AN EXPLORATION INTO THE LEVEL AND CHARACTERISTICS OF PAIN EXPERIENCED BY WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN JOHANNESBURG.

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DECLARATION

I Ilipo Kaila declare that this research is my own work. It is being submitted for the degree of Master of Science (Nursing) in the University of the Witwatersrand, Johannesburg, it has not been submitted before for any degree in any other university.

Signature: ..... Kaila .....

Ilipo Kaila

..... 08 .....day of ..... July 2016

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DEDICATION

To God be the glory. Thank you my Lord Jesus Christ, you have done it again.

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To the mercies of God for everything is possible to those who believe.

My father and mother for their prayers and encouragement, my sister Mary who strengthen me when I was almost giving up, my brothers and sisters for their prayers.

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ABSTRACT

The objectives of the study were to explore the level and characteristics of the pain women treated for cervical cancer at an academic hospital in Johannesburg experience before treatment, at six months after treatment and at twelve months after treatment for cervical cancer and to describe the pattern of pain over the specific period. A quantitative approach using a cross-sectional design was used. The study was conducted at the radiotherapy department of an academic hospital in Johannesburg. The population consisted of all women treated for cervical cancer and all women 18 years and older, treated with curative intent were eligible for the study. Convenience sampling was used and sample size was 168 (n = 168), 58 (n= 58) in each of the three groups. A structured interview was used using Brief Pain Inventory (BPI) as data collecting instrument. Data were analyzed using the SPSS version 22 computer programme. The Kruskal-Wallis test was used to determine statistical significant differences between the groups. The majority of respondents (78%; n=131) experienced pain before treatment. In addition, pain persisted and although it became less intense at six months after treatment, it increased at twelve months after treatment. The pain patients' experienced was not well managed and the level of pain and pain medication used did not match. In addition, pain medication was not taken continuously, which added to the patients' suffering. Pain management could start with a regular and thorough assessment and the use of the WHO step ladder when prescribing pain medication. Patient education on compliance and the use of physical therapies and psychological approaches used in the management of cancer pain can also be explored.

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CHAPTER 1

ORIENTATION FOR THE STUDY

1.1 INTRODUCTION

This chapter presents an overview for the study and includes the background, the problem statement, the purpose and the study's significance. A summary of the research design and methods and the operational definitions are also presented.

1.2 BACKGROUND

Cancer is a health problem faced globally. According to the World Health Organization (WHO) (2015), it is expected that the number of people diagnosed with cancer will rise from 14 million in 2012 to 22 million within the next decades. According to the 2012 GLOBOCAN statistics, an estimated 14.1 million people were newly diagnosed with cancer and 8.3 million cancer-related deaths occurred in 2012 compared to 12.7 million and 7.6 million respectively in 2008.

Cervical cancer is a worldwide public health problem and according to the World Health Organization, it is the second most common cancer in women worldwide (WHO, 2006). However, according to the 2012 GLOBOCAN (IARC, 2014) statistics, cervical cancer is the fourth most common cancer affecting women worldwide. Cervical cancer is the sixth most common cancer in the developed regions of the world and the second in developing regions. In Africa, cervical cancer is ranked first accounting for 28.01% of all cancers. In sub-Saharan Africa, cervical cancer is the most common cancer with an age standardised rate of 34.8% per 100 000 of the population. According to the South African National Cancer Registry (2009), cervical cancer ranks the second most common, accounting for 17.63% of all cancers in women, with the highest percentage affected age range being between 45 and 49.

Various treatment modalities are used to treat cervical cancer. Patients with pre-invasive disease can be treated with cryotherapy, whilst those with invasive cancer are treated with surgery, radiotherapy and chemotherapy or a combination of these treatment modalities. Treatment is determined by the stage of the disease, co-morbidities and educational factors (Grigsby & Herzog, 2001). Recurrence of disease is most common after treatment and usually recurs two years after treatment, therefore patients have to be followed up every three months during the first two years after treatment, then six months for two years and yearly thereafter (International Atomic Energy Agency, 2012).

Pain is synonymous with cancer and nearly 75% of cancer patients experience pain. Sadly, many people live with cancer pain despite the fact that 90% of patients can receive adequate

pain relief with simple drugs (WHO, 2003). According to Nersesyan (2007), approximately 30 to 50% of cancer patients who are not suffering from advanced disease and 70% to 90% of those suffering from advanced cancer experience cancer related pain. Russell and Pauline (1999) estimates the prevalence of chronic pain is about 30% to 50% amongst patients with solid tumours undergoing ant-cancer treatment. According to Vistadi et al. (2011), chronic pain is significantly more prevalent in women treated for cervical cancer than women in the general population. Experiencing chronic cervical cancer related pain has a negative influence on the physical, emotional and psychological life of a patient (WHO, 2014).

The most common cause of pain is the cancer itself. However, cancer survivors, also have chronic pain which interferes with function especially in the first few years after treatment (Glare, 2014). According to Gwenael et al. (2013), cervical cancer survivors also experience side effects such as abdominal cramps and lower abdominal pain. In addition, Ntinga (2014) found that women, 12 months after receiving radiotherapy for cervical cancer, still struggled with pain in the abdomen and lower back.

1.3 RESEARCH PROBLEM AND RESEARCH QUESTION

Pain is a reality for women suffering from cervical cancer; not only before treatment but also after treatment. However, little is known about the level and characteristics of the pain women living with cervical cancer experience. In addition, pain related to cervical cancer, a problem of women primarily living in the developing world, seems to be an under-researched topic as no studies focusing on this phenomenon seems to be available. The research question for this study is: *What are the levels and characteristics of pain women treated for cervical cancer at an academic hospital in Johannesburg experience before and after receiving treatment?*

1.4 PURPOSE AND OBJECTIVES OF STUDY

The purpose of the study was to explore the level and characteristics of pain women treated for cervical cancer at an academic hospital in Johannesburg experience before and after receiving treatment. Specifically, the objectives were to explore the level and characteristics of the pain women experience before treatment, at six months after treatment and at twelve months after treatment for cervical cancer and to describe the pattern of pain over the specific period.

1.5 SIGNIFICANCE OF THE STUDY

As already mentioned, little is known about the levels and characteristics of pain in women receiving treatment for cervical cancer. The significance of the study related to the fact that it provided baseline data regarding the level and characteristics of pain women experience before and after cervical cancer treatment, thus addressing the knowledge gap. Having baseline data will serve as a guide for nurses to develop, implement and test interventions to address the pain thus improving patient outcomes.

1.6 RESEARCH DESIGN AND METHODS

A quantitative approach using a cross-sectional design was used. The study was conducted at the radiotherapy department of an academic hospital in Johannesburg. The population consisted of all women treated for cervical cancer at the specific academic hospital and all women 18 years and older, treated with curative intent were eligible for the study. Convenience sampling selected the sample. The sample size was calculated and consisted of a total of 168 (n = 168), 58 (n= 58) in each of the three groups: before treatment (Group 1), six months after treatment (Group 2) and twelve months after treatment (Group 3).

Structured interviews were used to collect the data and the Brief Pain Inventory (BPI) served as data collection instrument. Data were analysed using the SPSS version 22 computer programme and presented as descriptive statistics. The Kruskal Wallis test was used to determine statistical significant differences between the groups.

1.7 OPERATIONAL DEFINITIONS

Cervical cancer: Cancer that affects the uterine cervix; the uterine cervix is the neck of the uterus in women (Brooker, 2006).

Pain: Pain is unpleasant physical and emotional experience caused by actual or potential tissue damage (Kumar & Lin, 2007). Pain is whatever the person says he or she is experiencing, whenever he or she says it occurs (McCaffery, 1999).

Radiotherapy: The use of ionising radiation to interfere with the replication of cancer cells with the body (Kinghorn & Gaines, 2015).

1.8 CHAPTERS OF THE STUDY

This chapter introduced the reader to the study and presented the research problem, question, purpose of study, objectives, design and methods and significance. The next chapters are as follows:

Chapter 1	Orientation for the study
Chapter 2	Literature review
Chapter 3	Research methods
Chapter 4	Findings
Chapter 5	Discussion, limitations, recommendations and conclusion.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

The previous chapter introduced the study to the reader. The literature review presented in this chapter focuses on the available information on the subject under study. This chapter will review literature related to cervical cancer globally, in sub-Saharan Africa and in South Africa, staging, treatment and the pain women treated for cervical cancer experience.

2.2 CERVICAL CANCER AS WORLD WIDE HEALTH PROBLEM

According to the 2012 GLOBOCAN statistics, there were 14.1 million new cancer cases, 8.2 million cancer deaths and 32.6 million people living with cancer (within 5 years of diagnosis) in 2012 worldwide. Fifty seven percent (8 million) of new cancer cases, 65% (5.3 million) of the cancer deaths and 48% (15.6 million) of the five year prevalent cancer cases occurred in the less developed regions. According to WHO (2015), cervical cancer is one of the world's deadliest, but most easily preventable forms of cancer for women and is responsible for more than 270 000 deaths annually, 85% of which occur in developing countries. Cervical cancer is the fourth most common cancer in women and the seventh overall, with an estimated 528,000 new cases in 2012, where it accounts for almost 12% of all female cancers. A large majority (around 85%) of the global burden occurs in the less developed regions; cervical cancer remains the most second common cancer in women in Africa.

In sub-Saharan Africa cervical, cancer ranks the second most common cancer for women in South Africa and is the biggest problem affecting one out of 41 South African women (WHO, 2000). It is estimated that this disease kills approximately eight women every day and according to WHO, the number will increase to about 12 deaths per day by 2025. Cervical cancer is not only a common cancer amongst poor women, but cure rates are low because they present with advanced disease (Denny et al, 2010). In sub-Saharan Africa, cervical cancer is however the most common cancer with an age standardised rate of 34.8% per 100 000 of the population. According to the South African National Cancer Registry (2010), cervical cancer ranks the second most common, accounting for 18.25% of all cancers in women.

2.3 CERVICAL CANCER AS A PREVENTABLE DISEASE

Cervical cancer is caused by the Human papillomavirus (HPV), the most common sexually transmitted infection. Primarily, HPV 16 is associated with 15% to 50% of invasive cervical

cancer lesions and is the most common papillomavirus found in women with adenocarcinoma of the cervix, while HPV 18 is commonly associated with squamous cell carcinomas (Borrayo et al, 2004; Yarbro et al, 2011). According to the WHO (2016), it takes 15 to 20 years for cervical cancer to develop in women with normal immune systems and it can take only 5 to 10 years in women with weakened immune systems, such as those with untreated HIV infections. Although most HPV infections clear up on their own and most pre-cancerous lesions resolve spontaneously, there is a risk for all women that HPV infection may become chronic and pre-cancerous lesions progress to invasive cervical cancer. In addition to HPV, there are other risk factors contribute to the cause of cervical cancer which include: immunosuppression (HIV/AIDS), presence of other sexually transmitted diseases, long term use of oral contraceptive, early age at first sexual intercourse, multiple sexual partners, smoking and high number of pregnancies (Castellsague & Munozo, 2003; Yarbro, 2011 et al).).

The high mortality rate from cervical cancer globally (52%) could be reduced by effective screening and treatment programmes, as the time it take to develop invasive cervical cancer awards the opportunity for timeous intervention to prevent the disease. Unfortunately a great proportion of women living in low- and middle-income countries present with very advanced disease, too late to be cured because they are only diagnosed once they experience symptoms (WHO, 2006).

2.3.1 Primary Prevention

Primary prevention is supportive of efforts to increase public knowledge, improve the ability of individuals to make wise lifestyle and health choices and decrease cancer incidence by medical intervention (South Africa Department of Health, 2012; Yarbro et al, 2011). Primary prevention begins with HPV vaccination of girls aged 9 to 13 years, before they become sexually active. A 3–dose intramuscular administration at 0, 1 to 2 and 6 months is required (Centres for Disease Control and Prevention, 2010). However, the age at which the immunisation should occur is a sensitive issue (Campbell, 2005). According to Ault (2007) and Stanley (2007), clinical trials have indicated that HPV vaccines resulted in vaccination coverage for periods up to 5 years.

Other recommended preventive interventions include:

- Education about safe sexual practices including delayed start of sexual activity.
- Promotion and provision of condoms for those already engaged in sexual activity.

- Warning about tobacco use.
- Effectively manage sexually transmitted diseases.
- Decrease parity.
- Male circumcision.
- Women who are sexually active should be screened for abnormal cervical cells and pre-cancerous lesions, starting from 30 years of age (WHO, 2006).

2.3.2 Secondary Prevention

Secondary prevention is the early detection and treatment of pre-cancerous lesions (Glaus & Rieger, 2006) and prevents up to 80% of cervical cancer (WHO, 2006). Various screening tests can be used including the Pap smear, Visual inspection with acetic acid (VIA) or Lugol`s iodine (VILI) and HPV DNA testing (Sankaranarayanan et al, 2005; Denny et al, 2010).

Resource restricted counties experience various challenges in terms of cervical cancer screening. Not only are limited resources a challenge, but non-symptomatic women do not present for screening even if it is available. Lack of knowledge about cervical cancer or a pap smear adds to this situation. Leeman (2002), in a study conducted in Durban, found that approximately 65% of women had no knowledge of cervical cancer or the Pap. This lack of knowledge is supported by various South African studies (Maree et al., 2012, Maree and Moitse, 2014, Maree and Wright, 2010).

