THE DEVELOPMENT AND VALIDATION OF A QUALITY OF LIFE ASSESSMENT INSTRUMENT FOR CANCER PATIENTS IN SOUTH-AFRICA

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A thesis submitted to the Faculty of Health Sciences. University of the Witwatersrand, Johannesburg, in fulfillment of the requirements for the degree of Doctor of Philosophy

Johannesburg, 2016

DECLARATION

I, Jacoba Johanna Maria Jansen van Rensburg declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signed: _____

June 2016

DEDICATION

This study is dedicated to my Heavenly Father for making this study possible, to my dear

husband Eugéne for his love and support

and to my supervisors and friends,

Professor Lize Maree and Professor Daleen Casteleijn.

ABSTRACT

Background: Quality of life (QoL) of cancer patients has been well researched, but not necessarily from the perspective of the patient and not in third world countries. Total care of cancer patients should encompass all aspects of the person, such as physical-, psychological- and social aspects, existential wellbeing and spirituality, in order to ensure optimal QoL. The purpose of the study was to explore QoL from the perspective of the cancer patient who accesses public health care services in South Africa for treatment and to develop and validate an appropriate patient-directed assessment instrument.

Method: The study was conducted in two phases. In Phase 1 assessment of QoL was done by means of in-depth qualitative interviews. Open coding and template analysis was conducted \during data analysis and the applicable domains of QoL were identified. In Phase 2 an appropriate QoL assessment instrument was developed for cancer patients in South Africa. The Rasch Measurement Model was utilized for the validation of the instrument.

Results: The domains of QoL identified by the cancer patients were: physical, psychosocial, financial, spiritual, existential and emotional. When compared with the domains included in available QoL assessment instruments such as the World Health Organization Quality of Life Instrument (shortened version) (WHOQOL-BREF), the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy General (FACT-G), the domains identified by cancer patients in South Africa were not fully addressed by these instruments.

Significance of results: Culture, psychosocial status, financial aspects and spirituality play a major role in QoL of South African patients, as indicated by this study as well as a previous study on QoL of palliative patients from a resource-poor community in South Africa. These aspects of QoL are not addressed by the most commonly used assessment instruments. The importance of the utilization of an instrument which addresses all the appropriate domains of QoL is highlighted by the study.

ACKNOWLEDGEMENTS

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ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ANOVA	Analysis of variance
CANSA	Cancer Association of South Africa
CaSUN	Cancer Survivors' Unmet Needs questionnaire
DIF	Differential item functioning
EORTC QLQ-C30	The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire
EORTC QLQ-BN20	The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for brain cancer patients
FACIT	Functional Assessment of Chronic Illness Therapy questionnaire
FACT-Cx	Functional Assessment of Cancer Therapy for Cervical cancer
FACT-G	Functional Assessment of Cancer Therapy – General
FACT-Lym	Functional Assessment of Cancer Therapy for Non-Hodgkin's Lymphoma
FACT-O	Functional Assessment of Cancer Therapy for Ovarian cancer
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HRQOL	Health-related quality of life
ICC	Item characteristic curve
INCTR	International Network for Cancer Treatment and Research
MVQOLI	Missoula-Vitas Quality of Life Index
PSA	Prostatic Serum Antigen
PSI	Person separation index
QoL	Quality of Life
RMM	Rasch Measurement Model
UK	United Kingdom
USA	United States of America

| WHO | World Health Organization |
| WHOQOL-BREF | World Health Organization Quality of Life instrument shortened version |

CHAPTER 1

ORIENTATION TO THE STUDY

1.1   BACKGROUND AND RATIONALE OF THE STUDY

Quality of life (QoL) of cancer patients has been well researched, but not necessarily from the perspective of resource poor cancer patients living in developing countries. It could be argued, that international literature can inform health care professionals caring for cancer patients; however South Africa faces unique health care challenges in terms of resources, access to care and late presentation with cancer. This study focused on the QoL of cancer patients accessing the public health care system in South Africa and aimed to add to the body of knowledge of cancer care in its attempt to develop and validate a patient-directed QoL instrument, which would be a first for South Africa.

Cancer is a major health problem worldwide and affects people of all ages and walks of life. During 2012, 32.6 million people were living with cancer and 8.2 million people died of cancer worldwide. According to the 2012 Globocan statistics, 57% of people newly diagnosed with cancer and 65% of cancer deaths occur in less developed regions annually (WHO, 2012). Cancer is one of the major causes of death in developed and less developed countries, including South Africa (CANSA, 2014a). Sixty thousand people newly diagnosed with cancer were reported in South Africa in 2008 (NHLS, 2008).

Cancer care involves various treatment modalities, depending on the stage of disease. Irrespective of whether the goal of treatment is cure, control of disease or palliation, patients need to be supported through the cancer experience to ensure the best QoL possible for the patient and family. QoL is a broad, complex and highly individual concept and involves the total assessment of all aspects of daily life (Bennett and Closs, 2008). People's QoL is influenced by their perceptions of their position in life in terms of their culture, value systems, personal goals and expectations (Diehr et al., 2007). QoL can also be described as the difference between the

hopes and expectations of an individual and what the person is experiencing at present. Expectations regarding QoL differ according to age and stage in the life cycle (Mitchell, 2001).

South Africa hosts two health care systems: a private and public system. The public health sector delivers services to approximately 80% of the population. Public health care supports a district health care approach and follows a hierarchical referral system. The entrance point to public health care is the nurse-led primary health care clinics. Patients who cannot be managed at primary health care level are referred to district hospitals, while those patients needing specialised care, such as cancer care, are referred to tertiary hospitals. The system is not always followed and private patients also access health care at public hospitals, especially emergency care, which places a high burden on the hospital (Mojaki et al., 2011). The public health system, rendering health care which is free of cost, is under-resourced and the situation is worsened by the burden of diseases such as HIV/AIDS and TB (SouthAfrica.info, 2015). Sophisticated cancer treatment is available to patients in both the private and public health care systems in South Africa (Abratt and Vorobiof, 2003).

1.2   RESEARCH PROBLEM AND QUESTION

The research problem for the study focused on the QoL of cancer patients using public health services. In a previous South African study, exploring QoL from the perspective of resource poor palliative patients, it was found that QoL focused primarily on the ability to buy food and other basic commodities (Jansen van Rensburg et al., 2012). QoL however consists of more than basic needs and includes physical-, emotional-, social-, cognitive- and subjective dimensions (Mitera et al., 2010). The complexity of QoL and the assessment thereof is highlighted by a study by Maree and Jansen van Rensburg (2015), which suggests that QoL needs to be explored from the patient's perspective, as commonly used QoL instruments might, similar to palliative patients, not be suitable for South Africa's cancer patients. It was not known what QoL means to South African cancer patients who access public health care services for treatment and which domains of QoL would be included in an appropriate assessment instrument.

The research question is thus:

What does quality of life mean, from the perspective of cancer patients in South Africa who access public health care services for treatment and which domains of quality of life would be included in an appropriate quality of life assessment instrument?

1.3   PURPOSE AND AIMS OF THE STUDY

The purpose of the study was to develop an appropriate QoL assessment instrument for cancer patients in South Africa. The study aimed to explore QoL from the perspective of South African cancer patients who access public health services for treatment and to develop and validate a patient-directed assessment instrument for cancer patients in South Africa.

To fulfil the aims of the study, the study was conducted in two phases. In Phase 1, QoL was explored from the perspective of the cancer patient, while Phase 2 focused on the development, validation and pilot testing of the newly developed QoL assessment instrument.

1.4   RESEARCH METHODS

The study used mixed methods and was conducted in two phases in an academic hospital in Gauteng. In mixed methods research, both qualitative and quantitative approaches are followed and the integration of the data may involve philosophical assumptions. The use of this type of research may lead to a better understanding of the research problem (Cresswell, 2014). In this study quantitative findings were explained by means of qualitative probing. According to Polit and Beck (2008), some research questions require a mixed methods approach, especially in the social-, behavioural- and health sciences. There are several advantages to a mixed methods study, such as that the qualitative and quantitative approaches complement each other, it enhances the evidence base through triangulation and avoids the limitations of a single approach. Validity of findings is enhanced by multiple types of data which complement each other. A mixed method was chosen for this study to validate an instrument developed from data collected by means of qualitative interviews. Phase 1 used a qualitative approach, whilst

Phase 2 was quantitative. The research methods for each phase of the study will be summarised separately.

1.4.1 Phase 1: Exploring QoL from the perspective of the cancer patient who accesses public health services in South Africa

A qualitative exploratory design was selected for this phase of the study. The target population consisted of patients receiving treatment for cancer at an academic hospital in Gauteng Province, where both chemotherapy and radiation are administered. The inclusion criteria were: 18 years and older, receiving chemotherapy or radiation or both and willing to participate in the study. Purposive and convenience sampling selected the sample to include participants representing both male and female genders, different cancers and different cultural groups. Data saturation determined the sample size and the sample realised at 20, but two more interviews were conducted with patients with different cancers to confirm saturation. The data were gathered by means of qualitative interviews and analysed using Patton's (2002) method of open coding. Thereafter template analysis was done.

1.4.2 Phase 2: Development, validation and piloting of a Quality of Life Assessment Instrument for Cancer Patients in South Africa

QoL categories identified during the qualitative interviews were operationalised into questions and two questionnaires were developed for the assessment of QoL; one questionnaire contained 67 questions regarding what reduced QoL (Addendum G) and the other questionnaire comprised 50 questions about what improved QoL (Addendum H). Each questionnaire was completed by 50 respondents, but nine of the questionnaires were incomplete and had to be discarded. The setting and target population was the same as for Phase 1 of the study. Convenience and purposive sampling selected a sample of 100 (n=100) to pilot test the questionnaires. The responses were captured on two Excel spread sheets and subjected to the Rasch Measurement Model for validation. During the validation process, 50 of the questions in the two questionnaires were removed and some of the questions were rephrased for clarity purposes. The remaining 67 questions were combined into a new questionnaire determining what makes life good and what makes life hard (Addendum I), which

was again pilot tested using convenience and purposive sampling to recruit 200 respondents (n=200). One hundred and ninety nine (199) questionnaires were completed, 100 by patients receiving cancer treatment and 99 by patients seen for follow up six or twelve months after treatment. Of the 199 questionnaires, 195 were completed in full and were used for the validation of the instrument. The data were again captured on an Excel spread sheet and subjected to the Rasch Measurement Model.

1.5   OUTLINE OF THE STUDY

Chapter 1:   Orientation to the study

Chapter 2:   Literature review

Chapter 3:   Research methods of Phase 1

Chapter 4:   Findings and discussion of Phase 1

Chapter 5:   Research methods of Phase 2

Chapter 6:   Results and discussion of Phase 2

Chapter 7:   Justification, limitations and recommendations

1.6   SUMMARY

In Chapter 1, the reader was orientated to the study. A background was given for the study, the research problem and methods were discussed; and the outline for the study was presented. Chapter 2 will present the literature review.

CHAPTER 2

LITERATURE REVIEW

2.1   INTRODUCTION

Chapter 1 explained the background to the study and an overview was given of the research methods. In Chapter 2 a review of the literature will be presented. Cancer as a worldwide problem will be discussed, followed by a discussion of QoL and the measurement of QoL.

2.2   CANCER AS A WORLD WIDE HEALTH PROBLEM

According to the 2012 Globocan statistics, there were an estimated 14.1 million people newly diagnosed with cancer, 8.2 million people who died of cancer and 32.6 million people living with cancer within five years of their diagnosis in 2012 (WHO, 2012). More than 50% of the people newly diagnosed with cancer (57%), as well as the cancer deaths (65%), occurred in the less developed regions of the world. In addition, 48% of the population living with cancer within five years of their diagnosis lived in the less developed regions. More men than women were affected, as the overall standardised incidence rate of cancer in men was almost 25% higher than in women.

In sub-Saharan Africa, the incidence of cancer is expected to increase by more than 85% in 2030. This high incidence of cancer in sub-Saharan Africa is attributed to a lack of awareness of the cancer burden and the potential for prevention of cancer (Morhason-Bello et al., 2013). Tobacco, diet and infection, which are linked to an unhealthy life style, are three of the major causes of cancer. Tobacco use, responsible for more than 80% of lung cancer in men and 45% in women worldwide, is considered to be the world's most avoidable cause of cancer. Dietary factors such as a low intake of fresh fruits and vegetables, being overweight and living a sedentary life style increase the risk of developing various cancers such as breast- and colorectal cancers. In addition, chronic infections with certain viruses can cause cancer. For instance, the human papillomavirus (HPV), a sexually transmitted virus, can increase a woman's risk for cervical cancer 100 times, whilst infection with HIV leads to cancers such as Kaposi

sarcoma and lymphoma (CANSA, 2014b). The South African Cancer Association (CANSA) supports these statements and indicates that the high incidence of cancer in developing countries is aggravated by the high incidence of HIV, which increases the incidence of HIV-related cancers such as Kaposi sarcoma, cervical cancer and lymphoma. In South Africa, an estimated one in six men and one in seven women would develop cancer in their life time (health24, 2014). According to CANSA (2014a), cancer is increasing in South Africa and is currently the sixth most common cause of death.

Lung-, breast-, bowel- and prostate cancer are the most common cancers worldwide, of which lung cancer is the most common in male patients and causes the most cancer deaths worldwide. The majority of cancer deaths are caused by lung-, liver-, stomach- and bowel cancer (Cancer research UK, 2012). The top five cancers in men living in Africa are Kaposi's sarcoma, liver-, prostate- and oesophagus cancer and non-Hodgkin's lymphoma. In women living in Africa, the most common cancer is cervical cancer, followed by breast cancer, Kaposi's sarcoma, liver- and stomach cancer (Sitas et al., 2006). In South Africa, the five most prevalent cancers in men are prostate cancer, cancer of an unknown primary, lung-, colorectal- and oesophageal cancer, and in women breast- and cervical cancer, cancer of an unknown primary, colorectal cancer and Kaposi's sarcoma (CANSA, 2014a).

According to the International Network for Cancer Treatment and Research (INCTR) (2015), more patients in developing countries die from cancer than in developed countries, due to late presentation at diagnosis and treatment. Various studies have been conducted in sub-Saharan Africa and have found that up to 90% of women present with advanced breast cancer (Stage III and IV), large tumours with a median size of 10cm and obvious lymph node disease (Porter, 2009). The WHO (Mojaki et al., 2011) states most women in developing countries present with cervical cancer at an advanced stage and too late for effective treatment. A study by Forbes et al. (2014) showed that there is a high incidence of males with prostate cancer who present with symptoms at a late stage. It is also the experience of the researcher that black African males are very reluctant to seek help from health service providers, even when symptomatic.

Late presentation and diagnosis of cancer is also reported in the United Kingdom, which impacts negatively on survival rate and quality of life (Forbes et al., 2014). The following

reasons are given for delayed diagnosis of cancer: people who do not go for screening, insufficient cancer screening, inability to diagnose cancer or initiate treatment, ignoring of incidental findings, patients who do not recognise symptoms of cancer or do not seek healthcare when recognising symptoms. Studies in the UK confirmed that delayed diagnosis and treatment of cancer can be ascribed by patient delay, doctor delay – delay by the primary care practitioner and system delay – hospital- or secondary care delay. Reasons for patient delay have been described as interpretation of symptoms as common illnesses such as indigestion or colds, fear and anxiety related to the cancer diagnosis and fear of medical judgment. Socio-demographic factors which have an impact on late presentation are age – the higher the age, the less the knowledge of breast cancer risks and symptoms-, and cultural issues such as difficulty examining Muslim patients for breast cancer due to Islamic laws prohibiting exposure of a woman to a man other than her husband. Factors which contribute to delays by healthcare practitioners are misdiagnosis, a lack of examination, co-morbidity and patient characteristics, such as socio-economic status and gender – men delay seeking help more than women. Delays caused by the health system are long waiting times for tests, referrals and follow up visits. In children delays in diagnosis and treatment of cancer are attributed to misinterpretation of symptoms by parents and healthcare providers (National Patient Safety Agency, 2010).

