnesses (Yeboah, 2000; Truter, 2007; Oduro et al., 2008; Akpomuvie, 2014; Agbiji & Swart, 2015; Ajima & Ubana, 2018). According to Mokgobi (2014), traditional healers serve many roles, which include, but are not limited to, custodians of the traditional African religion and customs, educators about culture, counsellors, social workers and psychologists.

2.2.12 Psychological Comorbidities of PDN

Clinicians and their patients need to be aware that apart from evaluating diabetes-related conditions, there are common comorbidities that affect people with diabetes and could complicate management (Tinetti et al., 2012; Sudore et al., 2012). Diabetes is known to be accompanied by other medical and psychological conditions that exacerbate, and in some instances, ameliorate glycaemic characteristics (Borgnakke et al., 2013). These diabetes comorbidities are conditions that affect people with diabetes more often than age-matched people without diabetes (Triolo et al., 2011). Comorbidity is, therefore, the occurrence of one or more chronic conditions in the same person with an index-disease such as frequently occurs among patients with diabetes (Beckman et al., 2002).

Comorbidities of PDM, in general, have been categorized as micro- and macrovascular comorbidity (Struijs et al., 2006). Vascular comorbidity is characterized as chronic conditions that have a vascular association with PDM, or which can be viewed as vascular entanglements of the treatment of diabetes. Non-vascular comorbidity is characterized as endless states of which the association with diabetes is random or still not seen, but rather are not the consequence of vascular damage (Van Weel & Schellevis, 2006). According to the Medical Expenditure Panel Survey, most adults with diabetes have at least one (1) comorbid chronic disease, and as many as 40% have at least three (Wolff et al., 2002).

A recent study of PDN indicates that comorbidities may compete for the attention of the patient and their healthcare team, and therapies to manage comorbidities may adversely affect a person's PDM (Hussain & Chowdhury, 2019). Chronic neuropathic pain sensation that arises from within the nervous system rather than from an external source can be initiated by different pathologies. This presents PDN as being accompanied by comorbid factors that equally affect the quality of health of patients, making neuropathic pain universally recognized as one of the most difficult pain syndromes to treat (Nicholson & Verma, 2004). Regardless of the cause, however, neuropathic pain affects multiple aspects of a patient’s life which, therefore, requires that the management of neuropathic pain involve a multidisciplinary approach. Such adjuvant comorbidities, if not managed along with the main pain symptoms, may hinder a patient's gratification by adversely impacting functionality and coping. Since comorbidities can negatively influence the reaction to pain treatment, healthcare providers should assess comorbidities as part of the diagnostic work-up, and management strategies should be designed to treat the whole patient, not just the pain (Argoff, 2007).

There is a substantial body of literature supporting the association of chronic pain with high levels of psychological issues such as emotional distress, particularly depression and anxiety (McNeil & Vowles, 2004). According to Jensen and Turk (2014), primary treatments have been established based on rational ideologies and models of pain, many of which have confirmed the efficacy for reducing pain and its impact on patients through psychotherapy. This burst of interest could also be partly due to the view that chronic pain is an essential area of study that offers insights about translational research for all psychologists (Turk & Okifuji, 2002; McNeil & Vowles, 2004; Jensen & Turk, 2014).

Turk and Okifuji (2002) “described a biopsychosocial model of chronic pain and provided an update on research implicating the importance of people’s appraisals of their symptoms, ability to self-manage pain and related problems, and their fears about pain and injury that motivate efforts to avoid exacerbation of symptoms and further injury.” Emotional wellness issues are related to prolonged diabetes crises and more unfortunate personal dissatisfaction for individuals with pain. It is significant for medical experts to have the option to recognize those affected, guarantee they get proper care, and give continuous help (Britneff & Winkley 2013). The mind, emotions, and attention play an essential role in the experience of pain in patients with chronic pain (Hassed, 2013). Despite this recent evidence, the primary treatment of chronic diabetic pain remains the consumption of large amounts of analgesics among patients.

According to Turk et al. (2010), the most critical part of this treatment difficulty is, therefore, the present inability to distinguish specific neuropathic characteristics in a patient and to choose the best medication for a specific condition. As a result, the choice for pharmacological treatments is most often inadequate. Turk et al. (2010) note that there is limited research on the efficacy of psychological treatment explicitly applied to patients with chronic neuropathic pain, but suggested that it is reasonable to extrapolate from successful trials in other types of chronic pain. Turk et al. (2010) further suggest that psychological approaches should not be viewed as alternatives, but rather should be integrated as part of a comprehensive approach to the treatment of patients with chronic neuropathic pain. Callin and Bennett (2008) recommend that there is a need to explore further correlation and to revisit the views of previous psychosocial management and treatments that have failed.

2.2.13 Depression and PDN

The anticipation of serious bitterness has long been recognized by the school of Hippocratic doctors and given the main known portrayal of despondency, expressed as “fear or sadness that lasts a long time known as melancholia” (Hippocrates, 1931, p. 185). Derivatives such as “hopelessness, sorrow, dejection, despondency, emptiness, despair, and discouragement have been mentioned as core features of depression” (Horwitz et al. 2016). Related side effects have included antipathy for sustenance, restlessness, exhaustion, crabbiness, eagerness, a dread of death, monotonous spotlight on a couple of negative thoughts, absence of delight or enthusiasm for normal exercises, and social separation (Kendell, 1976).

According to the WHO (2017), depression is a common mental disorder, characterized by persistent sadness and a loss of interest in activities that a person normally enjoys, accompanied by an inability to carry out daily activities for at least two weeks. Besides, people with depression normally have several of the following symptoms: a loss of energy; a change in appetite; sleeping more or less; anxiety; reduced concentration; indecisiveness; restlessness; feelings of worthlessness, guilt, or hopelessness; and thoughts of self-harm or suicide (WHO, 2017).

According to the DSM-5 (American Psychiatric Association, 2013), an individual must experience five or more symptoms during the same 2-week period, and at least one of the symptom should be either (1) depressed mood, or (2) loss of interest or pleasure. These symptoms are: 1. Depressed mood most of the day, nearly every day; 2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day; 3. Significant weight loss when not dieting or weight gain or decrease or increase in appetite nearly every day; 4. A slowing down of thought and a reduction of physical movement (observable by others, not merely subjective feelings of restlessness or being slowed down); 5. Fatigue or loss of energy nearly every day; 6. Feelings of worthlessness or excessive or inappropriate guilt nearly every day; 7. Diminished ability to think or concentrate, or indecisiveness, nearly every day; and 8. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide. To receive a diagnosis of depression, these symptoms must cause the individual clinically significant distress or impairment in other important areas of functioning and the symptoms must also not be a result of substance abuse or another medical condition (American Psychiatric Association, 2000).

The comorbidities of diabetes and depression together result in nearly twice the recurrences as would be forecast by chance alone and each condition is exacerbated by the other, making depression among diabetes patients a major clinical challenge (De Groot et al., 2001; Holt et al., 2014). With diabetes and mental illness affecting approximately 8.3 % and 10 % of the total world's population respectively, a degree of comorbidity between diabetes and depression is to be expected (WHO, 2000; Whiting et al., 2011). Comorbidity of diabetes and depression often co-occurs among individuals with diabetes compared with non-diabetic adults in the community (Fisher et al., 2008).

Current research suggests that the threat of developing depression has escalated in people with diabetes; (Roy & Lloyd, 2012; Anderson et al., 2001; Ali et al., 2006; Naskar et al., 2017; Udedi et al., 2018). Holt et al. (2014) observed that despite this evidence, depression is often undetected in people with diabetes, notwithstanding current screening apparatuses available. However, the view of research scientists confirms the comorbidity of diabetes and depression but suggests different conclusions. Some systematic reviews and meta-analyses (Knol et al., 2006; Cosgrove et al., 2008; Mezuk et al., 2008; Yu et al., 2015; Vancampfort et al., 2015) found that depression was associated with an increased risk of incident diabetes. But other systematic reviews and meta-analysis found that individuals with diabetes had a modestly increased risk of developing depression (Mezuk et al., 2008; Nouwen et al., 2010; Rotella & Mannucci, 2013; Hasan et al., 2015; Tong et al., 2016).

In an African population, Teshome et al. (2018) used data extraction designed with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses through electronic web-based search from PubMed, Cochrane Library, Google Scholar, Embase, and PsycINFO. The objective of this systematic review and meta-analysis was to estimate the pooled prevalence of depression among patients with diabetes mellitus in Ethiopia. According to subgroup analysis, the estimated prevalence of depression in Addis Ababa was 52.9% (95% CI: 36.93%, 68.88%) and in Oromia region was 45.49% (95% CI: 41.94, 49.03%), revealing that the overall prevalence of comorbid depression among diabetic patients in Ethiopia was high. In a cross-sectional study in Ghana, Akpalu et al. (2018) used the Patient Health Questionnaire-9 (PHQ-9) to assess depression in 400 T2DM patients aged 30–65 years. In a multivariable logistic regression model, being unmarried and poor glycaemic control was associated with an increase in odds of depression after adjusting for age, gender, and social factors. The study concluded that depression is common among Ghanaians with T2DM, and not associated with poor glycaemic control in a fully multivariable-adjusted model.

Chireh et al. (2019) examined the relationship between diabetes and depression risk in longitudinal cohort studies and determined by how much the incidence of depression in a population would be reduced if proper glycaemic control was practiced. The systematic review provided an objectively vigorous substantiation backing the hypothesis "that diabetes is an independent risk factor for depression while also acknowledging the impact of risk factor reduction, study design and diagnostic measurement of exposure which may inform preventive interventions" (Naskar et al., 2017). However, Roy and Lloyd (2012) suggest that further studies are required to establish the nature of the relationship between depression, glycaemic control, and the development of diabetes complications, and make appropriate recommendations for treatment and to support self-management of diabetes.

Research scientists have noted the relationship between diabetic pain and depression as a major factor in diabetes management (Peyrot & Rubin, 1997; De Groot et al., 2001; Vileikyte et al., 2005; Dziemidok et al., 2016). Vileikyte et al. (2005) examined the association between the severity of

DPN and depressive symptoms and the potential mediators of this association. The study found that there is a relationship between diabetic neuropathy and depressive symptoms and identified potential targets for interventions to alleviate depressive symptoms in persons affected by DPN. D'Amato et al. (2016) further claimed that "painful diabetic polyneuropathy is a greater determinant of depression than other diabetes-related complications and comorbidities, making painful symptoms enhance depression severity more than objective insensitivity.

Despite such evidence, the specific clinical characteristics that underpin comorbid depression and PDN remain unclear (Vas & Papanas, 2020). Though the co-existence of depression and PDN is recognised, individual patients' demographic characteristics, neuropathic pain and insulin treatment with poor glycaemic control are more distinctive in patients with both conditions (Zafeiri et al., 2018).

An investigation into these characteristics promises to elicit new arguments around PDN. Determining the relationship between specific PDN characteristics such as normal sensation, abnormal sensation, unpleasant sensations, and establish the group differences based on socio-demographic variables on depression and PDN will spark a renewed interest in the field of pain research.

2.2.14 Anxiety and PDN

According to the DSM-5 (American Psychiatric Association, 2013), the term General Anxiety Disorder (GAD) explains the excessive anxiety and worry (i.e., apprehensive expectation), occurring more days than not for at least six months, about some events or activities (such as work or school performance) and the individual may find it difficult to control the worry. Anxiety and worry are associated with three (or more) of the following six symptoms (with at least some symptoms having been present for more days than not for the past six months): 1. Restlessness, feeling keyed up or on edge; 2. Being easily fatigued; 3. Difficulty in concentrating or mind going blank; 4. Irritability; 5. Muscle tension; and 6. Sleep disturbance (i.e., difficulty falling or staying asleep, or restless, unsatisfying sleep).

The anxiety, worry, or physical symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. The disturbance is not attributable to the physiological effects of a substance (e.g., drug abuse, medication) or another medical condition (e.g., hyperthyroidism). The disturbance is not better explained by another medical disorder (e.g., anxiety or worry about having panic attacks in panic disorder, negative evaluation in social anxiety disorder (social phobia), contamination or other obsessions in obsessive-compulsive disorder, separation from attachment figures in separation anxiety disorder, reminders of traumatic events in posttraumatic stress disorder, gaining weight in anorexia nervosa, physical complaints in somatic symptom disorder, perceived appearance flaws in body dysmorphic disorder, having a serious illness in illness anxiety disorder, or the content of delusional beliefs in schizophrenia or delusional disorder).

Anxiety is conventionally associated with poor metabolic outcomes and increased homeopathic complications among people with diabetes mellitus (Bickett & Tapp, 2016; Shehata et al., 2018). In an experiment to examine anxiety in a diabetic group compared to a non-diabetic population, Shehata et al. (2018) found that there was a significant increase in anxiety among diabetic patients than the control group.

2.2.15 Anxiety, Depression and PDN

Jain et al. (2011) have affirmed that treating comorbid depression/anxiety impacts positively and improves PDN. The study to assess the correlation of comorbid depression and/or anxiety to patterns of treatment of diabetes pain reveals that depression and/or anxiety affects blood sugar control (Gore et al., 2005; Boulanger et al., 2009).

Gore et al. (2005) evaluated pain severity, pain-related interference with function, sleep impairment, symptom levels of anxiety and depression, and quality of life among patients with painful DPN. Participants in a burden of illness survey (n 5 255) completed the modified Brief Pain Inventory-DPN (BPI-DPN), MOS Sleep Scale, Hospital Anxiety and Depression Scale (HADS), Short Form Health Survey-12v2 (SF-12v2), and the EuroQoL (EQ-5D). The study concluded that painful DPN is associated with decrements in many aspects of patients' lives: physical and emotional functioning, affective symptoms, and sleep problems. The negative impact is higher in patients with greater pain severity.

Other findings validate anxiety and depressive symptoms in patients with peripheral neuropathies correlate positively with pain severity (McWilliams et al., 2004; Balhara & Sagar, 2011). In a systematic review to determine the prevalence of anxiety and depression in patients with diabetic neuropathic pain, Naranjo et al. (2019) concluded that although the data in the literature vary, a high prevalence of anxiety, depression and sleep comorbidities exist among patients with PDN.

2.2.16 Quality of Life and PDN

According to Clarke et al. (2000), the idea of QoL comprehensively incorporates how individuals measure the decency of various parts of their life. These assessments incorporate a person's passionate responses to life's occurrences, disposition, sense of life satisfaction, and fulfilment with work and individual connections (Theofilou, 2013). It has been contended that because of the emotional idea of an individual's quality of life, it is difficult to quantify and to define QoL, but that when all is said and done, the term might be seen as a multi-dimensional idea underscoring the self-view of a person's present perspective of general health (Bonomi et al., 2000). Health-related quality of life (HRQoL) is, however, concerned specifically with health aspects while also accounting for general QoL components (Theofilou, 2013). In assessing the quality of life across painful neuropathies of different aetiologies, Atalay et al. (2013) have examined aetiologically heterogeneous populations of patients with PDN. The findings concluded that the disability caused by PDN had been shown to correlate with a decrease in QoL, and it has been demonstrated that PDN is associated with a poorer QoL compared to painless DPN, regardless of the cause (Bestard & Toth, 2011; Bakkers et al., 2014; Poliakov & Toth, 2011).

The accumulation of diabetes-associated complications in the daily life of the patient results in a lower quality of life and clinicians have often had difficulties managing the patient's illness (Grundy et al., 2002; Marks & Raskin, 2000). In a cross-sectional and descriptive study conducted with 40 diabetic individuals diagnosed with diabetic neuropathy to investigate the effect of diabetic neuropathic pain on quality of life, the study concluded that diabetic neuropathic pain seriously affects the quality of life and increases susceptibility to psychological problems such as depression. The study further added that when using a patient-specific treatment approach for diabetes, considering the data on depression and quality of life would increase the patient's participation in the treatment process and the success of the treatment (Gökmen et al., 2018).

Many studies have established significant impact of pain in general on diabetic patients' quality of life. Painful DPN is associated with a poorer QoL compared to painless DPN, regardless of the cause (Bakkers et al., 2014; Poliakov & Toth, 2011; Atalay et al., 2013; Bestard & Toth, 2011; Toth, 2010; Otto et al., 2007). Only a few studies have been conducted to ascertain the association between specific PDN characteristics on specific quality of life characteristics. However, in this study, we have been able to establish the effect of specific PDN characteristics on specific quality of life characteristics. There are publications which have established that PDN leads to reduced physical activity (Galer et al., 2000) and that the higher the pain intensity experienced, the worse the quality of life (Won et al., 2017). This study discusses the effects in further detail where it was established how specific types of pain affect specific quality of life characteristics. For instance, in a Polish pilot study regarding 42 patients with type 2 diabetes, the perception of quality of life in addition to other factors was studied. Statistically significant differences were noted relating to the patients' overall perception of the quality of life, their satisfaction with life, and their physical sphere compared to patients without diabetes (Kalka, 2014). However, the specific pain characteristics compared to the specific quality of life domains are lacking.

2.2.17 Psychological Interventions for Chronic Pain Management

Psychological interventions over the past three decades have been suggested as a backbone of modern pain management practice and an endorsed feature of a contemporary pain treatment service (Eccleston et al., 2013). However, what psychotherapists mean by a 'psychological intervention' in the context of pain management varies across different pain conditions. It is, therefore, important to know how 'psychological intervention' applies to treatments among chronic pain patients and to investigate if data from diverse psychological treatment trials purported for pain therapy serves the intended purpose to inform clinical practice for the future.

A review of some literature for psychological interventions for chronic conditions have queried whether psychological interventions improve outcomes for patients and whether outcomes are validated and consistent (Newell et al., 2002; Osborn et al., 2006). However, in reviews of treatments for conditions such as heart disease, asthma, multiple sclerosis, and diabetes, psychological interventions have been grouped and defined differently, suggesting inconsistency in all these areas (Rees et al., 2004; Yorke et al., 2006; Thomas et al., 2006; Winkley et al., 2006).

Hodges et al. (2011), however, suggest there seems to be considerable heterogeneity in psychological interventions for chronic patients meeting psychosocial health needs.

Psychological interventions for pain management are, therefore, categorized either as cognitive or behavioural approaches intended to relieve psychological suffering and stimulate active participation with life (Eccleston et al., 2013). In chronic pain, cognitive and behaviour antecedents largely comprise sequestered procedures such as thoughts and feelings that initiate, sustain, or exacerbate pain (Eccleston et al., 2008; Morley, 2011). Psychotherapeutic methodologies of patients in pain may, therefore, differ and are contingent on whether the patient is suffering from acute, continuous, or chronic pain (Songer, 2005). Acute pain might be mild and last just a moment, or it might be severe and last for a few weeks or months. In most cases, acute pain does not last longer than six months and it disappears when the underlying cause of the pain has been treated or has healed. Treatment is relatively straightforward, particularly for acute pain with a specific cause, and analgesic therapies, combined with treatments directed at the underlying disease, are generally effective (Payne, 2000). Chronic pain is associated with a disease process, particularly for diseases associated with high mortality, and last longer than six months.

The International Association for the Study of Pain (IASP) defines pain as “An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” This proposal stems from the following characteristics of pain:

- Pain is always a subjective experience that is impacted on varying levels by biological, psychological, and social factors.
- Pain and nociception are distinct phenomena: the experience of pain cannot be reduced to activity in sensory pathways.
- Through their life experiences, individuals learn the concept of pain and its applications.

- A person’s report of experience as pain should be accepted as such and respected.
- Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.
- Verbal description is only one of several behaviours to express pain; inability to communicate does not negate the possibility that a human or animal experiences pain.

2.2.18 Cognitive Behavioural Therapy for Pain

Our thoughts regularly programmed and not evident in our immediate consciousness, profoundly affect both our transient responses and long-term changes following pain (Knapp & Beck, 2008). CBT centres explicitly around helping individuals perceive their reasoning patterns with the goal that they can change their relationship to the idea of conviction. This procedure may include changing the substance of the thought to align it more with reality. However, it might likewise include letting the idea go as "only an idea". CBT focuses on both behavioural and cognitive components of chronic pain, educating people with sustained pain about the association of pain to cognitive, affective, and physiological issues to help them conceptualize their ability to control pain (Kerns et al. 1986). Cognitive behavioural techniques teach skills to change the way people cope with pain daily. The approach is multi-modal and usually includes management methods such as relaxation training, visual imagery, pacing, assertiveness training, and goal setting, as well as practice and enhancement of coping skills through role-playing and other behavioural techniques. According to Majeed and Sudak (2017), CBT could be used effectively to treat chronic pain, either as a stand-alone treatment or with other non-opioid pharmacological treatments.

CBT is a commonly used technique in the treatment of pain (Knapp & Beck, 2008). Some of its uses include marital distress, childhood somatic disorders, and overeating problems, among others (Caudle et al., 2007). Beck (2005) provide a scientific account of how pain sensation is felt.

According to Beck (2008), it starts as a thought which, when focused on and evaluated, reflects as a pain sensation. They provided a list of some cognitive distortions found across different emotional disorders. These include ‘catastrophizing”, “emotional reasoning (or emotionalizing)”, “mental reading” and “imperatives”, among others. This, therefore, is how pain develops and intensifies or interferes with aspects of a person’s life. Patients or individuals who have chronic pain often experience functional disabilities that eventually impact negatively on their quality of life (Epping-Jordan et al., 1998).

Literature describing a cognitive behavioural approach for people with chronic pain has grown over the past decades and this approach is based on recent theoretical developments in cognitive and behavioural therapies. A literature review of cognitive behavioural treatments indicated that CBT could reduce complex pain, restore lost function, enhance health-related QoL, and decrease reliance on medical care compared to treatments based on the biomedical model (McCracken & Turk, 2002). Findings suggest web-based cognitive behavioural interventions as a potential therapeutic tool for chronic pain. “They can potentially help clinicians and patients with chronic pain by decreasing treatment costs and side effects” (Macea et al., 2010, pp. 917–929). Thus, CBT enhances pain-related results together with the quality of life, disability, and mood results. Compared with long-term consumption of opioids, CBT has dramatically lower risks and may, therefore, be worth pursuing (Keefe et al., 2005; Hoffman et al., 2007; Majeed & Sudak, 2017).

Despite the evidence regarding the efficacy of the CBT approach**,** Turk & Gatchel (2002) emphasize that no single treatment will be efficacious alone and that a combination of treatment modalities such as those used in CBT will yield the best results (Turk et al., 2008). In a study to assess the efficacy of CBT for painful diabetic peripheral neuropathy in a randomized, treatment as usual (TAU), controlled, non-blinded intervention, it was hypothesized that participants who received CBT, when compared to those who received TAU, would report significant decreases on self-reported measures of pain severity, interference, and depressive symptoms from pre-treatment to 4-month follow-up. However, at the end of the study, neither CBT nor TAU participants showed significant changes in their levels of depressive symptoms from pre-treatment to 4-month follow-up. Nonetheless, CBT may be an effective treatment approach for reducing pain severity and interference associated with painful diabetic peripheral neuropathy (Otis et al., 2013).

There are psychotherapies based on the cognitive model and frequently used terms such as cognitive therapy (CT) and cognitive behaviour therapy (CBT), which are synonymously used to describe such psychotherapies. There are also other strategies that are termed as CBT (Beck, 2005). CBT is a well-established efficacious pain management approach for multiple chronic pain conditions (Turner et al., 2005; Hoffman et al., 2007; Morley, 2008; Keefe et al., 2005; Ostelo et al., 2008; Lackner et al., 2004; Dixon et al., 2007). Additional outcome studies have documented the beneficial role of CBT for patients with various medical disorders in reducing depression and improving overall quality of life (Butler et al., 2006).

The efficacy of CBT for reducing pain, distress, pain’s interference with activities, and disability has been established in systematic reviews and meta-analyses. However, its benefits are often modest on average (Ehde et al., 2014). In Cochran review, randomized controlled trials (RCTs) to assess the effects of CBT treatments on adults with chronic neuropathic pain, disability, mood, and quality of life, with improvement in treatment, and the effects on control groups, there was no more improvement in the treatment group than in the control group for any outcome, either post-treatment or at follow-up. Although there was a lack of evidence on the efficacy and safety of psychological interventions for people with neuropathic pain, the authors concluded that there was insufficient evidence of the efficacy and safety of CBT for chronic neuropathic pain (Eccleston et al., 2015). Beck (1995) stated that “the steady progress in research and practice evidenced throughout the history of cognitive behavioural therapies can be taken as an indication that in the future, this field will undoubtedly witness continued advancement”.

2.2.19 Hypnosis for Pain

Hypnosis is a state of cognition that happens independently or occurs by obeying suggested words and is identified by focused attention, heightened receptivity for suggestions, a bypass of the standard critical nature of the mind, and delivery of acceptable recommendations (Elman, 1964; Fromm, 1987). A common supposition is that, during hypnosis, the subconscious mind is in a suggestible state, while the conscious mind is side-tracked or directed to become latent (Stewart, 2005).

According to Patterson and Jensen (2003), hypnosis has been demonstrated to correlate positively with pain in randomized controlled studies with clinical populations, indicating that hypnosis has a positive and significant impact on acute procedural pain and chronic conditions. The study, based on reviewed articles on the controlled trials of hypnosis for clinical pain, was conducted over the past two decades. It concluded that "findings from acute pain studies demonstrate consistent clinical effects with hypnotic analgesia that are superior to attention or standard care control conditions, and often superior to other viable pain treatments" (Patterson & Jensen, 2003). According to Patterson (2004), the use of hypnosis for pain control has a strong foundation in experimental literature as well as in numerous anecdotal reports. Patterson (2004) suggests that clinicians can, however, “optimize their effectiveness by attending to both the experimental literature (e.g., increasing patients’ expectations) and clinical findings” (e.g., matching hypnotic suggestions to the type of pain).

A similar study (Elkins et al., 2007) reviewed thirteen controlled prospective trials of hypnosis for the treatment of chronic pain involving studies of headaches and compared results from hypnosis for the management of sustained pain with either baseline data or a control condition. The findings indicated that hypnosis interventions consistently produce significant decreases in pain associated with a variety of chronic pain problems.

2.2.20 Cognitive Behavioural Therapy plus Hypnosis for Pain Intervention

Williams et al. (2012) have found CBT to have significant positive effect on pain, disability, and mood immediately after treatment in comparison with TAU. According to them, CBT is the most reliable approach in the treatment of chronic pain, as it comes with no side effects as compared to other TAU strategies, also referred to as pharmacologic approaches to treatment. Literature suggests that social and environmental variables are associated with pain behaviours and disability levels (Otis, 2013).

In other studies, CBT has also been shown to be a most useful tool for treatment of other chronic pain disorders including temporomandibular disorder, neck pain, chronic lower back pain, and migraine. In a recent randomized clinical trial, those who received CBT or mindfulness-based therapy had better results after 26 weeks than those in the usual-care group in relieving chronic lower back pain and functional limitations.

There is literature in support of the efficacy of emotional treatments such as CBT in reducing pain (Astin et al., 2002; Knittle et al., 2010) and fibromyalgia pain (Glombiewski et al., 2010). A new appraisal concluded that CBT, when compared with TAU, has statistically significant but small effects on pain and disability and moderate effects on mood (Williams et al., 2012).

Similar to the effect of hypnosis on treatment of pain at its worst in the week prior to the study, there turned out to be a statistically significant effect of hypnosis on participants' pain at its least in the week prior to the study. However, it has been said that pain is inadequately treated in primary, secondary, and tertiary care settings (Mularski et al., 2006), and psychosocial interventions in particular are underutilized (Keefe et al., 2005). Web-based CBT (with or without therapist contact), relative to wait-list control conditions, produced greater improvements in pain across studies and greater improvement in some studies for other outcomes such as mood, physical activity, work productivity, medication use, and physician visits (Macea et al., 2010).

Although no universally accepted definitions exist for chronic pain, it is often defined by the International Association for the Study of Pain Task Force on Taxonomy (Merskey & Bogduk, 1994) as pain that has persisted for three months or longer, whereas acute pain is often considered to be pain of less than seven weeks duration, and subacute pain is considered to be pain that has lasted between approximately 7 and 12 weeks (Goertz et al., 2012). There has been increasing interest in the application of CBT to acute and subacute pain following the trend in the level of pain's interference at its worst and least in the week before the study, where there was a statistically significant reduction of average pain experienced by participants in the week before the study as a result of the introduction of hypnosis in the treatment of the experimental group. Some secondary prevention efforts have included CBT techniques such as graded increases in activity, activity scheduling, relaxation training, and cognitive therapy for individuals with acute or subacute back or neck pain (Linton & Andersson, 2000; Linton & Ryberg, 2001; Slater et al., 2009; Sullivan et al., 2006; Sullivan & Stanish, 2003). Despite the appeal of secondary prevention with CBT and a few studies with promising results (Slater et al., 2009; Sullivan et al., 2006), a 2011 review concluded that there was insufficient evidence that psychological interventions for patients with acute and subacute back pain are effective in preventing chronic pain (Nicholas et al., 2011).

Similar to the trends spelt out early on, there was also a statistically significant reduction of average pain experienced by participants at the time of the study as a result of the introduction of hypnosis in the treatment of the experimental group. Hence hypnosis drastically and statistically significantly reduces pain's intensity in patients with PDN.

According to Ehde et al. (2014), CBT is the "gold standard" psychological treatment for individuals with a wide range of pain problems. The efficacy of CBT for reducing pain, distress, pain's interference with activities, and disability has been established in systematic reviews and meta-analyses. Knapp and Beck (2008) conducted a case-control study in which CBT was compared between control and experimental groups for pain and several chronic pain variables such as pain expression behaviour, activity level, social role functioning, and cognitive coping and appraisal, among others. The result showed CBT to be more efficacious than antidepressants in the face of pain and depression.

Ehde et al. (2014) found that although average effect sizes are small to moderate across pain outcomes, CBT lacks the risks associated with chronic pain medications, surgeries, and interventional procedures. In addition, CBT may well have benefits for common comorbid conditions such as diabetes and cardiovascular disease.

Randomized controlled trials have been conducted that have provided strong experimental evidence for the effectiveness of cognitive interventions, often as a support to therapy, in the treatment of a broad range of medical conditions including heart disease, hypertension, cancer, headaches, chronic pain, chronic lower back pain, chronic fatigue syndrome, rheumatoid arthritis, premenstrual syndrome, and irritable bowel syndrome (Beck, 2005). The inclusion of hypnotics also significantly reduced pain's interference with participants' relations with other people (Patterson & Jensen, 2003; Patterson, 2004; Elkins et al., 2007).

Additional outcome studies have documented the beneficial role of CBT for patients with various medical disorders in reducing depression and improving overall quality of life (Butler et al., 2006). However, in this study, the inclusion of hypnotics in the treatment of PDN patients significantly reduces pain's interference with participants' sleep. On the other hand, according to Adachi et al. (2014), hypnosis is regarded as an effective treatment for psychological and physical ailments. Their study indicated that the efficacy of hypnosis, as a strategy for managing chronic pain, has not been assessed through meta-analytical methods.

In a study to assess the efficacy of hypnosis for managing chronic pain, hypnosis was more effective in reducing pain than TAU (Adachi et al., 2014). The study also showed that the inclusion of hypnotics in the treatment of PDN patients significantly reduces pain's interference with participants' general activity.

According to Nielson and Jensen (2004), "programs using cognitive behavioural therapy (CBT) has been shown to be the most efficacious approach to symptom management as they address both psychological and functional components of health". In their study, Boschen et al. (2016) concluded, "the most significant changes occurred in mood (improved levels of depression and anxiety)."

According to Majeed and Sudak (2017), "Cognitive behavioural therapy (CBT) may be used effectively to treat chronic pain, either as a stand-alone treatment or with other nonopioid pharmacological treatments". They also found that "CBT improves pain-related outcomes along with mobility, quality of life, and disability and mood outcomes. Compared with long-term use of opioids, CBT has dramatically lower risks and may therefore be worth pursuing". Hoffman et al. (2007) concurred, "CBT is recommended for the management of most cases of chronic pain either as a stand-alone treatment or along with other non-pharmacological or pharmacological treatments". A growing body of evidence indicates that CBT is effective in the treatment of chronic pain (Majeed & Sudak, 2017).

Montgomery et al. (2000) investigated the effects of hypnosis for clinical pain management and found that hypnosis had a large effect in managing clinical pain and a moderate-to-large effect for managing chronic pain. Prior to this study, indications are that no meta-analytical study reporting on the efficacy of hypnosis that narrows the focus to only chronic pain had been conducted. Furthermore, the inclusion of hypnotics in the treatment of PDN patients significantly reduced pain's interference with participants' mood (Jensen & Patterson, 2006). CBT aimed at preventing acute/subacute pain from becoming chronic could potentially be applied to any type of pain although most studies have focused on back pain, most likely because of its prevalence. Aggarwal et al. (2011) stated in their study that CBT resulted in long-term improvements in pain intensity, depression, and pain-related activity interference.

Many studies have shown the efficacy of hypnosis for pain management (Haanen et al., 1991; Montgomery et al., 2000; Muraoka et al., 1996; Jensen, Barber, et al., 2009; Jensen & Patterson, 2006; Patterson & Jensen, 2003). The inclusion of hypnotics in the treatment of PDN patients has been shown to significantly reduce significantly pain's interference with participants' normal work.

It is reported that chronic pain is often accompanied by other complex health and medical conditions (Kuluski et al., 2013). Studies have reported on pain's interference with people's ability to attend to social and family events or even to participate in recreational activities and to carry out regular daily tasks (Moulin et al., 2002). Chronic pain is reported to be challenging to treat given that it consists of psychological and social components (Boschen et al., 2016). Boschen et al. (2016) further report that pharmacology, surgery, etc. do not address all the components of the experience of pain.

Finally, the inclusion of hypnotics in the treatment of PDN patients significantly reduces pain's interference with participants' enjoyment of life. Numerous studies have pointed to the correlation between pain-related assessments with pain intensity and related problems such as physical disability, and activity and social role limitations (Gatchel et al., 2007). It has also been shown that mood, anxiety, and sleep disorders are some of the issues that many individuals with chronic pain experience (Alsaadi et al., 2011; Demyttenaere et al., 2007; Gore et al., 2012; Tsang et al., 2008). It is also on record that CBT is used to treat such conditions.

2.3 Theoretical Framework of the Study

The theoretical framework of this study adopted the health belief model (Rosenstock, 1966), the religious coping model (Pargament, 1997), and the cortical processing model (Apkarian, Sosa, Sonty et al., 2004).

2.3.1 Health Belief Model

The health belief model (HBM) was created in the mid-1950s by social researchers at the U.S. General Health Service to address the reluctance of individuals to receive malady counteraction techniques or screening tests for the early detection of illness (Kirscht, 1988; Rosenstock, 1974). Subsequently, the idea was extended by researchers to explain divergent reactions to symptoms and to explain variations in adherence to treatment (Becker, 1974; Leventhal et al., 1984; Kirscht, 1974; Rosenstock, 1974; Kirscht, 1988). Later uses of the HBM were for patients' reactions to symptoms and compliance with clinical treatment (Janz et al., 2002). The HBM proposes that an individual's confidence in the threat of sickness or disease together with their belief in the viability of prescribed health conduct or action will anticipate the probability that the individual will adopt the behaviour (Kirscht, 1988).

Harvey and Lawson (2009) indicated that patients' management behaviours play a major role in diabetes management. Thus, researchers have seen the model as one of the important propositions that guide both action and research in the field of health and health-related management issues in diabetes care (Edgar & Skinner, 2003; Lawson et al., 2007; Keogh et al., 2007; Paschalides et al., 2004).

The proponents of the HBM took their cue from Kurt Lewin's psychological constructs and sources of brain cognitive activity. Kurt Lewin introduced "psychological force field analysis to describe psychological processes in topological spaces, focusing on conceptual representations and measurements of psychological forces" (Lewin, 1951). Lewin's theoretical postulations were that of the cognitive as a complex energy field containing systems of tension in various states of equilibrium and behaviour as a change in the state of this field (Lewin, 1951). Similar to this perception, health behaviours are predisposed by a person's yearning to circumvent ailment and by their self-reliance that the suggested action will achieve the purpose (Abraham & Sheeran, 2015; Hochbaum, 1958). According to Abraham and Sheeran (2003), this implies a phenomenological approach which is not the actual world, but the person's perceptions that tend to influence his or her behaviour.

The HBM argues that "people's beliefs about health problems, perceived benefits of action, barriers to action, and self-efficacy explain engagement in health-promoting behaviour" (Janz & Becker, 1984). Besides this, the proponents suggest that a "stimulus, or cue to action, must also be present to trigger the health-promoting behaviour" (Janz & Becker, 1984; Rosenstock, 1974). According to Glanz et al. (2008), the HBM theoretical constructs were a progeny of cognitive psychological theories. For instance, Lewin et al. (1944) postulated that mental actions are extreme forms of cognitive theories. These theories are viewed as anticipation models because they suggest that behaviour is an element of how much individuals regard an outcome and their assessment of the desire that a specific activity will precede that outcome (Glanz et al., 2008).

The HBM constructs break down health decisions into a series of stages that vary between individuals and predict engagement in health-related behaviours in the following areas; Perceived susceptibility, perceived severity, perceived benefits, perceived barriers, modifying variables, and cues to action (Becker, 1974; Leventhal et al., 1984; Hochbaum, 1958; Janz & Becker, 1984; Kirscht, 1974; Rosenstock, 1974), as illustrated in Diagram 1.

Diagram 1: The Health Belief Model (Source: BMC International Health and Human Rights)

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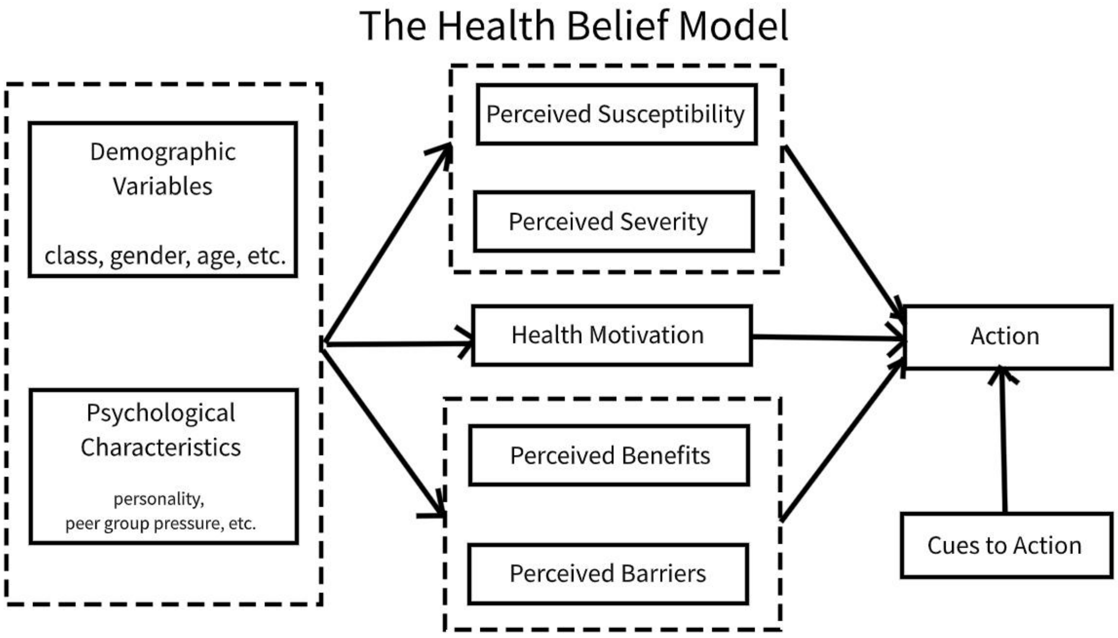


Perceived Susceptibility is about getting a disease or condition. This refers to a person's subjective perception of the risk of acquiring an illness or disease and the variation in a person's feelings of personal vulnerability to an illness or disease (Glanz et al., 2008; Janz & Becker, 1984). Perceived severity refers to the valuation of the impact of a health problem and its probable consequences on a person (Glanz et al., 2008; Janz & Becker, 1984). According to Hochbaum (1958), the HBM proposes that people who see a given medical issue are likely to take part in practices to keep the medical issue from happening (Rosenstock, 1974). Health-related behaviour is the perceived benefit of taking action (Glanz et al., 2008; Janz & Becker, 1984). Perceived benefits refer to an individual's valuation of the significance or efficiency of engaging in health-promoting behaviour to decrease the risk of disease (Hochbaum, 1958). Perceived barriers refer to an individual's valuation of the complications to behaviour modification (Glanz et al., 2008; Janz & Becker, 1984). According to Glanz et al. (2008), even if a person perceives a health problem as threatening and assumes that a specific action will effectively reduce the threat, barriers may prevent engagement in health-promoting behaviour.

Changing variables (individual characteristics), including demographic, psychosocial, and structural variables can affect perceptions (i.e., perceived seriousness, susceptibility, benefits, and barriers) of health-related behaviours (Glanz et al., 2008; Janz & Becker, 1984). The HBM argues that a cue, or trigger, is necessary for promoting engagement in health-promoting behaviours (Hochbaum, 1958). Cues to action can be inward or outward. Physiological cues (e.g., pain, symptoms) are an example of internal cues to action.

In a review of the HBM, some limitations in its use in public health have been observed (Jones et al., 2015). The limitations of the HBM include the following: (1) It does not account for a person's attitudes, beliefs, or other individual determinants that dictate a person's acceptance of a health behaviour. (2) It does not take into account behaviours that are habitual and thus may inform the decision-making process to accept a recommended action. (3) It does not take into account behaviours that are performed for non-health related reasons such as social acceptability. (4) It does not account for environmental or economic factors that may prohibit or promote the recommended action. (5) It assumes that everyone has access to equal amounts of information on the illness or disease. (6) It assumes that cues to action are widely prevalent in encouraging people to act and that "health" actions are the main goal in the decision-making process.

However, according to Hahm et al. (2008), the major strengths of the HBM are the following: (1) It addresses the social structure of the person with PDN. For example, it explains the reliance on family or friends to identify health problems and persuade the individual to seek medical care (Stromwall, 2001). (2) It also addresses the need factors and/or personal experiences of the person with the PDN. For example, it takes into consideration the ability, or inability, of the person with PDN to recognize his or her physical ailment and also takes into consideration the evaluation of the medical professional (Stromwall, 2001).

2.3.2 Religious Coping Model

Religious coping now epitomizes a significant debate in medical research regarding health consequences and quality of life (Lazarus & Folkman, 1984; Pargament, 1997; Pargament et al., 1988). According to Cummings and Pargament (2010), this finding is not just because numerous people seek solace in their faith during illness. Studies have found that religious coping correlates with well-being results. Experimental examinations have exhibited that many individuals turn to religion as an asset in their endeavours to comprehend and manage the most troublesome occasions of their lives (Greil et al., 2010; Segall & Wykle, 1988–1989; Schuster et al., 2001).

However, researchers have differentiated between positive and negative outcomes of religious coping. For example, Pargament et al. (1988) claim that positive methods of religious coping (e.g., seeking spiritual support, benevolent religious reappraisals) have positive improvements in health, while harmful ways of religious coping (e.g., punishing God, reappraisal, interpersonal religious discontent) were predictive of declines in health (Pargament et al., 1988).

Lazarus and Folkman's (1984) account of coping has established that the individual's perception of, and response to, stressors is fundamental to appreciating and envisaging the consequences of stress. However, Pargament (1997) demonstrates that through religious coping, an evaluation of their circumstances to determine how they ought to respond to them is by far one outstanding revelation in health and coping. According to Xu (2016), the theory of religious coping has entrenched itself in the field of religion and coping.

Pargament and Abu Raiya (2007) state that religious coping refers to methods for comprehending and managing adverse life outcomes that are identified with a person with a higher power. Pargament et al. (2011) accentuated that what religion may particularly add to coping lies in how it interestingly addresses sacrosanct issues. Pargament et al. (1988) identified three styles of religious coping, namely the collaborative, self-directed, and deferring coping styles. The collaborative form of religious coping involves an active and internalized personal exchange with God (Phillips et al., 2004; Pargament et al., 1988). The deferring coping style is when individuals rely heavily on God and delegate their stress without taking personal responsibility for the situation (Phillips et al., 2004; Pargament et al., 1988). The self-directed style of religious coping emphasizes the free will set by God that allows for the individual to solve crises on their own (Phillips et al., 2004; Pargament et al., 1988).

Most current studies conceptualize religious coping as comprising two distinct dimensions, namely positive strength and negative weakness (Pargament et al., 2013). Positive religious coping reflects a confident and trusting connection with God (Hebert et al., 2009) and includes strategies such as seeking religious support and making benevolent religious reappraisals. Negative religious coping reflects a less secure relationship with God (Hebert et al., 2009) and includes strategies such as religious discontent and making punitive religious reappraisals. This study, therefore, adopts the Religious Coping Model to explore both the negative and positive consequences of religious coping among patients with PDN.

2.3.3 Impact of Cortical Processing Model

The third theoretical framework of this study is the model of the impact of cortical processing in the development of pain experience proposed by Apkarian, Sosa, Sonty, et al. (2004). According to Apkarian, Sosa, Krauss, et al. (2004), chronic pain involves central sensitization that engages and restructures connectivity between the periphery, spinal cord, thalamus, and cortex.

Melzack and Wall (1965) are accredited with initiating studies on the need to incorporate psychotherapy into pain intervention through the Gateway theory. The Gate Control theory demonstrates how by descending neural messages from higher limbic brain centres (L), we are able to excite spinal gate (SG) neurons. According to Melzak (1999), increased discharge from SG neurons leads to an inhibition of the incoming sensory (S) information at the synapses in the spinal cord. Melzack and Casey (1968) add that inescapable synergy of pain through cognitive factors that influence our experience, including our thoughts and feelings, has the potential to modify the sensation of pain.

Two main methods of psychological interventions have evolved in behavioural medicine for the treatment of chronic pain. The first was when Fordyce (1984) experimented and explained the influence of maladaptive pain behaviours and the approach to modifying pain through analysing and changing their social and environmental contingencies. The second was cognitive behavioural approaches which do not focus on practice only but seek to determine the cognitive and affective interplay of the pain experience (Turk et al., 1983). The past three decades have produced works on the effectiveness of psychological pain interventions such as cognitive behavioural therapy (Castelnuovo et al., 2016; Ehde et al., 2014) and hypnotherapy (Jensen et al., 1991, Kirsch et al., 1995; Stoelb et al., 2009). It is evident from the above that multi-disciplinary and transdisciplinary interventions that integrate cognitive behavioural with other approaches represent the future direction of the management of chronic pain (Sveinsdottir et al., 2012).

There is now abundant evidence that a distinct cortical network contributes in human perception of acute pain (Treede et al., 2008; Bushnell et al., 1999; Apkarian, Sosa, Sonty, et al., 2004). When experts examine brain activity relating to dangerous thermal painful stimuli in chronic pain patients, the resultant pattern is very similar to that seen for acute pain in healthy subjects, independent of the type of chronic pain (Derbyshire et al., 2002). However, when brain activity specifically related to chronic pain is isolated, then activity seems to be prevalent in the prefrontal cortical regions (Apkarian, Sosa, Krauss, et al., 2004). The shift of activity from parietal and cingulate cortices to the prefrontal areas implies that there is also a shift in perceptual characteristics in the experience of pain. The simplest explanation would be that perception has become dominated by cognitive evaluations of the condition, with a decreased emphasis on its sensory properties. Apkarian, Sosa, Sonty, et al. (2004), therefore, conclude that chronic pain is reflected at the cortical level and is associated with the cortical reorganization and perhaps even neurodegeneration. Potential changes in the cortical region of the brain have been noted by Apkarian, Sosa, Krauss, et al. (2004) to be related to symptoms (other than pain) commonly exhibited by patients with chronic pain, including psychological comorbidities such as depression and anxiety, sleep disturbances, and decision-making abnormalities, which eventually lead to a poor quality of life for patients with chronic pain.

2.4 Conclusion

This chapter explained and discussed relevant literature pertaining to diabetes and painful neuropathy and provided a detailed discussion on the theoretical framework of the study. It also discussed the history, classification, clinical features, diagnosis, aetiology, and treatment of diabetes. The chapter further explained what PDN is and its clinical manifestations as well as the epidemiology, pathogenesis, and diagnosis of PDN. The literature reviewed explored the personal beliefs, experiences, and cultural, religious, and spiritual consideration of PDN patients. Psychological comorbidities of depression, anxiety, and quality of life to PDN were also discussed and the inclusion of psychological interventions of CBT or HYP in the management of PDN was explained in this chapter. It concluded by highlighting the gap in the inclusion of either CBT or HYP as standalone interventions for PDN and discussed the health belief, religious coping and impact of cortical processing models as the foundation theories for this study. The next chapter provides an in-depth account of the methodology used for this study.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter provides an in-depth account of the methodology used for the present study. The study used various techniques to collect data to support the research topic and meet the aim and objectives of the study. In its overall application, the information in this chapter is focused on how the research was applied. This chapter begins by describing the methodological approaches and the research design used to implement the study. The ethical considerations, trustworthiness and limitations of the study are also presented in this chapter.

3.2 Aim

This study aims to explore the role of personal beliefs as coping strategies for PDN, explore the relationship between depression, anxiety, and PDN, and further evaluate the efficacy of the combined intervention of medication, CBT and HYP for PDN.

3.2.1 Specific Objectives

The objectives of the study are to:

Objective 1: Explore the experiences of patients with PDN and their use of personal beliefs as a coping mechanism.

Objective 2: Examine the associations between socio-demographics variables (i.e., age, sex, marital status, education, and occupation) and depression, anxiety, and PDN.

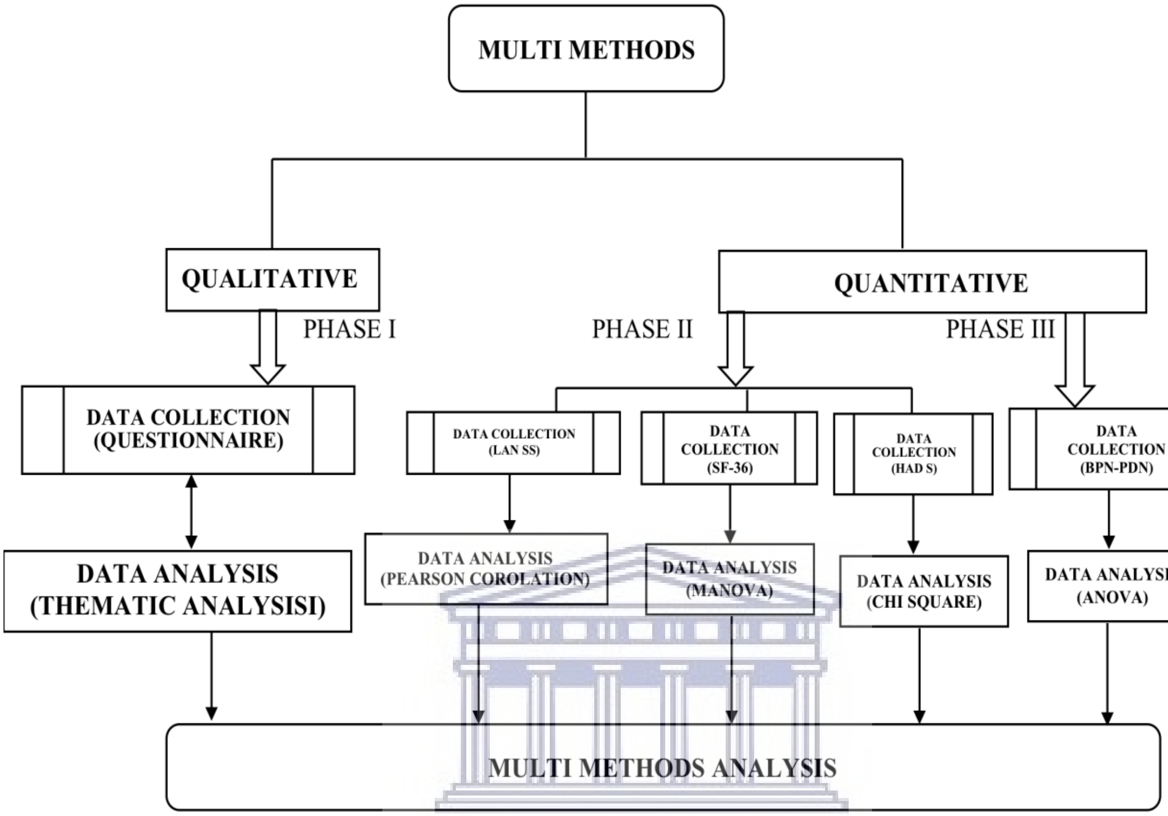
Objective 3: Determine the relationship between specific PDN qualities (i.e., aching, throbbing, shooting, stabbing, gnawing, sharp, tender, burning, exhausting, tiring, penetrating, nagging numb, miserable, and unbearable) and quality of life domains (i.e., physical function, psychological, energy/fatigue, social function, pain, general health, and physical health).

Objective 4: Evaluate the relative effects of medication management and CBT and hypnosis compered to medication management and CBT without hypnosis in a randomized controlled experiment.

3. 3 Methodology

This study therefore employed a sequential exploratory multiple-methods approach for collecting and analysing both qualitative and quantitative data. Through the use of mixed methods (both qualitative and quantitative data), this design allowed the researcher to execute three phases as three separate studies which represent a relatively complete project on their own, and was then integrated and synthesized to form a comprehensive whole (Mafuba & Gates, 2012). Mafuba and Gates (2012) further argued that this design allows the researcher to provide data of a subjective and objective nature to generate data that is thick and rich in descriptions from the participants' subjective accounts, as well as empirical and generalizable data that is representative for the Ghana population who endure PDN. Through triangulation based on the Crotty (1998) and Morse and Niehaus (2009) framework, the data for the entire study was analysed according to the framework in Diagram 2 for cohesive data which aligns with the overarching aim of this study (Mafuba & Gates, 2012). Each research question was therefore answered based on the qualitative (phase I) and quantitative (phase II and phase III) epistemologies to present well informed methodologies for each phase. The latter is to follow. See Diagram 2.

Diagram 2: Multi-Method Triangulation Model



3.4 Phase I

Phase I of this study sought to explore the role of personal beliefs as coping mechanisms for PDN. A qualitative methodological framework of the multiple methods, focusing on participants' experiences and personal beliefs in relation to PDN, was used (Sandelowski, 2004). It allows the researcher to draw on in-depth subjective views and opinions of the participants (Sandelowski, 2004). By using this methodology, the researcher was able to capture corresponding patterns, themes, categories, and regular similarities regarding pain experience (Cohen et al., 2007). Each respondent selected was invited to a face-to-face in-depth interview (IDI) to solicit their views and approach to the use of personal beliefs as a coping mechanism for PDN. These participants were provided with a general understanding of the study in relation to the personal beliefs and how they are used as coping mechanisms for PDN.

3.4.1 Objective 1

To explore how patients with PDN use personal beliefs as a coping mechanism.

3.4.2 Research Design

Objective 1 followed an exploratory research design. An exploratory research design is adopted when addressing a case that has limited research or an uncertainty and less knowledge about the subject (Burns & Grove, 2001). It was useful in this study because there was limited knowledge on how patients with PDN use personal beliefs as a coping mechanism (Selvarajah et al., 2014; Pires-Yfantouda & Evangeli, 2012; Al-Thani, Sathian, & El-Menyar, 2019; Al-Sahouri et al., 2019; Srisanthanakrishnan & Shah, 2016).

3.4.3 Research Setting

The study was conducted at the Diabetic Centre of the Komfo Anokye Teaching Hospital in Ghana. The Diabetic Centre is the largest referral diabetic clinic in Ghana receiving tertiary/referral cases from other hospitals in the country. The Diabetic Centre serves people from high- middle- and low-income communities with varying socio-demographic characteristics. Statistics from the Diabetic Centre revealed that 22929 cases were reported from January to December 2018, with 6 325 males and 16 604 females. The research setting was applicable for phases I, II and III of the study. Phase I provided a general understanding of the population characteristics for this setting in relation to the personal beliefs and how it is used as a coping mechanism for PDN.

3.4.4 Participants and Sampling

A sample of approximately 30 participants was purposively selected for phase I of the study. Purposive sampling allows the researcher to select participants based on specific criteria (Tashakkori & Teddlie, 1998). The inclusion criteria for this phase were: (a) adult patients attending the diabetic clinic of the Komfo Anokye Teaching hospital; (b) patients should have been diagnosed with PDN; (c) patients should be members of a religious body. These criteria were all met by each participant who was recruited to participate in the study. Having this experience and background allowed the participants to share their experiences and personal beliefs as coping mechanisms for PDN. Thus, purposive sampling was employed because the researcher wanted to select a sample that represents a broad group of cases as closely as possible, and to choose participants who had the requisite experience and knowledge to share on the topic (Tongco, 2007). A qualitative study requires a smaller sample size but should be large enough to obtain enough in-depth data to describe the phenomenon of interest sufficiently and address the research questions (Creswell, 1998). The sample size to be studied in Objective 1 aimed to elicit the patients' subjective experiences about the role of personal beliefs as a coping mechanism for PDN (Creswell, 2002). The age sample inclusion criteria in this study was adults who were 18 years and older.

3.4.5 Instrumentation

The participants were asked to complete a demographic questionnaire (Appendix A). A semi-structured interview guide (Appendix B) was used to explore participants' personal beliefs as a coping mechanism for PDN. A semi-structured interview guide involves open-ended questions that have some minimal structure but are still flexible, allowing the participants the freedom to answer in their own words (Mellor, 1998; Ulmer & Wilson, 2003; Noor, 2008; Creswell, 2007;

Corbin & Strauss, 2008). Sample semi-structured questions included: (1) How has having painful diabetic neuropathy influenced your life? (2) Tell me about some of your biggest difficulties or problems with regards to your diabetic pain. How do you overcome them?

3.4.6 Data Collection Procedure

Once ethics clearance was obtained by the Biomedical Research Ethics Committee (BMREC) at the University of the Western Cape (UWC), ethics approval was also sought from the Ghana Health Service Research Ethics Committee. Permission to conduct the study at the hospitals was also requested from the research committee at the Komfo Anokye Teaching Hospital and ethics approval from the KNUST/KATH Committee for Human Research Publication and Ethics. Once all the ethics approval was obtained, data collection commenced. Before the interviews were conducted, participants were informed about their rights (voluntary participation, could withdraw at any time, etc.). They were then given an information sheet and a consent form to peruse and sign. The participants were asked to give a time and date that was convenient for them to be interviewed. Each participant, after satisfying the inclusion and exclusion criteria, was interviewed by the researcher in the specified clinic so that the participants could share their subjective experiences of personal beliefs and how these are used as coping mechanisms for PDN. The duration of the interviews was approximately 35–45 minutes. With the participants' permission, interviews were recorded and transcribed in preparation for analysis. Regarding participants experiences during the interview, most participants were generally calm and eager to share their experiences. For most of them it was the first time they had the opportunity to express their feelings about their pain experiences. While a few were nervous in the beginning, the reception and use of the local language made it easier for them to share and articulate their thoughts and experiences. The tone of the interview was accommodating and none of them cried, except for two women, who became emotional during the interview and had to be referred to the hospital counsellor for post interview counselling (Bennett, 2001).

The researcher interviewed and audio recorded each participant, the whole exercise spanning one-month. All interviews were conducted in Twi and translated into English, after transcription. An independent bilingual English-Twi speaker to validate the translation conducted back-translation checks. The study adopted the thematic analysis approach (Braun & Clarke, 2012). Using this approach, various themes and sub-themes were collectively agreed upon by the researcher and his supervisor following the study objectives. The transcriptions were coded based on a pre-determined coding frame. The themes emerging from the interviews were added to the framework during the analysis and transcripts accordingly.