According to Fonn et al, (2002), the South African Department of Health, using best available data and taking into account resource constraints, has approved a National Screening Policy to screen all women in South Africa over the age of 30 years, at 10 year intervals (Moodley et al, 2006). The screening programme was expected to achieve over 75% coverage of the female population, yet the screening uptake is as low as 13% (Snyman, 2012). The aim of cervical cancer screening is to detect pre-cancerous lesions. Precancerous lesions are painless and if not treated result in invasive cervical cancer which is responsible for the signs and symptoms patients experience.

2.4 SIGNS AND SYMPTOMS OF CERVICAL CANCER

The WHO (2006) warns that micro-invasive cervical cancer could be asymptomatic and only detected by means of an abnormal Pap smear. Women with early invasive cervical cancer can present with vaginal discharge which could be offensive, irregular bleeding, post-menopausal bleeding, and postcoital spotting or bleeding. The late signs of cervical cancer includes urinary

frequency and urgency, backache and lower abdominal pain, whilst the very late symptoms include weight loss, severe back pain, rectovaginal fistulae, a decrease in urinary output due to renal failure or obstruction of the ureters, swelling of the lower limbs and breathlessness caused by anaemia.

2.5 THE MANAGEMENT OF CERVICAL CANCER

2.5.1 Diagnosis and staging

A definitive diagnosis of cervical cancer requires a biopsy of the suspicious lesion and a histopathology examination of the biopsy (Itano & Taoka, 2005). According to the IAEA (2012), the diagnostic workup to guide the staging and to evaluate the extent of the local lesion, possible metastasis to lymph nodes and distant metastasis include a medical history, physical examination using bimanual vaginal and rectal examination, cystoscopy, proctosigmoidoscopy laboratory studies to investigate the possibility of HIV and anaemia, evaluate renal and liver function and imaging studies including scans (WHO, 2006). Adherence to clinical staging allows appropriate comparison of treatment, survival and patient outcomes from diverse resource settings.

Tumour grading and staging is useful in determining the prognosis of the patient. The higher the grade of the tumour and stage of the disease the poorer the prognosis and patients ability to tolerate treatment (Rubin et al, 2001; IAEA, 2012). Clinical staging allows appropriate comparison of treatment, survival and patient outcomes from diverse resource settings. Cervical cancer is staged using the FIGO system (International Federation of Gynaecology and Obstetrics 2009), which classifies cervical cancer based on tumour size, extent of the disease in the pelvis, distant organs and is recommended for the staging of invasive cervical cancer**.** The FIGO system is presented in Table 2.1.

Table 2.1: International Federation of Gynaecology and Obstetrics (Figo) Staging System

Stage	**Description**	**TNM Categories**
	Primary tumour cannot be assessed.	TX
0	No evidence of primary tumour.	T0
	Carcinoma in situ (pre-invasive carcinoma).	Tis
I	The carcinoma is strictly confined to the cervix.	T1
IA	Invasive carcinoma diagnosed only by microscopy.	T1a
IA2	Stromal invasion more than 3.0 mm and not more than 5.0 mm with a horizontal spread 7.0 mm or less.	T1a2
IB	Clinically visible lesion confined to the cervix or microscopic lesion greater than IA2/T1a2.	T1b
IB1	Clinically visible lesion 4.0 cm or less in greatest dimension.	T1b1
IB2	Clinically visible lesion more than 4 cm in greatest dimension.	T1b2
II	Tumour invades beyond the uterus but not to pelvic wall or to lower third of the vagina.	T2
IIA	Without parametrial invasion.	T2a
IIB	With parametrial invasion.	T2b
III	Tumour extends to pelvic wall and/or involves lower third of vagina and/or causes hydronephrosis or non-functioning kidney.	T3
IIIA	Tumour involves lower third of vagina no extension to pelvic wall.	T3a
IIIB	Tumour extends to pelvic wall and/or causes hydronephrosis or non-functioning kidney.	T3b
IV A	Tumour invades mucosa of bladder or rectum and/or extends beyond true pelvis.	T4
IVB	Distant metastasis.	M1

Source: IAEA; FIGO, International Federation of Gynaecology and Obstetrics Staging (2012).

2.5.2 The treatment of cervical cancer

According to the IAEA guidelines (2012), treatment is given according to the (FIGO) staging. To facilitate the decision-making process for definite or curative treatment, patients may be classified into two groups based on the FIGO staging system:

- Early Stage: IA – IB1 – IIA1 – IB2 and IIA2 ≤ 4cm.
- Advanced stage: IB2 and IIA2 ≥ 4cm – IIB – IIIA – IIIB – IVA.

In addition to whether the patient has early or advanced stage disease, the patient's co-morbidity, social and educational factors are also taken into account and radiotherapy, surgery, chemotherapy or combination are the three approaches of treatment are administered especially in the curative stage (Grigsby & Herzog, 2001; IAEA, 2012). However, women with Stage IIB to IVA are not candidates for surgery but are treated with external beam radiation and intracavitary brachytherapy with or without chemotherapy. Curative treatment can also be considered for women with Stage IVB cervical cancer with para-aortic lymph node involvement, whilst patients with distant metastasis receive palliative treatment and care.

Cisplatin is the most commonly used chemotherapy drug and is administered weekly for five cycles when the patient is receiving external beam radiation. The overall radiotherapy treatment time, the period from administering the first dose of irradiation until the last radiotherapy treatment, plays an important role in the treatment outcomes and should not exceed eight weeks. Prolonged treatment results in an increase failure rate in patients in all stages of disease (IAEA, 2012).

Cervical cancer treatment is not without adverse effects. Even though the signs and symptoms of cervical cancer subside after treatment, women experience emotional and physical side effects related to the treatment and includes physical problems such as chronic fatigue, lymphoedema, fertility problems and secondary tumours (Vistad et al, 2011), as well as social and psychological effects such as anxiety, depression, worries about risk of recurrences, stress and coping problems and isolation (Klee et al, 2000). Other side effects such as dyspareunia, bleeding after intercourse, vaginal stenosis and fibrosis, difficulty in sleeping, reduced sexual desire, cystitis and pain have also been reported (Herzog & Wright, 2007).

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2.6 CANCER PAIN

Pain is a complex phenomenon and according to the International Association for Study of Pain, is an unpleasant sensory and emotional experience arising from actual or potential tissue damage (International Association for the Study of Pain (IASP), 2012). According to Everdingen et al. (2007), up to 70% of cancer patients suffer from pain caused by their disease and/or treatment. However, the American Cancer Society (2002) found 50% to 70% of people with cancer experience some degree of pain, which usually only intensifies as the disease progresses. Cancer pain can either be acute or chronic based and duration of pain may trigger fear of cancer progression or recurrence, worsen anxiety, hopelessness and depression (Brant et al, 2014). Cancer pain involves mechanisms of inflammation, compression and ischemia causing a combination of nociceptive and neuropathic symptoms and this neuropathic component has been adjudged to affect at least one-third of all assessed cancer patients (British Pain Society, 2010). According to Brant et al. (2014), nociceptive pain consists of somatic and visceral pain. Somatic pain is caused by activation of nociceptors in the periphery arising from the bone, skin, muscles, joint or connective tissue and is described as localised, aching, gnawing, sharp or throbbing pain or pressure and can be constant or intermittent. Visceral pain results from activation of nociceptor in the abdominal or thoracic cavity secondary to distention of viscera, compression or infiltration of the thoracic or abdominal tissue and is characterised by diffuse, aching or cramping sensations which are poorly localized, dull, aching or cramping. According to Bennett (2001) and Itano et al. (2015), peripheral pain is neuropathic pain caused by peripheral nerve injury, often characterised by numbness and a tingling sensation, whilst centrally mediated pain is neuropathic pain characterised by radiating and shooting sensations within a background of burning and aching.

Cancer pain can either be acute or chronic. Acute pain is pain which typically lasts less than 6 months, the cause is often known and pain behaviours are more frequently exhibited (Brant et al, 2014). Acute pain is pain that has a sudden, well-defined onset, an identifiable cause and is subject to sympathetic output (fight or flight response). Acute pain may be caused by diagnostic or treatment interventions including surgery, biopsy, reactions to anticancer

therapies such as chemotherapy or the infusion technique, radiotherapy (e.g., mucositis in response to chemotherapy toxicity, hormonal therapy and immunotherapy) and infection (Cherny 2006).

Chronic pain is pain which persists more than three months or reoccurs over several months beyond the usual course of an acute illness or injury (Valeberg, 2009). According to Lohman et al (2010), chronic pain is one of the most significant causes of suffering and disability worldwide, and a common symptom of both cancer and HIV/AIDS. Chronic pain is also linked to a collection of maladaptive physical, psychologic, family and social consequences and can be regarded as a disease entity. According to Cherny et al. (2006), chronic pain may be caused by the disease itself resulting in muscle pain, chronic headache, peripheral neuropathic pain and pain syndrome of the viscera and is also associated with cancer therapy such as hormonal therapy, chemotherapy, or surgical therapy. According to Vistad et al. (2011), chronic pelvic pain is defined as pain which persists longer than the time of natural healing located in hips, groins, lower back and radiating pain, pain in rest or activity, or pain influencing daily activities. Chronic pain is significantly more prevalent in women treated for cervical cancer than women in general.

Persistent pain is devastating for the quality of life of those suffering from cancer (Breivik et al, 2008). According to Siddall & Cousin, (2004), unrelieved pain results in many adverse effects that has a negative influence on the patient's physical, psychological, social and economic status. Physically the patients elicit pathophysiologic neural alterations including peripheral and neuronal sensitisation which includes chronic pain syndromes. In addition, the physiologic and psychologic impairments related to pain interfere with patient's ability to function at work, whilst persistent pain interferes with their ability to sleep, eat, concentrate and interact with others (Brennan et al, 2007). Emotional and psychological factors such as mood, fear and anxiety as well as environmental factors such as relationship with friends and families, influence the pain experience and is associated suffering (Cousins, 2007).

Unfortunately cancer pain is not always well managed. Deandrea et al. (2008), in a systemic review focusing on the prevalence of under-treatment of cancer pain, suggest that nearly one in two patients with cancer pain are undertreated. Despite several guidelines focusing on the management of cancer pain, including the WHO recommendations developed over two decades, 70% to 90% of cancer patients experience pain even if effective treatment is available. Of those cancer patients reporting pain, 42% report inadequate analgesia. Female gender, minority status and advanced age are risk factors for under-treatment of pain in the

adult population (Rannestad & Skjeldestad, 2007; NCCN, 2008). In addition, Yarbro et al. (2011) found that unrelieved pain is also related to sleep disturbances and depression in patients with cancer, which is more frequently reported by young cancer survivors, those with co morbidities, and Caucasian patients.

According to Deandrea et al. (2008), inappropriate management of pain, due to barriers relating to patients as well as health care providers, contributed significantly to the challenges of cancer pain management. According to Oldenmenger et al. (2009), patient and family barriers include misconceptions about analgesics and their side effects which lead to non-adherence to treatment regimens and poor communication of concerns to medical staff. Not reporting pain is also a barrier to effective management. Lai et al. (2002) and Campbell (2011), state that patients may not report pain for reasons such as; the desire not to bother the staff, fear that their pain is indicative of disease progression, fear of becoming addicted or tolerant to the pain medication and concern about the side effects. Additional barriers include, ignorance about pain medication, social, educational, economic and/or religious factors, family beliefs, culture and society's attitudes towards pain relief and the belief of patients that they can manage their own pain.

2.8 PAIN ASSESSMENT

A systematic assessment of cancer pain is the crucial first step in the management of pain and of little value if the assessment is inaccurate (Campbell, 2011). According to Campbell (2011), the current standard approach to the initial assessment of cancer pain includes a detailed history and physical examination, assessment of the psychosocial circumstances of the patient and a diagnostic work up considering what causes the pain and pain intensity. Brant (2003), suggests the `ABCDE` approach consisting of ask, believe the patient, choose an intervention and treatment, deliver treatment on time and empower the patient to have control of their situation, to assess and treat pain. However, according to Kinghorn and Gaines (2007), the pain assessment usually includes two areas; the initial assessment that consists of the sight of pain, pattern of pain, aggravating factors, relieving factors, patient´s description of pain and an ongoing assessment that includes the response to treatment.

2.8.2 Pain Assessment Instruments

The pain assessment instrument is an important tool to perform a proper assessment and likely to be communicated constantly and sustained over any period of time (Brant, 2003). Numerous assessment tools and pain rating scales have been developed for different types and sub types of acute and chronic pain which are either one-dimensional or multidimensional. One dimensional scales have one measure to rate pain, while multidimensional scales measure several factors in addition to severity, such as behaviour, mood, how pain affects certain activities of daily living and treatment used previously (Yarbro et al., 2011).

Approaches to the measurement of pain include verbal rating scales, word scales, nonverbal scales, face scales, behavioural pain scales and behavioural observation scales. Numerical rating scales are commonly used in adults and, according to Paice and Cohen (1997) and Yarbro et al, (2011), verbally administered numerical rating scales are preferred over a visual analogue scales and a word descriptor scales. Pain assessment instruments usually include a rating scale, but also assess other factors such as the quality of the pain, the location of the pain, what alleviates and what aggravates the pain. The brief pain inventory (BPI) (Bennett, 2001) is an example of such an instrument and used in this study.

2.9 PAIN AS PROBLEM OF CERVICAL CANCER PATIENTS

Cervical cancer is usually asymptomatic in its pre-invasive and early stage, unfortunately women seek medical attention in advanced stages of the disease when they are experiencing pain in the pelvis, hypogastrium, lumbosacral, or gluteus area, flank, or leg (Fischer, 2002; Yarbro et al, 2011). About 70 to 90% of patients in advanced stages experience pain which may have moderate to unbearable intensity (Costa & Chaves, 2012). About 5% of most cervical cancer patients complain of pain from the lumbar, spine and pelvis (Rangarajan et al., 2010). According to Bye et al. (2000) and Korfage et al. (2009), 19% to 22% of cervical cancer patients experience lower back pain and 18% complained of hip pain after radiotherapy. This seems lower than the findings of Glare (2014) who estimated that 36% to 61% of cancer survivors have chronic pain that interferes with function, especially in the first few years after treatment.