People presenting with advanced cancer in the developing world face additional challenges to those of the developed world. Developing countries face further challenges such as a high burden of infectious disease such as HIV/AIDS and non-communicable diseases, poverty, insufficient government funding for health care and a shortage of health care professionals, especially trained in cancer care, resulting in a lack of sufficient resources for the diagnosis and treatment of cancer. Health care priorities in developing countries give preference to communicable diseases and treatment of non-communicable diseases is often not well structured (Maher et al., 2012). A shortage of surgeons skilled in cancer surgery, radiation oncologists and medical physicists, as well as radiation equipment and cytotoxic drugs, compounds the lack of effective cancer treatment offered to the patients in developing countries. Palliative care available to cancer patients is insufficient in many developing countries and health care providers are not trained in effective pain control (INCTR, 2015, CANSA, 2014b).

The incidence and severity of many cancers can be prevented or reduced by means of effective cancer screening programmes. For instance, in the United Kingdom screening is done for cervical-, breast- and colorectal cancer. Cervical screening is done by means of a Pap smear every three years for women between ages 26 and 49 and every five years in women 50 to 64 years old. In case of a result which shows a low-grade lesion, an HPV test is done and if the virus is present, a colposcopy is done. Women between ages 50 and 70 are screened for breast cancer by means of mammogram. Men and women between ages 60 and 74 are screened for bowel cancer by means of a home testing kit for faecal occult blood and if the test is positive a colonoscopy is done (NHS, 2015).

The American Cancer Society (2015) recommends screening for breast-, colorectal-, cervical-, lung- and prostate cancer. Women are advised to do mammograms annually from age 40 and to have a clinical breast examination every three years in their 20s and 30s and annually from age 40, whilst men aged 50 and older are advised to discuss testing for prostate cancer with their doctors and if they decide to be tested, have a PSA test.

In the United States of America, screening for colorectal cancer is done by means of sigmoidoscopy every five years, colonoscopy every 10 years, barium enema every five years or CT colonography every five years to detect cancer or polyps, or annual faecal occult blood test, faecal immunochemical test or stool DNA test every three years to detect cancer. The American Cancer Society recommends screening for cervical cancer from age 21, by means of Pap smear every three years from age 21-29 and a Pap smear and HPV test every five years at age 30 to 65 years. After age 65, testing is only done in case of previous positive results.

In the USA, screening for lung cancer by means of a CT scan of the chest is advocated in persons 55 to 74 years of age and who have been smoking a pack of cigarettes per day for 30 years or two packs per day for 15 years (American Cancer Society, 2015).

Unfortunately a lack of financial and infrastructure resources in developing countries often makes screening for even cervical cancer, by means of Pap smear, testing for HPV and colposcopy, impossible. The result is that more than 85% of cervical cancer deaths worldwide

occur in developing countries (Denny, 2015). Not having screening services is especially negative considering the fact that the incidence of cancer in sub-Saharan Africa is increasing rapidly and an 85% increase is expected by 2030. The problem is aggravated by a lack of awareness of the magnitude of the cancer burden and a lack of comprehension of the potential benefit of prevention of cancer. Morhason-Bello et al. (2013) recognise that collaboration is needed between countries, economies and professions to curb the rapidly increasing cancer burden.

The South African National Department of Health's strategic plan for the prevention of cancer focuses primarily on the prevention of cervical cancer. At present population-wide screening is not undertaken in South Africa. Apart from a policy on the prevention of cervical cancer which allows asymptomatic women three free of cost Pap smears at an interval of 10 years starting at the age of 30 (South African HPV Advisory Board, 2010), the Department supports community-based screening and referral systems for adequate and relevant patient care. In addition, the strategic plan includes vaccination of 9 and 10 year old girls against the HPV virus, which was introduced in 80% of the poorest schools in the country from February 2014. Other cancer prevention strategies include regulations for limiting of trans-fats and salt in foods, reduction of tobacco use by means of limiting advertising of smoking and restrictions on smoking areas, and elimination of infant feeding bottles containing bisphenol A (CANSA, 2014a).

Cervical cancer patients are often diagnosed and referred for treatment at such a late stage that only palliative care can be given, even though radiation, chemotherapy and surgery are available. Many of these patients are single parents and breadwinners, and in the prime of their lives. Even though cervical cancer is curable in the early stages, most of the patients in developing countries present too late for cure and with a very poor QoL (Maree et al., 2014).

Cancer can be treated with surgery, radiotherapy, chemotherapy, biotherapy or hormonal therapy or a combination of different treatments, depending on the stage of the disease. The stage of the disease also dictates the goal of treatment which is cure, control or palliation. Surgery is used for diagnosis, staging of tumours, cure and palliation and can be used in combination with chemotherapy, radiation and immunotherapy as part of a multidisciplinary treatment and for prophylaxis in case of genetic predisposition to certain cancers (Gillespie,

2011). Radiotherapy is used as primary treatment or in combination with chemotherapy, surgery and biotherapy and for cure, control of disease and palliation (Gosselin, 2011), whilst chemotherapy is used as sole treatment in cancers such as haematological cancer, as neoadjuvant treatment before surgery in advanced disease, or in combination with radiation therapy as a radiation sensitizer (Tortorice, 2011).

Each of the modalities of treatment has its own effects and side-effects, which may have a serious influence on the QoL of the patient and family. It is not only the treatment but also the cancer which has an effect on all aspects of a patient's and family's lives. It not only causes physical symptoms such as pain, fatigue and nausea and vomiting, but has an influence on mental and physical functioning, body image, psychological wellbeing, social- and financial aspects, roles and spiritual life (Ferrans, 2011).

Ineffective communication about the diagnosis and goal of treatment can lead to confusion, anxiety and a lack of trust in the health care team. In addition, experiencing symptoms of cancer and not knowing what is wrong can be very distressing. Unfortunately patients are not always told the truth about the diagnosis due to medical traditions, religious values and cultural issues. Less than 50% of cancer patients globally are informed of their cancer diagnosis (Constantini et al., 2009).

Communication problems can occur due to language barriers, educational level and cultural differences between the health care provider and the patient and family (Kristjanson, 2001). Patient preferences differ with regards to the communication of information about their prognosis, especially in advanced disease and in the palliative stage. The way in which information is communicated has an influence on the patient's satisfaction, which is influenced by culture and educational level (Hagerty et al., 2005, Maree et al., 2014). In addition, factors such as being symptomatic, expecting the news or detecting the cancer during routine screening, previous experience and knowledge of cancer and whether the experience was positive or negative, influence the impact of a cancer diagnosis (Howard and Chady, 2012). Effective communication of the cancer diagnosis and the treatment plan is important for quality of life of the patient and family.

2.3   QUALITY OF LIFE

2.3.1   Defining Quality of Life

QoL is a complex phenomenon defined in various ways. There is no consensus on the definition of QoL. Bennett and Closs (2008) describe QoL as a broad, complex and highly individual concept and the total assessment of all aspects of daily life, whilst the WHO (1997) defines QoL as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment" [p1]. The QoL of a person depends on the domains of QoL that the person considers as important (Theofilou, 2012). Ferrans and Hacker (2011) also acknowledge the multi-dimensionality of QoL and add that QoL is unique to the science and practice of nursing, as oncology nurses view patients from a holistic perspective throughout the trajectory of the cancer journey, including palliative care, end-of-life care and survivorship. QoL includes all aspects of life which are influenced by cancer and treatment, including physical symptoms and functioning-, mental-, social-, psychological- and spiritual aspects.

As defined by the WHO (1997), QoL is based on the individual's perception of his position in life. QoL does not only consist of objective indicators, such as income, living conditions and physical functioning, but also of subjective aspects such as the individual's perception of important life domains and his/her satisfaction with those domains (Uwimana, 2005).

Health-related quality of life (HRQOL) gives an indication of the health status of populations as well as the effectiveness of health systems (Romero et al., 2013). Cella et al., as quoted by Ding, Hu and Hallberg (2012), confirm that health-related QoL is both multi-dimensional and subjective and includes physical-, functional-, emotional- and social well-being. Dunn et al. (2013) confirm the multi-dimensionality of health-related QoL and include the social-, psychological- and physical domain. Personal beliefs and traditions have an important influence on perceptions of QoL. Ferrans and Hacker (2011) agree that aspects of QoL are unique to

certain cultures, whilst Zeng et al. (2010) confirm the importance of culture by explaining the difference between the Western and Chinese concepts of QoL. In the Western culture, being healthy and independent, psychological wellbeing and having social relationships mean good QoL, whilst the Chinese cancer survivors value normal life, a good work, happiness, material resources and family support as important for QoL.

South Africa is a religious country with all the cultural groups participating in religious activities (Countries and their culture forum, 2015). Being religious also has an effect on the experience of cancer and QoL, as supported by the findings of a study on quality of life of South African palliative patients living in a resource-poor community (Jansen van Rensburg, 2011).

Apart from culture, various other factors influence QoL. According to Diehr and colleagues (2007), value systems, personal goals and expectations have an influence on a person's QoL, which reflects a person's evaluation of extrinsic and intrinsic circumstances. How persons rate their QoL depends on their subjective values of positive and negative aspects of life and does not depend on the presence or absence of problems. Patients in the same situation and stage of the illness trajectory may rate their QoL differently, as QoL is not equivalent to health status, but rather subjective wellbeing (Cohen, 2006). Poverty plays a very important role in the QoL of cancer patients in sub-Saharan Africa and can be so overwhelming that QoL is determined by having food to eat and basic commodities, despite experiencing serious health problems (Jansen van Rensburg et al., 2012, Maree and Jansen van Rensburg, 2015).

2.3.2   Domains of QoL

As already mentioned, QoL consists of various domains or dimensions and authors differ in terms of these domains. Ferrans (2011), for instance, indicates QoL has four dimensions, health and physical functioning, social and economic, psychological/spiritual and family. Ferrans and Grant (Ferrans, 2011) agree with the four domains, but define them as the physical wellbeing and symptoms domain and the psychological-, social- and spiritual domains. Fitzsimmons and Middleton (2006) add to the domains by describing physical functioning, psychological/emotional-, cognitive-, social- and occupational domains, satisfaction with care

and global assessments, whilst Mitera et al. (2010) include physical-, emotional-, social-, cognitive- and subjective dimensions in QoL.

For the purpose of the study, the researcher summarised the various domains as: physical-, social-, emotional/psychological-, financial- and spiritual, with each being discussed separately.

2.3.2.1   Physical domain

Ferrans (2011) describes the physical domain as the health and functioning domain, which includes the following: the person's own health, whether the person experiences pain, has energy or a lack of energy and is fatigued, the ability to independently care for oneself, the ability to take care of family responsibilities, being useful to others, having worries and control over life, having the potential of living as long as you would like, having chances for a happy future, having a satisfactory sex life, having leisure time activities and having access to health care. Fitzsimmons and Middleton (2006) include mobility, self-care activities, activities of daily living such as household tasks, physical activity, symptoms of disease, and side-effects of treatment in the physical domain. Ferrell and Grant (Ferrans, 2011) include symptoms such as pain, fatigue, nausea, appetite and constipation, as well as sleep and rest and functional ability, and call the domain physical well-being and symptom domain.

2.3.2.2   Social domain

The social domain encompasses support, roles, friendship, family and feelings of belonging, as well as objective factors such as housing and education (Mandzuk and McMillan, 2005). Ferrans (2011) combines the social and economic domains and includes emotional support from friends, housing, neighbourhood, employment/unemployment, the ability to take care of financial needs and education in this domain. Ferrans (2011) also separates the social- and family domain and stresses the importance of relationships with the spouse, lover or partner, children and other family members, the health of the family and emotional support received from family members. Fitzsimmons and Middleton (2006) however separate the social domain from the occupational domain, which includes work activities and financial status. The social domain described by Ferrans (2011) includes the caregiver burden, roles, appearance, financial

burden and sexual functioning. Fitzsimmons and Middleton (2006) also include sexuality in the social domain and add the ability to carry out hobbies and interests and social isolation.

2.3.2.3   Emotional/psychological domain

Emotional wellbeing, spirituality, fulfilment, personal satisfaction and cognitive state are included in the psychological domain (Becker, 2007). Self-esteem and body image seem to be placed in various domains, as Fitzsimmons and Middleton (2006) place it in the psychological/emotional domain, whilst Ferrans (2011) considers it to be part of the social domain. In addition, Ferrell and Grant (Ferrans, 2011) and Fitzsimmons and Middleton (2006) combine the psychological- and emotional- in the psychological domain, including feelings of anxiety, depression, enjoyment, fear, happiness, satisfaction and coping. Ferrell and Grant (Ferrans, 2011) also separate the psychological and spiritual- domains, but in the conceptual model of Ferrans (2011), faith in God is included in the psychological/spiritual domain. Self-esteem and satisfaction with life is sometimes also included in the spiritual domain (Tsewat, 2006).

2.3.2.4   Financial domain

The financial aspect plays an important role in QoL, as illustrated by a previous study on QoL of palliative patients in a resource-poor community in South Africa (Jansen van Rensburg et al., 2012). Financial aspects such as the cost of travelling, loss of income, medical costs and the cost of a caregiver play a major role in QoL, especially in patients from resource-poor communities (Fitzsimmons and Middleton, 2006). Factors such as being employed are also seen to be part of the social/economic domain and Ferrell and Grant include financial burden in the social domain (Ferrans, 2011).

2.3.2.5   Spiritual domain

The spiritual domain is very important to some patients but not important to others and may have a positive or negative influence on QoL (Mandzuk and McMillan, 2005). The term "spirituality" may mean different things to different people and the term is often misused in

literature (Wein, 2014). From the literature, it appears that the terms spirituality and religion are used interchangeably and are linked. Spirituality can be described as a person's values and beliefs, what gives meaning and purpose to the person's life, a sense of identity or religion (Egan et al., 2011), but Wein (2014) is of the opinion that the definition is vague and that the concepts overlap. He distinguishes between spirituality and emotion and describes spirituality as an awareness of becoming one with something other than the self and involves a changed state of consciousness, which is different from an emotion. Tsewat (2006) associates psychological characteristics such as optimism, self-esteem and satisfaction with life with spirituality, and religion with religious practice. According to Ferrell and Grant (Ferrans, 2011), religiosity is included in the spiritual domain, as well as hopefulness, suffering, meaning of illness, transcendence and uncertainty, but in the conceptual model of Ferrans, faith in God is included in the psychological/spiritual domain. Maree et al. (2015) describe religion and hope as existential issues. Other existential issues which have an impact on health-related QoL are increased dependency, loss of hope, finding meaning in life and illness, concerns about death and unresolved guilt (Bele et al., 2012).

2.3.3   Defining the QoL domains for this study

As seen from the discussion above, there is no consensus about the domains of QoL, therefore the researcher defined the domains for the purpose of the study. The physical domain includes symptoms of disease and side-effects of treatment, physical functioning with regards to activities of daily living and the ability to take care of oneself and family members. The social domain encompasses personal relationships, fulfilment of roles, sexual functioning, objective factors such as housing and education and the ability to carry out hobbies and keep busy. The emotional/psychological domain includes adjustment to illness and coping, self-esteem, body image, satisfaction with life, depression, anxiety and adjustment to illness. The financial domain includes being employed and having an income, being able to provide basic necessities and having money for transport. The spiritual domain encompasses spirituality/religion and religious practices such as prayer and attending church services, as well as existential issues such as hope, finding meaning and purpose in life and accepting death as part of life.

2.4   MEASUREMENT OF QOL

The importance of measuring QoL has been emphasised by various authors. The assessment of QoL during clinical interviews can ensure that problem areas are addressed timeously and interventions are planned to improve QoL (WHO, 1997).