3.4.7 Data Analysis

Before data analysis commenced, transcripts were translated into English to further facilitate data analysis. Ahuja (2010) described data analysis as the process of bringing order, structure and meaning to the mass of collected data. The data was analysed using thematic analysis (Clarke & Braun, 2013). It focussed on the coding (inductive or "bottom-up") of the data elicited from participants to produce clusters of text with similar meaning, search for concepts to capture the essence of the phenomenon under investigation, and produce mid-range theories (Madill & Gough, 2008). The analysis involved coding of data. from participants to produce clusters of text with similar meanings, and search for concepts to capture the essence of the phenomenon under investigation (Madill & Gough, 2008).The researcher followed the six-phase approach, as presented by Braun and Clarke (2012). (1) **Familiarity with the data**: The researcher engaged the data by transcribing the interactions and read the transcripts while listening to the recordings, and noting the initial ideas. The data was transcribed verbatim, including all of the verbal and nonverbal communication. After immersion, initial ideas were noted. Punctuation marks were added such as not to change the "true" meaning of the data. (2) **Generating initial codes:** After familiarizing with the data, identified preliminary codes, which were the features of the data that appeared interesting and meaningful. (3) **Searching for themes:** In the third step, relevant data extracts were sorted (combined or split) according to predominant themes. (4) **Reviewing themes:** A deeper review of identified themes followed where the researcher questioned whether to combine, refine, separate, or discard initial themes. This was done over two phases, where the themes were checked in relation to the coded extracts (phase 1), and then for the overall data set (phase 2). Following this, a thematic 'map' was generated. (5) **Defining and naming themes:** This step involved 'refining and defining' the themes and potential subthemes within the data. The researcher, however, provided theme names and clear working definitions that captured the essence of each theme in a concise manner. (6) **Producing the report:** Finally, the researcher transformed his analysis into an interpretable piece of writing by using vivid and compelling extract examples that related to the themes, research question, and literature.

3.5 Trustworthiness

Establishing rigor is essential for all qualitative research studies. Principles of trustworthiness should be adhered to throughout the process. Trustworthiness is one way of ensuring rigor in a qualitative study; this adds great value to the study. It also refers to being true and accurate to the participant's information without intentionally transcribing it. Research scientist agrees that qualitative research should be trustworthy and therefore should include and adhere to the following criteria: credibility, transferability, dependability and confirmability (Rolfe, 2006; Gunawan, 2015; Tracy, 2010; Miles et al. 2014; Nowell et al., 2017).

According to Nowell et al. (2017), the purpose of trustworthiness in qualitative research is to support the argument that the inquiry's results are "worth paying attention to". Trustworthiness therefore refers to the way in which qualitative research workers ensure that transferability, credibility, dependability, and conformability are evident in their study (Rolfe, 2006; Gunawan, 2015; Tracy, 2010; Miles et al., 2014; Nowell et al., 2017). When conducting the study, awareness of any preconceived ideas or assumptions should be a priority; this is referred to as reflexivity (Langdridge, 2007). To ensure that trustworthiness was upheld, this study had to comply with credibility, transferability, dependability, and confirmability.

3.5.1 Credibility

Credibility exists when the research findings reflect the perceptions of the participants forming part of the study (Polit & Beck, 2012; Terre Blanche et al., 2014). The credibility of the data refers to the confidence of the data. Internal validity is important in qualitative research; researchers are able to establish the reality of the participants through detailed description of the discussion (Polit & Beck, 2004). One technique of upholding credibility is having the researcher remain in the field for a long period of time, sourcing data from a variety of sources (Brink, 2003). The benefit of qualitative research is that it aims to explore a particular matter with an in-depth approach. During this study, consultation with experts in the field that had extensive knowledge increased the credibility of the study (De Vos et al., 2011). In this study, the development of early familiarity was done by allowing the participants to become familiar with responding to questions and becoming engaged in the data collection process (Shenton, 2004). The researcher established a rapport with the participants and encouraged them to answer questions frankly. Iterative questioning was utilized to uncover deliberate lies (Shenton, 2004). The researcher sometimes returned to issues previously raised, by rephrasing questions, and where contradictions or falsehoods were detected, the suspect data was not considered.

3.5.2 Transferability

According to Holloway and Wheeler (2010), transferability refers to the findings of the research that are relevant to a situation or participant commonality. Transferability designates that the findings have relevance in other contexts (Houghton et al., 2013; Polit & Beck, 2012; Terre Blanche et al., 2014). One strategy to achieve this was to compile a thick description of data (Creswell & Miller, 2000). Transferability also refers to the degree to which the research can be transferred to other contexts. Furthermore, Transferability refers to the generalisability of the study in other settings, which can be problematic when conducting qualitative research (Brink, 2003). Therefore, all audio recordings, transcriptions and field notes must be kept safe for evidence (De Vos et al., 2011). Transferability was ensured by providing a clear and detailed account of the research setting, methodology used, the analysis process and collating of the research results.

3.5.3 Dependability

According to Polit and Beck (2012), the term dependability refers to the stability of data and the research findings. This is measured by the standard to which the research is conducted, analysed and presented. Lincoln and Guba (1985) state that a dependable study should be consistent and accurate. This requires checking of data and involving another researcher or peer to validate the process and procedures involved. This is done to seek approval and establish whether the data was obtained through a thorough process (Brink, 2003). While conducting this study, consultation with senior colleagues and peers in the field was imperative. Their main task was to do checking of data collection and form part the research process to ensure dependability.

3.5.4 Conformability

This is a process to establish authenticity and determine whether there was any bias during the study (Shenton, 2004). Conformability refers to the neutrality or objectiveness of the study as well as concentrating on the characteristics of the study. It focuses on the characteristics of the data to ensure it is dependable (Holloway & Wheeler, 2010). One way to ensure conformability is to have member checking form part of the research process. This makes it easier to accept the findings, conclusions, and recommendations (Brink, 2003). Therefore, an audit trial was kept capturing the steps involved that lead to the conclusions and research findings. Field notes, transcripts and a reflective log were updated throughout the research process.

3.5.5 Member Checking

The credibility of a study can be ensured by including member checking as part of the research process. Member checking is primarily used in qualitative research and assists with quality control. It is a process that involves the checking and verifying the analysis of data obtained from participants (Radley & Chamberlain, 2001). According to Lincoln and Guba (1985), member checking is a process that occurs at the end of a study. The research report is handed back to participants for checking to see whether the information they provided is accurately described. They will either agree or disagree on whether the findings reflect their experience, feelings, or views (Creswell, 2013). Member checking eliminates error and the misinterpretation of data provided by participants. In conjunction with this, Creswell (2013) expresses a concern that participants might decide to change their mind about a comment they made. Some participants might have forgotten what they said previously, and this might become an issue. Member checking was not possible for all participants as time constraints were a major factor; however, the few that were done ensured that the data was accurate and valid in their opinion. Some participants felt the need to add some additional information, but this posed a challenge as the research emphasised that the activity was focused on the existing data they provided.

3.5.6 Reflexivity

While conducting the study, in order to minimise bias, the researcher needed to be aware of any pre-conceived ideas or assumptions. Qualitative interviewing involves a continuous process of reflection. Reflexivity is the process of examining both oneself as researcher and the research relationship (Flick, 2009). It involves making the research process a focus of inquiry, laying open preconceptions and becoming aware of situational dynamics in which the interviewer and respondent are jointly involved. Assessing qualitative research entails numerous readings that are considered a representation of understanding and meaning.

For example, the researcher ensured that journal entries were made throughout the research process in order to constantly reflect and engage actively in the process. The research was primarily focused on qualitative data and therefore the researcher had to be reflexive throughout. The nature of the enquiry was rather sensitive to many participants and the researcher was constantly mindful of this. Most of the participants were open to sharing their experiences although some were reluctant at times. What influenced this was not known to the researcher but is worth reflecting on. The individual interviews were rather anxiety-provoking as the researcher had to engage with individuals with different backgrounds. The researcher felt “brushed off”, especially when participants heard it was a research study being conducted. Feelings of frustration for the researcher at times were high and striking a balance between professionalism and lashing out was challenging at times. The frustration was based on the difficulty in accessing the information from certain individuals who failed to participate because it was a research study. Having the support of senior peers in the profession provided the researcher with guidance and support at all times.

3.6. Phase II

A quantitative research methodology was applied in phase II for objectives 2–3. A study is classified as quantitative if one wants to quantify the variation in a phenomenon, situation, problem, or issue (Araoye, 2003). Thus, the information gathered was predominantly quantitative variables and the analyses were geared to ascertain the magnitude of the variation (Araoye, 2003). Data for objectives 2, 3, and 4 were all collected in phase II, in which statistical analyses were used to explore the relationship between depression and anxiety PDN.

3.6.1 Objectives 2–3

The objectives of this phase were to;

2. Determine whether there were differences based on socio-demographics variables (i.e., age, sex, marital status, education, and occupation) on depression, anxiety, and PDN.

3. Determine the relationship between specific PDN characteristics (i.e., aching, throbbing, shooting, stabbing, gnawing, sharp, tender, burning, exhausting, tiring, penetrating, nagging numb, miserable, and unbearable) and specific quality of life domains (i.e., physical functioning, emotional problems, energy fatigue, social functioning, pain, general health, and physical health).

3.6.2 Research Design

The research design for this phase was a cross-sectional descriptive design. A descriptive research design is employed when a study attempts to describe systematically a situation, problem, and phenomenon and provides information about a condition or describes attitudes towards an issue in a defined population (Araoye, 2003; Bennett, Lubben, et al., 2005)

3.6.3 Sampling and Sample Size Calculation

Systematic random sampling was used to select 125 respondents for phase II. A list of participants made up of diabetic patients was obtained from the Records Department of the Diabetic Centre of the Komfo Anokye Teaching Hospital. After deciding on a random start, every second patient diagnosed with PDN was included in the sample until a total sample of 125 was reached. Sufficient patients were recruited to allow the researcher to have a high probability of detecting a clinically important difference between treatments if a difference truly existed. The sample size calculation below ensured that an estimated sample size for a quantitative case control study was suitable (Charan & Biswas, 2013).

$$n \geq \frac{(Z_\beta + Z_{\propto/2})^2 p(1-p)}{d^2}$$

$$= \frac{(0.8 + 1.96)^2 (0.036)(0.964)}{(0.05)^2} = 112.63$$

The power Z_β was pegged at 80%, while the critical value of the normal distribution used at $(Z_{\propto/2})$ was 1.96. Prevalence of diabetes in Ghana (p_1) is 3.6%. Substituting the figures in the formula above, the total sample size (n) became 112.63. Allowing a 10% loss to follow up, the total sample size (n) became 125 approximately. The inclusion and exclusion criteria for phase II (objectives 2–3) consisted of: (1) Participants recruited from the Komfo Anokye Teaching Hospital attending either regular clinics or who were referred to the study facility and who are 18 years or older; (2) Participants were required to have a confirmed diagnosis of PDN secondary to diabetes; (3) There was no exclusion made based on sex, marital status, educational background, and ethnicity.

3.6.4 Description and Properties of Instrumentation for Phase II

The Instrumentation for phase II was Leeds Assessment of Neuropathic Symptoms and Signs – LANSS, used for the inclusion and exclusion criteria to be admitted into the study. The Hospital Depression/Anxiety Scale (HADS) was used for objective 2. The Medical Outcomes Study Short Form -SF-36 (MOSSF-SF-36), was used for objective 3 and the Brief Pain Inventory for painful diabetic peripheral neuropathy (BPI-PDN) was used for objective 4. Qualified clinicians who were recruited to assist the process administered each instrument in this study. All data collection instruments were pre-tested within a 10% of the sample space (127) selected for this study. Hence the Hospital HADS, -SF-36 (MOSSF-SF-36), and (BPI-PDN) were pre-tested with 27 respodents at the Kumasi Poly Clinic to generate the nuances and to assure familiarity for use among the clinicians.

- **The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) – Appendix C**

The Leeds Assessment of Neuropathic Symptoms and Signs Scale (LANSS) is a simple bedside test in two parts – a patient-completed questionnaire and a brief clinical assessment (Bennett, 2001; Bennett, Lubben, et al., 2005). Five questions in the patient-completed section (maximum score 16) identify those who are experiencing phenomena associated with neuropathic pain: ‘pins and needles’ (paraesthesia); ‘red skin’ (autonomic changes); ‘sensitive skin’ (evoked dysaesthesia); ‘electric shock pain’; and ‘burning pain’ (spontaneous dysaesthesia). The physical assessment (maximum score 8) is designed to identify allodynia by stroking cotton wool over the painful area and the anatomically equivalent non-painful area and altered pinprick threshold (PPT) by using a 23-gauge needle to assess perception of pinprick in the same areas. The LANSS identified patients with neuropathic pain by combining the scores of patients’ verbal description of pain and the results of neurological examination. A cut-off score of 12 points or more (out of a total of 24), when compared with expert opinion, had a sensitivity of 83% and a specificity of 87% (Bennett, 2001). The LANSS Pain Scale is based on the analysis of sensory description and bedside examination of sensory dysfunction and provides immediate data for clinical settings. It has a Cronbach's αa of 0.70; and Guttmann split-half coefficient of 0.6; and cumulative contributions to the total variance of 61.945% (Bennett, 2001). The LANSS had been standardized and applied in an African (Libya) setting (Bennett, 2001). It was developed in two populations of chronic pain patients. In the first (*n* = 60), the use of sensory descriptors and questions were compared in patients with nociceptive and neuropathic pain, combined with an assessment of sensory function (Bennett, 2001). This data was used to derive a seven-item pain scale, consisting of grouped sensory description and sensory examination with a simple scoring system. The LANSS Pain Scale was validated in a second group of patients (*n* = 40) by assessing discriminant ability, internal consistency, and agreement by independent ratters (Bennett, 2001).

In phase I, the LANSS was used to assess neuropathic pain characteristics among participants to be included or excluded in the study. It was used to distinguish neuropathic pain from nociceptive pain (Bennet, 2001).

- **Medical Outcomes Study Short Form – SF-36 (MOSSF-SF-36) – Appendix D**

The 36-Item Short Form Health Survey (SF-36) was developed for the Medical Outcomes Study, a multi-year study of patients with chronic conditions (Ware & Sherbourne, 1992). This instrument contains 36 items, measuring eight dimensions (scores) of health and well-being: ‘physical functioning’, ‘role limitation due to physical problems’, ‘bodily pain’, ‘general health perceptions’, ‘vitality’, ‘social functioning’, ‘role limitation due to emotional problems’ and ‘mental health’. The eight-scaled scores are the weighted sums of the questions in their section. Each scale is directly transformed into a 0–100 scale with the assumption that each question carries equal weight. The higher the score, the less the disability. For example, a score of zero is equivalent to maximum disability; and a score of 100 is equivalent to no disability. It has a Cronbach's α of 0.94 (Bowling, 1995) and its reliability exceeds 0.80 (McHorney et al., 1994; Ware, 1993). It was used to evaluate the health-related quality of life (HRQoL) of patients with PDN. The MOSSF was standardized and applied in Morocco (Obtel et al., 2013).

- **Hospital Anxiety and Depression Scale – Appendix F**

The HADS was developed by Zigmond and Snaith (1983) and was used to identify the depression and anxiety level of participants. It assesses both anxiety and depression, which commonly coexist (McManus et al., 2009). The questionnaire comprises seven questions for anxiety and seven questions for depression and takes 2–5min to complete. For both scales, scores less than 7 indicate no cases (e.g., 8–10, Mild, 11–14, Moderate and 15–21, Severe). Cut-off scores are available for quantification, for example, a score of 8 or more for anxiety has a specificity of 0.78 and sensitivity of 0.9, and for depression a specificity of 0.79 and a sensitivity of 0.83 (Bjelland et al., 2002). Its Cronbach's α varies from 0.68 to 0.93, which indicates a high degree of internal consistency (Bjelland et al., 2002).

The HADS questionnaire has been validated in many languages, countries, and settings including general practice and community settings (Snaith & Zigmond, 2003; Bjelland et al., 2002). The Hospital Depression and Anxiety Scale has been standardized and is used in Sub Saharan Africa (Sweetland et al., 2013).

- **Brief Pain Inventory for Painful Diabetic Peripheral Neuropathy (BPI-PDN) Appendix G**

The BPI allows patients to rate the severity of their pain and the degree to which their pain interferes with common dimensions of feeling and function (Cleeland, 2002; Cleeland & Ryan, 1994; Zelman et al., 2005). The BPI measures two domains – pain intensity (severity) and the impact of pain on functioning (interference) (Turk et al., 2003). The severity and interference items of the BPI are rated on a 0–10 scale, as one of the two scales recommended for assessment of pain-related functional impairment (Dworkin et al., 2005). The pain intensity (severity) assesses pain at its “worst,” “least,” “average,” and “now/current” pain (Dworkin et al., 2005; Turk et al., 2003; Dworkin et al., 2008). The pain interference measures how much pain has interfered with seven daily activities, including general activity, walking, work, mood, enjoyment of life, relations with others, and sleep.

The BPI also allows patients to screen for 15 pain sensations characteristic with a YES/NO response. The PBI pain sensation characteristics are: aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, radiating, penetrating, nagging, numb, miserable and unbearable. It has a Cronbach's coefficient of 0.750 and Guttmann split-half coefficients of 0.726. BPI-PDN was revised and validated to assess patients with PDN (Zelman et al., 2005). A study in an African setting has evaluated the psychometric properties of a modified Brief Pain Inventory (BPI-DPN) for patients with painful diabetic peripheral neuropathy (Yoo et al., 2015). The Brief Pain Inventory-Diabetic Peripheral Neuropathy was used to assess pain intensity (worst, least, average, now) and pain’s interference with daily life (activity, mood, walk, normal work, relationship, sleep, enjoyment of life) pre intervention and post intervention (Yoo et al., 2015).

3.6.5 Data Collection Procedure

Before the data collection commenced, participants were informed of their rights (voluntary participation, can withdraw at any time, etc.). They were given an information sheet and a consent form to study and to sign. Before signing, any other questions they had were answered. After satisfying the inclusion and exclusion criteria, each participant was included in the study of phase

II (objectives 2–3) to elicit the needed response. The participants were asked to give a time and date that was convenient for them so that the session could be scheduled accordingly. Each participant in phase II with permission was asked to complete three instruments; the LANSS, SF-36, HAD and BPI-PDN forms based on each objective. A group of qualified clinicians and psychologists were recruited to assist with the administration of all the interventions (CBT and hypnosis) from the Department of Medicine and Behavioural Sciences of the Komfo Anokye Teaching Hospital (KATH). The motivation for including a team of professionals was to reduce errors and to cut down on the duration for training these professionals before the study. However, the Department of Behavioural Sciences, School of Medical Sciences, Kwame Nkrumah University of Science and Technology used two weeks to train all four professionals. The advantage of using professionals for data collection was: (1) It ensured accuracy and conformability in the usage of the instruments, (2) Because of their familiarity with the instruments, it reduced the time of administration.

3.6.6 Data Analysis for Phase II

The researcher checked whether all questionnaires had been received and ensured that they were valid and complete. Double data entry was conducted with validation in Epi data 3.1; and entered into the Statistical Package for the Social Sciences, SPSS® (version 22.0). Data was prepared by logging the data, making a codebook, entering the data into the computer, and checking for accuracy to eliminate errors (Trochim et al., 2016). The data was analysed using both descriptive and inferential statistics. Descriptive statistics provides meaningful summaries about the sample in order for potential patterns to emerge from the data (Longnecker & Ott, 2016). Summary tables and graphs were used to show the most relevant information (Gravetter & Forzano, 2016; Trochim et al., 2016). An ANOVA was used to determine whether there are differences in the effect of social and demographic variables on depression, anxiety and PDN for objective 2 (Trochim et al., 2016). It determines whether the independent variables (age, sex, marital status, employment, and educational background) are equal across specific dependent variables (depression, anxiety, and PDN) among patients with PDN (Maldonado & Greenland, 1993). Chi Square and Pearson’s Correlation analysis was used to determine the relationship between PDN characteristics and quality of life for objective 3 (Trochim et al., 2016).

3.6.7 Description and Properties of Inferential Analyses Tools

The inferential analyses tools utilized in this study are Pearson’s Correlation coefficient, Chi-squared Test of Association, Student’s *t*-test and ANOVA.

- **Pearson’s Correlation Coefficient**

The degree of association between any two quantitative (i.e., ratio or interval) variables is measured by a correlation coefficient (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015). There are different types of correlation coefficients in use. These include Pearson’s Correlation, Spearman’s Correlation, Kendal’s Tau Correlation, etc. The Pearson’s Correlation coefficient, sometimes called the product-moment correlation, of a sample is symbolized by r and that of a population is symbolized by ρ. The formula for calculating the product-moment correlation coefficient is given by

$$r = \frac{\sum(x-\bar{x})(y-\bar{y})}{\sqrt{[(x-\bar{x})^2(y-\bar{y})^2]}}$$

for any two quantitative variables x and y. This can also be shown to be equal to

$$r = \frac{\sum xy - n\bar{x}\bar{y}}{(n-1)SD_{(x)}SD_{(y)}}$$

where r ranges from -1 through 0 to +1. The closer r is to -1 and +1, the stronger the relationship is between x and y. This implies that as x increases by one unit in a direction, so y increase by one unit in the same direction ($+1$) or in the opposite direction (-1). As r gets closer to 0, we say there is no correlation. An assumption in the use of the Pearson's correlation coefficient is that the relationship between the variables in question (i.e., x and y) is linear. For a curvilinear relationship between x and y, Pearson's correlation coefficient does not apply (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015).

For the observed correlation to be accepted as significant, or by chance, an accompanying significance test will have to be conducted using the test statistic

$$t = r\sqrt{\frac{n-2}{1-r^2}}$$

at n-2 degrees of freedom, where r is the correlation coefficient and n is the sample size while t is the student-t statistic, while the '2' represents the two quantitative variables (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015).

The correlation between any two quantitative variables, x and y, could occur by chance. Where it is by chance, the accompanying t-test for a small sample indicates a significance level that shows how likely the observed relationship is by chance probably due to the form of random sampling error or some other human related error.

- **Chi-Squared Test of Association**

When one is interested in the test of association between two categorical variables, then two-way tables, also known as contingency tables, are best suited. It is also called a goodness-of-fit test. It is a type of statistical test called a "non-parametric" test. It is not based on the values of the variables in question, but rather on the frequency of some specific occurrences of observations in the data set. It therefore tests the frequency with which participants fall into a category, also referred to as the observed frequency (*O*), against some frequency expected in a category of the sample data based on the underlying characteristics of the population from which the sample was drawn, also referred to as the expected frequency (*E*) (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015).

The ***chi-square test statistic*** is computed as

$$\chi^2 = \sum \frac{(O - E)^2}{E}$$

where O and E are as defined above.

The underlying probability distribution is skewed and hence the alternative hypothesis is non-directional. This means that the null hypothesis, mathematically, cannot be stated as "not equal to". The distribution of the statistic χ^2 is **chi-square** with (r-1) (c-1) degrees of freedom, where the number of rows and columns in the two-way table are represented by r and c respectively. The chi-squared distribution is denoted$\chi^2_{(df)}$, where df is the number of degrees of freedom. The chi-square distribution is defined for all positive values. The resulting P-value of the chi-square test is given as P ($\chi^2 \geq \chi^2$), the probability of observing a value, at least, as extreme as the test statistic for a chi-square distribution with (r-1)(c-1) degrees of freedom.

- **Student's *t*-Test**

The Student's *t*-test, also simply referred to as the *t*-test, is a parametric statistical test of the null hypothesis for a single sample (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015). It is therefore a means by which we can determine the number of standard deviations (s) by which the score of a variable (x_i) is from its mean (μ) in a distribution. In other words, we use the student's t-test to test for the difference in mean for small samples drawn from populations or to test whether the mean of a small sample is greater or less than a specified value in the population.

The t-test statistic is given by

$$t = \frac{\bar{X} - \mu}{s_{\bar{x}}}$$

which is distributed as $t_{(n-1)}$ with (n-1) degrees of freedom, where

$$s_{\bar{x}} = \frac{S}{\sqrt{N}}$$

is the estimated standard error of the mean, and

$$S = \sqrt{\frac{(X - \bar{X})^2}{N - 1}}$$

is the unbiased estimator of the population standard deviation. It provides us with enough evidence to decide whether some differences that we observe in the sample data occurred by chance or not. As a parametric test, the Student's t-test must meet certain assumptions. The first assumption underlying the Student's t-test is that the population distribution of scores is symmetrical and that the data is quantitative (i.e., interval or ratio scale variable) and the population mean, μ, is known.

- **ANOVA**

ANOVA is a statistical test that is used in determining whether or not there is a difference between the quantitative measures between groups. The test statistic for the ANOVA is the F-distribution, which is the ratio of two Chi-squares. It is also, therefore, a non-symmetric distribution (Dean et al., 2017). The test statistic is given, using the computational formula, as

$$F = \frac{MS_b}{MS_w}$$

where MS_b is the mean of squares between groups and MS_w is also the mean of squares within groups (Jackson, 2009; Vanderstoep & Johnston, 2009; Ruppert & Matteson, 2015). The Mean of Squares between groups is computed as follows:

$$MS_b = \frac{SS_b}{df_b}$$

where SS_b, the Sum of Squares between groups, is given by

$$SS_b = \sum\left[\frac{(\sum X_g)^2}{n_g}\right] - \frac{(\sum X)^2}{N}$$

SS_b is the sum of squares between groups df_b is the degrees of freedom between groups ($=k-1$), n_g is the number of elements in group g.

The Mean of Squares within groups is computed as follows:

$$MS_w = \frac{SS_w}{df_w}$$

where SS_w, the Sum of Squares within groups, is computed by

$$SS_w = \sum\left[\sum X_g^2 - \frac{\left(\sum X_g\right)^2}{n_g}\right]$$

with N-k degrees of freedom (df_w)

while the Mean of Squares within groups is computed as follows:

$$MS_w = \frac{SS_w}{df_w}$$

The Total Sum of Squares (SST) is computed as $\sum X^2$ - $\frac{(\sum X)^2}{N}$ with N-1 degrees of freedom. Hence the (Total Sum of Squares) = (Between Sum of Squares) + (Within Sum of Squares).

- **Simple Linear Regression Analysis**

In Linear Regression Analyses, the objective is to establish the linear relationship between dependent (response) and independent (explanatory) variables.

Consider a linear regression model denoted by

$$Y = a + bX + \varepsilon$$

where Y is the dependent (or response) variable, X, the independent variable, a, the constant, also referred to as the intercept on the vertical axis, while ε is the error term. One very important assumption here is that the variables will never be perfectly related in reality, hence, there is always the error term ε. The total variation in the model is decomposed into two: the explained variation, which is accounted for by the independent variable, and the unexplained variation, which is unaccounted for by the independent variable, also referred to as the error term.

In the general linear regression model, our interest is to establish that the relationship between the dependent variable and the independent is linear and this is done by establishing the coefficient of the independent variable, where Y is the dependent variable, measured in units of the dependent variable, X is the independent variable, measured in units of the independent variable, and a and b are constants defining the nature of the relationship between the variables X and Y. The intercept

a is also referred to as the value of Y when $X = 0$, while the coefficient b is the slope of the line and is known as the regression coefficient and is interpreted as the change in Y associated with a one-unit change in X. The greater the slope or regression coefficient, the more influence the independent variable has on the dependent variable, and the more change in Y associated with a unit change in X (Harrell, 2015).

Coming back to the equation, we also have a term to capture the error in our estimating equation, denoted ε or e. Also known as the residual, it reflects the unexplained variation in Y, and its magnitude reflects the goodness of fit of the regression line. The smaller the error, the closer the points are to our line.

So, our general equation describing our regression line is:

$$Y = a + bX + e$$

The coefficient b, the regression coefficient, is the change in Y associated to a one-unit change in X. Hence the whole process of modelling a linear regression line is to establish the alternative hypothesis that

$$Ha\colon b \neq 0$$

In drawing our linear regression line, our aim is to minimize the distance between the points and our line. However, since we cannot minimize the distance between all the points simultaneously, we get a way of averaging the distances, which gives us a line of “best fit”. The approach here is to find the sum of the squared values of the vertical distance:

$$\sum \left(Y_i - \hat{Y}_i\right)^2$$

referred to as the Ordinary Least Squares (OLS). This has two very important characteristics:

$$1. \quad \sum \left(Y_i - \hat{Y}_i\right) = 0$$

$$2. \quad \sum \left(Y_i - \hat{Y}_i\right)^2 = \text{Minimum}$$

Hence to establish our simple linear regression model, Y = a + bX, we need to establish the alternative hypotheses that:

Ha: $b \neq 0$ and Ha: $a \neq 0$.

As stated above, the averaging of the distances is done mathematically with the formulae

$$b = \frac{\sum (Y - \overline{Y})(X - \overline{X})}{\sum \left(X - \overline{X}\right)^2} \quad \text{and } a = \overline{Y} - b\overline{X}$$

with the test statistics being

$$t = \frac{a}{se(a)}$$

and

$$t = \frac{b}{se(b)} \sim t_{n-1}$$

For a Multiple Linear Regression model, the general model looks thus:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_k X_k,$$

where β_0 is the vertical intercept while β_i are the coefficients of the explanatory variables (Harrell, 2015).

Hence the alternative hypotheses is to establish that

Ha: $\beta_i \neq 0, i = 1, 2, 3, \ldots, k$

with the test statistics being

$$t = \frac{\beta_i}{se(\beta_i)} \sim t_{n-k-1}, \qquad i = 0, 1, 2, \dots, k$$

3.7 Phase III

This phase of the study (objective 4) employed an experimental treatment design using a randomized control trial method to study a controlled and an intervention group. A randomized controlled trial (RCT) is a study in which people are allocated at random (by chance alone) to receive one of several clinical interventions (Chow, 2002). Refer to intervention Diagram 3 for the flow chart of phase III.

3.7.1 Objective 4

To evaluate the effect of the treatment of PDN with medication plus CBT plus hypnosis (HYP) compared to treatment with medication.

3.7.2 Research Design

The research design for objective 4 is an experimental research design embedded in a randomized control and intervention study. The study design randomly assigned participants into both the experimental group (Medication + CBT+ HYP) and the control group (Medication + CBT). This approach is usually appropriate when a researcher wants to measure the expected difference between the control and experimental groups in order to observe the outcome variable being studied (Müller et al., 2006).

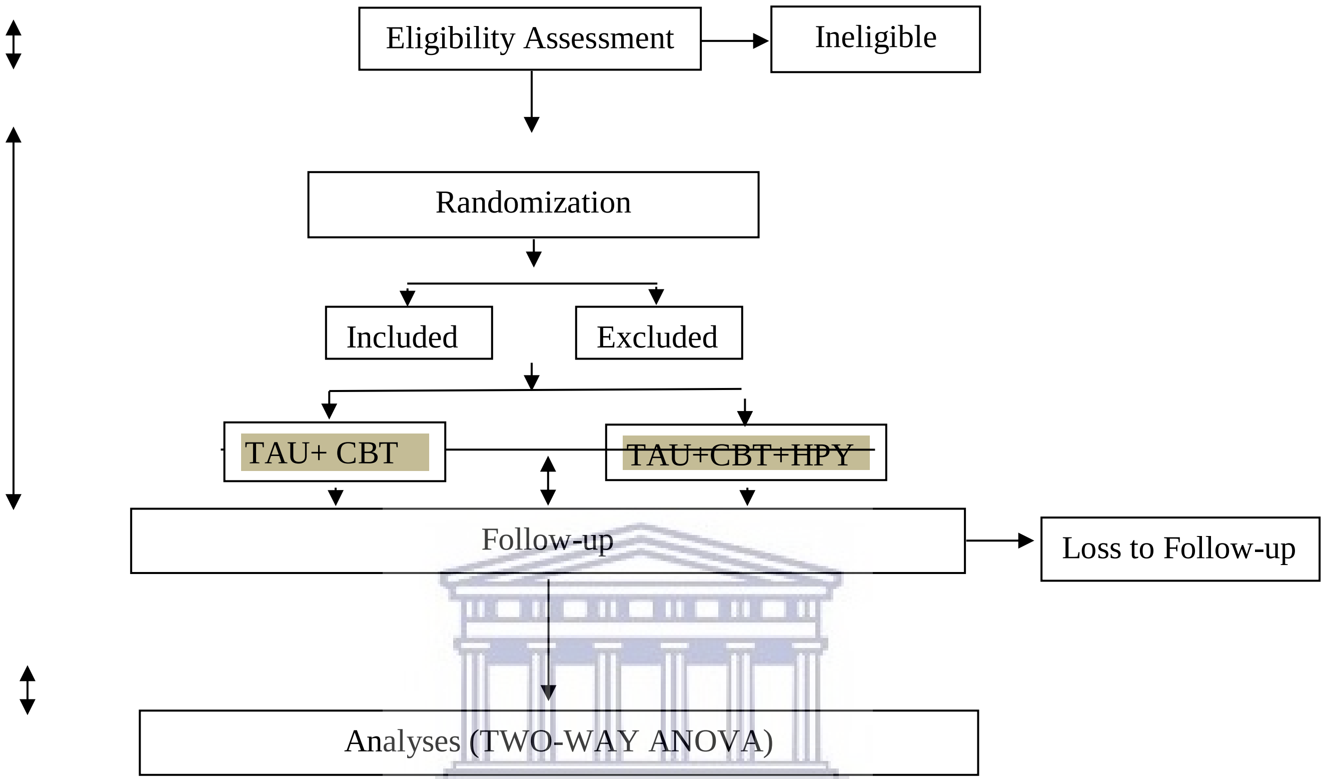
3.7.3 Research Setting and Sampling

The study area remained the Diabetic Clinic of the Komfo Anokye Teaching Hospital in Ghana. All participants in phase II who consented to be included in the study were included in phase III.

3.7.4 Procedure for group allocation of participants

Inclusion and Exclusion Criteria: All participants from phase II who were willing to remain in the study were included in phase III. Only adults who were 18 years and older were included in this study. **Allocation of intervention**: Participants were randomly allocated to either the study group, that is the group receiving the treatment under investigation (TAU + CBT + HYP) and the control group, or the group receiving the standard treatment (TAU + CBT). The randomization was done such that equal numbers of men and women were allocated to the treatment group or the control group, and the numbers of participants with severe pain (i.e., 7–10 on a 0–10 measure of average pain in the past week) and moderate pain (i.e., 5–6 on a 0–10 scale). Equal numbers of pieces of paper were labelled “treatment” or “control” (0 = treatment, 1 = control) put in a box and well-shuffled. Participants were made to draw from the box in order to determine which group they were to be placed in. Allocation into groups was by single blinding because researchers knew what group participants were in, but the participants did not know if they were in the control group or experimental group.

Diagram 3: Flow Chart of Study Design



Follow-up: All participants will be followed up for a period of 12 months. For each month of follow-up, data will be collected on a monitoring form, where the variables under study will be measured from baseline to final data collection. In the end, analyses were done to assess the effect of the intervention on the participants and to assess whether there was a significant difference between the factors under study across cases and controls.

3.7.5 Intervention and Procedure

Interventions were administered as follows:

I. Control Group which included participants who received **TAU + CBT only**

Treatment as Usual: participants at the start of the trial were given the standard medication (amitriptyline and duloxetine) for painful diabetic neuropathy and remained on the standard treatment for a period of six months.

Cognitive Behavioural Therapy: participants at the start of the trial received a CBT intervention within a six-month period. All participants receiving CBT were given a standard CBT for chronic pain adopted from the protocol used by Murphy et al. (2014) for pain management among veterans (see Appendix G). The cognitive behavioural therapy treatments consisting of 12 sessions were conducted by the same trained therapists as in phase II using a treatment manual indicated in Appendix G. Individuals participated in 10 weekly group sessions of 90 minutes each (Murphy et al., 2014).

II. Experimental Group which included participants who received **TAU + CBT + HYP** consisting of:

- **Treatment as Usual**: same as in the control group
- **Cognitive Behavioural Therapy**: same as in the control group
- **Hypnosis**: received one week of group training sessions in self-hypnosis and were monitored to apply the intervention within a three-week period. The hypnosis sessions were adapted from the work of Jensen et al. (2016).

Four individual sessions over a 4-week period were done (1 session per week; sessions were scheduled more or less frequently of 50–60 minutes each) (see Appendix H).

3.7.6 Data Collection Procedure

Data collection took place after one month, whereby data was collected from participants where the variables under study were measured from baseline before the intervention to final data collection after the intervention.

3.7.7 Instrumentation

The instrument was the Brief Pain Inventory for painful diabetic peripheral neuropathy (BPI-PDN). This inventory was administered to each participant in the study to elicit responses on their pain experiences. Responses were taken from each participant at baseline both before the intervention and after the final intervention.

3.7.8 Data Analysis

Double data entry was done with validation in Epi data 3.1 and analysis in SPSS® (version 22.0). After preliminary descriptive analyses, inferential analyses such as a two-way ANOVA was performed for objective 5. Summary tables and graphs were used to show the most relevant information which answers the research questions (Gravetter & Forzano, 2016; Trochim et al., 2016). ANOVA is a technique that assesses potential differences in a scale-level dependent variable by a nominal-level variable having two or more categories (Algina & Olejnik, 2003). Using a two-way ANOVA, the researcher can make interpretations between the pain characteristics measure after each intervention to determine which therapy significantly impacts pain intensity among diabetic neuropathic patients based on the aim of phase III (Rahn et al., 2008).

3.8 Ethics

Research ethics is concerned with the responsibility of researchers to be honest, authentic, and deferential to all persons who are affected by a research study (Gravetter & Forzano, 2016). Research ethics is not a matter of morality; rather, it involves the proper conduct of researchers. Basic rights of the participants include protecting them from any undue physical or psychological harm; strictly voluntary participation in the study through the process of informed consent and respecting the participants’ right to privacy and confidentiality (Leedy & Ormrod, 2001).

For this study, ethical clearance was twofold. The first level of ethical clearance was the institutional, where the University of the Western Cape requires that all students’ projects be ethically cleared for stringent ethical scrutiny prior to conducting research. After ethical application, the Biomedical Research Ethics Committee (BMREC) at the University of the Western Cape ratified and approved this project after all recommended changes were accepted. The second level of clearance was granted by the Research and Development Unit of the Komfo Anokye Teaching Hospital and the Research and Ethics Committee of the School of Medical Sciences, Kwame Nkrumah University of Science and Technology.

Respondents were required to sign an informed consent form prior to participation as evidence of their agreement to participate in the study as well as of their full understanding of the research procedures (see Appendix I). Trochim et al. (2016) describe informed consent as a policy of informing all study participants about the research procedures, risks involved, how the findings will be disseminated, and also to ensure that the participants give their consent to participate. Similarly, Gravetter and Forzano (2016), Rubin and Babbie (2016), and Shaughnessy et al. (2006) state that informed consent refers to human participants being given thorough information about the research and their roles and rights as participants before agreeing to participate. There are three elements for a consent decision which includes: information, comprehension, and voluntariness. To meet the information criterion, consent needs for research include: the purpose, procedures, risks, benefits, alternatives to participation, protection of privacy, contact information, and information about the right to withdraw at any time (Festinger et al., 2014).

The participants were also informed that medical personnel would be accessible if needed as a result of possible sensitivity or distress regarding any research process that they were involved in. Privacy is an indispensable element to human participation, which necessitates anonymity and confidentiality. Anonymity is the assurance that no one, excluding the researchers, will be able to connect the data to a specific individual response. This is done by attributing a number to each participant to keep all personal information concealed. Confidentiality is an agreement with study participants that information will be safe, private and not divulged to anyone outside the study (Rubin & Babbie, 2016; Shaughnessy et al., 2006; Terre Blanche et al., 2014; Trochim et al., 2016). Thus, the right to anonymity and confidentiality was established and respected throughout the research process. Data collection commenced once all of the forms were signed by the participants and all participants felt comfortable with the proposed procedures. All participants who provided consent were contacted to arrange interviews for data collection to commence.

All qualitative interviews were audio recorded with permission and transcribed verbatim to allow qualitative data analysis to commence. All of the documents were secured in a cupboard in a locked office. The acceptable guideline is that research records need to be retained for a minimum of five years; however, if research records are kept in a secure location, they may be kept indefinitely. The researcher also conducted a debriefing with all the participants in the study. Debriefing refers to the process of providing participants with full information about the purpose of a study and establishing how they experienced participating in the entire study (Jackson et al., 2007, Shaughnessy et al., 2006; Trochim et al., 2016). Respondents were offered a document which included a standard description of the study and why it needed to be conducted. They were also given the opportunity to have their data removed from the study, if they were not satisfied with what was disclosed and the manner in which it was disclosed. Participants were finally informed of the benefits of this study, the researcher and his supervisors' names, and the fact that they had the right to withdraw from the study at any point.

3.9 Triangulation of Phase I, Phase II and Phase III

Each phase of this study was presented as separate projects and was integrated and synthesized to present a more holistic view of factors that might have implications for adult patients (18 years and older) with PDN in relation to treatment options that might optimize their coping mechanisms through a combined intervention (i.e., medication, hypnosis, and CBT) (Mafuba & Gates, 2012). Triangulation aims to compensate for the weaknesses of one method by incorporating the strengths of another. Hence, the use of sequential multiple methods-design using a combination of qualitative and quantitative data to increase the volume of data on this phenomenon (Mafuba & Gates, 2012). Findings for each phase aim to bridge the gap in limited scientific evidence on the subject matter and to optimize treatment outcomes in the context of psycho-medical management and research into diabetes in Ghana.

3.10 Conclusion:

This chapter described the research design used as well as the research context in which the study was conducted. It provided a full description of the population, sampling used, data collection techniques for each objective, and the analysis process under three phases. A detailed account was provided of the ethics pertaining to the study and its trustworthiness. The chapter concluded with the method for triangulation used in this study. This next chapter presents the results of the qualitative study under three phases.

CHAPTER FOUR: QUALITATIVE RESULTS

4.1 Introduction

This chapter presents the results of the qualitative study. Phase I provides results under the sub-headings; General information on diabetes/PDN, qualitative self-assessment of the impact of PDN on diabetic patients, how PDN patients experience and describe their pain, participants' social/medical history of PDN, religious experience and PDN among diabetic patients, evidence of religious coping among patients with PDN, other coping methods among PDN patients, and evidence of financial burden among PDN patients.

4.2 Objective 1 PHASE I (QUALITATIVE)

The objective of phase I was to explore the experiences of patients with PDN and their use of personal beliefs as a coping mechanism.

This phase presented the qualitative data that emerged using thematic analysis. A total of 30 PDN patients who reported to the Diabetic Center of Komfo Anokye Teaching Hospital (KATH), Kumasi, for regular and referred clinics were recruited for this study. Qualitative research is inductive and generally explores connotations and understandings in a given condition (Corbin & Strauss, 2008; Levitt et al., 2017). It refers to a range of data collection and analysis techniques that use purposive sampling and semi-structured, open-ended interviews (Dudwick et al., 2006; Gopaldas, 2016). The study adopted the case study approach to understand and appreciate the experiences and personal beliefs of PDN patients attending the clinic.

According to Creswell (2013), a case study "explores in-depth a program, an event, an activity, a process, or one or more individuals". Hence the structure of a case study should comprise the problem, the context, the issues, and the lessons learned (Creswell, 2013). Sagadin (1991) stated that "A case study is analysing and describing each person individually for his/her activity, special needs, life situation, and life history (Sagadin, 1991). According to Helen Simons, a case study is an in-depth exploration from multiple perspectives of the complexity and uniqueness of a particular project, policy, institution, programme, or system in a real-life situation (Simons, 2009). The case study, in this regard, considered the multiple perspectives of the complexity and uniqueness of PDN patients’ purposefully vis-à-vis their experiences and personal beliefs as a unit.

4.2.1 Demographic and Social Characteristics of Participants

The study purposively selected a total of 30 respondents for this exercise, of which nineteen were females and eleven males. The youngest respondent was 24 years old while the oldest was 77. Regarding marital status, two (2) participants were single, 23 were married, and (5) five (one female and four males) were widowed. Regarding the level of education of participants, three (3) had either no education or had only completed primary, 24 had either completed Junior Secondary or Form 4, while three (3) had completed post-secondary education. In terms of economic status, the respondents were presented with three levels of economic status (Low, Medium, and High) in order to establish to which of them they belonged, subjectively. The majority of the respondents (i.e., 20) had a low financial situation while ten of them had a middle-class status. There was, however, no respondents with an upper-class status. On current health status, three of the respondents indicated that they had poor health status 13 indicated a fair health status, 10 indicated a good health status, and four indicated that they had a very good health status. On their family history of PDN, 23 respondents, representing 76.7 %, said that at least one family member had pain.

4.2.2 Qualitative Results

This study provided a qualitative insight into the role of personal beliefs and coping mechanisms for PDN among patients. The qualitative results pointed to Nine main themes; (1) General information on diabetes/PDN (e.g., Knowledge and perception of patients regarding diabetes (sad moments or proud moments), (2) Qualitative self-assessment of the impact of PDN on diabetic patients, (3) How PDN patients experienced and described their pain, (4) Participants' social and medical history of PDN, (5) Religious experience and PDN among diabetic patients, (6) Testimony of religious coping among patients with PDN, (7) Other coping methods among PDN patients, and (8) Psychosocial Implications of PDN (9) Evidence of financial burden among PDN patients.

Themes	**Titles**
Theme1:	General information on diabetes/PDN
Theme 2:	Qualitative self-assessment of the impact of PDN on diabetic patients
Theme 3:	How PDN patients experienced and described their pain
Theme 4:	Participants' social and medical history of PDN
Theme 5:	Religious experience and PDN among diabetic patients
Theme 6:	Testimony of religious coping among patients with PDN
Theme 7:	Other coping methods among PDN patients, and
Theme 8:	Psychosocial Implications of PDN
Theme 9:	Evidence of financial burden among PDN patients

4.2.2.1 Theme 1: Ability to Share General Information on Diabetes and PDN

In this study participants were asked about their knowledge of or general information on diabetes/PDN. Most of the participants appeared to lack adequate information as many did not know their diabetic type or what caused their diabetic state (i.e., how they got diabetes). This is similar to studies by Moosa et al., (2019): Karaoui et al., (2018) which indicated that patients lacked sufficient knowledge regarding their diabetic status. However, some of the participants could describe their diabetic symptoms. Most of the participants could not give the exact date of the onset of their condition, and lacked in-depth knowledge of the complications. with PDN. This findings is similar to Obirikorang et al. (2016) who aimed at determining the knowledge of diabetic complications among DM patients at Sampa Government Hospital, Ghana, and revealed that participants knew the individual complications of DM but lacked in-depth knowledge of the complications. On the contrary to this study, some research in a similar environment on the knowledge of patients on diabetes by Kugbey et al., (2017); Kpekura et al. (2018);Tabong et al., (2018) demostrated that most participants seemed to know their diabetic type.

Significantly in this study, most participants did not know that the lack of insulin in the blood caused their diabetic state. While most of the respondents could relate their diabetes status to the inevitable rise of sugar in their blood, some attributed it to the probable intake of raw sugar. Participants also did not know about PDN and what causes it. However, participants could describe their pain experience as neuropathic.

The following quotes illustrate these points:

> "*I don't know the type of diabetes I have. Does sugar cause diabetes? I even wanted to ask what causes it. No one has taught me what brings about the disease. I know it can bring a stroke, but I don't know what causes it. I have heard of insulin. I've even stopped drinking alcohol because of this*" (Participant 14, Female).

> "*No, I don't know the type of diabetes I have. I don't also know there are types of diabetes. I don't know the number of years I have had diabetes, for about 20 years. It has made life difficult for me, but I don't think so much about it. There are some things I could do but I won't over-do it. Since I had diabetes, I haven't been able to go to work. The strength I was using to work has reduced significantly. Yes, I feel sad sometimes. I will ask that: I don't know how I got diabetes, so I feel sorry for myself. When I'm alone in my room, I*

> *always ask myself how I got this disease. No, I don't know the name of the drug. Whenever I get weak and restless, I blend herbs and drink it like water*" (Participant 12, Female).

> "*When it started, I didn't know I had it. I lost a lot of weight, and at night I used to drink a lot of water. I also peed a lot, but I didn't pay much attention to it. Later I heard on the radio that when you pee and taste it and it's sugary or you check where you peed and there are ants it means that disease. I tasted my pee and realized it was sugary. I also noticed ants wherever I peed, and that was when I went to the Clinic. My sugar level was 17, and I had lost significant weight. I started going to the hospital*" (Participant 6, Male).

> "*I don't know how I got diabetes because my parents and siblings don't have diabetes*" (Participant 19, Male).

Due to limited or lack of knowledge of diabetes and PDN, some participants did not know that their eating habits, such as consistent dependence on carbohydrate diets, precipitated their diabetic symptoms, thereby progressing to PDN (Bruno & Landi, 2011; Bertram et al., 2013; Okur et al., 2017; ADA, 2019). In addition, some participants did not know that their status was permanent. However, one respondent was able to recount some facts about PDN being incurable, While another claimed to have been taught about diabetes and could demonstrate some knowledge of the condition.

> "*Doctors have told me that diabetes is a fatal disease. So I have to take care of my diet, the food I make. It doesn't mean that when you have diabetes, you can't work, you need to. That's what they told me. They also said to me that the food we eat could turn into sugar and taking in sugar doesn't cause the disease*" (Participant 30, Female).

> "*I know about diabetes. The nurses have taught me what to eat. I know diabetes is caused by sugar when the sugar is more. Every food we eat contains sugar. I don't see the type of diabetes I have. When you don't have insulin, sugar can accumulate and cause diabetes*" (Participant 21, Female).

Most participants in this study did not know the type of medications prescribed by their doctors for the PDN condition and demonstrated little or no knowledge about their medicine. Participants also expressed the need to have potent drugs that could manage their pain more effectively. Furthermore, participants trusted their doctors to give them the right medication and therefore did not think it necessary to ask about their medication, thus they did not show any interest to know about their medication.

> "*I don't know the medications I'm on. I know for one of the medicines I have to wait for ten minutes before I take the other one. I know I have to eat before I take them. The medications work. Whenever I don't take medicine, my sugar level goes up. I was taking the herbal remedy, but I stopped a year ago*" (Participant 25, Female).

> "*When it comes, I buy medications to reduce pain. Some time ago, during a doctor's visit, I complained about it, and remedies for me. Some of the drugs I had to put them in water. I don't know the names of the drugs but if it works for me I'm happy. But when I also get a much more powerful medication, I shall also be satisfied*" (Participant 4, Male).

4.2.2.2 Theme 2: Self-Assessment of the Impact of PDN on Diabetic Patients

On the self-assessment of PDN, participants were asked to assess themselves and describe the impact of PDN on their daily functions and quality of life. They assessed their pain as mild, moderate and severe. Most participants were able to discuss the implications of PDN on their everyday life, expressing various adverse health outcomes including restricted movements, hyperglycaemia, feeling of sadness, crying, body weakness, and inactiveness(Al-Thani, Sathian, & El-Menyar, 2019; Al-Sahouri et al., 2019; Srisanthanakrishnan & Shah, 2016). However in this study other consequences included suicidal ideation, suicidal attempts, paralysis, eye problems, and tooth problems.

In this study participants (both males and females) complained of their inability to maintain a regular sex life though they lived with their spouses. They claimed they were unable to engage in and enjoy sex because their consistent pain frequently caused agony. The male participants claimed that whenever they attempted to engage in sexual activity, they were unable to have an erection. Similar to this finding, marital disruption and sexual malfunctioning were identified by Cano et al., 2004 and Sofaer-Bennett et al., (2007) as having a significant debilitating effect on PDN by both male and female participants.

> "*Since the disease started, my wife has refused to have sex with me. I complained to church authorities, and she says her friends are telling her it can affect her too if we do so and I was wondering if it's true. Yes, the pain has changed my life in a lot of ways. An example is when I want to have sex with my wife; I can't have a lasting erection. Also, my waist is always hurting and my knee*" (Participant 19, Male).

> "*I sleep, and she wakes me up for sex, but when I start, I don't have an erection. You know women if you don't have sex with them, they get angry. Diabetes is a disease which when you get, you get into a lot of complications. It can come at any time and go at any time. None of these reasons is good*" (Participant 18, Male).

While some female participants claimed a similar lack of interest for sex, they added that their husbands were unhappy and some had pursued other women to satisfy their sexual desires. Others also claimed that their lack of interest in sex had led to separation from husbands or partners and some participants even experienced divorce, resulting in single parenting.

> "*Due to my waist pain, I haven't had sex with my husband for over five years, but he is alive. This sickness makes me feel sad because whenever I come to the Clinic, I feel exhausted. I have to sit down for some time, and also I see other people such as children who have diabetes, and this makes me feel sad too. As they are always saying if you are not careful about your diet, diabetes will take a longer time before it disappears out of the system*" (Participant 23, Female).

One participant remarked that she was of the view that being a single parent with PDN was difficult because of the burden of raising her children alone while at the same time managing her condition. She had, therefore, resorted to sleeping with men in order to buy her medications and move on with her life.

> "*I was once married, and I divorced with four children. I completed form 4. I don't have any help from anywhere. Right now, what borders my religious life is fornication. I am in difficult hardship, and that is why I do that. I can't buy my drugs if I don't do so. I am guilty. My man divorced me when he saw that I had diabetes. He said he couldn't be with me anymore. I asked him; what have I done for him to tell me he doesn't want to be with me any longer? He said I hadn't done anything wrong. He just can't be with me*" (Participant 20, Female).

4.2.2.3 Theme 3: Experience of PDN and Pain Description

Concerning participants' experience of pain, most described their pain as being a tingling sensation, sharp pain, burning feet or fingers, and swollen feet (Bouhassira et al., 2008; Bouhassira et al., 2013; Abraham et al., 2018). In this study participants complained of waist hurting, intense pain from thigh to the leg, pain under legs, joint pains, flare sensations in the fingertips, dizziness, or sleeplessness. This is similar to studies which reported that PDN patients complained of being sensitive to touch and felt intense pain whenever an object touched certain parts of their feet or fingers (Tavakoli & Malik, 2008; Callaghan et al., 2012; Colloca et al., 2017; Quattrini & Tesfaye, 2003).

> "*It's been 28 years since I got this disease. When it comes, I pee a lot, and I become weak. I live with my children. I feel tingling sensations in my leg, and sometimes I feel a sharp pain. When I experience this sharp pain, I put salt from Ada into warm water in a bucket and place my legs in it. Sometimes I get swollen feet, so when I do this salted warm water, by morning, it would have subsided. My leg has also become sensitive to touch. Since it came some 28 years ago, the swollen feet are a recent development. It wasn't there before. My waist used to hurt a lot. It started six years ago. Right now, what bothers me is my leg. The sharp pain travels from my thigh to my leg. I'm unable to work because of this. Whenever I walk any short distance, I get fatigued. I feel sharp pains in my leg such that whenever I walk any short distance, I have to stop and rest. Whenever I get the chance to sit, I take it, but if there is nowhere to sit, I stand till I'm ready to move on*" (Participant 4, Female).

> "*My toes hurt especially the part that enters a shoe. I feel a burning sensation, and sometimes it feels numb. I also feel a burning sensation within my feet. It feels like there*

> *are needles in my feet and sometimes it feels like there is an animal in it biting me. I don't feel any pain when my leg is touched. I just feel it deep within my foot. Sometimes the bone hurts. I can't walk barefooted*" (Participant 6, Female).

Some participants also complained of constant urination, tummy aches, knee pains, lower back pains, numbness, chest pains, and pulling nervous sensations.

> "*My leg gets numb and my fingertips sometimes, especially when I work. I'm a building contractor, and my fingertip sometimes closes by itself. When it comes, when an object touches it, I feel no pain. Sometimes it happens to both my feet and fingers at the same time, and I have to wait for 30mins or an hour before it stops. I feel a lot of pain. When it comes, there is this pulling effect from the nerves within my feet and fingertips. It feels like there are pins and needles in my feet and fingertips. Yes, I believe diabetes is from witchcraft. If you look at how it comes about, it is possible. For me, it started by peeing a lot, and after a week I started experiencing tummy ache whiles bathing, so I pooped in the bathroom, and after bathing as I was leaving the place, I fainted. That day I had peed about 15 times*" (Participant 21, Female).

> "*I felt uneasy. I was having burning sensations in my leg, and it started two weeks ago. As I'm sitting right here, I'm still having burning sensations, and it feels as if someone has smeared hot ointment on it. My feet feel numb. When I'm walking, I lack the energy to walk. Yes, the power I used to have at first is not the same energy I'm having right now. If I take a walk, I get tired quickly. I also can't walk as fast as I used to*" (Participant 31, Male).

4.2.2.4 Theme 4: Biological, Social and Medical History of PDN

Regarding the social and medical history of participants, many of participants said they were aware of family members who had diabetes and had complained of severe pains. Hence, they believed that their condition could be genetic as indicatted in similar studies (Dorman & Bunker, 2000; Radha et al., 2003; Rich et al., 2006; Rich, 2017). When asked whether participants had any other previous diseases before PDN, they generally mentioned diseases conditions such as hypertension, obesity, severe headaches, asthma, and stroke (Madigan et al., 2005;). However, when asked whether participants currently had any other condition apart from PDN, they listed waist pain, prostrate conditions, low sex drive, poor vision, body or private part itches, and breast pain (Piette & Kerr, 2006).

> "*My mum and two sisters have diabetes, so I think it is in my family. Before I had diabetes, I had hypertension and prostrate, but after condition, I have severe headache and body pain*" (Participant 17, Male).

> "*I don't blame God because my biological mum had the same disease and my eldest son got it, but because he's young and exercises, he doesn't take a lot of medications as I do now. I don't believe it's any witchcraft causing this disease because this disease is in my family*" (Participant 4, Male).

4.2.2.5 Theme 5: Religious Experience and PDN

Regarding the causes of their condition, most participants were of the view that the root cause of PDN was spiritual and were of the opinion that they might have contracted it because they were bewitched or that some supernatural forces caused them to have this condition. This is similar to studies which reports that religion and spirituality can be significant factors in handling the difficulties of emotive care and glycaemic control among patients (Esteghamati et al., 2008;

Namageyo-Funa et al., 2015; Rivera-Hernandez, 2016). However a primary view shared by many participants in this study was that their diabetic situation was a bewitchment or punishment from close relatives or people who took an interest in their lives.

> "*I got it first followed by my elder sister and my cousin also got it. After two or three years, the disease struck me again and continued for four years. It halted all my progression, so now I'm broke. I spent a lot of money, so I lost all my capital due to my frequent hospital visits. You know we as Africans, we believe everything is spiritual, so I lost all my money. When the disease struck me, my uncle came for me thinking I had snatched someone's wife, had been cursed, or taken someone's money. I went to shrines, but when I got there, I didn't like it but because of the severity of my illness. I even informed my mum that a shrine isn't a place I should go and that I don't believe in that. Whenever they were performing their rituals, I used to laugh. Later, I left the place. They told me someone cursed me and they had to reverse it. I spent about 5 thousand Ghana Cedis (US$1,000) there. My mum had a plot of land, and there was a big tree on it. And a certain carpenter cut down the tree for use. The carpenter refused to pay my mum, and I went to him to confront him. I sent police officers to arrest, and when he came to beg, I informed him I didn't want the rest of the money, and he should go for the rest of the wood. The carpenters cursed me with a river close to the plot of land. The fetish priest even mentioned the carpenter's name. I almost died after this happened. The disease became severe. I stopped my medications because I was seeking spiritual direction*" (Participant 6, Male).