Pain is one of the most frustrating side effects of cancer and one of its main complications, and the cause can be attributed to tumour involvement or to the cancer treatment (Breivik et al, 2004; Foley, 2004; Schuit et al, 1998, Everdingen et al, 2007). Pain is one of the symptoms

experienced by cervical cancer patients which seriously affects their physical, emotional and psychological life (WHO, 2000), not only before diagnosis and treatment, but also after treatment has been completed.

Pain experienced during treatment is one of the biggest causes of disability and distress in cancer patients. Approximately 80% of patients experience either acute or chronic pain during the treatment of their disease (Dallabrida et al, 2014). According to Rabelo and Borella (2013), pain can be as a result of chemotherapy, radiotherapy or surgical treatment, but it may also be caused by the tumour, presence of metastasis, or for reasons unrelated to cancer, such as functional loss, metabolic, infection and degenerative changes. In addition, Fotiou (2001), Faithfull and Well (2003) and Abayomi et al. (2005) state that pain frequently occurs as part of a cluster of symptoms alongside nausea, diarrhoea, frequent urination, fatigue, proctitis, cystitis and abdominal cramps.

Cervical cancer pain is one of the complications of radiotherapy to the pelvic region and can result in lumbosacral plexopathies, myelopathy, lymphoedema pain and burning perineum syndrome (Vistad et al, 2011). Abayomi et al. (2005) found that radiotherapy tends to trigger abdominal pain and diarrhoea leading to limited food intake as large meals may cause pain. Waldenstron (2013) found that cervical cancer pain may present within one year after completion of radiotherapy and can be severe enough to impair walking ability, whilst Ntinga (2014) found that women, twelve months after receiving radiotherapy for cervical cancer, still struggle with pain in the abdomen and lower back.

Experiencing pain is detrimental to the quality of life of cervical cancer patients. Not only does it influence their physical, emotional and psychological life (WHO, 2000) but also their sexual functioning. The prevalence of pain during sex in combination with difficulty in lubricating have a very high incidence amongst cervical cancer survivors resulting in post-coital bleeding, inability to climax and lack of interest in having sex (Vistad, 2008). Chitashi (2012) adds that patients who were sexually active before treatment become sexually inactive after treatment due to severe pain caused by vaginal stenosis and fibrosis.

2.10 SUMMARY

This chapter provides statistical information on cervical cancer globally, sub-Saharan Africa and South Africa. Treatment for cervical cancer, side effects and pain is reported in this chapter. The next chapter will describe the research design and method.

CHAPTER 3

RESEARCH METHODS

3.1 INTRODUCTION

In Chapter 2, literature pertaining to cervical cancer and pain were presented. This chapter presents the research setting and design and the research methods including the population, sampling, data collection, data analysis, validity and reliability and ethical considerations. The data management will be discussed in the Chapter 4.

3.2 RESEARCH DESIGN

The research design is the overall plan for addressing a research question, including specifications for enhancing the study's integrity (Pilot & Beck, 2012). In this study a quantitative approach and a cross-sectional design was used. Quantitative research refers to a formal, objective, systematic study process to describe and test relationships and examine cause-and-effect interactions among variables (Burns & Grove, 2013). A cross-sectional design is a study design in which data are collected at one point in time; sometimes used to infer change over time when data are collected from different age or developmental groups (Pilot & Beck, 2012). Using a cross sectional design was appropriate for this study as it allowed the researcher to describe the relationships among phenomena at a fixed point in time and permitted inferences evolving over time.

3.3 RESEARCH SETTINGS

The study setting is the specific place or places where the data are collected (Brink, 2013). This study was conducted at a radiation oncology unit of an academic hospital in Johannesburg, South Africa. This hospital has a bed capacity of 1088 and offers primary, secondary, tertiary, referral and specialised care to individuals throughout South Africa and other neighbouring countries such as Mozambique and Lesotho. In addition, the hospital offers training opportunities for undergraduate and postgraduate students in various fields of health sciences. The radiation oncology unit treats a variety of cancer patients using high tech

equipment which includes linear accelerators, cobalt radiation units, brachytherapy and hyperthermia. Computed tomography assists with treatment planning and magnetic resonance imaging are used for diagnostic purposes. The hospital radiation unit is the largest in the country and treats approximately 3500 cancer patients annually (Msadabwe, 2009).

The radiation oncology unit is an outpatient department, although it has an admission ward for patients who are too ill to treat on an outpatient basis. In addition, interim homes, which are managed by non-governmental organisations, are also available to patients who need treatment but live far from the hospital. The hospital provides transport to fetch the patients from the interim homes for radiotherapy and return them at the end of the day. The radiotherapy department has four clinics namely gynaecology, head and neck, breast and skin clinic. The department also hosts a chemotherapy room to accommodate patients receiving concomitant chemotherapy and a resting room for patients who need bed rest as they wait to be treated. The average waiting time for new patients to commence radiotherapy is approximately two weeks and about 662 to 721 women are treated for cervical cancer annually. Patients treated for cervical cancer are reviewed six weeks after completion of treatment, thereafter every three months for two years, then every six months for two years and lastly yearly for the rest of their lives. Approximately 360 women treated for cervical cancer are reviewed each month (Msadabwe, 2009). The unit's staff consists of radiation oncologists, registered oncology nurses and registered nurses without an oncology qualification, medical interns studying towards becoming radiation oncologists, physicists and radiotherapists.

3.4 POPULATION AND SAMPLING

According to Polit and Beck (2012), the population, also referred to as the target population, consists of the entire set of individuals or subjects having some common characteristics. The target population is the entire population in which a researcher is interested and to which he or she would like to generalise the study results (Pilot & Beck, 2012). The target population for this study consisted of all women treated for cervical cancer at the specific hospital in Johannesburg. Only women 18 years and older, treated with curative intent and either in the phase before commencing treatment, six months after completion of treatment and 12 months after treatment were included in the study.

Sampling is the process of selecting a portion of the population to represent the entire population (Pilot & Beck, 2012). In this study convenience sampling, a nonprobability sampling

method, was used to select 168 (n=168) respondents, 56 (n=56) in each three groups: before commencing treatment, three months after treatment and twelve months after treatment. Convenience sampling involves the selection of the most readily available people for a study (Brink, 2013). The sample size was based on a population of 721, a confidence level of 95% and a 5% confidence interval. The sample size was calculated using the following formula:

$\eta = (Z\alpha/\Delta)^2$ that is; η – Sample size

Z – Desired level of statistical significance (typically 1.96)

α - Standard deviation of the outcome variables. (From other studies)

Δ – Margin of error. (0.5)

. $\eta = (Z\ \alpha/\Delta)^2$

$\eta = 1.96 \times 3.3/0.5$

$\eta = 167.34$

The sample size for the study was 167.34. It was rounded off to 168 (n=168) in order to have same number of respondents (n=56) in each of the three groups - before treatment, six months and twelve months after treatment. The sample size refers to the number of people who participate in a study; an important factor in the power of the analysis and in statistical conclusion validity (Pilot & Beck, 2013).

3.5 DATA COLLECTION AND PROCEDURE

Data collection is the gathering of information to address a research problem (Pilot & Beck, 2012). Structured interviews were used to collect the data. Using structured interviews allowed the researcher who collected the data, to ask the same questions in the same manner to all respondents (Brink, 2013). The data collection instrument is the formal written document used to collect and record information, such as a questionnaire (Pilot & Beck, 2012). The Brief Pain Inventory (BPI) (Appendix C) served as data collection instrument and was used with permission (Appendix D). Data were collected from June to July 2015.

The BPI was initially developed to assess pain in cancer patients but has shown to be appropriate in many other clinical conditions. The BPI enables patients to rate the severity of their pain and indicate to which degree the pain influences their functioning and feelings. The

BPI asks 32 questions. The first part of the questionnaire (questions 1 to 6) collects general information, whilst questions 7 to 10 investigates whether the patient experienced pain relating to their current disease. Only patients who answered they had experienced pain caused by their current disease are eligible to answer the rest of the questions, focusing on the location of their pain for which a body diagram is provided (question 11), the severity of their pain for which numerical scales are provided (questions 12 to 15) and open ended questions on what makes the pain better or worse and the treatments and/or medications used (questions 16 to 18). Questions 19 to 22 ask about the percentage of pain relief over a period of time, side effects of pain medication experienced and what they believe could be the cause of pain and type of pain, interferences of activities and preference of taking medication and how often, indicating yes, no, or uncertain (questions 23 to 27), with questions 28 to 32 focusing on concerns regarding the effects of pain medication and what other methods were used to relieve the pain.

Permission to conduct the study was obtained from the relevant authorities of the academic hospital (Appendix E) and the Human Research Ethics Committee (Medical) of the University. After receiving ethical clearance (certificate number M150455) and approval from the institution, the researcher approached women who came to the radiotherapy department for a scheduled appointment and met the inclusion criteria to participate in the study. Some were recruited before their scheduled medical assessment and some afterwards whilst waiting for transport to take them to their place of residence. Those who were willing to participate in the study were handed an information sheet containing details of the study (Appendix A) and the researcher also explained it to them. Those who volunteered to participate in the study were given a consent form to sign (Appendix B); 168 women were recruited and all agreed to participate. The interview was taking 15 to 20 minutes to finish answering the questionnaire. The respondents were interviewed in a private room with only the researcher and respondent present. Arrangements were made for counselling should respondents become emotionally distressed, but none was required.

3.5.1 Validity and Reliability

The BPI was developed by the pain research group at the University of Wisconsin, Madison, led by Charles S. Cleeland in the 1980s. The BPI was designed to measure the intensity and

severity of pain and the interference with activities of daily living (Beecher, 1959; Cleeland, 2009), with the objective of providing a detailed update of evidence of applicability of the tool. The BPI demonstrated good construct and concurrent validity and reliability (Cleeland & Ryan, 1994). The tool was validated and translated into various languages in different countries. In a study by Eastern Cooperative Oncology group on metastatic cancer, findings reveal internal consistence ranging from 0.80 to 0.87 for four pain severity items and from 0.89 to 0.92 for seven interference items. Data from other studies demonstrated a high internal consistence of two dimensions of the BPI (severity and interference) (Caracine et al., 1996; Cleeland,1989; Ger et al., 1999; Mystakidou et al., 2001; Klepstad et al., 2002 and Yen et al., 2004). The BPI was validated in patients with bone metastasis and breast cancer as well as post-operative cancer patients and was recommended to be used in cancer patients for pain assessment. The European Association for Palliative Care also recommended the use of BPI as a principal tool in palliative care (Caracine et al., 1996).

3.6 DATA ANALYSIS

Data analysis is the systematic organisation and synthesis of research data. In quantitative studies, data analyses are also used to test the data (Polit & Beck, 2012).The data were entered onto an Excel Spreadsheet and the SPSS version 22 programme was used to analyse the data. Descriptive statistics were used to report the findings. According to Burns and Grove (2011), descriptive statistics assist the researcher to organise the data in a way that gives meaning and insight. Frequency (f), percentages (%), ranges, means and standard deviations (SD) were used to describe the demographic data and summarise responses to each item of BPI scale. Tables were used to present the results for easy interpretation. The Kruskal Wallis test, a non-parametric test, were used to determine whether there were statistically significant differences between the groups (Marusteri & Bacarea, 2010). The level of significance was 0.05 (p=0.05).

3.7 ETHICAL CONSIDERATIONS

Ethics is a system of moral values concerned with the degree to which research procedures adhere to professional, legal and social obligations to the study's respondents. Ethical research is important as it protects the rights of the respondents and prevents research misconducts (Pilot & Beck, 2012). The following steps were taken to enhance ethical conduct:

- Ethical clearance was obtained from the Human Ethics Committee (Medical) of the University of the Witwatersrand (Appendix G). Permission was also obtained from to use BPI (Appendix D).
- The Chief Executive Officer of the institution where the study was conducted also approved the study (Appendix H). The Clinical Head and Nursing Unit Manager of the radiotherapy department also supported the study.
- Participation was voluntary and respondents were recruited during their scheduled appointments. No impairment would be suffered if they decided not to participate.
- Convenience sampling was used in selecting participants and stopped once the sample size was realised. Informed written consent was obtained from volunteers and an information leaflet explaining the procedure was handed to them (Appendix B).
- An arrangement was made with a councillor to council the respondents, if needed, should they experience emotional distress.
- Code numbers marked the data collection and sheets to promote anonymity.
- Only the researcher and supervisor had access to the data until the submission of the research report.

3.8 SUMMARY

This chapter presented the research methods. This includes research design, setting, population, sampling, data collection and analysis, the instrument used including its validity and reliability and ethical consideration of the study. The next chapter is about the research findings.

CHAPTER 4

RESULTS OF THE STUDY

4.1. INTRODUCTION

The previous chapter presented the study's research design and methods and this chapter describes the results.

4.2 DEMOGRAPHIC DATA AND SOCIAL ECONOMIC STATUS

The ages of the respondents ranged from 24 to 76 years, with a mean of 50.3 (SD ±12.2) and a median of 49. The majority (54.1%; n=91) of the sample were single and more than 64.2% (n=108) were unemployed; those who were employed were mainly domestic workers (20.8%; n=35). Most of the spouses (54.1%; n=20) were unemployed. Only 4.1% (n=7) of the respondents had never been to school. The demographic and socio-economic status of the sample is presented in Table 4.1.