The importance of assessing QoL from the perspective of the patient is highlighted by a study conducted in South Africa, which revealed that the severity of problems as reported by cancer patients was different from the severity of problems as perceived by oncology nurses (Maree, 2011). Ferrans and Hacker, as well as Ferrell and Grant, developed conceptual models for QoL based on qualitative analysis of cancer patients' perspectives and stress the importance of assessing QoL from the perspective of the patient (Ferrans and Hacker, 2011). An understanding of the impact of cancer and treatment on QoL of the patient is important in nursing practice. When nurses and other clinicians understand different experiences of cancer and treatment, they are better equipped to assess the needs of the patient and family and care can be planned according to their expectations of treatment (Moore, 2007). Health care providers should realise that a patient's experience is influenced by context, timing and personal circumstances and frequent assessments of QoL should be carried out to identify problems timeously.

Measuring QoL has various advantages. Reasons for measuring QoL are: measurement of change during treatment, interaction between doctor and patient, assessment of benefits versus disadvantages of treatment, appraisal of the quality of health care services, research on the influence of diseases on QoL and the assessment of the effect of new policies on QoL of patients (WHO, 2005). Bele et al. (2012) agree that measurement of QoL can assess quality of health services and improve the relationship between the patient and health care providers, and state the assessment of health-related quality of life does not only provide information about mortality and morbidity, but also about the patient's experience, expectations and overall wellbeing.

QoL instruments can be described as objective means of measurement of patients' subjective experiences (Hodgson and Tannock, 2005), and include three types of QoL instruments: generic-, disease-specific-, and symptom-specific instruments. *Generic instruments* are used for

comparisons across broad categories of illnesses and assess general aspects of QoL. The Medical Outcomes Short Form 36- item Health Survey is an example of such an instrument (Zeng et al., 2010). *Disease-specific instruments* are intended for the utilisation for specific patient groups such as cancer patients and even patients with specific types of cancers (Zeng et al., 2010). The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy-General (FACT-G), for patients receiving treatment for cancer, are examples of disease-specific instruments (Khoshnevisan et al., 2012). *Symptom-specific instruments* are used for the measurement of symptoms and are used to determine the effect of illness and treatment on QoL. The McGill Pain Questionnaire and the Karnofsky Performance Index, which measures a patient's ability to take care of him/herself, are examples of these instruments (Hodgson and Tannock, 2005, Dunn et al., 2013, Mitchell, 2001).

QoL instruments usually consist of a series of items to be rated by the patient (Corner, 2008). For instance, the WHOQOL-BREF is a validated instrument which is a shorter version of the WHOQOL-100, which includes 100 questions, and comprises 26 items. The instrument was developed by health care providers in consultation with patients with different illnesses, well people and health professionals in 15 health centres around the world (WHO, 1997). This instrument is not cancer-specific, but assesses QoL from the perception of the patient within the context of his/her culture, value systems, personal goals, standards and concerns. The WHO's aim was to develop a QoL instrument which could be used internationally and in different cultures for the measurement of health, the effects of health care and the assessment of personal wellbeing and QoL (WHO, 1997).

QoL assessment instruments are also used to determine outcomes in cancer treatment, but not necessarily from the perspective of the patient's experience of treatment. In clinical trials the focus is on increasing the survival rate of cancer. Current QoL instruments, such as the Functional Assessment of Cancer Therapy-Cervix (FACT-Cx) used for patients receiving treatment for cervical cancer and the Cancer Survivors' Unmet Needs (CaSUN) used for cancer survivors, assess one or more of the following domains of QoL: physical-, functional-, emotional- and social wellbeing (Zeng et al., 2010). *Physical wellbeing* measures symptoms such as pain, nausea and vomiting, fatigue, the degree of experience of symptoms of disease, side-

effects of treatment and other physical problems. *Functional wellbeing* determines the ability of the patient to carry out activities of daily living, such as walking, eating, taking care of personal hygiene, working and taking part in social activities. *Emotional wellbeing* identifies emotional or psychological problems such as anxiety or depression, while *social wellbeing* assesses aspects of social support, such as family functioning, intimacy and sexual functioning (Corner, 2008). However, QoL instruments such as the Missoula-Vitas Quality of Life Index (MVQOLI) add existential items such as feeling disconnected, experiencing a sense of meaning and being prepared for death to the other domains, which includes the physical/symptoms, functional-and interpersonal wellbeing (Maree and Jansen van Rensburg, 2015).

QoL instruments also measure quality of survival after cancer treatment, such as late physical and psychological consequences of treatment, and can be applied to predict the duration of survival from cancer. Identification of problems experienced during or after treatment and the management thereof is very important for the enhancement of QoL of cancer patients. QoL instruments can also be utilised for comparing the effects of different treatments of cancer (Corner, 2008).

When selecting a measuring instrument, the health care provider should determine whether the instrument measures all aspects of QoL applicable to the patient, whether the instrument is validated for the population and setting of interest and whether the results obtained by the instrument are internally consistent and reproducible. The instrument should be sensitive enough to detect changes in QoL during the illness trajectory and should be easy to complete, score and analyse. When used for assessment of QoL of cancer patients, it is important to ensure that the completion of the assessment instrument does not place a high burden on a patient (Bennett and Closs, 2008). In addition, the importance of the cultural aspect in assessment of QoL of patients is stressed by Zeng et al. (2010), who suggest that if the available QoL instruments are not relevant for a population, an applicable instrument needs to be developed.

Various QoL instruments have been used in cancer care. The Functional Assessment of Chronic Illness Therapy (FACIT) has been claimed to be one of the most popular instruments used for cancer patients (Fitzsimmons and Middleton, 2006) and is a general multidimensional measure

of health-related quality of life (Lyons et al., 2009). The FACIT was previously known as the FACT-G, which was developed by Cella and colleagues (Ding et al., 2012), and consists of 27 general quality of life items. Domains included in the FACIT are: physical, social/family, emotional and functional wellbeing. The FACIT is usually combined with a disease-specific subscale such as the FACIT-Pal, which comprises 19 items, to measure quality of life of palliative patients. The domains of quality of life included in the FACIT-Pal are: physical, social, emotional and functioning (Lyons et al., 2009). Cancer-site specific sub-scales have also been developed, such as the FACT–Cx for cervical cancer and the FACT-O for ovarian cancer (Ding et al., 2012). The FACT-Lym was developed for assessing quality of life of Non-Hodgkin's lymphoma patients.

The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) is a generic, validated instrument for use in determining QoL in cancer patients. The instrument comprises 30 items, including five functional scales which measure physical-, role-, cognitive-, emotional- and social function; three symptom scales which rate fatigue, pain and nausea/vomiting; general health and QoL; single items assessing other symptoms specific to cancer patients such as dyspnoea, anorexia, insomnia, diarrhoea and constipation; as well as the financial impact of disease (Donahoe et al., 2011). As in the FACIT instruments, the EORTC QLQ is also combined with disease-specific subscales, such as the EORTC QLQ-BN20, which is a questionnaire used for brain cancer patients. The EORTC QLQ-BN20 comprises 20 items and four scales which test future uncertainty, visual disorder, motor function, communication deficit and seven symptoms: headaches, seizures, drowsiness, hair loss, itchy skin, weakness of the legs and bladder control (Khoshnevisan et al., 2012). The EORTC QLQ-Cx24 is suitable for use in cervical cancer patients (Zeng et al., 2010) and the EORTC QLQ-OES18 for patients with oesophageal cancer (Albers et al., 2010).

Established instruments for the measurement of QoL measure predetermined aspects of QoL. Corner (2008) warns that standardised QoL measures with fixed questions, which do not include a subjective aspect, may be appropriate for specific groups or specific domains, but not for the assessment of QoL in individuals, as patients do not necessarily regard specific aspects of QoL as equally important. Thus, QoL assessment instruments developed in first-world countries are not necessarily appropriate for cancer patients in third-world countries, such as sub-Saharan Africa. A patient's experience of a symptom such as pain is influenced by

psychological and social factors and is often very different from the objective assessment of a health care professional (Bennett and Closs, 2008). The subjective experience of QoL of the patient always needs to be taken into consideration, especially the cultural background of the patient. Combining an established instrument with a subjective assessment of QoL will result in a better understanding of the difficulties faced by individual patients (Corner, 2008).

2.5   SUMMARY

Chapter 2 presented the literature review. Cancer as a world-wide health problem was discussed, followed by a discussion of QoL and the measurement of QoL. In Chapter 3, the research methods will be presented.

CHAPTER 3

RESEARCH METHODS OF PHASE 1

3.1 INTRODUCTION

Chapter 2 presented a literature review. In Chapter 3, the research methods for Phase 1 of the study will be discussed. In Phase 1, QoL was explored from the perspective of cancer patients in South Africa who access public health care for treatment. The research setting will be discussed first, followed by the research design, the population, data gathering and data analysis will be explained and the principles followed to ensure trustworthiness and ethical research will be discussed.

3.2 RESEARCH SETTING

The setting, also referred to as the context, is critical for the understanding of the findings of qualitative research and implies the physical, geographic, temporal, historic, cultural and aesthetic aspects of the place where the research is conducted (Patton, 2002). Burns and Grove (2009) support Patton's description of the setting and its importance and add that climate, home, health care system and community setting, the social setting and individual variables are environmental factors that can have an influence on the outcomes of a study. The setting selected for the study was an academic hospital in the Gauteng Province in South Africa, which forms part of the public health services, providing cost-free health care services to patients in Gauteng and surrounding provinces. The health service provided by the hospital is funded by the Gauteng Department of Health, as well as a National Tertiary Services Grant. The hospital has 1088 beds, more than 4000 staff members and provides health services to people living in South Africa, as well as patients from outside South Africa. The hospital provides specialised services to cancer patients including surgery, radiotherapy and chemotherapy on an outpatient- and inpatient basis.

In addition, this hospital is the main teaching hospital for one of the universities in Johannesburg. Under- and post-graduate training is done in all areas of health professions. The

Department of Radiation Oncology offers external beam radiotherapy, brachytherapy and radio-chemotherapy to patients and treats more than 3500 patients per year (Wikipedia, 2015). Patients who make use of public health services are mostly from low income communities and do not have health insurance (SouthAfrica.info, 2015).

3.3   RESEARCH DESIGN

An exploratory qualitative design was selected for Phase 1 of the study. Exploratory work is done when no other studies have been done in the area of interest or no definite answer exists, despite previous studies on the topic. Exploratory research begins with a phenomenon of interest, of which the full nature and related factors are investigated (Polit and Beck, 2008, Begley, 2008). Qualitative research methods are used to find out what people do, know, think and feel by observing, interviewing and analysing documents (Patton, 2002; Cresswell, 2014). In qualitative research, the researcher focuses on aspects such as meaning, experience and understanding, and does not focus on specific concepts or his/her own interpretation of events and circumstances. Words are used rather than numbers and data are collected in the natural setting of participants. The qualitative researcher does not attempt to control the context of the research, but attempts to capture the context as a whole. Subjectivity is essential for the understanding of the human experience (Brink, 2006). In qualitative research data analysis is done inductively and meaning is generated from the data. The researcher interprets the data and themes emerge from the analysis (Cresswell, 2014). The researcher chose a qualitative exploratory design as it allowed her to conduct an in-depth exploration of what QoL means to cancer patients using holistic enquiry (Patton, 2002).

3.4   POPULATION AND SAMPLING

In this study, the population was cancer patients in South Africa who access public health services for treatment. The target population differs from the population and according to Polit and Beck (2008), is the total set of people about which the researcher would like to generalise the findings. The target population has to meet specific criteria, but may still be too large for a study. Therefore, due to time, money and personnel constraints, the accessible population, which is available and meets the criteria of the target population, is used (LoBiondo-Wood and

Haber, 2010). The target population for this study was cancer patients receiving chemotherapy, radiotherapy or both at a public health care facility in the Gauteng Province. Inclusion criteria for the accessible population were: 18 years and older, receiving radiotherapy, chemotherapy or both, and willing to participate in the study.

Sampling is the selection of a portion of the population to represent the population so that conclusions can be made about the population (Polit and Beck, 2008). In this study purposive and convenience sampling was used, which is a method which can be used by a researcher who has enough knowledge about the population to enable him/her to choose participants to be included in the sample. Purposive sampling is often used in qualitative research, where the researcher selects subjects who are typical of the population (LoBiondo-Wood and Haber, 2010). Convenience sampling implies choosing participants who are available on the days when data gathering takes place and meet the inclusion criteria. In this study, the researcher included participants who received anti-cancer treatment for different types of cancer, represented different cultural groups in South Africa, were of both male and female gender and lived in both rural and urban communities.

3.5   DATA GATHERING

Patients who attended the oncology clinics in the Department of Radiation Oncology were recruited to participate in the study. Twenty-six participants were recruited and two refused.

Qualitative interviews were used to gather the data, as qualitative interviews are the most effective way of obtaining information from participants about what they think, feel and believe (Quinne and Clare, 2008). In addition, qualitative interviews have the benefit of allowing the researcher to follow up on interesting topics emerging from the interview, as well as to ensure that all key areas are addressed. Demographic data were gathered first by means of a pre-interview questionnaire (Addendum A) and a topic guide (Addendum B) was used to guide the interviews. The findings of a previous study on QoL, from the perspective of palliative patients (Jansen van Rensburg, 2011), guided the researcher in compiling the topic guide.

Two initial questions were asked: *What makes life hard for you*? (Addendum G) and *What makes life good for you*? (Addendum H). Probes and prompting question were used to facilitate an in depth discussion, explore sensitive topics introduced by the participants and to clarify issues (Tong et al., 2007). The interviews were conducted by the researcher, who has been an oncology nurse for more than 10 years and has been practicing in the field of cancer and palliative care nursing for the past five years. In addition, the researcher had conducted interviews at the oncology clinics for research purposes prior to the current study and was able to establish a rapport with the participants. During the interviews, enough time was allowed for the researcher and participants to reflect on the issues raised. The input of the researcher is very important and the qualitative researcher is a research tool who, through reflexivity, is vital for the conduct of the research (Thompson and Baker, 2008). The interviews took place during February and March 2013.

The first interview was used as a pre-test, to determine whether the desired information could be obtained during the interview and whether the audiotape worked correctly. (The typed transcription of Interview 1 was included as Addendum J). The first participant was reluctant to talk and was asked to choose a pseudonym to ensure confidentiality. Choosing a pseudonym had the desired effect and encouraged the participant to talk about her experience freely. The rest of the participants were also asked to choose pseudonyms to facilitate in depth discussions. Data saturation was reached after 20 interviews and two more interviews were conducted to ensure redundancy. This implied that the same topics emerged during consecutive interviews, as saturation of data is achieved when further interviews yield no new information (Polit and Beck, 2008).

Data gathering was planned as follows:

Approval was obtained from the Department of Nursing Education, the School of Therapeutic Sciences Research Assessor Group and the Ethics Committee of the University of the Witwatersrand and the Department of Health of Gauteng. The Chief Executive Officer of the hospital where the study took place also approved the application to conduct the research (Addendum C).

Interpreters, who were conversant in English and African languages, were used to assist with language issues should they arise. A confidentiality agreement was signed by the interpreters before the interviews (Addendum D). Interpreters were used during two interviews. Before conducting an interview, the researcher introduced herself and allowed time for the participant to introduce him/herself, in order to establish a trusting relationship before posing the research questions. Informed consent was obtained before the interviews (Addendum E).

Consent was obtained for the use of a voice recorder during the interviews, which none of the participants refused. The researcher also made use of field notes during the interviews. Interviews were conducted in a private room, as arranged with the unit manager in charge of the clinics at the Department of Radiation Oncology, to ensure confidentiality and privacy. An hour was allocated for each interview. The researcher, who is an oncology nurse, conducted the interviews and only she and the participants, and where necessary an interpreter, were present during the interviews. Participants were reassured that they could stop the interview if they became emotionally or physically distressed and that the interview could be interrupted for a while or rescheduled. Arrangements were made for counselling, should a participant need counselling. None of the participants needed counselling during the interviews. The researcher emphasised the principle of confidentiality, by explaining that the participants' names would not appear on any forms, nor would they be mentioned in the research report.

3.6   DATA ANALYSIS

Data analysis was done concurrently with data gathering, in order to determine when data saturation occurred. The researcher transcribed each interview verbatim and used Patton's (2002) method of content analysis to analyse the data.