In this study, the three most dominant religious affiliations among the participants were Christianity, Islam, and African Traditional Religion. All three religious categories were requested to relate their condition to their faith and explain/describe how their religious affiliation had impacted their health and social life. The consensus among all three religious groups was that their faith had played a significant role in how they understood and managed their condition. This was because their religious practices helped them to rely on God for all their needs, including alleviating their pain. However, the understanding of their pain circumstances and its source differed among these groups. For example, Muslim participants in this study believed their pain comes from Allah, while the Christians claimed their pain was the work of the devil.

For instance, a Christian recounted as follows:

> "*Initially, when this disease started, I could cry but after all the teachings of the church that this disease can stay with you when you take good care of yourself. Some people get headaches and die so if you take good care of yourself, you will live long to the age God has purposed for your life. From that time, I have let go of that sadness that I can die. The church hasn't said anything regarding where the disease came from into my life. There is nothing too hard for God to do. As for me, I keep praying to my God because He brought us to this world and if it's food and drink that brought this is up to God or if the disease is from the devil, in all only God can fight this battle for me. It is my prayer that I live my life*" (Participant 7, Male).

A Muslim respondent also explained as follows:

> "*I'm a Muslim. I always pray to Allah that he brought this illness, and only He can heal me. All my family members are Muslims apart from my younger sister called Memuna. I have a strong relationship with God that any time I call on Him, He responds. I believe that God can heal me with the help of doctors. Whenever I'm about to take my medication,*

> *I ask God that He said we should take medications when we are sick, and it's the healer of all our diseases then I take the medication with water*" (Participant 16, Female).

The non-Christian and Muslim participants also believed that supernatural powers could have caused their condition. Others explained that their situation was as a result of their wrongdoing:

> "*I know it's not because of my evil ways that brought this disease. I thought someone might have sinned that is how come people in the family were getting the disease*" (Participant 17, Male).
>
> "*Sometimes you may think it's because of a crime or you have offended someone. My uncle said it's because of my mum's sins that why I got diabetes*" (Participant 26, Male).

However, two of the 30 participants were of the view that diabetes and PDN were a result of natural cause and did not attribute it to a spiritual cause. Their statement was captured as follows:

> "*No, if someone tells me someone is bewitching me, I even quarrel with the person. God is the one who created me, and he knows how I got my disease. It's not someone who is bewitching me*" (Participant 22, Female).
>
> "*I've never thought anyone had charmed me. As soon as I opened the gate, I fell. Three days ago, when I was bathing, I was shaking. I feel dizzy, and my feet get swollen. It hurts, and there is this burning sensation within and around it. Every time it burns. Sometimes I think a sharp pin-like pain. When I touch it, I don't feel the pain. It feels like pins and needle. It can come at any time. When I'm walking, I feel like I've stepped on a needle, so I have to pause before I continue*" (Participant 26, Male).

4.2.2.6 Theme 6: Testimony of Religious Coping among Patients with PDN

Almost all participants claimed that, when they were in pain, they prayed to God and trusted God to help them overcome their illness (Newlin, 2003; Newlin et al., 2008; Park, 2007; Cattich & Knudson-Martin, 2009; Devlin et al., 2006; Gupta & Anandarajah, 2014; Underwood & Teresi, 2002; Amadi et al., 2016). However, in this study respondents claimed they sang hymns and praises to forget their pain. Significantly, some participants were of the view that it was their prayers to God that was sustaining them even though they came to the hospital regularly for their pain medications.

> "*Whenever the pain comes, I pray to God to take away this illness, and I always trust God to help me out of my misery*" (Participant 2, Male).

> "*I'm a Presbyterian. I always pray about it. Whenever I wake up at dawn and pray, I tell God that He's my strength and He brought me into this world, but I am now sick, and He's a prayer-answering God. If I wake up, walk, I lift my life to him. Some people, doctors cannot diagnose them, and they die, but my situation God has made my diagnosis known and He's the most exceptional doctor. My interaction with God is that whatever you say and ask God from the bottom of your heart that is how He will use it to help you. It has never occurred to me that anyone caused it. Whenever you do that, you allow those people to have power and feel rewarded for doing such things. I don't think its God's doing this has happened. I always use Job's story. He was very close to God, but Satan tried to use this to discourage him, but he kept his faith, and he was able to overcome Satan. My condition makes me rely on only God. For my work, since the doctor diagnosed me, I make sure I do everything with caution. It all comes down to God's word. You have to follow God's word. I believe that all churches follow God's word, so the name you take and apply*

will always encourage you even when you are sad. The more you pray you get encouraged" (Participant 5, Male).

"*I'm a Christian. I'm a member of the Church of Pentecost. I believe that everything is God. I lost much money due to the illness, and God restored me because before, I didn't have even ten pesewas due to this illness but when He restored me, now I'm ok. I held on to my faith. A believer is someone who believes in God and whatever happens whether good or bad he/she trusts God to deliver. He/she doesn't rely on their strength. I have an excellent relationship with God. I never miss church. God helps me through all the pain. Paul could raise the dead, but he had his issues*" (Participant 6, Male).

"*The way I am, I didn't have that in mind that this is from a spiritual source. If I wasn't a good Christian, I might have thought about that because of the level I see God. I didn't know God brought me this disease. Yes, even now, I continue to pray and ask God to heal me. Yes, I believe in God. Yes, I think that my faith has had an effect, and it has helped me through tough times. If not for the confidence I have, this would have put me down. How come God has allowed me to have this sickness? People may say how come God allowed a person with strong faith to get diabetes. I will tell the person that I believe and trust God. My belief isn't because I'm a pastor's wife. No, it's not because I believed in him that's why I became a pastor's wife. What I know is that one day, as he told Jeremiah that he has plans for him. Yes, I have a strong relationship with God. It has helped me to face the test of time because I didn't find it easy from the beginning*" (Participant 29, Male).

4.2.2.7 Theme 7: Other Coping Methods for PDN

Participants also mentioned other coping methods used to relieve them from their PDN crises. These coping methods included watching television, placing both feet in warm water, rubbing with ointment, and taking herbal medication as reported in other studies (Modak et al., 2007; Preethi, 2013; Kumar et al., 2015). Almost all participants indicated that they had either bought herbal preparations previously, been introduced to a herbal product, or had visited a traditional medicine practitioner for a cure (Modak et al., 2007). Similar to Damnjanovic, (2015). participants in this study turned to self-medication and medicinal plant preparations when in pain.

> "*When that happens, I set my feet in hot water, and it helps. Ok, I will put it in lukewarm water*" (Participant 25, Female).

> "*I watch the television to help relieve the pain*" (Participant 29, Female).

4.2.2.7.1 Theme 8 Psychosocial Implications of PDN

Most participants complained of various of psychological challenges that invariably exacerbated their pain and, more especially, interfered with their daily lives (Beckman et al., 2002; Borgnakke et al., 2013;Tinetti et al., 2012; Sudore et al., 2012). The main challenge raised by participants was the feeling of depression anxiety and quality of life because of the diabetic condition. These findings are similar in studies which indicates that depression and anxiety are the most dominant psychological crises among PDN patients (Chireh et al. 2019; Galer et al., 2000; Bouhassira et al., 2013; Davies et al., 2006; Gore et al., 2005; Vileikyte et al., 2005; Van Hecke et al., 2015; Themistocleous et al., 2016; Bai et al., 2017; Geelen et al., 2017)

> "*Sometimes I feel sad about life because I wasn't like this. The disease has affected me because I used to do the pawpaw business, but now I can't anymore*" (Participant 3, Female).

> *"This disease has caused a lot of harm because I used to be very strong and I could go trade in goods. Ever since this disease came, I can't go anywhere. I always think about this*

> *disease. You can imagine me getting this when I was a baby. So I use to think a lot and I get sad too. If I were strong, I would have been able to help take good care of them. When I got this disease, I got unfortunate*" (Participants 5, Female).

> "*I always say that this disease is what will slow me down as I grow. My condition makes me sad that I can't walk. This disease, combined with the ulcer made things worse for me. My sugar level went low, and my family took me to St Theresa's hospital. According to them, I was shaking because I wasn't taking the medications the right way. The reason why I was doing that is that I heard if you keep taking the pills, the side effects of the drug could be cancer. After hearing this, sometimes when I think about it, it makes it difficult to choose the medications. As for me, I know that if it's in your family, you can get it. It's in the blood because my dad was diabetic*" (Participant 20, Male).

> "*This disease has caused a lot of harm because I use to be very strong and I could go trade in goods. Ever since this disease came, I can't go anywhere. I always think about this disease. You can imagine me getting this in my youthful days so I use to think a lot and I get sad too. If I were healthy, I would have been able to help take good care of them. When I got this disease, I got despondent*" (Participant 25, Female).

A male respondent complained that his wife refused to have sex with him and assumed that friends had advised her that if she sleeps with her husband, she will be infected with the diabetic condition.

> "*Since the disease started, my wife has refused to have sex with me. I complained to church authorities, and she says her friends are telling her it can affect her too if we do, so I was wondering. Yes, the pain has changed my life in a lot of ways. An example is when I want*

> *to have sex with my wife, I can't have a lasting erection. Also, my waist is always hurting and my knee*" (Participant 6, Male).

4.2.2.8 Theme 9: Evidence of Financial Burden and PDN

An important observation among participants were complaints about their inability to afford their pain medication or use them regularly because of financial burden (Hart et al., 1997; ADA, 2019; Barcelo et al., 2017; Kirigia et al., 2009; Gray et al., 1995; WHO, 2000; WHO, 2019). Participants also complained of economic hardships and their inability to buy their pain drugs. These financial problems had increased their pain and they were not able to cope (Zhang et al., 2010).

> "*I'm not working at the moment. My sibling who helps me has lost his job. In the past three months, he has given me GHC 100.00. If he doesn't give me money, sometimes I get the money from people. Yes, please. I have no hope. The past three days, I told the Lord I was going through a lot of difficulties*" (Participant 4, Female).

> "*The financial burden on me sometimes makes me think a lot because my husband is the man of the house now cannot work and myself right now I can't work either. We are both sick and cannot do hard labour, so It's hard. Right now, my biggest worry is money*" (Participant 1, Female).

> "*Right now, I don't work, and none of my kids has good jobs, so if I fall sick that will take care of me. If the doctors admit me to the hospital, how will I be able to pay my bills? As a man, what makes us happy is to have enough money to provide for your wife and also to provide food for the two of you. When all these things aren't available, it makes you sad*" (Participant 2, Female).

4.3 Conclusion

This chapter presented the results of the qualitative study under the following sub-themes: General information on diabetes/PDN, qualitative self-assessment of the impact of PDN on diabetic patients, How PDN patients experience and describe their pain, participants social medical history of PDN, religious experience and PDN among diabetic patients, evidence of religious coping among patients with PDN, other coping methods among PDN patients, psychosocial implications of PDN, and evidence of financial burden among PDN patients. The next chapter presents the results of the quantitative data collected in phase II.

CHAPTER FIVE: QUANTITATIVE RESULTS

5.1 Introduction

This chapter presents the results of the quantitative data collected in phase II. It begins with a presentation of objective 2, which is a presentation on the differences between participants' socio-demographic characteristics and depression, anxiety and PDN severity. The relationships between specific PDN characteristics and quality of life domains are discussed in objective 3, while objective 4 considers the evaluation of TAU plus CBT plus HYP compared to CBT plus TAU only.

5.2 PHASE II (Quantitative)

Statistical analyses were used to explore the relationships between specific PDN characteristics and participants' quality of life to determine differences between participants' socio-demographic characteristics and specific PDN characteristics as well as their quality of life and examine the relationships between their hypertension and PDN intensity characteristics.

5.2.1 Quantitative Results

5.2.1.1 Objective 2

The aim of objective 2 was to determine whether there was any statistically significant difference between the effects of socio-demographic variables on depression of PDN patients and the effects of socio-demographic variables on anxiety of PDN patients.

Descriptive:

The majority of respondents were females (86.4%), and all 125 respondents interviewed answered this question (Table 5.1). Of these, just under half were married (45.6%), while around 20% were either divorced or separated, and almost 30% were widowed. The rest were single (Table 5.1).

Regarding educational status, 24.0% had no form of education, the largest group had completed only primary education (34.4%), followed by those who had completed Senior High School (26.4%). Only 15.2% had completed at least a tertiary education. (Table 5.1).

Table 5.1: Sex, Marital and Educational Status of Participants

	n	%
Sex participant		
Female	108	86.4
Male	17	13.6
Total	125	100.0
Marital Status of participants		
Single	6	4.8
Married	57	45.6
Widowed	37	29.6
Separated/Divorced	25	20.0
Total	125	100.0
Highest Grade of education Completed		
None	6	24.0
Primary	43	34.4
JHS	24	19.2
SHS	33	26.4
Tertiary	19	15.2
Total	125	100.0

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

A little over half of the respondents (54.4%) had a normal anxiety score, followed by around 23.2% who had an abnormal anxiety score. The rest were on the borderline. A majority of respondents (57.6%) had a normal depression score, while, around 23.2% had an abnormal depression score and the rest had a borderline depression score. On the effect of neuropathic mechanism on a patient’s pain, a large majority of respondents (82.4%) reported that it was likely to contribute to their pain (see Table 5.2).

Table 5.2: Anxiety, Depression and Pain Scores

	n	%
Total Anxiety Score		
Normal	68	54.4
Borderline case	20	16.0
Abnormal Case	35	28.0
Total	123	98.4
Total Depression Score		
Normal	72	57.6
Borderline case	22	17.6
Abnormal Case	29	23.2
Total	123	98.4
Effect of Neuropathic mechanisms on patient's pain		
Unlikely to be contributing to pain	22	17.6
Likely to be contributing to pain	103	82.4
Total	125	100.0

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

The ages of the respondents ranged between 32 and 98 years old , with a mean age of 58.8 years (Table 5.3). Respondents were asked when they were diagnosed for the first time as being diabetic. This was done in order to understand their situation, particularly for how long they had endured their diabetic condition. The aim was to assist the researcher to appreciate their responses and understand the extent to which the answers were attributable to the respondents' experiences of their PDN situation. The minimum time of diagnosis was less than two months before the interview, while the maximum was 35 years ago, with a mean of almost 11 years. The respondents' depression scores ranged from 0 to 19, with a mean of 6.59, while their anxiety scores ranged from 0 to 20, with a mean of 7.26. This implies that while, in general, the respondents were a little more anxious than they were depressed, there were some who were not depressed and others who were not anxious despite their diabetic situation.

Table 5.3: Descriptive Statistics on Age, Highest level of education, duration since first diagnosis, Depression and Anxiety Scores

	N	Minimum	Maximum	Mean	Std. Deviation
Current Age	125	32.00	98.00	58.81	12.88
How long since first diagnosis	119	.17	35.00	10.86	8.48
Depression Score	123	0.00	19.00	6.59	4.86
Anxiety Score	123	0.00	20.00	7.26	5.05

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

On a pain scale of 0 to 10, where 0 meant no pain at all and 10 indicated the greatest pain, respondents were asked to determine, subjectively, the level of the pain they felt the week before the time the data was collected (Table 5.4). The mean score of their pain was 4.0, with a standard deviation of 2.97. The mean score of the extent to which pain had interfered with their general activity in the week prior to the time the data was collected was 4.5, with a standard deviation of 3.11. Similarly, the mean score of pain's interference with participants' mood the week before the data was collected was 4.22, with a standard deviation of 2.95. A similar trend could be seen in the interference of pain with participants' walking ability.

Table 5.4: Descriptive Statistics on Pain intensity and pain interference

	N	Mean	Std. Deviation
How much pain do you have right now?	122	4.00	2.97
Pain's interference with participants' general activity	123	4.50	3.11
Pain's interference with participants' mood	123	4.22	2.95
Pain's interference with participants' walking ability	121	4.64	3.12
Pain's interference with participants' normal work	122	3.83	3.00
Pain's interference with participants' relations with other people	122	2.68	3.18
Pain's interference with participants' sleep	121	3.91	3.18
Pain's interference with participants' enjoyment of life	121	3.91	2.78

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

However, the mean score of pain’s interferences with participants’ walking ability, sleep and enjoyment of life were a little lower than their general activity, mood, and walking ability. Furthermore, the mean score of pain’s interferences with participants’ relations with other people the week before the data was collected was the lowest (Table 5.4).

Inferential:

Determinants of Anxiety and Depression among PDN Patients

A linear multiple regression model was run to determine how several factors predict PDN patients’ level of anxiety. The hypothesis was that PDN patients’ level of anxiety can be predicted by the five presented factors, namely age, sex, highest level of education completed, their employment status, and depression level ($F\ (5,115) = 54.760, p < 0.001$), with $R2 = 0.769$, suggesting that 76.9% of the variability in the model is predicted by the listed factors. This implies that the probability that the variability observed in the model was due to chance is less than 0.001.

Table 5.5: Determinants of PDN Patients' level of Anxiety and Social Demographics Charateristics

	Anxiety			
	B	***t***	***p***	**95% *CI* (*B*)**
(Constant)	2.497	2.052	.042	(0.087, 4.907)
Sex of Participant	.171	.245	.807	(1.212, 1.554)
Current Age	.000	-.018	.986	(-0.038, 0.037)
Employment status	-.672	-1.390	.167	(-1.628, 0.285)
Education				
PRIMARY	-1.321	-2.017	.046	(-2.618, -0.024)
JHS	-1.883	-2.533	.013	(-3.355, -0.410)
SHS	-0.666	-0.982	.328	(-2.010, 0.678)
TERTIARY	-	-	-	-
Depression Score	.926	19.061	<0.001	(0.830, 1.023)

Source: Field Data Collection, 2020 (Diabetes Centre – KATH, Ghana)

The depression score was found to be the highest predictor of anxiety ($t = 19.061, p < 0.001$), followed by JHS level of education ($p = 0.013$) and primary level of education ($p = 0.046$). SHS level of education (p =0.328), sex of patient ($p = 0.807$), current age ($p = 0.986$) as well as employment status ($p = 0.167$) did not contribute significantly to the level of anxiety of PDN patients. These results, therefore, imply that with a unit rise in depression score, anxiety score also rises by almost one unit. Thus, as evidenced by the data on hand, one extra year at primary school results in a reduced level of anxiety by almost one-and-a half units. Also, one extra year at JHS results in a reduced level of anxiety by almost two units. However, depression score ($t = 19.061$) turned out to be the most important predictor of anxiety, followed by JHS ($t = -2.533$) and primary school level of education ($t = -2.017$).

A simple linear regression was calculated to predict PDN patients' level of depression based on their age, sex, highest level of education completed, their employment status and anxiety level. A significant regression equation was found ($F(5{,}115) = 54.760, p < 0.001$), with $R2$ of 0.780 meaning that 78.0% of the variability in the depression variable is accounted for by the variations in PDN patients' age, sex, highest level of education completed, their employment status and anxiety level. Thus, the probability that the variability observed in the model was due to chance is less than 0.001.

Table 5.6: Determinants of PDN Patients' level of Depression and Socoal Demographic Charateristics

	Depression			
	$\boldsymbol{B}$	$\boldsymbol{t}$	$\boldsymbol{p}$	$\mathbf{95\%}\ \boldsymbol{CI}\ (\boldsymbol{B})$
(Constant)	-1.993	-1.732	.086	(-4.272, -0.286)
Sex of Participant	-1.158	-.240	.810	(-1.459, 1.143)
Current Age	.018	1.018	.311	(-0.017, 0.053)
Employment status	.563	1.238	.218	(-0.338, 1.465)
Education				
PRIMARY	1.779	2.943	.004	(0.581, 2.876)
JHS	2.159	3.129	.002	(0.792, 3.526)
SHS	1.028	1.622	.108	(-0.228, 2.283)
TERTIARY	-	-	-	-
Anxiety Score	.820	19.061	<0.001	(0.735, 0.905)

Source: Field Data Collection, 2020 (Diabetes Centre – KATH, Ghana)

In this second model on depression, as in the first one on anxiety, anxiety score was found to be the highest predictor of depression ($t = 19.061, p < 0.001$), followed by JHS level of education ($p = 0.002$) and primary level of education ($p = 0.004$). SHS level of education ($p = 0.108$), sex of patient ($p = 0.810$), current age ($p = 0.311$) as well as employment status ($p = 0.218$) turned out not to have any significant contribution to the level of depression of PDN patients. These results, therefore, imply that, as in the case of the anxiety model, a unit rise in anxiety score also results in a rise by almost one unit in depression score ($B = 0.820$). Thus, as evidenced by the data on hand, one extra year at primary school results in a rise in the level of depression by almost two units ($B = 1.779$). Also, one extra year at JHS results in a rise in the level of depression by a little over two units ($B = 2.159$). However, anxiety score ($t = 19.061$) turned out to be the most important predictor of depression, followed by JHS ($t = 3.129$) and primary school level of education ($t = 2.943$).

Therefore, the determinants of anxiety and depression in PDN patients are very similar in behaviour. While it was evident that the sex of participants, current age, employment status and SHS level of education were not significant determinants of anxiety and depression, primary, JHS and depression were seen to be the only significant determinants of anxiety while primary, JHS and anxiety were observed as the only significant determinants of depression. Thus, while depression emerged as the most important determinant of anxiety, anxiety emerged as the most important determinant of depression. Therefore, while a rise in anxiety leads to a rise in depression, a rise in depression leads to a reduction in the level of anxiety based on the available data.

5.2.1.2 Objective 3

To determine the relationship between specific PDN characteristics (i.e., aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, penetrating, nagging numb, miserable, and unbearable) and specific quality of life domains (i.e., physical functioning, emotional problems, energy fatigue, social functioning, pain, general health, and physical health).

The PDN characteristics were recoded as binary variables (i.e., presence or absence of the characteristic in question) due to the smallness of the sample size, and the eight quality of life indicators were computed as quantitative composite indicators using the "36-Item Short Form Survey (SF-36) Scoring Instructions". Student's independent samples' *t*-test was conducted between each of the quality-of-life domains and the pain characteristics. The results are presented in Table 5.7. and Appendix K:1. To ascertain the relationship(s) between Specific PDN characteristics and quality of life, an ANOVA was computed between each of the pain types and the quality of life domains.

The results did not reflect any significant differences between eleven pain characteristics, namely throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain on the one hand, and the quality of life domains on the other as indicated in table in Appendix K:1. However, there were significant associations between aching pain and emotional well-being on the one hand, and between aching pain and social functioning on the other. There was also a significant association between burning pain and social functioning. Similarly, there was a significant association between numbness and role limitation due to emotional problems on the one hand, and between numbness and emotional well-being, social functioning, pain in general and general health on the other. There was also a significant association between miserable pain and role limitation due to physical health.

- **Aching Pain Characteristic**

Table 5.7: Test of Association between Aching Pains and Quality of Life Domains

	I feel aching pains	N	Mean	Std. Deviation	Std. Error Mean
Physical Functioning	No	7	62.70	34.05	12.87
	Yes	118	55.55	33.88	3.12
Role Limitations Due to Emotional Problems	No	7	71.43	40.50	15.31
	Yes	118	40.11	43.05	3.96
Energy Fatigue	No	7	56.43	16.00	6.05
	Yes	118	47.88	17.50	1.61
Emotional Well-Being	No	7	76.57	5.86	2.21
	Yes	118	68.98	21.83	2.01
Social Functioning	No	7	78.57	30.37	11.48
	Yes	118	52.12	28.84	2.65
Pain	No	7	53.57	41.20	15.57
	Yes	118	56.91	26.69	2.46
General Health	No	7	67.14	18.22	6.89
	Yes	118	55.46	21.90	2.02
	No	7	60.71	40.46	15.29

Role Limitations Due to Physical Health	Yes	118	35.03	44.94	4.14

- **Source: Field Data Collection (Diabetes Centre – KATH, Ghana)**

Physical Functioning by Aching Pain

A test of association was conducted between the group that felt no aching pain (*N* = 7) and their physical functioning *M* = 62.7 (*SD* = 34.05). By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically smaller physical functioning, *M* = 55.6 (*SD* = 33.9). To test the hypothesis that the group that did not feel aching pain and that did was associated with statistically significantly different mean physical functioning, an independent samples *t*-test was performed, as can be seen in Table 5.7 and Appendix K:1. The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.173, *p* = 0.678] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 0.542, *p* = 0.589] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, aching pain is not associated with physical functioning given the evidence provided by the field data as illustrated in Table 5.7 Appendix K:1.

Role Limitation due to Emotional Problems by Aching Pain

A *t*-test was conducted to ascertain whether the group that felt no aching pain (*N* = 7) was associated with role limitation due to emotional problems [*M* = 71.43 (*SD* = 40.50)]. By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically smaller role limitation due to emotional problems [*M* = 40.11 (*SD* = 43.05)] than the group that felt no aching pain. To test the hypothesis that the group that did not feel aching pain and that which did was associated with statistically significantly different mean role limitation due to emotional problems, an independent samples *t*-test was performed (Table 5.7 and Appendix K:1). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.998, *p* = 0.320], at 95% confidence level, as before. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.875, *p* = 0.063], at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, aching pain is not associated with role limitation due to emotional problems, given the evidence provided by the field data in Table 5.7 and Appendix K:1.

Energy Fatigue by Aching Pain

In another test of association conducted between the group that felt no aching pain (*N* = 7) and their energy fatigue status [*M* = 56.43 (*SD* = 16.00)]. By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically smaller energy fatigue [*M* = 47.88 (*SD* = 17.50)]. The associated hypothesis test to ascertain any statistically significant difference between the group that did not feel aching pain and that which did with respect to energy fatigue, was conducted using an independent samples *t*-test (Table 5.7 and Appendix K:1). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.211, *p* = 0.647] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.261, *p* = 0.210], at 95% confidence level, implying that the numerical difference that is observed might have occurred by chance. This points to the fact that aching pain is not associated with energy fatigue, given the evidence provided by the field data in Table 5.7 and Appendix K:1.

Emotional Well Being by Aching Pain

A test of association was also conducted between the group that felt no aching pain ($N = 7$) and their emotional well-being $M = 76.57$ ($SD = 5.86$). By comparison, the group that felt aching pain ($N = 118$) was associated with a numerically smaller emotional well-being, $M = 68.98$ ($SD = 21.83$). To test the hypothesis that the group that did not feel aching pain and that which did was associated with statistically significantly different mean emotional well-being, an independent samples *t*-test was performed (Table 5.7 and Appendix K:1). The assumption of homogeneity of variance was tested and satisfied using Levene's *F* test, [F (123) = 9.714, $p = 0.002$] at 95% confidence level, implying that equal variances was not assumed. The independent samples *t*-test was found to be statistically significant [t (123) = 2.538, $p = 0.020$] at 95% confidence level. This implies that the numerical difference that is observed did not occur by chance. Therefore, the data significantly supports the difference in emotional well-being, implying that aching pain is statistically significantly associated with emotional well-being, given the evidence provided by the field data, Table 5.7.

Social Functioning by Aching Pain

To test the hypothesis that the group that did not feel aching pain and that which did were associated with statistically significantly different mean social functioning, an independent samples *t*-test was performed. The test of association that was conducted between the group that felt no aching pain ($N = 7$) and their social functioning $M = 78.57$ ($SD = 30.37$) in comparison with the group that felt aching pain ($N = 118$) which was associated with a numerically smaller social functioning, $M = 52.12$ ($SD = 28.84$) (Table 5.7). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [F (123) = 0.016, $p = 0.900$] at 95% confidence level. The accompanying independent samples *t*-test was associated with a statistically significant effect [*t*

(123) = 2.352, *p* = 0.020] at 95% confidence level. Therefore, the numerical difference that is observed did not occur by chance. Thus, aching pain is associated with social functioning, given the evidence provided by the field data, Table 5.7 and Appendix K:1.

Pain by Aching Pain

Another test of association was conducted between the group that felt no aching pain (*N* = 7) and their pain status in general [*M* = 53.57 (*SD* = 41.20)]. By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically greater pain [*M* = 56.91 (*SD* = 26.69)]. To test the hypothesis that the group that did not feel aching pain and that which did was associated with statistically significantly different mean, pain in general, an independent samples *t*-test was performed. As can be seen in Appendix K:1, the assumption of homogeneity of variance was tested and not satisfied via Levene's *F* test, [*F* (123) = 6.195, *p* = 0.014] at 95% confidence level. The independent samples *t*-test was also not associated with a statistically significant effect, [*t* (123) = -0.212, *p* = 0.839] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, aching pain is not associated with pain in general, given the evidence provided by the field data (Table 5.7 and Appendix K:1).

General Health by Aching Pain

A further test of association was conducted between the group that felt no aching pain (*N* = 7) and their general health [*M* = 67.14 (*SD* = 18.22)]. By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically smaller general health [*M* = 55.46 (*SD* = 21.9)]. To test the hypothesis that the group that did not feel aching pain and that which did was associated with statistically significantly different mean physical functioning, an independent samples *t*-test was performed. As can be seen in Table 5.7 and Appendix K:1, the assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 1.100, *p* = 0.296] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect [*t* (123) =1.382, *p* = 0.169] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, aching pain is not associated with general health, given the evidence provided by the field data, Table 5.7 and Appendix K:1.

Role Limitations due to Physical Health by Aching Pain

A test of association was conducted between the group that felt no aching pain (*N* = 7) and their role limitation due to physical health [*M* = 60.71 (*SD* = 40.46)]. By comparison, the group that felt aching pain (*N* = 118) was associated with a numerically smaller role limitations due to physical health, *M* = 35.03 (*SD* = 44.94). To test the hypothesis that the group that did not feel aching pain and that which did was associated with statistically significantly different mean role limitations due to physical health, an independent samples *t*-test was performed (Appendix K:1). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 1.304, *p* = 0.256] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) =1.476, *p* = 0.143] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance, implying that aching pain is not associated with role limitations due to physical health, given the evidence provided by the field data (Table 5.7. and Appendix K:1).

- **Burning Pains Characteristic**

Table 5.8: Test of Association between Burning Pains and Quality of Life Domains

	I feel burning pains	N	Mean	Std. Deviation	Std. Error Mean
Physical Functioning	No	31	58.47	36.60	6.57
	Yes	94	55.12	32.97	3.40
Role Limitations Due to Emotional Problems	No	31	51.61	46.22	8.30
	Yes	94	38.65	42.14	4.35
Energy Fatigue	No	31	49.35	18.87	3.39
	Yes	94	48.03	17.07	1.76
Emotional Well-Being	No	31	71.74	18.36	3.30
	Yes	94	68.64	22.25	2.29
Social Functioning	No	31	63.31	30.61	5.50
	Yes	94	50.40	28.48	2.94
Pain	No	31	60.32	30.10	5.41
	Yes	94	55.53	26.62	2.75
General Health	No	31	58.55	21.88	3.93
	Yes	94	55.31	21.85	2.25
Role Limitations Due to Physical Health	No	31	45.97	47.04	8.45
	Yes	94	33.33	44.05	4.54

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

Physical Functioning by Burning Pain

A test of association was conducted between the group that felt no burning pain (*N* = 31) and their physical functioning [*M* = 58.47 (*SD* = 36.60)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a smaller mean physical functioning, *M* = 55.12 (*SD* = 32.97). To test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean physical functioning, an independent samples *t*-test was performed, as can be seen in Table 5.8 and Appendix K:8. The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.935, *p* = 0.335] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 0.478, *p* = 0.634] at 95% confidence level. Therefore, the numerical difference that is observed between the group that did not feel Burning Pain and that which did might have occurred by chance. Thus, burning pain is not associated with physical functioning, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

Role Limitation due to Emotional Problems by Burning Pain

The group that felt no burning pain (*N* = 31) was associated with role limitation due to emotional problems [*M* = 51.61 (*SD* = 46.22)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller role limitation due to emotional problems [*M* = 38.65 (*SD* = 42.14)]. To test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean role limitation due to emotional problems, an independent samples *t*-test was performed (see Table 5.8 and Appendix K:8). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 2.584, *p* = 0.111] at 95% confidence level. The resulting independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.450, *p* = 0.150] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, burning pain is not associated with role limitation due to emotional problems, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

Energy Fatigue by Burning Pain

Another test of association was conducted between the group that felt no burning pain (*N* = 31) and their energy fatigue status [*M* = 49.35 (*SD* = 18.87)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller energy fatigue [*M* = 48.03 (*SD* = 17.07)]. To test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean energy fatigue, an independent samples *t*-test was performed, as is seen in Table 5.8 and Appendix K:8. The assumption of homogeneity of variance was once again tested and satisfied via Levene's *F* test, [F (123) = 0.729, p = 0.395] at 95% confidence level. The resulting independent samples *t*-test was not associated with a statistically significant effect, [t (123) = 0.364, p = 0.716] at 95% confidence level. Therefore, the numerical difference that is observed between the group that did not feel burning pain and that which did might have occurred by chance. Thus, burning pain is not associated with energy fatigue, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

Emotional Well Being by Burning Pain

To test the hypothesis that the group that did not feel burning pain [N = 31, M = 71.74, SD = 18.36] and that which did [N = 94, M = 68.64, SD = 22.25] was associated with statistically significantly different mean emotional well-being, an independent samples *t*-test was performed (see Table 5.8 and Appendix K:8). The assumption of homogeneity of variance was tested and not satisfied via Levene's *F* test, [F (123) = 3.150, p = 0.078] at 95% confidence level, implying that equal variances were assumed. The follow-on independent samples *t*-test was not associated with a statistically significant effect, [t (123) = 0.701, p = 0.484] at 95% confidence level. Therefore, the numerical difference that is observed did not occur by chance. Thus, the data significantly supports the difference in emotional well-being, implying that burning pain is not statistically significantly associated with emotional well-being, given the evidence provided by the field data, Table 5.8: and Appendix K:8.

Social Functioning by Burning Pain

A test of association was also conducted between the group that felt no burning pain (*N* = 31) and their social functioning [*M* = 63.31 (*SD* = 30.61)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller social functioning, *M* = 50.40 (*SD* = 28.48). An independent samples *t*-test was performed to test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean social functioning (see Table 5.8 and Appendix K:8). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.202, *p* = 0.654] at 95% confidence level. The resulting independent samples *t*-test was associated with a statistically significant effect, [*t* (123) = 2.148, *p* = 0.034] at 95% confidence level. Therefore, the numerical difference that is observed did not occur by chance. Thus, burning pain is statistically significantly associated with social functioning, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

Pain in General by Burning Pain

A further test of association was conducted between the group that felt no burning pain (*N* = 31) and their pain status in general [*M* = 60.32 (*SD* = 30.10)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller physical functioning [*M* = 55.53 (*SD* = 26.62)]. To test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean pain in general, an independent samples *t*-test was performed, as can be seen in Table 5.8 and Appendix K:8. The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.267, *p* = 0.606] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 0.841, *p* = 0.402] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, burning pain is not associated with pain in general, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

General Health by Burning Pain

A test of association was also conducted between the group that felt no burning pain (*N* = 31) and their general health [*M* = 58.55 (*SD* = 21.88)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller mean general health, [*M* = 55.31 (*SD* = 21.85)]. To test the hypothesis that the group that did not feel burning pain and that which did was associated with a statistically significantly different mean general health, an independent samples *t*-test was performed (Table 5.8 and Appendix K:8). As in previous cases, the assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.012, *p* = 0.914] at 95% confidence level. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 0.716, *p* = 0.475] at 95% confidence level, suggesting that the numerical difference that is seen in the group that did not feel burning pain and that which did might have occurred by chance. Thus, burning pain is not associated with general health, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

Role Limitations due to Physical Health by Burning Pain

A test of association was conducted between the group that felt no burning pain (*N* = 31) and their role limitations due to physical health [*M* = 45.97 (*SD* = 47.04)]. By comparison, the group that felt burning pain (*N* = 94) was associated with a numerically smaller role limitations due to physical health, [*M* = 33.33 (*SD* = 44.05)]. To test the hypothesis that the group that did not feel burning pain and that which did was associated with statistically significantly different mean role limitations due to physical health, an independent samples *t*-test was performed, as is seen in Table

5.8 and Appendix K:8. The assumption of homogeneity of variance was tested and satisfied as usual via Levene's *F* test, [*F* (123) = 1.539, *p* = 0.217] at 95% confidence level. The follow-on independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.362, *p* = 0.176] at 95% confidence level, suggesting that the numerical difference observed between the group that did not feel burning pain and that which did might have occurred by chance, implying that burning pain is not associated with role limitations due to physical health, given the evidence provided by the field data, Table 5.8 and Appendix K:8.

- ***Numbness Pain Characteristic***

Table 5.9: Test of Association between Numbness and Quality of Life Domains

	I feel numbness	N	Mean	Std. Deviation	Std. Error Mean
Physical Functioning	No	16	62.15	33.35	8.34
	Yes	108	54.88	34.03	3.27
Role Limitations Due to Emotional Problems	No	16	64.58	47.87	11.97
	Yes	108	38.27	41.97	4.04
Energy Fatigue	No	16	53.13	17.78	4.45
	Yes	108	47.64	17.47	1.68
Emotional Well-Being	No	16	79.00	17.31	4.33
	Yes	108	67.93	21.64	2.08
Social Functioning	No	16	79.69	21.83	5.46
	Yes	108	49.54	28.54	2.75
Pain	No	16	70.16	26.39	6.60
	Yes	108	54.63	27.29	2.63
General Health	No	16	69.38	23.66	5.91
	Yes	108	54.20	21.04	2.02
Role Limitations Due to Physical Health	No	16	53.13	45.53	11.38
	Yes	108	34.34	44.63	4.29

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

Physical Functioning by Numbness

Another test of association was conducted between the group that felt no numbness (*N* = 16) and their physical functioning [*M* = 62.15 (*SD* = 33.35)]. By comparison, the group that felt numbness (*N* = 108) was associated with a numerically smaller physical functioning [*M* = 54.88 (*SD* = 34.03)]. A test of the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean physical functioning using an independent samples *t*-test was performed, as can be seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was also tested and satisfied using the Levene's *F* test, [*F* (123) = 0.147, *p* = 0.702] at 95% confidence level. The resulting independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 0.800, *p* = 0.425] at 95% confidence level, implying that the numerical difference observed between the group that did not feel numbness and that which did might have occurred by chance. Thus, numbness is not associated with physical functioning, given the evidence provided by the field data, Table 5.9 and Appendix K:13.

Role Limitation due to Emotional Problems by Numbness

The group that felt no numbness (*N* = 16) was associated with role limitation due to emotional problems [*M* = 64.58 (*SD* = 47.87)]. By comparison, the group that felt numbness (*N* = 108) was associated with a numerically smaller role limitation due to emotional problems [*M* = 38.27 (*SD* = 41.97)]. To test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean role limitation due to emotional problems, an independent samples *t*-test was performed, as is seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was again tested and satisfied via Levene's *F* test, [*F* (123) = 1.932, *p* = 0.167] at 95% confidence level. The independent samples *t*-test was, however, associated with a statistically significant effect, [*t* (123) = 2.298, *p* = 0.023] at 95% confidence level. Therefore, the numerical difference observed between the group that did not feel numbness and that which did indicates that this did not occur by chance. Thus, numbness is associated with role limitation due to emotional problems, given the evidence provided by the field data in Table 5.9 and Appendix K:13.

Energy Fatigue by Numbness

A test of association was conducted between the group that felt no numbness (*N* = 16) and their energy fatigue status [*M* = 53.13 (*SD* = 17.78)]. Here too, by comparison, the group that felt numbness (*N* = 108) was associated with a numerically smaller energy fatigue [*M* = 47.64 (*SD* = 17.47)]. To test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean energy fatigue, an independent samples *t*-test was performed, as can be seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was also tested and satisfied via Levene's *F* test, [*F* (123) = 0.096, *p* = 0.757] at 95% confidence level. The resulting independent samples *t*-test turned out not to be associated with a statistically significant effect, [*t* (123) = 1.169, *p* = 0.245] at 95% confidence level. Therefore, the numerical difference that is seen between the group that did not feel numbness and that which did might have occurred by chance. Thus, numbness is not associated with energy fatigue, given the evidence provided by the field data, Table 5.9 and Appendix K:13.

Emotional Well Being by Numbness

To test the hypothesis that the group that did not feel numbness [*N* = 16, *M* = 79.00, *SD* = 17.31] and that which did [*N* = 108, *M* = 67.93, *SD* = 21.64] was associated with statistically significantly different mean emotional well-being, an independent samples *t*-test was performed (Table 5.9 and Appendix K:13) and the assumption of homogeneity of variance was also tested and not satisfied via Levene’s *F* test, [*F* (123) = 4.589, *p* = 0.034] at 95% confidence level, implying that equal variances was not assumed. The resulting independent samples *t*-test was also associated with a statistically significant effect, [*t* (123) = 2.306, *p* = 0.031] at 95% confidence level. Therefore, the numerical difference between the group that felt numbness and that which did not indicates that this did not occur by chance. Thus, the data significantly supports the difference in emotional well-being, implying that numbness is statistically significantly associated with smaller emotional well-being, given the evidence provided by the field data, Table 5.9 and Appendix K:13. In other words, numbness in PDN patients significantly lowers their emotional well-being.

Social Functioning by Numbness

A test of association was conducted between the group that felt no numbness (*N* = 16) and their social functioning [*M* = 79.69 (*SD* = 21.83)]. By comparison, the group that felt numbness (*N* = 108) was associated with a numerically much smaller social functioning [*M* = 49.54 (*SD* = 28.54)]. To test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean social functioning, an independent samples *t*-test was again performed, as can be seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was also tested and satisfied via Levene’s *F* test, [*F* (123) = 0.835, *p* = 0.362] at 95% confidence level. The resulting independent samples *t*-test turned out to be associated with a statistically significant effect, [*t* (123) = 4.048, *p* < 0.001] at 95% confidence level. Therefore, the numerical difference observed between the group that did not feel numbness and that which did indicates that this did not occur by chance. Thus, numbness is associated with social functioning, given the evidence provided by the field data in Table 5.9 and Appendix K:13. This further implies that numbness in PDN patients significantly lowers their social functioning.

Pain in General by Numbness

Another test of association was conducted between the group that felt no numbness (*N* = 16) and their pain status in general [*M* = 70.16 (*SD* = 26.39)]. By comparison, the group that felt numbness (*N* = 108) was associated with a numerically smaller pain in general [*M* = 54.63 (*SD* = 27.29)]. In order to test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean pain in general, an independent samples *t*-test was performed (Table 5.9 and Appendix K:13). The assumption of homogeneity of variance was again tested and satisfied via Levene's *F* test, [*F* (123) = 0.135, *p* = 0.714] at 95% confidence level. The resulting independent samples *t*-test was associated with a statistically significant effect, [*t* (123) = 2.132, *p* = 0.035] at 95% confidence level. Therefore, the numerical difference observed between the group that did not feel numbness and that which did indicates that this did not also occur by chance. Thus, numbness is associated with pain in general, given the evidence provided by the field data (Table 5.9 and Appendix K:13). This implies that numbness in PDN patients significantly suppresses their pains.

General Health by Numbness

A test of association was also conducted between the group that felt no numbness (*N* = 16) and their general health [*M* = 69.38 (*SD* = 23.66)]. The group that felt numbness (*N* = 108) was associated with a numerically smaller mean general health [*M* = 54.20 (*SD* = 21.04)]. To test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean general health, an independent samples *t*-test was performed, as seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.055, *p* = 0.816] at 95% confidence level. The follow-on independent samples *t*-test turned out to be associated with a statistically significant effect, [*t* (123) = 2.649, *p* = 0.009], at 95% confidence level. Therefore, the numerical difference that is observed did not occur by chance. Thus, numbness is associated with general health, given the evidence provided by the field data, Table 5.9 and Appendix K:13. This also means that numbness in PDN patients worsens their general health significantly.

Role Limitations due to Physical Health by Numbness

A further test of association was conducted between the group that felt no numbness (*N* = 16) and their role limitations due to physical health [*M* = 53.13 (*SD* = 45.53)]. By comparison, the group that felt numbness (*N* = 108) was associated with a numerically smaller role limitations due to physical health [*M* = 34.34 (*SD* = 44.63)]. To test the hypothesis that the group that did not feel numbness and that which did was associated with statistically significantly different mean role limitations due to physical health, an independent samples *t*-test was performed as can be seen in Table 5.9 and Appendix K:13. The assumption of homogeneity of variance was also tested and satisfied via Levene's *F* test, [*F* (123) = 0.002, *p* = 0.968] at 95% confidence level. The resulting independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) =1.568, *p* = 0.120] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance, implying that the numbness is not associated with role limitations due to physical health, given the evidence provided by the field data, Table 5.9 and Appendix K:13.

- ***Miserable Pain Characteristic***

Table 5.10: Test of Association between Miserable Feeling and Quality of Life Domains

	I feel miserable	N	Mean	Std. Deviation	Std. Error Mean
Physical Functioning	No	56	59.95	31.91	4.26
	Yes	69	52.71	35.13	4.23
	No	56	48.21	44.00	5.88

Role Limitations Due to Emotional Problems	Yes	69	36.71	42.45	5.11
Energy Fatigue	No	56	48.57	18.48	2.47
	Yes	69	48.19	16.74	2.01
Emotional Well-Being	No	56	72.79	19.87	2.65
	Yes	69	66.67	22.19	2.67
Social Functioning	No	56	57.81	28.76	3.84
	Yes	69	50.18	29.74	3.58
Pain	No	56	57.37	27.23	3.64
	Yes	69	56.20	27.87	3.35
General Health	No	56	59.62	20.48	2.74
	Yes	69	53.26	22.59	2.72
Role Limitations Due to Physical Health	No	56	46.13	44.61	5.96
	Yes	69	28.62	43.99	5.30

Source: Field Data Collection (Diabetes Centre – KATH, Ghana)

Physical Functioning by Miserable Pain

A test of association was conducted between the group that did not feel miserable pain ($N = 56$) and their physical functioning [$M = 59.95$ ($SD = 31.91$)]. By comparison, the group that felt miserable pain ($N = 69$) was associated with a numerically smaller physical functioning, [$M = 52.71$ ($SD = 35.13$)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with statistically significantly different mean physical functioning, an independent samples *t*-test was performed (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [F (123) = 0.745, $p = 0.390$] at 95% confidence level. The resulting independent samples *t*-test was not associated with a statistically significant effect, [t (123) = 1.193, $p = 0.235$] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance, implying that feeling of miserable pain is not associated with physical functioning, given the evidence provided by the field data, Table 5.10 and Appendix K:14.

Role Limitation due to Emotional Problems by Miserable Pain

The group that did not feel miserable pain (*N* = 56) was associated with role limitation due to emotional problems [*M* = 48.21 (*SD* = 44.00)]. By comparison, the group that felt miserable (*N* = 69) was associated with a numerically smaller role limitation due to emotional problems [*M* = 36.71 (*SD* = 42.45)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with a statistically significantly different mean role limitation due to emotional problems, an independent samples *t*-test was performed (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was also tested and satisfied using the Levene's *F* test, [*F* (123) = 0.865, *p* = 0.354] at 95% confidence level. The follow-on independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.482, *p* = 0.141] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, feeling miserable pain is not associated with role limitation due to emotional problems, given the evidence provided by the field data, Table 5.10 and Appendix K:14.

Energy Fatigue by Miserable Pain

Another test of association was conducted between the group that had no miserable pain (*N* = 56) and their energy fatigue status [*M* = 48.57 (*SD* = 18.48)]. By comparison, the group that felt miserable pain (*N* = 69) was associated with a numerically smaller energy fatigue [*M* = 48.19 (*SD* = 16.74)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with statistically significantly different mean energy fatigue, an independent samples *t*-test was performed (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was again tested and satisfied via Levene's *F* test, [*F* (123) = 0.173, *p* = 0.678] at 95% confidence level. The resulting independent samples *t*-test was not associated with any statistically significant effect, [*t* (123) = 0.121, *p* = 0.904] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, miserable feeling is not associated with energy fatigue, given the evidence provided by the field data, Table 5.10 and Appendix K:14.

Emotional Well Being by Miserable Pain

To test the hypothesis that the group that did not feel miserable pain [*N* = 56, *M* = 72.79, *SD* = 19.87] and that which did[*N* = 69, *M* = 66.67, *SD* = 22.19] was associated with statistically significantly different mean emotional well-being, an independent samples *t*-test was performed as can be seen in Table 5.10 and Appendix K:14. The assumption of homogeneity of variance was tested and not satisfied via Levene's *F* test, [*F* (123) = 1.985, *p* = 0.161] at 95% confidence level, implying that equal variances was not assumed. The independent samples *t*-test was not associated with a statistically significant effect, [*t* (123) = 1.606, *p* = 0.111] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. Thus, the data significantly supports the difference in emotional well-being, implying that feeling miserable pain is statistically significantly not associated with emotional well-being, given the evidence provided by the field data in table 5.10 and appendix K:14.

Social Functioning by Miserable Pain

A test of association was conducted between the group that felt no miserable pain (*N* = 56) and their social functioning [*M* = 57.81 (*SD* = 28.76)]. By comparison, the group that felt miserable pain (*N* = 69) was associated with a numerically smaller social functioning, [*M* = 50.18 (*SD* = 29.74)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with statistically significantly different mean social functioning, an independent samples *t*-test was performed (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was tested and satisfied via Levene's *F* test, [*F* (123) = 0.322, *p* = 0.571] at 95%

confidence level. The follow-on independent samples *t*-test turned out not to be associated with any statistically significant effect, [t (123) = 1.448, p = 0.150] at 95% confidence level. Therefore, the numerical difference that is observed might have occurred by chance. This implies that feeling of miserable pain is not associated with social functioning, given the evidence provided by the field data in Table 5.10 and Appendix K:14.

Pain in General by Miserable Pain

Another test of association was conducted between the group that felt no miserable pain (N = 56) and their pain status in general [M = 57.37 (SD = 27.23]). By comparison, the group that felt miserable pain (N = 69) was associated with a numerically smaller pain in general, [M = 56.20 (SD = 27.87)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with a statistically significantly different mean pain in general, an independent samples *t*-test was performed as before (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was again tested and satisfied using the Levene's *F* test, [F (123) = 0.543, p = 0.463] at 95% confidence level. The resulting independent samples *t*-test was not associated with any statistically significant effect, [t (123) = 0.236, p = 0.814] at 95% confidence level. Therefore, the numerical difference that is observed between the group that did not feel miserable pain and that which did might have occurred by chance. Thus, feeling miserable pain is not associated with pain in general, given the evidence provided by the field data in Table 5.10 and Appendix K:14.

General Health by Miserable Pain

A test of association was also conducted between the group that felt no miserable pain (N = 56) and their general health [M = 59.62 (SD = 20.48)]. By comparison, the group that felt miserable pain (*N* = 69) was associated with a numerically smaller general health [*M* = 53.26 (*SD* = 22.59)]. To test the hypothesis that the group that did not feel miserable pain and that which did was associated with a statistically significantly different mean general health, an independent samples *t*-test was performed, as is seen in Table 5.10 and Appendix K:14. The assumption of homogeneity of variance was tested and satisfied using Levene's *F* test, [*F* (123) = 1.130, *p* = 0.290] at 95% confidence level. The independent samples *t*-test turned out not to be associated with any statistically significant effect, [*t* (123) = 1.632, *p* = 0.105] at 95% confidence level. Therefore, the numerical difference that is observed between the group that did not feel miserable pain and that which did might have occurred by chance. Thus, miserable pain is not associated with general health among PDN patients, given the evidence provided by the field data, Table 5.10 and Appendix K:14.

Role Limitations due to Physical Health by Miserable Pain

Finally, on miserable pain, a test of association was conducted between the group that felt no miserable pain (*N* = 56) and their role limitations due to physical health [*M* = 46.13 (*SD* = 44.61)]. By comparison, the group that felt miserable pain (*N* = 69) was associated with a numerically smaller mean role limitations due to physical health [*M* = 28.62 (*SD* = 43.99)]. In testing the hypothesis that the group that did not feel miserable pain and that which did was associated with statistically significantly different mean role limitations due to physical health, an independent samples *t*-test was performed (Table 5.10 and Appendix K:14). The assumption of homogeneity of variance was tested and satisfied using Levene's *F* test, [*F* (123) = 0.618, *p* = 0.433] at 95% confidence level. The resulting independent samples *t*-test was associated with a statistically significant effect, [*t* (123) = 2.199, *p* = 0.030] at 95% confidence level. Therefore, the numerical difference that is observed between the group that did not feel miserable pain and that which did shows that this did not occur by chance, implying that feeling miserable pain is statistically significantly associated with role limitations due to physical health, given the evidence provided by the field data, Table 5.10 and Appendix K:14. In other words, PDN patients who suffered miserable pains had lowered role limitations due to physical health.

5.2.1.3 Objective 4

Evaluation of TAU, plus CBT, plus HYP compared to CBT plus TAU only.

Pain Intensity

At baseline, both control group and experimental group received TAU + CBT. However, at intervention, the experimental group received HYP in addition to TAU and CBT. This was done with the aim of ascertaining whether or not HYP has any significant effect to the treatment of PDN patients.

Table 5.11: Group Statistics on Pain's Intensity for Experimental and Control Groups at Baseline

Study Group	Baseline			Intervention		
	N	M	SD	N	M	SD
Pain at its worst during the past week						
Control	60	7.83	1.669	60	7.53	1.610
Experimental	60	7.67	1.258	60	4.02	1.172
Pain at its least during the past week						
Control	60	7.02	1.097	60	6.35	1.313
Experimental	60	6.92	1.253	60	2.48	1.455
Average pain during the past week						
Control	60	7.10	1.020	60	6.58	1.139
Experimental	60	7.02	.965	60	3.55	1.489
Average pain right now						
Control	60	7.25	1.019	60	6.78	1.250
Experimental	60	7.20	.953	60	3.12	1.485

Source: Field Data, 2020; N – Sample size; M – Mean; SD – Standard deviation

Results showed that at baseline, the mean pain at its worst during the past week for the control group (CBT + TAU) was a little higher (M = 7.83, SD = 1.67) than that of those in the experimental group (M = 7.67, SD = 1.26), Table 5.11. An independent samples *t*-test found the difference in mean pain at its worst during the past week between the experimental group and the control group (0.167) not statistically significant, t (118) = 0.618, $p > 0.05$, Table 5.11. This suggests that the mean level of pain at its worst during the past week at baseline was the same for both control and experimental groups. This may be due to chance rather than any inherent difference between the two groups.

At intervention, the mean pain at its worst during the past week before data collection was much lower for the experimental group (M = 4.02, SD = 1.17) which received hypnosis in addition to the other treatments (TAU + CBT + HYP) than for the control group (M = 7.53, SD = 1.61), Table

5.11. The accompanying *t*-test conducted to ascertain whether this difference in mean pain at its worst during the past week between the two groups (3.517) was statistically significant or not indicated that the difference in pain at its worst during the past week was actually statistically significant [t (107.8) = 13.681, p < 0.001], Table 5.11. This implies that the mean difference in pain at its worst during the past week is attributable to the intervention of hypnosis.

At baseline, results again showed that the mean pain at its least during the past week before the data collection for the experimental group (CBT + TAU + HYP) was slightly lower (M = 6.92, SD = 1.25) than that for the control group (M = 7.02, SD = 1.097), Table 5.11. A follow-up independent samples *t*-test found the difference in mean pain at its least during the past week between the experimental group and the control group (0.10) not to be statistically significant, t (118) = 0.465, p > 0.05, Table 5.11. The combination of these two preliminary findings suggests that at baseline, the mean level of pain at its least during the past week was the same for both the control and experimental groups. This implies that whether a person was in the experimental group or the control group, they felt the same level of pain at its least during the past week. This may be due to chance rather than any inherent difference between the two groups.

To ascertain the situation of pain at intervention, the mean pain at its worst during the past week before data collection was significantly lower for the experimental group (M = 2.48, SD = 1.46) which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 6.35, SD = 1.31), Table 5.11. The accompanying *t*-test conducted to ascertain whether this difference in mean pain at its least during the past week between the two groups (3.867) was statistically significant or not indicated that the difference in pain at its least during the past week was statistically significant [t (118 = 15.282, p < 0.001], Table 5.11. This implies that the mean difference in pain at its least during the past week is attributable to the intervention of hypnosis, suggesting that hypnosis accounts for the difference in mean pain at its least during the past week.

Study results showed that at baseline, the average pain during the past week for the control group (CBT + TAU) was slightly higher (M = 7.10, SD = 1.02) than for the experimental group (M = 7.02, SD = 0.965), Table 5:11. An independent samples *t*-test found the difference in average pain during the past week between the experimental group and the control group (0.083) not to be statistically significant, t (118) = 0.460, p > 0.05, Table 5.11. This suggests that at baseline, the average pain during the past week was the same for both the control and the experimental groups. In other words, whether a person was in the experimental group or the control group, they felt the same level of average pain during the past week. This may be due to chance rather than any inherent difference between the two groups.

At intervention, the average pain during the past week before data collection was significantly lower for the experimental group (M = 3.55, SD = 1.489) which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 6.58, SD = 1.139), Table 5.11. The accompanying *t*-test conducted to ascertain whether this difference in average pain during the past week between the two groups (3.033) was statistically significant or not indicated that the difference in average pain during the past week was statistically significant [t (110.441) = 12.531, p < 0.001], Table 5.11 This implies that the average pain during the past week is attributable to the intervention of hypnosis.

Table 5.12: Test of Mean Difference in Pain Intensity between Baseline and Intervention

	t-test for Equality of Means at Baseline					*t*-test for Equality of Means at intervention				
				95% CI of the MD					95% CI of the MD	
	T	df	MD	Lower	Upper	t	Df	MD	Lower	Upper
Pain at its worst in the last one week										
	.618	118	*0.167	-.368	.701	13.681	107.801	**3.517	3.007	4.026
Pain at its least in the past one week										
	.465	118	*0.1	-.326	.526	15.282	118	**3.867	3.366	4.368
Average pain in the past one week										
	.460	118	*0.083	-.276	.442	12.531	110.441	**3.033	2.554	3.513
Average pain right now										
	.278	118	*0.05	-.307	.407	14.630	114.652	**3.667	3.170	4.163

Source: Field Data, 2020; * p>0.05; ** p<0.001; MD – Mean Difference

Finally, results from the study’s data showed that at baseline, the average pain at the time of data collection for the control group (CBT + TAU) was slightly higher (M = 7.25, SD = 1.02) than that for the experimental group (M = 7.20, SD = 0.953), Table 5.12. An independent samples *t*-test found the difference in average pain at the time of data collection between the experimental group and the control group (0.05) not to be statistically significant, t (118) = 0.278, p > 0.05, Table 5.12. This suggests that at baseline, the average pain at the time of data collection was the same for both the control and experimental groups. In other words, whether a person was in the experimental group or the control group, they felt the same level of average pain at the time of data collection. This may be due to chance rather than any inherent difference between the two groups.

At intervention, the average pain at the time of data collection was significantly lower for the experimental group (M = 3.12, SD = 1.49), which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 6.78, SD = 1.25), Table 5.12. The accompanying *t*-test conducted to ascertain whether this difference in average pain at the time of data collection between the two groups (3.667) was statistically significant or not, indicated that the difference in average pain at the time of data collection was statistically significant [t (114.65 = 14.630, p < 0.001], Table 5.12 This implies that the average pain at the time of data collection is attributable to the intervention of hypnosis, suggesting that hypnosis accounts for the difference in average pain at the time of data collection.

Pain Interference

Presented in Table 5.13 are the descriptive statistics on pain interference both at baseline and at intervention. The mean and standard deviation for pain’s interference with walking ability for the experimental group (M = 7.35, SD = 0.880) and control group (M = 7.70, SD = 1.062) before intervention and that for the experimental group (M = 3.25, SD = 1.58) and control group (M = 7.17, SD = 1.509) after intervention.