Table 4.1. Demographic data and socio-economic status (n=168)

	Before treatment (n=56)		Six months after treatment (n=56)		Twelve months after treatment (n=56)		Total (n=168)	
Age	n	%	n	%	n	%	n	%
20-29	14	25.0	11	19.6	6	10.7	31	18.5
30-39	18	32.1	21	37.5	14	25.0	53	31.5
40-49	14	25.0	12	21.4	20	35.7	46	27.4
50-59	6	10.7	8	14.3	11	19.6	25	14.8
60-69	4	7.1	4	7.1	4	7.1	12	7.1
70 and older	0	0.0	0	0.0	1	0.6	1	0.6
Marital status								
Single	35	62.5	30	53.6	26	46.4	91	54.1

Married	8	14.3	15	26.8	12	21.4	35	20.8
Widowed	12	21.4	7	12.5	13	23.2	32	19.0
Divorced	1	1.8	4	7.1	5	8.9	10	6.0
Education level								
Never been to school	2	3.6	2	3.6	3	5.4	7	4.1
Primary school	21	37.5	22	39.3	22	39.3	65	38.5
High school	20	35.7	21	37.5	22	39.3	63	37.3
Matric	13	23.2	11	19.6	9	16.1	33	19.5
Current occupation								
Unemployed	37	66.1	36	64.3	35	62.5	108	64.2
Domestic worker	8	14.3	13	23.2	14	25.0	35	20.8
Office work	4	7.1	3	5.4	4	7.1	11	6.5
Self employed	1	1.8	0	0	1	1.8	2	1.2
Health professional	1	1.8	0	0	1	1.8	2	1.2
Cleaner	3	5.4	2	3.6	0	0	5	3.0
Factory worker	1	1.8	2	3.6	1	1.8	4	2.4
Educator	1	1.8	0	0	0	0	1	0.6
Spouse occupation								
Unemployed	5	8.9	10	17.9	5	8.9	20	11.9
Office work	1	1.8	1	1.8	1	1.8	3	1.8
Self employed	1	1.8	0	0	0	0	1	0.6
Cleaner	0	1.8	0	0	1	1.8	1	0.6
Factory worker	2	3.6	3	5.4	1	1.8	6	3.6
Driver	1	1.8	3	5.4	0	0	4	2.4
Casual work	1	1.8	1	1.8	0	0	2	1.2
No spouse	45	80.4	38	67.9	48	85.7	131	78

Employment status								
Full time outside the home	13	23.2	13	23.2	16	28.6	42	25.0
Part time	6	10.7	4	7.1	5	8.9	15	8.9
Retired	4	7.1	6	10.7	5	8.9	15	8.9
Unemployed	33	58.9	33	58.9	30	53.6	96	57.1

4.3. CANCER DIAGNOSIS AND PAIN EXPERIENCE

When the sample was asked when they had learnt about their diagnosis, the majority in the before treatment group (87.8%; n=44) indicted they were informed about their diagnosis within the previous 3 months, ranging from 1 week to 7 months with a mean of 2.5 (±1.7) months. In addition, the majority of the total sample (n=168) had had pain due to their current disease (78%; n=131) and experienced pain as one of the symptoms at diagnosis (55.4%; n=93). Only a small percentage of the respondents (14.3%; n=24) indicated they had had surgery in the month prior to the collection of data; 83.3% (n=20) underwent a hysterectomy and 16.7% (n=4) a colostomy (Table 4.2).

Table 4.2. Cancer diagnosis and pain history (n=168)

Criteria	Before treatment (n=56)		Six months after treatment (n=56)		Twelve months after treatment (n=56)		Total (n=168)	
Time since being diagnosed (months)	n	%	n	%	n	%	n	%
1 month and less	22	39.3	0	0	0	0	22	13.1
2 to 3	21	37.5	0	0	0	0	21	12.5
4 to 6	8	14.3	0	0	0	0	8	4.8
7 to 12	5	8.9	49	87.5	0	0	54	32.1
13 to 24	0	0	7	12.5	44	78.6	51	30.4
More than 24	0	0	0	0	12	21.4	12	7.1

Ever had pain due to current disease								
Yes	46	82.1	43	76.8	42	75	131	78.0
No	10	17.9	11	19.6	13	23.2	34	20.2
Uncertain	0	0	2	3.6	1	1.8	3	1.8
Pain one of the symptoms when diagnosed with cancer								
Yes	32	57.1	31	55.4	30	53.6	93	55.4
No	24	42.9	25	44.6	26	46.4	75	44.6
Uncertain	0	0	0	0	0	0	0	0
Had surgery during the past month								
Yes	4	7.1	9	16.1	11	19.6	24	14.3
No	52	92.9	47	83.9	45	80.4	144	85.7

When the respondents were asked if they had pain other than the everyday kinds of pain, more than 50% (58.9%; n=99) experienced pain during the last week. In addition, 45.2% (n=92) indicated they had used pain medication during the past seven days, whilst 51.2% (n=86) confirmed they experienced pain requiring medication every day. The respondent's pain experience is presented in Table 4.3.

Table 4.3. Pain experience (n=168)

Pain history	Before treatment (n=56)		Six months after treatment (n=56)		Twelve months after treatment (n=56)		Total (n=168)	
	n	%	n	%	n	%	n	%
Had pain other than everyday kind of pain during the last week								
Yes	39	69.4	27	48.2	33	58.9	99	58.9
No	17	30.4	29	51.8	23	41.1	69	41.1
Did take medication in last 7 days								
Yes	33	58.9	30	53.6	29	31.5	92	45.2
No	23	41.1	26	46.4	27	48.2	76	45.2
Feel have pain now that requires medication each and every day								
Yes	35	62.5	21	37.5	30	53.6	86	51.2
No	21	37.5	35	62.5	26	46.4	82	48.8

4.4. LOCATION OF THE PAIN

When the respondents, who confirmed they experienced pain during the past seven days and/or those who took medication for pain in the past seven days and/or those who experienced pain requiring medication each and every day, were asked to indicate where their pain was located (n=115), 87.2% (n=101) were able to indicate where their pain was, whilst 8.3% (n=14) could not say. The location of the pain is summarised in Table 4.4 and Figure 4.1.

Table 4.4. Site of the pain (n=115)

	Before treatment (n=41)		Six months after treatment (n=35)		Twelve months after treatment (n=39)		Total n=115	
Painful site	n	%	n	%	n	%	n	%
Unable to identify the location	2	4.9	7	20.0	5	15.0	14	12.2
Head and neck	0	0	1	2.9	0	0	1	0.9
Chest	0	0	0	0	0	0	0	0
Arms	0	0	3	8.6	13	32.5	16	13.9
Abdomen	21	51.2	17	48.6	15	37.5	54	47.0
Legs	0	0	0	0	0	0	0	0
Upper back	0	0	0	0	0	0	0	0
Lower back	16	39.0	7	20.0	6	15.0	30	26.1

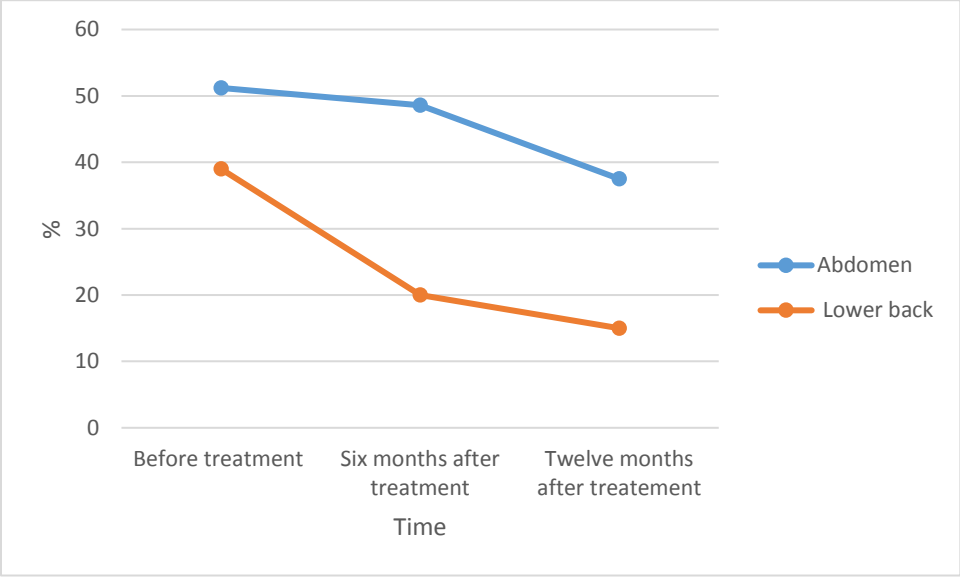

Figure 4.1 Percentage of respondents experiencing abdominal and lower back pain

4.5. PAIN SEVERITY

Respondents who experienced pain (n=115) were asked to rate their pain at its worst during the previous weeks. More than one quarter (26.8%; n=11) of the respondents in the before treatment group rated their worst pain as 10, similar to 11.4% (n=4) of those in the group six months after treatment and 12.8% (n=5) in the twelve months after treatment groups. Pain at its worst during the past week is presented in Table 4.5.

Table 4.5. Pain at its worst pain during the past week in the different groups (n=115)

	Before treatment (n=41)		Six months after treatment (n=35)		Twelve months after treatment (n=39)		Total (n=115)	
Worst pain during the past week	n	%	n	%	n	%	n	%
Severe (8 to 10)	22	53.7	8	22.9	14	35.9	44	38.2
Moderate (5 to 7)	8	19.5	12	34.2	12	30.8	32	27.8
Mild (1 to 4)	10	24.4	8	22.9	7	17.9	25	21.7
No pain (0)	1	2.4	7	20.0	6	15.4	14	12.9
Average pain rating	6.7		4.9		5.5		5.7	

A Kruskal-Wallis H test showed there was a statistically significant difference in the pain scores between the different groups, χ^2 (2) = 6.03, p = 0.049.

When respondents were asked to rate the least pain they had had in the past week, a larger percentage in the before treatment group (12.2%; n=5) rated their pain as severe, compared to the 0.9% (n=1) and 7.7% (n=3) in the six months and twelve months after treatment groups. (Table 4.6)

Table 4.6. Pain at its least pain during the past week in the different groups (n=115)

	Before treatment (n=41)		Six months after treatment (n=35)		Twelve months after treatment (n=39)		Total (n=115)	
Least pain during the past week	n	%	n	%	n	%	n	%
Severe (8 to 10)	5	12.2	1	0.9	3	7.7	9	7.8
Moderate (5 to 7)	15	36.6	10	28.6	18	46.2	43	37.4
Mild (1 to 4)	17	41.5	14	40.0	10	25.6	41	35.7
No pain	4	9.7	10	28.6	8	20.1	22	19.1
Average pain rating	4.5		2.9		3.9		3.8	

A Kruskal-Wallis H test showed there was no statistically significant difference in the pain scores between the different groups.

When asked to indicate the average pain they experienced during the past week, the greatest percentage (35.7%; n=41) of respondents rated their pain as moderate. The largest percentage in the before treatment group however had mild pain (36.6%; n=15) (Table 4.7).

Table 4.7. Average pain during the past week in the different groups (n=115)

	Before treatment (n=41)		Six months after treatment (n=35)		Twelve months after treatment (n=39)		Total (n=115)	
Average pain during the past week	n	%	n	%	n	%	n	%
Severe (8 to 10)	13	31.7	4	11.4	4	10.3	21	13.5
Moderate (5 to 7)	12	29.3	13	37.1	17	43.6	41	35.7
Mild (1 to 4)	15	36.6	11	31.4	9	23.1	35	30.4
No pain (0)	1	2.4	7	20.0	9	23.1	17	14.8
Average pain rating	7.2		4.0		4.1		4.6	

A Kruskal-Wallis H test showed there was a statistically significant difference in the pain scores between the different groups, χ^2 (2) = 13.12, p = 0.001.

When respondents were asked to rate the pain they were experiencing at the very moment, the average pain score of the total sample (n=115) was 4.6. The greatest percentage of the respondents in the before treatment group (39%; n=16) and in the twelve months after treatment group (30.8%; n=12) experienced severe pain. The current pain respondents were experiencing is presented in Table 4.8.

Table 4.8. Current pain in the different groups (n=115)

	Before treatment (n=41)		Six months after treatment (n=35)		Twelve months after treatment (n=39)		Total (n=115)	
Current pain during the past week	n	%	n	%	n	%	n	%
Severe (8 to 10)	16	39.0	6	17.1	12	30.8	34	29.6
Moderate (5 to 7)	9	22.0	8	22.9	9	23.1	26	22.6
Mild (1 to 4)	12	29.3	9	25.7	8	20.5	29	25.2
No pain	4	9.8	12	34.3	10	25.6	26	22.6
Average pain rating	5.7		3.3		4.6		4.6	

A Kruskal-Wallis H test showed there was a statistically significant difference in the pain scores between the different groups, χ^2 (2) = 6.19, p =0.045.

The mean pain scores of the groups during the past week is illustrated in Figure 4.2.