The data were analysed according to the two questions asked during the interview; factors which had a positive influence on QoL (what makes life good) and factors that had a negative influence on QoL (what makes life hard). During the analysis, the researcher read through the field notes and verbatim transcriptions of the interviews and made comments in the margin about concepts which emerged. The comments were organised into topics by looking at what was important and describing them. A new reading was done to start coding the data in a

systematic way. Several readings of the data were done for complete coding of field notes and interviews. Topics which fit together were sorted into themes and categories. The process was continued until no new categories emerged and until all sources of information had been exhausted. The data were co-coded by the two study supervisors and a meeting was held to discuss the themes and categories.

After the open coding, template analysis was done. Polit and Beck (2008) explain template analysis as a method where the researcher develops a template or guide to which narrative data are applied. The template was based on the domains of QoL outlined by the literature: physical-, psychological/emotional-, social-, financial-, spiritual- and existential factors.

3.7   TRUSTWORTHINESS

Trustworthiness confirmed the rigor of the study. Trustworthiness refers to the confidence which qualitative researchers have in their data, which is assessed by means of certain criteria (Polit and Beck, 2008). One way of ensuring trustworthiness is by means of narratives to display the richness of the data and the relationship between the themes and the quotes from the interviews (Streubert, 2010).

The four criteria of Lincoln and Guba for trustworthiness: credibility, dependability, transferability and confirmability, are still regarded as appropriate for ensuring rigor of qualitative research (Shenton, 2004, Barroso, 2010).

3.7.1   Credibility

Credibility involves conducting the study in a way which enhances the believability of the findings and taking steps to demonstrate credibility to external readers (Patton, 2002). Qualifications and experience of the researcher are relevant in establishing confidence in the data (Polit and Beck, 2008). Credibility in qualitative research can be compared to internal validity in quantitative research (Polit and Beck, 2008). As guided by Shenton (2004), credibility of the findings of the research was enhanced by using well established research methods, for instance during data gathering and data analysis, and through prolonged engagement between

the researcher and participants. This approach fostered a trusting relationship and understanding. Triangulation of data improves credibility of the research. Burns and Grove (2009) define triangulation as "the combined use of two or more theories, methods, data sources, investigators, or analysis methods in the study of the same phenomenon" [p231]. Triangulation of data implies the collection of data from multiple sources to capture different experiences of an event. Triangulation of investigator is achieved when more than one investigator with different expertise examine the same phenomenon. Analysis triangulation takes place when the researcher uses two or more analysis techniques (Burns and Grove, 2009). In this study data were collected from 22 participants treated for different cancers, who were of different genders, ages and cultural groups. Two methods and three investigators with different backgrounds analysed the data.

Shenton (2004) also adds that ways should be devised to ensure honesty in participants by not forcing anybody to participate in the study and encouraging participants to talk freely. In this study, honesty of responses by the participants was enhanced by giving participants the choice whether to participate in the study or not. Allowing participants to choose a pseudonym for the interview reassured them that they could talk freely and that their identities would not be disclosed. Participants were informed that they could withdraw from participating in the study without any negative consequences to them. During the interviews probing questions were used and questions were rephrased when answers were not sufficiently clear to elicit detailed and truthful data, as supported by Shenton (2004). Lincoln and Guba, as quoted by Shenton (2004), mention member checks as an important aspect in ensuring the accuracy of the data. Polit and Beck (2008) explain member checks as a method used to validate the credibility of qualitative data by means of discussing data with the participants. Although the transcribed interviews were not given to the participants to read, the researcher used questions such as "do I understand you correctly" during the interviews and summarised the interviews as member checks.

Thick description is another way of ensuring credibility and is defined by Polit and Beck (2008) as "a rich and thorough description of the research context in a qualitative study" [768]. The research setting was discussed in detail in the study.

Researcher credibility must be verifiable by other researchers in order to have faith in the credibility of the data, as qualitative researchers, according to Polit and Beck (2008), are "data collecting instruments and creators of the analytic process" [550]. The researcher is a post-graduate student who completed her Masters' degree in Nursing in 2011. Prolonged engagement in the field was achieved by the researcher being qualified as an oncology nurse since 2004 and having practiced in an oncology care setting for the past five years. The researcher became acquainted with the study population during previous data gathering at the oncology clinic as a research assistant in 2012.

Shenton (2004) suggests that credibility of the research can be enhanced further by frequent collaboration between the researcher and supervisors to widen the vision of the researcher and identify errors and biases. Frequent meetings took place between the researcher and her study supervisors to discuss the data analysis and findings. Peer review is also mentioned as a method to ensure credibility, as well as feedback given during presentation of the research at conferences. The research proposal was subjected to peer review, as both the members of the Department of Nursing Education as well as the PhD Assessors Committee of the Faculty of Health Sciences critiqued and approved the proposal. The research was presented at an oncology conference and feedback was received.

3.7.2   Dependability

Dependability of research refers to stability and reliability of data over time, comparable to reliability of quantitative research, to ensure integrity in qualitative research (Polit and Beck, 2008). According to Shenton (2004) dependability can be enhanced by describing the research processes in detail, to enable other researchers to repeat the work and obtain the same results. Lincoln and Guba, as quoted in Polit and Beck (2008), mention that credibility is linked to dependability and one is not valid without the other. In this study, the research process was described as thoroughly as possible. By developing a research proposal and describing the research design and how the study would be implemented also enhanced dependability.

3.7.3 Transferability

Transferability in qualitative research can be described as the possibility of transferring the data to another setting and is achieved by means of thick description of the research context and setting (Polit and Beck, 2008). Shenton (2004) mentions that the qualitative researcher cannot claim that the research is transferable, but describing the setting and research process as comprehensibly as possible, would allow readers to determine whether the study could be repeated in another setting. In this study, the setting where the data gathering was done was described in detail.

3.7.4 Confirmability

Confirmability refers to objectivity, or congruence between two or more independent people about the accuracy, relevance and interpretation of the data (Polit and Beck, 2008). According to Shenton (2004), confirmability is achieved when the findings of the research are obtained from the experiences and ideas of the participants and are not biased by the researcher's preferences. Confirmability is also enhanced by means of triangulation and a detailed description of the research methodology. In this study, the completeness of the research proposal was assessed by the supervisors and the proposal was subjected to peer review.

The findings were based on raw data. Applicable themes and categories were identified by following Patton's (2002) approach in analysing data. An audit trail was developed to provide evidence that the findings were grounded in the data. An audit trail is a systematic collection of documentation, that allows an independent auditor to come to conclusions about the data by tracing the research step-by-step (Polit and Beck, 2008, Shenton, 2004). Records which were included in the audit trail were the transcribed interviews, field notes, data analysis products, process notes and data construction products, such as drafts of the final report.

3.8 ETHICAL PRINCIPLES

The ethical principles outlined by Haigh (2008) were applied in the study: autonomy, beneficence, informed consent, non-maleficence and dissemination of results.

3.8.1 Autonomy

Autonomy of participants in a study implies that the final decision whether to participate in the study lies with the participants (Burns and Grove, 2009). The participants' right to self-determination was respected and participation in the study was entirely voluntary. The researcher explained to the participants that they could refuse to participate, or withdraw, at any stage during the interviews without any consequences to them.

3.8.2 Beneficence

Beneficence implies the obligation of the researcher to promote good, which is the opposite of non-maleficence, where the researcher is under obligation not to do harm (Burns and Grove, 2009). The researcher explained to the participants that she wished to understand what was important to them in terms of QoL and what impacted negatively on their QoL, in order to develop an appropriate QoL assessment instrument for cancer patients in South Africa.

3.8.3 Informed consent

After explaining the study and the participants' rights, written consent was obtained from the participants (Addendum E).

3.8.4 Non-maleficence

Participants were not forced to disclose information and all information was given to the researcher voluntarily. Participants were selected for reasons directly related to the problem

being studied and were treated respectfully and courteously at all times. Participants were reassured that the interviews could be interrupted or postponed in case of physical or emotional distress during the qualitative interviews. The principle of non-maleficence also applies to data gathered (Haigh, 2008). Participants' identities were protected at all times by omitting their names on forms and by using pseudonyms during interviews. Permission was asked for the use of a voice recorder during the interviews and none of the participants refused. Participants were reassured that the data would only be discussed with the study supervisors and that their names would not be mentioned, to protect their identities. Privacy was ensured by conducting the interviews in a private room.

3.8.5   Dissemination of findings

Non-maleficence is also applicable to the dissemination of the findings of the study, especially with regards to confidentiality and protecting personal characteristics of the participants (Haigh, 2008). When publishing the research findings, the participants' identities will be protected. The findings will be published in peer reviewed journals and will be presented at a national and international conference.

3.9   SUMMARY

The research methods for Phase 1 of the study were discussed in Chapter 3. The research setting was discussed in detail, followed by the research design, population and sampling, data gathering and data analysis. Measures taken to ensure trustworthiness were discussed, as well as ethical principles which guided the research. Chapter 4 will present the findings and discussion of Phase 1.

CHAPTER 4

FINDINGS AND DISCUSSION OF PHASE 1

4.1   INTRODUCTION

In Chapter 3, the research methods for Phase 1 were discussed. Chapter 4 will present and discuss the findings of Phase 1 of the study. Pseudonyms will be used when presenting the findings. The demographic data will be presented first; the themes and categories will then be described, followed by the discussion of the findings.

4.2   PARTICIPANTS

The sample for the first phase of the study consisted of 22 participants (n=22), all of whom were given pseudonyms to protect their identities. Saturation of data was achieved after 20 interviews but two more interviews were conducted with participants treated for different cancers to ensure saturation. The first interview served as a pre-test to test the topic guide and audiotape. The ages of the participants ranged from 20 to 79 years, with the majority being between 40 and 69 years. Both genders were represented, but most (14 of 22) of the participants were female. Most of the participants were Black, representing seven different cultural groups, with the other participants being Caucasian, Coloured (mixed race) and Asian. The demographic data are presented in Table 4.1 on page 34.

4.3   THEMES AND CATEGORIES ARISING FROM THE DATA

As already mentioned in section 3.6, the data from the in-depth interviews were analysed according to factors which had a positive and negative influence on quality of life.

Table 4.1:   Demographic data of participants (n=22)

Pseudonym	Age	Diagnosis	Treatment received	Cultural group	Educational level
Poppy	28	Cervical cancer	Brachytherapy	Sesotho	Grade 11
Mammy	44	Cervical cancer	Radiation	Zulu	Grade 11
Thabo	69	Breast cancer	Radiation	Tswana	Grade 8
Peace	44	Breast cancer	Chemo-radiation	Xhosa	Tertiary
Pieter	74	Prostate cancer	Chemo-radiation	Caucasian	Grade 10
Peter	63	Prostate cancer	Radiation	Tswana	Grade 10
Joseph	64	Prostate cancer	Radiation	Zulu	Grade 7
Mapule	56	Cervical cancer	Radiation	Sesotho	Grade 12
Oprah	39	Cervical cancer	Chemo-radiation	Zulu	Grade 10
Steve	54	Prostate cancer	Chemo-radiation	Sepedi	Grade 12
Doctor	39	Kaposi sarcoma	Chemo-radiation	Zulu	Grade 8
Martjie	62	Ovarian cancer	Radiation	Coloured	No formal education
Elvis	26	Kaposi sarcoma	Radiation	Tsonga	Grade 12
Busie	41	Cervical cancer	Radiation	Zulu	Grade 11
Harriet	49	Cervical cancer	Radiation	Congolese	Tertiary
Sam	56	Kaposi sarcoma	Chemotherapy	Xhosa	Tertiary
Nicole	33	Breast cancer	Chemo-radiation	Zulu	Grade 12
Cindy	55	Breast cancer	Chemo-radiation-surgery	Malayan	Grade 12
Delilah	62	Rectal cancer	Chemo-radiation	Sesotho	Grade 3
Sandy	46	Cervical cancer	Chemo-radiation	Caucasian	Grade 12
Petrus	50	Stomach cancer	Chemo-surgical	Tswana	Grade 3
Nomsa	40	Head and Neck cancer	Radiation	Xhosa	Grade 8

The themes and categories identified during data analysis were summarised in Table 4.2.

Table 4.2:   Themes and categories

Themes	Categories	
	Factors which had a positive influence on quality of life	**Factors which had a negative influence on quality of life**
Social aspects of QoL	Being with other people. Support of family, friends and church members. A safe, clean place to stay, food, transport	Role changes. Being separated from children and family for long periods. Difficulty with transport to the hospital. Lack of employment and income. Inability to support the family. Boredom due to lack of money for hobbies.
Physical	Ability to carry out household tasks and stay busy. Ability to take care of him/herself. Stable body weight. Symptom control.	Side-effects of cancer and treatment. Symptoms: anorexia, weight loss, nausea and vomiting, diarrhoea, fatigue, stomach cramps, pain, dizziness, joint pain, alopecia, skin discoloration, hot flushes, memory loss, sexual dysfunction, visual disturbances, bleeding, insomnia, poor body image.
Spiritual	Spiritual growth. Stronger relationship with God. Hope of eternal life. Relationships with church members.	Difficulty praying. Not being able to take part in religious activities. Not being able to attend church services.
Financial	Having a regular income.	Debt incurred to pay for transport.

	Categories	
Themes	**Factors which had a positive influence on quality of life**	**Factors which had a negative influence on quality of life**
	Being able to support him-/herself and family.	Having to use money from provident fund.
		Defaulting on treatment to go back to work.
		Not being able to buy "healthy foods" prescribed by the dietician.
		Having to use the child support grant for transport.
		Not having money for food.
		Being financially dependent on family members.
Existential	Opportunity for learning and growing.	Not being able to make long term plans.
	Supporting others in the same situation.	
	Focusing on the future.	
	Accepting death as part of life.	
Emotional	Resilience: acceptance of diagnosis and treatment.	Life is difficult and challenging.
	Positive attitude.	Fear of treatment and weight loss.
	Gratitude for treatment and caring health professionals.	Anger and frustration about inability to carry out household tasks.
		Feeling overwhelmed by illness and responsibilities.
		Stress caused by lack of income.
		Embarrassment about symptoms.

Themes	Categories	
	Factors which had a positive influence on quality of life	Factors which had a negative influence on quality of life
		Depression.
		Sadness due to poor body image.
		Confusion about mixed messages.