Table 5.13: Descriptive Statistics for Pain Interference Before and After Intervention (I)

Study Group	N	Mean	Std. Deviation	Std. Error Mean
Pain's interference with Walking Ability (Before)				
Control	60	7.70	1.062	.137
Experimental	60	7.35	.880	.114
Pain's interference with Walking Ability (After)				
Control	60	7.17	1.509	.195
Experimental	60	3.25	1.580	.204
Pain's interference with Relations with Other People (Before)				
Control	60	7.43	1.212	.157
Experimental	60	7.32	.873	.113
Pain's interference with Relations with Other People (After)				
Control	60	6.77	1.454	.188
Experimental	60	2.32	1.467	.189
Pain's interference with Sleep (Before)				
Control	60	7.38	1.223	.158
Experimental	60	7.37	.758	.098
Pain's interference with Sleep (After)				
Control	60	7.00	1.262	.163
Experimental	60	3.45	1.741	.225

Source: Field Data, 2020

The mean and standard deviation for pain’s interference with relations with other people for the experimental group (M = 7.32, SD = 0.873) and control group (M = 7.43, SD = 1.212) before intervention and that for the experimental group (M = 2.32, SD = 1.467) and control group (M = 6.77, SD = 1.454) after intervention. Also, in Table 5.13 are the mean and standard deviation for pain’s interference with sleep for the experimental group (M = 7.37, SD = 0.758) and control group (M = 7.38, SD = 1.223) before intervention and that for the experimental group (M = 3.45, SD = 1.741) and control group (M = 7.00, SD = 1.262) after intervention.

An associated paired samples *t*-test was conducted to establish whether or not there was any statistically significant difference in pain's interference between the experimental and the control groups with walking ability before intervention. The result indicated that there was not any statistically significant mean difference in pain’s interference with walking ability before intervention [MD = 0.350, t (118) = 1.966, $p > 0.05$] at 95% confidence level, implying that the numerical mean difference that is observed might have occurred by chance. After the intervention, another paired samples *t*-test was conducted to establish whether or not there was any statistically significant difference in pain's interference with walking ability between the experimental and the control group. The result indicated that there was a statistically significant mean difference in pain’s interference with walking ability after intervention [MD = 3.917, $t(118) = 13.887$, $p < 0.05$] at 95% confidence level, implying that the numerical mean difference that is observed did not occur by chance. This implies that the introduction of hypnosis in the treatment of PDN had a statistically significant effect on the reduction of pain’s interference with the walking ability of the study’s participants, Table 5.13.

There was an additional associated paired samples *t*-test conducted to establish whether or not there was any statistically significant difference in pain's interference with relations with other people between the experimental and the control groups before intervention. The results indicated that there was not any statistically significant mean difference in pain’s interference with relations with other people before intervention [MD = 0.117, t (118) = 0.605, $p > 0.001$] at 99% confidence level, implying that the numerical mean difference that is observed might have occurred by chance. After the intervention, another paired samples *t*-test was conducted to establish whether there was any statistically significant difference in pain's interference with walking ability between the experimental and the control groups. The results indicated that there was a statistically significant mean difference in pain’s interference with relations with other people after the intervention [MD = 4.45, *t* (118) = 16.688, *p* < 0.0.001] at 99% confidence level, implying that the numerical mean difference that is observed did not occur by chance. This implies that the introduction of hypnosis in the treatment of PDN had a statistically significant effect on the reduction of pain’s interference on relations with other people by the study’s participants, Table 5.13.

Finally, a follow-up paired samples *t*-test was conducted to establish whether there was any statistically significant difference in pain's interference with participants’ sleep between the experimental and control groups before the intervention. The indicated that there was not any statistically significant mean difference in pain’s interference with participants’ sleep before the intervention [MD = 0.017, *t* (99) = 0.090, *p* > 0.05] at 95% confidence level. This implies that the numerical mean difference that is observed might have occurred by chance. After the intervention, another paired samples *t*-test was conducted to establish whether or not there was any statistically significant difference in pain's interference with participants’ sleep between the experimental and control groups. The results indicated that there was a statistically significant mean difference in pain’s interference with participants’ sleep after intervention [MD = 3.55, *t* (108) = 12.787, *p* < 0.001] at 99% confidence level, implying that the numerical mean difference that is observed did not occur by chance. This implies that the introduction of hypnosis in the treatment of PDN contributes a statistically significant effect on the reduction of pain’s interference with participants’ sleep by the study’s participants , Table 5.13.

Table 5.14: Independent Samples Test

	t-test for Equality of Means					
					95% C. I. MD	
	T	df	MD	S.E. MD	Lower	Upper
Pain's interference with Walking Ability (Before)	1.966	118	.350	.178	-.003	.703
Pain's interference with Walking Ability (After)	13.887	118	*3.917	.282	3.358	4.475
Pain's interference with Relations with Other People (Before)	.605	118	.117	.193	-.265	.499
Pain's interference with Relations with Other People (After)	16.688	118	*4.45	.267	3.922	4.978
Pain's interference with Sleep (Before)	.090	98.551	.017	.186	-.352	.385
Pain's interference with Sleep (After)	12.787	107.595	*3.55	.278	3.000	4.100

Source: Field Data, 2020; * p<0.001

Table 5.14 presents the descriptive statistics on pain's interference with participants' general activity both at baseline and at intervention. The mean and standard deviation for pain's interference with participants' general activity before intervention for the experimental group (M = 7.07, SD = 1.056) and control group (M = 7.53, SD = 0.929) and that for the experimental group (M = 3.37, SD = 1.615) and control group (M = 7.10, SD = 1.145) after intervention. Additional descriptive statistics were computed for pain's interference with participants' mood both before and after intervention. The mean and standard deviation for pain's interference with participants' mood before intervention for the experimental group (M = 7.22, SD = 0.783) and control group (M = 7.60, SD = 0.906) and that for the experimental group (M = 3.35, SD = 1.482) and control group (M = 7.02, SD = 1.112) after the intervention.

A follow-up paired samples *t*-test (Table 5.14) found the difference in Pain's interference with general activity at baseline between the experimental group and the control group (0.467), though marginal, to be statistically significant, $t\ (118) = 0.467, p < 0.05$. This suggests that at baseline, the difference in mean level of pain's interference with general activity was marginally greater for the control group than the experimental group.

In ascertaining the situation of pain's interference with general activity after intervention, the mean of pain's interference with general activity was significantly lower for the experimental group (M = 3.37, SD = 1.615) which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 7.10, SD = 1.145), Table 5.14.

Table 5.15: Descriptive Statistics for Pain Interference (II)

Study Group	N	Mean	Std. Deviation	Std. Error Mean
Pain's interference with General Activity (Before)				
Control	60	7.53	.929	.120
Experimental	60	7.07	1.056	.136
Pain's interference with General Activity (After)				
Control	60	7.10	1.145	.148
Experimental	60	3.37	1.615	.209
Pain's interference with Mood (Before)				
Control	60	7.60	.906	.117
Experimental	60	7.22	.783	.101
Pain's interference with Mood (After)				
Control	60	7.02	1.112	.144
Experimental	60	3.35	1.482	.191
Pain's interference with Normal Work (Before)				
Control	60	7.60	1.045	.135
Experimental	60	7.08	1.013	.131
Pain's interference with Normal Work (After)				
Control	60	7.03	1.275	.165
Experimental	60	2.87	1.535	.198
Pain's interference with Enjoyment of Life (Before)				
Control	60	7.67	1.244	.161
Experimental	60	7.18	1.334	.172
Pain's interference with Enjoyment of Life (After)				
Control	60	7.13	1.065	.138
Experimental	60	3.45	1.741	.225

Source: Field Data, 2020

The accompanying paired samples *t*-test conducted to ascertain whether this difference in mean of pain’s interference with general activity after the intervention between the two groups (3.733) was statistically significant or not, indicated a statistically significant difference [t (106.4 = 14.604, p < 0.001], Table 5.15. This suggests that the mean difference in pain’s interference with general activity is attributable to the intervention of hypnosis. In other words, the inclusion of hypnosis results in a faster reduction in pain than only TAU and CBT.

Table 5.16: Independent Samples *T*-Test For Pain’s Interference Before and After Intervention (II)

	t-test for Equality of Means					
					95% CI of MD	
	t	Df	MD	S. E. MD	L	U
Pain's interference with General Activity (Before)	2.571	118	*0.467	.182	-.826	-.107
Pain's interference with General Activity (After)	14.604	106.359	**3.733	.256	-4.240	-3.227
Pain's interference with Mood (Before)	2.480	118	*0.383	.155	-.689	-.077
Pain's interference with Mood (After)	15.326	109.441	**3.667	.239	-4.141	-3.193
Pain's interference with Normal Work (Before)	2.750	118	*0.517	.188	-.889	-.145
Pain's interference with Normal Work (After)	16.176	114.173	**4.167	.258	-4.677	-3.656
Pain's interference with Enjoyment of Life (Before)	2.052	118	*0.483	.235	-.950	-.017
Pain's interference with Enjoyment of Life (After)	16.284	105.002	**3.733	.242	-4.412	-3.454

Source: Field Data, 2020; ** p<0.01; * p<0.005; MD – Mean Difference in Pain's Interference

The study results also showed that at baseline, the mean of pain's interference with mood before the intervention for the control group (CBT + TAU) was slightly higher (M = 7.60, SD = 0.906) than for the experimental group (M = 7.22, SD = 0.783), Table 5.15. A paired samples *t*-test found the difference in the average of pain's interference with mood between the experimental group and the control group at baseline (0.383) to be statistically significant, t (118) = 2.480, p < 0.05, Table 5.16, though marginal. This suggests that at baseline, the average of pain's interference with mood was slightly lower for the experimental group than the control group. In other words, at baseline, a person in the experimental group had slightly less pain than a person in the control group.

After the intervention, the average of pain's interference with mood was significantly lower for the experimental group (M = 3.35, SD = 1.482) which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 7.02, SD = 1.112), Table 5.15. The accompanying paired samples *t*-test conducted to ascertain whether this difference in the average of pain's interference with mood between the two groups (3.667) was statistically significant or not, indicated that this difference in the average of pain's interference with mood was statistically significant [t (109.441) = 15.326, p < 0.001], Table 5.16. This implies that the average of pain's interference with mood is attributable to the intervention of hypnosis, suggesting that hypnosis accounts for the difference in the average of pain’s interference with mood.

Results from the study’s data showed that at baseline, the average of pain's interference with normal work for the control group (CBT + TAU) was slightly higher (M = 7.60, SD = 1.045) than for the experimental group (M = 7.08, SD = 1.013), Table 5.15. A paired samples *t*-test found the difference in the average of pain's interference with normal work between the experimental group and the control group (0.517) before the intervention, to be statistically significant, t (118) = 2.750, p < 0.05, Table 5.16. This suggests that at baseline, the average of pain's interference with normal work was significantly smaller for the experimental group than the control group, though marginal.

After the intervention, the average of pain's interference with normal work was significantly lower for the experimental group (M = 2.87, SD = 1.535), which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP), than for the control group (M = 7.03, SD = 1.275), Table 5.15. The accompanying paired samples *t*-test conducted to ascertain whether the difference in the average of pain’s interference with normal work at the time of data collection between the two groups (4.167) was statistically significant or not indicated that the difference was statistically significant [t (114.173) = 14.176, p < 0.001], Table 5.16. This implies that the average of pain's interference with normal work after the intervention is attributable to the intervention of hypnosis, suggesting that hypnosis accounted for the difference in the average of pain’s interference with normal work at the time of data collection.

On pain’s interference with enjoyment of life at baseline, results from the study showed that the mean of pain’s interference with enjoyment of life before the intervention for the experimental group (CBT + TAU + HYP) was slightly lower (M = 7.18, SD = 1.334) than for the control group (M = 7.67, SD = 1.244), Table 5.15. In a follow-up paired samples *t*-test (Table 5.16) conducted, the difference in pain's interference with enjoyment of life at baseline between the experimental group and the control group (0.483), though marginal, was found to be statistically significant, t (118) = 0.467, $p < 0.05$. This suggests that at baseline, the difference in mean level of pain's interference with enjoyment of life was marginally greater for the control group than the experimental group.

Finally, in ascertaining the situation of pain's interference with enjoyment of life after the intervention, the mean of pain's interference with enjoyment of life was found to be significantly lower for the experimental group (M = 3.20, SD = 1.538) which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group (M = 7.13, SD = 1.065), Table 5.15. A follow-up paired samples *t*-test conducted to ascertain whether this difference in the mean of pain's interference with enjoyment of life after intervention between the two groups (3.733) was statistically significant or not indicated that the difference was statistically significant [t (105.002) = 16.284, $p < 0.001$], Table 5.16. This implies that the mean difference in pain's interference with enjoyment of life is attributable to the intervention of hypnosis. In other words, the inclusion of hypnosis resulted in a faster reduction in pain's Interference with the enjoyment of life for the experimental group (TAU + CBT + HYP) than only TAU and CBT.

5.3 Conclusion

The chapter outlined the quantitative results of the data collected in phase II. It began with a presentation on objective 2 and examined the association between participants' socio-demographic characteristics and depression, anxiety and PDN severity. In this chapter, objective 3 presented the relationships between specific PDN characteristics and quality of life domains And the chapter concluded with objective 4, which considered the evaluation of TAU plus CBT plus HYP compared to CBT plus TAU only. The next chapter discusses the findings of this study in accordance with the objectives of the study.

CHAPTER SIX: DISCUSSION OF FINDINGS

6.1 Introduction

Chapter 6 discusses the findings of this study in accordance with the objectives of the study which focused on the qualitative findings and later the quantitative findings of the study. The qualitative discussion is centred on the data that emerged from the study pertaining to general information on diabetes, self-assessment of the impact of PDN, experiences of PDN patients, biological/social medical history, religious experiences, evidence of religious coping, other coping methods, psychosocial implications, and the evidence of financial burden and PDN. The quantitative discussion on the other hand considers social demographic characteristics and depression, social demographic characteristics and anxiety, as well as anxiety versus depression. It also explains the relationship between PDN characteristics and quality of life domains and the relationship between hypertension and PDN, as well as intensity and PDN interference. The chapter also considers the evaluation of TAU plus CBT plus HYP compared to CBT plus TAU only. It concludes with an attempt to triangulate the results of the qualitative and quantitative data.

6.2 Discussion of Qualitative Findings

This discussion focuses on the qualitative findings of the study regarding general information on diabetes, self-assessment of the impact of PDN, experiences of PDN patients, biological/social medical history, religious experiences, evidence of religious coping, other coping methods, psychosocial implications, and the evidence of financial burden and PDN.

6.2.1 General information on Diabetes/PDN

In this study participants appeared to lack general information on their diabetic condition, notably their diabetic type in contrast to some previous studies in Ghana, which had reported that most participants in their study seemed to know their diabetic type (Kugbey et al., 2017; Tabong et al., 2018). However, in this study, few respondents could demonstrate some degree of knowledge on what diabetes was, including its signs and symptoms. Evidence from this study, therefore, indicates that participants have inadequate knowledge and understanding of diabetes and PDN.

This study found that participants appear to lack adequate knowledge of proper glycaemic control through their diet. Participants also appear to have little or no idea of their medications although they adhere to taking their drugs regularly. A similar study indicated that patients lacked sufficient knowledge regarding the management of their disease (Moosa et al., 2019; King et al., 2017; Karaoui et al., 2018). However, some studies indicated that patients have a significant amount of knowledge related to the taking of medicines, insulin, and a healthy diet (Al-Maskari et al., 2013; Abouammoh & Alshamrani, 2020). It could, therefore, be argued that patients would take their medication even if they did not have that much information about their drugs. This could be because they observed that they felt better when they took their medication.

Regarding PDN, participants in this study appeared to recognize the signs and symptoms precipitating their pain and could describe the pain associated with PDN as tingling pain, numbness, burning, stabbing, and deep aching (Backonja & Krause, 2003). However, participants appeared to lack adequate information on these signs and symptoms although they could describe it in their own words. In a similar study, participants appeared to lack adequate or better understanding of the mechanisms underlying diabetic neuropathic pain (Schreiber et al., 2015). This finding indicates that although PDN patients are aware and can describe the nature of their pain, they lack the basic understanding of how these various pain characteristics exacerbate or ameliorate their condition.

6.2.2 Qualitative Self-Assessment of the Impact of PDN on Diabetic Patients

Participants affirmed that PDN had an adverse health effect on their daily life, resulting in poor quality of life as demonstrated in studies investigating the association between PND and daily functioning among patients. For instance, studies have essential questions concerning the relationship between neuropathic pain, its physical and emotional consequences, and social outcomes (Sofaer-Bennett et al., 2007; Atalay et al., 2013; Bakker et al., 2014; Brod et al., 2015). These studies have emphasized the significance of viewing neuropathic pain as a social phenomenon in which treatment and management should pay closer attention to the interpersonal and social needs and quality of life outcomes for the spouse or partner and family as well as the patient (Sofaer-Bennett et al., 2007; Girach et al., 2019; Gökmen et al., 2018).

Marital disruption and sexual malfunctioning were identified as having a significant debilitating effect on PDN by both male and female participants. The situation has been termed by some studies as marriage/relationship disruption (Cano, 2004; Cano et al., 2004; Sofaer-Bennett et al., 2007). A worrying concern was that a respondent in this study stated that after her husband had divorced her because of her PDN condition, she resorted to sleeping with other men to take care of herself and her children. Some participants, however, indicated that they continued to receive support from their spouses/partners despite their PDN condition. It is, therefore, indicative that while PDN has the potential to cause marriage/relationship disruption, in some cases, patients receive appreciable support from their partners. This study confirms the view of Cattich and Knudson-Martin (2009) that both male and female respondents complain of spousal challenges which leads to separation and sometimes to divorce.

6.2.3 How PDN Patients Experience and Describe Their Pain

In this study, Participants were able to locate their pain in various parts of their body. They could describe the intensity and characteristics of their illness/pain (Bouhassira et al., 2008; Bouhassira et al., 2013; Abraham et al., 2018). Participants had complaints of pain in the waist, sharp pain from the thigh to the leg, pain underneath the legs, joint pains, burning sensation in their fingertips, dizziness, and sleeplessness. These complaints are similar to those ascribed to neuropathic pain types in the literature reviewed. Similar to this, the study some PDN characteristics included burning pain, asleep, knife-like, “dead” electrical sensations, numbness, squeezing, tingling, constricting prickling, hurting, freezing, throbbing, and allodynia (Tavakoli & Malik, 2008; Callaghan et al., 2012; Colloca et al., 2017). However, in this study, most participants complained of being sensitive to touch (allodynia) and feelings of sharp and burning pain, particularly in their feet or fingers. This possibly suggests that in this study, the main complaint among participants was about irritability to touch and the feeling of sharp and burning pain in the limbs.

6.2.4 Biological/ Social Medical History of PDN

Participants in this study confirmed that there were traces of diabetes and pain-related issues among family members. The data from diabetes studies suggest that genetic factors are involved with the development of the disease (Dorman & Bunker, 2000; Radha et al., 2003; Rich et al., 2006; Rich, 2017). The striking evidence in this study was that most participants attributed their diabetes to hereditary rather than lifestyle factors such as eating. In this study participants indicated that, apart from their current diabetes/PDN condition, they had conditions such as hypertension, obesity, severe headaches, asthma, and stoke. According to Young et al. (2016), patients with diabetes mellitus may also have other comorbidities and complications which require treatment. Some major comorbid conditions and complications that occur in patients with diabetes include coronary artery disease, stroke, heart failure, breast cancer, pancreatic cancer, colorectal cancer, stroke, and obesity (Madigan et al., 2005; Piette & Kerr, 2006).

6.2.5 Religious Experience and PDN among Diabetic Patients

Participants in this study affirmed that their relationship with God or a higher being has a positive influence on their management of pain in their blood sugar control, similar to what pertains in other studies have affirmed (Esteghamati et al., 2008; Namageyo-Funa et al., 2015; Rivera-Hernandez, 2016). Religious activities such as church meetings and seeking the support of men of God were essential features of this population (Rivera-Hernandez, 2016; Newlin et al., 2008; Koenig et al., 2012). Participants also confirmed that prayers and singing of Christian songs and hymns were essential paths of taking solace during their difficult moments of pain (Strawbridge et al., 1997; How et al., 2011; Polzer & Miles, 2007; Shamsalinia et al., 2016). The sources of their distress were a significant feature in all the various religious adherents in this study. Some participants did not believe that their pain condition was due to poor glycaemic control and lifestyle habits, but rather attributed them to evil spirits and witches. While Christians did not directly say their situation was from God, they believed God might have permitted their current crises, hence when they are in difficulty, they turn to Him for solace. Many of the Christian participants and those of other religions, who are not regular church attendants, attributed the source of their condition to 'evil spirits' or the 'devil'. Others also claimed that it was either a curse or bewitchment by their enemies. One participant claimed that because there were traces of diabetes/PDN in the family, his pain was due to 'sins' or 'wrongdoing' by the family. Two participants indicated that they had visited fetish priests to enquire about the source of their condition and seek a remedy for their pain crises. This study, therefore, suggests that PDN patients resort to religious and spiritual ways to mitigate their quest for solutions for their pain condition and pain relief.

6.2.6 Evidence of Religious Coping among Patients with PDN

The study noted evidence of religious/spiritual coping among the participants of this population (Rivera-Hernandez, 2015). Almost all participants claimed to have a connection with a higher being which helped them cope with their pain. Participants claimed that they prayed to God and sang hymns when in pain (Heidari et al., 2017; Cattich & Knudson-Martin, 2009; Newlin et al., 2008). However, the participants who used prayer and hymns as coping strategies belonged to an organized church body and attended church meetings regularly. Evidence in other studies demonstrats that Moslems who are devoted to their faith employ prayer as a coping mechanism during crises (Hassan, 2015; Haque, 2004; Saad et al., 2019). Almost all the participants indicated that God was their source of hope and strength in order to cope with their pain crises. These studies, however, noted that besides the belief in God, respondents also attended hospitals regularly and adhered to the strict drug regimen. It therefore confirms the view of Gupta and Anandarajah (2014) and Rivera-Hernandez (2015) that there is convincing evidence that religion/spirituality can potentially be an avenue for handling the physical frailty emanating from diabetes crises.

6.2.7 Other Coping Mechanisms among PDN Patients

Participants' responses also indicated that other coping techniques such as watching television, applying warm water to the affected area, applying ointment, and the consumption of herbal preparations were characteristic of this population. The use of herbal preparation among participants was significant and well noted (Preethi, 2013; Kumar et al., 2015). Almost all participants indicated that they had either bought herbal preparations previously, been introduced to a herbal product, or had visited a traditional medicine practitioner for a cure (Modak et al., 2007). Some participants suffering from PDN turned to self-medication using medicinal plant preparations (Damnjanovic, 2015). Others affirmed that when they are in pain, they resort to medications over the counter or from relatives.

6.2.8 Psychosocial Implications of Diabetes/PDN to Patients

Participants complained of several psychological stresses they suffer due to their diabetes (Tinetti et al., 2012; Sudore et al., 2012; Borgnakke et al., 2013). The chief complaint among this population was the feeling of intense sadness (depression) and the fear of dying or death. Similar to the study by McNeil and Vowles (2004), thinking a lot and the inability to engage in social activities was viewed as a significant concern by participants in this study. Stress due to the inability to cope with pain and the re-occurrences of the illness were a considerable burden to participants (Gupta & Anandarajah, 2014). This study also confirmed participants' inability to cope with daily activities such as sleep, diet, personal/social relationships, and work. It therefore confirms the conclusion of other studies that, in patients with diabetes crises, chronic neuropathic pain is related to a decreased QoL, poor sleep, and symptoms of anxiety and depression (Galer et al., 2000; Bouhassira et al., 2013; Davies et al., 2006; Gore et al., 2005; Vileikyte et al., 2005; Van Hecke et al., 2015; Themistocleous et al., 2016; Bai et al., 2017; Geelen et al., 2017).

6.2.9 Evidence of Financial Burden among PDN Patients

In this study, participants complained that due to their painful condition, they were often unable to afford their medication because they had lost their jobs. This finding is consistent with what pertains other countries and points to the fact that whenever there is PDN, there is the likelihood of loss of job (Hart et al., 1997; ADA, 2019; Barcelo et al., 2017; Kirigia et al., 2009; Gray et al., 1995; WHO, 2000; WHO, 2019). In similar study participants attributed the increase in economic hardship to their pain because of their inability to afford a proper diet and to make regular hospital visits (Zhang et al., 2010).

6.3 Discussion of Quantitative Findings

6.3.1 Socio-Demographic Characteristics of PDN Patients versus Anxiety and Depression

The objective was to determine whether there was any statistically significant difference between the effects of socio-demographic variables on depression of PDN patients and the effects of socio-demographic variables on anxiety of PDN patients. The first hypothesis was that PDN patients' level of depression can be predicted by age, sex, highest level of education, employment status, and anxiety level. The second hypothesis was that PDN patients' level of anxiety can be predicted by age, sex, highest level of education, employment status, and depression level.

6.3.2 Socio-Demographic Characteristics and Depression of PDN Patient

According to D'Amato et al. (2016), age is associated with depression and PDN, hence as a PDN patient ages, depression increased. However, in this study, a regression analysis to ascertain the determinants of age and depression on PDN revealed that age and depression are not significant determinants of PDN. D'Amato et al. (2016) further indicated that sex and depression is associated with PDN. This is also contrary to the finding in this study of gender being a determinant of depression in PDN patients. In a study by Akpalu et al. (2018), it was said that traditionally, females have been associated with higher rates of depression among the general population in Ghana as well as those suffering from diabetes, however, this is not the case in this study. It would be interesting to further investigate the reason for this marked difference in the respective findings.

According to Akpalu et al. (2018), marital status has a significant association with depression, but this also happens to be contrary to the finding in this study where marital status such as being single, married, widowed, or separated/divorced were found not to be significant predictors of depression of PDN patients.

When it came to the association between education background and level of depression of PDN patients, this study found a significant association. This is similar to a cross-sectional study at the National Diabetes Management and Research Centre of the Korle Bu Teaching Hospital in Accra, Ghana, where Akpalu et al. (2018) found an association between diabetes and education. This study found in addition that whereas primary education is responsible for a reduction in depression when compared with a university level, a rise in educational level to JHS is responsible for a further reduction in depression as compared to the university level. However, the SHS level of education showed no significant reduction in depression compared to the university level, implying that the higher a person's education, the lower the level of depression they experience as PDN patients.

In their study, Vileikyte et al. (2005) also found that the more educated respondents reported fewer depressive symptoms which is similar to the finding in this study. However, they did not thoroughly investigate the effect of the full effect of education on Depression.

Very few studies in Africa have evaluated the occurrence of depression and its effects among patients with diabetes (Hapunda et al., 2015). The prevalence of depression among type 2 diabetes patients in this study was similar to that reported in other studies (Anderson et al., 2001; Sotiropoulou et al., 2008; Collins et al., 2009; Van Steenbergen-Weijenburg et al., 2010; Papelbaum et al., 2011). Depression in the general population in Ghana was reported to be rare decades ago. However, in recent years, the prevalence has been shown to be comparable to that in other western countries (Akpalu et al., 2018). In this study, a significant finding was the comparatively high prevalence of depression recorded. However, in contrast to the findings in this study of a significantly high prevalence of depression among PDN patients (41%), a relatively lower prevalence was found in Brazil (18.6%) (Papelbaum et al., 2011) while a lower prevalence (14.7%) also emerged from studies in rural Pakistan conducted by Zahid et al. (2008) and in the

United States (a lower prevalence of 8.3%) according to a study conducted by Spanakis and Golden (2013). This wide variation in depression across various studies may be attributed to the difference in the socio-cultural backgrounds of the participants (Akpalu et al., 2018). A person's cultural background refers to the environment and surroundings in which they grew up and the collection of influences in a person's life. Depression attributed to diabetes in different socio-cultural backgrounds due to diversity in social support may vary among participants (Akpalu et al., 2018).

The literature reviewed on diabetes has established strong associations between diabetes and its complications, and depression (Leone et al., 2012; Shehata et al., 2018; De-Graft Aikins et al., 2015; Akpalu et al., 2018; Anderson, 2001). In other words, a person with diabetes is most likely to also have depression. This emerged as a strong finding in our study. It is on record that individuals with depression are more susceptible to the development of diabetes than those belonging to non-depressive populations (Moulton et al., 2015; Pan et al., 2010), referred to in literature as a bidirectional association between diabetes and depression. Similar to Moulton et al. (2015), Dziemidok et al. (2016) also found that depression may be both a consequence and cause of type 2 diabetes.

6.3.3 Socio-Demographic Characteristics and Anxiety of PDN Patients

According to this study current age, sex, educational level, and marital status do not have any significant contribution to the level of anxiety of PDN patients. However, as per the evidence provided by this study, a rise in class in primary school by one additional year results in a reduced level of anxiety by almost one-and-a-half units. Also, a rise in class in JHS by one additional year accounts for a reduction in the level of anxiety by almost two units. However, depression score turned out to be the most important predictor of anxiety, followed by JHS and primary school level of education. It is worth noting at this point that, having perused literature quite extensively

(Vileikyte et al., 2005; Roy & Lloyd, 2012; Ell et al., 2015), very few authors discuss the effect or association between depression and high school level of education (D'Amato et al., 2016), and between depression and primary school level of education, as in this study, at this point. What emerges is a general association between education and depression. However, in this specific study, it emerged that it is only at the primary and JHS levels of education that a rise in education by a year results in a reduction in depression levels. However, this does not pertain to the SHS and university levels as indicated in this study.

6.3.4 Anxiety versus Depression of PDN Patients

Depression has often received the lion's share of attention from clinicians, but anxiety disorders are very common in the context of diabetes. This study found that majority (82.8%) of depressed patients simultaneously had anxiety; while, by contrast, only 68.6% of anxiety patients had depression. In a study by Jain et al. (2011), anxiety disorders were found to be more prevalent than depression in diabetes, similar to the finding in this study, where overall prevalence of anxiety was a little higher (28.5%) than that of depression (23.6). This study also found a strong positive association between depression and anxiety such that not only is anxiety a significant determinant of depression, and vice versa, but also, as anxiety rises in PDN patients, they either develop depression or their depression situation worsens.

The behaviour of anxiety patients towards diabetes is very similar to that of depression and this is highlighted in this study. For instance, as was indicated above in the case with depression, sex, current age, and employment status, whether one was employed or not, were not significant predictors or determinants of diabetes. Just as anxiety and depression negatively impact diabetic complications, it is equally important to note that the reverse is also true: diabetic complications can powerfully increase depression and anxiety with all their attendant disabilities (Jain et al., 2011). This study concurred with that finding. Moreover, it is also worth noting that the diabetic environment is one that enables anxiety and depression to thrive. This is because diabetes involves intense pain and increasing levels of pain which are linked to increases in depression and anxiety (Gore et al., 2005), while depression and anxiety are conditions associated with significant emotional stress (Jain et al., 2011).

With depression comes elevated cardiovascular risk factors (Rubin et al., 2010), the reason why diabetes patients with depression have an increased risk of metabolic syndromes, higher waist circumference, and increased triglycerides. These are all factors known to worsen outcomes for depression (Ahola et al., 2010). In this study, the researcher did not go to the extent of ascertaining the relationship between depression and anxiety on one hand and cardiovascular risk factors on the other, although it would have made for an interesting discussion.

It is worth noting that in recent times, there is growing evidence from several well-designed, prospective epidemiologic trials that emotional stress may increase an individual's chances of developing diabetes (Kinder et al., 2006; Pouwer et al., 2010; Levy et al., 2017), which highlights the strong correlation between depression and anxiety among the PDN patients interviewed Abundant data has also recently become available suggesting a bidirectional relationship between depression and diabetes, such that no matter which condition develops first, it sets the stage for the onset of the other disorder (Pan et al., 2010; Atlantis et al., 2010; Nouwen et al., 2010).

In this study, one significant finding worth discussing was the fact that on the one hand, almost 83% of the PDN patients who had depression also concurrently had anxiety, while on the other, only 68.6% of the patients with anxiety had depression. This further points to the fact that depression has a greater impact on anxiety than anxiety has on depression. Whereas in some literature, every 25% of patients with diabetes have depression (Voinov et al., 2013; Semenkovich et al., 2015), in this study, a slightly lower prevalence of depression among the PDN patients was noted. However, the prevalence of anxiety was much higher (28.9%).

6.3.5 Relationship between PDN Characteristics and Quality of Life Domains

The following quality of life domains were assessed in this study: Physical functioning, emotional problems, energy fatigue, social functioning, pain, general health, and physical health, while among the specific PDN characteristics considered were aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, penetrating, nagging, numb, miserable, and unbearable pain.

Gore et al. (2005) have established in their study that patients with DPN experience neuropathic pain, typically characterized as burning, tingling, electric, sharp, shooting, and lancinating, which initially starts in both feet and may progress to involve calves, fingers, and hands (stocking and glove pattern). Neuropathic pain is a common presenting complaint of patients with peripheral neuropathy (PN) and is considered one of the most debilitating neuropathic symptoms with detrimental effects on patients' quality of life (Girach et al., 2019). This study established that there is no statistically significant association between eleven identified pain characteristics, namely throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain on one hand, and some quality of life domains such as participants' physical functioning and their energy fatigue. This implies that no matter what form of pain participants felt, and how much of each type of pain they felt, that pain had nothing to do with their quality of life. In other words, the quality of life of the PDN patients did not change even if they felt any form of pain. Whenever a person is in some form of pain, they are unable to do certain basic things necessary for their quality of life. Literature informs that sufferers of painful DPN have often suffered from diabetes for a long period of time

(DiBonaventura, 2011). However, this study has established that specifically throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain have no statistically significant association with quality of life. It can, therefore, be conclusively stated that a person's quality of life is not determined by the kind of pain they experience. Ultimately, there were no significant differences between the eleven pain characteristics, namely throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain on the one hand, and the quality of life domains on the other as indicated in the tables in Appendix K. However, this study did reveal significant associations between aching pain and emotional well-being on one hand and between aching pain and social functioning on the other. There was also a significant association between burning pain and social functioning. Similarly, there were significant associations between numbness and role limitation due to emotional problems on the one hand, and between numbness and emotional well-being, social functioning, pain in general and general health on the other. There was also a significant association between miserable pain and role limitation due to physical health.

This study further established significant associations between aching pain and emotional well-being on the one hand and between aching pain and social functioning on the other. This implies that, as per the data analysis, whenever any PDN patient had any form of pain, it affected their emotional well-being. Hence, for a PDN patient to have emotional well-being, they need relief from any form of pain. Similarly, for any PDN patient to be able to function well socially, they need relief from all forms of pain. There is a dearth of literature on physical functioning, quality of life and diabetes. One study on this subject was that of Dziemidok et al. (2016), which found that symptoms of pain interfered with walking ability, normal work, sleep, enjoyment of life, mood, and general activity.

There was also a significant association between burning pain and social functioning implying that for a PDN patient to be able to function well socially, there should be relief from every form of burning pain. In other words, burning pains affected PDN patients' social functioning, a finding similar to that of Dziemidok et al. (2016). Similarly, there were significant associations between numbness and role limitations due to emotional problems on the one hand, and between numbness and emotional well-being, social functioning, pain in general and general health on the other. Hence, in order to enhance a PDN patient's emotional roles, social functions and even manage pain in general, they should be treated for every form of numbness. These findings concur with those of Gore et al. (2005), where it was established that pain associated with diabetic neuropathy substantially affects the quality of life of patients with painful DPN. They further reported on the substantial interference of diabetic neuropathy pain with PDN patients' sleep, enjoyment of life, recreational activities, normal work, mobility, general activity, social activities, and greater impairment in energy, sleep, physical mobility, and emotional reactions when compared to diabetic and non-diabetic controls.

In this study it was established that there was a significant association between miserable pain and role limitation due to physical health, a quality of life characteristic. Thus, as pain reduces, quality of life increases, a finding which is corroborated in a similar study by Gore et al. (2005) which established that pain, a common problem in DPN patients, could reduce quality of life. This implies that the improvement of quality of life is incumbent upon the elimination of pain in PDN patients. Gore et al. (2005) further indicated that chronic pain often restricts a patients' ability to perform important daily activities, thereby compounding the negative impact of pain. A number of studies ascertained that PDN, which is characterized by tingling, burning, sharp, shooting sensations, among others (Tesfaye, Wilhelm, et al., 2013; Bansal et al., 2006), usually affects the quality of life of patients and commonly affects their ability to perform their daily activities, thereby leading to their withdrawal from recreational and social activities (Bansal et al., 2006; Quattrini & Tesfaye, 2003; Gore et al., 2005).

Besides pain intensity, pain interferences such as general activity, walking, work, mood, enjoyment of life, relations with others and sleep were assessed in terms of their association with hypertension in this study. None of the respondents had any association with hypertension. However, none of the pain interference characteristics were found to be statistically significantly associated with hypertension. However, Rajan et al. (2014) report in their community-based population study that the majority of diabetic patients find it difficult to express the character of their pain. They also found that "Patients with neuropathic pain have markedly lower scores on quality-of-life domains, including enjoyment of life, sleep, physical mobility, self-care, and energy levels". If the statement of Rajan et al. about patients' difficulty in expressing the character of their pain is anything to go by, then it casts a doubt on the reliability of pain studies. The fact remains that diabetes and hypertension coexist (Contreras et al., 2000).

6.3.6 Evaluation of Treatment as Usual plus CBT plus Hypnosis Compared to CBT plus Treatment as Usual Only

Respondents in this study were grouped into a control group and an experimental group. Individuals in the control group received an intervention of TAU and CBT, while individuals in the experimental group received TAU and CBT plus HYP. Both groups were measured on pain intensity and pain interference scales after one month and the results were compared. Pain intensity measured: pain at its worst during the past week, pain at its least during the past week, average pain during the past week, and the average pain at the time of data collection. Pain interference measured: Walking ability, relations with other people, sleep, general activity, mood, normal work, and enjoyment of life.

The known mechanisms for the treatment of pain in PDN include TAU and CBT. There is evidence that there is pain that does not respond to currently available and known treatments (Merskey & Bogduk, 1994). As part of the objectives for this study, the researcher sought to investigate the impact that the inclusion of hypnosis would have on the treatment of PDN and its possible inclusion in the treatment mechanisms for PDN in future if its impact turned out to be positive. Therefore, as part of the study design, the impact of hypnosis on pain's interference as well as pain's intensity was studied. Boschen et al. (2016) and Turk et al. (2008) conducted a study in Canada to examine the outcomes of a pain self-management outpatient programme based on CBT because they suspected traditional uni-modal interventions might not be enough in the treatment of complex pain. In their study, they introduced interventions such as education, cognitive behavioural skills, exercise, and self-management strategies. Among their outcome measures were intensity of pain experience, pain disability, general health functioning, etc. They reported pre- and post-improvements in all the outcomes measured, including pain.

Pain's Intensity

In this study, at baseline, there was no statistically significant difference in the intensity of pain at its worst during the week prior to the study between the control group (TAU + CBT) and experimental group (TAU + CBT). However, after the introduction of HYP to the experimental group, there was a statistically significant difference in pain between the control group (TAU + CBT) and experimental group (TAU + CBT + HYP). The introduction of hypnosis lead to a significant reduction in pain for the experimental group. This, therefore, implies that the inclusion of hypnosis in the treatment of pain at its worst during the week prior to the study resulted in a significant reduction in pain when compared with the existing treatment mechanisms. Aggarwal et al. (2019) reported in their study that CBT resulted in long-term improvements in pain intensity, depression, and pain-related activity interference.

This study further found that at baseline, the level of pain at its least during the past week was the same for both the control and experimental groups. This implies that a person in the experimental group felt the same level of pain at its least during the past week as a person in the control group. The test to ascertain whether this difference in pain at its least during the past week between the two groups was statistically significant or not indicated that it was statistically significant. This suggests that this difference in pain at its least during the past week is attributable to the additional intervention, suggesting that hypnosis accounted for the difference in mean pain at its least during the past week. In other words, the lowering of pain in the experimental group was attributable to hypnosis. Otis et al. (2013) came to a similar conclusion in their study, although their study design varied from a combined intervention of TAU + CBT + HYP.

This study also suggested that at baseline, the average pain during the past week was the same for both the control and experimental groups. In other words, a person in the experimental group felt the same level of average pain during the past week as a person in the control group. At intervention, average pain during the past week prior to data collection was lower for the experimental group, which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP), than for those in the control group. A further test to ascertain whether this difference in average pain during the past week between the two groups was statistically significant or not, indicated that the difference was statistically significant. This, therefore, implies that average pain during the past week is attributable to the intervention (hypnosis), further suggesting that hypnosis accounts for the difference in average pain during the past week. This finding is contrary to that of Eccleston et al. (2015), whose study did not provide sufficient evidence of the efficacy and safety of CBT for chronic neuropathic pain.

At baseline, the average pain at the time of data collection was the same for both the control and experimental groups. In other words, a person in the experimental group felt the same level of average pain at the time of data collection as a person in the control group. This suggests that at baseline, the difference in average pain at the time of data collection between the two groups might have occurred by chance and not by any inherent difference between the two groups. At intervention, the average pain at the time of data collection was again far lower for the experimental group, which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP), than for the control group. The accompanying *t*-test conducted to ascertain whether this difference between the two groups was statistically significant or not indicated that it was statistically significant. This, therefore, implies that the average pain at the time of data collection was attributable to the inclusion of hypnosis as an intervention. While Patterson and Jensen (2003) reported a positive correlation between hypnotics and pain, this present study found a negative correlation between hypnotics and pain. Thus, as hypnosis is applied on pain, it causes pain to reduce significantly.

Pain's Interference

In determining whether or not there was any statistically significant difference in pain's interference with walking ability before the intervention between the experimental and the control groups, there turned out not to be any statistically significant difference either before or after the intervention. At intervention, pain at its worst during the past week was lower for the experimental group that received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for those in the control group. This implies that the mean difference in pain at its worst during the past week is attributable to the intervention, suggesting that hypnosis accounted for the difference in mean pain at its worst in the last week.

On pain's interference with relations with other people between the experimental and the control groups before intervention, there turned out to be no statistically significant difference before intervention, implying that the numerical difference that is observed in this study might have occurred by chance. After the intervention, however, there was a statistically significant difference in pain’s interference with relations with other people. This indicates that the introduction of hypnosis in the treatment of PDN has a statistically significant effect on the reduction of pain’s interference with the study participants’ relations with other people.

There was also a statistically significant difference in pain’s interference with walking ability after the intervention. This, therefore, implied that the introduction of hypnosis in the treatment of PDN has a statistically significant effect on the reduction on pain’s interference with the study participants’ walking ability, though marginal. Considering the two findings, this suggests that at baseline, the average pain's interference with walking ability was a little lower for the experimental group than for the control group. No other study was found with a similar finding.

At baseline, participants in the experimental group had a little less pain than participants in the control group. After the intervention, the average of pain's interference with mood was much lower for the experimental group, which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP), than those in the control group. This therefore implies that this average of pain's interference with mood is attributable to the intervention (hypnosis), further suggesting that hypnosis accounts for the difference in average pain ($p < 0.001$) in the last one week (Table 5.8). No studies were found to also have a similar or contrary finding.

Furthermore, results from the data analysis in this study showed that at baseline, the average of pain's interference with normal work for the control group (CBT + TAU) was slightly higher than that for the experimental group. A paired samples *t*-test found the difference in the average of pain's interference with normal work between the experimental croup and the control group before the intervention to be statistically significant. This suggests that at baseline, the average of pain's interference with normal work was significantly smaller for the experimental group than for the control, though marginal. It implies that the average of pain's interference with normal work after the intervention was attributable to the intervention of introduction of hypnosis, suggesting that hypnosis accounted for the difference in average pain's interference with normal work (Table 5.8).

In ascertaining the situation of pain's interference with enjoyment of life after the intervention, the mean of pain's interference with enjoyment of life after intervention was once again found to be significantly lower for the experimental group which received hypnosis in addition to the other existing treatments TAU + CBT + HYP) than for the control group. This implies that the mean difference in pain's interference with enjoyment of life is attributable to the intervention (hypnosis), suggesting that hypnosis again accounted for the difference in the mean of pain's interference with enjoyment of life after intervention. In other words, the inclusion of hypnosis resulted in a faster reduction in pain's interference with the enjoyment of life for the experimental group (TAU + CBT + HYP) than only TAU and CBT.

On pain's interference with participants' general activity both at baseline and at intervention, the study found that the difference in pain's interference with general activity at baseline between the experimental group and the control group, though marginal, was statistically significant. This suggests that at baseline, the difference in mean level of pain's interference with general activity was marginally greater for the control group than for the experimental group (Table 5.16). In ascertaining the situation of pain’s interference with general activity after intervention, the mean of pain’s interference with general activity was significantly lower for the experimental group which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group. This suggests that the mean difference in pain’s interference with general activity was attributable to the intervention (hypnosis), suggesting that hypnosis again accounted for the difference in mean pain’s interference with general activity after the intervention. In other words, the inclusion of hypnosis resulted in a faster reduction in pain than only TAU and CBT.

The study results also showed that at baseline, the mean of pain's interference with mood before the intervention, for the control group (CBT + TAU), was a little higher than that of those in the experimental group. A paired samples *t*-test found the difference in the average of pain's interference with mood between the experimental group and the control group, at baseline, to be statistically significant.

6.4 Conclusion

This chapter discussed the qualitative and quantitative results of this study as well as the triangulation of phases I, II and III. It presented a discussion of the findings of the study in accordance with its objectives and relevant literature. The qualitative discussion centred on the analysis of data respondents provided for general information on diabetes, self-assessment of the impact of PDN, experiences of PDN patients, biological/social medical history, religious experiences, evidence of religious coping, other coping methods, psychosocial implications, and the evidence of financial burden and PDN. The quantitative discussion considered social demographic characteristics and depression, social demographic characteristics and anxiety, as well as anxiety versus depression. It also explained the relationship between PDN characteristics and quality of life domains and PDN as well as intensity and PDN interference. The chapter also contained an evaluation of TAU + CBT + HYP compared to CBT + TAU only. The next chapter presents the general conclusion of the entire study and makes some recommendations for further research.

CHAPTER SEVEN: GENERAL CONCLUSION AND RECOMMENDATIONS

7.1 Introduction

This chapter outlines the general conclusion of the entire study and makes some recommendations for further research. It highlights the core findings of both the qualitative and quantitative data. The chapter also discusses the synthesis of the qualitative and quantitative phases of the study. It finally draws on the limitations of the study and recommendations for further reasearch.

7.2 Core Findings

The study proposed to address the following research questions in a sample of individuals with PDN: (1) What are the experiences of patients with PDN and their use of personal beliefs as coping mechanism?, (2) What is the association between socio-demographic variables (i.e., age, sex, marital status, education and occupation) on depression, anxiety, and PDN?, (3) Is there a relationship between specific PDN characteristics (i.e., aching, throbbing, shooting, stabbing, gnawing, tender, burning, exhausting, tiring, penetrating, nagging, numb, miserable, and unbearable) and specific quality of life domains (i.e., physical functioning, emotional problems, energy fatigue, social functioning, pain, general health, and physical health), (4) Is there a significant difference in the efficacy of the treatment of PDN with medication, CBT and hypnosis compered to medication and CBT in a randomized controlled experiment. The core findings of this study in both the qualitative and and quantitative data are as follows;

7.2.1 Core Findings in the Qualitaive Data

Regarding the experiences of patients with PDN and their use of personal beliefs as coping mechanism, participants appeared to lack general information on their diabetic condition. Evidence therefore, indicates that participants have inadequate knowledge and understanding of diabetes and

PDN. This study found that participants appear to lack adequate knowledge of proper glycaemic control through their diet

The sources of participant’s PDN were a significant feature in all the various religious adherents in this study. Many of the Christian participants and those of other religions, who are not regular church attendants, attributed the source of their condition to 'evil spirits' or the 'devil'. Others also claimed that it was either a curse or bewitchment by their enemies. This study, therefore, suggests that PDN patients resort to religious and spiritual ways to mitigate their quest for solutions for their pain condition and pain relief.

This finding indicates that although PDN patients are aware and can describe the nature of their pain, they lack the basic understanding of how these various pain characteristics exacerbate or ameliorate their condition. Participants Also affirmed that PDN had an adverse health effect on their daily life, resulting in poor quality of life as demonstrated in studies investigating the association between PND and daily functioning among patients.

Participants in this study affirmed that their relationship with God or a higher being has a positive influence on their management of pain in their blood sugar control. Participants also confirmed that prayers and singing of Christian songs and hymns were essential paths of taking solace during their difficult moments of pain. The study therefore noted evidence of religious/spiritual coping among the participants of this population. Participants’ responses also indicated that other coping techniques such as watching television, applying warm water to the affected area, applying ointment, and the consumption of herbal preparations were characteristic of this population. Participants also complained of several psychological stresses such as the feeling of intense sadness (depression) and the fear of dying or death.

7.2.1 Core Findings in the Quantitative Data

With reference to socio-demographic characteristics of PDN patients versus anxiety and depression, this study found that age and sex are not significant determinants of depression among PDN patients. It also confirmed that marital status such as being single, married, widowed or separated/divorced were not significant predictors of depression in PDN patients. However, when it came to the association between education background and level of depression in PDN patients, this study found a significant association. Age, sex, educational level, and marital status did not make any significant contribution to the level of anxiety of PDN patients. However, a rise in class in primary school and in JHS by one more year resulted in a reduced level of anxiety by almost one-and-a-half units.

This study also found a strong positive association between depression and anxiety in that not only is anxiety a significant determinant of depression, and vice versa, but as anxiety increases in PDN patients, they either develop depression or their depression situation worsens. This points to the fact that depression impacts anxiety more than anxiety impacts depression.

Regarding the relationship between PDN characteristics and quality of life domains, this study established that there is no statistically significant association between eleven identified pain characteristics, namely throbbing pain, shooting pain, stabbing pain, gnawing pain, sharp pain, tender pain, exhausting pain, tiring pain, penetrating pain, nagging pain and unbearable pain on the one hand, and some quality of life domains such as physical functioning and energy fatigue. This implies that no matter what form of pain PDN patients felt and how much of each type of pain they felt, that pain had nothing to do with their quality of life. In other words, the quality of life of PDN patients did not change despite the pain they experienced.

The study also established significant associations between aching pain and emotional well-being on the one hand and between aching pain and social functioning on the other. This implies that whenever any PDN patient had any pain, it affected their emotional well-being. Hence, for a PDN patient to experience emotional well-being, pain should be alleviated. Similarly, for any PDN patient to function well socially, pain should be alleviated.

Furthermore, the study found a significant association between burning pain and social functioning, implying that for any PDN patient to be able to function well socially, all burning pain should be alleviated. In other words, their burning pains affected PDN patients' social functioning as indicated in the findings of Dziemidok et al. (2016). Similarly, there were significant associations between numbness and role limitations due to emotional problems on the one hand, and between numbness and emotional well-being, social functioning, pain in general, and general health on the other. In this study, a significant association between miserable pain and role limitation due to physical health, a quality-of-life characteristic was found. Thus, as pain reduces, quality of life also increases.

The study found that after the introduction of hypnosis to the experimental group, there was a statistically significant difference in pain between the control group (TAU + CBT) and the experimental group (TAU + CBT + HYP). This difference manifested in a significant reduction in pain for the experimental group. This implies that the inclusion of hypnosis in the treatment of pain at its worst during the week prior to the study resulted in a drastic reduction in the pain compared to the remaining existing treatment mechanisms. The study also found that pain at its least during the week prior to the study is attributable to the additional intervention, suggesting that hypnosis accounts for the difference in mean pain at its least during the week prior to the study. In other words, the lowering of pain in the experimental group is attributable to hypnosis.

The study goes on to suggest that average pain during the week prior to the study is attributable to the intervention (hypnosis), further suggesting that hypnosis accounts for the difference in average pain during the week prior to the study. At intervention, the average pain at the time of data collection was again significantly lower for the experimental group that received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group. Thus, when hypnosis is used for pain, it causes a significant reduction in pain.

In pain's interference with walking ability at intervention, pain at its worst during the week prior to the study was lower for the experimental group that received hypnosis in addition to the other existing treatments (TAU + CBT + HYP) than for the control group. This implies that the decrease in pain at its worst during the week prior to the study is attributable to the intervention, suggesting that hypnosis accounted for the difference in mean pain at its worst during the week prior to the study.

Pain's interference with relations with other people between the experimental and the control groups after the intervention resulted in a statistically significant difference. This affirms that the introduction of hypnosis in the treatment of PDN has a statistically significant effect on the reduction of pain’s interference with the study participants’ relations with other people.

After the intervention, the average of pain's interference with mood was lower for the experimental group, which received hypnosis in addition to the other existing treatments (TAU + CBT + HYP), than for the control group. This implies that the average of pain's interference with mood is attributable to the intervention (hypnosis), further suggesting that hypnosis accounts for the difference in average of pain’s interference with mood.

The study found that the average of pain's interference with normal work after the intervention is attributable to the intervention of hypnosis, suggesting that hypnosis accounts for the difference in average pain at the time of data collection. It also confirmed that the inclusion of hypnosis results in a faster reduction in pain's interference with the enjoyment of life for the experimental group (TAU + CBT + HYP) than only TAU and CBT.

In ascertaining the situation of pain's interference with general activity after intervention, the study suggested that the decrease in pain is attributable to the intervention (hypnosis), suggesting that hypnosis again accounts for the difference in mean pain's interference with general activity after the Intervention. In other words, the inclusion of hypnosis results in a faster reduction in pain than only TAU and CBT. Finally, the study found that the decrease in pain's interference with mood after the intervention for the experimental group was due to the inclusion of hypnosis in the intervention.

7.3 Synthesis of the Study Phases (Qualitative and Quantitative)

Even though in this study, many participants were not sufficiently informed about their basic diabetic conditions and diabetes as a health situation in general, in contrast to previous studies which had stated the opposite, participants were able to provide reliable information about the experiences of their diabetic condition. In the qualitative analysis, it was evident that a significant number of the respondents had no idea what caused diabetes, yet these same respondents provided reasonably accurate information about their experiences of their condition. They could not recall for how long they had been diagnosed with diabetes, but they knew exactly how they felt as a result. However, literature on studies conducted in Ghana and elsewhere indicate that patients generally are knowledgeable on diabetes, its causes, symptoms, related medications, etc. (Kugbey et al., 2017; Tabong et al., 2018; Al-Qazaz et al., 2011; Abouammoh & Alshamrani, 2020).

In this study, patients' lack of knowledge on diabetes together with their ability to provide adequate information, as evidenced in the quantitative segment, could be attributed to the fact that most of the measurements taken in this study were done using tools, such as LANSS, SF-36, HADS and BPI-PDN, which did not require any knowledge of a person's diabetic situation to provide information or a response (Backonja & Krause, 2003). Their self-assessment centred on the participants' pain experiences and their associated coping mechanisms, and extended to their personal beliefs as well, which is normally expected of participants (Tavakoli & Malik, 2008; Callaghan et al., 2012; Colloca et al., 2017). On family history in relation to diabetes and PDN, although participants did not know much about diabetes, they could relate their families' historical experiences about pain, depression, their general health status, etc., which provided vital information needed for this study. Respondents, in the qualitative phase of this study, could relate that they experienced depression, noticed a reduction in the strength with which they performed their daily chores, etc., which coincided with their quantitative responses in the use of the quality of life domains such as physical functioning, role limitation, energy fatigue, social functioning, etc. (Sofaer-Bennett et al., 2007; Girach et al., 2019; Gökmen et al., 2018), which enabled the participants in this study to better identify their pains, contrary to what pertained in similar studies (Schreiber et al., 2015; Sofaer-Bennett et al., 2007; Atalay et al., 2013; Bakkers et al., 2014; Brod et al., 2015), which stated that participants appeared to lack adequate or better understanding of the mechanisms underlying their diabetic neuropathic pain.

Respondents were clear on how they felt depressed as a result of their medical situation and its attendant pains in the qualitative phase of this study. This was corroborated by the empirical evidence obtained from the quantitative phase of the study which revealed that the majority of the participants were depressed, resulting in a significant number of them suffering from anxiety.

These findings were corroborated by other similar studies (Tinetti et al., 2012; Sudore et al., 2012; Borgnakke et al., 2013). It is also worth noting that the knowledge of some of the respondents could be a reason they might have allowed themselves to voluntarily fall into such situations. For instance, a respondent, during the qualitative interview, indicated that she knew that as long as the situation could be hereditary, she was certainly going to get diabetes. This might have been a reason why she did not take any precautionary measures against the disease. However, the empirical aspect of the study did not delve much into this area.

7.4 Limitation of the Study

The limitations to this study included: (1) Difficult access to clinicians and their unwillingness to partake in this research. Professionals working in the field of psychology and pain are limited in Ghana, which implies that access to such clinicians was restricted. (2) The hesitance of patients to voluntarily take part in the study because it was a research study. (3) The study was conducted in the Ashanti Region of Ghana only. This is one of 16 regions in Ghana and this might limit the generalisability of the study. (4) The inventories (data collection tool) used in this study were relatively new to the administrators and the respondents, therefore there were some difficulties experienced such as spending lots of time to familiarise the respondents with these inventories. (5) There was also the problem of language and translation since most of the respondents spoke only Twi (an Akan dialect from Ghana).

7.5 Recommendations

1. The findings of Forrest et al. (1997), AlQuliti (2015), and Harris et al. (1993) are contrary to the finding in this study that hypertension influences PDN. It would be interesting to conduct further research into what could be the cause of the variation between the findings

of the various studies. Contreras et al. (2000) suggest that there is an association between hypertension and diabetes.

2. Although some of the respondents stated how their diabetic situation had affected their sexual life, no quantitative questions were asked about their level of fertility. It would have been interesting to establish the effect of diabetes on fertility levels from the quantitative questionnaire so as to provide specific empirical effect of diabetes on fertility levels, but this was not a specific objective. Therefore, the absence of any fertility questions in the quantitative phase of this study is excusable. However, it would be useful for future studies to establish how participants’ experiences, as stated in their qualitative responses, support or refute their empirical responses to questionnaire(s), as reported in other studies (Cano, 2004; Sofaer-Bennett et al., 2007; Cattich & Knudson-Martin, 2009). It would also be enlightening if future studies could focus on collecting empirical information in support of how the effect of diabetes on fertility has influenced divorce, polygamy, etc.
3. Participants in this study demonstrated practical knowledge of their families’ social medical history of diabetes and this reflects as an aspect of the qualitative data. This study inadvertently omitted to collect empirical data on body mass index, which would have helped to link participants’ experiences with obesity.
4. There was no empirical evidence to the qualitative religious experiences in this study. It would have been useful to have some quantitative findings in support of the qualitative narrations of the respondents in this study as it pertains to other studies (Esteghamati et al., 2008; Namageyo-Funa et al., 2015; Rivera-Hernandez, 2016).

5. Among the coping mechanisms emanating from the qualitative data collected in this study were prayer, singing of hymns and songs of praises, and church attendance. However, no empirical data was collected to corroborate these findings as other studies have shown that patients take a great deal of solace in religious coping mechanisms. It would have been useful to have included this in this study.
6. Participants clearly indicated how much financial burden they had as a result of the cost of all the medication they require. A useful empirical aspect of this study, that was inadvertently omitted in the quantitative data collection due to its being absent in the objectives, was the costing of their medication on a weekly and monthly basis as an estimation of the financial burden suffered. It would be useful to investigate these factors further.