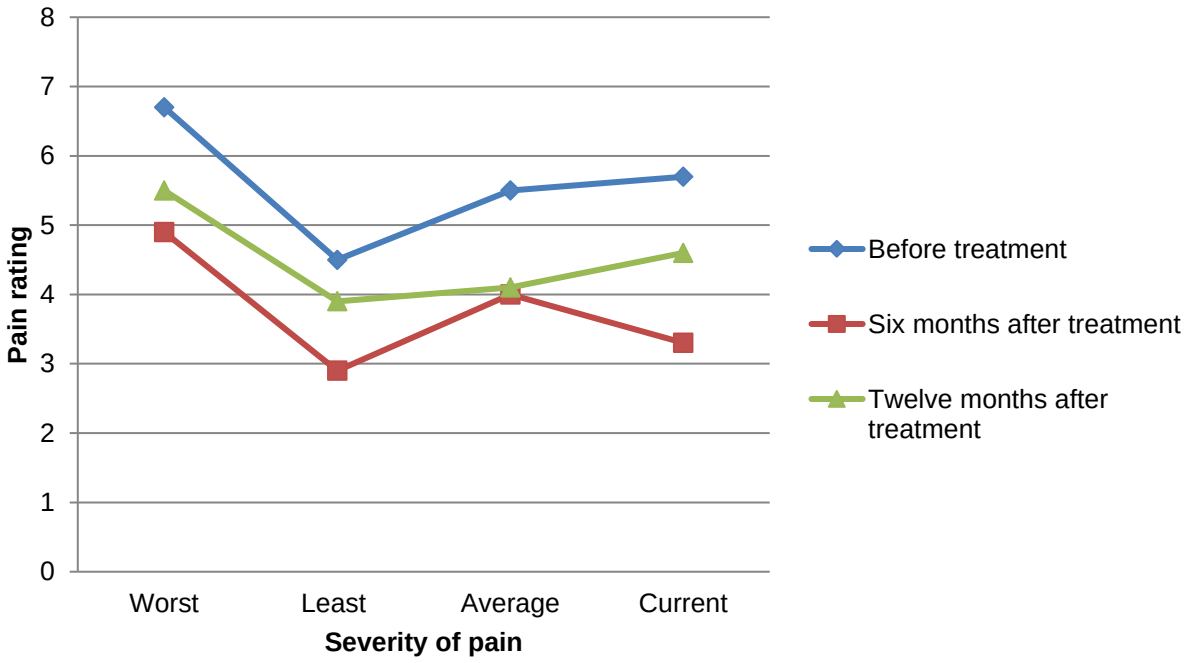

Figure 4.2 Mean pain ratings during the past week

A Kruskal-Wallis H test did not show a statistically significant difference in the pain scores of the previous week between the different groups.

4.6. FACTORS INFLUENCING PAIN

When the respondents were asked what made their pain better, the majority (71.3%; n=83) answered medicine, 15.7% (n=18) said nothing makes the pain better and 7.7% (n=10) indicated rest. When asked what makes the pain worse, 22.6% (n=26) indicated nothing makes the pain worse, whilst 22.6% (n=26) indicated walking (Table 4.9).

Table 4.9: Factors influencing pain according to the groups (n=115)

Factor	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total (n=115)	
What makes pain better	n	%	n	%	n	%	n	%
Medication	33	80	24	68.6	25	64.1	82	71.3
Nothing	5	12.2	8	22.9	5	12.8	18	15.7
Rest	2	4.9	3	8.6	5	12.8	10	7.7
Other	1	2.4	0	0	4	10.3	5	4.3
What makes pain worse								
Walking	9	22	9	25.7	8	20.5	26	22.6
Sitting	8	19.5	0	0	4	10.3	12	10.4
Standing	3	7.3	3	8.6	3	7.7	9	7.8
Working	3	7.3	3	8.6	3	7.7	9	7.8
Lifting things	4	9.8	2	5.7	0	0	6	5.2
Cold	4	9.8	0	0	4	10.3	8	7.0
Nothing	4	9.8	12	34.3	10	25.6	26	22.6
Stress	3	7.3	3	8.6	3	7.7	9	7.8
Other	3	7.3	3	8.6	4	10.3	10	8.7

When asked which pain medication they were taking, the majority of respondents indicated paracetamol (42.6%; n=49), some did not take any pain medication (22.6%; n=26), whilst a small percentage took morphine (7.8%; n=9). The pain medication respondents were using is illustrated in Table 4.10.

Table 4.10: Types of medication taken (n=115)

Medication	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total (n=115)	
	n	%	n	%	n	%	n	%
None	5	12.2	14	40.0	7	17.9	26	22.6
Unable to name analgesic	1	2.4	1	2.8	0	0	2	1.7
Paracetamol	18	43.9	10	28.6	21	53.8	49	42.6
Ibuprofen	6	4.9	0	0	2	5.1	8	7.0
Mypaid	1	2.4	0	0	0	0	1	0.9
Myprodol	2	4.9	0	0	0	0	2	1.7
Tramadol	3	7.3	5	14.3	4	10.3	12	10.4
Morphine	5	12.2	3	8.6	1	2.6	9	7.8
DF118	0	0	1	2.8	0	0	1	0.9
Other	0	0	1	2.8	4	10.3	5	4.3

The types of pain medication and percentages of respondents using the different types are summarised in Figure 4.3

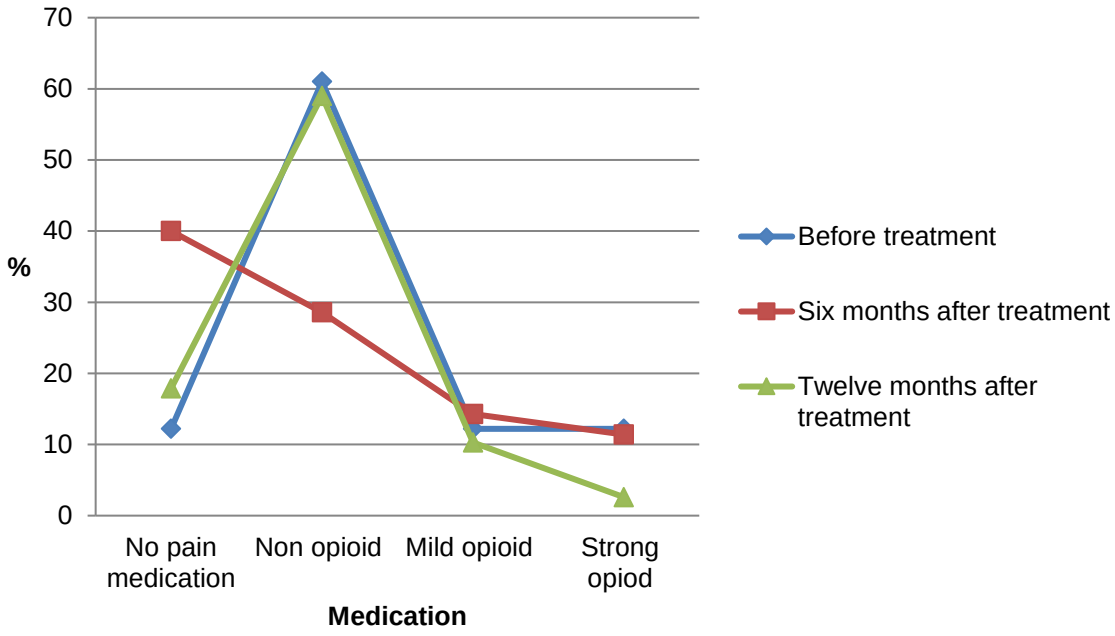

Figure 4.3. Pain medication used by the respondents

4.7. PAIN RELIEF AFTER TAKING MEDICATION

When the respondents who indicated they used pain medication (n=89) were asked to what extent the pain medication relieved their pain, answers ranged from 0 to 100%. The greatest percentage of respondents 43.8% (n=39) indicated they experienced 100% pain relief, whilst 15.7% (n=14) experienced less than 50% relief. The percentage of pain relief according to the groups are presented in Figure 4.4.

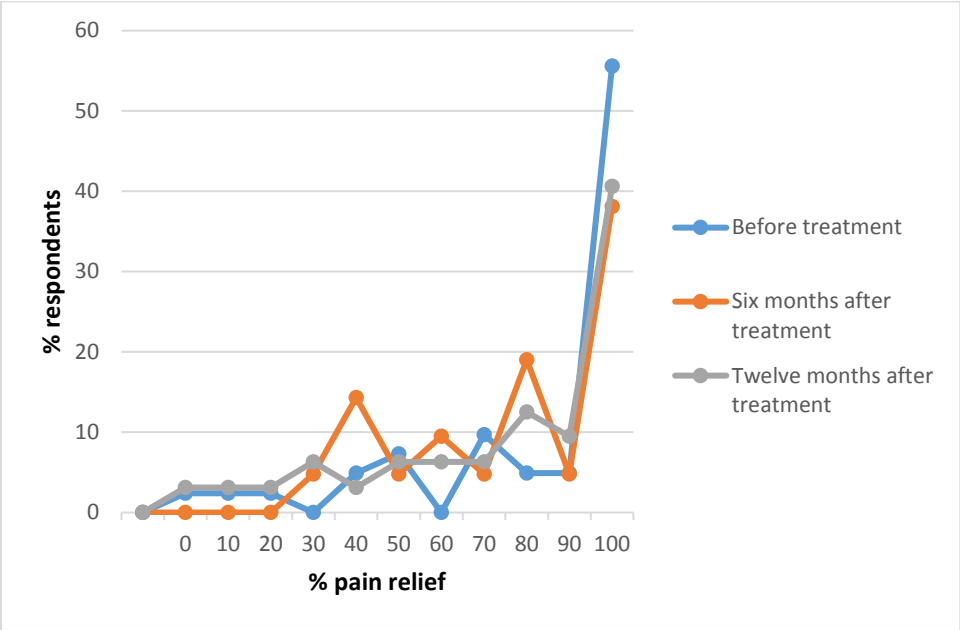

Figure 4.4: Percentage of pain relief after taking pain medication

The respondents were asked how long it takes for the pain to return after taking pain medication, to which the majority (n=31; 34.8%) indicated more than 12 hours. Figure 4.11 summarises how long it takes for pain to return.

Table 4.11: Time taken for pain to return after taking pain medication (n=89)

	Before treatment n=36		Six months after treatment n=21		Twelve months after treatment n=32		Total (n=89)	
Hours it take for pain to return	n	%	n	%	n	%	n	%
One hour	2	9.8	0	0	3	10.0	5	5.6
Two hours	3	4.9	2	11.4	4	10.0	9	10.1
Three hours	2	4.9	3	11.4	4	10.0	9	10.1
Four hours	9	19.5	3	14.3	7	17.5	19	21.3
Five to twelve hours	8	26.8	4	25.7	4	30.0	16	18.0
More than twelve hours	12	26.8	9	25.7	10	30.0	31	34.8

4.8. CAUSES AND CHARACTERISTICS OF PAIN

Respondents were asked what they believed could be the cause of their pain. More than 60% were of the opinion their pain was caused by their primary disease (64%, n=75), whilst 67% (n=77) were of the opinion that their pain was not caused by the effects of their treatment. Table 4.12 provides the detail.

Table 4.12. Beliefs regarding the causes of the pain respondents were experiencing (n=115)

Pain caused by	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total n=115	
The effects of treatment	n	%	n	%	n	%	n	%
Yes	2	4.9	4	11.4	14	35.9	20	17.4
No	37	90.2	20	57.1	20	51.3	77	67.0
Don't know	2	4.9	11	31.4	5	12.8	18	15.7
Primary disease								
Yes	34	82.9	21	60.0	20	50.0	75	64.7
No	5	12.2	3	8.6	14	35.0	22	19.0
Don't know	2	4.9	11	31.4	6	15.0	19	16.4
Medical condition not related to the primary disease								
Yes	2	4.9	2	5.7	7	17.5	11	9.5
No	37	90.2	22	62.9	28	70.0	87	75.0
Don't know	2	4.9	11	31.4	4	10.3	17	14.8

When asked to describe the characteristics of their pain, not all the respondents were able to say what the pain felt like, however it was mainly described as sharp and burning. The details are presented in Table 4.13.

Table 4.13. The characteristic of the pain experienced (n=115)

Characteristic	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total n=115	
	n	%	n	%	n	%	n	%
Aching								
Yes	4	9.8	5	14.3	10	25.0	19	16.4
No	37	90.2	25	71.4	26	65.0	88	75.9
Don't know	0	0	5	14.3	4	10.0	9	7.8
Throbbing								
Yes	0	0	5	14.3	7	17.5	12	10.3
No	41	100.0	25	71.4	28	70.0	94	81.0
Don't know	0	0	5	14.3	5	12.5	10	8.6
Shooting								
Yes	4	9.8	4	11.4	1	2.5	9	7.8
No	37	90.2	26	74.3	34	85.0	97	83.6
Don't know	0	0	5	14.3	5	12.5	10	8.6
Stabbing								
Yes	5	12.2	5	14.3	6	15.0	16	13.8
No	36	87.8	25	71.4	29	72.5	90	77.6
Don't know	0	0	5	14.3	5	12.5	10	8.6
Sharp								
Yes	8	19.5	6	20.0	8	20.0	22	19.0
No	33	80.5	24	68.6	27	67.5	84	72.4
Don't know	0	0	5	14.3	5	12.5	10	8.6
Tender								
Yes	4	9.8	2	5.7	4	10.0	10	8.6
No	37	90.2	28	80.0	31	77.5	96	82.8

Don’t know	0	0	5	14.3	5	12.5	10	8.6
Burning								
Yes	15	36.6	4	11.4	4	10.0	23	19.8
No	26	63.4	26	74.3	31	77.5	83	71.8
Don’t know	0	0	5	14.3	5	12.5	10	8.6
Exhausting								
Yes	4	9.8	1	2.9	3	7.5	8	6.9
No	37	90.2	29	82.9	32	80.0	98	84.5
Don’t know	0	0	5	14.3	5	12.5	10	8.6
Tiring								
Yes	2	4.9	2	5.7	3	7.5	7	6.0
No	39	95.1	28	80.0	32	80.0	99	85.3
Don’t know	0	0	5	14.3	5	12.5	10	8.6
Penetrating								
Yes	1	2.4	2	5.7	2	5.0	5	4.3
No	40	97.6	28	80.0	32	80.0	100	86.2
Don’t know	0	0	5	14.3	6	15.0	11	9.5
Nagging								
Yes	0	0	1	2.9	4	10.0	5	4.3
No	41	100	29	82.9	30	75.0	100	86.2
Don’t know	0	0	5	14.3	6	15.0	11	9.5
Numb								
Yes	0	0	1	2.9	2	5.0	3	2.6
No	41	100	29	82.9	33	82.5	103	88.8
Don’t know	0	0	5	14.3	5	12.5	10	8.6
Miserable								
Yes	1	2.4	6	17.1	3	7.5	10	8.7
No	40	97.6	24	68.6	32	82.1	96	83.5

Don't know	0	0	5	14.3	4	10.3	9	7.8
Unbearable								
Yes	4	9.8	4	11.4	3	7.5	11	9.5
No	37	90.2	26	74.3	32	80.0	95	81.9
Don't know	0	0	5	14.3	5	12.5	10	8.6

4.9. PAIN INTERFERENCE

When respondents were asked to what extent the pain they experienced interfered with their lives during the past week, answers ranged from "does not interfere" (rated 0) to "completely interferes" (rated 10). The mean scores of the different groups are presented in Figure 4.5.