4.3.1   Theme 1: Social aspects of QoL

Being supported by a spouse, family, friends and church members and having their company enhanced the QoL of the participants, as they were able to talk to them and share their experiences. Peter explained: "*I'm always enjoyed with somebody, got my daughter, granddaughter…I like to socialise with my neighbours, go to church.*" Oprah added: "*There is this sister of mine from the church…I'm calling her my sister, because she's been like a sister to me. I can talk to her.*" Doctor said: "*What I can say…it's my wife, because she always is there and always if I want to speak with somebody, my wife is there…*"

In contrast, being separated from their family during treatment caused emotional distress for many of the participants. Participants were not only worried about the treatment they were receiving, but also about who would care for their children at home. Participants with small children had the additional burden of having to manage the separation anxiety of their children. Thabo explained: "*I left my daughter there at home, I came to the hospital. I did not have a choice… Now I worry about the treatment, I worry about my daughter and her child… what are they going to eat?*" Busie added: "*They (small children) say 'Mama, please don't go, wait for me… don't go there, wait for me, because I'm not sure are you going to die or not, so wait for me' and when I phoned the children, the youngest one said 'Mama, when do you come back? Are you going to die there?'*"

Transport between their homes and the hospital was a major problem for the participants. Some had to get up very early to drive to the hospital, whilst others had to use public transport, which was cumbersome, exhausting and costly, to get to the hospital. Pieter said: "*We stay far*

from here. I stay in another province. When we have finished here we drive home, more than a hundred kilometres. Tomorrow morning I have to leave at four o'clock. That is very hard for me." Peace added: *"I'm taking a train from Tembisa to Kempton Park, then, from Kempton Park I take a taxi to Jo'burg. From Jo'burg I take another taxi here (*hospital) *and going back every day… for the whole month I have to do that…"*

Affordable, safe and clean accommodation and transport whilst receiving treatment added to the quality of life of the participants, especially those who had no income and had to travel far to the hospital. Thabo explained: *"… the home was only R40-00 per week, then we sleep at the home and the transport bring us here. That made also my life easier, you see… and the food also was very nice at the home…it was a nice place. An old age home, it was a very nice place, very clean. The food also was very nice. Where we sleep the blankets were very nice. That also made our lives better."*

Cancer caused role changes and deprived the participants from being breadwinners, part of the workforce and sex partners. In addition, some also lost their role as spouse and had to become the strong one in the family. Poppy explained: *"It didn't change. I played all my roles well, except the girlfriend part, then there was no sex anymore…*and *I feel it's unfair to him, that it's been months now…I feel inside I'm depriving him of that."*

Harriet added: *"It's painful for them. Since they told me I've got cancer, the house is quiet. I know it's painful, even for my husband, but I must be strong. I'm a woman… I must help my family to be strong… they can't lie down because of me…"*

Not receiving a salary or wage forced some participants to use the social support grants allocated to their children, or having to ask family members for financial support. Additionally, some participants depleted their sick leave, whilst others who were working in the informal sector still had to try to keep working to provide for their families. Doctor explained: *"Always I do my things, like I know every day I go to work, on Friday end of month I've got my pay… but now I'm suffer to get that things I need, because I'm not working…I must ask my mother, my father and my kids the grant… my life had changed like that…"*

4.3.2   Theme 2: Physical aspects of QoL

Being physically strong enough to be able to work, carry out normal household tasks and take care of him/herself was an important aspect of QoL, not only did it allow participants to earn an income, but also kept them busy. Thabo said: "*I enjoy cleaning my house, doing my own washing with my own hands… since this cancer, I am going to enjoy things more… To do things for yourself is better than to lie there…*" Busie added: "*The thing that make life good for me is if I'm working, like I say I'm sewing, getting money, feeding my children… to do things for myself.*"

In contrast, the physical sequellae of cancer and its treatment influenced the QoL of the participants negatively. Fatigue made it hard to carry out household tasks and to engage in paid work. Participants were of the opinion that their bodies were drawing them back and they couldn't do what they wanted. Oprah said: "*Since I'm on chemo, I'm always weak, always sickly, like a zombie or something. I don't know how to describe it, but the department where I work, you are supposed to be energetic and fun to be around… We work long hours, thirteen plus hours… maximum fourteen…*"

Maintaining their body weight was important to the participants and added to their QoL. Poppy explained what made life good for her: "*It's a stable body… I don't like to lose weight…being thin, thin, thin….*" Weight loss led to a poor body image, embarrassed participants and suggested, to them, that they would not get better and were going to die. Busie said: "*I feel bad. It's not nice, because I can't even walk in front of people. Now I'm hiding myself… I'm not going around, because people say 'oh, Busie, you're so slim', you know. So I don't want this shame, shame thing… It's like I'm going to die, you see… It's like…I won't get better… I don't even believe that I'll be okay… I don't know the way forward…*"

Pain had a negative influence on the QoL of the participants and good symptom control was important. Steve said: "*If you haven't got pains that day, it's a big happy day…*" In addition, symptoms such as anorexia, nausea and vomiting, diarrhoea and stomach cramps also had a negative influence on QoL. Poppy said: "*I lost weight, vomited, loss of appetite… that's how it affected me… and diarrhoea also…. It was not easy, but… I thought I was strong… but it was not easy, not easy at all…*" Alopecia and hyperpigmentation were of great concern to some of the

participants. Peace explained: *"You know, yes you lose hair, and you look strange. My colour was…I was so dark, dark, dark. I was so dark…you know…I was, even though I was pressing on, but you don't feel like being in an environment where there are people who would just keep on asking you 'hey, why did you cut (your hair), what's happening, what did you put on your face?'"*

Sexual function changes led to a decrease in QoL. Some participants were acutely aware of these changes and how it affected the relationship with their partners. Cindy said: *"When I started the cancer and then my sex life was not the same. When you're busy with chemo, your vagina is very dry, completely dry… and husbands don't like it to be dry. Also I know when you go to the toilet all the chemo that gush out and you always have that smell on you… he didn't like that* (Cindy).*"*

4.3.3   Theme 3: Spiritual factors influencing QoL

Spirituality played an important role in the lives of the participants and in their QoL. Prayer and being able to go to church was important to many of the participants, as it meant being accepted for what they are, and being accepted reduced their stress levels. Having cancer led to spiritual growth and a closer relationship with God for most. Thabo said: *"You know how it is, when you are in difficulty, that is when you think more of God than when you are not sick. You speak to God more than when you are not sick, you feel nearer to God."*

Peace added: *"First of all, I am a child of God. Prayer makes life good for me, and the love, peace, honesty, forgiveness and my work. When it comes to spiritual life, you know, it took me to a higher level. Instead of feeling like wow, there's no God, then, you know, when it comes to that, it really made me to be strong. It made me to come close to God, it made me appreciate God more than before."*

Some participants had problems with their spiritual lives and having cancer and being treated hindered them from praying and taking part in religious practices. Busie explained: *"The problem is when I'm praying… maybe I'll only say two or three words, then I'll cut…I don't know why."*

A Muslim woman was unable to fast during Ramadan due to the fact she was "unclean," as she could not wash her whole body with soap and water because of the radiation. She was weak because of chemotherapy and therefore could not cook and bake as she usually did during the fasting period. She was also not allowed to pray on the special mat due to being regarded as "unclean." Cindy said: *"In this month you must give to the poor and you must pray, like at the moment I can't… we got our mat which is called a Masala, now at the present moment I can't even get onto that Masala, because I'm not clean, I can't touch the Koran, our Bible, because I'm not clean…"*

Believing in God resulted in feeling safe and protected and gave participants the opportunity and courage to continue their lives and get their lives in order. Petrus explained: "*…so I just pray, I give everything to God…it's up to You what's happening to me. I ask Him to protect me.*" Sandy added: "*I took it as a blessing, because I had a second chance to get my life in order…I talk to my children and my friends and everybody… we must get closer to the Lord, because that is your only solution.*"

Hope played an important role in the QoL of the participants. Having faith gave many hope and the courage to go on with their lives. Steve explained how faith gave him hope, "*At present it's a bit special thing, because I'm a Christian. Then I'm hoping to get the better life in future, because now we can struggle there and there, but in future I'm hoping to get the better life. Even if I die now, the resurrection is there, and then that's my hope, that's what makes me happy, even if I'm sick. It gives me peace.*"

4.3.4   Theme 4: Financial factors that influence QoL

Financial problems had the greatest influence on the QoL of the participants. Apart from having to cope with cancer and its treatment, most of the participants struggled to survive without an income, living only on old age pensions, disability grants and child support grants. The cost of transport played a major role in participants' financial difficulties and many were unable to afford the necessary nutritional food. Thabo said: *"At the moment, what made my life bad… where I stay is a bond house. Now I must pay electricity, water, food. My daughter is not working… now I worry about my daughter and her child… what are they going to eat?"* Poppy

explained: "*My mother is not working, nobody is working at home so we don't get, like, nutritious food… you know, for me to eat to keep fit. When I had chemo, I had to eat healthy food, but I could not as there was no money and we had to spare money for transport also.*"

Some participants became financially dependent on family members, which was hard for many of them. Sandy described: "*…I'm used to being independent, and I don't like to stand with my hand the whole time… When I, on the spur of the moment, want to eat a chocolate, I don't want to say 'Hey, please give me ten rand, I want to buy a chocolate'… you know what I mean…*"

Having a regular income enhanced the QoL of the participants. Some participants were employed, whilst others had a business or received financial support from children and family members. Not only did a regular income allow participants to care for their daily needs, but also gave them a sense of self-worth. Nicole said: "*My work makes me feel good, the people I'm working for… I started sewing and sewing and I'm selling all that. Just makes me feel good to look at what I'm doing with my own hands…just comes perfect and I sell to people. That's self-support. I'm not short of money, because of all that.*" Steve added: "*Yes, yes we manage with the finance. Ja, everything is still going fine at home, because the government helped us with the free medication and treatment we get from the hospital. So it makes us easy even if you haven't got that big business you can still survive. So I haven't got a problem financial at home.*"

4.3.5   Theme 5: Existential factors influencing QoL

Some of the participants regarded the experience of cancer as an opportunity for learning and growing, while others experienced it negatively because they could not make long term plans. Oprah said: "*I have actually grown since I've known that I've got cancer, because now, on top of everything, I now respect people who tell their stories about cancer and I now listen. I never used to… but now I pay attention and I…I would like to be more of an involved person…now I want to grow deeper, to knowing the people. I think after I go through this phase, I will be able to empower two, three people in my life with this phase I've gone through.*" Steve said: "*Everything really does change when you have cancer… the thinking has changed. You feel like your life is shorter. You cannot plan things for five years, ten years to come… cancer it keeps you there…*"

Being able to support others in the same situation gave meaning to the lives of some of the participants. Some also compared themselves with other patients who, according to them, were in a worse situation than they were, making them grateful for what they experienced. Peace said: *"I want to really see myself standing up strong and supporting other people... and to uplift and counsel them...that's my mission, you know, that's what I'm looking forward to do."* Pieter explained: *"If you look at what's going on around you, you have to say thank you."*

Accepting death as part of life enhanced the QoL of some of the participants; however some did not want to be confronted with death and focused on the future which gave them hope. Nicole said: *"People they tell 'Oh, you're going to die' and I never wanted people like that and say no, this person is not right for me. I need someone who's going to tell me that I'm going to be better, because I know that I was going to be better and I'm better right now."* Harriet said: *"It's okay, it's life. Born one day, you can suffer and you can die. It's life, it's part of life."*

4.3.6   Theme 6: Emotional factors influencing QoL

Having to live with cancer was not easy and the participants used words such as '*horrible'* and '*my life is a mess'* to describe what it was like to be diagnosed with cancer. Participants also feared their diagnosis, the treatment, dying and what would happen to their children after their death. Doctor explained: *"Now I was in the machine, I don't know what it look like that machine, it was my first time to go there... I was scared, because the people they said: 'hey, you're going to burn.'"* Busie added: *"You know what I'm scared of? I'm scared of about the people who are left, because maybe I won't feel pain, but what about the others...?"*

Despite the negative emotions, most of the participants accepted the diagnosis of cancer and the treatment and displayed resilience. They were grateful for knowing what was wrong with them and for the treatment they received, some even got used to the treatment. Participants were also grateful for being alive and for the company of other people. Nicole said: *"When I found out that I've got cancer, I accepted and I told myself that I was going to be better and cancer was not going to ruin my life, was not going to take my life down... Another thing which makes me feel good, I talk... communicate with everyone... I speak to other patients..."*

Some participants confessed to feeling angry and frustrated when they could not carry out household tasks due to weakness and fatigue. They felt overwhelmed and tired of taking all the responsibilities and felt that others were expecting too much from them. In addition, participants were emotionally distressed about the lack of income, weight loss and the side effects they were experiencing. Oprah said: *"Ah, the emotional part of this journey. I haven't come to grasp with it… it's the mood swings. I don't know, maybe it's me or it's the treatment or is the chemo, I don't know, but I've become a very moody person, an angry person…ja, don't understand that. I do not understand how to handle it. It's giving me so much pressure. On an emotional level I'm not so… I'm not good."* Elvis added: *"Other people, if I show them, (the lesions on his legs) they start joking… but as they start to, I feel like I'm not a person. I feel like I am not a person anymore, because you feel you are sick every day. My life, it's a mess at the moment."*

Participants became depressed when confronted with body image changes and the sexual complications of their cancer. Pieter said: *"Before I got cancer, we could do something, but now we can't* (have sex)." He added that his breasts were tender and said he had told the doctor: *'You are busy making a woman out of me.'* Cindy added: *"When I look in the mirror I just don't like it, honestly I don't, and I tell my husband I'm a half woman now, I don't have a breast…"*

Meeting other cancer patients and being able to talk to them allowed the participants to share the emotional burden of their cancer and accept their diagnosis. Thabo explained: *"With the cancer treatment you are not alone, you meet people and you discuss…you know, and that also helps you to accept your cancer, because there are a lot of us…"*

Receiving treatment, care and support eased the emotional burden the participants had to bear. Peace explained: *"Luckily there is this help we are getting and what I know is all those things are expensive, the treatment and all that… and I really appreciate, and the environment also. What I've realised, people who are working with cancer people, they are different from other people… you can see there is that heart…of taking care and trying to attend us and giving that support."*

4.4   DISCUSSION

To guide the discussion, the themes identifying the domains of quality of life applicable to the study population were compared to the FACT-G, the EORTC QLQ-C30 and the WHOQOL-BREF QoL instruments (Table 4.3) and only those domains not included in these instruments will be discussed.

Table 4.3:   Comparison of domains of QoL in the current study, the FACT-G, EORTC QLQ-C30 and WHOQOL-BREF

Domain	CURRENT STUDY	FACT-G	EORTC QLQ-C30	WHOQOL-BREF
Physical/functional	X	X	X	X
Social	X	X	X	X
Spiritual	X			
Financial	X		X	
Psychological				X
Emotional	X	X	X	
Environmental	X			X
General health			X	X
Role	X		X	
Cognitive			X	
Existential	X			

Spirituality played an important role in the QoL of the study participants and various factors, such as prayer and ability to attend church services, influenced the spiritual domain both positively and negatively. Fitzsimmons and Middleton (2006) support this finding and state that spiritual factors can have a positive or negative influence on the experience of cancer and the treatment thereof. Spiritual distress can be defined as "a state of experiencing a disturbance in one's belief or value system that provides strength, hope, and meaning in life" and is often mistaken for psychological problems (Grimm, 2005) [p39]. Cancer patients have spiritual needs such as finding meaning in illness and life, a relationship with God and others and expectations regarding life after death (Crowley, 2005). Participants mentioned spiritual growth and a closer relationship with God. Faith in a spiritual world, religion and religious practices foster hope (Buckley, 2008), which was confirmed by participants in this study.

The finding that spirituality played an important role in QoL of the study population was expected. In a previous study where South African patients from a resource-poor community were involved, spirituality was identified as an important aspect of QoL (Maree and Jansen van Rensburg, 2015). Several participants mentioned that the support of members of their church and participating in religious activities such as prayer and attending church services were meaningful to them.

Financial factors played a major role in QoL of the participants. Having a regular income and being able to support themselves and their families had a positive influence on QoL of participants, whilst debt, being unemployed and having to depend on others and other sources of income influenced QoL negatively. In addition, the inability to work and provide for children and family members was hard for participants. Fitzsimmons and Milddleton (2006) acknowledge the fact that financial factors have an important influence on QoL and indicate that financial aspects, such as the costs of travelling, loss of income, medical costs and the cost of a caregiver, play a major role in QoL, especially in patients from resource-poor communities (Fitzsimmons and Middleton, 2006).

Ferrans (2011) confirms that employment/unemployment and the ability to take care of financial needs are very important for QoL and Ferrell and Grant (Ferrans, 2011) recognise financial burden as an important aspect of QoL. The incidence of poverty in patients accessing public health care in South Africa is high, which aggravates their suffering when coping with cancer and treatment. In 2011 the unemployment rate was 24% in South Africa and 20.2% of South Africans lived below the food poverty line (Maree and Jansen van Rensburg, 2015). These findings are confirmed by a study of minority groups in the United States of America who experience severe poverty and food insecurity (Gany et al., 2015).

Gany et al. (2015) agree that cancer patients face severe financial strain and that their financial and logistical needs are often not met. The authors acknowledge the fact that patients sometimes default on cancer treatment when they have to choose between spending their small income on food or medical care, as was confirmed by this study.

Role changes had a negative impact on QoL, especially with regards to sex, being the bread winner and the role of caregiver. Additionally, participants' roles changed from being independent and able to care for their families to being dependent on others. Factors such as heavy bleeding due to cervical cancer and dryness of the vagina due to the side-effects of chemotherapy had a negative impact on sexuality and the role of participants as sexual partners. Ferrans (2011) includes sexual functioning as an important component of social wellbeing. A patient with prostate cancer mentioned erectile dysfunction and gynecomastia, which are side-effects of hormonal therapy (Nishimoto, 2005).