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Appendix A

Social Demographic Questionnaire

You are invited to participate in this study is to explore a biopsychological intervention of painful diabetic neuropathy in Ghana. Any information that you provide will be treated with absolute confidentiality and anonymity. Do not write your name or anything that could be used to identify you on this questionnaire. There are no risks involved in taking part in the study. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

A. DEMOGRAPHIC INFORMATION

Please tick the box that applies to you:

i. **Sex:** Male []Female []
ii. **Age:** []
iii. Which region of Ghana do you come from [ACC] [VR] [CR] [WR] [ER] [AR] [BAR] [NR] [UWR] [UER]
iv. Ethnicity []
v. **Marital Status:** Married [] Single [] Separated [] Divorced []
vi. **Highest Education:** No education/primary school [] junior high/form four [] Secondary/vocational school [] Tertiary []
vii. **How will you rate your Socio economic Status: Upper** Class [] Middle Class [] lower class

B. GENERAL HEALTH INFORMATION

1. In general, would you say your health is? Excellent [] 1 Very good [] 2 Good [] 3Fair [] 4 Poor [] 5

2. What type of Diabetic are you? Type 1 [] Type 11 [] Gestational Diabetes []

3. Compared to two months ago, how would you rate your health in general now? Much better now than two months [] 1 somewhat better now than two months [] 2 about the same [] 3 somewhat worse now than two months [] 4 Much worse now than two months

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Appendix B

Semi Structure Interview Guide on Personal Beliefs Coping of Painful Diabetic Neuropathy

Today we are going to talk for one hour and tape the conversation. I'm interested in knowing more about you regarding your experiences and beliefs in coping with your pain. First we are going to talk about you in general and about your faith, religious beliefs and its relationship with your painful diabetic neuropathy. There are no right answers. Please take your time in answering each question. Answer each question in your own words and you do not have to answer each question or tell me things you are not comfortable sharing.

General:

Tell me about yourself.

1. How has having painful diabetic neuropathy influenced your life?
2. Tell me about some of your biggest difficulties or problems with regards to your diabetic pain. How do you overcome them?
3. Tell me about some of your proudest moments or biggest source of happiness during your pain crises. How has this influenced your life?
4. Tell me about some of your saddest moments because of your pain. How has this influenced your life
5. Do you feel or think there is meaning to people's lives? Are we here on earth for a reason or purpose?
6. What do you feel is the purpose of your life? What gives your life meaning?

Personal Beliefs:

7. Now, I'd like to ask you a few questions about your personal beliefs:
8. Are you a religious person?
9. What faith or religion do you belongs to
10. Can you tell me a little about your feelings, thoughts, or beliefs regarding your faith?
11. Tell me about your family's religious beliefs.
12. Tell me about what things you consider religious?
13. Do you feel as though you have a relationship with a higher power? What do you call that higher power? Tell me about your relationship with a higher being (or God).
14. How important if any, does your beliefs have in your life?
15. Does Religion help you to cope with Painful Diabetic neuropathy, (How)
16. How do you deal with major problems regarding your pain and to what extent do you apply religion to cope positively or negatively?

Positive coping

17. I look for a stronger connection with God/a higher power during my pain crises. **yes/no**
18. I seek God/a higher power's love and care for a remedy to my pain. **yes/no**
19. I seek help from God/a higher power in letting go of my anger during my pain crises. **yes/no**
20. I try to put my plans into action together with God/a higher power during my pain crises. **yes/no**
21. I try to see how God/a higher power might be trying to strengthen me in this situation. **yes/no**
22. I ask forgiveness for my sins/wrongdoing when am in a pain crises. **yes/no**
23. I focus on religion to stop worrying about my pain. **yes/no**

Negative coping

24. I wonder whether God/a higher power had abandoned me because of my pain.
25. I feel punished by God/a higher power for my lack of devotion that is why I have pains.
26. I wondered what I did for God/a higher power to punish me with this pain.
27. I question God/a higher power's love for me during my pain crises.
28. I wonder whether my church/mosque/shrine/fellow followers had abandoned me because of my pain.
29. I have concluded the devil/evil forces made this happen.
30. I question the power of God/a higher power during my pain crises.

Religious Beliefs and Coping

31. Now I'd like to talk about how your religious beliefs influence your day–to-day life regarding your pain.
32. Do you think that your religious beliefs have any effect on your pain condition? If yes, what type of effect?
33. What sorts of things or people help you feel better when in pain
34. How has religious beliefs influenced your decisions or personal choices.
35. What role do your beliefs have during your pain crisis?
36. How will you use your religious beliefs to deal with personal pain?
37. How would you have handled the pain without your religious beliefs?

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Appendix C

THE LEEDS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGNS (LANSS) PAIN SCALE

Name... Date

This pain scale can help to determine whether the nerves that are carrying your pain signals are working normally or not. It is important to find this out in case different treatments are needed to control your pain.

A. PAIN QUESTIONNAIRE

- ■ Think about how your pain has felt over the last week.
- ■ please say whether any of the descriptions match your pain exactly.

1. Does your pain feel like strange, unpleasant sensations in your skin?
Words like pricking, tingling, pins and needles might describe these sensations.
a) NO – My pain doesn't really feel like this
b) YES – I get these sensations quite a lot

2. Does your pain make the skin in the painful area look different from normal?
Words like mottled or looking more red or pink might describe the appearance.
a) NO – My pain doesn't affect the colour of my skin
b) YES – I've noticed that the pain does make my skin look different from normal

3. Does your pain make the affected skin abnormally sensitive to touch?
Getting unpleasant sensations when lightly stroking the skin, or getting pain when wearing tight clothes might describe the abnormal sensitivity.
a) NO – My pain doesn't make my skin abnormally sensitive in that area
b) YES – My skin seems abnormally sensitive to touch in that area.

4. Does your pain come on suddenly and in bursts for no apparent reason when you're still?
Words like electric shocks, jumping and bursting describe these sensations.
a) NO – My pain doesn't really feel like this
b) YES – I get these sensations quite a lot

5. Does your pain feel as if the skin temperature in the painful area has changed abnormally?
Words like hot and burning describe these sensations.

a) NO – I don’t really get these sensations
b) YES – I get these sensations quite a lot

B. **SENSORY TESTING**

Skin sensitivity can be examined by comparing the painful area with a contralateral or adjacent non-painful area for the presence of allodynia and an altered pin-prick threshold (PPT).

1. Allodynia

Examine the response to lightly stroking cotton wool across the non-painful area and then the painful area. If normal sensations are experienced in the non-painful site, but pain or unpleasant sensations (tingling, nausea) are experienced in the painful area when stroking, allodynia is present.

a) NO – Normal sensations in both areas
b) YES – Allodynia in painful area only

2. Altered pin-prick threshold

Determine the pin-prick threshold by comparing the response to a 23-gauge (blue) needle mounted inside a 2ml syringe barrel placed gently onto the skin in a non-painful and then painful areas.

If a sharp pin prick is felt in the non-painful area, but a different sensation is experienced in the painful area, eg. none/ blunt only (raised PPT) or a very painful sensation (lowered PPT), an altered PPT is present.

If a pinprick is not felt in either area, mount the syringe onto the needle to increase the weight and repeat.

a) NO – Equal sensation in both areas
b) YES – Altered PPT in painful area

SCORING:

Add values in parentheses for sensory description and examination findings to obtain overall score.
TOTAL SCORE (maximum 24)

If score < 12, neuropathic mechanisms are *unlikely* ***to be contributing to the patient’s pain.***
If score ≥ 12, neuropathic mechanisms are *likely* ***to be contributing to the patient’s pain.***

Source: Bennett M, The LANSS Pain Scale: The Leeds assessment of neuropathic symptoms and sign. Pain 2001;92: 147-157

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Appendix D

THE MEDICAL OUTCOMES STUDY SHORT FORM (SF-36)
(HEALTH QUALITY OF LIFE)

Choose one option for each questionnaire item.

1. In general, would you say your health is:
    1 - Excellent
    2 - Very good
    3 - Good
    4 - Fair
    5 - Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

    1 - Much better now than one year ago
    2 - Somewhat better now than one year ago
    3 - About the same
    4 - Somewhat worse now than one year ago
    5 - Much worse now than one year ago

HEALTH
The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?
Yes, limited a lot
Yes, limited a little
No, not limited at all

3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports
1 2 3

4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
1 2 3
5. Lifting or carrying groceries 1 2 3
6. Climbing **several** flights of stairs 1 2 3
7. Climbing **one** flight of stairs 1 2 3
8. Bending, kneeling, or stooping 1 2 3

9. Walking **more than a mile** 1 2 3
10. Walking **several blocks** 1 2 3
11. Walking **one block** 1 2 3
12. Bathing or dressing yourself 1 2 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?
Yes No
13. Cut down the **amount of time** you spent on work or other activities 1 2
14. **Accomplished less** than you would like 1 2
15. Were limited in the **kind** of work or other activities 1 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort) 1 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
Yes No
17. Cut down the **amount of time** you spent on work or other activities 1 2
18. **Accomplished less** than you would like 1 2
19. Didn't do work or other activities as **carefully** as usual 1 2
20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
1 - Not at all
2 - Slightly
3 - Moderately
4 - Quite a bit
5 – Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?
1 - None
2 - Very mild
3 - Mild
4 - Moderate
5 - Severe
6 - Very severe
22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?
1 - Not at all
2 - A little bit
3 - Moderately
4 - Quite a bit
5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...
All of the time
Most of the time
A good bit of the time
Some of the time
A little of the time
None of the time
23. Did you feel full of pep? 1 2 3 4 5 6
24. Have you been a very nervous person? 1 2 3 4 5 6
25. Have you felt so down in the dumps that nothing could cheer you up? 1 2 3 4 5 6
26. Have you felt calm and peaceful? 1 2 3 4 5 6
27. Did you have a lot of energy? 1 2 3 4 5 6
28. Have you felt downhearted and blue? 1 2 3 4 5 6
29. Did you feel worn out? 1 2 3 4 5 6
30. Have you been a happy person? 1 2 3 4 5 6
31. Did you feel tired? 1 2 3 4 5 6
32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.
Definitely true
Mostly true
Don't know
Mostly false
Definitely false
33. I seem to get sick a little easier than other people 1 2 3 4 5
34. I am as healthy as anybody I know 1 2 3 4 5
35. I expect my health to get worse 1 2 3 4 5
36. My health is excellent 1 2 3 4 5

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Appendix E

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don’t take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up': I feel as if I am slowed down:			**I feel as if I am slowed down:**
	3	Most of the time 3 Nearly all the time	3		Nearly all the time
	2	A lot of the time 2 Very often	2		Very often
	1	From time to time, occasionally Sometimes	1		Sometimes
	0	0 Not at all	0		0 Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
	0	Definitely as much			Not at all
	1	Not quite so much			Occasionally
	2	Only a little			Quite Often
	3	Hardly at all			Very Often
		I get a sort of frightened feeling as if something awful is about to Happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly			Definitely
	2	Yes, but not too badly			I don't take as much care as I should
	1	A little, but it doesn't worry me			I may not take quite as much care
	0	Not at all			I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**

	0	As much as I always could			Very much indeed
	1	Not quite so much now			Quite a lot
	2	Definitely not so much now			Not very much
	3	Not at all			Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		0 Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
	3	Not at all			Very often indeed
	2	Not often			Quite often
	1	Sometimes			Not very often
	0	Most of the time			Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	3	Definitely			Often
	2	Usually			Sometimes
	1	Not Often			Not often
	0	Not at all			Very seldom

Please check you have answered all the questions
Scoring:
Total score: Depression (D) ____________ Anxiety (A) _______________
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

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Appendix F

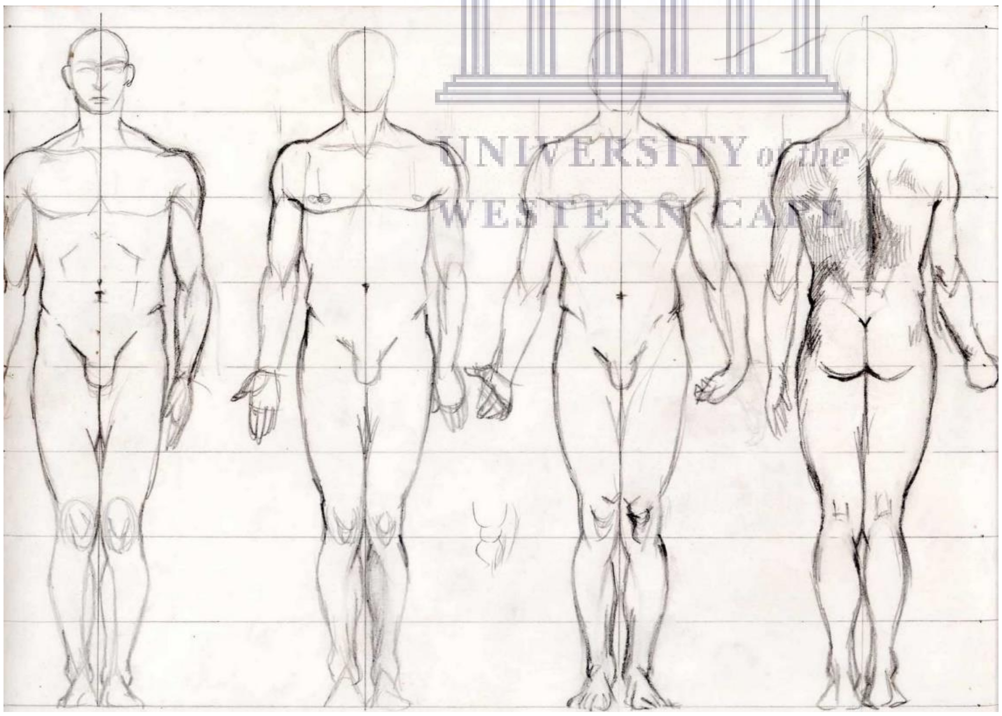
BRIEF PAIN INVENTORY

Date.
Time:

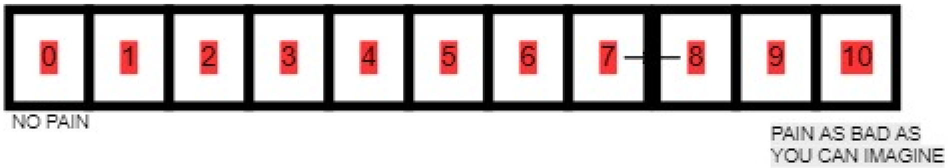
1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. Yes 2. No

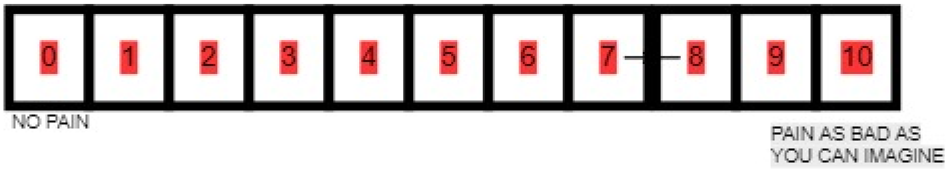
2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



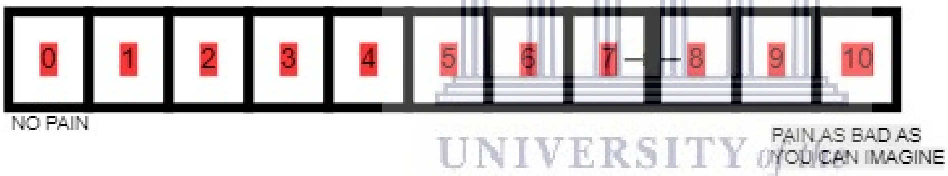
3) Please rate your pain by circling the one number that best describes your pain at its WORST in the last 24 hours.



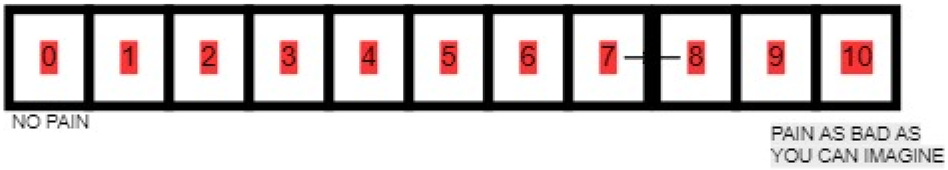
4) Please rate your pain by circling the one number that best describes your pain at its LEAST in the last 24 hours.



5) Please rate your pain by circling the one number that best describes your pain on the AVERAGE.



6) Please rate your pain by circling the one number that tells how much pain you have RIGHT NOW.



7) What treatments or medications are you receiving for your pain?

8) In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that shows how much RELIEF you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
NO RELIEF										COMPLETE RELIEF

9) Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General activity

0	1	2	3	4	5	6	7	8	9	10
DOES NOT INTERFERE										COMPLETELY INTERFERES

B. Mood

0	1	2	3	4	5	6	7	8	9	10
DOES NOT INTERFERE										COMPLETELY INTERFERES

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
DOES NOT INTERFERE										COMPLETELY INTERFERES

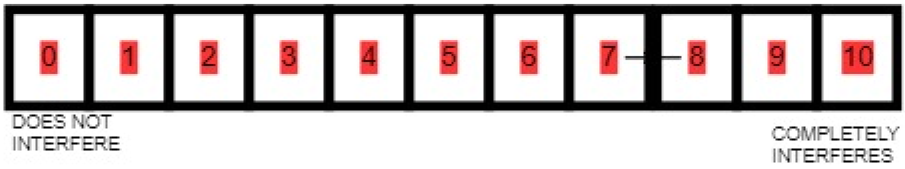
D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
DOES NOT INTERFERE										COMPLETELY INTERFERES

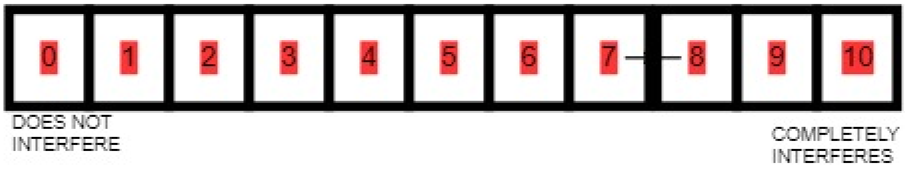
E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
DOES NOT INTERFERE										COMPLETELY INTERFERES

F. Sleep



G. Enjoyment of life



10) In addition to completing the Brief Pain Inventory, to help your doctor better manage your pain, please tell us:

aching
stabbing
sharp
exhausting
nagging
unbearable
squeezing

throbbing
gnawing
tender
tiring
numb
dull
cramping

shooting
pricking
burning
penetrating
miserable
radiating
deep

11) How long have you had this pain (Circle one)

less than a week 1 to 2 weeks
2 to 4 weeks more than a month

12) What kinds of things makes your pain feel better (heat, medicine, rest).

…………………………………………………………………………………………

13) What kinds of things makes your pain feel worse (example walking, standing, and lifting)

……………………………………………………………………………………………

14) Do you have any other symptom, Cycle one below if its applies

nausea
constipation
lack of appetite
difficulty sleeping
nightmares
tiredness
urinary problems
weakness

vomiting
diarrhea
indigestion
feeling drowsy
dizziness
itching
sweating
headaches

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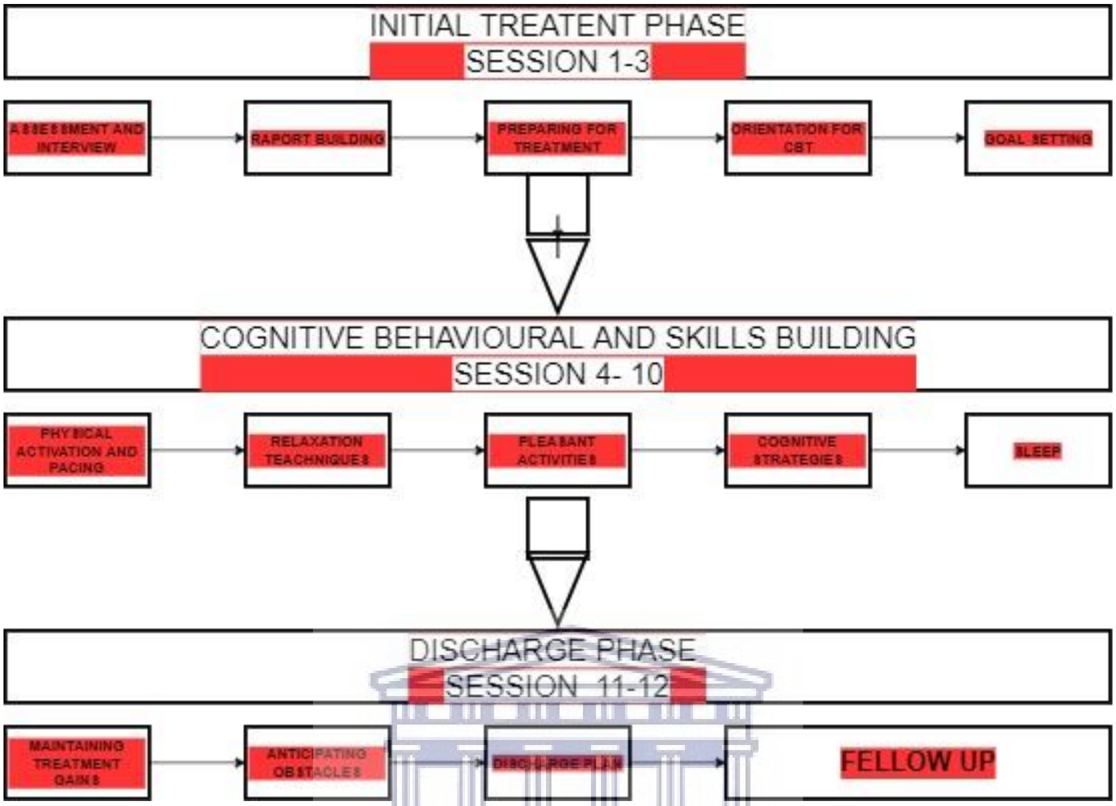
Appendix G

COGNITIVE BEHAVIORAL TREATMENT STRUCTURE FOR PAINFUL DIABETIC NEUROPATHY

Cognitive Behavioral Therapy (CBT) is a widely researched, time-limited psychotherapeutic approach that has been shown to be efficacious across a number of mental and behavioral conditions. CBT involves a structured approach that focuses on the relationships among cognitions (or thoughts), emotions (or feelings), and behaviors. Treatments based on cognitive behavioral theory have been successfully applied to the management of chronic pain, either delivered alone or as a component of an integrated, multiplemodal, and interdisciplinary pain management program. Evidence suggests that CBT-CP improves functioning and quality of life for a variety of chronic pain conditions (e.g., Hoffman, Papas, Chatkoff, & Kerns, 2007; Morley, Williams, & Eccleston, 1999; Turner, Mancl, & Aaron, 2006). CBT-PDN is an approach rooted in the development of a strong therapeutic relationship that encourages clients to adopt an active, problem-solving approach to cope with the many challenges associated with chronic pain (Burns et al., in press). It is adopted from The CBT-CP intervention Manual for Patients to change their thoughts and behaviors associated with chronic pain by learning a variety of adaptive pain coping skills in support of developing a strong sense of self-efficacy (Murphy et al. 2014).

The CBT-PDN treatment consists of 12 sessions as indicated in the diagram. The overall structure, components, and goals of the intervention will be reviewed. In addition, individuals who are likely to benefit from the intervention, as well as the specific structure of each individual session, are discussed.



Session 1: Interview and Assessment

The focus of this session is the initial clinical interview, the patient assessment measures, and contact with the Veteran's PCP. During the interview, Patients are able to share their chronic pain history and discuss how it has affected their lives. The assessment tools provide data that supplement information gained in the clinical interview. Finally, informing PCPs about CBTCP and obtaining their support is a key to facilitate successful treatment. This important meeting establishes the first face-to-face contact with the patient and is vital in setting the tone for the rest of treatment.

Session 1 Agenda

a. Conduct clinical interview
b. Have PDN patients complete assessment measures
c. Discuss next session
d. PCP

Session 1 Materials

1. CBT-CP Clinical Interview form
2. All assessment measures except WAI-SR
3. Communication with PCP

Clinical Interview

The initial clinical interview in CBT-CP is an opportunity to gather much of the general information that is acquired at the beginning of any psychotherapy course such as psychosocial status, mental health issues, and substance abuse history. However, since this intervention is specific to chronic pain, additional pain-specific information should also be obtained, such as:

- Pain location, onset, and intensity
- Current medications
- Previous and current treatments
- Areas of functional impairment

TALKING TIPS: *Assessment*
I appreciate you taking the time to complete the measures that I provided. The information will help me better individualize this treatment to help meet your needs. I will also be giving you some direct feedback in a later session about what you reported and how we can incorporate it into our treatment. I know that some people are hesitant about completing measures and view it as a waste of time. But the assessment actually serves a purpose similar to that of vital signs measured at a doctor's visit. The information is useful and can highlight an area that needs attention, like if your blood pressure was high. It can also help us measure the progress that you are making over time in a more concrete way – that is information that is helpful to us both.

Clinical Assessment Measures

Pain Numeric Rating Scale (NRS; Jensen & Karoly, 2001) Assesses pain intensity on a scale of 0-10 with 0 being "no pain"and 10 being "the worst pain imaginable." Ratings for average, worst, and least pain over the last week are obtained.

Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995) Assesses tendency to ruminate, magnify, and feel helpless about pain (i.e., catastrophize). Level of catastrophizing is a primary predictor of disability level. Decreased catastrophizing is associated with decreased depressive symptoms and improved pain-related outcomes (Sullivan & D'Eon, 1990).

West-Haven Yale Multipledimensional Pain Inventory-Interference Subscale (WHYMPI/MPI-INT; Kerns, Turk, & Rudy, 1985) Assesses interference of pain in various areas such as socialization, work, daily activities, and relationships with others including family/marital.

Session 2: Treatment Orientation

This session will be used to provide an orientation to the CBT-CP treatment model as well as education about the complex nature of chronic pain. In addition, the therapeutic alliance will begin to develop and will be measured at the conclusion of the session.

Session 2 Agenda

a. Administer SUDS
b. Establish agenda
c. Ensure all measures from previous session are completed
d. Present session 2 content: CBT-CP treatment plan, pain cycle and biopsychosocial approach
e. Ask patients to complete WAI-SR at session conclusion

Session 2 Materials
a. CBT-CP Model Handout
b. Chronic Pain Cycle Handout
c. Factors That Impact Pain Handout
d. WAI-SR

CBT-CP Orientation

It is important to orient the patients to both the structure and process of CBT-CP. This may include information about CBT and how it differs from other types of therapy. Orientation to CBT-CP involves the therapist providing the following types of information:

1. The structure of treatment
2. Expectations for attendance and participation
3. Role of the therapist
4. An overview of the CBT-CP model
5. Rationale of home practice
6. Responses to any questions from the Veteran about CBT-CP

The therapist will introduce the specifics of the CBT-CP treatment intervention. The goal is to provide the Veteran with a roadmap for what can be expected during treatment and to establish clear expectations for both the therapist and the Veteran. The information below is straightforward and can be presented while allowing time for questions:

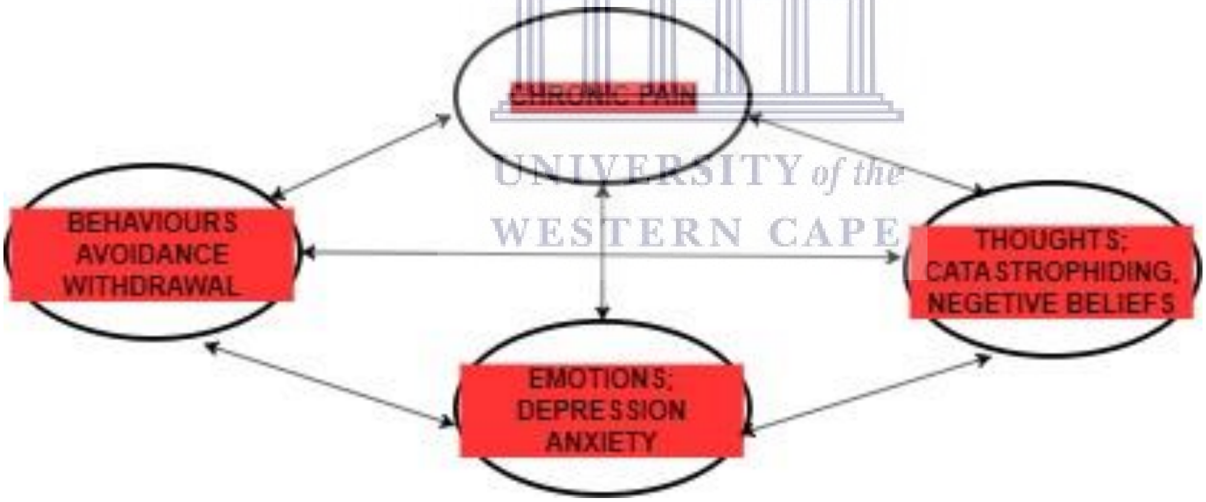
- Treatment Structure (see Figure 6)
- A brief overview of the treatment
- The length and frequency of sessions (11 weekly individual sessions and one follow-up session)
- A review of the session format – example provided below;

    - ➢ Check on mood and complete one measure
    - ➢ Set an agenda for the day
    - ➢ Review material from the previous session
    - ➢ Introduce the new material and introduce the next session
    - ➢ Discuss helpful practice for the next session

- Expectations for attendance and participation
- Regular attendance
- Emphasize the importance of regular attendance as a measure of participation and as critical for learning CBT-CP skills
- Completion of home practice

- Review the importance of actively practicing skills learned between sessions so that mastery can be achieved
- The role of the therapist
- Collaborative nature of this treatment
- Since the focus is on learning specific tools for pain management, explain that the therapist may need to redirect the conversation to stay on task but is always listening and interested in input from the Veteran
- Overview of the CBT-CP
- CBT-CP targets thoughts, emotions, and behaviors in order to improve functioning and promotes a problem-solving approach that emphasizes personal responsibility [Use the CBT-CP Model Handout (figure below) to illustrate the CBT-CP model]
- It promotes the adoption of self-managed tools by patients so that they can take an active role in effectively addressing chronic pain and its associated negative effects Q & A
- Ensure understanding and elicit feedback from the Veteran throughout the orientation process

FIG 1: CBT-CP MODEL



Chronic Pain Education

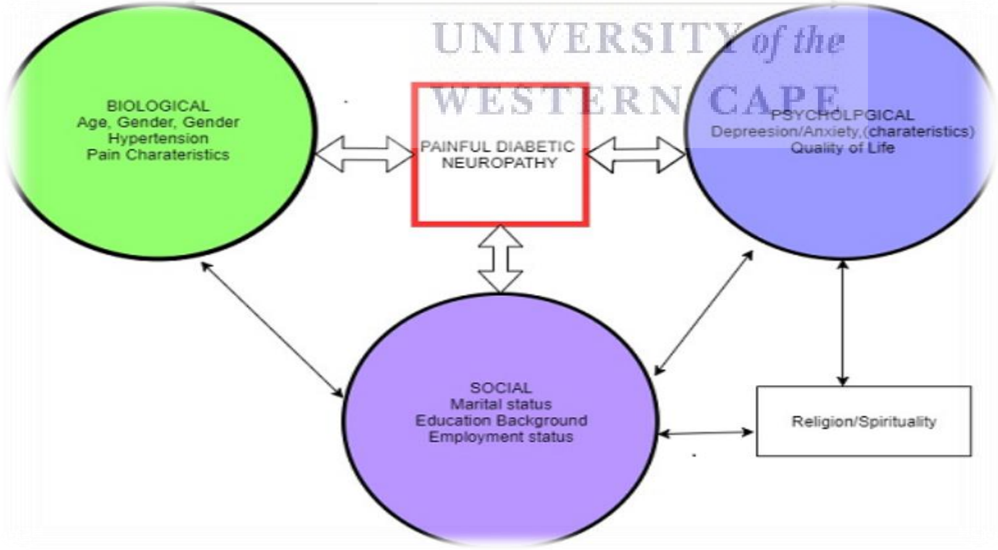
Chronic pain is a condition that affects various aspects of daily functioning and areas of life. Use the Chronic Pain Cycle Handout (see Figure 4) to discuss the process and stages that may occur over time for those with chronic pain. As the figure illustrates, the onset of chronic pain often leads to a decrease in activities, which leads to physical deconditioning. Dealing with constant pain may also lead to negative thoughts ("I can't do anything when I have pain like this") and emotions such as frustration and depression. These factors contribute to increased avoidance of family and friends, and anything that involves movement since it hurts to move. This combination means more distress and disability, leading to increased pain. Most Patients will be able to recognize this

process in their own lives. The CBT-CP Model Handout can also be used to illustrate how pain, thoughts, emotions, and behaviors interact and affect each other.
Below is an example of how the therapist might discuss the cycle of chronic pain:

TALKING TIPS: Chronic Pain Cycle
Think of yourself like a machine. All the gears work together to keep your body going. When you are not in pain life tends to be easier, you feel good and it's easier to get things done. When you have chronic pain, it's like having a bad gear that doesn't go away. It disrupts all the other gears and slows down the whole machine. Over time, it can bring the entire machine to a stop. Chronic pain touches many parts of your life, and each piece affects how the others run. Once we discuss more about the areas of your life that are affected, we will talk about how this treatment may be able to help you manage the effects of your pain.

Effects of Pain

Chronic pain affects many different areas of life. The interaction between biological/physical (pain and medical issues), psychological (cognition and affect/emotion), and social influences helps to explain the variability between individuals and their reports of pain. Figure 3 shows the overlap between these areas (Bio-psychosocial Model)



Use the Factors That Impact Pain Handout to review some of most important biological, psychological, behavioral, and social variables that may influence chronic pain. Discuss with Patients how pain has impacted their lives from all aspects: (a) the biological or medical factors (e.g., pain condition; comorbidities); (b) the psychological factors (e.g., negative mood; lowered self-esteem; and (c) the social factors (e.g., relationships; employment). Explain that each of these areas must be addressed in treatment – since chronic pain is a complex problem, it must be approached in a comprehensive way. While some factors such as previous injuries cannot be changed, emphasize that many of the factors that impact pain can be adapted with the assistance of CBT-CP.

Below is an example of potential pain effects and the ways in which participating in CBT-CP may be helpful to Patients. Sharing how this intervention can be beneficial across domains will help motivate Patients while tying together the discussion of CBT-CP, the chronic pain cycle, and the biopsychosocial model.

TALKING TIPS: *Effects of pain and what you can do!*

BELIEFS – You may begin to believe that it is better to try and restrict your movement.
CBT-CP and You – You will learn about your body and make some changes that will show moving is actually helpful.
ACTIVITY – Cutting back on activity can make your muscles stiff and cause you to lose strength.
CBT-CP and You – We will focus on slowly introducing activities to get you back to things that you enjoy and want to do.
PHYSICAL – Not moving may have led you to gain weight or to feel fatigued and tired much of the time.
CBT-CP and You – Starting to move and walk will improve your physique and give you more energy.
MOOD – The effects of chronic pain may make you feel down, frustrated, anxious, angry, and more.
CBT-CP and You – Beginning to engage in pleasant activities and resuming regular activities will help improve your mood and self-esteem.
SOCIAL LIFE – You may have withdrawn from others and feel irritable or guilty from your pain and its effects.
CBT-CP and You – We will focus on interacting more with others and having positive social experiences.
THOUGHTS – You may spend a lot of time worrying about your pain or thinking negative thoughts.
CBT-CP and You – We will help you learn how to change your thinking so that you can manage your outlook.

Treatment Initiation Assessment

Now that the interview, assessment, and general chronic pain education has occurred, discuss with Patients whether they would like to participate in the full course of CBT-CP. Use the following questions to determine interest in continuing treatment beyond this session:

- *Based on what you have learned, do you think CBT-CP may be a good fit for you?*
- *If you have any reservations about participating, what are they?*
- *Do you feel ready to take a more active approach to managing your chronic pain?*
- *Do you have any other questions that you would like answered regarding CBT-CP?*

If Patients do not wish to continue with treatment, recommendations for follow-up care should be made. If they do wish to participate, Patients will return for Session 3.

In the case of the latter, remember to congratulate them on taking an important step towards learning to better manage their pain and improve their lives.

Session 3: Assessment Feedback and Goal Setting

During this session, the therapist provides direct feedback to the Veteran on information reported in the assessment measures. Using the Patients' report is a valuable way to reflect back the pain-related impairments in their lives, and perhaps draw attention to the significant impact of pain across domains. Areas where the patient is using adaptive coping strategies should also be noted. The feedback delivered will help inform the second part of the session, which is to develop individualized goals for treatment. Providing assessment feedback will highlight specific areas that may need the most attention and facilitate the formulation of meaningful, Veteran-centric goals.

Session 3 Agenda

a. Administer SUDS
b. Establish agenda
c. Review session 2
d. Present session 3 content: Assessment Feedback and Goal Setting
e. Discuss Home Practice

Session 3 Materials
- SMART Goals Worksheet

Assessment Feedback

Spend time after the initial sessions reviewing the results of each self-report measure to gain a better understanding of the Veteran's experience of pain. Combining data from the assessment tools with the information provided during the clinical interview will help in developing an overall picture of the pain-related interference in various domains and general emotional functioning. Reviewing the results of the self-report measures in session can elucidate the negative effects of chronic pain and help motivate Patients to engage in treatment. The summarization of pain-related impairment can help with connecting how the short-term effort involved in CBT-CP will be worthwhile for the potential long-term gains. In addition, the information revealed through the assessment can greatly assist in determining goals for treatment that will be developed later in the session.

In delivering assessment feedback, provide the brief but meaningful messages ascertained from each tool. It is unnecessary to review numerous specific items in detail; on occasion, however, it may be relevant to discuss a particularly relevant, representative, or concerning response.

Pain Numeric Rating Scale (NRS; Jensen & Karoly, 2001)

- Acknowledge reported pain intensity and note significant highs/lows or patterns (e.g., consistency across time).
- *Based on your report, it seems that your pain intensity stays around a seven most of the time without much fluctuation.*

Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995)

- Note general tendency to catastrophize or not; use specific items as examples.
- *You often agreed with pain-related statements such as, "It's terrible and I feel it's never going to get better." Based on your responses, you seem to experience a lot of negative pain-related thoughts, which may lead to frustration or sadness for you.*

Multiple-dimensional Pain Inventory-Interference (MPI-INT; Kerns, Turk, & Rudy, 1985)

- Review areas where there is specific pain-related interference, highlighting the most significant areas.
- *While pain affects many areas of your life, it seems to cause significant issues in your relationships. I recall you mentioning this several times during the interview as well so this may be an important area of focus during treatment.*

Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001)

- Provide feedback on general level of depression, noting specific areas of concern.
- *Your report suggests that you are experiencing a moderate level of depression, and that it interferes with things such as your energy level and concentration.*

World Health Organization Quality of Life-Brief Version (WHOQOL-BREF; WHOQOL Group, 1995)

- Comment on general level of reported health.
- *You seem to feel that your health is poor, and are discouraged that you don't feel the level of interest in things that you used to.*

Working Alliance Inventory-Short Revised (WAI-SR; Hatcher & Gillaspy, 2006)

- Note any areas of strong disagreement and agreement, and determine how issues might be resolved or enhanced depending on need.
- *I know we have only seen each other for a brief period, but thus far it appears that you are comfortable with my style and feel that we are on the same page regarding your treatment.*

Elicit Patients reactions to the assessment results and the consequences of their pain conditions. Ask them to identify the benefits of reducing the negative impacts of their pain. This is an ideal way to transition to the development of goals in the latter portion of the session.

Goal Planning

CBT-CP Objectives

The focus of CBT-CP is to improve quality of life by improving functioning in multipleple domains. Reducing the negative effects of pain on daily life by engaging in more activities, improving mood, and increasing coping skills should be highlighted. While decreased pain intensity may occur, try to help Patients shift their preoccupation away from pain and towards functioning. It is important to be clear and direct about the objectives of treatment so that expectations are realistic for patient and therapist.

The SMART Goals Worksheet should be used with the Veteran in session. This worksheet includes both short-term goals that can be accomplished over the course of the CBT-CP treatment timeline, as well as long-term goals that may span over the next year but are important in serving as a motivator. It is critical that these are Veteran-centric and are personally meaningful to the patient. While engaging in CBT-CP requires time and effort, these goals should help illuminate why the long-term benefits outweigh the short-term investment. Once individualized treatment goals are established, they should be monitored on an ongoing basis for positive reinforcement and to make adjustments in goals and treatment as indicated. It is recommended that both the Veteran and therapist have a copy of the goals sheet available throughout the course of treatment so that it can be referred to regularly.

Practice

Ask Patients to continue to contemplate both short- and long-term goals. Stress the importance of following the SMART formula reviewed during the session. Remind Patients that the general CBT-CP objectives will be the framework for all sessions, while the individualized objectives will help motivate Patients to engage in activities that will improve the quality of their life and reduce the negative consequences of pain. The SMART Goals Setting Worksheet should be completed at home prior to the next session.

Session 4: Exercise and Pacing

This session introduces several critical issues in conceptualizing and managing chronic pain effectively. Providing an explanation of the difference between the physical sensation of hurt and the physical damage of harm will help Patients understand important differences between the management of acute and chronic pain. Because pain is often associated with avoidance of activity, fear of movement, and a cycle of negative consequences, elucidating this pattern highlights the need for physical activation. With the support of a medical provider, Patients will be asked to begin a walking program to initiate gradual exposure to movement. Finally, introducing time-based pacing as a means to manage pain more effectively through thoughtful activity will help define the parameters for consistent, moderate engagement in physical, recreational, and social activities.

Session 3 Agenda

a. Administer SUDS
b. Establish agenda

c. Review session 3
d. Present session 3 content: hurt vs. harm, exercise program and time based pacing
e. Discuss Home Practice

Session 4 Materials

- Chronic Pain Cycle Handout
- Walking Log
- Pacing Activities Worksheet

Hurt versus Harm

Often times, one of the greatest challenges for those with chronic pain is the belief that they can no longer engage in life fully or do the things that they want to do. Patients with chronic pain may believe that activity will lead to increased pain and cause physical damage. This belief, while typically true in acute pain, is often inaccurate in chronic pain.

Use the Chronic Pain Cycle Handout to discuss the negative consequences that often result from inactivity. A sample of how this information may be presented by the therapist follows Figure 4. Chronic Pain Cycle

Below is an example of how the therapist might discuss all of these related and very important concepts with the Veteran:

TALKING TIPS: *Hurt vs Harm, Kinesiophobia, and the Chronic Pain Cycle*

There is a difference between acute and chronic pain. Acute pain is a signal that an injury or damage has occurred, like with a broken arm. You need to protect that arm until the injury has healed. Chronic pain lasts beyond 3 months and persists after all the healing that is going to occur has already happened. Although you are still hurting, the pain is no longer alerting you of additional injury or damage. Acute pain is a symptom; chronic pain is a condition. Often when people have chronic pain, they decrease their level of activities because it hurts to move.

The term *kinesiophobia*, or fear of movement, is the name for that hesitation that often develops. While this is understandable as a means of protection from pain and injury, the inactivity actually makes the pain worse over time. As you can see in the Pain Cycle Handout, inactivity can cause you to get into a rut that creates deconditioning with problems like decreased flexibility and stamina, increased weakness and fatigue, and even spasms from tight muscles. All of this can lead to increased risk of injury, weight gain, and feelings of sadness, frustration, or boredom. Unfortunately, these experiences may only make you feel worse and encourage you to further avoid people and places.

But there is good news – we are going to help you find ways to break out of this destructive cycle!

Exercise Program

In order to break the chronic pain cycle, it is necessary to begin increasing physical activity. This is often a daunting idea for Patients who may be sedentary or believe that they cannot or should not engage in physical activity. It is important to stress that the initiation of any activity will be based on Patients' current level of functioning and will increase at a gradual pace.
Furthermore, assure patients that their current PCP has provided support for the planned activity. It may also be helpful to remind patients about the negative consequences of pain that they have previously shared, and the ways in which increasing activity may positively impact those areas. Implementing a regular walking program for Patients is one simple way to incorporate sensible and achievable activity into their lives.
As people age they do not develop as much synovial fluid (i.e., lubrication) in the joints, often making movement more challenging.

Because of this, those in orthopedics sometimes say that "*motion is lotion*" for the joints, since movement is a critical piece of good overall health. Walking is a low-impact, accessible, aerobic form of movement that can benefit almost everyone, especially those with chronic pain.

It can increase flexibility and strength, decrease pain and flare-ups, and improve mood. In addition, since walking is an integral part of most daily activities it can enhance overall functioning by making engagement easier
(e.g., trip to the grocery store). While patients may experience increased pain secondary to increased soreness after initiating activity, explaining that this is a normal process for those with and without pain can be helpful.
Before beginning any walking or exercise program, each therapist has already requested and received permission from the Veteran's PCP. *No exercise program should be initiated until approval is obtained.* If the PCP has responded and indicated that participation is appropriate, a walking program should be coordinated with the input of patients based on current level of ability. Patients should be encouraged to walk on a flat, even surface and to maintain constant movement, even if the pace is slow. In addition, the following directions for general proper walking mechanics are helpful and should be used as basic guidelines:

- Hold head high
- Focus eyes 15 to 20 feet in front of you
- Keep chins parallel to ground
- Move shoulders and arms naturally, freely
- Position feet shoulder-width apart

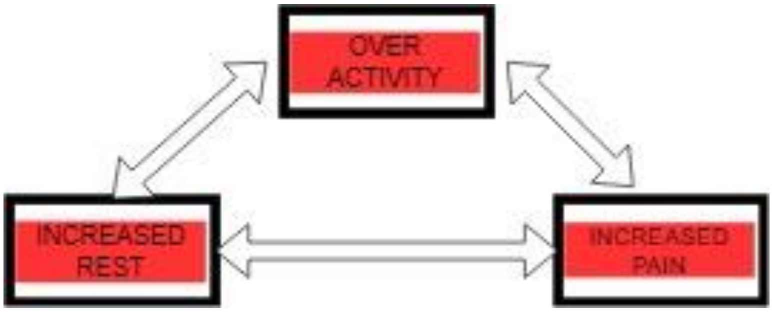
Use the Walking Log to help Patients develop a plan. If patients can currently walk 6 minutes without stopping and plan to walk 5 days this week, days 1 and 2 can be set for 6 minutes, with an increase to 7 minutes on days 3 and 4. Again, the emphasis should be on making purposeful movement part of the routine and overcoming fears associated with activity. It is important that walking is a planned part of the day, and is not simply incorporated into other activities. For example, Patients may say that when they have an appointment at the VA they are sure to walk for "more than the six scheduled minutes" getting to appointments. While this may be accurate, during this part of the protocol it is important to plan for separate walking times. Getting Patients into the habit of incorporating exercise into daily life is part of the goal. By doing so, walking that arises during trips to VA or grocery store will become easier.

TALKING TIPS: *Exercise*
****NOTE: This is one of the most difficult ideas for people to accept – it seems unnatural that movement will make their pain better. Emphasize that movement is the foundation for building a better body, that walking is safe (PCP approved), and that engagement and increases will be individualized and gradual.*** Tight muscles, decreased stamina, fatigue, and extra weight can worsen your chronic pain and make it harder for you to do different activities. But adding exercise and walking to your life has been shown to help your body combat chronic pain and improve your mood. Physical activity helps: • Increase endurance and strength • Return muscles to normal size • Help you have less pain when you move While starting something new is tough for all of us, as you practice walking and engage in more activities, things will get easier each day as your muscles are strengthened.

Time-Based Pacing

Some people are prone to "pushing through" pain in the name of accomplishing a task and will not stop until it is complete, while others may be preoccupied with fears about harming themselves and avoid activity altogether. Often times, those with chronic pain use a "good pain day" when they are feeling better to try to complete one or more rigorous activities that have fallen by the wayside. For example, they clean the garage or mow the grass without excessive pain – but wake up the next day feeling like they cannot move and thus are "laid up" for several days in a row. This cycle of over activity, increased pain, and increased rest seen in Figure 8 often happens on a recurring basis. It can lead to various negative consequences such as increased stress and anxiety, decreased efficiency, lowered self-esteem, and avoidance of any activity.

FIG 3. Over activity Cycle



Engaging in a moderate, safe level of activity on a regular basis is how to avoid this cycle. Using the skill of pacing, where time is the guide for activity engagement, can be a helpful strategy. It allows Patients to consistently engage in activities without causing detrimental consequences. Pacing is often about balancing activities and planning ahead, or working "smarter not harder."
Breaking tasks into "chunks" such as painting a room for 45 minutes per day over 4 days instead of for 3 hours on a single day is one example of pacing. Being more thoughtful about activity allows Patients to get more done on a more consistent basis, which also encourages mood improvements brought about by accomplishment. Without pacing, the cycle of being sedentary or overactive with pain flare-ups can be very discouraging.

During this session, use the Pacing Activities Worksheet to explore how to pace an activity with the Veteran. Use examples to illustrate how pacing can enable Patients to consistently carry out activities while minimizing the likelihood of increased pain.
It is the middle ground between doing nothing and over-exertion that enables Patients with chronic pain to engage in reasonable amounts of activity and improve quality of life.

TALKING TIPS: *Time-Based Pacing*
Pacing involves taking breaks at regular times, not just when the task is done. By resting regularly, you can actually get more done in the long run and not "pay for" extended periods of activity. Pacing helps you maintain a consistent activity level over time, which is good for your body and mind. Remember: • Take breaks based on how much time you have worked not on how much you have accomplished. • Take breaks before the pain begins to increase, not after it gets bad. • Practice makes perfect – your body must learn how to respond. This is about working smarter not harder!

Once the concept of pacing has been reviewed, it is important to discuss in session how Patients will apply it to their own lives. Ask the Veteran to choose an activity where they can use pacing over the next week such as washing the dishes or doing yard work. With the worksheet and sample provided, use the following steps to develop a plan for incorporating the activity into the week:

- Ask Patients to identify one activity that they are planning to do or would like to do this week, particularly something that they are concerned may increase their pain.
- Write this in the *Activity* row
- In collaboration with the Veteran, approximate how long they can safely do the activity without causing a significant pain flare up.
- Add this to the *Active Goal* row
- In collaboration with the Veteran, estimate the amount of rest time that will be needed in between periods of engagement/exertion.
- Add this to the *Rest Goal* row
- Ask the Veteran to complete this form over the next week for one to three activities.

The minutes set initially are approximations and it is expected that they may need to be increased or decreased. Remind Patients that pacing is a skill that must be practiced in order to be effective, so they should avoid pain-based decisions of what to do and not do on a daily basis. Although this may be a very difficult concept, it is critical in effective self-management of pain.

Practice

Ask Patients to begin implementing walking plans and tracking the number of minutes that they complete each day using the Walking Log. This will help maintain a gradual increase of activity and can facilitate a discussion about successes or issues next session. In addition, they should begin to initiate pacing of activities during their days using the Pacing Activities Worksheet. Again, remind them of the importance to log what they do so that it can be shared in session and adjusted as needed.

Session 5: Relaxation Training

This session introduces Patients to the pain management benefits of relaxation and then reviews three specific techniques: diaphragmatic or deep breathing, progressive muscle relaxation, and guided imagery. Since these are used in the treatment of various mental health conditions, many therapists may already be familiar with them. Two of these strategies will be practiced with the Veteran during this session, and all of them will be continued as home practice between sessions. Emphasize that practicing these techniques regularly between sessions is critical to mastery and effective application.

Session 5 Agenda

a. Administer SUDS
b. Establish agenda
c. Review session 4
d. Present session 5 content: Relaxation rational and strategy
e. Discuss Home Practice

Session 5 Materials

- Relaxation Benefits and Tips Handout
- Deep Breathing
- Progressive Muscle Relaxation
- Guided Imagery
- Relaxation Record
- WAI-SR

Rationale

Relaxation techniques are fundamental skills for managing chronic pain. However, the notion of relaxation in the service of pain management is an unfamiliar concept to most individuals with chronic pain. The rationale behind the use of relaxation techniques for pain management can be explained most easily by focusing on chronic pain as a chronic stressor, both physically and psychologically.

When patients experience chronic pain, their bodies react with a “fight or flight” response. This stress response, controlled by the sympathetic nervous system, is critical to survival when individuals face a dangerous or often done unconsciously. In addition, coping with the chronicity of the pain condition, not feeling understood by others, reduced involvement in enjoyable activities, and negative thoughts may also increase the stress related to pain. Since stress and pain have a bidirectional relationship – pain influences stress and stress influences pain – gaining greater control over the response to stress can help to better manage pain. Threatening situation. In the case of chronic pain, however, the physiological stress response is prolonged, is no longer adaptive, and creates additional wear and tear on the body. Since the body is chronically stressed due to persistent pain, it does not have the chance to recuperate.

Patients may hold certain areas of their bodies rigidly to brace or protect against pain. They may tense their necks or shoulders in anticipation of or in response to pain. These types of reactions only increase tension levels and pain intensity, but are often done unconsciously. In addition, coping with the chronicity of the pain condition, not feeling understood by others, reduced involvement in enjoyable activities, and negative thoughts may also increase the stress related to pain. Since stress and pain have a bidirectional relationship – pain influences stress and stress influences pain – gaining greater control over the response to stress can help to better manage pain.

TALKING TIPS: *Relaxation*
Relaxation is a skill that can help people better manage stress and muscle tension that can increase pain. There are many relaxation skills that are easy to use, and we want to find some that work for you. It’s important to make them part of your daily routine, and they can help when you have a pain flare-up. The goal of relaxation is to reduce the effects of stress on your health. Chronic pain taxes your body and creates increased muscle tension so even if you don’t feel “stressed” emotionally, it is likely that your body is impacted. While we can’t avoid all stressors or pain, we can change how we respond. Relaxation is more than resting or enjoying a hobby. It involves taking a break and reducing tension in your body and mind.

Implementation Assistance

It is useful to discuss specific benefits of relaxation and tips that may make implementation easier. One point that should be emphasized is the importance of practicing relaxation at least once every day. Explain to the Veteran that, as with any new skill, practice is necessary for mastery. It can be helpful to offer an analogy such as learning to play the guitar. While at first it may be difficult and uncomfortable with little noticeable improvement, regular practice helps a person become a skilled musician over time. In fact, fingers may begin to play certain songs on “autopilot” as the body develops a memory for the movements. This is the case with practicing and learning relaxation as well. Over time, relaxation exercises become easier to implement, with less thought, and will result in greater benefit with regard to managing stress and pain. Daily practice is required to develop these skills.

Use the handout on Relaxation Benefits and Tips in session, which further outlines the advantages to developing the skill of relaxation and ways to implement it successfully.

Techniques

Three relaxation techniques will be introduced, though only the first two will be practiced with the therapist in this session.

All relaxation techniques have two basic foundational components:

1. Focusing attention on something such as a process, image, phrase, or sensation.
2. Passive disregard of everyday thoughts when they occur in order to return to focus of attention.

Deep Breathing

The first relaxation technique is diaphragmatic breathing, often called "deep breathing," and it is the foundation for all other relaxation techniques. It uses deep breathing to contract the diaphragm by expanding the chest cavity and allowing more room for the lungs to fill with air. This serves the purposes of slowing breathing, increasing oxygen intake, and even increasing energy.

Diaphragmatic breathing is a brief and portable strategy that can be done anywhere, at any time, and usually without others becoming aware that it is being done. It involves normal breathing, but uses breaths that are intentionally smoother, slower, and deeper than the breaths usually taken throughout the day. It is one of the easiest, most effective ways to decrease tension in the body. The steps for teaching this exercise are detailed here. The clinician can help model effective technique by engaging in the exercise along with the Veteran.

STEPS

- Establish good posture.
- Explain chest/shallow versus belly/deep breathing.
- Have Veteran place one hand on chest and one hand on abdomen.
- Determine if the Veteran is "chest breathing" or "belly breathing."
- Close eyes completely or look downward and fix gaze on one spot.
- Observe the hands and ensure they are free of tension.
- Have the Veteran keep one hand on chest and one hand on abdomen and keep eyes closed or fixed on one spot.
- Have the Veteran inhale slowly through the nose (if possible), causing the abdomen to expand, and extending inhale to 3-5 seconds in duration.
- Instruct the Veteran to exhale slowly and completely through mouth, extending exhale to 3-5 seconds in duration.
- Continue this exercise for 3-5 minutes.

During the exercise, the clinician may wish to coach the Veteran with statements such as: "Feel your body become more and more relaxed with each exhalation," or "Each time you exhale, think of the word *relax*," or "Breathe in feelings of relaxation and breathe out any tension." Please also refer to the Deep Breathing Handout for a sample script of this exercise, which will be provided to the Veteran.

TALKING TIPS:
One idea is to try and use mini-sessions of deep breathing during the day. Incorporating brief sessions of breathing will help with frequent practice and because this exercise is so portable and easy, it can help any time you are "on the go."

For example, when you are standing in a line at the store, you may find yourself becoming increasingly tense or impatient. Instead of focusing on that:

- Take a deep breath in; as you breathe out imagine the tension and negativity leaving your body.
- On your next breath, imagine breathing in feelings of calm and relaxation.
- Count to six taking a slow, deep breath; breathe out slowly, again to a count of six.

Before you know it, you will feel less tense and more in control. What are some other situations where you might be able to do a mini-session during the day?

Progressive Muscle Relaxation

The second technique is progressive muscle relaxation (PMR). This exercise is focused on systematically tensing and relaxing specific muscle groups. The underlying explanation for the utility of this technique is that a muscle group cannot be both tense *and* relaxed at the same time. By deliberately tensing the muscles and then relaxing them, patients can learn to observe the difference between these two sensations; the body can then learn to notice tension in muscles and to release that tension.

Gentle contraction (i.e., mild to moderate tension) of each muscle group is required, not severe tension. Tensing the muscle should not hurt, but it may feel unfamiliar and thus slightly uncomfortable on the first practice of PMR. Muscle groups that are particularly tense may be repeated, if desired

Major Muscle Groups

Please also refer to the handout entitled Progressive Muscle Relaxation for a sample script of this exercise. The following are the muscle groups to be tensed and relaxed:

1. Lower arms/upper arms
2. Lower legs
3. Upper legs/buttocks/lower back
4. Abdomen
5. Chest
6. Neck/shoulders/upper back
7. Mouth/jaw/throat
8. Eyes/upper forehead/scalp

STEPS

- Start with relaxed, deep breathing.
- Systematically tense and relax each major muscle group.
- Tension should last 5-10 seconds then relax for 10-20 seconds.
- May spend additional time on muscles that are difficult to relax.
- Conduct a mental scan of the body.
- Mentally scan the body in systematic order of muscle groups, looking for remaining tension.
- Allow Veteran to relax any residual tension.

Guided Imagery

Practice

Encourage Patients to practice relaxation techniques at least once per day over the next week, more if possible. Instructions for all three types of relaxation reviewed are provided. In addition, ask them to use the Relaxation Practice Record to track practice and progress. Ask the Veteran to write down a tension rating before starting the exercise and then return to the record afterward to self-assess and rate tension again. Set realistic expectations by sharing that there may not be tension differences before and after the practice the first couple of times the exercise is used. Remind patients, however, that as the skill develops, the techniques will become easier and benefits will increase.

- Handouts of Relaxation Techniques
- Relaxation Practice Record

Session 6: Pleasant Activities 1

Many Patients living with chronic pain tend to avoid engaging in activity, including enjoyable activities. One reason may be that they believe they are no longer able to do the things they once enjoyed, such as golf or gardening, because of pain. Since activities often include interacting with others, they may want to avoid talking about their pain or feel embarrassed about their limitations. Not only may this avoidance contribute to physical deconditioning, but it can also lead to lowered self-esteem and increased depressed mood.

Sessions 6 and 7 are designed to help Patients increase the number of pleasant activities in their lives. The benefits include providing opportunities for healthy distraction, increasing socialization, improving concentration, and developing a sense of purposeful direction.

Session 6 will provide the opportunity to articulate and clarify what types of activities Patients have enjoyed historically while exploring new ideas for the future. Session 7 will create an action plan to implement activities in a paced manner.