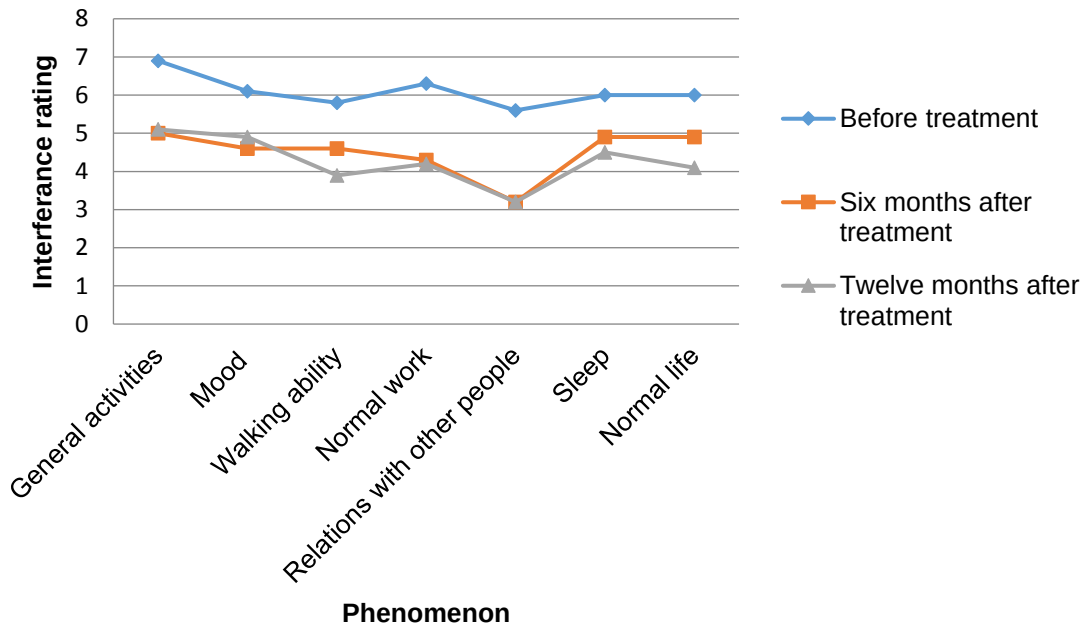

Figure 4.5 Mean scores of interference in the lives of the respondents

Kruskal-Wallis tests indicated a significant statistical difference between general activities amongst the three groups $\chi^2(2) = 6.383$, $p = 0.0411$, normal work $\chi^2(2) = 7.188$, $p = 0.0275$, and relations with other people $\chi^2(2) = 10.354$, $p = 0.0056$. Kruskal-Wallis tests did not show

significant statistical differences between the groups in terms of mood, walking ability, sleep and enjoyment of life.

4.10. PREFERENCE OF TAKING PAIN MEDICATION

When respondents were asked whether they preferred to take their medication on a regular basis or only when necessary, 32.2% (n=37) indicated they prefer to take their pain medication regularly, 58.3% (n=67) preferred to take their medication when necessary and 9.7% (n=11) indicated they do not take medication. When asked how frequent they take their pain medication, the highest percentage (41.7%; n=48) indicated they do not take pain medication every day (Table 4.14).

Table 4.14. Preference of taking medication and frequency of use (n=115)

	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total n=115	
	n	%	n	%	n	%	n	%
Preference of taking pain medication:								
on a regular basis	17	36.6	9	25.7	11	30.0	37	32.2
only when necessary	22	29.3	20	57.1	25	62.5	67	58.3
do not take pain medication	2	34.1	6	17.1	3	7.5	11	9.7
Frequency of pain medication use in 24 hours:								
Not everyday	28	68.3	27	77.1	20	50.0	48	41.7
1-2 times per day	13	31.7	1	2.9	10	25.0	24	20.7
3-4 times per day	0	0	7	20.0	8	20.0	15	12.9

5-6 times per day	0	0	0	0	2	5.0	2	1.2
More than 6 times per day	0	0	0	0	0	0	0	0

When the respondents were asked if they feel they need a stronger type of pain medication, the majority (62.6%; n=72) said yes. In addition, 35.7% (n=41) were of the opinion they need to take more of the pain medication than what the doctor has prescribed. Figure 4.6 illustrates the respondent's needs in terms of their medication.

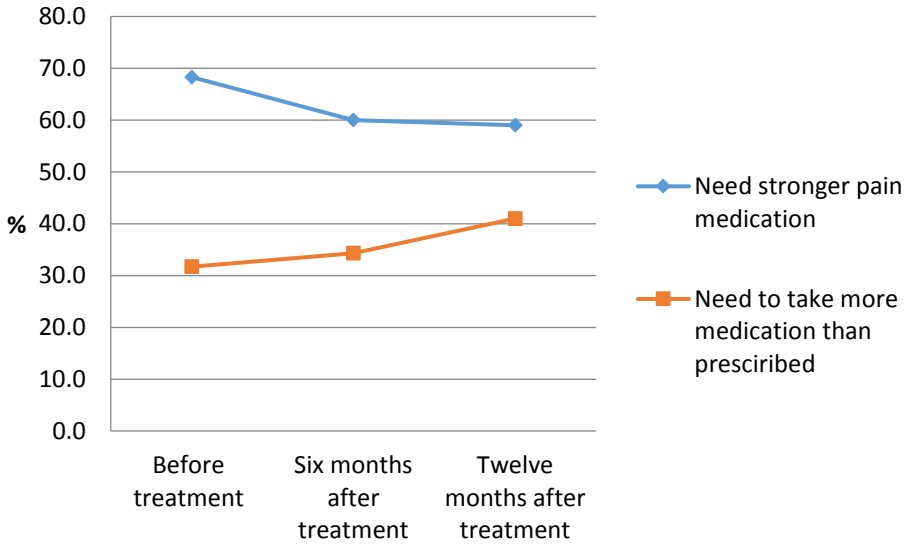

Figure 4.6. The respondent's needs in terms of their medication.

The respondents were asked whether they are concerned about the use of too much pain medication. The majority said no (n=89; 75.7%) and those who said yes gave reasons such as nausea, addiction, unpleasant taste and worried of the effect to the body. They were further asked what side effects they experienced; half of the respondents (50%; n=13) complained of fear of addiction.

Figure 4.15. **Concerns about pain medication and side effects experienced (n=115**

	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total n=115	
Concerned about using too much pain medication								
Yes	10	24.3	8	14.3	8	20.5	26	22.6
No	31	75.6	25	71.4	31	79.5	87	75.7
Uncertain	0	0	2	3.6	0	0	2	1.7
Reasons for concern								
Fear of addiction	5	50.0	3	37.5	5	62.5	13	50.0
Causes nausea	3	30.0	3	37.5	1	80.0	7	26.9
Unpleasant taste	1	10.0	2	25.0	2	25.0	5	19.2
Worried of effect to the body	1	10.0	0	0	0	0	1	3.8
Having problems with the side effects from the pain medication								
Yes	8	19.5	4	8.9	5	12.8	17	14.8
No	33	80.5	31	88.6	34	87.2	98	85.2
Side effects experienced								
Heart burn	1	12.5	0	0	2	40.0	3	17.6
Nausea	4	50.0	2	50.0	2	40.0	8	47.1
Dizziness	2	25.0	1	25.0	0	0	3	17.6
Weakness	1	12.5	1	25.0	1	20.0	3	17.6

When respondents were asked if they feel they need further information about their pain medication, the majority (68.7%; n=79) answered no. When asked what other pain methods they used to relief their pain, most indicated none (72.2%; n=83). Finally, the respondents were

asked whether they take pain medication not prescribed by the doctor, such as paracetamol, ibuprofen, pain block, marijuana oil, green capsule and Grandpa, to which the majority (78.3%; n=90) indicated no. The summary is shown in table 4.16.

Table 4.16. Need for information on pain medication and other methods used to relieve pain (n=115)

	Before treatment n=41		Six months after treatment n=35		Twelve months after treatment n=39		Total n=115	
	n	%	n	%	n	%	n	%
Need further information								
Yes	19	33.9	5	15.3	12	30.7	36	31.3
No	22	53.7	30	85.7	27	69.2	79	68.7
Other methods used to relieve pain (more than 1 could apply)								
Warm compresses	6	14.6	4	11.4	7	17.9	17	14.8
Cold compresses	0	0	0	0	1	2.6	1	0.9
Relaxation techniques	0	0	2	5.7	3	7.7	5	4.3
Distraction	1	2.4	0	0	2	5.1	3	2.6
Biofeedback	0	0	0	0	0	0	0	0
Hypnosis	0	0	0	0	1	2.6	1	0.9
Other	0	0	0	0	5	12.8	5	4.3
None	34	82.9	29	82.9	20	51.3	83	72.2
Taking medication not prescribed by the doctor								
Yes	7	17.1	4	11.4	14	35.9	25	21.7
No	34	78.6	31	80.4	25	71.4	90	78.3

Type of medication taken not prescribed by the doctor								
Paracetamol	6	85.7	3	75.0	1	7.1	10	40
Green capsule	0	0	0	0	1	7.1	1	4.0
Ibuprofen	0	0	0	0	5	35.7	5	20.0
Grandpa	0	0	1	25.0	4	28.6	5	20.0
Marijuana oil	0	0	0	0	1	7.1	1	4.0
Pain block	1	14.3	0	0	2	14.3	3	12.0

4.11 SUMMARY

This chapter described the results of the study. The results were presented in tables and figures and Kruskal-Wallis tests determined statistically significant differences between specific variables. The next chapter presents the discussion of the results and concludes the study.

CHAPTER 5

DISCUSSION, JUSTIFICATION, LIMITATIONS AND RECOMMENDATIONS

5.1. INTRODUCTION

Chapter 4 presented the results of the study. This chapter discusses the results, justifies the study, present the limitations, makes recommendations and concludes the study.

5.2. DISCUSSION OF THE RESULTS

More than half the respondents included in this study were between the ages of 30 and 50. Sitas et al. (1998) and Hoque et al. (2008) reported that the incidence of invasive cancer arises in the age group 35 to 39, whilst 87% of cervical cancers occur in women over 35 years. In South Africa, age specific incidence of cervical cancer, compared to other cancers amongst women, is between 15 and 44 years of age (information centre on HPV and cancer, 2016).

This study provides evidence that more than half of the women experienced pain when they were diagnosed. Vuorinen (1993) and Fishman (2012), in a study conducted in Finland focusing on pain in cancer patients, found that 19 to 48% of respondents had pain as a symptom preceding diagnosis. Given et al (2001) and Mwaka et al, (2015) found that women with cervical cancer perceived their initial symptoms not to be serious, whilst those whose symptoms were painless, intermittent or mild, were more likely to take a long time to seek professional care. Other cervical cancer respondents experienced service seeking when they experienced severe abdominal pain, heavy vaginal bleeding and excessive foul smelling vaginal discharge.

It was interesting to note that a greater percentage of respondents who were twelve months after treatment, were of the opinion they experience pain which requires medication each and every day compared to the six months after treatment group. Pasek et al. (2012), in a study conducted in Poland, report a different trend and found patients evaluated pain to be the greatest before treatment and at five to six months after the treatment. In addition, Ljuca and Marosevic (2009) also found that pain in women with gynaecological cancer reduced after radiotherapy due to tumour regression. Why a greater percentage of women twelve months after treatment, compared to those six months after treatment, needed pain medication each and every day is not clear. Reid and Forbe (2007) however, in a study conducted in United Kingdom, found the majority (63%) of elderly patients 60 years and older, treated with curative intent, will experience chronic pain, possibly due to co-morbidities rather than cancer pain.

The study provided evidence that respondents across all three groups most commonly experienced abdominal and lower back pain. Vistad et al. (2011), in a study focusing on chronic pain after radiotherapy in survivors of locally advance cervical cancer, found that patients experienced daily lower back and pelvic pain. Only a small percentage of respondents in the current study experienced pain in other sites, which is not exceptional as Li et al. (1999), and Vistad et al (2011), in a study conducted in United States, found cervical cancer survivors not only experience back pain but also headache and pain in their legs.