Several participants complained about being dependent on family members due to the fact they were too sick to work or lost their jobs when they got cancer. Apart from not being able to meet financial needs, the demands of taking care of the family and household tasks while undergoing treatment for cancer took their toll on participants who suffered from fatigue.

Existential factors include purpose and meaning in life (Searle, 2001). Maree et al. (2015) add religion and hope. Other existential issues which have an impact on health-related quality of life are increased dependency, loss of hope, finding meaning in life and illness, concerns about death and unresolved guilt (Bele et al., 2012). Uwimana (2005:10) supports these findings and describes QoL as a person's sense of wellbeing and satisfaction with life, despite objective aspects such as income and physical functioning.

In this study various factors played in role in the existential domain, those influencing the QoL of participants negatively to a greater extent than those with a positive influence. Participants described their experience with cancer as an opportunity for learning and growing and others found meaning in their circumstances by supporting other people going through the same experience.

4.5   SUMMARY

Chapter 4 presented the findings and discussion of Phase 1 of the study in view of the literature. The demographic data of the participants were presented and the themes and categories which emerged during data analysis were discussed. The data were organised

according to factors which had a positive and negative influence on QoL, as well as the domains of QoL which were used as a template during the analysis. The domains of QoL which were applicable to the study participants were compared to the domains included in the FACT-G, the EORTC QLQ-C30 and the WHOQOL-BREF. A discussion of the domains applicable to the study participants, but which are not included in the FACT-G, the EORTC QLQ-C30 and the WHOQOL-BREF, followed.

In Chapter 5 the methods of Phase 2 will be presented.

CHAPTER 5

RESEARCH METHODS OF PHASE 2

5.1   INTRODUCTION

Chapter 4 presented the findings of Phase 1 of the study. Chapter 5 will discuss the research methods of Phase 2 of the study. The aim will be explained first, followed by the research process which was used in the development of a QoL assessment instrument for cancer patients in South Africa.

5.2   AIM OF PHASE 2

As already mentioned in Chapter 1 (1.3), the aim of Phase 2 was to develop and validate a QoL instrument appropriate for cancer patients in South Africa.

5.3   RESEARCH DESIGN

The overall design of the study was a mixed methods design. In mixed methods research, both qualitative and quantitative approaches are followed and the integration of the data may involve philosophical assumptions and theoretical frameworks (Cresswell, 2014). In Phase 1, a qualitative approach was followed.

In Phase 2 of the study a quantitative design was used to validate the questionnaires. Quantitative research is applicable for the statistical analysis of numeric data for the description of a phenomenon (Polit and Beck, 2008). The design is applicable for the validation of an instrument to ensure that the instrument reflects what it intends to measure (Adnane et al., 2016). The questionnaires were validated by means of rigorous psychometric testing using the Rasch Measurement model.

5.4   RESEARCH PROCESS

The research process will be discussed with regards to the development of the QoL instrument, the population, sampling and pilot testing, as well as the validation of the instrument.

5.5   THE QOL INSTRUMENT

The categories which emerged during analysis of the interviews conducted in Phase 1 were operationalised into questions and two questionnaires were compiled according to factors which had a negative and positive influence on QoL, as mentioned in the topic guide:

Questionnaire 1: What makes life hard for you? (Addendum G) comprised 67 questions and Questionnaire 2: What makes life good for you? (Addendum H) comprised 50 questions.

A section for demographic data of respondents was included in the questionnaires to ensure that all the inclusion criteria were met: different genders, cultural groups and cancers. The highest level of education was included to evaluate whether the questionnaires would be suitable for participants with different levels of education. The ages of participants were included in the demographical data to determine what the influence of age was on QoL. The demographic data gathered are summarised in Table 6.1.

The guidelines of Khadka et al. (2012) were applied in the development of the questionnaires. The following characteristics are needed for a good rating scale or questionnaire: hierarchical ordering of responses from lower to higher value, unconnected categories, respondents/participants must understand the response categories and categories for the question must be appropriate. There should not be too many response categories as it causes confusion and respondent burden. Examples of response categories: Pain: none =1, mild =2, moderate =3, severe =4, very severe =5 and Yes =1, no =2, not applicable =3.

Short descriptions are needed for categories and neutral categories should be avoided. Non-overlapping categories should be created which are mutually exclusive and collectively exhaustive and conceptually overlapping categories, such as "hardly at all" and "a little," should

be avoided. Simple questions are more effective, rather than difficult or branching questions (Khadka et al., 2012).

Respondents' perceptions of the influence of disease and treatment on their QoL were measured by means of the questionnaires or self-reported outcome instruments. A rating scale with different response options was used for each question in order to determine the participant's status with regards to QoL issues. The response categories for the questionnaires were: yes/no/unsure.

For the assessment of QoL, the researcher attempted to develop a simple questionnaire, due to the literacy level and the health status of the respondents, to prevent placing a high burden on them during completion of the questionnaire. The number of questions in each questionnaire was also limited to prevent overburdening of sick patients. From previous experience with the type of patients seen at the clinics, the researcher knew the patients had a low educational level and cancer patients are often very sick. For this reason a three-category global rating scale was used: yes/no/unsure.

5.6   POPULATION AND SAMPLING

The target population for this phase of the study was the same as for Phase 1: cancer patients receiving chemotherapy or radiotherapy, or both, at a public health care facility in South Africa. The accessible study population was cancer patients receiving treatment at the same academic hospital where the first phase of the study was conducted.

Purposive and convenience sampling was used to select respondents. Purposive sampling is used where the researcher selects subjects who are typical of the population (LoBiondo-Wood and Haber, 2010) and convenience sampling implies the selection of respondents who are available at the location and time of the data gathering (Polit and Beck, 2008). The researcher recruited respondents who received anti-cancer treatment for different types of cancer, represented different cultural groups, were of both male and female gender and lived in both rural and urban communities.

The inclusion criteria for the accessible population were: 18 years and older, receiving chemotherapy or radiotherapy, or both, for cancer at the oncology clinics at the Department of Radiation Oncology of the chosen hospital and willing to participate. Questionnaires 1 and 2 were completed during February and March 2014.

The sample size for the first two questionnaires was 91. Fifty respondents completed Questionnaire 1: *What makes life hard for you?* and 50 completed Questionnaire 2: *What makes life good for you?,* however, three questions in Questionnaire 1 and six in Questionnaire 2 were only filled in partially and had to be discarded. The sample size for the first two questionnaires was small, as the instrument was still in the developmental phase.

5.7   DATA GATHERING

During data gathering the two questionnaires were pilot tested. Two fieldworkers, both Oncology Nursing Masters' students, were enlisted to assist with the completion of the questionnaires. This occurred under the supervision of the researcher at the Department of Radiation Oncology at the academic hospital where the data gathering for Phase 1 of the study was conducted. Respondents were given information sheets about the study and written informed consent was obtained (Addendum F). Respondents who were illiterate were assisted with the completion of the questionnaires by the fieldworkers.

5.8   VALIDATION OF THE INSTRUMENT BY MEANS OF THE RASCH MEASUREMENT MODEL

The raw data from the questionnaires were captured onto Excel spread sheets. Eight questionnaires from Questionnaire 1 and 2 were found to be incomplete and discarded. It was clear that the participants who completed only half of the questions did not understand the questions or were not really interested in completing the questionnaire. The data were then exported into the RUMM 2030 program and subjected to the Rasch Measurement Model (RMM) for validation. In order to determine fit of a scale to the Rasch model, RUMM 2030, Winsteps, Facets, Quest or ConQuest software can be used (Hagquist et al., 2008). For the analysis of the questionnaires in this study, RUMM 2030 software was used.

The researchers selected the Rasch Measurement Model, which is used for examining the psychometric properties and dimensionality of an assessment instrument (Pallant and Tennant, 2007), as it had been used successfully in the development of measurement instruments in nursing research (Hagquist et al., 2008).

By using the Rasch model for analysis, measurement issues can be detected. The model assumes that the probability of a participant endorsing an item is a logistic function of the relative difference between the item's location (difficulty of the item) and the person's location (ability of the person) (Zucca et al., 2012). The Rasch model can be described as a latent trait model, with overlapping characteristics of item response theory (IRT). The model is applied to an instrument to test unidimensionality, invariance, proper item categorisation and differential item functioning (DIF) (Tennant and Conaghan, 2007).

In the RMM, item measures are presented as logits or scaled logits. Items which report item statistics must be arranged from most to least challenging. Item fit statistics are important to determine how well data fits the model (Pallant and Tennant, 2007).

There are two derivations of the Rasch model, the Andrich Rating Scale Model and the Masters Partial Credit Model. If the distance between the thresholds or categories is the same across all the items, the Rating Scale Model is used, if the distances vary, the Partial Credit Model is used (Zucca et al., 2012). An equal distance between thresholds is expected, where the thresholds are "probabilistic midpoints between any two adjacent categories" (Tennant and Conaghan, 2007) [p1359]. The category structure is tested to determine if the thresholds are ordered or disordered. In the case of disordered thresholds, categories may be collapsed where possible to make the data fit the model.

For the QoL assessment instrument developed in this study the Masters Partial Credit Model was used, as the distances between the thresholds varied. When subjecting an instrument to the Rasch model, the researcher tests how well the observed responses conform to Rasch model expectations. It is important to note that the Rasch model requires the data to fit the model and not the other way round, as in classical test theory techniques where the researcher will explore different models until one is found that best fits the data (Andrich, 2004).

The following aspects need to be assessed in the Rasch model: model fit statistics, item and person fit statistics, response format, local dependency, targeting, item bias or differential item functioning (DIF), dimensionality (do the items of the proposed scale measure a single underlying construct), the person separation index (PSI) and reliability, which is assessed by means of Crohnbach's alpha (Zucca et al., 2012). The requirements for each of these aspects are explained below.

5.8.1 Determining fit of data to the Rasch model

When testing how well data fit the RMM, three statistics need to be computed: item fit statistics; person fit statistics and item-trait interaction statistics or chi-square, which indicates invariance. If the chi-square value is less than 0.05, the item does not fit the model, because this points to a statistically significant difference between observed and expected values. An item-trait interaction chi-square can be obtained by adding the total chi-square values of all the items, which is an indication of the level of invariance of the items. If items and persons fit the model, the mean location score will be ± zero with a standard deviation of 1. In an analysis, individual person fit residuals of between +2.5 and -2.5 are regarded as an adequate fit to the model. Item fit deviations can be displayed graphically by means of an item characteristic curve (ICC) function (Pallant and Tennant, 2007).

Another criteria for evaluating a rating scale is threshold ordering, that is: thresholds must be ordered, categories must be even - not too close together, overlap, or be too far apart, and the range of response categories - a large range creates greater measurement coverage of the latent trait (Khadka et al., 2012). This is visually displayed by the category probability curves and the threshold map.

5.8.2 Item and person fit statistic

Person fit has to be tested, as inconsistent response patterns of individuals have an effect on item fit. In case of serious misfit of individuals, the person's response can be removed from the analysis to improve construct validity. This is seen as extreme persons in the Rasch Model. An example of an extreme person is where the responses for the entire questionnaire are the same. Inconsistent responses may be due to co-morbidities or cognitive impairment (Pallant and Tennant, 2007).

In order to identify items and persons causing misfit, individual item and person fit residual values are computed; values >2.5 indicate misfit and <-2.5 indicate item redundancy (Pallant and Tennant, 2007).

5.8.3 Response category functioning

Item misfit is often the result of inconsistent use of response options by respondents, which is displayed as disordered thresholds. Disordered thresholds indicate that response categories are not used in a way that corresponds with the level of the trait being measured and that rescoring is necessary according to the item's category probability curve. Disordered thresholds often occur when there are too many response options or when the labeling of response options is potentially confusing, for example: sometimes, often and frequently. In this instance fit can be improved by means of the collapsing of categories which display disordered thresholds (Pallant and Tennant, 2007). When thresholds are arranged orderly, the rating scale functions well between response categories. If respondents do not use all the categories and cannot discriminate between categories, the rating scale is dysfunctional and the thresholds are disordered (Pallant and Tennant, 2007).

5.8.4 Targeting

Good measurement depends on good targeting, which implies the relative locations of persons and items. The number and difficulty levels of the items must cover the ability levels of the

persons with whom the instrument will be used. Incorrect targeting will result in incorrect estimates of item and person parameters and reversed thresholds. Mistargeting also increases the scoring of persons in the highest and lowest categories, which makes the estimation of person parameters difficult. Targeting is determined by comparing the mean location score for the persons with that of the value of zero; if the score is close to zero, the measure is well targeted (Tennant and Connaghan, 2007). In a well-targeted measure, which is not too easy or too hard, the mean location of persons is ± zero (Pallant and Tennant, 2007).

5.8.5   Differential item functioning

The validity of the scoring system and of individual item fit is tested and potential bias of items is assessed (Pallant and Tennant, 2007). When different groups of respondents respond differently to an item, differential item functioning (DIF) occurs. For example, if males respond differently to a question than females, the question might favour one gender. Invariance means there is no DIF across the group examined. DIF is also known as item bias (Pallant and Tennant, 2007).

When comparing groups from questionnaire data, items should not show DIF between these group variables, for instance, gender, age, race and level of education. Real DIF in items favouring one group can lead to artificial DIF in another group, which in turn can lead to incorrect identification of items as having real DIF. In order to detect artificial DIF, groups with real DIF must be identified. The item which shows the greatest DIF (the highest mean square) should be resolved by splitting it into two items. If the DIF was real, artificial DIF in other items is removed. The item with the greatest DIF can also be removed (Andrich and Hagquist, 2012).

In RUMM2030, DIF is presented in graphs. The expected curve for an item is plotted with the group variable's real performance alongside the curve. For example, if gender is the group variable, a separate curve for male and female is plotted alongside the expected curve. (Refer to Figures 6.2 – 6.6 in Chapter 6 for a clear understanding of the graphical presentation of DIF).

A two-way analysis of variance (ANOVA) uses class intervals and compares it to the means of the group variables. Class intervals are constructed by dividing the sample into three groups of

ability (one group for low scores, one for in-between and one for high scores). Class intervals can be grouped into more classes depending on the sample size, but for the purpose of this study, class intervals were divided into three groups. ANOVA then reports on the interaction between the class intervals and group variables for examples gender groups. A p-value is calculated by RUMM2030 (based on the specific sample) as a criterion for significant difference between class intervals and the group variable.

5.8.6   Local dependency

Construct validity is further tested by means of testing response dependency. Where the response to one item determines the response to another item, the items are linked and breach of local independence occurs (Tennant and Connaghan, 2007). Local dependency between items is examined by means of the residual correlation matrix; if the correlation between pairs of items exceeds 0.3, it indicates dependency (Zucca et al., 2012).

5.8.7   Dimensionality

Unidimensionality must be demonstrated when validating an instrument. This implies the instrument is measuring the construct it claims to measure. For example, if the instrument claims to measure QoL, it should only measure this construct and no other related constructs. For a scale to conform to the Rasch model's requirement for unidimensionality, items should be independent. When there are subsets of items intended to include different aspects of a construct, it leads to multidimensionality (Hagquist et al., 2008).

The Rasch model provides a template for the development and testing of a unidimensional scale and for the conversion of ordinal data to a linear scale if the data fit the model. Unidimensionality is achieved if there is no meaningful pattern in the residuals and local independence between items is evident. Under these circumstances, the scores of items or questions in an instrument may be added up or summated for one total score per person (Tennant and Connaghan, 2007).

5.8.8   Person Separation Index and reliability

An instrument needs to be sensitive enough to differentiate between high and low levels in persons. Values higher than 2 in the person separation index (PSI), points to the sensitivity of the instrument. A Crohnbach's alpha larger than 0.8 indicates the instrument will consistently be sensitive (Mallinson, 2007). For an instrument to be reliable, the minimum Crohnbach's alpha score must be 0.7 (Adnane et al., 2016).