Session 6 Agenda

1. Administer SUDS
2. Establish agenda
3. Review session 5 and do visual exercise
4. Present session 6 content: Exploring pleasant activities
5. Discuss Home Practice

Session 6 Materials

- Guided Imagery Handout
- Pleasant Activities List

Guided Imagery

After reviewing home practice of the relaxation techniques from Session 5, begin this session with the guided imagery exercise. Ask Patients for information about the idyllic place that they would like to mentally visit, reminding them that the place should be peaceful and calm, with positive associations. While the majority of this session will be focused on exploring pleasant activities, starting with thoughts and images about a pleasing place that create a relaxed state will set the stage for gathering that information.

Patients' choices for this technique may vary widely – some may find the beach or mountains relaxing, others may have a city of which they are fond. Some may have a specific location/time such as a childhood memory of grandma's kitchen while she bakes cookies or being on a farm with a sibling.

Allow the Veteran flexibility and creativity in selecting the location. The key to developing a deeply immersive experience, where the Veteran completely engages in the imagery exercise, is to give full attention to all the specific details of the scene. Encourage a focus on detailed images that take the Veteran away from stressful thoughts and bodily tension. It is crucial to involve all five senses, to consider specifically what would be seen, heard, smelled, felt, and tasted in this location (e.g., white sand path beneath feet, sweet and sour taste of cold lemonade, vivid color of tree leaves, soft texture of blanket, smell of cookies baking).

Once the mental scene and the details of the patient's relaxing place are gathered, guide Patients through the steps below. A sample for the therapist is presented below. Please refer to the Guided Imagery Handout for a sample script of this exercise.

STEPS

- Begin with comfortable posture and relaxed breath with eyes closed or gaze fixed.
- Imagine the "entryway" into the location (e.g., path, door, staircase, lake dock.)
- Enter the relaxing place (focus on five senses).
- Spend 5-10 minutes in the relaxing scene.
- Have the Veteran "leave" the location through the same "entryway".

TALKING TIPS: *Guided Imagery*
Before we begin talking about pleasant activities that we can incorporate into your life, I want you to think about a pleasant location. This can be a positive memory or an ideal place that creates a relaxed feeling. Consider how the pace looks, feels, and smells. Close your eyes and put yourself there. Imagine yourself walking slowly down a path toward your relaxing place. The path is comforting and peaceful. As you walk down this path, imagine that all of your stresses, worries, and tension are leaving you. Enjoy this journey to your relaxing place. Reach out and touch something in this place… Notice its texture and how it feels against your skin. Notice the different objects around you…their shapes, textures, and colors. Notice the light and shade of this place and how the light reflects off of these objects…

Practice

Before the next session, Patients should continue to contemplate pleasant activities to incorporate into their lives. For practice, ask them to identify at least three activities using the assistance of the Pleasant Activities List. Although the next session will focus on implementation of activities, suggest that they try to engage in at least one of their chosen activities before the next meeting. This will facilitate a discussion about potential obstacles.

Session 7: Pleasant Activities 2

Session 6 focused on identifying pleasurable activities. During Session 7, Patients will solidify the activities that they wish to pursue and develop a concrete plan for implementation. In all activity scheduling, pacing should be used to maintain a balanced approach.

Session 7 Agenda

1. Administer SUDS
2. Establish agenda
3. Review session 6 and do visual exercise
4. Present session 6 content: Establishing and scheduling pleasant activities
5. Discuss Home Practice

Session 7 Materials

- All assessment measures except WAI-SR
- Pleasant Activities List
- Pleasant Activities Schedule

Pleasant Activity Implementation

Review the home practice and discuss any engagement in pleasant activities since the last session. If Patients are still uncertain about activities that they would like to adopt, more time should be spent discussing the list of possibilities and any other considerations. Activities such as excessive television watching or computer activities are discouraged due to their passive or often solitary nature.

Once two to three activities have been identified, scheduling these activities into each week will increase the likelihood that

Patients will follow through with implementation. Remind patients of the benefits of increasing pleasurable activities such as improved mood and increased socialization, as well as a healthy distraction from pain. It is important that the activities chosen as well as the schedule devised is feasible for Patients to achieve. Creating an unrealistic plan only sets the stage for lack of completion and the accompanying negative emotions. In addition, the use of pacing during chosen activities is critical. Remind

Patients to use pacing and discuss in detail how it may be applied to their chosen activities. Use the Pleasant Activities Schedule to plan how the selected activities will be implemented over the next week. Have Patients add their choices in the *Activity* column. While playing basketball would require pacing, playing cards may not. Encourage Patients to start with easily achievable activities in order to develop a sense of mastery, and move to more difficult tasks after some proficiency has been established. Patients may feel motivated to expand the schedule of activities after initial successes have boosted mood and self-esteem. It may be helpful to provide a reminder that when adopting a new activity, the enjoyment may increase over time like with the guitar example from last session.

Discuss the details of the plan and be as specific as possible. Review not only the day or days of the week that will be best for the activity, but the time of day, location, frequency, and other relevant information. Being specific will help Patients visualize enacting the plan, which has several benefits?

First, it will bring attention to barriers that may be encountered and these can be addressed in session. For example, if a Veteran wants to play basketball, what if it is raining and the outdoor court is not an option? Is there an indoor court that might be accessible? It is helpful to process such real life circumstances with Patients.

Second, reviewing the specific details will encourage adherence to the plan. If Patients have a clear picture when they leave session of what they will do and what to expect, they are more likely to implement activities as discussed.

Anticipating Obstacles

Discuss anticipated barriers to Patients' participation in scheduled activities and collaboratively brainstorm possible solutions or backup plans. Below are some frequently cited barriers and strategies for addressing them in session. These issues may arise during Session 6 while reviewing activity options or in Session 7 when discussing how Patients will implement activities into their lives.

Review the benefits of engaging in pleasant activities on both mood and pain. Tell Patients that pushing themselves to engage in the behavior, even when they don't feel like it, will improve their mood and overall motivation to try again.

Practice

Ask Patients to complete the Pleasant Activities Schedule. Once their plan is complete, request that they track their progress and note, not only when they participated in the scheduled activity but, when they did not and why. Remind patients that multipleple attempts are common and provide reassurance that through collaboration with the therapist they will find an activity schedule that is realistic and enhances their lives.

Session 8: Cognitive Coping 1

Sessions 8 and 9 target the cognitive component of the CBT-CP model by helping Patients develop cognitive coping skills. Session 8 focuses on understanding the dynamic interplay between thoughts and pain, and recognizing common cognitive distortions. This will help Patients gain awareness about how their thoughts relate to pain or negative mood. Session 9 helps Patients actively challenge negative thoughts with the use of a thought record and coping plan.

Session 8 Agenda

1. Administer SUDS
2. Establish agenda

3. Review session 7
4. Present session 6 content: Recognizing and monitoring negative thoughts
5. Discuss Home Practice

Session 8 Materials

- Pain Thoughts Handout
- Catching ANTs Worksheet
- WAI-SR

Relationship between Thoughts and Pain

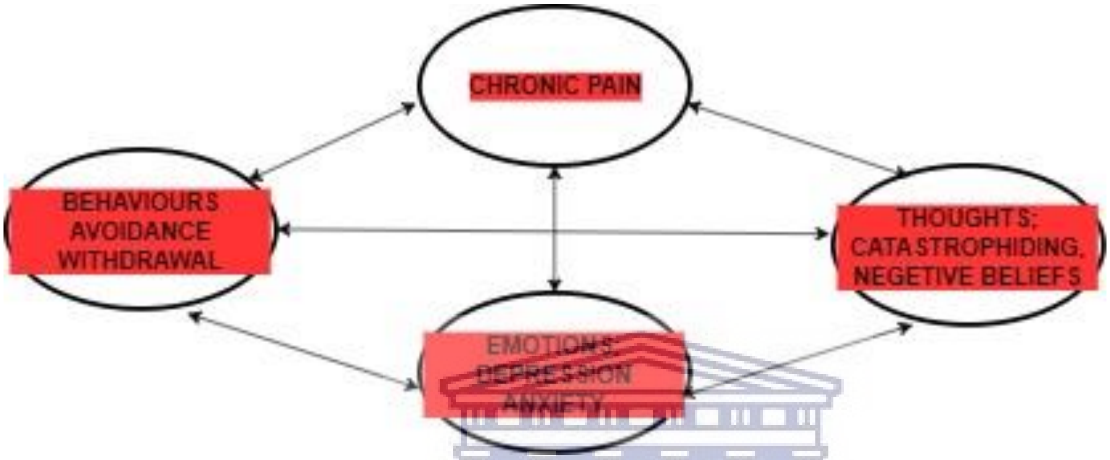
For those with chronic pain, the role of negative cognitions can be powerful. As pain fails to improve over time, Patients' thoughts may become increasingly negative and exert a greater influence on pain. Research shows that negative thoughts are directly associated with pain perception (Lawrence, Hoeft, Sheau, & Mackey, 2011). Often times, negative thoughts are automatic and outside of a person's awareness but may still significantly impact emotions and behaviors.

Use the previously reviewed CBT-CP model and Chronic Pain Cycle to discuss the relationships between thoughts, pain, mood, and behaviors. Patients will often recognize that with increased stress or negative emotions, they also notice an increase in pain intensity.

TALKING TIPS: *Negative Thoughts*
So far we have focused on things that you can physically do to manage your pain such as walking and engaging in activities you enjoy. Today we are going to talk about something different - how your thoughts can affect your pain and how changing them can help improve your satisfaction with life. When you are in pain, what kinds of thoughts go through your head? In general, we find that as pain gets worse, thoughts become more negative. And research even shows us that negative thoughts actually increase pain. Negative thoughts also get in the way of doing the things that we know help make pain better. Unhealthy thoughts lead to unhealthy choices. Everyone has negative thoughts! Often these thoughts are automatic. For example, you may have thought, "My pain is never going to get better," or "I can't do anything with this pain." Embracing these thoughts may lead to avoiding activities and people, and make it less likely to use the pain management skills you have. This chain reaction of negative, unhealthy thinking, feeling upset, avoiding others, and not using active coping skills isthe cycle that we are trying to break!

Introduce the term *automatic negative thoughts*, or ANTs, as this will be the helpful acronym used during these sessions and in practice. Ask Patients for one or two negative thoughts they have in response to their pain. Use their examples to review the relationship between thoughts, feelings, and behaviors using the CBT-CP model from Session 2 (Figure 5 below). Discuss the downward spiral that can contribute to increased anxiety, tension, and pain followed by isolation and avoidance. Again, ask Patients for examples from their own lives where ANTs may have contributed to the experience of pain or where negative thoughts occurred in response to an increase in pain.

FIG 5. CBT-CP Model



Cognitive Distortions

Another method for discussing negative thinking and its potentially automatic nature is through a discussion of common cognitive distortions, or erroneous thought processes. In this session these will be introduced to Patients through the use of the Pain Thoughts Handout, which includes all-or-none thinking, should statements, and emotional reasoning. While it is not necessary to review this entire list with Patients, applying the appropriate labels to the examples on the handout and those provided by patients may be helpful. It is important to make note of one cognitive distortion in particular: *catastrophizing*.

Catastrophizing, or believing the worst, is particularly salient in the treatment of pain as it has consistently been associated with important pain-related outcomes. Catastrophizing is characterized by the tendency to magnify the threat value of pain and to feel helpless in the context of pain. In addition to presenting the types of cognitive distortions, the Pain Thoughts Handout also provides examples of these unhelpful thoughts as well as alternatives that are more balanced and healthy. While challenging ANTs will not be fully explored until next session, this is a passive way to introduce another way of thinking.

Self-Monitoring of Thoughts

Having explored the role of ANTs in the CBT-CP model, Patients must now begin the process of increasing awareness of the frequency of negative thoughts associated with pain or negative mood. Clarify to Patients that since many of these thoughts happen without conscious awareness, this initial process requires some effort. Knowing *when* to look for the ANTs is an important part of this process. While they may occur at any time, they are most likely to occur during situations that are stressful, painful, or a combination of the two. The questions below can also help in identifying ANTs in situations where Patients have noticed higher levels of negative mood, stress, or pain.

- *What was going through my mind just before or just after I started to feel this way?*
- *What is the thing I am most afraid might happen?*
- *What is the worst thing that could happen?*
- *What memories does this lead me to experience?*
- *What does this mean about my future, my life, my health?*

Practice

Encourage Patients to review the Pain Thoughts Handout on their own to facilitate the understanding and identification of their own ANTs. Stress the importance of completing as many examples as possible on the Catching ANTs Worksheet. The goal is to increase Patients' awareness of their own thoughts and to catch as many ANTs as possible. Once they identify thoughts, circling whether it had a helpful/positive or harmful/negative effect on their pain and/or mood will help to connect the important role of thoughts in pain management. Patients should begin to note consistencies in their thought patterns that lead to negative emotions or increased pain.

Session 9: Cognitive Coping 2

Now that Patients have been asked to monitor their negative thoughts and have increased their awareness of such thoughts' power and prevalence, Session 9 highlights how to make adaptations to unhealthy, inaccurate thoughts. As this session focuses on ways to challenge ANTs, it may be helpful at session initiation to remind Patients that since they can *choose* the way that they think about and react to experiences, they are empowered to help determine the course of each day.

Session 9 Agenda

1. Administer SUDS
2. Establish agenda
3. Review session 8
4. Present session 9 content: Challenging negative thoughts
5. Discuss Home Practice

Session 9 Materials
- Catching ANTs Worksheet
- Coping Statements Checklist

Challenging Negative Thoughts

Briefly discuss Session 8 with Patients and inquire about the process of identifying and evaluating ANTs. Ask about the types of thoughts they noticed and if they were surprised at the frequency. In addition, discuss any impact that their negative thoughts had on pain experiences or moods, as well as any barriers encountered in the process. If they did not arrive at session with the home practice completed, inquire about why. Since it is important for Patients to have some experience in recognizing ANTs and considering their impact, complete two retrospective examples in session together. This important session focuses on the task of challenging ANTs and trying to help Patients minimize their occurrence and impact in the future.

Using the same Catching ANTs thought record introduced in Session 8, explore how these negative thoughts can be challenged. The idea is not to generate happy, unrealistic thoughts but to create a more balanced, accurate way of looking at experiences. After identifying an ANT, Patients are encouraged to weigh the evidence that supports and does not support the cognition. This promotes a more realistic and healthy way to interpret the world.

TALKING TIPS: *Challenging Negative Thoughts*
Once you notice an ANT, pause to consider the cognition. Challenge the negative thought by trying to collect the facts. Ask questions such as: • Is this 100% true? • Is there a different way to look at this issue? • What would I tell a close friend if they had this thought? • Is this thought helpful to me? • Is there evidence that I am not taking into account? When you answer these questions, you have a more balanced and realistic view of the situation. Replacing unhealthy thoughts with more accurate ones will help you cope better and allow you to practice more effective pain management.

During the session, use at least two examples provided by the Veteran to complete the *Challenge It* column on the worksheet. Review the full thought record and determine if participants understand the process and rationale. It may be helpful to remind them that while it is understandable to have pain-related ANTs, they often lead to increased pain and reinforce the maladaptive cycle CBT-CP is helping Patients change.

Coping Statements

Completing the process of identifying and challenging ANTs is beneficial in understanding the cognitive processes that influence mood and pain. Another technique that can also be helpful in managing pain flare-ups or negative mood is to use positive coping statements. Evidence suggests that those who use positive coping statements tolerate pain more effectively than those who use catastrophizing statements (Roditi, Robinson, & Litwins, 2009).

Practice

Patients should continue to add personal examples to the Catching ANTs Worksheet, including positive/balanced statement challenge ANTs. In addition, using the Coping Statements Checklist ask that they identify several statements that they find calming and reassuring which can be used before the next session.

Session 10: Sleep

Sleep is among the most common complaints voiced by individuals with chronic pain (Turk et al., 2008), and the relationship between sleep and pain is complex. The presence of pain may make falling and staying asleep more difficult and disturbed, and insufficient sleep may increase next day pain. Furthermore, chronic pain may "lighten" sleep and prolong return to sleep following awakenings (Harman et al., 2002). Session 10 reviews the relationship between pain and sleep and explores approaches for improving sleep among those with chronic pain. The Insomnia Severity Index (ISI) will be administered to determine whether clinical insomnia is present (i.e., score over 14), indicating that an additional treatment referral is needed.

Session 9 Agenda

1. Administer SUDS
2. Establish agenda
3. Review session 9
4. Present session 10 content: Chronic pain and sleep education and challenges
5. Discuss Home Practice

Session 10 Materials

- Insomnia Severity Index
- Sleep Hygiene Checklist
- Sleep Behavior Change Log

Pain-Sleep Interaction

Sleep provides an opportunity for the body to repair itself physically and mentally. Sleeplessness can increase pain sensitivity within the body (Affleck, Urrows, Tennen, Higgins, & Abeles, 1996) and reduce the effectiveness of the body's normal reparative processes. Restorative sleep, on the other hand, can reduce pain sensitivity and assist in tissue replenishment and growth (Onen, Alloui, Gross, Eschallier, & Dubray, 2001). Unfortunately, those with chronic pain frequently struggle with obtaining quality sleep for several reasons. First, pain flare-ups that occur during the day and extend into the night may contribute to difficulties falling asleep while the sharp burst of pain associated with muscle spasms during the night may wake a sleeper. Moderate chronic pain, however, does not typically cause awakenings (Kelly, Blake, Power, O'Keeffe, & Fullen, 2012). Poor sleep can cause effects such as fatigue, muscle tenderness, irritability, decreased in activities and lack of concentration.

TALKING TIPS: *Sleep Hygiene*
Many Patients with chronic pain also have problems with sleep. Some of the basic things associated with increasing your chances of having the best night of sleep possible are on this Sleep Hygiene Handout. I am going to highlight a few of these areas: • Environment

- Minimal noise, and appropriate light (dark at night, bright in the morning) and temperature (not too hot) are typically controllable factors that should be adjusted.
- Clock-Watching
- Avoid watching the clock or counting down time.
- Remember to get out of bed if you are unable to sleep.
- Stress
- Worries may surface once the house is quiet and dark but this is not a good time to problem-solve.
- Set aside time earlier in the day to focus on troubleshooting issues.
- Relaxation
- • Use relaxation techniques you have acquired to help reduce tension and initiate sleep – it is an ideal use of one of your new skills!

Stimulus Control

Stimulus Control is an important component of CBT for insomnia (CBT-I) interventions. It is based upon the finding that individuals who spend excessive time in bed without sleep create negative associations around pre-sleep rituals or the bed environment, which results in bed-related distress. For example, Patients may report being able to sleep easily in a recliner in front of the television, but "tossing and turning" once they are in bed. Some may even report sleeping better in a hotel bed. The goal of Stimulus Control is to establish a new, more positive association where the bed equates with sleepiness.

The stimulus control instructions below are designed to re-associate bedtime with the rapid onset of sleep and to establish a regular sleep-wake schedule that is consistent with the circadian sleep/wake cycle:

1. Only go to bed when sleepy(not just fatigued or tired)
2. Use bed only for sleep
3. If unable to sleep after 20 minutes, get up from bed and return when sleepy.
4. Wake at the same time and everyday
5. Don't nap

Sleep Hygiene

Basic sleep hygiene principles should also be reviewed with Patients using the Sleep Hygiene Checklist. Combining these tips with the principles of Stimulus Control is ideal.

TALKING TIPS: *Sleep Hygiene*
Many Patients with chronic pain also have problems with sleep. Some of the basic things associated with increasing your chances of having the best night of sleep possible are on this Sleep Hygiene Handout. I am going to highlight a few of these areas: • Environment

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- Set aside time earlier in the day to focus on troubleshooting issues.
- Relaxation
- • Use relaxation techniques you have acquired to help reduce tension and initiate sleep – it is an ideal use of one of your new skills!

Practice

Make sure that Patients understand the concepts reviewed in Stimulus Control and the recommendations described on the Sleep Hygiene Checklist. Encourage them to review and reference the information regularly as a reminder of good sleep habits.

Provide the Sleep Behavior Change Log, which can be used to identify specific elements of sleep behavior that they would like to change. On the log, Patients identify behaviors to improve sleep and record use of these behaviors. Finally, if Veteran's score on the ISI is above 14, discuss a referral to a local CBT-I provider if available.

Session 11: Discharge Planning

This is the final regular session with Patients. While many skills have been learned and implemented, completing a successful transition to self-management following the treatment is critical. While functioning, mood, and pain intensity have likely improved, chronic pain remains a part of daily life and pain flare-ups are expected in the future. This session focuses on developing a discharge plan, which includes anticipating obstacles that may arise including increases in pain. Finally, since all clinical measures must be completed again, it is recommended that Patients arrive early to complete them before session or make plans to stay late to complete them after the session.

Session 11 Agenda

- Patients completeness assessment
- Establish agenda
- Review session 10
- Present session 11 content: anticipating obstacles and discharging plans
- Discuss Home Practice

Session 11 Materials

- All assessment measures except WAI-SR
- Anticipating Obstacles Worksheet
- Weekly Activities Schedule

Review of Progress

Begin the session by reminding Patients of where they were when they entered treatment and how much progress they have made. Be specific in the feedback provided, as patients may have lost sight of their gains over the course of the last few months.

For example, highlighting that a Veteran is hardly using an assistive device anymore or that someone who barely left the house is socializing weekly can be helpful. Since change happened gradually, it may be easy for patients to lose sight of or minimize the benefits that engagement in CBT-CP has had. Obtain feedback from Patients about areas where they feel they have made the most progress, and what has worked best for them. Inquiring about reactions from friends and family can also be reinforcing: "When I talk to my mom on the phone lately she says that I sound much more upbeat."

Asking questions such as the following may facilitate discussion and help Patients identify their own progress:

- *Have you become more active?*
- *Has your mood improved?*
- *Do you feel like your life is more fulfilling, even though you still have pain?*
- *Are you accomplishing more?*
- *Have you noticed a difference in your pain intensity? What about how you react to your pain?*

Before examining the things that may get in the way of pain management in the future, it is important to reflect on what the
Veteran has already accomplished as a means of motivation.

Coping with Flare-Ups

Flare-ups are relatively short increases in usually stable pain intensity that may last from minutes to weeks. Continuing to institute CBT-CP by staying active, engaging in enjoyable activities, and getting restful sleep are the best way to minimize flare-ups; however, these spikes are expected for those with chronic pain. While they may be managed in part by medication,

Patients should be encouraged to prepare for these times and identify newly acquired skills that can be used to address flare-ups most effectively. Acknowledge that it is often difficult to use these tools when pain has increased, but stress that it is also the most important time to implement CBT-CP skills.

The best way to prevent a relapse to previous poor functioning is to be prepared for pain exacerbations and difficult days. Planning ahead will make it easier to cope during challenging times. Discuss anticipated obstacles that are likely to arise in the future as well as how those issues will be addressed.

TALKING TIPS: *Anticipating Obstacles*

You have done a great job in learning and implementing CBT-CP skills. Since this is our last regular session and we will
no longer be meeting weekly, it is helpful to anticipate any obstacles you believe may interfere with continuing to keep up with the skills you've learned.
- What do you think might get in the way of engaging in your skills as planned?
- What things have already sidetracked you through the course of treatment?
- How have you coped with difficult issues in the past, and how might you cope with them in the future?

It's important for us to openly discuss your fears so that you are prepared – remember the best offense is a good defense

Use the Anticipating Obstacles Worksheet, to identify Patients' triggers for pain increases.
Common triggers are:
- Emotional stress
- Weather changes
- Lack of sleep

Discharge Planning

Now Patients are ready to develop a specific daily plan. Having a clear schedule helps patients feel more prepared for several reasons. First, it can assist in mitigating difficult situations and minimizing the triggers previously discussed. Second, it shows
Patients how to incorporate various positive coping techniques into their everyday lives. Third, creating a plan helps imbue a sense of structure and purpose into daily life, something that is valuable for everyone. Working through a plan together will help reveal how all of the pieces fit together and increase confidence moving forward.

Use the Weekly Activities Schedule, to formulate an example of a typical week for Patients. Add items such as walks, relaxation, hobbies, and other standard activities. Encourage them to think of each piece of the plan as an "appointment" that is not optional. Without this commitment to an identified and distinct structure, Patients are more likely to fall back into a sedentary lifestyle where one day is difficult to discern from the next. In addition, a concrete schedule may help in ensuring follow-through and increasing feelings of accomplishment. It may be beneficial for Patients to get a large whiteboard for home where the weekly calendar can be posted, and where each activity can be checked off as "completed" as the day progresses. Rewarding one for engaging in all scheduled activities for one week may be another incentive to stay the course.
Collaborate with Patients to develop a plan for activities in their words. Ask about specific behaviors that they want to avoid doing or saying, and use these to develop items for the schedule that will combat negative habits.

For example, if someone wants to avoid isolating from others, perhaps "Meeting my friend John at Java Hut for coffee" can be scheduled for every Tuesday morning. Noting specific distractions to help keep the Patients' minds occupied such as "garden (if nice weather)/puzzles (if bad weather)" or "play with my dog" will help create a concrete plan for the future. It is important that the schedule is realistic, since making unreasonable plans will only make self-disappointment more likely if goals are not achieved.

Goals

Following completion of the schedule, revisit objectives for the future. Explore goals that have been achieved throughout the course of treatment and how they may be expanded. For example, if the Veteran has begun meeting with friends once a week as a way to increase socialization, ask how that goal might change over the next 6 to12 months. Patients may want to increase the frequency of outings to twice per week, or join an organization like their local Elks Lodge. This is also the opportunity to develop new objectives. Perhaps now that the Veteran has largely overcome a fear of movement, finding and using a bicycle regularly is desired. If negative cognitions have kept Patients from considering dating, they may now feel confident enough to begin exploring ways to meet others. Discuss what the individual Veteran is motivated to accomplish in the future, and tailor goals to meet specific interests and needs.

Practice

Provide positive feedback about all that has been accomplished so that Patients leave feeling supported and confident. Assure them that even if obstacles or setbacks are encountered, they now have all of the tools necessary to manage their chronic pain.

Remind them that they have the Anticipating Obstacles Worksheet as well as the Weekly Activities Schedule and should finish them if that was not completed in session. Stress the importance of scheduling activities each week to help ensure continuing benefit from what they have learned. Finally, discuss scheduling a booster session in four to six weeks to follow up with progress and challenges that occur following this session. It is important to make sure that the Veteran also knows what to do in the event of any significant crises that might arise prior to the booster session.

Session 12: Booster Session

In this session, the focus will be on Patients' implementation of the CBT-CP skills since the final regular CBT-CP session.

Overall mood, significant life events since the last contact, and current pain-related functioning should be assessed. The information gathered will aid in adapting the focus of the session to meet each Veteran's individual needs. Because of this, while each booster session will have certain underlying similarities, the specifics depend on the Patients' presenting issues. Because of this, it is recommended that the therapist review all of the sessions prior to this meeting so that accessing the most relevant topics based on the Veteran's feedback is easy.

Session 12 Agenda

- Patients completeness assessment
- Establish agenda
- Review session 10
- Present session 11 content: anticipating obstacles and discharging plans
- Discuss Home Practice

Session 12 Materials

- CBT-CP Model Handout
- Determine others during session

Progress Update and Implementation

Begin by asking Patients about their mood since the last therapy session four to six weeks ago. Attempt to gain an overall sense of mood and emotional state in the absence of weekly contact. If mood has been poor, additional time should be spent determining the root of issues with negative effect. If additional follow-up from a mental health provider is indicated but not established, take appropriate steps for follow-up (e.g., ensure that appointment is scheduled, enter new consult). If significant negative life events are reported, appropriate time and attention should be spent addressing the issues revealed.

While it is important to gain an understanding of the Veteran's overall wellbeing, the focus of the session should be how the CBT-CP tools have been implemented thus far. The following questions may be helpful in facilitating this discussion:

- *What has gone well?*
- *Why have those things worked?*
- *What has not gone well?*
- *What are the specific problems?*
- *What have been the biggest barriers in the implementation of the skills that you have learned?*
- *In the areas where you have been successful, why have you been successful?*

CBT-CP Model Refresher

Reviewing the CBT-CP model and the relationship between thoughts, feelings, and behaviors can provide an opportunity to identify issues that Patients are having and reinforce any positive changes. Use the CBT-CP Model Handout (below) and other resources from Session 2 (Chronic Pain Cycle and Factors That Impact Pain) to review important variables and patterns. Focus on areas that are more salient based on the data gathered during the session. Use Patients' own examples to illustrate what has gone well or not up to this point. For example, if the Veteran has reported several occasions of not attending family activities because of pain, discussing the dangers of avoidance and potential benefits of approach would be appropriate.

Future Plans

Since each person will have a different presentation at the time of the booster session, the therapist must skillfully choose the materials and feedback that will be most beneficial. Assessing Patients' status during the meeting and determining the materials that are most appropriate can be challenging, particularly since there may be numerous issues that must be prioritized.

At the conclusion of the session, determine if another booster session is needed. Some individuals may be doing well and not need a second follow-up. Others may present with greater difficulties and benefit from another session. Decide what is most therapeutic based on the needs of the Veteran. If this is the last session, then the relationship is terminated. If there is a plan for one more session, then provide home practice. In either case, the treatment goal is for Patients to be discharged with a sense that they have acquired the CBT-CP tools and must now continue on the journey of self-management.

CBT-CP CLINICAL INTERVIEW

Review Patients's medical chart prior to first session to become familiar with all relevant information included in this form.
Verify any information collected with the Veteran.

PSYCHOSOCIAL INFORMATION
Marital Status *(circle)*: **(a) Married** **(b)** Single (c) Divorced (d) Widowed

Children
Y N
#: ______ Age(s): ______

Vocational Background
Employed Currently: Y N
If no, last worked: _____
Occupation *(past/present):*

Resides ________________________________

(a) Alone
(a) Spouse/Partner Roommate
(c) Family

PAIN INFORMATION
Measure pain using the 0-10 scale with '0' being no pain and '10' being the worst pain imaginable.
Current Pain Intensity: _____ Usual Pain Intensity *(average in last week):* _____
Worst Pain Intensity *(in last week):* _____ Least Pain Intensity *(in last week):* _____
Primary Pain Location *(circle one only):*

1) Abdomen Elbow Head/Headache
2) Ankle (R/L/BL) Face Hip (R/L/BL)
3) Arm (R/L/BL) Foot (R/L/BL) Knee (R/L/BL)
4) Back – Low Generalized Joint Leg (R/L/BL)
5) Mid Generalized muscle Neck
6) Upper Groin Shoulder (R/L/BL)
7) Buttocks Hand (R/L/BL) Wrist (R/L/BL)
8) Other(s):
   ____

Primary Pain Duration: date/year *(if known)* ________ _____years _____months

Precipitating Event:

Primary Pain Qualities *(circle all that apply)*:

Aching
Burning/Hot
Cold
Heavy
Numb
Pressure
Sore
Stabbing
Tender

Cramping
Dull
Electrical
Pinching
Sharp
Shooting
Throbbing
Tight
Tingling

Other(s):
____

Other Pain Locations *(circle all others)***:**

Abdomen
Ankle (R/L/BL)
Arm (R/L/BL)
Back – Low
    Mid
    Upper
Buttocks
Elbow
Face
Foot (R/L/BL)
Generalized Joint
Generalized
Groin
Hand (R/L/BL)
Head/Headache
Hip (R/L/BL)
Knee (R/L/BL)
Leg (R/L/BL)
muscle Neck
Shoulder (R/L/BL)
Wrist (R/L/BL)
Other(s):

What makes your pain worse?
____

What provides some relief for your pain?
____

How do you cope with your pain?
____

How does pain impact your life? *(circle all that apply; provide details/examples)***:**

Mobility Recreation Sleep
-How?_______________ -How?_______________ -
How?_______________

Mood Relationships Social
-How?_______________ -How?_______________ -
How?_______________
Physical Activities Sexual Functioning Work/School
-How?_______________ -How?_______________ -
How?_______________

Other(s): ____

Provide information about current pain medications

Pain Med	Dosage	Pain Med	Dosage

Provide information about treatments used currently or in the past

Previous Pain Treatment	Yes	No	Relief	Still nursing
Surgery NA				
Injections (e.g., ESI, blocks)				
Implanted Device (e.g., SCS)				
Physical Therapy				
TENS Unit				
Aquatic/Pool Therapy				
Headache Treatment (e.g., Botox)				
Biofeedback				
Pain-focused Psychotherapy				
Relaxation Techniques				
Chiropractic				
Acupuncture				
Other:				

Do you use ambulation aids *(e.g., cane, rolling walker, wheelchair, powered chair/scooter):*

Describe a typical day:

MEDICAL INFORMATION

Acute medical concerns *(e.g., chest pain, falls):*

Medical history *(e.g., COPD, DM, HTN, TBI, obesity, apnea?):*

PSYCHIATRIC INFORMATION

Current Mood:

Psychiatric Symptoms:

Diagnoses:

Treatment:

Psychiatric Hospitalizations:

Suicidal/Homicidal History? Current Ideation/Plan/Intent?

Psych. Med	Dosage	Psych. Med	Dosage

SUBSTANCE USE INFORMATION

	CURRENT		PAST		TYPE QUANTITY
	YES	NO	YES	NO	
Tobacco					
Alcohol					
Illicit Drugs					

Treatment history for substance abuse/dependence:

MENTAL STATUS
Appearance:

Mood:

Affect:

Pain Behaviors:

Eye contact:

Speech:

Thought Content/Process:

Perceptions:

Orientation/Cognition:

Insight/Judgment:

CLINICAL IMPRESSIONS/COMMENTS:

____
____
____
____
____
____
____
____
____
____

PRIMARY CARE PROVIDER COMMUNICATION

Your patient has requested to be enrolled in Cognitive Behavioral Therapy for Chronic Pain (CBT-CP). This intervention involves helping Patients better manage their chronic pain by learning more effective strategies for coping with pain and related issues.

CBT-CP is an evidence-based, time-limited intervention that teaches patients how to better manage chronic pain and improve overall quality of life. CBT-CP encourages patients to adopt an active, problem-solving approach to cope with the many challenges associated with chronic pain. Central components of the treatment include increasing and improving physical functioning, implementing routine use of relaxation techniques, and teaching methods to cope with negative thoughts that increase pain and dysfunction.

Our intervention includes 12 sessions with the following structure:

1. Interview and Assessment
2. CBT-CP Orientation and Education
3. Goal Planning
4. Increasing Physical Activity and Time-based Pacing
5. Relaxation Training
6. Pleasant Activity Scheduling 1
7. Pleasant Activity Scheduling 2
8. Cognitive Coping 1
9. Cognitive Coping 2
10. Pain and Sleep
11. Discharge Planning and Coping with Flare-ups
12. Booster Session

One component of our intervention involves increasing physical activity. As the Veteran's primary care provider, we request your assistance in determining the physical activity that is appropriate for this Veteran. The standard activity in this protocol is a low intensity, graduated walking program. Based on your knowledge of the patient, please indicate your recommendation:

1. Walking Program: The walking program is very low intensity with the Veteran setting a reasonable walking goal with gradual increases.

a. *If a walking program is indicated, please note any restrictions.*

2. If you do not believe that a graduated walking program is safe or appropriate for this Veteran, please recommend an alternative activity such as use of pedicycle, pool therapy (if available), physical therapy, etc.

SMART GOAL SETTING

A SMART goal is set using the following guidelines:

SPECIFIC	
MEASURABLE	
ACHIEVABLE	
RELEVANT	
TIME BOUND	

Adapted from Doran, 1981

Short-term goals can be accomplished over the course of the CBT-CP sessions. Once goals are identified, track them on a weekly basis to ensure that progress is occurring. If it is not, make adjustments as needed. For each goal, consider if it fits the

SMART criteria listed above. These should be personally meaningful goals that motivate you to complete the CBT-CP program and improve your pain management skills.

Short-Term Goals

1____

2.____

3.____

Long-term goals are those for the next 6-12 months, or perhaps even longer. Although they will not be accomplished fully during the CBT-CP course, they can be worked towards and are often our most important goals for the future so they can be an important motivator.

Long-Term Goals

1.
____
____

2.
____
____

3. ____

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Appendix H

Hypnotic Cognitive Therapy Protocol[1]

Mark P. Jensen, Dawn M. Ehde, M. Elena Mendoza, Ivan R. Molton,
Tiara Dillworth, and David R. Patterson

Sources used for the protocol content:

This protocol is designed to use the advantages of hypnosis (focused attention and perceived automaticity) to enhance the efficacy and extend the duration of positive effects of cognitive restructuring. Many of the ideas for the suggestions used in this protocol come from the writings of clinicians who describe using hypnosis for the treatment of depression (cf. Yapko, 2006a). The specific protocol is a revision of the protocol used in the pilot study for this intervention (Jensen et al., 2011).

Whereas the hypnotic suggestions for the HYP intervention focus on sensations (primarily replacing focus on pain with development and focus on comfortable sensations and replacing concern and negative affect about pain with a sense of detachment) associated with pain, the hypnotic suggestions in the CR-HYP protocol, specified below, focus on the meaning that the participants give to pain. In neurophysiological terms, and in light of the CNS areas associated with pain, the HYP protocol can be viewed as targeting CNS processes associated with the sensory cortex (sensations), the periphery (nociception), the insula (the global sense of the body's state), and the anterior cingulate cortex (the affective aspect of the body's state; related to a sense of a need to take action or not to alter the body's state), while the CR-HYP protocol targets CS processes associated with the pre-frontal cortex (the meaning(s) given to sensations) (Jensen, in press).

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Mark P. Jensen, PhD, mjensen@uw.edu.

This manual should be referenced as follows:

Jensen, M. P. (2016). *Power over Pain (POWER POP) Hypnotic Cognitive Therapy: Clinician Manual*. Unpublished manuscript, Department of Rehabilitation Medicine, University of Washington, Seattle, Washington, USA.

General goals of the CR-HYP intervention:

The CR-HYP module has four primary goals. All of the suggestions, including the post-hypnotic suggestions, are geared towards one or more of these three these goals:

- To encourage the participant's comfort with having a sense of ambiguity about the meaning of pain sensations (that is, that no one, including the participant, his or her physician, or scientists in the field of pain understands everything there is to know about the cause(s) of the patient's pain). This means that it does not make sense to draw firm conclusions about the reasons for pain, its impact, or its course. Future intensity, pain's impact, and general course cannot be predicted with certainty. Thus, it does not make sense to catastrophize, assume, or worry about the worst meanings. If the patient can tolerate ambiguity of meaning, it is assumed that this will free them up to avoid taking the step of catastrophizing.
- To encourage the belief that the participant can gain control over pain and its impact (i.e., self-efficacy beliefs), and that continued practice using cognitive coping strategies will help the participant achieve this.
- To automatize the processes of CR, such that alarming or catastrophizing cognitions are automatically monitored and adjusted into more reassuring and realistic cognitions; and that this can occur all of the time, even below the participants' awareness, before the maladaptive cognitions can have any negative effects on mood, pain, or functioning.
- To increase a sense of control over pain and its effects via imagining what this would feel like (in the future), and integrating these feelings of increased control into the present.

The CR-HYP intervention is viewed as both a treatment (that the hypnotic suggestions themselves will have a long-lasting beneficial impact on the way that participants think about pain) and a training procedure (that the intervention will teach specific hypnosis-enhanced CR skills that participants can then use on a regular basis to improve their sense of comfort and control over pain and its impact).

Intervention structure and format:

- Four individual sessions over a 4-week period (generally, 1 session per week; but sessions could be scheduled more or less frequently depending on the needs of the participant) of 50-60 minutes each.
- The basic session format for the CR-HYP sessions include:
- Pre-session discussion of the participants' experiences since the last treatment session (see Session Assessment Form).
- Pre- and post-session assessment of pain.
- Assessment of the frequency, length, and type (i.e., on own or with practice recording) of home practice, discussion of questions concerning home practice and homework, trouble-shooting of any barriers to practice, and Motivational Interviewing to encourage ongoing and continued use of home practice.
- A 20 – 35 minute session of formal hypnosis.
- Post-session discussion of the participant's experience during the session, with the clinician addressing any questions or concerns.

<u>Not all of the sessions will be the same</u>:

- Session 1 will focus specifically on increasing the participants comfort with ambiguity about conclusions regarding pain and its impact (under the assumption that increased acceptance of ambiguity is inconsistent with jumping to negative conclusions about pain, including catastrophizing conclusions, so this intervention can be viewed as a type of de-catastrophizing intervention) largely following the protocol described by Yapko (2006b) for this component of treating depression with hypnosis.
- Sessions 2 and 3 will use hypnotic suggestions as well as cognitive skills to encourage automatization of the process of altering pain-related catastrophizing and any other alarming or maladaptive cognitions into more reassuring and realistic cognitions. Also it will be used a metaphor for externalizing physical discomfort that combines visual and tactile-kinesthetic system (adaptation of Marble induction (Zarren, 2002)).
- Session 4 will use an age progression strategy (based in large part to the "Back from the Future" strategy described by Torem, 2006) to increase the participant's sense of control over pain and its effects on their lives.

In order to facilitate practice and use of the skills learned in treatment outside of the treatment setting, audio recordings will be made of each session (starting with the induction and continuing through re-orientating) of each of the four treatment sessions. Participants will be also asked to listen to the material recorded in the CD or file the clinician give them in every session.

<u>Homework:</u>

- Participants will receive a recording of the part of the session with the hypnosis practice in each session. They will be told the following: "*We have made recordings so that you can listen to them to get the most out of the treatment. Because listening to them more rather than less will likely provide more reinforcement for what we are teaching, you might find it useful to consider listening to the recordings at least once per day. By doing this, you can learn how often you should listen to get the most out of treatment. You might end up deciding to listen once or even more often every day. Or you might decide that you do not need to listen this often to reinforce what you are learning, and so may choose to listen just a couple of times a week or even less. It is completely up to you to decide the frequency that works best for you*". If the participant prefers the recording of a previous session's recording over the most recent one, the participant will be encouraged to listen to the preferred recording. However, participants will also be encouraged to listen to each of the recordings made at least once/week (that is, to 'rotate' listening to the recordings to some extent) to help ensure that they obtain the potential benefits of each one. Specifically, they will be told: *"Because the recordings of the four sessions are different, if you decide to listen to them regularly, it would be a good idea to 'rotate' the recordings to some extent. For example, if you listen to one recording every day, you might choose to listen each of the recordings at least once in one week. Or, if you listen to the recordings once/week, you might choose to listen to a different recording every week. Ultimately, though, it is completely up to you to determine which recordings you find most helpful, and how often you choose to listen to them".* Participants will be asked to listen to the recordings whenever they feel more alert and to avoid listening to them before going to sleep. If they want to use the hypnosis skills before going to sleep, they will be asked to use self-hypnosis.

- Participants will be asked to practice without the recording several times during the day, but at least three times every day, by taking 2 to 5 minutes (or more if they wish) and go through the steps to be in self-hypnosis, then relax and imagine going down an elevator and getting to their special place.

- Participants also will be asked to complete a cognitive thought worksheet between sessions 1 and 2 and 2 and 3. This form includes identification of thoughts associated with positive and negative feelings, so that the clinician then discuss and encourage the patient to come up with thoughts that might be more appropriate and reassuring than the ones they had when they did not feel well.

- Thought worksheets will be checked by therapists at the beginning of each session in order to track homework completion.

- Frequency of home practice will be assessed at the beginning of each session. Participants will be encouraged to discuss and troubleshoot any barriers to practicing using Motivational Interviewing.

A note about the therapist's role:

At times during treatment the participant may raise issues (e.g., questions re applying for disability, questions re MS/SCI/MD/Amp/LBP treatments, etc.) that are outside of the scope of the treatment interventions being studied. If such issues come up during the sessions, the therapist should redirect the participant in a supportive but firm manner.

An example of such a redirection is: "Because you have probably been receiving services from many different health care providers, I want to explain my role in your treatment and to clarify what our time together will focus on. I recognize that in addition to pain, you may have a number of other concerns and things that are stressful in your life right now in managing your MS/SCI/MD/Amp/LBP. It's very understandable and normal that you may be experiencing those things. At the same time, the research study is focused specifically on pain, and so the primary focus of our sessions together will be on your pain. That doesn't mean that I think the other concerns you may have are not important. My job is to help us stay focused on pain concerns."

In the same way, when working with the thought recording, the participant may want to use thoughts that although are stressful for them are not directly related to pain. In that case, the therapist will redirect the discussion and the work of restructuring thoughts to those that only has to do with pain. If the participant continues bringing up other stressful topics the therapist will explain that the focus of the study is working with those thoughts that are strictly related to pain.

Protocol for the Hypnosis Section

Peaceful place description

Prior to the induction, inform participants that the session will include inviting them to imagine themselves in a place where they feel comfortable, safe, and at ease. Inform participants that this can be a real place that they have actually been to, or that the place can be imaginary. Also inform them that it need not always be the same place. In fact, if they can change the place or details about the place every so often, this can keep the place 'fresh' for them and make it even more interesting and engaging. The important thing is for participants to select a place that they can very clearly imagine in detail. Elicit from them details of what such a place might be like (e.g., sandy beach, mountain meadow, meadow filled with flowers, mountain top, living room; ideal temperature; color of any water and the sky; plants or other objects around them). Record the responses in the ***Combined CR and Hypnosis Log Sheet*** (see the last pages of this manual).

Pre-hypnosis cue and induction

Each CR-HYP session will begin using the same pre-hypnosis cue ("Allow yourself to take a deep breath...").

The bulk of hypnotic portion of Session 1 of the CR-HYP module uses the structure, and much of the wording, of the procedures described for increasing participant tolerance for ambiguity described by Yapko (2006b), although it has been modified to emphasize pain-related thoughts. These components (see the specific script for general wording) include: (1) suggestions that build a response set regarding uncertainty; (2) suggestions that introduce concepts concerning inference; (3) suggestions that introduce concepts concerning the drive to "know" or draw conclusions; (4) suggestions that introduce the concept of the value of "not knowing;" (5) suggestions that reframe "not knowing" as potentially useful and desirable, especially in the context of pain; Introduction of the process of inference; and (6) post-hypnotic suggestions for integration and generalization. These components should take about 20 minutes.

The bulk of Sessions 2 and 3 will consist of suggestions to (1) incorporate specific adaptive cognitions that the participant has identified as helpful and reassuring in the CR part of the treatment; (2) remember that how one feels in response to pain is a direct consequence of the meaning given to the pain; (3) automatically monitor the meaning given to pain when one experiences pain, and 'short circuit' any maladaptive cognitions and replace them with more adaptive and reassuring ones; (4) imagine oneself as feeling relaxed and calm and even happy, regardless of the existence or extent of any sensations, identify at least one specific thought associated with this feeling, and then incorporate and integrate that thought into one's mind; and (5) use a metaphor for externalizing physical discomfort that combines visual and tactile-kinesthetic system (adaptation of Marble induction (Zarren, 2002)).

Session 4 will include suggestions for age progression to a time when the participant is managing his or her pain extremely well. He/she will then be encouraged to bring back into the present any imagined feelings and skills that were an important and useful part of being in control of any pain and its effects.

All sessions should end with re-alerting suggestions.

Homework

Recordings for home practice

As mentioned before, audio recordings will be made of each session (starting with the induction, and continuing through re-orientating) of each of the four treatment sessions. Each recording will be made using a digital recorder, saved on the network drive (Hemingway), and burned to a CD or recorded on an audiotape (participant's choice). Each participant will be given 2 CDs/audiotapes of each session (so they will have back-ups) with which to practice the skills learned in treatment.

Participants will be asked to listen to the recordings as often as they find them helpful for them, but particularly in the time of the day they feel more alert, avoiding using them before going to sleep. They will also be encouraged to experience hypnosis multipleple times during every day by engaging in the pre-hypnosis cue, and allowing themselves to experience any of the benefits they obtain from their use of hypnosis.

Clinicians should keep in mind that participants will be listening to the recordings of the session at home and therefore out of the clinician's "control". Considering the context in which the CDs/audiotapes will be listened to can assist the clinician in making the recordings as helpful as possible for the participant to use outside the clinical setting.

The clinician will explain to the participant that the recordings are made for their personal use and therefore, we ask them not to share them with other people.

CR-HYP Handbook

Participants will be provided a handbook in the first session to reinforce the skills taught during the sessions, to facilitate homework, and to prepare him or her for the next session.

Increasing and Maintaining Motivation for Practice

Clinicians will use a number of strategies, based in large part on the principals and practice of Motivational Interviewing (MI; Miller and Rollnick, 2005), to increase and maintain motivation for self-hypnosis practice outside of the session. Thus, throughout the course of treatment, clinicians should be attuned to any comments made by participants about the ease or difficulty of practicing, fitting practice into their schedules, or other issues related to their likelihood of using these skills after treatment ends. Clinicians should use active listening to reflect back to the study participant any positive statements the participants make about their abilities to use these skills to manage pain in order to increase their sense of self-efficacy. Each session sheet includes the request, “Tell me about your home practice,” to be stated to the participant in the early part of the session as a way to elicit motivation statements about practice, and to help facilitate problem solving if the participant is finding practice challenging.

During the last two sessions, additional questions should be asked that will elicit additional motivational statements about practice.

For Session 3, the questions include:

- Tell me your thoughts about the benefits of continuing to practice.
- What would it take to make it (easy or even easier) to practice every day?

For Session 4, the additional questions that will be included in the relapse prevention section at the end of the session are:

- How do you feel about your ability to reduce your pain or how much any pain bothers you using these skills?
- What times of day have you found are best for regular practice?

Additional Protocol Information

Scripts

Therapists do not need to memorize the standard scripts described for each session. However, the script should not be read word for word, and the clinician should feel comfortable modifying the wording slightly, as needed, to enhance the flow for their own use. The clinician should speak using an engaging and “relaxing” voice tone, providing alterations in timing and emphasis to keep the text interesting. During the sessions, the clinician should also observe the patient carefully, and time the wording and suggestions to match the patient’s behavior. For example, time phrases with the participant’s breathing when possible and appropriate.

Myths and Misconceptions about hypnosis

Due to the way hypnosis is portrayed in TV shows and movies it is common that people hold myths and misconceptions about how hypnosis works. These myths may reduce the outcomes of the intervention because they foster negative attitudes toward hypnosis and unrealistic expectancies about the experience of being hypnotized. As a result, the patients may be afraid of using hypnosis and therefore be reluctant to do the practice asked for homework.

Some of the most common myths are explained in the first session of treatment. However, it is possible that in the next sessions some patients comment something about their practice of hypnosis that may indicate that they hold another myth or that they did not understand completely the ones previously explained. In these cases, in order to foster adequate beliefs about hypnotic techniques and realistic expectancies of the outcomes, the clinicians should dispel and explain any misconception that come up during the treatment.

Language and Word selection

Language facilitates the hypnotic responses. However, some "language traps" can create unintended and negative responses in the patients, what is called the nocebo effect.

Hypnotized people typically are intensely focused on the therapist, so small nuances in word usage can affect the response. Moreover, patients in distress are prone to take literally what they hear from someone they consider being an expert. Therefore, it is very important that the clinicians avoid certain wording in the sessions.

These are some examples:

- ✓ One of these traps is the use of "DON'T". Many imperative sentences that begin with these words typically produce exactly the opposite result from the one seemingly intended. Use positive sentences including the response that wants to be elicited instead of the response that wants to be decreased or eliminated. For example, say: "Let your arm be very limp", instead of "Don't tense your arm muscles".
- ✓ Avoid using "TRY". When a provider tells a patient to *try* to comply with a treatment recommendation (i.e., try to listen to the recordings), it may convey that the provider does not really expect the patient to succeed. Use sentences like: "Please, listen to the recordings", "Get in the habit of practicing these new skills you are learning", etc.
- ✓ Use WHEN instead of IF. IF may lead to the patient to feel challenged or suggest that an event may not happen. WHEN infers that the desired response will occur.
- ✓ Avoid I WANT YOU TO.... or YOU WILL FEEL..... More effective is wording such as YOU MAY WISH TO... or YOU MAY…. WHEN YOU ARE READY........
- ✓ When you don't know what is happening, focus on the response you want to elicit, using permissive language. For example, replace YOU ARE FEELING RELAXED with LET ME KNOW WHEN YOU ARE FEELING RELAXED or YOU MAY FEEL RELAXED OR HAVE OTHER COMFORTABLE SENSATIONS.
- ✓ Vague references to time are more effective than specific ones: "IN A FEW MOMENTS".
- ✓ To promote dissociation use articles which are less specific rather than pronouns. Replace "YOUR HAND MAY BEGIN TO FEEL WARMER" with "THE LEFT HAND MAY BEGIN TO FEEL WARMER".

Overview of the Treatment

Session 1:

1. Introductions and intervention overview.
2. Brief initial evaluation to develop rapport and obtain information to be used during treatment.
3. Brief conversation about ideas/attitudes/myths about hypnosis.
4. Brief conversation about the importance of thoughts and adjustment.
5. Pre-hypnosis cue and induction.

6. Relaxation.
7. Deepening.
8. Peaceful place imagery.
9. Suggestions:
    - Building a response set concerning ambiguity.
    - Introduce concepts concerning inference.
    - Suggestions that introduce concepts concerning the drive to “know” or draw conclusions.
    - Suggestions that introduce the concept of the value of “not knowing”.
    - Suggestions that reframe “not knowing” as potentially useful and desirable.
    - Post-hypnotic suggestions.
10. Arousal and re-orientating.

Homework:

- ✓ Listen to the Session recording.
- ✓ Review Session 1 materials of the handbook.
- ✓ Fill in the cognitive thought worksheet regarding at least 4 situations (2 positive and 2 negative).

Session 2:

1. Pre-session assessments and discussion.
2. Homework review.
3. Identifying/generating reasonable and reassuring cognitions from the cognitive thought worksheet.
4. Exercise to practice the identification of reasonable and reassuring cognitions.
5. Pre-hypnosis cue and induction.
6. Relaxation.
7. Deepening.
8. Peaceful place imagery.
9. Suggestions:
    - Building a response set concerning how learning processes become automatic.
    - Suggestions that bring previously identified reasonable thoughts into the participant’s awareness.
    - Suggestions that make the altering alarming thoughts into reasonable ones automatic.
    - Imagery of a caring thought monitor and developing realistic thoughts automatically.
    - Post-hypnotic suggestions.
10. Arousal and re-orientating.

Homework:

- ✓ Listen to the recordings.
- ✓ Review Session 2 materials of the handbook.
- ✓ If the participant wants to change the thoughts for the next session, complete another cognitive thought worksheet with at least 4 situations (2 positive and 2 negative).

Session 3:

1. Pre-session assessments and discussion.

2. Homework review.
3. Identifying reasonable and reassuring cognitions from the thought worksheet.
4. Pre-hypnosis cue and induction.
5. Relaxation.
6. Deepening.
7. Peaceful place imagery.
8. Suggestions:
    - Building a response set concerning how learning processes become automatic.
    - Suggestions that bring previously identified reasonable thoughts into the participant's awareness.
    - Suggestions that make the altering alarming thoughts into reasonable ones automatic.
    - Metaphor of a marble as an object to externalize worries or negative thoughts.
    - Post-hypnotic suggestions.
9. Arousal and re-orientating.
10. Brief explanation of how to use hypnotic suggestions.

Homework:

- ✓ Listen to the recordings.
- ✓ Review Session 3 materials of the handbook.

Session 4:

1. Pre-session assessments and discussion.
2. Homework review.
3. Identifying reasonable cognitions from the thought worksheet.
4. Pre-hypnosis cue and induction.
5. Relaxation.
6. Deepening.
7. Peaceful place imagery.
8. Suggestions:
    - Awareness of the future when goal(s) are met and the patient is functioning better with pain.
    - Post-hypnotic suggestions.
9. Arousal and re-orientating.
10. Post-hypnotic discussion.
11. Relapse prevention.

Homework:

- ✓ Listen to the recordings.
- ✓ Use hypnosis every time they need it during the day.
- ✓ Review Session 4 materials of the handbook.

Session 1
Increasing Tolerance to Uncertainty

Session Objectives

- Provide intervention overview.
- Clarify any questions the participant may have about hypnosis and how it works.
- Introduce the relevance of thoughts and adjustment.

- Assist the participant in learning how to identify reassuring thoughts associated with feeling good.
- Give hypnotic suggestions aimed to increase tolerance to uncertainty.

Write time in *Treatment Recording Sheet*.

Introductions, Confidentiality, and Intervention Overview (7 minutes)

Say, "Hello. I'm Dr. (*name*). I talked with you on the telephone. Thanks so much for coming in today and welcome to the Power Over Pain Program! This program is funded by the National Institute of Health."

- ☐ Introduce self and background working with participants with chronic pain.
- ☐ Explain tape recording
    - ☐ (For purposes of consistency in research & treatment).
    - ☐ Request permission; explain that if patient ever wants a session or part of a session erased, to let us know.
    - ☐ Recording will only be kept with an ID number and date.

IF RECORDING TODAY'S SESSION:

- ☐ If it is okay with you, I will record today's session. Is it okay for me to record today's treatment session?
    - ○ ***If Yes:*** Okay. I will begin recording the treatment session.
    - ○ According to state law, I am required to record your permission for the treatment session to be recorded, so I will ask your permission again once I begin recording.
- ☐ *Begin recording.*
- ☐ Okay, I have begun recording.

TO ENSURE ACCURATE FIDELITY CODING, SAY:

Do I have permission to audio record today's treatment session?

- ○ ***If Yes:*** *Proceed with treatment session.*
- ○ ***If No:*** All right, I will stop recording now, and will not record today's treatment session. *Stop recording.*

- ☐ ***Review limits of confidentiality*** (required by law to report child or elder abuse, intent to harm self/others). Study psychologists may also consult with one another. Otherwise, information discussed during treatment is confidential.
- ☐ ***Answer any related questions.***
- ☐ ***Remind that clinicians do not have access to individual data or to the questions of the interviews.***
- ☐ ***Remind them not to talk about treatment with research staff.***

- ☐ ***Request that the participant not discuss any specifics of the treatment*** they are receiving with anyone who is currently participating in the study or might participate in the study in the future (e.g., members of any support groups that the participant attends).

Overview of the intervention

TO ENSURE ACCURATE FIDELITY CODING, SAY: "I'm now going to give you an **overview of the intervention**."

Before we focus on the main content of today's session, I want to review with you the overall program and answer any questions you may have regarding it. As you may recall from the consent form, the goal of this study is to determine the benefits of the Power over Pain Program. It will teach you some new information and skills to better cope with pain and we will focus on using hypnosis to help you think about pain in ways that will contribute to an experience of decreased pain and an experience of not being as bothered by pain.

To accomplish this, the program consists of four sessions of treatment. When possible, the sessions will be scheduled to occur once each week, so that the total time in treatment will be 4 weeks. However, the sessions might be scheduled to occur more or less often than that, depending on your schedule and the clinician's schedule. Also, I'd like to point out that participating in this study does not mean that you have to stop other pain treatments. You should continue to take any medications for pain and participate in any other treatments for pain that are recommended by your medical providers.

Participant role: During our sessions, you'll spend a lot of time relaxing and listening to my voice. However, we'll be asking you to do some practicing on your own during the week between each session. Also, I'll be making an audio recording of all four of our sessions, and I'll give you the recordings to listen to at home. I will talk with you about some ways of practicing without the digital files/CDs.

Pre-session assessment elements (3 minutes)

TO ENSURE ACCURATE FIDELITY CODING:

- **Ask for a relapse or Exacerbation in participant's MS since completing the phone interview (only for MS Participants).**
- **Obtain current 0-10 pain intensity ratings (at the beginning of the session).**
- **Obtain average 24-hour 0-10 pain intensity ratings.**
- **Ask for adverse reactions to intake session (using the Adverse Events Tracking Form).**

Summarize what will happen during the session (3 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: "Now let me **summarize** what is going to happen in the session:

- First, we will talk briefly about your pain.