What is of concern is that more than one third of patients had severe pain during the collection of the data. It would be expected that patients who were newly diagnosed would experience pain as, according to Ger et al. (1999) and Mathews et al (2011), anticancer treatment such as surgery, radiotherapy, chemotherapy and hormonal therapy can lead to significant pain relief, however it was not expected that 45% of the twelve months after treatment group had severe pain. To add to this dilemma most respondents, irrespective of whether they were in the before or after treatment group, used paracetamol, a non-opioid suitable for mild pain for the pain they were experiencing.

The finding that more than 60% of respondents did not use their pain medication every day, or only one or two times per day, also aggravates the pain experienced. Considering these facts, it comes as no surprise that 37.5% of the respondents felt a need for stronger pain medication, a result which concurs with the WHO (2003) statement that people are living with cancer pain despite the fact that 90% of patients can receive adequate pain relief with simple drugs. In addition, it seems as if pain medication was not administered according to the pain ladder and was not adhered to timewise (World Health Organization, 1986; Kumar & Lin, 2007). The exact reasons for this mismanagement is unclear. However, in the study by Alexopoulose et al (2011), non-compliance was observed in more than 15% of respondents, while 61% (n=115) revealed negative attitudes toward treatment including fear of side effects, fear of addiction and fear of continually taking medication once the pain has been controlled. In a study by Yen et al (2012), unrelieved acute pain commonly elicits pathophysiologic neural alterations, including peripheral and central neuronal sensitisation, which evolves into chronic pain syndromes. According to Brennan et al (2007), the prevalence of pain in gynaecological cancer patients seeking help from alternative therapies such as acupuncture, massage or shiatsu is approximately 38%, indicating that nearly two–thirds of patients remain undertreated when pain is moderate to severe, which is similar to the results of this study where respondents either took no medication or used warm compresses.

With advances in anticancer treatment patients with gynaecological malignancy have witnessed an increase in the likelihood of survival, however as a by-product of this success pain suffering may continue.

According to Lohman et al (2010), up to 70% of cancer patients suffer from pain and from pain caused by their disease or its treatment. In this study, most of the respondents believed their pain was due to primary treatment. The same trend was reported by Vuorinen (1993) and Carr et al, (2002) who, in a study conducted in Finland, found only a little data existed on the prevalence of pain at the early stages of the disease and on pain as the first symptom of cancer, while Banning et al. (1991) and Parala-Metz and Davis (2013), in a study conducted in Denmark, found that 52% of respondents were of the opinion their pain was caused by tumour growth, 38% believed it was caused by treatment and 11% believed it was unrelated to cancer. In this study, the results indicate that 10.7% believed it was due to the effects of treatment, 67.9% from primary disease and 6% from medical conditions unrelated to the primary disease. Other estimations range from 40% to 100% in those with uterine, cervical or ovarian cancers and this lack of accurate prevalence scoring is surprising given gynaecological malignancies are a common cause of cancer with treatment strategies strongly associated with pain (Fitzggibbon et al, 2001; Statistical Information Team, Cancer Research, UK, 2011).

It was interesting to find the pain the respondents experienced interfered mainly with their general activities. What is positive is the fact their ability to walk and their relations with other people became less affected as time went by. The study by Carter et al. (2005); Pasek et al. (2012) found that female cancer survivors suffer changes in their emotions and relationships after treatment. The study supports the findings of that emotional function was better after treatment than at the initiation of radiotherapy treatment.

5.3 JUSTIFICATION

The study will be justified in terms of the purpose and objectives. As stated in Chapter 1, the purpose of the study was to explore the level and characteristics of pain women treated for cervical cancer, at an academic hospital in Gauteng, experience before and after receiving treatment. The objectives of the study were to explore the level and characteristics of the pain women experience before treatment, at six months after treatment and at twelve months after treatment for cervical cancer and to describe the pattern of pain over the specific period. In Chapter 3, the researcher described the research design and methods selected for the study.

Chapter 4 presented the results of the study and comparisons between the groups were made. It can therefore be stated that the study is justified as the study fulfilled its purpose and objectives.

5.4 LIMITATIONS

The researcher selected a cross sectional research design for this study and collected data from three groups of women at different times in the trajectory of their disease. This did not reflect the pain pattern of the same group of women and a longitudinal design could have resulted in more accurate findings. However, the researcher believes this study provides baseline data in terms of pain in cervical cancer patients from before diagnosis, to twelve months after treatment.

5.5 RECOMMENDATIONS

Pain management should start with a thorough assessment and meticulous documentation of the findings when patients present to the radiotherapy department. Thereafter pain should be assessed and documented at least 12 hourly by nurses, other health care professionals or the patients. The WHO step ladder should be used when prescribing pain medication. Patients should also be educated about the WHO pain step ladder, the medication suitable for their level of pain and the importance of taking the medication by the clock. The use of physical therapies and psychological approaches used in the management of cancer pain can also be explored. A longitudinal study can be done to provide more accurate information about the pain patterns experienced by women living with cervical cancer.

5.6 CONCLUSION

Cervical cancer patients presents with pain that interfere with normal life and relationship with other people compromising with quality of life. Although, pain in cancer patients is experienced more before cancer treatment, this study has shown that cancer treatment helps reduce the intensity of pain and helps patients to lead a normal life after treatment. In addition, Pain medication reduces pain severity in more than 90% cancer patient therefore assessment of pain is cardinal in cancer patients in order to promote pain free life.

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APPENDICES

APPENDIX A

Information Sheet

STUDY NUMBER: 604054

STUDY TITLE: AN EXPLORATION INTO THE LEVEL AND CHARACTERISTICS OF PAIN EXPERIENCED BY WOMEN TREATED FOR CERVICAL CANCER

SPONSOR: MINISTRY OF HEALTH (ZAMBIA)

INVESTIGATOR: ILIPO KAILA

INSTITUTION: CHARLOTTE MAXEKE AN ACADEMIC HOSPITAL IN JOHANNESBURG.

DAYTIME AND AFTER HOURS: DAYTIME

TELEPHONE NUMBER(S): +270840610622

Dear Madam

Good day! My name is Ilipo Kaila and I am currently registered as a student at the University of the Witwatersrand in the Department of Nursing Education. I would like to invite you to consider participating in a research study, entitled An Exploration into the Level and Characteristics of Pain Experienced by Women Treated for Cervical Cancer. Before you agree to participate, you should fully understand the following explanation of the purpose of study, benefits, risk, discomforts, and your right to withdraw from the study. This information leaflet is to help you decide if you would like to participate and you need to understand what is involved before you agree to take part in this study. If you have any questions, do not hesitate to ask me. You will be asked to sign this document to confirm that you understand the study and agree to participate. You will be given a copy to keep.

If you have a personal doctor, please discuss with or inform him/her of your possible participation in this study.

PURPOSE OF THE STUDY

You have been diagnosed as suffering from cervical cancer and I would like you to consider taking part in the research of pain assessment. The purpose of the study is to explore the levels and characteristics of pain women treated for cervical cancer at an academic hospital in Gauteng experience before and after treatment.

RESTRICTIONS CONCERNING PARTICIPATION IN THIS STUDY

The study will be performed in South Africa at an Academic Hospital in Johannesburg at an oncology unit. In order for you to participate in this study, you must be between the ages18 years and above, being treated for cervical cancer with curative intent and sign a consent form which is a legal document that you have voluntarily agreed to participate in this study. I will interview you using a questionnaire and tick and write down what you tell me and this will take about 15 minutes of your time.

BENEFITS FROM THE STUDY

By taking part in this study you will help me find out the level and characteristics of pain experienced when treated for cervical cancer and does pain decrease after treatment?

This would help to look for ways to assist women with this illness. There are no benefits for you personally. However, you may not benefit from this study.
Your participation in this study will contribute to medical knowledge that may help other patients that are like you, and have similar problem you are facing.

RISKS INVOLVED IN THIS STUDY

You might become sad when writing about your illness. Unfortunately this is the only way that I can find out what the illness is doing to you and your life. If you are upset I will be able to refer you to an oncology nurse experienced in counseling to give you some assurance about your illness and the treatment you are undergoing.

RIGHTS AS A PARTICIPANT IN THIS STUDY

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time even during the interview without stating any reason. Your withdrawal will not affect your access to other medical care. Once I have written what you have answered and your questionnaire has been put together with other questionnaires, this means I cannot retrieve your questionnaire as I also would not know which information is yours and which information has been given to me by another person.

HOW WILL CONFIDENTIALITY AND ANONYMITY BE ENSURED FOR THE STUDY?

I will do my best to keep all personal information confidential but absolute confidentiality cannot be guaranteed. Personal information may be made known if the law says do, research records may be inspected look at the quality and the Research Ethics Committee can inspect how I analyzed what you told me. Other people would however not know that this is what you said as the questionnaire and data sheet will be coded. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

Any information uncovered regarding your state of health as a result of your participation in this study will be held in strict confidence. The only exception to this rule will be cases of communicable diseases where a legal duty of notification of the Department of Health exists. In this case, you will be informed of my intent to disclose such information to the authorised state agency.

NOTIFICATION OPTION:

Please indicate below, whether you want me to notify your personal doctor or your specialist of your participation in this study:

- YES, I want you to inform my personal doctor / specialist of my participation in this study.
- NO, I do not want you to inform my personal doctor / specialist of my participation in this study.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

Before asking you to take part in the study, this clinical study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee. If you would like more information about the ethical permission of the study or would like to report or complain about how the study was done, please contact Prof Peter Cleaton-Jones. His telephone number is 011 717 2301 during office hours and his e-mail address is Peter.Cleaton-Jones@wits.ac.za.
Thank you for taking the time to think of joining the study. If you have any further questions, please contact me.

Yours sincerely,

Ilipo Kaila

Cell phone: **+270840610622**

APPENDIX B

13.2 INFORMED CONSENT

AN EXPLORATION INTO THE LEVEL AND CHARACTERISTICS OF PAIN EXPERIENCED BY WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN JOHANNESBURG.

I confirm that I have been informed by the investigator about the nature, conduct, benefits and risks of the study. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the study.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.

In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher

I may, at any stage, without prejudice, withdraw my consent and participation in the study.

I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant' signature _____ Date _____

I Ilipo Kaila herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Investigator's name _____ (Please print)

Investigator's signature _____ Date _____

The Brief Pain Inventory

PROTOCOL # _____ INSTITUTION _____

PATIENT SEQUENCE # _____ HOSPITAL CHART # _____

DO NOT WRITE ABOVE THIS LINE

Brief Pain Inventory

Date: ___/___/___

Name: _____ _____ _____

Last First Middle Initial

Phone: (___)_____ Sex: ☐ Female ☐ Male

Date of Birth: ___/___/___

1) Marital Status (at present)

1. ☐ Single
2. ☐ Married
3. ☐ Widowed
4. ☐ Separated/Divorced

2) Education (Circle only the highest grade or degree completed)

Grade	0	1	2	3	4	5	6	7	8	9
	10	11	12	13	14	15	16	M.A./M.S.		

Professional degree (please specify) _____

3) Current occupation _____

(specify titles; if you are not working, tell us your previous occupation)

4) Spouse's occupation _____

5) Which of the following best describes your current job status?

1. ☐ Employed outside the home, full-time
2. ☐ Employed outside the home, part-time
3. ☐ Homemaker
4. ☐ Retired
5. ☐ Unemployed
6. ☐ Other

6) How long has it been since you first learned your diagnosis? _____ months

7) Have you ever had pain due to your present disease?

1. ☐ Yes
2. ☐ No
3. ☐ Uncertain

8) When you first received your diagnosis, was pain one of your symptoms?

1. ☐ Yes 2. ☐ No 3. ☐ Uncertain

9) Have you had surgery in the past month? 1. ☐ Yes 2. ☐ No

If YES, what kind? _____

10) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, toothaches). Have you had pain other than these everyday kinds of pain during the last week?

1. ☐ Yes 2. ☐ No

10a) Did you take pain medications in the last 7 days?

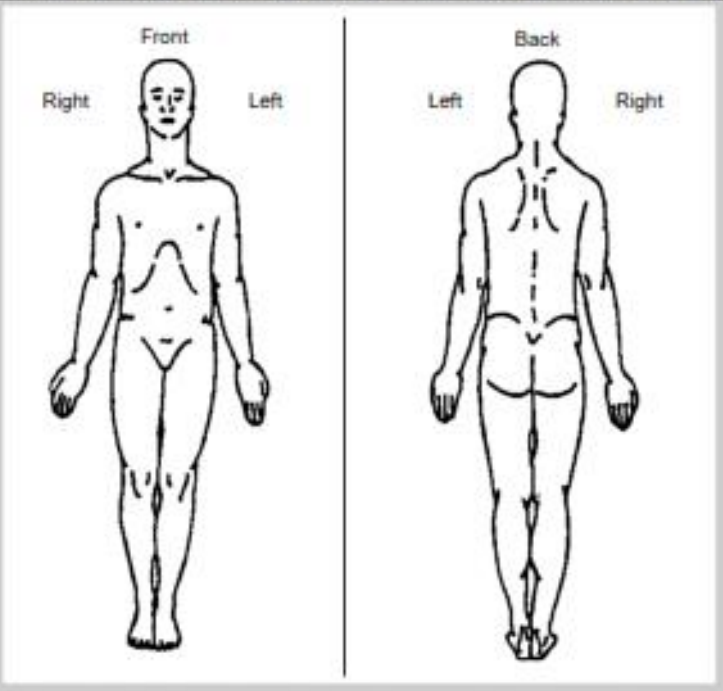
1. ☐ Yes 2. ☐ No

10b) I feel I have some form of pain now that requires medication each and every day.