5.8.9   Resolutions in the Rasch model

During examination of a scale by means of the Rasch model, weakness in the functioning of the instrument is discovered, but can be resolved. If thresholds are disordered, categories can be collapsed on the response format to reduce confusion of the points on the scale. Furthermore, the scale can be adjusted by means of new items or by removing items which do not fit. Items which do not fit can be removed one by one until the problem is resolved. Items should rather be resolved than removed, as removal of too many items may decrease the reliability of the measure (Andrich and Hacquist, 2012). When local dependency is detected, it may be resolved by sub-testing of items. This is done by grouping items with residual correlations above 0.2 into one subtest. Theoretical support and clinical reasoning should accompany decisions when grouping items into subtests.

When all the above aspects conform to the Rasch model expectations the instrument's raw data are converted to linear scales, which can be used for comparing differences in patient function over time during cancer treatment, differences between patients suffering from different cancers, different genders and patients treated in public and private hospitals.

The above analyses were applied to Questionnaire 1 and 2. The results of the analyses are presented in Chapter 6. The data of both questionnaires did not fit the requirements of the Rasch model and many resolutions had to be made, the major resolution being to combine Questionnaire 1 and 2 and create a third questionnaire. During this process, questions which proved to be unclear and were a misfit were removed. It also appeared there were too many questions in the two questionnaires, which in turn was too tiring for the respondents. Some questions were not removed but rephrased. Questionnaire 3: *What makes your life good and*

hard (Addendum I) contained 67 questions. The same process of data analysis was followed with the third questionnaire as with the first two questionnaires. New data were gathered at the same oncology clinics during June to August 2014, with the assistance of the two Oncology Nursing Masters' students. The data from Questionnaire 3 were again captured on an Excel spread sheet and transferred to the RUMM 2030 program before being submitted to the Rasch Measurement model for validation. The results of the validation process are discussed in Chapter 6.

5.9   ETHICAL PRINCIPLES

The same ethical principles, as described in Phase 1, applied to Phase 2 of the study. Respondents took part in the study voluntarily. Before completing the questionnaire, an information leaflet was handed to each respondent and the purpose of the study and what was expected from the respondent was explained. Informed consent was obtained (Addendum F).

5.10   VALIDITY AND RELIABILITY

To ensure validity and reliability of the research, the researcher should ensure rigour and control throughout the research process. Rigour can be described as striving for excellence in the research process, by means of precision and control. Each step in the research process should be carried out with meticulous attention to detail and should be linked together in a logical way. The research process should be described accurately and in detail (Burns and Grove, 2009). In this study the researchers described each step in the research process in detail.

The researcher needs to control extraneous variables as much as possible to be able to identify relationships between study variables accurately. Ways to control extraneous variables are: random sampling of the study population, inclusion criteria and choosing the setting to control variables, such as temperature and noise levels (Burns and Grove, 2009). The sampling procedure and inclusion criteria must be described in detail, which was adhered to in this study. The characteristics of the respondents must be described, as it could influence the findings of the study.

Data gathering should be done in a structured way, with the procedure described in detail (McCarthy and O'Sullivan, 2008). Data gathering took place in the Department of Radiation Oncology of the hospital where the study took place and private rooms were available to ensure privacy, comfort and confidentiality. Data gathering must be controlled by means of a good quality measurement instrument. The data analysis from the first phase of the study was used for compiling the questionnaires, which were used for data gathering.

Research outcomes can be influenced by respondents' knowledge of the study, for example the Hawthorne effect, which implies that being part of a study can have an influence on respondents' behaviour (Burns and Grove, 2009). During data gathering, respondents were informed about the study and that all data gathered would be anonymous, as questionnaires did not contain the respondents' names, only numbers. Respondents took part in the study voluntarily and were assured there would be no consequences if they refused to take part.

In quantitative research the researcher should explain the rationale for conducting the study, based on the identification of a gap in the knowledge base according to the literature. Sample sizes are usually larger than in qualitative research (McCarthy and O'Sullivan, 2008). In this study the sample sizes for Questionnaires 1 and 2 were 47 and 44 respectively and for Questionnaire 3, 195. The sample size was not very large, due to the fact that the instrument was still in the developmental stage.

In addition, the data analysis process should be described comprehensively, with graphs and tables explained and labeled clearly. Interpretation of the results must be explained and the researchers must indicate whether the aims of the study were met, as well as what the implications of the research are for clinical practice (McCarthy and O'Sullivan, 2008). The data analysis process, which entailed validation of the questionnaires by means of the Rasch Measurement Model, will be discussed in detail in Chapter 6.

5.11   SUMMARY

Chapter 5 presented the Methods for Phase 2 of the study in terms of the purpose and aim, the research design and research process. The development of the questionnaires was described,

followed by the data gathering- and validation of the instrument. The Rasch Measurement Model was discussed, as well as the ethical principles which underpinned the study and measures taken to ensure validity and reliability. The results of the validation of the instruments will be discussed in Chapter 6.

CHAPTER 6

RESULTS AND DISCUSSION OF PHASE 2

6.1 INTRODUCTION

Chapter 5 discussed the Methods of Phase 2. In Chapter 6, the results of Phase 2 will be discussed. Psychometric testing was done to validate each of the three questionnaires which were developed for a QoL instrument for cancer patients.

The demographic data are presented and results of the validation process for each questionnaire are described. The chapter ends with a discussion of the results of the psychometric testing.

6.2 RESULTS OF RASCH ANALYSIS

The QoL instrument consisted of two questionnaires, namely Questionnaire 1: *What makes life hard for you?* and Questionnaire 2: *What makes life good for you?* Each questionnaire consisted of questions which the respondent had to endorse by choosing between three response options: Yes, No or Unsure. In the reporting of the results, the term *item* is used for the questions in the QoL instrument.

The demographic data of the respondents who completed Questionnaires 1 and 2 are summarised in Table 6.1

Table 6.1:   Demographic data of respondents who completed Questionnaires 1 and 2

Variable	Questionnaire 1 (n=47)	Questionnaire 2 (n=44)
Age		
19-29	6	5
30-39	6	6
40-49	6	5
50-59	14	13
60-69	10	11
70-79	4	4
80-89	1	0
Gender		
Male	21	20
Female	26	24
Cultural group		
Coloured	5	6
Asian	3	4
Black African	27	24
White	12	10
Highest level of education		
Grade 10-12	26	25
None	3	4
Grade 1-9	10	9
Tertiary	8	6
Cancer group		
Head and neck	4	3
Gynaecological	8	8
Haematological	13	12
Breast	9	9
Lung and oesophageal	6	5
Prostate	1	2
Colon and kidney	6	5

The majority of respondents who completed the first two questionnaires was between 50 and 69 years old, had a greater number of females than males and consisted mainly of the Black African cultural group. The educational level of the majority of respondents was grade 10 to 12 level; three respondents who completed Questionnaire 1 and four who completed Questionnaire 2 had not attended school at all. Twenty seven per cent of respondents who completed Questionnaire 1 and 29.5% who completed Questionnaire 2 did not have any high school education. The majority of respondents suffered from haematological cancers, followed

by gynaecological and breast cancer. When combining gynaecological and breast cancer, female cancer was the most common.

The analyses of the different questionnaires will be discussed separately.

6.2.1 Analysis of Questionnaire 1: What makes life hard for you?

6.2.1.1 *Fit of data to the Rasch Model*

The fit statistics of the Rasch model for Questionnaire 1: *What makes life hard for you?* are summarised in Table 6.2. This includes the chi-square statistic, the mean location of items, the standard deviation, item fit, the person separation index (PSI) and the threshold ordering. The criteria for each of these fit statistics are provided in brackets.

Table 6.2: Fit statistics of Questionnaire 1: What makes life hard for you?

Run Number	Chi square (>0.05)	Person mean location (= 0)	Person standard deviation (=1)	Item fit (± 2.5)	PSI (>0.85)	Threshold ordering
1	0.098	-1.736	0.790	Item 1 misfit (3.019)	0.907	Item 24 disordered
2 Item 1 deleted	0.141	-1.741	0.814	Item 28 misfit (2.534)	0.911	Item 24 disordered
3 Clinical evaluation to reduce number of questions	0.502	-1.788	0.824	All items fit	0.886	Item 24 disordered
4 Item 24 deleted and Category 3 collapsed	0.021	-0.003	1.099	All items fit	0.891	Ordered
5 Six Subtests	0.156	-0.246	1.022	All subtests fit	0.85	N/a
6 Five Subtests	0.673	-0.226	0.947	All subtests fit	0.839	N/a

Several rounds of analyses were done to conform to the requirements of the Rasch model. The first round (see Table 6.2 Run 1) indicated a fitting chi-square statistic with a value of 0.098. The mean location and standard deviation of items and persons are reported in Table 6.2 columns 3 and 4. Item 1 (question 1) was highlighted as over-fitting (3.019). The PSI showed good discrimination between groups and good internal consistency of the questionnaire. Item 24 (question 24) was disordered. The other 66 items were all ordered. A second analysis was done (run 2) to resolve the misfit of item 1 and the disordering thresholds of item 24. Item 1 was deleted but item 24 was still disordered and item 28 showed over-fit (2.534).

Due to the fact the respondents were cancer patients, the researcher wanted to reduce the number of questions to prevent over-burdening when completing the questionnaire. Despite the relatively sufficient fitting statistics for Questionnaire 1, the questions were evaluated from a clinical perspective and 17 items, which were unclear or duplicated, were deleted in the third round of analysis (run 3). After the reduction of the number of questions, item 24 was still disordered, but all remaining items fit between ±2.5.

When looking at the completed questionnaires, the researcher observed a great deal of doubt in the respondents between response options and realised the format of the questions was not the same, for example, when determining what made life hard, one question asked: _Not being able to_ work: yes/no/unsure and another question: _Being too tired to carry out your normal activities of daily living:_ yes/no/unsure. The third category (unsure) seemed to have created the doubt and for this reason the response format was changed for all the items. The response category of _unsure_ was collapsed throughout, to create a dichotomous format of _yes/no_ for all the questions (run 4). The mean location improved markedly from -1.736 in the first analysis to -0.003 in the fourth round of analysis. The standard deviation also improved from 0.79 to 1.099. All items were ordered with a dichotomous response format. The chi-square statistic however was not fitting at 0.021.

A fifth round of analysis was done by creating subtests according to the domains of QoL to improve the chi-square statistics. Six subtests were created namely Physical, Financial, Emotional, Existential, Social and Spiritual. After Run 5 of the analysis the data fitted the model. Subtest Existential consisted of only two questions and Spiritual only one question. It was

decided to combine Existential and Spiritual into one subtest as, theoretically, these two concepts are strongly associated. This combination proved to be successful as the final and sixth round of analysis resulted in an even better fit (χ^2 = 0.673) with the Rasch Model requirements. A mean location of -0.226 and standard deviation of 0.947 were achieved. Throughout the six rounds of analyses, person mean location and person standard deviation, as well as the PSI, were within normal limits.

6.2.1.2 *Targeting difficulty of items to ability levels of persons*

Targeting showed some categories with no responses (Figure 6.1). Persons had a mean of -0.226 and standard deviation of 0.947, which showed the items were well targeted for the sample.
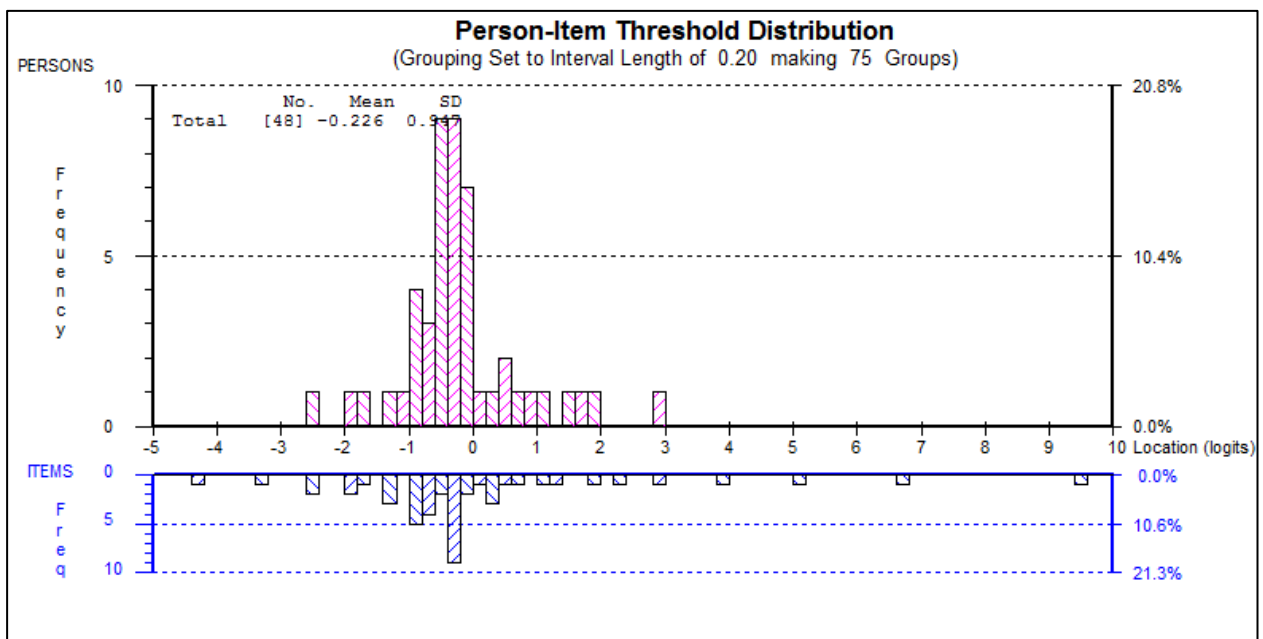
Figure 6.1: Person-item threshold distribution of Questionnaire 1

6.2.1.3 *Differential item functioning*

Differential item functioning (DIF) was only done for gender as the other person factors, such as age group, highest level of education, culture and cancer group, had too few respondents per category. The two-way ANOVA statistic in RUMM2030 was done for each of the five subtests. This was done to see if there was a significant difference between the mean of the class

intervals and the mean of the gender variable. The p-value criterion was set at 0.0033; iterations below 0.0033 would show DIF for gender in that specific subtest. Table 6.3 shows the results of the two-way ANOVA. It is interesting to note that there was no DIF for gender according to the ANOVA results, however, the graphical presentations of DIF (Fig 6.2 to 6.6) show that the curves for males and females do not follow the expected curve exactly.