- Then, we are going to talk about what hypnosis is and how it works and we will discuss some of the popular misconceptions about hypnosis.
- Also, we are going to talk about how the way we think affects to our experience of pain and how to identify our automatic thoughts about pain.
- Then, you will have the opportunity to experience hypnosis. We will start with an induction including relaxation and imagery, and then we will work with the hypnosis suggestions of today's session.
- Finally, we will discuss the homework."

Brief conversation about patient's pain (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: **"**I'd like to hear from you about your MS/SCI/MD/Amp/LB pain experience so that I can use this information during the treatment."

The point of this section is to learn about the patient's pain problem to engage the patient in discussion, to obtain information to be used in the treatment, and to build rapport.

Brief conversation about ideas/attitudes/myths about hypnosis (10 minutes)

TO ENSURE ACCURATE FIDELITY CODING, ASK: "Now let me review some basic information about hypnosis. First, please, tell me what you know or think about hypnosis? *Reinforce everything said that is correct. Then, briefly review the following issues:*

Myth 1: Hypnosis is sleep.

The relationship between the term hypnosis and sleep is a historic one, since the word hypnosis stems from *hypnos* that means "sleep" in Greek. However, in fact, the hypnotized person is not sleeping. Rather, he or she is awake and conscious all the time being aware of what is happening. The only difference is that the hypnotized person is more focused and concentrated on the suggestions or in what s/he is experiencing than a non-hypnotized person.

Myth 2: One might get stuck in a "trance" and not being able to "wake up" from hypnosis.

According to the clinical and experimental evidence, people do not get "stuck" in a "trance". Some people may choose to come out from hypnosis slowly because they feel very comfortable or relaxed. But this is not unique to hypnosis. People, who are learning any technique that is enjoyable, such as relaxation and imagery, might elect to take their time to 'come out' from these procedures.

Myth 3: Hypnosis can be used to induce people to perform antisocial acts.

Hypnotic procedures cannot in themselves cause people to commit acts against their will. If a person would not do something when s/he is not hypnotized, s/he is not going to do it under hypnosis.

Myth 4: Hypnotized people lose control over their behavior.

The hypnotized person acts voluntarily and s/he never lose his/her decision making capacity over his/her behavior. The responses to the suggestions are experienced as automatic, but they are voluntary acts. The hypnotized subject always chooses to respond or not respond to any suggestion offered.

🎭 *Myth 5: Hypnotized people do NOT remember what happened when they were in hypnosis.*

Reports of profound, spontaneous (i.e., non-suggested) amnesia during and following hypnosis are rare. Instead, most hypnotic amnesia occurs following specific suggestions to forget.

Also, any ‘forgotten’ material can normally be retrieved following a prearranged signal from the hypnotist, indicating that the phenomenon involves a disruption of getting access to the memory rather than a disruption in remembering the material in the first place. If no such signal is given, the amnesia tends to dissipate with successive attempts to remember.

🎭 *Myth 6: Hypnotic procedures accurately enhance the memory of past facts.*

There is little evidence that the introduction of hypnotic procedures accurately enhances the memory of past facts. Instead, hypnosis can result in false memories and misplaced confidence in recall. Consequently, if hypnosis is used at all for investigative purposes, the information elicited is (and should be) treated with the utmost caution.

🎭 *Myth 7: Hypnosis weakens the mind.*

Since hypnosis helps individuals gain self-control and fosters an ability to focus attention, it does not weaken the mind but enhances concentration and activation of the mind.

🎭 *Myth 8: Only gullible or unintelligent or dependent people respond to hypnosis.*

According to the research evidence, the only characteristics of people susceptible to hypnosis are: absorption, imaginative involvement, and fantasy proneness. Therefore, gullibility, intelligence, and dependency do not have anything to do with a person’s responses to hypnosis.

Brief conversation about the importance of thoughts and adjustment (6 minutes)

The goal of this part of the session is to introduce participants to the role of cognitions in driving many of our emotions and reactions to situations. Explain the patient the connection between the thoughts or interpretations we make of a particular situation with the emotions we feel relative to that situation, and how we can elicit the emotions or feelings we would like to feel by choosing different thoughts and making them our automatic response to similar situations.

Use pain experience as an example of how what people think about their pain has an influence over how well they adjust to pain including the following concepts.

TO ENSURE ACCURATE FIDELITY CODING, SAY:

- “Now let me tell you a little about the cognitive model of pain, and the role of thinking and automatic thoughts. The way we think affects our emotions, behaviors, and physical reactions, including pain.
- You might notice feelings or physical sensations that are related to your pain, like more muscle tension and feeling angry, worried, or sad.
- What you might not be aware of is that your thoughts change along with your level of pain.

- We all have thousands of thoughts that run through our minds each day. It's kind of like breathing is so automatic we are not aware we are doing it until we focus our attention on it.
- We are often not aware of what we are thinking, either because we are focused on something else or just not paying attention to our thoughts.
- Although our thoughts seem to happen naturally and automatically at times, we can learn how to pay closer attention to them and how to change them.
- We call these thoughts "**automatic thoughts**" because they happen very quickly and often seem automatic.
- Sometimes these thoughts are helpful, sometimes they are unhelpful.
- Many people with pain have a tendency to have negative or unhelpful thoughts about their pain. [give a couple examples, such as "This is horrible" or "I can't stand this"
- Although such thoughts are understandable, they are not helpful. How people think about their pain has been found to be a really important predictor of how well they adjust to pain.
- Studies as well as our experience with MS/SCI/MD/Amp/LB pain have shown that such unhelpful thoughts are associated with increased pain, distress, and suffering.
- Sometimes when people hear this information they think I mean that pain is "all in their heads." That's not at all what I am saying. Instead, what I'm saying is that pain is a very real experience that can be made worse by stress. And our level of stress is greatly affected by how we think about things. This means that you can learn how to better manage your pain by learning strategies to help you make automatic more helpful thoughts that elicit positive feelings, particularly when you are under stress.
- We will talk more about this when we review your homework for today's session."

Note: the therapist can go into more detail about what is meant by "thoughts" and the hypothesized associations between thoughts and pain here, as needed, so that the participant "gets it". This material should be gone over as slowly or in as much detail as needed to maximize participant understanding.

Pre-hypnosis discussion (3 minutes)

Peaceful Place Description

The goal of this part of the session is to inform participants that the session will include inviting them to imagine themselves in a place where they feel comfortable, safe, and at ease, and to clarify how the exercise will be as well as to collect relevant information about his/her preferences relative to certain details of the script that may be incorporated or not according to the participant's responses.

TO ENSURE ACCURATE FIDELITY CODING, SAY: Also during the hypnosis practice I will invite you to imagine yourself in a place where you feel comfortable, safe, and at ease. This can be a real place that you have actually been to, or it can be an imaginary place. It does not have to be the same place every time you practice this exercise. In fact, if you can change the place or details about the place every so often, this can keep the place ‘fresh’ for you and make it even more interesting and engaging. The important thing is for you to select a place that you can very clearly imagine in detail.

Could you please let me know what such a place might be like? What details you would like to include (e.g., sandy beach, mountain meadow, meadow filled with flowers, mountain top, living room; ideal temperature; color of any water and the sky; plants or other objects around them)?

Record details about the peaceful place in the ***Combined CR and Hypnosis Log Sheet*** *so that you can refer to them during treatment.*

Before starting formal hypnosis, discuss with the participant getting physically comfortable, for example, taking off his or her coat, getting into a comfortable position, etc.

Hypnosis session (20 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to start the hypnosis session.

Start recording with the second recorder for the hypnosis practice. Remind the participant to silence his/her cell phone.

INDUCTION

Okay… just settle back**…**

if eyes open, say, and close your eyes.

if eyes closed say, and let the eyes stay closed.

Now… I’m going to talk to you for a while … all you have to do is listen to what I’m saying and allow yourself to have as pleasant an experience as you know how. Go ahead and adjust yourself to the most comfortable position you can.

Observe subject. Wait until adjusting is completed before continuing.

That’s fine. And remember, you can feel free to make any adjustments, at any time, to help yourself be comfortable, and this need not interrupt your concentration or ability to maintain a deep state of comfortable relaxation.

Initial Relaxation

Goal: *To relax the participants by focusing on areas of their body.*

General Ideas: *To do a body scan, inviting relaxation and comfort into the different areas of the body. You can incorporate pleasant sensations mentioned by the participant and avoid any unpleasant sensations.*

Sample Script:

Go ahead and take a very deep, satisfying breath and hold it just for a moment. That's right, … hold it for a moment and let it go. Now just let the entire body relax… Allow all your muscles to go limp…. Just notice that the top of your head is becoming relaxed, limp, and heavy. And just let that relaxation and comfort spread down to your forehead, in your eyes, down through your cheeks, in your mouth and jaw, down in your neck, deep relaxing, and heaviness. Just let that relaxation spread in your neck now, letting your neck goes, in your shoulders, deep, warm, heavy. Down heavy down to your right arm, down to your right hand, down to your left arm, and your left hand. Deeper and deeper relaxed. And now that relaxation spread down in the chest, slowing down your breathing even more deeply, even more completely, down in the pelvis, down in the right thigh, right calf, the right foot. Down in the left thigh, left calf, the left foot. The entire body now very very relaxed. Deep, comfortable, relaxation, not a care in the world. It may even be the sense of lightness and drifting. It just becomes very easy and effortless.

Deepening

And as you remain drifting, comfortable, not a care in the world, you find yourself in an elevator. It is a special elevator with me. And you are in the 10th floor and looking up you can see the light that says 10th on it, or actually it says 1 on it. And in a moment we are going to start counting from 1 to 10 and with each level that we go down, with each number, you will become deeper and deeper relaxed. Maybe you find yourself somewhere else, altogether, perhaps on a set of stairs perhaps walking down a comfortable path. It really does not matter, as long as you feel deeper relaxed and more comfortable with each number, it is fine.

Let's begin now.

One. One level into deeper comfort. …You might already notice a sense of warmth, a sense of the muscles letting go even more.

Two. Two levels down. That's right…deeper into you. Focusing more and more in the sound of my voice, understanding the words that I am saying.

Three. Three levels down… Perhaps noticing, every sensation you can feel…just becomes easy and effortless.

Four. Four levels down…And I wonder if you are beginning to notice and enjoy the freedom of this experience. There is nothing you have to do. Just listen and enjoy the ride.

Five. Half way down…So completely absorbed in the moment…no need to focus on the past, or the future…just focusing on your breath in this moment.

Six. Six levels down… Again just feeling that sense of comfort washing down to the forehead again down to the face, in your mouth and jaw down in the neck. The shoulders, arms, down in the chest, waist, legs and feet. The entire body profoundly relaxed.

Seven. Seven levels down… Even though you can feel the body becoming heavier and heavier, you also may have the sensation of floating in space and enjoy a sense of weightlessness… drifting, floating…

Eight. Eight levels down. Hearing the sound of my voice, without even trying. Listening to the words that I say.

Nine.. Deeply, deeply relaxed. Almost there…and now…

Ten. The tenth level of relaxation. Comfort … well-being…profoundly, profoundly relaxed.

Peaceful place imagery

Goal: *Deepening and to provide a place of comfort and relaxation before giving suggestions.*

General Ideas: *Talk patient through experiencing a peaceful place of their choice, including invitations to experience sights, sounds, touch, and positive emotions they might be having. The patient should interact with environment as if they are really there.*

Invite the participant to continue to experience the place using all of his or her senses for about 2.5 minutes. Keep in mind that they will be listening to a recording of this session, so do not provide so much detail that might ultimately be inconsistent with a new place they imagine months or even years from now. Rather, invite them to create the place and experience it in great detail; to touch objects, and experience how they feel. Invite them to experience the colors. Add sensations that they described previously as present as being a part of the place. Encourage them to experience positive emotional experiences (calmness, a sense of confidence, a warmth and connectedness to nature and others). Suggest that the individual see, hear, and smell all the possible details of this place, wherever they are as he/she approaches it and moves through it. Pause long enough to let them create these experiences for themselves.

Sample Script:

And the elevator doors open, and you find yourself in your peaceful place. It can be whatever you want, as long as it is comfortable... Notice what you are able to see in front of you, notice what you are able to hear,… notice what you are able to feel… Maybe you find yourself lying down in your place or walking around, it really does not matter. You may notice that the nature of your special place changes each time you listen to my voice or even within this relaxing experience, it can change, it can stay the same. The only thing that matters is that you feel comfortable, peaceful, restful. And aware that when you are in your peaceful place, your mind can serve you in wonderful ways, and allow you to have profound experiences that serve your ability to be comfortable.

Continue with the description according to the participant's responses to the peaceful place section in the ***Combined CR and Hypnosis Log Sheet.***

Suggestions

Goal: *To encourage the participants' comfort with having a sense of ambiguity about the meaning of pain, and to help them accept their sensations without catastrophizing.*

General Ideas: *That they can be comfortable in ambiguous situations; that it is normal to speculate about the reasons why some things happen but sometimes it is difficult to know for sure. That when one is looking for reasons, sometimes the conclusions we reach are not based on evidence and it is wiser to accept that we do not know and that the sensations are there and they are only sensations.*

Sample Script:

1. Building a response set concerning ambiguity.

As you sink deeper into comfort, you can be aware that there are many things that I could say that could help you feel more relaxed…and there are many things you could think to yourself or imagine that would help you feel more comfortable, and at ease…and I don't know which of these would be most valuable to you right now …. And you don't know what pleasant images and ideas will come to you as I talk….and you do not know yet in what specific ways you will continue to learn about how the thoughts and the images you carry with you impact how you feel about yourself and your health ….or what thoughts and images you will discover and create for yourself, so that you can feel so much better... And you do not really know just yet at what moment you will find yourself feeling so comfortable and relaxed… so comfortable with the possibilities of how things are becoming better and better….

2. Introduce concepts concerning inference

I am sure that you have had the experience of calling someone….getting his or her answering machine…and leaving a message…and when the person does not call back in a time frame you think reasonable….you might wonder what it means…. Whether the person is busy…. Whether the answering machine worked properly…. If the person is avoiding you for some reason… or any of the many possible reasons… and how do you know what the real reason is? But it is human nature to speculate about what things that happen mean… and the real skill is knowing when you are speculating, when you are guessing … and when you have evidence to affirm your interpretation… after all… you don't want to react to something on the basis of an incorrect interpretation….

3. Suggestions that introduce concepts concerning the drive to "know" or draw conclusions

And all of the speculation about why the person didn't call back… are normal and reflect our desire to make sense out of things that don't seem to make sense… and whether you want to understand something like why someone did not call back, or something much more complex like how the universe works… or how your sensations are created and how you can gain control over them and your response to them… It's one of human beings' greatest strengths… that we strive to understand … and make sense out of the things that go on around us and within us…..

4. Suggestions that introduce the concept of the value of "not knowing"

And the fact that you can generate so many different explanations for why someone doesn't call back… gives you the opportunity to realize you don't know why he or she didn't call back… you can make lots of guesses…but you really don't know for sure… and when you don't know how to explain something… it is perfectly all right to say you don't know…. After all, no one really expects you to know why someone else doesn't return a phone call. *It's a gift of honesty and clear thinking when someone says, "I don't know,"* instead of making up an answer that might well be wrong…or not very helpful… There are so many times in life when you'd rather be given no answer than a wrong one….

5. Suggestions that reframe "not knowing" as potentially useful and desirable

Before your reach a conclusion, any conclusion…it might be useful to ask yourself, "How do I know?" and if your answer is "I just feel it is so" or "I just think so" ... then *know* that you are forming a conclusion with no apparent hard evidence …. That does not mean you are wrong, necessarily, but it increases the chances considerably… So you can remind yourself to go to the next step and ask yourself, "Is there any hard evidence to support this?" And maybe there will be and maybe there won't be, but as you ask yourself these questions, you'll notice the quality and accuracy of your ideas and conclusions getting better and better over time….

The human body is wonderfully complex…and the brain, which is a part of the body, is a particularly complex part of a complex system. Everything works together to create your experience of your physical and emotional self. Mostly, this happens automatically…so we really do not know, when we experience a nice warm comfortable sensation…. How the body created that sensation… we don't always know how sensations are going to change… how we can learn to alter those sensations, to pay even more attention to comfortable sensations to enhance them … And when we experience sensations that are not so pleasant … when those sensations are new, it certainly might be reasonable to try and find out the cause of those sensations …. in a detached sort of way, especially when we have not felt them before… we want to know that we are safe … and to take care of ourselves … But if they are old sensations … we may know on the one hand that we are medically safe … but if we do not always know the cause of the sensations, it might not make any sense to draw conclusions about what will happen to them… we cannot really predict the future, we do not have a crystal ball… it might be wiser to simply accept the sensations for what they are …. Sensations… and allow ourselves to leave it at that … it might be the most honest thing to do… and also allow a kind of freedom…. From worry… and concern….

And now, for 30 seconds, just allow yourself to any experiences that you would like to have, deep within the comfort of your own mind. 30 seconds of silence, starting now.

<u>Post-hypnotic suggestions</u>

Goal: *To reinforce the previous suggestions and to generalize them into participants' everyday life.*

General Ideas: *That whenever the participants face a situation or a sensation with an ambiguous meaning they will remind themselves that they can feel comfortable with not knowing for sure what it means yet, and that they can find and adopt a perspective that is the most helpful, reassuring, and accurate.*

Sample Script:

And each time throughout the day you encounter a situation or a sensation where the meaning is not clear to you, or can even anticipate such an event before it happens, you can remind yourself that there are many different ways to interpret the event… and you can also, instantly and automatically, remind yourself you don't know what it means just yet… but you can entertain a variety of interpretations… and you can ask yourself directly how you will know which interpretation – if any – is a correct one …which one is most helpful, reassuring, and accurate….. and it can lead you to look deeper and you can do so comfortably… knowing that you can look for evidence for your views if it exists… and comfortably know you can adopt any perspective that might feel good to you… when one interpretation is merely as plausible as another. And, as you ponder these issues and allow them to sink in… you can…

Re-Orienting

Goal: *To bring patient out of hypnosis, bringing feelings of calm and relaxation into their day.*

General Idea: *To use a countdown to signal patient to become more and more alert and back to the present. Suggestions for keeping any benefit they may have gained during hypnosis (e.g., relaxation) should be included.*

The alerting process should take rough 3 minutes. Follow what you see in the patient. Allow your voice to model more alertness and energy as you return to the first floor.

Sample Script:

Now…Find yourself back in the elevator. You are looking at the number 10 in front of you and in a moment as you may have already guessed, I am going to start counting with you from 10 to 1. The smaller the number the more alert, awake, and refreshed you will feel. No hurry, we have plenty of time, and you actually won't let yourself come to a full state of alertness until you are ready.

Let's begin now.

Ten, you see the 10th floor light comes on and off.

And nine, eight, slowly going upward, becoming more and more awake, more and more refreshed.

Seven, more and more awake… Slowly beginning to move your arm and legs.

Six and five.

When we reach one your eyes will still be closed and almost ready to open, awaiting the signal from your mind that you are feeling awake, alert and refreshed.... picturing the room around you…what it looks like…the colors and the textures.

Four, more and more awake, more and more refreshed.

Three, that is right, more and more alert. Just feeling profoundly relaxed but alert and refreshed.

Two, and now one. Just set your own pace feeling your eyes open as a signal that you are feeling alert, refreshed, but also very comfortable and retaining the things that are going to useful from what you just have been through.

Post-hypnosis discussion (5 minutes)

After the subject gets out of hypnosis and is activated after the relaxation, observe that s/he is really alert, not just sitting, compliantly, with eyes open. Give suggestions for being alert, if necessary.

TO ENSURE ACCURATE FIDELITY CODING, DISCUSS:

Using the ***Combined CR and Hypnosis Log Sheet,*** *how they are feeling right now and how was his/her experience during the hypnosis session. Modifications in the hypnosis suggestions may be made based on the information obtained from this discussion (e.g., if a participant states that a suggestion was not helpful or did not like it, that suggestion should be dropped or reworded; if the participant describes a specific suggestion or image that was very helpful, that suggestion or image should be emphasized in the next session). Record this information in the* ***Combined CR and Hypnosis Log Sheet****.*

Address any questions or concerns as appropriate.

Arrange with the participant how you are going to get a copy of the recording to him or her (i.e., make a CD while they wait; make it later and mail it to him or her, etc.)

Explanation of how to practice self-hypnosis

SAY: You can practice hypnosis with the recording we made in the session and you can also **practice on your own**.

When you are practicing self-hypnosis on your own you will enter into a state of focused attention (hypnosis), and let your mind play with the ideas in order to experience more comfort. Several times during the day, but at least three times every day, take 2 to 5 minutes (or more if you wish) and go through the steps to enter a state of hypnosis, starting with taking a deep breath and holding it… and letting it go. Allow the body to relax, imagine going down the elevator, and go to your special place. Give yourself suggestions for comfort, relaxation in general or for any other sensation that is helpful for you to cope with pain. Stay there for as long as you like.

Homework (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to go over the **homework** for next session.

- ***Say,*** "Please, review the material for this session."
- ***Give*** *the participant a recording of the part of the session with the hypnosis session. Then* ***say*** *the following:* "We have made recordings so that you can listen to them to get the most out of the treatment. Because listening to them more rather than less will likely provide more reinforcement for what we are teaching, you might find it useful to consider listening to the recordings at least once per day. By doing this, you can learn how often you should listen to get the most out of treatment. You might end up deciding to listen once or even more often every day. Or you might decide that you do not need to listen this often to reinforce what you are learning, and so may choose to listen just a couple of times a week or even less. It is completely up to you to decide the frequency that works best for you".

- *Remind the participants to listen to the recordings whenever they feel more alert and to avoid listening to them before going to sleep. If they want to use the hypnosis skills before going to sleep, they will be asked to use self-hypnosis.*
- ***Say,*** “Also, to get the most out of this treatment, practice self-hypnosis for 2 to 5 or more minutes without the recording several times a day.”
- ***Say:*** The next two sessions will focus on generating helpful automatic thoughts about pain, and instilling any beliefs that are important for the participant to hold. Therefore, ask the participant to complete the cognitive thought worksheet at home (page 9 of the handbook). Ask them to write down at least 2 situations when they feel particularly good relative to their pain problem and 2 when they feel particularly bad and feel more pain and then describe the feelings they had in that situation and the thoughts they had associated with these feelings. Ask them to write down anything they think of, even if they are not sure about it. There are no right or wrong “answers” on this worksheet. It is just designed to help participants practice becoming more aware of their thoughts.
- ***Say***, “Please, bring the worksheet to the next session to go over the responses and use them in the next hypnosis session”.

Post-session assessment elements (2 Minutes)
TO ENSURE ACCURATE FIDELITY CODING:

- **Obtain current 0-10 pain intensity ratings (at the end of the session).**
- **Obtain average during session 0-10 pain intensity ratings.**
- **Ask for adverse reactions to the session (using the *Adverse Events Tracking Form*).**
- **Ask: Do you have any questions for me at this point? (*Give enough time to address all questions*.)**

Session 2
Identifying and Enhancing Reassuring Cognitions (I)

Session Objectives

- Assist the participant in identifying reasonable and reassuring cognitions from thought worksheet and practice exercise.
- Give hypnotic suggestions aimed to make automatic these realistic and reassuring cognitions.

Write time in *Treatment Recording Sheet*.

Pre-session assessment elements (5 minutes)

- **Ask for permission to record the session.**
- **Ask for a relapse or Exacerbation in participant's MS since completing the phone interview (only for MS Participants).**
- **Obtain current 0-10 pain intensity ratings (at the beginning of the session).**
- **Obtain average 24-hour 0-10 pain intensity ratings.**
- **Collect data about homework using the *Treatment Recording Sheet*.**
- **Obtain pain relief on average after listening to the recordings.**
- **Obtain pain relief on average after practicing skills or using the information learned in the treatment.**
- **Ask for adverse reactions to previous session (using the *Adverse Events Tracking Form*).**

Review of last session (1 minute)
TO ENSURE ACCURATE FIDELITY CODING, SAY:

In our last session we discussed the importance of our thoughts about pain in how we experience pain. We also did a hypnosis session with an induction and hypnotic suggestions.

Summarize what will happen during the session (2 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY:

In today's session we will review your homework together and will discuss the reassuring thoughts you identified and recorded in your worksheet.

Then we will do another hypnosis session similar to the one we did last time. It will start with an induction including relaxation and imagery, and continue with the hypnosis suggestions of today's session, which will include the reassuring thoughts we discuss in the first exercise.

Homework Review

Review of the hypnosis practice

TO ENSURE ACCURATE FIDELITY CODING:

Ask questions about the hypnosis practice with and without the recording and write down the responses in the ***Combined CR and Hypnosis Log Sheet****.*

If the participant mentions something that indicates that they hold a misconception about hypnosis and/or that they do not understand well how to use self-hypnosis because of a myth, the clinician will dispel again the myth as appropriate and reinforce the correct information.

If the participant reported in the questions about practicing self-hypnosis that s/he practiced only some parts of it (deep breathing, imagery or suggestions), or that s/he had difficulties in doing the exercises, explain the steps like in the previous session:

"Several times during the day, but at least three times every day, take 2 to 5 minutes (or more if you wish) and go through the steps to enter a state of hypnosis, starting with taking a deep breath and holding it… and letting it go. Allow the body to relax, imagine going down the elevator, and go to your special place. Give yourself suggestions for comfort, relaxation in general or for any other sensation that is helpful for you to cope with pain. Stay there for as long as you like."

Address all the questions and difficulties the patient may have in doing this exercise and, if necessary, do a short practice so that the patient has the experience of how to use self-hypnosis.

Encourage participants to discuss and troubleshoot any barriers to practicing using Motivational Interviewing. Be attuned to any comments they have about the ease or difficulty of practicing, fitting practice into their schedules, or other issues related to their likelihood of using these skills in their everyday life and after treatment ends.

Cognitive thought worksheet review

TO ENSURE ACCURATE FIDELITY CODING, SAY: At the end of our last session I asked you to complete the cognitive thought worksheet of your handbook to help you practice identifying the thoughts associated with at least 2 situations when you feel particularly good relative to your pain problem and 2 when you feel particularly bad and feel more pain. We are going to take a few minutes now to go over that worksheet.

If the participant completed the worksheet and demonstrates an understanding of how to complete it, spend a few minutes reviewing the worksheet and then continue with the session.

If the participant attempted to complete the worksheet but had difficulty determining what to write in each of the columns on the worksheet, assist the participant in completing it in session. Once the participant appears to understand the basic concepts, continue with the session.

If the participant did not complete the worksheet, spend a few minutes problem-solving about how to overcome any barriers or obstacles to homework completion, including challenges that may be related to his/her MS/SCI/MD/Amp/LBP. Reiterate the importance of homework completion in maximizing the effects of the treatment. Complete the worksheet in session with the participant and then continue with the session.

For all participants, reflect back to them any statements they make about their ability to use these skills, and provide reinforcement for any efforts they have made, even if they encountered difficulties completing the worksheets.

Once the worksheet is complete take notes of the positive thoughts and discuss and encourage the patient to come up with thoughts that might be more appropriate than the ones they had in the situations they described in which they did not feel well.

Exercise to practice the identification of reasonable and reassuring cognitions (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY:

As a practical example, the clinician will do the following exercise. The thoughts resulted from this exercise can be used to reinforce or clarify how to complete the self-recording of thoughts and feelings, and to identify new or more specific thoughts than those discussed in the previous section for incorporating them in the hypnotic suggestions of this session.

For these thoughts, remember that if the patient brings up thoughts unrelated to pain, the clinician should gently change the focus back to pain thoughts. The key positive thoughts to encourage are control over pain and its impact (self-efficacy), that hurt does not necessarily mean harm, and hope for the future. Any pain-related catastrophizing should also be replaced by appropriate pain-related adaptive thoughts inconsistent with whatever catastrophizing thought the patient identifies.

The clinician will ask the following questions:

What positive feelings would you like to enhance and make automatic?

Write down the participant's responses and for each feeling ask the following:

Now, imagine that you are feeling "……." You can close your eyes if that helps you focus on that feeling and you may find helpful to remember a situation in which you felt that feeling very intensely. Take a moment to experience as vividly as possible how that feels, and let me know when you are feeling that feeling, perhaps by nodding your head.

[If the patient does not achieve to imagine how that feels, help him/her by asking him to elaborate a description of the feeling out loud or by asking questions about the details of the situation s/he is trying to recreate.]

[When the participant reports that s/he is feeling that feeling, ask about the related thoughts.]

Now, can you tell me what thoughts or images you are having right now as you feel "……"?

[Write down a list of thoughts and ask the participant:]

You have listed a number of thoughts that were associated with feeling this particular feeling. They were "……..", "……..", and "……..". As you ponder these now, which of these seems to be most reassuring to you?

Identifying reassuring and helpful cognitions

Prior to the induction, inform participants that the session will include inviting them to ponder the reasonable and realistic thoughts that they developed and found most helpful in the worksheet and the practice exercise. Discuss this with them, and list up to three of those cognitions/beliefs considered as more helpful in the ***Combined CR and Hypnosis Log Sheet.***

If the participant finds it difficult to come up with reassuring thoughts the following list can be used to give them some ideas.

1. I am confident in myself.
2. I am my own pain manager.
3. I know what is most important to me.
4. I can remain calm and focused, no matter what is happening around me.
5. I can achieve what is most important to me.
6. I can handle the pain.
7. It is only pain.
8. I am strong.
9. I am stronger than this pain.
10. I am learning to be more comfortable.
11. I am making progress.
12. I can manage any sensations in my body.
13. I have more self-control every day.

Hypnosis session (20 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to start the **hypnosis session**.

Start recording with the second recorder for the hypnosis practice. Remind the participant to silence his/her cell phone.

Reminders before hypnosis practice

Invite the participants to experience something "new" and "interesting" during the induction; allow much of the wording to be permissive to facilitate this. Also remind them that the peaceful place does not have to be the same place every time they practice this exercise, and to try to pay attention to the details of that place.

Also discuss with the participant getting physically comfortable, for example, taking off his or her coat, getting into a comfortable position, etc.

INDUCTION

Okay… just settle back**…**

If eyes open, say, and close your eyes.

if eyes closed say, and let the eyes stay closed.

Now… I'm going to talk to you for a while … all you have to do is listen to what I'm saying and allow yourself to have as pleasant an experience as you know how. Go ahead and adjust yourself to the most comfortable position you can.

Observe subject. Wait until adjusting is completed before continuing.

That's fine. And remember, you can feel free to make any adjustments, at any time, to help yourself be comfortable, and this need not interrupt your concentration or ability to maintain a deep state of comfortable relaxation.

Initial Relaxation

Goal: *To relax the participants by focusing on areas of their body.*

General Ideas: *To do a body scan, inviting relaxation and comfort into the different areas of the body. You can incorporate pleasant sensations mentioned by the participant and avoid any unpleasant sensations.*

Sample Script:

Go ahead and take a very deep, satisfying breath and hold it just for a moment. That's right, … hold it for a moment …. and let it go. Now just let the entire body relax… Allow all your muscles to go limp…. Just notice that the top of your head is becoming relaxed, limp, and heavy. And just let that relaxation and comfort spread down to your forehead, in your eyes, down through your cheeks, in your mouth and jaw, down in your neck, deep relaxing, and heaviness. Just let that relaxation spread in your neck now, letting your neck go, in your shoulders, deep, warm, heavy. Down heavy down to your right arm, down to your right hand, down to your left arm, and your left hand. Deeper and deeper relaxed. And now that relaxation spread down in the chest, slowing down your breathing even more deeply, even more completely, down in the pelvis, down in the right thigh, right calf, the right foot. Down in the left thigh, left calf, the left foot. The entire body now very very relaxed. Deep, comfortable, relaxation, not a care in the world. It may even be the sense of lightness and drifting. It just becomes very easy and effortless.

Deepening

And as you remain drifting, comfortable, not a care in the world, you find yourself in an elevator. It is a special elevator with me. And you are in the 10th floor and looking up you can see the light that says 10th on it, or actually it says 1 on it. And in a moment we are going to start counting from 1 to 10 and with each level that we go down, with each number, you will become deeper and deeper relaxed. Maybe you find yourself somewhere else, altogether, perhaps on a set of stairs perhaps walking down a comfortable path. It really does not matter, as long as you feel deeper relaxed and more comfortable with each number, it is fine.

Let's begin now.

One. One level into deeper comfort. …You might already notice a sense of warmth, a sense of the muscles letting go even more.

Two. Two levels down. That's right…deeper into yourself. Focusing more and more in the sound of my voice, understanding the words that I am saying.

Three. Three levels down… Perhaps noticing, every sensation you can feel…just becomes easy and effortless.

Four. Four levels down…And I wonder if you are beginning to notice and enjoy the freedom of this experience. There is nothing you have to do. Just listen and enjoy the ride.

Five. Half way down…So completely absorbed in the moment…no need to focus on the past, or the future…just focusing on your breath in this moment.

Six. Six levels down… Again just feeling that sense of comfort washing down to the forehead again down to the face, in your mouth and jaw down in the neck. The shoulders, arms, down in the chest, waist, legs and feet. The entire body profoundly relaxed.

Seven. Seven levels down… Even though you can feel the body becoming heavier and heavier, you also may have the sensation of floating in space and enjoy a sense of weightlessness… drifting, floating…

Eight. Eight levels down. Hearing the sound of my voice, without even trying. Listening to the words that I say.

Nine.. Deeply, deeply relaxed. Almost there…and now…

Ten. The tenth level of relaxation. Comfort … well-being…profoundly, profoundly relaxed.

Peaceful place imagery

Goal: *Deepening and to provide a place of comfort and relaxation before giving suggestions.*

General Ideas: *Talk patient through experiencing a peaceful place of their choice, including invitations to experience sights, sounds, touch, and positive emotions they might be having. The patient should interact with environment as if they are really there.*

Invite the participant to continue to experience the place using all of his or her senses for about 2.5 minutes. Keep in mind that they will be listening to a recording of this session, so do not provide so much detail that might ultimately be inconsistent with a new place they imagine months or even years from now. Rather, invite them to create the place and experience it in great detail; to touch objects, and experience how they feel. Invite them to experience the colors. Add sensations that they described previously as present as being a part of the place. Encourage them to experience positive emotional experiences (calmness, a sense of confidence, a warmth and connectedness to nature and others). Suggest that the individual see, hear, and smell all the possible details of this place, wherever they are as he/she approaches it and moves through it. Pause long enough to let them create these experiences for themselves.

Sample Script:

And the elevator doors open, and you find yourself in your peaceful place. It can be whatever you want, as long as it is comfortable... Notice what you are able to see in front of you, notice what you are able to hear,… notice what you are able to feel… Maybe you find yourself lying down in your place or walking around, it really does not matter. You may notice that the nature of your special place changes each time you listen to my voice or even within this relaxing experience, it can change, it can stay the same. The only thing that matters is that you feel comfortable, peaceful, and restful. And aware that when you are in your peaceful place, your mind can serve you in wonderful ways, and allow you to have profound experiences that serve your ability to be comfortable.

Continue with the description according to the participant's preferences.

Suggestions

Goal: *To encourage the belief that continued practice using cognitive coping strategies will help the participant gain control over pain and its impact. To automatize the processes of cognitive restructuring so that they are active all the time, even without the participant's awareness.*

General Ideas: *That the hypnotic and cognitive skills the participants are learning become automatic. To reinforce the reassuring thoughts they have identified. That cognitions are automatically monitored and adjusted into more reassuring and realistic cognitions. It can be used the imagery of a caring thought monitor that is watching out for the thoughts and encouraging and enhancing those reassuring thoughts that help them feel good.*

Sample Script:

1. Building a response set concerning how learning processes become automatic

Perhaps you might wonder how the things you learn and practice and somehow happen to become automatic...helpful thoughts about your pain life that once took some practice to learn and now just seem natural and effortless because you have thought about them enough.... Isn't it interesting that at least certain thoughts about your body, your sensations and your coping now seem to occur naturally and almost without effort.

2. Suggestions that bring previously identified reasonable thoughts into the participants awareness.

Sometimes it is so easy to forget that you have a gold vault of adaptive, helpful, and reassuring thoughts about your body, your sensations, and what you do to cope that you have developed over the years and so often is simply a matter of calling these powerful resources. We have already talked and identified together a number of potential thoughts that will be useful in coping with your life situation (List examples generated from specific patient).

Include a suggestion about what the mind will do with these thoughts. For example, that they will come forward and repeat. Not just list them, but suggest what will happen with them. Something like:

"These thoughts are there, in your mind. They can come forward when needed, like a trusted friend, to reassure you and bring you comfort, just when they are needed and most appropriate…"

3. Suggestions that make the altering alarming thoughts into reasonable ones automatic.

One of the most amazing gifts of our brain is for it to be able to detect and transform negative thoughts into positive ones and we can simply trust its ability to do that, when we are offered a thought or idea that is less than helpful, when we are in good relationship with our brain, the brain can simply ignore them they are of no benefit to anyone.

4. Imagery of a caring thought monitor and developing realistic thoughts automatically

We have talked about the potential of the brain to not only identify negative thoughts, but to transform them into truly helpful ones. What is much more compelling about this is the notion of a part of your brain that operates at a much higher, objective an even more noble screener of thoughts and ideas. That indeed this part of your brain seems to have the wisdom to screen out less helpful thoughts early, to differentiate the distinction between helpful and less helpful thoughts and transforms them accordingly and appropriately. But perhaps most optimally, this part of brain allows you the unique ability to watch your thoughts from the level of a spectator. To realize that while the thoughts might happen, you are more in the role of a detached observer and you can experience what it means to observe all thoughts without being attached to them on any way; knowing that they are just coming and going.

And now, for 30 seconds, just allow yourself to any experiences that you would like to have, deep within the comfort of your own mind. 30 seconds of silence, starting now.

Post-hypnotic suggestions

Goal: *To reinforce the previous suggestions and to generalize them into participants' everyday life.*

General Ideas: *That whenever the participants face situations or sensations, a wise friend inside (the metaphor they developed in the previous suggestion) will be there for them monitoring their thoughts and developing automatically those thoughts that are more helpful, reassuring, and accurate.*

Sample Script:

And each time throughout the day as you encounter events, or feel feelings, the wise friend inside can monitor any and all thoughts, and develop and nurture, automatically, those thoughts that are most helpful to you… because you know that there are many different ways to interpret the event… and you can allow yourself to entertain a variety of interpretations… and allow yourself to select which one is most helpful, reassuring, and accurate….. and as you do this, it will become more and more automatic, knowing that you will easily and automatically adopt the perspectives that are just right for you at the moment.

Re-Orienting

Goal: *To bring patient out of hypnosis, bringing feelings of calm and relaxation into their day.*

General Idea: *To use a countdown to signal patient to become more and more alert and back to the present. Suggestions for keeping any benefit they may have gained during hypnosis (e.g., relaxation) should be included.*

The alerting process should take rough 3 minutes. Follow what you see in the patient. Allow your voice to model more alertness and energy as you return to the first floor.

Sample Script:

Now…Find yourself back in the elevator. You are looking at the number 10 in front of you and in a moment as you may have already guessed, I am going to start counting with you from 10 to 1. The smaller the number the more alert, awake, and refreshed you will feel. No hurry, we have plenty of time, and you actually won't let yourself come to a full state of alertness until you are ready.

Let's begin now.

Ten, you see the 10th floor light comes on and off.

And nine, eight, slowly going upward, becoming more and more awake, more and more refreshed.

Seven, more and more awake… Slowly beginning to move your arm and legs.

Six and five.

When we reach one your eyes will still be closed and almost ready to open, awaiting the signal from your mind that you are feeling awake, alert and refreshed.... picturing the room around you…what it looks like…the colors and the textures.

Four, more and more awake, more and more refreshed.

Three, that is right, more and more alert. Just feeling profoundly relaxed but alert and refreshed.

Two, and now one. Just set your own pace feeling your eyes open as a signal that you are feeling alert, refreshed, but also very comfortable and retaining the things that are going to useful from what you just have been through.

Post-hypnosis discussion (5 minutes)

After the subject gets out of hypnosis and is activated after the relaxation, observe that s/he is really alert, not just sitting, compliantly, with eyes open. Give suggestions for being alert, if necessary.

TO ENSURE ACCURATE FIDELITY CODING, DISCUSS:

Using the ***Combined CR and Hypnosis Log Sheet,*** *how they are feeling right now and how was his/her experience during the hypnosis session. Modifications in the hypnosis suggestions may be* *made based on the information obtained from this discussion (e.g., if a participant states that a suggestion was not helpful or did not like it, that suggestion should be dropped or reworded; if the participant describes a specific suggestion or image that was very helpful, that suggestion or image should be emphasized in the next session). Record this information in the* ***Combined CR and Hypnosis Log Sheet****.*

Address any questions or concerns as appropriate.

Arrange with the participant how you are going to get a copy of the recording to him or her (i.e., make a CD while they wait; make it later and mail it to him or her, etc.)

Homework (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: **Now we are going to go over the homework for next session.**

- ***Say,*** "Please, review the material for this session."
- ***Give*** *the participant a recording of the part of the session with the hypnosis session. Then* ***say*** *the following*: "We have made recordings so that you can listen to them to get the most out of the treatment. Because listening to them more rather than less will likely provide more reinforcement for what we are teaching, you might find it useful to consider listening to the recordings at least once per day. By doing this, you can learn how often you should listen to get the most out of treatment. You might end up deciding to listen once or even more often every day. Or you might decide that you do not need to listen this often to reinforce what you are learning, and so may choose to listen just a couple of times a week or even less. It is completely up to you to decide the frequency that works best for you".
- *If the participant prefers the recording of a previous session's recording over the most recent one, the participant will be encouraged to listen to the preferred recording. However, participants will also be encouraged to listen to each of the recordings made at least once/week (that is, to 'rotate' listening to the recordings to some extent) to help ensure that they obtain the potential benefits of each one. Specifically,* ***say****,* "Because each of the recordings of the four sessions are different, if you do elect to listen to the recordings regularly, we think it would be a good idea to 'rotate' the recordings to some extent. For example, if you listen to one recording every day, you might choose to listen each of the recordings at least once in any one week. Or, if you listen to the recordings once/week, you might choose to listen to a different recording every week. Ultimately, though, it is completely up to you to determine which recordings you find most helpful, and how often you choose to listen to them".
- *Remind the participants to listen to the recordings whenever they feel more alert and to avoid listening to them before going to sleep. If they want to use the hypnosis skills before going to sleep, they will be asked to use self-hypnosis.*

- ***Say,*** "Also, to get the most out of this treatment, practice self-hypnosis for 2 to 5 or more minutes without the recording several times a day."
- ***Say,*** "The next session will also focus on making automatic positive cognitive restructuring, and instilling any beliefs that you think are important for you to hold. Therefore, between now and the next session, please consider the positive thoughts you brought to Session 2. And please complete the cognitive thought worksheet at home (page 14 of your handbook), you may use the exercise you learned in this session for identifying thoughts associated with reassuring feelings."
- ***Say***, "Please, bring the worksheet with you to our next session so that we can go over your responses together and use them in our next hypnosis session".

Post-session elements (2 Minutes)

TO ENSURE ACCURATE FIDELITY CODING:

- **Obtain current 0-10 pain intensity ratings (at the end of the session).**
- **Obtain average during session 0-10 pain intensity ratings.**
- **Ask for adverse reactions to the session (using the *Adverse Events Tracking Form*).**
- **Ask: Do you have any questions for me at this point? *(Give enough time to address all questions.)***

Session 3

Identifying and Enhancing Reassuring Cognitions (II)

Session Objectives

- Assist the participant in identifying reasonable and reassuring cognitions from thought worksheet.
- Give hypnotic suggestions aimed to make automatic these realistic and reassuring cognitions.
- Provide hypnotic suggestions for externalizing negative/unhelpful cognitions.
- Briefly explain some tips on how to create effective hypnotic suggestions.

Write time in *Treatment Recording Sheet*.

Pre-session assessment elements (5 Minutes)

- ➢ **Ask for permission to record the session.**
- ➢ **Ask for a relapse or Exacerbation in participant's MS since completing the phone interview (only for MS Participants).**
- ➢ **Obtain current 0-10 pain intensity ratings (at the beginning of the session).**
- ➢ **Obtain average 24-hour 0-10 pain intensity ratings.**
- ➢ **Collect data about homework using the *Treatment Recording Sheet*.**
- ➢ **Obtain pain relief on average after listening to the recordings.**
- ➢ **Obtain pain relief on average after practicing skills or using the information learned in the treatment.**
- ➢ **Ask for adverse reactions to previous session (using the *Adverse Events Tracking Form*).**

Review of last session (1 minute)
TO ENSURE ACCURATE FIDELITY CODING, SAY:

In our last session we reviewed your homework together and identified some reassuring thoughts about pain that you want to reinforce and make automatic. We also did a hypnosis session with an induction and hypnotic suggestions including these thoughts.

Summarize what will happen during the session (2 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY:

In today's session we will review your homework and will discuss the reassuring thoughts you identified and recorded in your worksheet.

Then we will do another hypnosis session similar to the one we did last time. It will start with an induction including relaxation and imagery, and continue with the hypnosis suggestions of today's session, which will include the reassuring thoughts we discuss in the first exercise. I will also explain to you how to create your own hypnotic suggestions for your practice.

Homework Review

Review of the hypnosis practice (3 minutes)

TO ENSURE ACCURATE FIDELITY CODING:

Ask questions about the hypnosis practice with and without the recordings and write down the responses in the ***Combined CR and Hypnosis Log Sheet****.*

If the participant mentions something that indicates that they hold a misconception about hypnosis and/or that they do not understand well how to use self-hypnosis because of a myth, the clinician will dispel again the myth as appropriate and reinforce the correct information.

If the participant reported in the questions about practicing self-hypnosis that s/he practiced only some parts of it (deep breathing, imagery or suggestions), or that s/he had difficulties in doing the exercises, explain the steps like in the first session:

"Several times during the day, but at least three times every day, take 2 to 5 minutes (or more if you wish) and go through the steps to enter a state of hypnosis, starting with taking a deep breath and holding it… and letting it go. Allow the body to relax, imagine going down the elevator, and go to your special place. Give yourself suggestions for comfort, relaxation in general or for any other sensation that is helpful for you to cope with pain. Stay there for as long as you like."

Address all the questions and difficulties the patient may have in doing this exercise and, if necessary, do a short practice so that the patient has the experience of how to use self-hypnosis. Encourage participants to discuss and troubleshoot any barriers to practicing using Motivational Interviewing. Ask questions that elicit additional motivational statements about practice such as:

- *Tell me your thoughts about the benefits of continuing to practice.*
- *What would it take to make it (easy or even easier) to practice every day?*

Discussion about participant's completed cognitive thought worksheet (10 minutes)

In the last session, as in the first one, I asked you to complete another cognitive thought worksheet of your handbook to help you practice identifying the thoughts associated with at least 2 situations when you feel particularly good and 2 when you feel particularly bad. We are going to take a few minutes now to go over that worksheet.

Remember that if the patient brings up thoughts unrelated to pain, the clinician should gently change the focus back to pain thoughts.

If the participant completed the worksheet and demonstrates an understanding of how to complete it, spend a few minutes reviewing the worksheet and then continue with the session.

If the participant attempted to complete the worksheet but had difficulty determining what to write in each of the columns on the worksheet, assist the participant in completing it in session. Once the participant appears to understand the basic concepts, continue with the session.

If the participant did not complete the worksheet, spend a few minutes problem-solving about how to overcome any barriers or obstacles to homework completion, including challenges that may be related to his/her MS/SCI/MD/Amp/LBP. Reiterate the importance of homework completion in maximizing the effects of the treatment. Complete the worksheet in session with the participant and then continue with the session.

For all participants, reflect back to them any statements they make about their ability to use these skills, and provide reinforcement for any efforts they have made, even if they encountered difficulties completing the worksheets.

Once the worksheet is complete take notes of the positive thoughts and discuss and encourage the patient to come up with thoughts that might be more appropriate than the ones they had in the situations they described in which they did not feel well.

Also, remind the patient that s/he can use the practice exercise carried out in the second session to identify more easily the reassuring cognitions. If necessary the exercise can be repeated.

Identifying reasonable cognitions

TO ENSURE ACCURATE FIDELITY CODING:

Prior to the induction, inform participants that this session will also include inviting them to ponder the reasonable and realistic thoughts that they developed and found most helpful in the worksheet and the practice exercise. Discuss this with them, and list up to three of those cognitions/beliefs considered as more helpful in the ***Combined CR and Hypnosis Log Sheet.***

Hypnosis session (20 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to start our **hypnosis session**.

Preparation for exercise with marble:

Say: Before we start, I am going to give you something that you can use in one of the exercises and you can also use at home if you wish to practice these suggestions.

In the table there is a jar containing some beautiful marbles of different colors. [*It may be helpful to ask here to the participant what kind of feelings the marbles bring to his/her mind so that the script can be adapted to the specific feelings the participant has, and to be careful with the next suggestions in case the patient reports a negative experience or association with marbles.*]

Reach into the jar and choose a marble that you would like to be *your special* marble. Choose that one that looks and feels most comfortable for you. Try them out. Pick up as many as you want until you find the one that you like the most… [*When the participant has chosen his/her marble, continue. If s/he shows hesitation on picking a marble, help him/her out to choose one and then start the hypnosis session.*]

Start recording with the second recorder for the hypnosis practice. Remind the participant to silence his/her cell phone.

Reminders before hypnosis practice

Invite the participants to experience something "new" and "interesting" during the induction; allow much of the wording to be permissive to facilitate this. Also remind them that the peaceful *place does not have to be the same place every time they practice this exercise, and to try to pay attention to the details of that place.*

Also discuss with the participant getting physically comfortable, for example, taking off his or her coat, getting into a comfortable position, etc.

INDUCTION

Okay… just settle back**…**

if eyes open, say, and close your eyes.

if eyes closed say, and let the eyes stay closed.

Now… I'm going to talk to you for a while … all you have to do is listen to what I'm saying and allow yourself to have as pleasant an experience as you know how. Go ahead and adjust yourself to the most comfortable position you can.

Observe subject. Wait until adjusting is completed before continuing.

That's fine. And remember, you can feel free to make any adjustments, at any time, to help yourself be comfortable, and this need not interrupt your concentration or ability to maintain a deep state of comfortable relaxation.

Initial Relaxation

Goal: *To relax the participants by focusing on areas of their body.*

General Ideas: *To do a body scan, inviting relaxation and comfort into the different areas of the body. You can incorporate pleasant sensations mentioned by the participant and avoid any unpleasant sensations.*

Sample Script:

Go ahead and take a very deep, satisfying breath and hold it just for a moment. That's right, … hold it for a moment …. and let it go. Now just let the entire body relax… Allow all your muscles to go limp…. Just notice that the top of your head is becoming relaxed, limp, and heavy. And just let that relaxation and comfort spread down to your forehead, in your eyes, down through your cheeks, in your mouth and jaw, down in your neck, deep relaxing, and heaviness. Just let that relaxation spread in your neck now, letting your neck go, in your shoulders, deep, warm, heavy. Down heavy down to your right arm, down to your right hand, down to your left arm, and your left hand. Deeper and deeper relaxed. And now that relaxation spread down in the chest, slowing down your breathing even more deeply, even more completely, down in the pelvis, down in the right thigh, right calf, the right foot. Down in the left thigh, left calf, the left foot. The entire body now very very relaxed. Deep, comfortable, relaxation, not a care in the world. It may even be the sense of lightness and drifting. It just becomes very easy and effortless.

Deepening

And as you remain drifting, comfortable, not a care in the world, you find yourself in an elevator. It is a special elevator with me. And you are in the 10th floor and looking up you can see the light that says 10th on it, or actually it says 1 on it. And in a moment we are going to start counting from 1 to 10 and with each level that we go down, with each number, you will become deeper and deeper relaxed. Maybe you find yourself somewhere else, altogether, perhaps on a set of stairs perhaps walking down a comfortable path. It really does not matter, as long as you feel deeper relaxed and more comfortable with each number, it is fine.

Let's begin now.

One. One level into deeper comfort. …You might already notice a sense of warmth, a sense of the muscles letting go even more.

Two. Two levels down. That's right…deeper into yourself. Focusing more and more in the sound of my voice, understanding the words that I am saying.

Three. Three levels down… Perhaps noticing, every sensation you can feel…just becomes easy and effortless.

Four. Four levels down…And I wonder if you are beginning to notice and enjoy the freedom of this experience. There is nothing you have to do. Just listen and enjoy the ride.

Five. Half way down…So completely absorbed in the moment…no need to focus on the past, or the future…just focusing on your breath in this moment.

Six. Six levels down… Again just feeling that sense of comfort washing down to the forehead again down to the face, in your mouth and jaw down in the neck. The shoulders, arms, down in the chest, waist, legs and feet. The entire body profoundly relaxed.

Seven. Seven levels down… Even though you can feel the body becoming heavier and heavier, you also may have the sensation of floating in space and enjoy a sense of weightlessness… drifting, floating…

Eight. Eight levels down. Hearing the sound of my voice, without even trying. Listening to the words that I say.

Nine... Deeply, deeply relaxed. Almost there…and now…

Ten. The tenth level of relaxation. Comfort … well-being…profoundly, profoundly relaxed.

Peaceful place imagery

Goal: *Deepening and to provide a place of comfort and relaxation before giving suggestions.*

General Ideas: *Talk patient through experiencing a peaceful place of their choice, including invitations to experience sights, sounds, touch, and positive emotions they might be having. The patient should interact with environment as if they are really there.*

Invite the participant to continue to experience the place using all of his or her senses for about 2.5 minutes. Keep in mind that they will be listening to a recording of this session, so do not provide so much detail that might ultimately be inconsistent with a new place they imagine months or even years from now. Rather, invite them to create the place and experience it in great detail; to touch objects, and experience how they feel. Invite them to experience the colors. Add sensations that they described previously as present as being a part of the place. Encourage them to experience positive emotional experiences (calmness, a sense of confidence, a warmth and connectedness to nature and others). Suggest that the individual see, hear, and smell all the *possible details of this place, wherever they are as he/she approaches it and moves through it. Pause long enough to let them create these experiences for themselves.*

Sample Script:

And the elevator doors open, and you find yourself in your peaceful place. It can be whatever you want, as long as it is comfortable... Notice what you are able to see in front of you, notice what you are able to hear,… notice what you are able to feel… Maybe you find yourself lying down in your place or walking around, it really does not matter. You may notice that the nature of your special place changes each time you listen to my voice or even within this relaxing experience, it can change, it can stay the same. The only thing that matters is that you feel comfortable, peaceful, restful. And aware that when you are in your peaceful place, your mind can serve you in wonderful ways, and allow you to have profound experiences that serve your ability to be comfortable.

Continue with the description according to the participant's preferences.

Suggestions

Goal: *To encourage the belief that continued practice using cognitive coping strategies will help the participant gain control over pain and its impact. To automatize the processes of cognitive restructuring so that they are active all the time, even without the participant's awareness.*

General Ideas: *That the hypnotic and cognitive skills the participants are learning become automatic. To reinforce the reassuring thoughts they have identified. That cognitions are automatically monitored and adjusted into more reassuring and realistic cognitions. It can be used the imagery of a caring thought monitor that is watching out for the thoughts and encouraging and enhancing those reassuring thoughts that help them feel good.*

Sample Script:

1. Building a response set concerning how learning processes become automatic

Perhaps you might wonder how the things you learn and practice and somehow happen to become automatic...helpful thoughts about your pain life that once took some practice to learn and now just seem natural and effortless because you have thought about them enough.... Isn't it interesting that at least certain thoughts about your body, your sensations and your coping now seem to occur naturally and almost without effort.

2. Suggestions that bring previously identified reasonable thoughts into the participants awareness.

Sometimes it is so easy to forget that you have a gold vault of adaptive, helpful, and reassuring thoughts about your body, your sensations, and what you do to cope that you have developed over the years and so often is simply a matter of calling these powerful resources. We have already talked and identified together a number of potential thoughts that will be useful in coping with your life situation (List examples generated from specific patient).

Include a suggestion about what the mind will do with these thoughts. For example, that they will come forward and repeat. Not just list them, but suggest what will happen with them. Something like:

"These thoughts are there, in your mind. They can come forward when needed, like a trusted friend, to reassure you and bring you comfort, just when they are needed and most appropriate…"

3. Suggestions that make the altering alarming thoughts into reasonable ones automatic.

One of the most amazing gifts of our brain is for it to be able to detect and transform negative thoughts into positive ones and we can simply trust its ability to do that, when we are offered a thought or idea that is less than helpful, when we are in good relationship with our brain, the brain can simply ignore them they are of no benefit to anyone.

4. Imagery of a caring thought monitor and developing realistic thoughts automatically

We have talked about the potential of the brain to not only identify negative thoughts, but to transform them into truly helpful ones. What is much more compelling about this is the notion of a part of your brain that operates at a much higher, objective and even more noble screener of thoughts and ideas. That indeed this part of your brain seems to have the wisdom to screen out less helpful thoughts early, to differentiate the distinction between helpful and less helpful thoughts and transform them accordingly and appropriately. But perhaps most optimally, this part of the brain allows you the unique ability to watch your thoughts from the level of a spectator. To realize that while the thoughts might happen, you are more in the role of a detached observer and you can experience what it means to observe all thoughts without being attached to them on any way; knowing that they are just coming and going.

5. Suggestions to externalize negative/unhelpful cognitions: Metaphor of the Marble

Goal: *To decrease unpleasant sensations by suggesting that their unhelpful or negative thoughts are externalized and absorbed by an object.*

General Ideas: *To guide patients to imagine that their unhelpful or negative thoughts are collected and then go to the marble that the patients are holding. Once the unhelpful thoughts get there, they will be absorbed by the marble and fade away from their experience. Suggestions for feelings of relief and being lighter can be used.*

[The clinician should adapt the script for those participants without mobility in their hands or arms. The tactile-kinesthetic part of the exercise cannot be carried out and, therefore, only the visual part can be used. In this case, participants will not be told to close their eyes during the whole exercise.]

Sample Script:

Now, I would like you to picture that marble you chose. It's …… [***describe the marble, for instance, "it is green with yellow bands, red bands]***. Get a clear image of that shiny, perfectly round marble. I am just going to turn this hand over here if you don't mind and put that marble in your hand. [***Adapt this in case participant does not have mobility in his/her arms/hands.***] Just go ahead and do exactly what you are doing. Feel it…. Notice that just holding the marble brings a smile to your lips and a nice feeling inside you. This is because marbles somehow instantly bring us back to a time in childhood when we were enjoying ourselves. [*This can be changed to other feelings or experiences the participant has reported before, if necessary*.]

I want you to remain comfortably relaxed and open your eyes with an intense focus on that marble. Look at the way the light changes the colors embedded in the marble. Feel the slight imperfections in the round glass globe that you are holding. Realize that something this beautiful does not have to be perfect and yet can still be very special. Look at the marble and notice what color it is and any interesting qualities about it. Now just close your eyes again and return to an even deeper level of relaxation.

As you do this, you are aware that you are feeling much more relaxed and you feel like closing your eyes again. Now, pay attention to the feeling of the marble in your hand and imagine that it is a special marble that has the ability to absorb any unhelpful or negative thought that you want to be free from. So, now imagine that you are collecting in your mind these thoughts that don't give you positive feelings and when you have them, they travel through your neck, … go to your shoulder, … to your arm, … to your hand,… and finally they are absorbed by your special marble. Notice the feeling of relief, as if you were lighter, you feel more clear minded… and you may even notice how in your mind only the positive and reassuring thoughts that you want to have and reinforce remain, taking all the space, getting stronger and more automatic and accessible to you whenever you need them.