1. ☐ Yes 2. ☐ No

IF YOUR ANSWERS TO 10, 10a, AND 10b WERE ALL NO, PLEASE STOP HERE AND GO TO THE LAST PAGE OF THE QUESTIONNAIRE AND SIGN WHERE INDICATED ON THE BOTTOM OF THE PAGE.
IF ANY OF YOUR ANSWERS TO 10, 10a, AND 10b WERE YES, PLEASE CONTINUE.

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



12) Please rate your pain by circling the one number that best describes your pain at its worst in the last week.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

13) Please rate your pain by circling the one number that best describes your pain at its least in the last week.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

14) Please rate your pain by circling the one number that best describes your pain on the average.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

15) Please rate your pain by circling the one number that tells how much pain you have right now.

0 1 2 3 4 5 6 7 8 9 10
No Pain — Pain as bad as you can imagine

16) What kinds of things make your pain feel better (for example, heat, medicine, rest)?

_____

_____

17) What kinds of things make your pain worse (for example, walking, standing, lifting)?

_____

_____

18) What treatments or medications are you receiving for pain?

_____

_____

19) In the last week, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Relief — Complete Relief

20) If you take pain medication, how many hours does it take before the pain returns?

1. ☐ Pain medication doesn't help at all
2. ☐ One hour
3. ☐ Two hours
4. ☐ Three hours
5. ☐ Four hours
6. ☐ Five to twelve hours
7. ☐ More than twelve hours
8. ☐ I do not take pain medication

21) Check the appropriate answer for each item.
I believe my pain is due to:

☐ Yes ☐ No 1. The effects of treatment (for example, medication, surgery, radiation, prosthetic device).
☐ Yes ☐ No 2. My primary disease (meaning the disease currently being treated and evaluated).
☐ Yes ☐ No 3. A medical condition unrelated to my primary disease (for example, arthritis).
Please describe condition: _____

22) For each of the following words, check Yes or No if that adjective applies to your pain.

Aching	☐ Yes	☐ No
Throbbing	☐ Yes	☐ No
Shooting	☐ Yes	☐ No
Stabbing	☐ Yes	☐ No
Gnawing	☐ Yes	☐ No
Sharp	☐ Yes	☐ No
Tender	☐ Yes	☐ No
Burning	☐ Yes	☐ No
Exhausting	☐ Yes	☐ No
Tiring	☐ Yes	☐ No
Penetrating	☐ Yes	☐ No
Nagging	☐ Yes	☐ No
Numb	☐ Yes	☐ No
Miserable	☐ Yes	☐ No
Unbearable	☐ Yes	☐ No

23) Circle the one number that describes how, during the past week, 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

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

24) I prefer to take my pain medicine:

1. ☐ On a regular basis
2. ☐ Only when necessary
3. ☐ Do not take pain medicine

25) I take my pain medicine (in a 24 hour period):

1. ☐ Not every day
2. ☐ 1 to 2 times per day
3. ☐ 3 to 4 times per day
4. ☐ 5 to 6 times per day
5. ☐ More than 6 times per day

26) Do you feel you need a stronger type of pain medication?

1. ☐ Yes 2. ☐ No 3. ☐ Uncertain

27) Do you feel you need to take more of the pain medication than your doctor has prescribed?

1. ☐ Yes 2. ☐ No 3. ☐ Uncertain

28) Are you concerned that you use too much pain medication?

1. ☐ Yes 2. ☐ No 3. ☐ Uncertain

If Yes, why? _____

_____

29) Are you having problems with side effects from your pain medication?

1. ☐ Yes 2. ☐ No

Which side effects? _____

30) Do you feel you need to receive further information about your pain medication?

1. ☐ Yes 2. ☐ No

31) Other methods I use to relieve my pain include: (Please check all that apply)

Warm compresses ☐ Cold compresses ☐ Relaxation techniques ☐

Distraction ☐ Biofeedback ☐ Hypnosis ☐

Other ☐ Please specify _____

32) Medications not prescribed by my doctor that I take for pain are:

_____

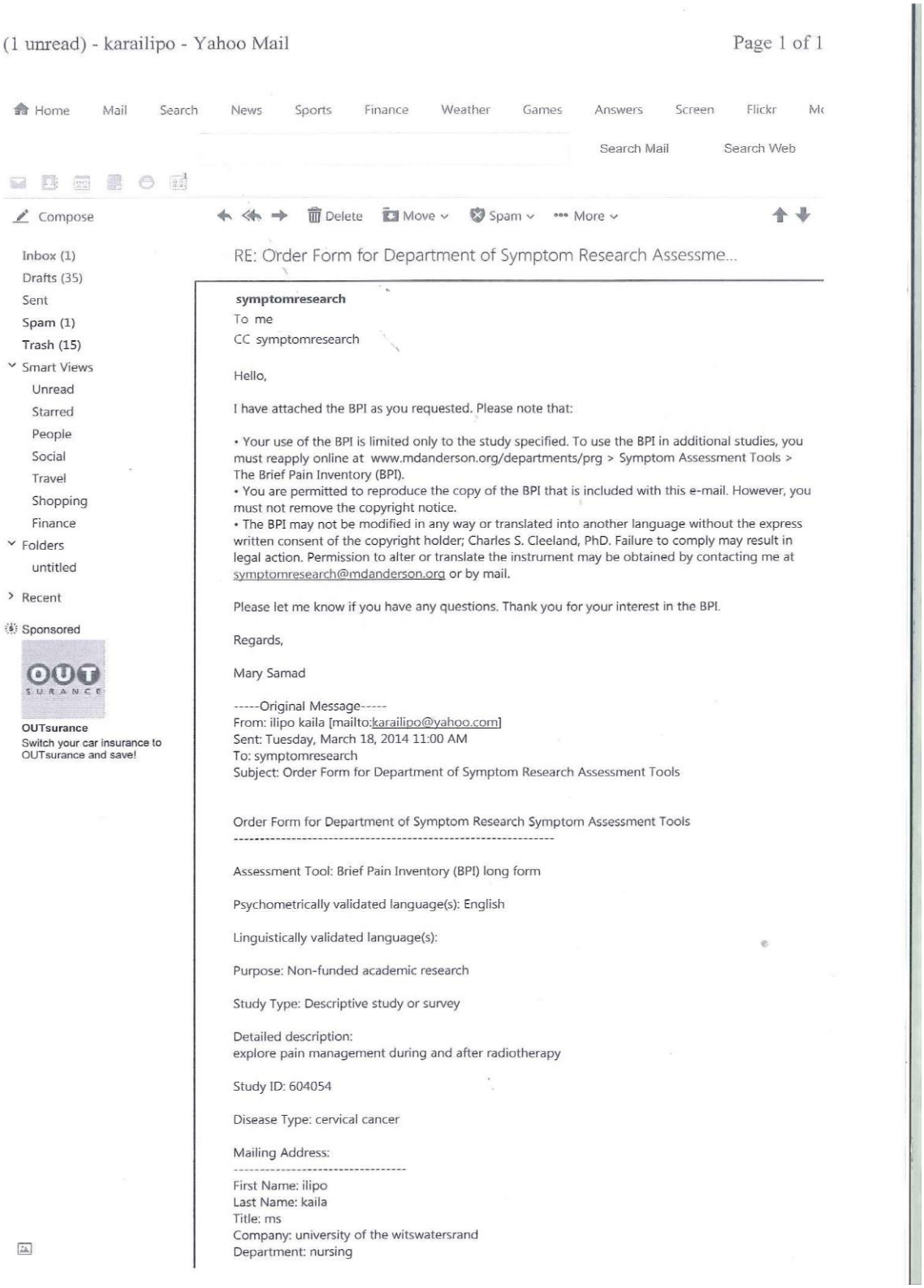
_____

Please sign the back of this questionnaire.

Patient's Signature

Thank you for your participation.

APPENDIX D



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Inbox (1)
Drafts (35)
Sent
Spam (1)
Trash (15)
Smart Views
Unread
Starred
People
Social
Travel
Shopping
Finance
Folders
untitled
Recent
Sponsored

OUTsurance
Switch your car insurance to OUTsurance and save!

RE: Order Form for Department of Symptom Research Assessme...

symptomresearch
To me
CC symptomresearch

Hello,

I have attached the BPI as you requested. Please note that:

• Your use of the BPI is limited only to the study specified. To use the BPI in additional studies, you must reapply online at www.mdanderson.org/departments/prg > Symptom Assessment Tools > The Brief Pain Inventory (BPI).
• You are permitted to reproduce the copy of the BPI that is included with this e-mail. However, you must not remove the copyright notice.
• The BPI may not be modified in any way or translated into another language without the express written consent of the copyright holder; Charles S. Cleeland, PhD. Failure to comply may result in legal action. Permission to alter or translate the instrument may be obtained by contacting me at symptomresearch@mdanderson.org or by mail.

Please let me know if you have any questions. Thank you for your interest in the BPI.

Regards,

Mary Samad

-----Original Message-----
From: ilipo kaila [mailto:karailipo@yahoo.com]
Sent: Tuesday, March 18, 2014 11:00 AM
To: symptomresearch
Subject: Order Form for Department of Symptom Research Assessment Tools

Order Form for Department of Symptom Research Symptom Assessment Tools
---

Assessment Tool: Brief Pain Inventory (BPI) long form

Psychometrically validated language(s): English

Linguistically validated language(s):

Purpose: Non-funded academic research

Study Type: Descriptive study or survey

Detailed description:
explore pain management during and after radiotherapy

Study ID: 604054

Disease Type: cervical cancer

Mailing Address:

First Name: ilipo
Last Name: kaila
Title: ms
Company: university of the witswatersrand
Department: nursing

APPENDIX E

Date: .....

University of the Witwatersrand

Faculty of Health Sciences

Ethics committee
7 York Road

Parktown 2193

Dear sir/madam,

REF: APPLICATION FOR ETHICAL APPROVAL FOR PROPOSED RESEARCH INVOLVING HUMAN RESPONDENTS

Request is made to the above subject

I hereby request for your approval to conduct a study entitled **"AN EXPLORATION INTO THE LEVEL AND CHARACTERISTICS OF PAIN EXPERIENCED BY WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN JOHANNESBURG*".***

This study will provide base line evidence for designing and testing interventions to improve patient outcomes by means of evidence-based nursing practice.

A Copy of the research proposal is attached for your perusal. Your consideration is highly appreciated.

Yours faithfully

.....

Ms Ilipo Kaila.

APPENDIX F

University of the Witwatersrand

Faculty of Health Sciences

Department of Nursing Education

7 York Road

Parktown 2193

The Chief Executive Officer, the Nursing Manager and the Unit Manager

Academic Hospital

Parktown 2193

Johannesburg

Dear Sir/Madam,

RE: PERMISSION TO CONDUCT RESEARCH AT THE ONCOLOGY DEPARTMENT

I am Ilipo kaila, a student at the University of the Witwatersrand, Johannesburg. I am currently registered for Master of Science in Nursing Oncology in the Department of Nursing Education. I am hereby asking for permission to undertake a research study at the Johannesburg Academic Hospital. My research study is on: **"AN EXPLORATION INTO THE LEVEL AND CHARACTERISTICS OF PAIN EXPERIENCED BY WOMEN TREATED FOR CERVICAL CANCER AT AN ACADEMIC HOSPITAL IN JOHANNESBURG*".***

The purpose of the study is to explore the level and characteristics of pain women treated for cervical cancer experience and whether it decreases after treatment. The study aims to explore the level and characteristics of the pain women experience during treatment for cervical cancer and to compare the findings with the level and characteristics of pain experienced before treatment, six and 12 months after treatment.

Participation to this study is completely voluntary and confidential. The respondents name will not appear anywhere and only code numbers will be used. The respondents are free to withdraw from the study at any time if they so wish without any negative consequence to their

care. An informed written consent will be obtained from all patients to be included in the study. I hope to conduct this study in the Oncology department where women come for treatment and follow up care after radiotherapy treatment.

The name of the participating Hospital and patients involved will not be divulged in the research report. Ethical clearance will be sought from the Human Research Ethics Committee of the University of the Witwatersrand. Find the attached copy of my research proposal.

Thanking you in advance for allowing me to conduct the study. Your permission is valuable and highly appreciated.

Yours faithfully

Ilipo Kaila (MSc Nursing Student)

Date……..

APPENDIX G

M14/49 Ms Llipo Kaila

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150455

NAME: (Principal Investigator)	Ms Llipo Kaila
DEPARTMENT:	Nursing Education Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	An Exploration into the Level and Characteristics of Pain Experienced by Women Treated for Cervical at an Academic Hospital in Johanesburg
DATE CONSIDERED:	24/04/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Liza Maree
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	29/05/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

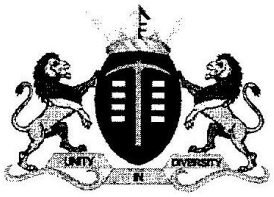
To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.**

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX H



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. G. Ngwenya
Office of the Nursing Director
Tell: (011): 488-4558
Fax: (011): 488-3786
05 JUNE 2015

Ms. Llipo Kalia
Department of Nursing Education
University of Witwatersrand

Dear Llipo Kalia

RE: "An exploration into the Level and Characteristics of Pain Experienced by Women Treated for Cervical Cancer at an Academic Hospital in Johannesburg"

Please note that permission to conduct the above mentioned study is provisional approved. Your study can only commence once ethics approval and supporting letter from Head of Department is obtained. Please forward a copy of your ethics clearance certificate as soon as the study is approved by the ethics committee for the CEO's office to give you the final approval to conduct the study.

Supported / not supported

Ms. M.M Pule
Nursing Director
DATE: 05/06/2015

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 08/06/2015