Notice how the marble is getting warmer and maybe heavier, it is because all those unhelpful thoughts have been captured by the marble. …. When you are feeling this, you are going to feel that the marble drop out of your hand so that it can release all those unhelpful thoughts into the air, or you may like to rub the marble so that all those thoughts go away... [*Adapt this in case participant does not have mobility in his/her arms/hands.*] And interestingly, it won't be like you moved or did anything to make it happen. It just seems to move out all by itself. That's right. Anyway it happens, that's fine. Anywhere it falls it's fine. Just let it go…Good, that's fine.

And now you can focus away from the marble, focus on how lighter, clearer, and more positive your mind is right now as you have released all these unhelpful thoughts. Recreate in these feelings as you wish… and know that you can count on the marble anytime you need it to help you be free from all the unhelpful thoughts you want to release and to boost all these feelings of a clearer and more expansive mind with more positive and reassuring thoughts.

And now, for 30 seconds, just allow yourself to any experiences that you would like to have, deep within the comfort of your own mind. 30 seconds of silence, starting now.

<u>Post-hypnotic suggestions</u>

Goal: *To reinforce the previous suggestions and to generalize them into participants' everyday life.*

General Ideas: *That whenever the participants face situations or sensations, a wise friend inside (the metaphor they developed in the previous suggestion) will be there for them monitoring their thoughts and developing automatically those thoughts that are more helpful, reassuring, and accurate.*

Sample Script:

And each time throughout the day as you encounter events, or feel feelings, the wise friend inside can monitor any and all thoughts, and develop and nurture, automatically, those thoughts that are most helpful to you… because you know that there are many different ways to interpret the event… and you can allow yourself to entertain a variety of interpretations… and allow yourself to select which one is most helpful, reassuring, and accurate….. and as you do this, it will become more and more automatic, knowing that you will easily and automatically adopt the perspectives that are just right for you at the moment.

Re-Orienting

Goal: *To bring patient out of hypnosis, bringing feelings of calm and relaxation into their day.*

General Idea: *To use a countdown to signal patient to become more and more alert and back to the present. Suggestions for keeping any benefit they may have gained during hypnosis (e.g., relaxation) should be included.*

The alerting process should take rough 3 minutes. Follow what you see in the patient. Allow your voice to model more alertness and energy as you return to the first floor.

Sample Script:

Now…Find yourself back in the elevator. You are looking at the number 10 in front of you and in a moment as you may have already guessed, I am going to start counting with you from 10 to 1. The smaller the number the more alert, awake, and refreshed you will feel. No hurry, we have plenty of time, and you actually won't let yourself come to a full state of alertness until you are ready.

Let's begin now.

Ten, you see the 10th floor light comes on and off.

And nine, eight, slowly going upward, becoming more and more awake, more and more refreshed.

Seven, more and more awake… Slowly beginning to move your arm and legs.

Six and five.

When we reach one your eyes will still be closed and almost ready to open, awaiting the signal from your mind that you are feeling awake, alert and refreshed.... picturing the room around you…what it looks like…the colors and the textures.

Four, more and more awake, more and more refreshed.

Three, that is right, more and more alert. Just feeling profoundly relaxed but alert and refreshed.

Two, and now one. Just set your own pace feeling your eyes open as a signal that you are feeling alert, refreshed, but also very comfortable and retaining the things that are going to useful from what you just have been through.

Post-hypnosis discussion (5 minutes)

After the subject gets out of hypnosis and is activated after the relaxation, observe that s/he is really alert, not just sitting, compliantly, with eyes open. Give suggestions for being alert, if necessary.

TO ENSURE ACCURATE FIDELITY CODING, DISCUSS:

Using the ***Combined CR and Hypnosis Log Sheet,*** *how they are feeling right now and how was his/her experience during the hypnosis session. Modifications in the hypnosis suggestions may be made based on the information obtained from this discussion (e.g., if a participant states that a suggestion was not helpful or did not like it, that suggestion should be dropped or reworded; if the participant describes a specific suggestion or image that was very helpful, that suggestion or image should be emphasized in the next session). Record this information in the* ***Combined CR and Hypnosis Log Sheet****.*

Address any questions or concerns as appropriate.

Brief explanation of how to use hypnotic suggestions (10 minutes)

The clinician should explain briefly some tips of how to create effective hypnotic suggestions in case the patient wants to incorporate new suggestions to his/her self-hypnosis practice. Also, the therapist should inform the participant that some tips and examples are summarized in this session material of the handbook for him or her to review them whenever s/he needs them.

TO ENSURE ACCURATE FIDELITY CODING, SAY:

Now, I will explain to you how is the effective way you can **create your own hypnotic suggestions** for your future practice. You may want to use different suggestions when you are doing your practice without the recording so there are some rules that will help you create suggestions that give you the results you are looking for. Remember that the suggestions always work, if you are using a hypnotic suggestion and you do not get the response you want, there may be a problem in the way you are wording the suggestion in a way that you are getting the opposite response. For example, if you use a sentence that includes the symptom or response you want to get rid of, you will activate it anyway. That is, if you say: I don't want to feel pain, your brain will not process the negative part and you will focus more in pain. It is the same if I tell you: Please, don't think in a pink elephant, what are you thinking? [*Wait for the patient's response.*]

Another rule that is important is to limit the period of time that the suggestions are going to work. If you say that "from now on, you will feel relaxed", the suggestion will lose power as the time pass if you do not reinforce it and you will start doubting about its effects when something happens that make you feel stressed. However, if you say: "In the next couples of hours I am going to feel relaxed", it is more likely that you get the results you are looking for, and then you can repeat the suggestion any time you need it.

Also, it is important that your suggestions are credible. If you say something that you do not believe, you will not get the responses you are looking for. For instance, if you say: "From now on, I will be completely free of pain", the fact that you do not believe that that is a possible thing to happen for you will make the suggestion not to work. If you say: "Every day I feel more comfortable and in control of my sensations", it is going to be more effective because that is a possible and credible goal that you can pursue.

Finally, it is good to change the suggestions from time to time so you do not get tired of the same sentences. The more creative you are, the more results you will get with your hypnosis practice.

You have a summary of these rules in your handbook and you can try and ask me questions about your own suggestions in the next session.

The clinician should also use the examples in the table that is the same the participants have in their handbook.

	It is better to say:	Than:
Use sentences expressed in positive terms.	"I feel full of energy."	"I do not feel any fatigue."
Limit the suggestions in time. If necessary, suggestions can be repeated and reinforced later.	"In the next half an hour, I will feel refreshed and active."	"I will feel refreshed and active all day long."
Credible responses.	"As I face those situations that I am afraid of, it will be easier and easier to manage them and I will feel more comfortable dealing with them."	"From now on, I will enjoy all of the situations that used to make me anxious."
Use a variety of sentences so that you do not get bored of, or used to, the same ones.	"Every day I feel more comfortable in situations that used to be difficult". "I feel more and more relaxed in all situations". "I am getting better and better in handling all situations, including ones that used to be difficult."	"Every day I feel more relaxed in difficult situations."

Post-session discussion (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING:

***Ask** additional questions that will elicit motivational statements about practice.*

- Tell me your thoughts about the benefits of continuing to practice.
- What would it take to make it (easy or even easier) to practice every day?

Address any questions or concerns as appropriate.

Arrange with the participant how you are going to get a copy of the recording to him or her (i.e., make a CD while they wait; make it later and mail it to him or her, etc.)

Homework (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to go over the **homework** for next session.

- ***Say,*** "Please, review the material for this session."
- ***Give*** *the participant a recording of the part of the session with the hypnosis session. Then* ***say*** *the following:* "We have made recordings so that you can listen to them to get the most out of the treatment. Because listening to them more rather than less will likely provide more reinforcement for what we are teaching, you might find it useful to consider listening to the recordings at least once per day. By doing this, you can learn how often you should listen to get the most out of treatment. You might end up deciding to listen once or even more often every day. Or you might decide that you do not need to listen this often to reinforce what you are learning, and so may choose to listen just a couple of times a week or even less. It is completely up to you to decide the frequency that works best for you".
- *If the participant prefers the recording of a previous session's recording over the most recent one, the participant will be encouraged to listen to the preferred recording. However, participants will also be encouraged to listen to each of the recordings made at least once/week (that is, to 'rotate' listening to the recordings to some extent) to help ensure that they obtain the potential benefits of each one. Specifically,* ***say****,* "Because each of the recordings of the four sessions are different, if you do elect to listen to the recordings regularly, we think it would be a good idea to 'rotate' the recordings to some extent. For example, if you listen to one recording every day, you might choose to listen each of the recordings at least once in any one week. Or, if you listen to the recordings once/week, you might choose to listen to a different recording every week. Ultimately, though, it is completely up to you to determine which recordings you find most helpful, and how often you choose to listen to them".
- *Remind the participants to listen to the recordings whenever they feel more alert and to avoid listening to them before going to sleep. If they want to use the hypnosis skills before going to sleep, they will be asked to use self-hypnosis.*
- ***Say,*** "Also, to get the most out of this treatment, practice self-hypnosis for 2 to 5 or more minutes without the recording several times a day."

Post-session assessment elements (2 Minutes)

TO ENSURE ACCURATE FIDELITY CODING:

- **Obtain current 0-10 pain intensity ratings (at the end of the session).**
- **Obtain average during session 0-10 pain intensity ratings.**
- **Ask for adverse reactions to the session (using the *Adverse Events Tracking Form*).**
- **Ask: Do you have any questions for me at this point? (Give enough time to address all questions.)**

Session 4
Awareness of the Future

Session Objectives

- Hypnotic suggestions for age progression to a time when the participant is managing his or her pain extremely well. He/she will then be encouraged to bring back into the present any imagined feelings and skills that were an important and useful part of being in control of any pain and its effects.
- Relapse prevention.

Write time in *Treatment Recording Sheet*.

Pre-session assessment elements (5 Minutes)

- **Ask for permission to record the session.**
- **Ask for a relapse or Exacerbation in participant's MS since completing the phone interview (only for MS Participants).**
- **Obtain current 0-10 pain intensity ratings (at the beginning of the session).**
- **Obtain average 24-hour 0-10 pain intensity ratings.**
- **Collect data about homework using the *Treatment Recording Sheet*.**
- **Obtain pain relief on average after listening to the recordings.**
- **Obtain pain relief on average after practicing skills or using the information learned in the treatment.**
- **Ask for adverse reactions to previous session (using the *Adverse Events Tracking Form*).**

Review of last session (1 minute)

TO ENSURE ACCURATE FIDELITY CODING, SAY:
In our last session we reviewed your homework together and identified some reassuring thoughts about pain that you want to reinforce and make automatic. We also did a hypnosis session with an induction and hypnotic suggestions including these thoughts.

Summarize what will happen during the session (1 minute)
TO ENSURE ACCURATE FIDELITY CODING, SAY:

Today we will do our last hypnosis session. It will start with an induction like in all the previous sessions, and continue with the hypnotic suggestions of today's session. We will also talk about things that you can do to help ensure that you will use the skills that you have learned in the treatment.

Review of the hypnosis practice (3 minutes)

TO ENSURE ACCURATE FIDELITY CODING:

Ask questions about the hypnosis practice with and without the recordings and write down the responses in the ***Combined CR and Hypnosis Log Sheet****.*

If the participant mentions something that indicates that they hold a misconception about hypnosis and/or that they do not understand well how to use self-hypnosis because of a myth, the clinician will dispel again the myth as appropriate and reinforce the correct information.

If the participant reported in the questions about practicing self-hypnosis that s/he practiced only some parts of it (deep breathing, imagery or suggestions), or that s/he had difficulties in doing the exercises, explain the steps like in the first session:
"Several times during the day, but at least three times every day, take 2 to 5 minutes (or more if you wish) and go through the steps to enter a state of hypnosis, starting with taking a deep breath and holding it… and letting it go. Allow the body to relax, imagine going down the elevator, and go to your special place. Give yourself suggestions for comfort, relaxation in general or for any other sensation that is helpful for you to cope with pain. Stay there for as long as you like."
Address all the questions and difficulties the patient may have in doing this exercise and, if necessary, do a short practice so that the patient has the experience of how to use self-hypnosis. Encourage participants to discuss and troubleshoot any barriers to practicing using Motivational Interviewing. Be attuned to any comments they have about the ease or difficulty of practicing, fitting practice into their schedules, or other issues related to their likelihood of using these skills after treatment ends.

Hypnosis session (25 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: Now we are going to start our hypnosis session.

Start recording with the second recorder for the hypnosis practice. Remind the participant to silence his/her cell phone.

Reminders before hypnosis practice

Invite the participants to experience something "new" and "interesting" during the induction; allow much of the wording to be permissive to facilitate this. Also remind them that the peaceful place does not have to be the same place every time they practice this exercise, and to try to pay attention to the details of that place.

Also discuss with the participant getting physically comfortable, for example, taking off his or her coat, getting into a comfortable position, etc.

INDUCTION

Okay… just settle back**…**

  if eyes open, say, and close your eyes.

  if eyes closed say, and let the eyes stay closed.

Now… I'm going to talk to you for a while … all you have to do is listen to what I'm saying and allow yourself to have as pleasant an experience as you know how. Go ahead and adjust yourself to the most comfortable position you can.

Observe subject. Wait until adjusting is completed before continuing.

That's fine. And remember, you can feel free to make any adjustments, at any time, to help yourself be comfortable, and this need not interrupt your concentration or ability to maintain a deep state of comfortable relaxation.

Initial Relaxation

Goal: *To relax the participants by focusing on areas of their body.*

General Ideas: *To do a body scan, inviting relaxation and comfort into the different areas of the body. You can incorporate pleasant sensations mentioned by the participant and avoid any unpleasant sensations.*

Sample Script:

Go ahead and take a very deep, satisfying breath and hold it just for a moment. That's right, … hold it for a moment …. and let it go. Now just let the entire body relax… Allow all your muscles to go limp…. Just notice that the top of your head is becoming relaxed, limp, and heavy. And just let that relaxation and comfort spread down to your forehead, in your eyes, down through your cheeks, in your mouth and jaw, down in your neck, deep relaxing, and heaviness. Just let that relaxation spread in your neck now, letting your neck go, in your shoulders, deep, warm, heavy. Down heavy down to your right arm, down to your right hand, down to your left arm, and your left hand. Deeper and deeper relaxed. And now that relaxation spread down in the chest, slowing down your breathing even more deeply, even more completely, down in the pelvis, down in the right thigh, right calf, the right foot. Down in the left thigh, left calf, the left foot. The entire body now very very relaxed. Deep, comfortable, relaxation, not a care in the world. It may even be the sense of lightness and drifting. It just becomes very easy and effortless.

Deepening

And as you remain drifting, comfortable, not a care in the world, you find yourself in an elevator. It is a special elevator with me. And you are in the 10th floor and looking up you can see the light that says 10th on it, or actually it says 1 on it. And in a moment we are going to start counting from 1 to 10 and with each level that we go down, with each number, you will become deeper and deeper relaxed. Maybe you find yourself somewhere else, altogether, perhaps on a set of stairs perhaps walking down a comfortable path. It really does not matter, as long as you feel deeper relaxed and more comfortable with each number, it is fine.

Let’s begin now.

One. One level into deeper comfort. …You might already notice a sense of warmth, a sense of the muscles letting go even more.

Two. Two levels down. That’s right…deeper into yourself. Focusing more and more in the sound of my voice, understanding the words that I am saying.

Three. Three levels down… Perhaps noticing, every sensation you can feel…just becomes easy and effortless.

Four. Four levels down…And I wonder if you are beginning to notice and enjoy the freedom of this experience. There is nothing you have to do. Just listen and enjoy the ride.

Five. Half way down…So completely absorbed in the moment…no need to focus on the past, or the future…just focusing on your breath in this moment.

Six. Six levels down… Again just feeling that sense of comfort washing down to the forehead again down to the face, in your mouth and jaw down in the neck. The shoulders, arms, down in the chest, waist, legs and feet. The entire body profoundly relaxed.

Seven. Seven levels down… Even though you can feel the body becoming heavier and heavier, you also may have the sensation of floating in space and enjoy a sense of weightlessness… drifting, floating…

Eight. Eight levels down. Hearing the sound of my voice, without even trying. Listening to the words that I say.

Nine.. Deeply, deeply relaxed. Almost there…and now…

Ten. The tenth level of relaxation. Comfort … well-being…profoundly, profoundly relaxed.

Peaceful place imagery

Goal: *Deepening and to provide a place of comfort and relaxation before giving suggestions.*

General Ideas: *Talk patient through experiencing a peaceful place of their choice, including invitations to experience sights, sounds, touch, and positive emotions they might be having. The patient should interact with environment as if they are really there.*

Invite the participant to continue to experience the place using all of his or her senses for about 2.5 minutes. Keep in mind that they will be listening to a recording of this session, so do not provide so much detail that might ultimately be inconsistent with a new place they imagine months or even years from now. Rather, invite them to create the place and experience it in great detail; to touch objects, and experience how they feel. Invite them to experience the colors. Add sensations that they described previously as present as being a part of the place. Encourage them to experience positive emotional experiences (calmness, a sense of confidence, a warmth and connectedness to nature and others). Suggest that the individual see, hear, and smell all the possible details of this place, wherever they are as he/she approaches it and moves through it. Pause long enough to let them create these experiences for themselves.

Sample Script:

And the elevator doors open, and you find yourself in your peaceful place. It can be whatever you want, as long as it is comfortable... Notice what you are able to see in front of you, notice what you are able to hear,… notice what you are able to feel… Maybe you find yourself lying down in your place or walking around, it really does not matter. You may notice that the nature of your special place changes each time you listen to my voice or even within this relaxing experience, it can change, it can stay the same. The only thing that matters is that you feel comfortable, peaceful, restful. And aware that when you are in your peaceful place, your mind can serve you in wonderful ways, and allow you to have profound experiences that serve your ability to be comfortable. *Continue with the description according to the participant's preferences.*

Suggestions

1. Awareness of the future

Goal: *To increase the participant's sense of control over pain and its effects on their lives, by suggesting an increased ability to manage and adjust their thoughts.*

General Idea: *To guide participants to imagine a trip to their future when they feel well and have successfully learned the cognitive and hypnotic skills that allow them to note and evaluate automatically their thoughts, and adjust them to feel more comfortable physically and emotionally. These skills have become automatic and it is easy for them to calmly manage their symptoms so that they do not bother them. To give suggestions for the patients to bring back to the present these skills so that they can use them any time they need them.*

Sample Script:

And now, you can open up a new channel of concentration… whereby you focus on taking a special trip into the future… Experience yourself in a special imaginary time machine… you can now push the button that takes you into the future when you are managing even better than you are now. I do not know when that will be…, it might be a year from now… two years… five… or even 10 years from now… it might be different every time you practice this exercise… but you are moving forward in your time machine, and stopping at some period of time when you are doing well. You have successfully learned the cognitive and hypnosis skills you are practicing right now. Your mind is able to note your thoughts and evaluate them quickly, easy, and automatically, and adjust them for you as needed so you can feel more comfortable, physically and emotionally… you are able, whenever you wish, to enter a state of total relaxation… and to calmly evaluate your symptoms… so that they do not bother you at all… you can see yourself feeling so good, actually see yourself… so relaxed… able to manage any symptoms comfortably and easily… any symptoms really do not bother you… the part of you that is YOU is able to focus on and enjoy the things that really matter.

You are no longer surprised at your abilities to manage your thoughts and symptoms… your skills in this area are now second nature… when you were first learning to add numbers together as a child, 1 and 1 = 2, 2 and 2 = 4, you might have had to use your fingers, you really had to concentrate and focus…and you may not even remember when you first learned to walk… but when you did.. you had to focus your attention on each step… you needed help… and to hold on to people and to furniture… but with time and continued practice…walking became second nature… so automatic that you never really had to even think about it anymore … and in your mind's eye, as you see yourself sometime in the future…your ability to manage your symptoms,.. and even more importantly your reaction to your symptoms… is automatic …. You see yourself as confident… you can actually see yourself smiling…feeling so good…

And now… in this time in the future… you move into the body… and can feel, actually feel, what it is like to feel so good… so confident…before you saw yourself smiling…now you can feel yourself smiling… so relaxed… and in control… you are feeling even better than you imagined you might… you have the abilities and the skills to manage…your thoughts…and your sensations…

And taking a deep breath… go ahead…. A deep breath… and hold it… that's right… hold it for a moment, and let go… and as you exhale, you really experience an enhanced tranquility… and now get ready to travel back from the future in your imaginary time machine. As you come back, bring with you all of these positive experience of joy, comfort, delight, accomplishments … and SKILLS. Bring them back as your special gifts from the future, and let them stay with your consciously and subconsciously, guiding you on your own journey of healing… and now your time machines has arrived to the present, and you can see yourself moving out of the time machine carrying with you, inside these special gifts you have brought with you…

And now, for 30 seconds, just allow yourself to any experiences that you would like to have, deep within the comfort of your own mind. 30 seconds of silence, starting now.

Post-hypnotic suggestions

Goal: *To integrate the participants' sense of control over pain in their everyday life.*

General Idea: *To reinforce the idea of the previous suggestion and to extend its effects to more situations, by using suggestions for these skills being automatic and permanently activated in their everyday life.*

Sample Script:

And these gifts are now really a part of you… and you can carry them now… in the present… with you, outside of the session. New skills and feelings that you have brought back from the future… they are a part of you now, in the present… today… and they will stay with you… you will carry them into the future over time… so that they will be with you, when you are actually living in the future… they will have been with you for all of this time…. Now a permanent part of how your mind works…. Isn't it interesting how you are using these skills and your ability to imagine to make a positive difference in your life right now, today, and every day.

Re-Orienting

Goal: *To bring patient out of hypnosis, bringing feelings of calm and relaxation into their day.*

General Idea: *To use a countdown to signal patient to become more and more alert and back to the present. Suggestions for keeping any benefit they may have gained during hypnosis (e.g., relaxation) should be included.*

The alerting process should take rough 3 minutes. Follow what you see in the patient. Allow your voice to model more alertness and energy as you return to the first floor.

Sample Script:

Now…Find yourself back in the elevator. You are looking at the number 10 in front of you and in a moment as you may have already guessed, I am going to start counting with you from 10 to 1. The smaller the number the more alert, awake, and refreshed you will feel. No hurry, we have plenty of time, and you actually won't let yourself come to a full state of alertness until you are ready.

Let's begin now.

Ten, you see the 10th floor light comes on and off.

And nine, eight, slowly going upward, becoming more and more awake, more and more refreshed.

Seven, more and more awake… Slowly beginning to move your arm and legs.

Six and five.

When we reach one your eyes will still be closed and almost ready to open, awaiting the signal from your mind that you are feeling awake, alert and refreshed.... picturing the room around you…what it looks like…the colors and the textures.

Four, more and more awake, more and more refreshed.

Three, that is right, more and more alert. Just feeling profoundly relaxed but alert and refreshed.

Two, and now one. Just set your own pace feeling your eyes open as a signal that you are feeling alert, refreshed, but also very comfortable and retaining the things that are going to useful from what you just have been through.

Post-hypnosis discussion (5 minutes)

After the subject gets out of hypnosis and is activated after the relaxation, observe that s/he is really alert, not just sitting, compliantly, with eyes open. Give suggestions for being alert, if necessary.

TO ENSURE ACCURATE FIDELITY CODING, DISCUSS:

*Using the **Combined CR and Hypnosis Log Sheet,** how they are feeling right now and how was his/her experience during the hypnosis session. Modifications in the hypnosis suggestions may be made based on the information obtained from this discussion (e.g., if a participant states that a suggestion was not helpful or did not like it, that suggestion should be dropped or reworded; if the participant describes a specific suggestion or image that was very helpful, that suggestion or image should be emphasized in the next session). Record this information in the **Combined CR and Hypnosis Log Sheet**.*

Address any questions or concerns as appropriate.

Relapse Prevention (8 minutes)

TO ENSURE ACCURATE FIDELITY CODING:

Ask additional questions that will elicit motivational statements about practice.

Say: Now we are going to talk about things that you can do to help ensure that you will use the skills that you have learned in the treatment.

- How do you feel about your ability to reduce your pain or how much any pain bothers you using these skills?
- What times of day have you found are best for regular practice?
- Thinking about the future, how do you think that the hypnosis practice will fit into your daily routine?
- Is there anything that you can anticipate getting in the way of using hypnosis to reduce your pain?
    - ***If the patient cannot think of anything***: Sometimes if people are doing well managing their pain, they stop using their skills. How does that fit for you?
- It is very common for people to slip back into old habits. One sign that someone has not been using their skills is if they notice an increase in pain. Think of this as a learning opportunity and a reminder to continue practicing your skills to help get you back on track.

Arrange with the participant how you are going to get a copy of the recording to him or her (i.e., make a CD while they wait; make it later and mail it to him or her, etc.)

Homework (5 minutes)

TO ENSURE ACCURATE FIDELITY CODING, SAY: **“**Now we are going to go over the homework.

- Please, review Session 4 materials of the handbook.
- ***Give*** *the participant a recording of the part of the session with the hypnosis session. Then **say** the following:* "We have made recordings so that you can listen to them to

get the most out of the treatment. Because listening to them more rather than less will likely provide more reinforcement for what we are teaching, you might find it useful to consider listening to the recordings at least once per day. By doing this, you can learn how often you should listen to get the most out of treatment. You might end up deciding to listen once or even more often every day. Or you might decide that you do not need to listen this often to reinforce what you are learning, and so may choose to listen just a couple of times a week or even less. It is completely up to you to decide the frequency that works best for you".

- *If the participant prefers the recording of a previous session's recording over the most recent one, the participant will be encouraged to listen to the preferred recording. However, participants will also be encouraged to listen to each of the recordings made at least once/week (that is, to 'rotate' listening to the recordings to some extent) to help ensure that they obtain the potential benefits of each one. Specifically,* ***say****,* "Because each of the recordings of the four sessions are different, if you do elect to listen to the recordings regularly, we think it would be a good idea to 'rotate' the recordings to some extent. For example, if you listen to one recording every day, you might choose to listen each of the recordings at least once in any one week. Or, if you listen to the recordings once/week, you might choose to listen to a different recording every week. Ultimately, though, it is completely up to you to determine which recordings you find most helpful, and how often you choose to listen to them".
- *Remind the participants to listen to the recordings whenever they feel more alert and to avoid listening to them before going to sleep. If they want to use the hypnosis skills before going to sleep, they will be asked to use self-hypnosis.*
- ***Say:*** "You may choose to also continue to practice self-hypnosis on your own for 2 to 5 or more minutes several times a day by allowing yourself to enter in hypnosis, go to your safe place, and enjoy the comfort that this provides for you."
- ***Say:*** "You might also keep track of and develop additional helpful/reassuring images and thoughts to incorporate into your self-hypnosis sessions."

Post-session assessment elements (2 Minutes)

TO ENSURE ACCURATE FIDELITY CODING:

- **Obtain current 0-10 pain intensity ratings (at the end of the session).**
- **Obtain average during session 0-10 pain intensity ratings.**
- **Ask for adverse reactions to the session (using the *Adverse Events Tracking Form*).**

Ask: Do you have any questions for me at this point? *(Give enough time to address all questions.)*

Reference

Jensen, M. P., Ehde, D. M., Gertz, K. J., Stoelb, B. L., Dillworth, T. M., Hirsh, A. T., . . . Kraft, G. H. (2011). Effects of self-hypnosis training and cognitive restructuring on daily pain intensity and catastrophizing in individuals with multipleple sclerosis and chronic pain. *International Journal of Clinical and Experimental Hypnosis., 59*(1), 45-63. doi: 929905703 [pii] 10.1080/00207144.2011.522892

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Appendix I

CONSENT FORM

Title of Research Project: **Exploring a Biopsychological Intervention for Painful Diabetic Neuropathy**

The study has been described to me in a language that I understand. My questions about the study have been answered. I understand what my participation will involve and I agree to participate of my own choice and free will. I understand that my identity will not be disclosed to anyone. I understand that when I give permission to have the interviews audio-recorded it will be stored in a safe place with only the researcher and primary investigator having access to the audio-file. I understand that I may withdraw from the study at any time without giving a reason and without fear of negative consequences or loss of benefits.

Please tick your answer below.

I hereby agree to have the interview audio-recorded. _____

I hereby disagree to have the interview audio-recorded. _____

Participant's name………………………..

Participant's signature……………………………….

Date……………………………….

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Appendix J

INFORMATION SHEET

Project Title: Exploring a Biopsychological Intervention for Painful Diabetic Neuropathy

What is this study about?

This is a research project being conducted by ADZIKA A. VINCENT of the University of the Western Cape. We are inviting you to participate in this research project because you are a diabetic patient with painful diabetic neuropathy. The purpose of this study is to assess how your personal beliefs help you to cope with painful diabetic neuropathy. It also aims to explore the way in which your painful diabetic neuropathy characteristics can affect your quality of life, and how effective a combined intervention (i.e., medication, CBT and Hypnotherapy) is for treating painful diabetic neuropathy.

What will I be asked to do if I agree to participate?

You will be asked to participate in an interview so that the researcher can understand your experiences of painful diabetic neuropathy. The researcher will conduct the interview with you which will take approximately 35 to 45 minutes. The interview questions will pertain to how your general personal beliefs can be used as a way of coping with painful diabetic neuropathy.

Alternatively, you can participate by filling out a series of questionnaires which will be administered by qualified clinicians at the Diabetic Centre of the Komfo Anokye teaching Hospital in Ghana. The procedure for participating in a series of questionnaires will be once off, which means it will only take place for a day. The series of questionnaires pertain to how your painful diabetic neuropathy characteristics can affect your quality of life.

You can also take part in the study by participating in any of the three proposed treatment groups which include patients who either receive: (a) Cognitive Behavioural therapy and Medication; or (b) Cognitive Behavioural therapy, Hypnosis and Medication; or (c) Medication Only. Qualified clinicians and psychotherapists will facilitate your participation in any of the three treatment groups will be once off, which means it will only take place for a day. If you take part in the treatment groups, you will enable the researcher to understand which treatment could best assist with relieving your painful diabetic neuropathy.

The overall duration of your participation is approximately one day that is most convenient for you.

Would my participation in this study be kept confidential?

The researchers undertake to protect your identity and the nature of your contribution. To ensure your anonymity, you will be assigned a number as you participate in this study to avoid revealing your real names, thereby keeping all personal information safe. The nature of your contribution will therefore be kept anonymous as no third parties outside the study will know what you have shared during your participation in the study. Only the researchers involved in the research study will have access to identifiable information for data collection and analysis purposes. Your rights to anonymity will be established and respected throughout the interviewing, questionnaire and treatment intervention process within this study.

To ensure confidentiality, all electronic data will be stored on a password protected computer, and all hardcopies/physical copies of data will be locked up in a filing cabinet to keep all data safe. We aim to disseminate research findings in a form of publications; however using identification codes/ using numbers on all the data forms will also ensure that researchers cannot link the true identity of participants to their contribution of the study.

All of the data will be stored in an electronic file on a password-protected computer, and physical copies of data will be kept in a locked cupboard at a research office at Regent University College for a period of five years. Thereafter, the electronic file will be deleted to make data untraceable, and the physical copies of data will be shredded and thrown away to destroy any physical traces of the data. You have the right to withdraw from the study at any time without any negative consequences. We will do our best to minimise risks (if there are any) and act promptly to assist you if you experience any discomfort, psychological or otherwise during the process of your participation in this study. Your participation will be greatly appreciated.

We will be writing a report and article about this research project in which your identity will be protected through upholding anonymity and confidentiality.

What are the risks of this research?

There may be some risks from participating in this research study. All human interactions and talking about yourself or others carry some amount of risks. We will nevertheless minimise such risks and act promptly to assist you if you experience any discomfort, psychological or otherwise during the process of your participation in this study. Where necessary, an appropriate referral will be made to a suitable professional for further assistance or intervention. Some risks may include: (a) stress of sitting for at least one hour to participate in filling the inventory and the psychotherapy; (b) experience of some amount of boredom; (c) anxiety due to the newness of the psychotherapeutic process which will be facilitated by a qualified clinician/ psychotherapist to minimize harm; as well as (d) the need to attend the clinic of the Komfo Anokye Teaching hospital in Ghana to treat painful diabetic neuropathy which will be handled by respective medical personnel.

To ensure your wellbeing during the study, debriefing sessions will be provided to all participants in which information about the purpose of a study and their experiences of contributing to the study will be reflected upon.

What are the benefits of this research?

This research is not designed to help you personally, but the results may help the investigator learn more about painful diabetic neuropathy. However during this period any diabetic related issue will be treated in the clinic free of charge to participants.

The nature of your contribution will help the researcher achieve his goal by generating research findings which aims to stress the need for clinicians in Ghana to invest an interest in this subject matter. Your contribution will further add to the body of research and knowledge relating to psycho-medical interventions and research of painful diabetic neuropathy in Ghana. Research findings for this study could further provide evidence for optimizing the current and future care of patients with painful diabetic neuropathy. I hope that, in the future, other people might benefit from this study through improved understanding of pain management.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.

What if I have questions?

This research is being conducted by Adzika A Vincent and supervised by Dr Athena Pedro who are qualified Research Psychology professionals at the Psychology Department at the University of the Western Cape. If you have any questions about the research study itself, please contact **ADZIKA VINCENT** at the University of the Western Cape. If you have any questions about the research study itself, please contact 0246884670 or Vin.adzika@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

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This research has been approved by the University of the Western Cape's Biomedical Research Ethics Committee (REFERENCE NUMBER: _______).

Appendix K

The tables below are T-Text results of Neuropathic pain Characteristics and Quality of life Domains

Appendix 1: T-Test Result between Aching Pain and Quality of Life Domains

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.173	.678	.542	123	.589	7.147	13.182	-18.945	33.239
	Equal variances not assumed			.540	6.724	.607	7.147	13.243	-24.431	38.725
Role Limitations Due To Emotional Problems	Equal variances assumed	.998	.320	1.875	123	.063	31.316	16.699	-1.738	64.369
	Equal variances not assumed			1.980	6.830	.089	31.316	15.812	-6.264	68.895
Energy Fatigue	Equal variances assumed	.211	.647	1.261	123	.210	8.547	6.779	-4.872	21.967
	Equal variances not assumed			1.366	6.880	.215	8.547	6.258	-6.302	23.397
Emotional Well Being	Equal variances assumed	9.714	.002	.914	123	.362	7.588	8.299	-8.839	24.016
	Equal variances not assumed			2.538	19.306	.020	7.588	2.990	1.338	13.839
Social Functioning	Equal variances assumed	.016	.900	2.352	123	.020	26.453	11.247	4.189	48.716
	Equal variances not assumed			2.245	6.658	.062	26.453	11.783	-1.704	54.609
Pain	Equal variances assumed	6.195	.014	-.311	123	.756	-3.335	10.728	-24.571	17.900
	Equal variances not assumed			-.212	6.302	.839	-3.335	15.766	-41.468	34.798
General Health	Equal variances assumed	1.100	.296	1.382	123	.169	11.687	8.455	-5.049	28.424
	Equal variances not assumed			1.628	7.069	.147	11.687	7.177	-5.251	28.625
Role Limitations Due To Physical Health	Equal variances assumed	1.304	.256	1.476	123	.143	25.686	17.402	-8.761	60.133
	Equal variances not assumed			1.621	6.909	.150	25.686	15.842	-11.874	63.246

Appendix 2: T-Test Result between Throbbing Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means					of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.550	.460	-.294	123	.769	-1.785	6.071	-13.804	10.233
	Equal variances not assumed			-.293	120.385	.770	-1.785	6.088	-13.839	10.268
Role Limitations Due To Emotional Problems	Equal variances assumed	.291	.591	-0.461	123	.646	-3.590	7.787	-19.004	11.825
	Equal variances not assumed			-0.460	120.968	.646	-3.590	7.803	-19.037	11.858
Energy Fatigue	Equal variances assumed	.886	.348	0.648	123	.518	2.032	3.135	-4.173	8.237
	Equal variances not assumed			0.643	115.098	.521	2.032	3.158	-4.223	8.287
Emotional Well Being	Equal variances assumed	3.972	.048	.465	123	.643	1.779	3.829	-5.800	9.359
	Equal variances not assumed			0.462	116.750	.645	1.779	3.852	-5.850	9.409
Social Functioning	Equal variances assumed	1.955	.165	-0.021	123	.983	-0.112	5.291	-10.586	10.362
	Equal variances not assumed			-0.021	115.859	.983	-0.112	5.327	-10.664	10.440
Pain	Equal variances assumed	0.791	.376	.499	123	.619	2.462	4.934	-7.305	12.228
	Equal variances not assumed			.498	120.858	.620	2.462	4.945	-7.328	12.251
General Health	Equal variances assumed	0.639	.426	1.429	123	.156	5.558	3.889	-2.141	13.256
	Equal variances not assumed			1.425	120.015	.157	5.558	3.901	-2.167	13.282
Role Limitations Due To Physical Health	Equal variances assumed	0.008	.928	0.378	123	.706	3.056	8.075	-12.928	19.039
	Equal variances not assumed			0.378	122.133	.706	3.056	8.076	-12.931	19.042

Appendix 3: T-Test Result between Shooting Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.001	.969	1.056	123	.293	6.383	6.046	-5.585	18.351
	Equal variances not assumed			1.056	122.231	.293	6.383	6.046	-5.585	18.351
Role Limitations Due To Emotional Problems	Equal variances assumed	2.878	.092	1.612	123	.109	12.436	7.713	-2.831	27.703
	Equal variances not assumed			1.608	120.578	.110	12.436	7.732	-2.872	27.744
Energy Fatigue	Equal variances assumed	4.995	.027	-1.093	123	.276	-3.417	3.125	-9.602	2.769
	Equal variances not assumed			-1.083	112.132	.281	-3.417	3.154	-9.667	2.833
Emotional Well Being	Equal variances assumed	0.058	.810	-.071	123	.944	-0.272	3.832	-7.857	7.314
	Equal variances not assumed			-0.071	122.967	.943	-0.272	3.822	-7.838	7.294
Social Functioning	Equal variances assumed	.025	.875	0.738	123	.462	3.894	5.280	-6.556	14.345
	Equal variances not assumed			0.739	122.933	.461	3.894	5.267	-6.532	14.321
Pain	Equal variances assumed	3.590	.060	2.472	123	.015	11.917	4.821	2.374	21.459
	Equal variances not assumed			2.486	122.523	.014	11.917	4.793	2.428	21.405
General Health	Equal variances assumed	1.010	.317	-1.122	123	.264	-4.378	3.901	-12.101	3.344
	Equal variances not assumed			-1.122	122.270	.264	-4.378	3.901	-12.100	3.344
Role Limitations Due To Physical Health	Equal variances assumed	1.995	.160	1.077	123	.283	8.665	8.042	-7.253	24.582
	Equal variances not assumed			1.075	120.409	.285	8.665	8.063	-7.299	24.628

Appendix 4: T-Test Result between Stabbing Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.180	.672	-.660	123	.511	-4.020	6.091	-16.077	8.037
	Equal variances not assumed			-.662	119.097	.509	-4.020	6.072	-16.043	8.003
Role Limitations Due To Emotional Problems	Equal variances assumed	.056	.813	-0.046	123	.963	-0.362	7.830	-15.862	15.137
	Equal variances not assumed			-0.046	118.350	.963	-0.362	7.820	-15.847	15.122
Energy Fatigue	Equal variances assumed	.016	.898	-0.443	123	.659	-1.396	3.152	-7.636	4.843
	Equal variances not assumed			-0.442	116.559	.659	-1.396	3.160	-7.655	4.863
Emotional Well Being	Equal variances assumed	2.922	.090	.346	123	.730	1.331	3.848	-6.286	8.949
	Equal variances not assumed			0.351	122.383	.726	1.331	3.793	-6.177	8.839
Social Functioning	Equal variances assumed	.258	.612	0.066	123	.947	0.353	5.316	-10.170	10.875
	Equal variances not assumed			0.067	119.977	.947	0.353	5.287	-10.115	10.820
Pain	Equal variances assumed	0.202	.654	-.188	123	.851	-0.932	4.961	-10.753	8.888
	Equal variances not assumed			-.188	117.002	.852	-0.932	4.970	-10.774	8.910
General Health	Equal variances assumed	4.332	.039	0.311	123	.756	1.224	3.938	-6.571	9.019
	Equal variances not assumed			0.318	122.991	.751	1.224	3.850	-6.397	8.845
Role Limitations Due To Physical Health	Equal variances assumed	0.228	.634	0.530	123	.597	4.298	8.108	-11.751	20.347
	Equal variances not assumed			0.529	117.022	.598	4.298	8.121	-11.784	20.381

Appendix 5: T-Test Result between Gnawing Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means					of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	2.443	.121	-.041	123	.968	-0.281	6.884	-13.907	13.345
	Equal variances not assumed			-.044	65.336	.965	-0.281	6.403	-13.066	12.505
Role Limitations Due To Emotional Problems	Equal variances assumed	1.962	.164	-0.381	123	.704	-3.360	8.828	-20.835	14.116
	Equal variances not assumed			-0.389	58.901	.699	-3.360	8.638	-20.646	13.926
Energy Fatigue	Equal variances assumed	.271	.603	-0.010	123	.992	-0.036	3.559	-7.081	7.008
	Equal variances not assumed			-0.011	61.216	.992	-0.036	3.415	-6.865	6.793
Emotional Well Being	Equal variances assumed	0.096	.757	-.555	123	.580	-2.407	4.338	-10.994	6.180
	Equal variances not assumed			-0.589	63.562	.558	-2.407	4.088	-10.574	5.760
Social Functioning	Equal variances assumed	8.654	.004	-1.340	123	.183	-7.979	5.954	-19.764	3.806
	Equal variances not assumed			-1.175	45.722	.246	-7.979	6.792	-21.652	5.694
Pain	Equal variances assumed	0.760	.385	-.307	123	.759	-1.719	5.596	-12.796	9.357
	Equal variances not assumed			-.291	51.278	.773	-1.719	5.916	-13.595	10.156
General Health	Equal variances assumed	2.411	.123	0.448	123	.655	1.992	4.441	-6.799	10.782
	Equal variances not assumed			0.478	64.195	.634	1.992	4.165	-6.328	10.311
Role Limitations Due To Physical Health	Equal variances assumed	11.070	.001	-1.107	123	.270	-10.090	9.112	-28.126	7.946
	Equal variances not assumed			-1.188	65.006	.239	-10.090	8.495	-27.056	6.876

Appendix 6: T-Test Result between Sharp Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.568	.453	.145	123	.885	0.907	6.238	-11.441	13.256
	Equal variances not assumed			.143	93.935	.887	0.907	6.354	-11.709	13.523
Role Limitations Due To Emotional Problems	Equal variances assumed	1.607	.207	0.949	123	.345	7.567	7.977	-8.223	23.357
	Equal variances not assumed			0.936	95.385	.352	7.567	8.088	-8.489	23.623
Energy Fatigue	Equal variances assumed	3.083	.082	-0.908	123	.366	-2.918	3.215	-9.282	3.446
	Equal variances not assumed			-0.872	87.021	.386	-2.918	3.347	-9.571	3.735
Emotional Well Being	Equal variances assumed	0.690	.408	-.997	123	.321	-3.909	3.921	-11.670	3.852
	Equal variances not assumed			-0.979	94.018	.330	-3.909	3.992	-11.836	4.018
Social Functioning	Equal variances assumed	.729	.395	0.091	123	.927	0.497	5.435	-10.261	11.256
	Equal variances not assumed			0.093	106.110	.926	0.497	5.331	-10.071	11.066
Pain	Equal variances assumed	0.036	.850	-.100	123	.920	-0.509	5.073	-10.552	9.533
	Equal variances not assumed			-.100	98.827	.920	-0.509	5.090	-10.608	9.590
General Health	Equal variances assumed	0.039	.845	-0.955	123	.342	-3.831	4.013	-11.775	4.113
	Equal variances not assumed			-0.947	97.296	.346	-3.831	4.045	-11.859	4.197
Role Limitations Due To Physical Health	Equal variances assumed	4.572	.034	1.787	123	.076	14.642	8.194	-1.577	30.861
	Equal variances not assumed			1.748	92.817	.084	14.642	8.375	-1.989	31.273

Appendix 7: T-Test Result between Tender Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.603	.439	-.169	123	.866	-1.061	6.264	-13.460	11.338
	Equal variances not assumed			-.167	92.224	.868	-1.061	6.365	-13.701	11.579
Role Limitations Due To Emotional Problems	Equal variances assumed	2.308	.131	1.566	123	.120	12.466	7.960	-3.290	28.222
	Equal variances not assumed			1.539	91.801	.127	12.466	8.099	-3.621	28.553
Energy Fatigue	Equal variances assumed	3.307	.071	-0.982	123	.328	-3.168	3.226	-9.554	3.218
	Equal variances not assumed			-0.942	84.610	.349	-3.168	3.365	-9.859	3.523
Emotional Well Being	Equal variances assumed	0.341	.560	1.372	123	.173	5.381	3.923	-2.384	13.146
	Equal variances not assumed			1.396	102.492	.166	5.381	3.854	-2.263	13.026
Social Functioning	Equal variances assumed	1.015	.316	1.696	123	.092	9.148	5.395	-1.530	19.827
	Equal variances not assumed			1.762	108.716	.081	9.148	5.192	-1.143	19.440
Pain	Equal variances assumed	0.169	.682	.800	123	.425	4.063	5.081	-5.995	14.121
	Equal variances not assumed			.797	96.259	.427	4.063	5.095	-6.050	14.176
General Health	Equal variances assumed	0.132	.717	1.383	123	.169	5.552	4.013	-2.392	13.496
	Equal variances not assumed			1.404	101.645	.163	5.552	3.954	-2.292	13.396
Role Limitations Due To Physical Health	Equal variances assumed	0.998	.320	0.763	123	.447	6.344	8.314	-10.112	22.801
	Equal variances not assumed			0.755	93.879	.452	6.344	8.401	-10.337	23.026

Appendix 8: T-Test Result between Burning Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.935	.335	.478	123	.634	3.354	7.020	-10.541	17.250
	Equal variances not assumed			.453	47.114	.652	3.354	7.402	-11.535	18.244
Role Limitations Due To Emotional Problems	Equal variances assumed	2.584	.111	1.450	123	.150	12.960	8.941	-4.737	30.658
	Equal variances not assumed			1.383	47.547	.173	12.960	9.370	-5.884	31.805
Energy Fatigue	Equal variances assumed	.729	.395	0.364	123	.716	1.323	3.631	-5.864	8.510
	Equal variances not assumed			0.346	47.267	.731	1.323	3.820	-6.361	9.007
Emotional Well Being	Equal variances assumed	3.150	.078	.701	123	.484	3.104	4.425	-5.655	11.862
	Equal variances not assumed			0.773	61.446	.443	3.104	4.017	-4.928	11.135
Social Functioning	Equal variances assumed	.202	.654	2.148	123	.034	12.908	6.010	1.012	24.803
	Equal variances not assumed			2.071	48.312	.044	12.908	6.233	0.377	25.438
Pain	Equal variances assumed	0.267	.606	.841	123	.402	4.791	5.698	-6.487	16.069
	Equal variances not assumed			.790	46.483	.433	4.791	6.063	-7.410	16.991
General Health	Equal variances assumed	0.012	.914	0.716	123	.475	3.243	4.527	-5.719	12.204
	Equal variances not assumed			0.716	51.198	.477	3.243	4.530	-5.851	12.336
Role Limitations Due To Physical Health	Equal variances assumed	1.539	.217	1.362	123	.176	12.634	9.277	-5.729	30.998
	Equal variances not assumed			1.317	48.550	.194	12.634	9.592	-6.646	31.915

Appendix 9: T-Test Result between Exhausting Pain Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	4.685	.032	.820	123	.414	5.083	6.199	-7.187	17.352
	Equal variances not assumed			.857	116.192	.393	5.083	5.934	-6.670	16.836
Role Limitations Due To Emotional Problems	Equal variances assumed	.212	.646	-0.217	123	.829	-1.728	7.975	-17.513	14.058
	Equal variances not assumed			-0.217	103.545	.828	-1.728	7.952	-17.497	14.042
Energy Fatigue	Equal variances assumed	1.490	.225	1.694	123	.093	5.383	3.177	-0.905	11.670
	Equal variances not assumed			1.629	89.030	.107	5.383	3.305	-1.185	11.950
Emotional Well Being	Equal variances assumed	0.152	.697	.300	123	.765	1.175	3.920	-6.585	8.935
	Equal variances not assumed			0.303	106.722	.762	1.175	3.872	-6.502	8.852
Social Functioning	Equal variances assumed	.934	.336	0.457	123	.649	2.470	5.410	-8.239	13.180
	Equal variances not assumed			0.448	96.265	.655	2.470	5.510	-8.467	13.408
Pain	Equal variances assumed	0.010	.920	-.527	123	.599	-2.661	5.049	-12.655	7.333
	Equal variances not assumed			-.521	98.338	.604	-2.661	5.111	-12.804	7.481
General Health	Equal variances assumed	2.150	.145	1.482	123	.141	5.895	3.978	-1.979	13.768
	Equal variances not assumed			1.534	113.766	.128	5.895	3.842	-1.716	13.505
Role Limitations Due To Physical Health	Equal variances assumed	0.117	.733	0.460	123	.647	3.797	8.261	-12.555	20.150
	Equal variances not assumed			0.462	104.140	.645	3.797	8.223	-12.509	20.104

Appendix 10: T-Test Result between Tiring Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.055	.816	.185	123	.853	1.131	6.101	-10.945	13.208
	Equal variances not assumed			.186	118.999	.853	1.131	6.083	-10.915	13.177
Role Limitations Due To Emotional Problems	Equal variances assumed	.391	.533	0.229	123	.819	1.794	7.829	-13.702	17.290
	Equal variances not assumed			0.228	116.000	.820	1.794	7.857	-13.768	17.357
Energy Fatigue	Equal variances assumed	1.729	.191	0.429	123	.668	1.354	3.152	-4.886	7.593
	Equal variances not assumed			0.421	106.708	.674	1.354	3.214	-5.018	7.725
Emotional Well Being	Equal variances assumed	1.193	.277	-1.105	123	.271	-4.233	3.831	-11.816	3.351
	Equal variances not assumed			-1.095	113.293	.276	-4.233	3.865	-11.889	3.423
Social Functioning	Equal variances assumed	1.715	.193	-0.390	123	.697	-2.074	5.313	-12.589	8.442
	Equal variances not assumed			-0.396	122.377	.693	-2.074	5.236	-12.439	8.291
Pain	Equal variances assumed	1.366	.245	-.941	123	.349	-4.653	4.944	-14.440	5.134
	Equal variances not assumed			-.929	110.637	.355	-4.653	5.010	-14.580	5.275
General Health	Equal variances assumed	1.084	.300	-0.604	123	.547	-2.375	3.934	-10.161	5.412
	Equal variances not assumed			-0.607	119.962	.545	-2.375	3.912	-10.121	5.372
Role Limitations Due To Physical Health	Equal variances assumed	1.805	.182	0.231	123	.818	1.872	8.115	-14.192	17.936
	Equal variances not assumed			0.229	114.943	.819	1.872	8.162	-14.295	18.039

Appendix 11: T-Test Result between Penetrating Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.006	.936	.330	122	.742	2.055	6.232	-10.282	14.393
	Equal variances not assumed			.330	105.644	.742	2.055	6.227	-10.290	14.401
Role Limitations Due To Emotional Problems	Equal variances assumed	.185	.668	0.573	122	.568	4.577	7.990	-11.241	20.394
	Equal variances not assumed			0.576	107.277	.566	4.577	7.947	-11.177	20.330
Energy Fatigue	Equal variances assumed	.637	.426	0.925	122	.357	2.970	3.210	-3.384	9.324
	Equal variances not assumed			0.904	96.495	.368	2.970	3.286	-3.553	9.493
Emotional Well Being	Equal variances assumed	1.201	.275	.002	122	.998	0.009	3.933	-7.778	7.795
	Equal variances not assumed			0.002	111.843	.998	0.009	3.860	-7.639	7.656
Social Functioning	Equal variances assumed	.000	.988	0.423	122	.673	2.297	5.428	-8.449	13.043
	Equal variances not assumed			0.423	104.827	.673	2.297	5.436	-8.481	13.075
Pain	Equal variances assumed	0.038	.847	.101	122	.920	0.509	5.039	-9.466	10.484
	Equal variances not assumed			.100	101.940	.920	0.509	5.085	-9.577	10.596
General Health	Equal variances assumed	0.228	.634	0.827	122	.410	3.320	4.015	-4.628	11.267
	Equal variances not assumed			0.835	108.855	.405	3.320	3.975	-4.559	11.198
Role Limitations Due To Physical Health	Equal variances assumed	1.179	.280	1.169	122	.245	9.617	8.227	-6.670	25.904
	Equal variances not assumed			1.159	102.243	.249	9.617	8.296	-6.838	26.072

Appendix 12: T-Test Result between Nagging Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	1.206	.274	.649	123	.518	3.976	6.130	-8.157	16.109
	Equal variances not assumed			.659	118.053	.511	3.976	6.032	-7.969	15.920
Role Limitations Due To Emotional Problems	Equal variances assumed	.004	.949	0.476	123	.635	3.747	7.872	-11.835	19.330
	Equal variances not assumed			0.477	112.807	.634	3.747	7.860	-11.826	19.320
Energy Fatigue	Equal variances assumed	.207	.650	0.433	123	.666	1.373	3.172	-4.906	7.652
	Equal variances not assumed			0.428	106.989	.670	1.373	3.210	-4.991	7.737
Emotional Well Being	Equal variances assumed	0.075	.785	-.768	123	.444	-2.969	3.865	-10.619	4.682
	Equal variances not assumed			-0.764	109.966	.447	-2.969	3.886	-10.669	4.732
Social Functioning	Equal variances assumed	.040	.842	0.056	123	.955	0.301	5.349	-10.287	10.890
	Equal variances not assumed			0.056	111.359	.955	0.301	5.360	-10.319	10.922
Pain	Equal variances assumed	0.001	.972	-.813	123	.418	-4.051	4.980	-13.908	5.807
	Equal variances not assumed			-.814	112.400	.417	-4.051	4.977	-13.912	5.811
General Health	Equal variances assumed	4.418	.038	-0.156	123	.877	-0.617	3.964	-8.463	7.229
	Equal variances not assumed			-0.159	120.331	.874	-0.617	3.868	-8.276	7.042
Role Limitations Due To Physical Health	Equal variances assumed	2.333	.129	0.303	123	.762	2.476	8.165	-13.685	18.638
	Equal variances not assumed			0.307	116.503	.760	2.476	8.073	-13.512	18.465

Appendix 13: T-Test Result between Numbness and Quality of Life Domain

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.147	.702	.800	122	.425	7.271	9.093	-10.729	25.270
	Equal variances not assumed			.812	19.918	.427	7.271	8.957	-11.418	25.959
Role Limitations Due To Emotional Problems	Equal variances assumed	1.932	.167	2.298	122	.023	26.312	11.449	3.647	48.976
	Equal variances not assumed			2.083	18.577	.051	26.312	12.631	-0.166	52.789
Energy Fatigue	Equal variances assumed	.096	.757	1.169	122	.245	5.486	4.691	-3.801	14.773
	Equal variances not assumed			1.154	19.542	.262	5.486	4.753	-4.444	15.416
Emotional Well Being	Equal variances assumed	4.589	.034	1.954	122	.053	11.074	5.667	-0.145	22.293
	Equal variances not assumed			2.306	22.579	.031	11.074	4.803	1.128	21.020
Social Functioning	Equal variances assumed	.835	.362	4.048	122	.000	30.150	7.448	15.406	44.895
	Equal variances not assumed			4.935	23.349	.000	30.150	6.110	17.522	42.779
Pain	Equal variances assumed	0.135	.714	2.132	122	.035	15.527	7.281	1.112	29.941
	Equal variances not assumed			2.187	20.061	.041	15.527	7.100	0.719	30.334
General Health	Equal variances assumed	0.055	.816	2.649	122	.009	15.174	5.727	3.836	26.511
	Equal variances not assumed			2.427	18.686	.025	15.174	6.251	2.076	28.272
Role Limitations Due To Physical Health	Equal variances assumed	0.002	.968	1.568	122	.120	18.789	11.986	-4.939	42.516
	Equal variances not assumed			1.544	19.520	.139	18.789	12.166	-6.629	44.206

Appendix 14: T-Test Result between Miserable Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	.745	.390	1.193	123	.235	7.235	6.067	-4.774	19.244
	Equal variances not assumed			1.205	121.406	.231	7.235	6.006	-4.655	19.126
Role Limitations Due To Emotional Problems	Equal variances assumed	.865	.354	1.482	123	.141	11.499	7.761	-3.864	26.862
	Equal variances not assumed			1.476	115.960	.143	11.499	7.790	-3.931	26.929
Energy Fatigue	Equal variances assumed	.173	.678	0.121	123	.904	0.383	3.154	-5.861	6.627
	Equal variances not assumed			0.120	112.332	.905	0.383	3.187	-5.932	6.698
Emotional Well Being	Equal variances assumed	1.985	.161	1.606	123	.111	6.119	3.810	-1.423	13.661
	Equal variances not assumed			1.625	121.784	.107	6.119	3.767	-1.337	13.575
Social Functioning	Equal variances assumed	.322	.571	1.448	123	.150	7.631	5.271	-2.803	18.065
	Equal variances not assumed			1.453	119.251	.149	7.631	5.253	-2.769	18.032
Pain	Equal variances assumed	0.543	.463	.236	123	.814	1.170	4.961	-8.649	10.990
	Equal variances not assumed			.237	118.816	.813	1.170	4.949	-8.629	10.970
General Health	Equal variances assumed	1.130	.290	1.632	123	.105	6.360	3.898	-1.355	14.075
	Equal variances not assumed			1.648	121.455	.102	6.360	3.858	-1.278	13.997
Role Limitations Due To Physical Health	Equal variances assumed	0.618	.433	2.199	123	.030	17.508	7.962	1.747	33.268
	Equal variances not assumed			2.196	117.089	.030	17.508	7.974	1.717	33.299

Appendix 15: T-Test Result between Unbearable Pain and Quality of Life Domains

		Equality of		t-test for Equality of Means						
									of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Physical Functioning	Equal variances assumed	2.567	.112	-.411	123	.682	-2.608	6.349	-15.176	9.959
	Equal variances not assumed			-.428	99.384	.669	-2.608	6.092	-14.695	9.478
Role Limitations Due To Emotional Problems	Equal variances assumed	2.620	.108	0.393	123	.695	3.199	8.148	-12.930	19.327
	Equal variances not assumed			0.402	94.875	.688	3.199	7.949	-12.582	18.979
Energy Fatigue	Equal variances assumed	.354	.553	-0.780	123	.437	-2.555	3.277	-9.041	3.931
	Equal variances not assumed			-0.792	92.603	.430	-2.555	3.224	-8.957	3.848
Emotional Well Being	Equal variances assumed	1.285	.259	.579	123	.564	2.316	4.003	-5.608	10.241
	Equal variances not assumed			0.590	93.317	.557	2.316	3.928	-5.484	10.117
Social Functioning	Equal variances assumed	.138	.711	0.661	123	.510	3.651	5.525	-7.286	14.588
	Equal variances not assumed			0.654	85.666	.515	3.651	5.585	-7.453	14.755
Pain	Equal variances assumed	4.257	.041	.148	123	.882	0.765	5.166	-9.461	10.992
	Equal variances not assumed			.157	104.193	.875	0.765	4.870	-8.892	10.422
General Health	Equal variances assumed	6.552	.012	1.214	123	.227	4.951	4.078	-3.121	13.022
	Equal variances not assumed			1.316	109.859	.191	4.951	3.762	-2.505	12.407
Role Limitations Due To Physical Health	Equal variances assumed	5.863	.017	-0.192	123	.848	-1.620	8.450	-18.348	15.107
	Equal variances not assumed			-0.198	97.154	.843	-1.620	8.175	-17.844	14.604