Table 6.3:   DIF summary for five subtests with criterion at P<0.00333

	Class interval					Gender					Class interval by gender			
Subtest	MS	F	DF	Prob		MS	F	DF	Prob		MS	F	DF	Prob
Physical	0.096	0.12856	2	0.879		0.096	0.128	1	*0.722*		0.390	0.520	2	0.598
Financial	0.482	0.61067	2	0.548		0.390	0.494	1	*0.486*		1.122	1.421	2	0.253
Emotional	0.064	0.05948	2	0.942		1.052	0.967	1	*0.331*		0.558	0.512	2	0.602
Existential & Spiritual	1.476	2.24412	2	0.119		3.638	5.530	1	*0.023*		-0.056	-0.08	2	0.999
Social	1.290	1.67129	2	0.200		0.167	0.216	1	*0.643*		2.019	2.615	2	0.085

This discrepancy between ANOVA results and graphical presentation could be explained by the small sample size of 47 and then split into male (n=21) and female (n=26). One would have expected DIF due to the fact that only women had breast and gynaecological cancers, which represented the largest group, while only men had prostate cancer, which represented the smallest group of participants. The results for DIF for this study are thus inconclusive at this stage.
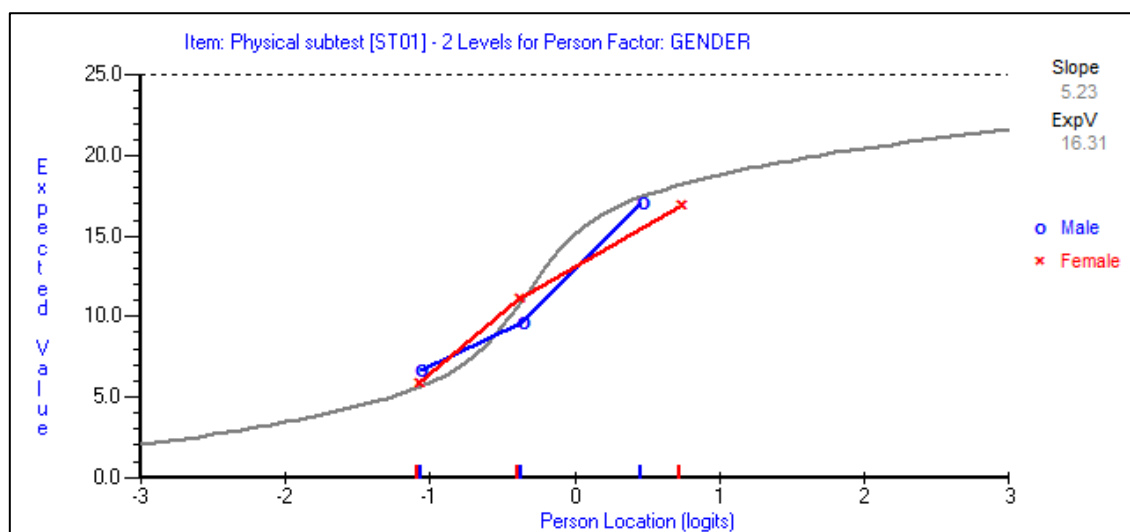
Figure 6.2: Physical factors DIF for gender
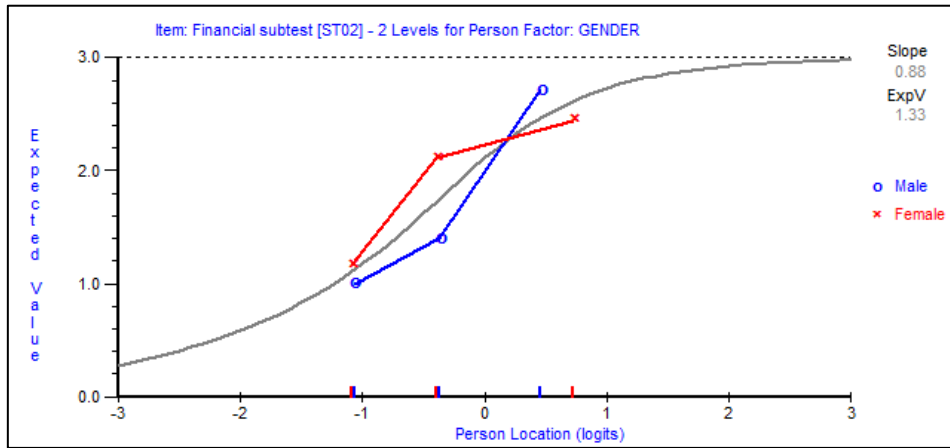
Figure 6.3: Financial factors DIF for gender
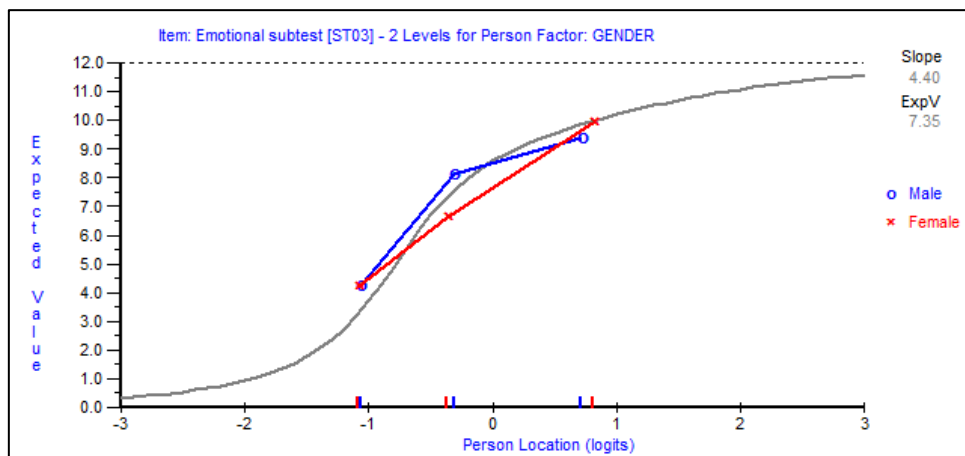
Figure 6.4: Emotional factors DIF for gender
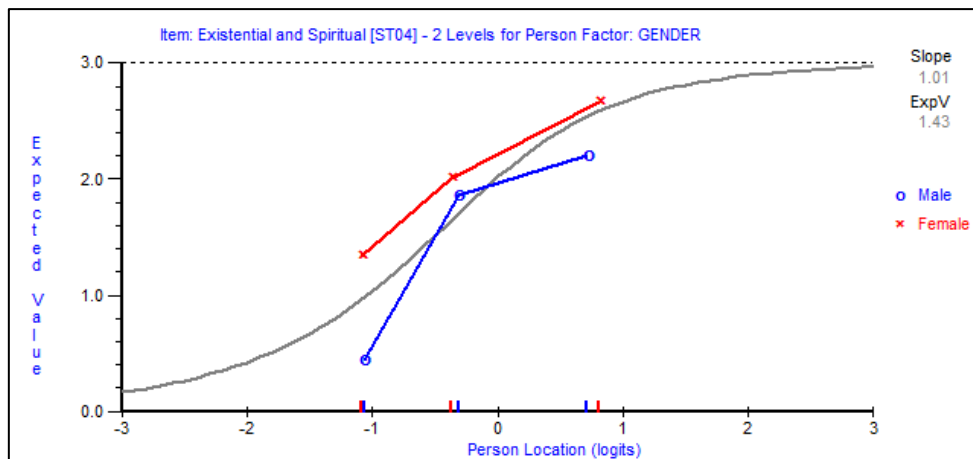
Figure 6.5: Existential- and spiritual factors DIF for gender
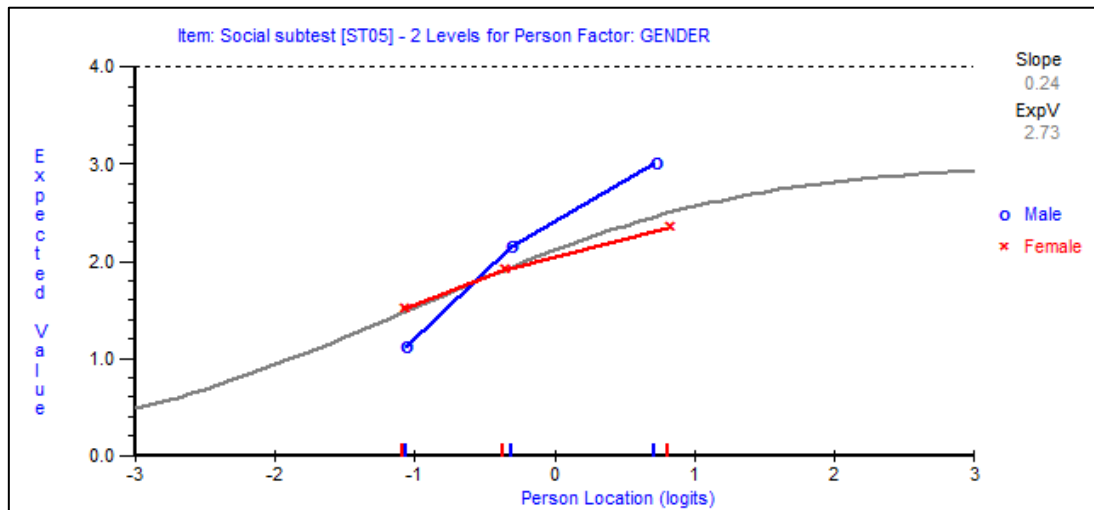
Figure 6.6: Social factors DIF for gender

6.2.1.4 Local dependency

Local independence between the five subtests was achieved. The implication was that subtests do not overlap significantly or provide cues for another subtest. Table 6.3 shows the residual correlations between subtests were all well below the criteria of 0.3 correlation.

The interpretation in terms of validity of this questionnaire was that each subtest contributes something towards quality of life in a person with cancer.

Table 6.4:   Residual correlations of the 5 subtests of Questionnaire 1

Subtests	Physical	Financial	Emotional	Existential and spiritual	Social
Physical	1				
Financial	-0.242	1			
Emotional	-0.853	-0.127	1		
Existential and spiritual	-0.369	0.144	0.034	1	
Social	-0.172	-0.187	-0.074	-0.016	1

6.2.1.5 Unidimensionality

Unidimensionality was achieved. The t-test showed an insignificant difference between groups and only 4.65% fell outside the recommended criteria of 5%. This means the individual scores

of each subtest may be summed to get a total that will indicate the degree of QoL in a cancer patient.

6.2.1.6   Summary of results of Questionnaire 1

The results of the analysis when using the Rasch model generally fitted the requirements of the model after certain resolutions were done. These resolutions include deleting items, collapsing the response options to a dichotomous scale of yes/no and sub-testing the items. Differential Item Functioning was the one criterion that was inconclusive.

6.2.2   Analysis of Questionnaire 2: What makes life good for you?

The results of the analysis of Questionnaire 2 - *What makes life good for you?* - are summarised in Table 6.5.

Table 6.5:   Analysis of Questionnaire 2: What makes life good for you?

Run number	Chi square (>0.05)	Mean location (= 0)	Standard deviation (=1)	Item fit (± 2.5)	PSI (>0.85)	Threshold ordering
1 Collapsed category 3	0.029	-2.217	1.241	All items fit	0.778	Ordered
2 Deleted 12 items	0.086	-2.351	1.249	All items fit	0.705	Ordered
3 Subtests (6)	0.099	-2.137	0.999	All items fit	0.183	Ordered

During the first round (run 1) of analysis of Questionnaire 2, response category 3 was collapsed due to the fact that in the analysis of Questionnaire1 it showed better fit with the Rasch model when there were only two categories. It was apparent that the category *unsure* created confusion. The response options thus changed from a three point (polytomous) to a dichotomous scale.

In the second round (run 2) of analysis the questions were clinically evaluated and those that were unclear, similar or duplicated were removed to reduce the number of questions. Twelve items were removed in total. Sub-testing was done by dividing the remaining questions into six groups according to the domains of QoL, similar to those in Questionnaire 1.

The data did not fit the Rasch model expectations and even with attempts to resolve the issues, the chi-square was constantly below 0.05 and the PSI indicated the instrument did not distinguish between high and low QoL (Table 6.5). It also reflected that the data were of poor quality. It was decided not to go ahead with any resolutions, but rather attempt to combine the two questionnaires into one, resulting in Questionnaire 3.

As discussed in Chapter 5 (5.8), Questionnaire 3 (Addendum I) was developed by combining the remaining questions of Questionnaire 1 and 2 and by rephrasing the questions which were problematic. The questionnaire consisted of 67 questions.

The accessible population consisted of patients who received anti-cancer treatment at the clinics in the Department of Radiation Oncology of the academic hospital where the study was conducted. Like in the first two questionnaires, purposive and convenience sampling was applied and respondents who were present in the clinics during data gathering were recruited and included patients who were receiving treatment for different cancers, were of both genders and different cultural groups.

During data gathering the questionnaire was pilot tested with the assistance of the Oncology Nursing Master's students who assisted with the first two questionnaires. Inclusion criteria were the same as for the first two questionnaires: respondents had to be 18 years or older, receiving treatment for cancer at the clinics where data gathering took place and willing to take part in the research.

The sample size for Questionnaire 3 was initially 199, however, four questionnaires were only completed partially and had to be rejected. Two groups of respondents completed the questionnaire: 100 respondents were receiving active treatment for cancer and 95 respondents were seen for follow up at six months or twelve months after completion of treatment. The

sample size was bigger than with the first two questionnaires, as the researcher wanted to determine what the effect of cancer treatment was on QoL by comparing the findings of respondents on active treatment with the findings of those seen for follow up after treatment.

6.2.3 Analysis of Questionnaire 3: What makes your life good or hard?

The demographic data of the respondents who completed Questionnaire 3 were summarised in Table 6.6.

Table 6.6: **Demographic data of respondents who completed Questionnaire 3**

Variable	Questionnaire 3 (n=195)
Age	
19-29	9
30-39	47
40-49	51
50-59	43
60-69	29
70-79	13
80-89	3
Gender	
Male	48
Female	147
Cultural group	
Coloured	19
Asian	6
Black African	147
White	23
Highest level of education	
Grade 10-12	89
None	7
Grade 1-9	55
Tertiary	44
Cancer group	
Head and neck	12
Gynaecological	88
Haematological	25
Breast	34
Lung and esophageal	11
Prostate	9
Colon and kidney	9
Bone and skin	7

In this sample the average age was lower than the previous sample, with the majority of respondents being between 30 and 70 years old and females comprised 75.3% of the sample. As in the previous sample, Black African patients were also in the majority, numbering 147 in total (75.3%). Gynecological cancers comprised the biggest group of respondents, followed by breast cancer, which implies that female cancers formed the largest section of the sample. The average educational level was higher in this sample, with 44 respondents (22.6%) tertiary qualified, compared to the sample of the first two questionnaires, which comprised 17% and 13.6% who had a tertiary qualification. The greatest majority of respondents (73.8%) had attended school and only seven (3.6%) had not attended school at all. A total of 62 respondents (31.8%) did not have a high school education, which confirmed the suspicion of the researcher that the educational level of many of the respondents would be low.

After completion of the questionnaires, the data were again captured on an Excel spread sheet and transferred to the RUMM 2030 program for validation by means of the Rasch model. The results of the analysis of Questionnaire 3 are summarised in Table 6.7. The data sets of the first 100 respondents receiving active treatment and the 95 respondents who were seen for follow up were combined due to the fact that a comparison between QoL during treatment and follow up was not intended at this stage, but served to increase the sample size to improve the data quality of the validation process.

While capturing the data on the Excel spread sheet, four questionnaires were found to be incomplete and discarded. The total number of questionnaires for analysis was 195. The sample size was greater than for the first two questionnaires as the researcher expected the third questionnaire to show better results during the validation process, but it was not too big as the questionnaire was still in the developmental phase.

A dichotomous scale was used to make the questionnaire easy to complete for patients suffering from cancer. During the first round of analysis all thresholds were ordered. Items 3, 23, 27, 28, 30, 37 and 49 showed misfit. The questions were evaluated clinically and reasons were sought why the questions did not fit. The Chi Square was 0.000.

In round 2, the misfit items 3, 23, 27, 28, 30, 37 and 49 were deleted. All items fit, but the chi-square values did not change significantly.

Table 6.7:   **Analysis of Questionnaire 3: What makes life good or hard?**

Run number	Chi square (>0.05)	Mean location (= 0)	Standard deviation (=1)	Item fit (± 2.5)	PSI (>0.85)	Threshold ordering
1	0.000	-1.409	1.266	Item 3 (-2.679) Item 23 (3.479) Item27 (-3.332) Item 28 (-2.576) Item 30 (-2.529) Item 37 (3.977) Item49 (-2.717)	0.910	All ordered
2 Deleted Items 3, 23, 27, 28, 30, 37, 49	0.000	-1.494	1.261	All items fit	0.892	Ordered
3 Deleted extreme persons 66, 98, 121	0.000	-1.437	1.182	All items fit	0.891	Ordered
4 Subtests Individual Item Fit	0.000	-1.021	1.038	Subtests misfit	0.856	Ordered
5 Subtests clinical	0.000054	-1.154	0.6738	Subtests fit	0.788	Ordered

During round 3, extreme persons 66, 98 and 121 were deleted. All items fit, but again the reported chi-square values did not change significantly.

In round 4, subtests were created according to individual item fit, but the subtests did not fit.

Further resolutions were sought and during round 5, subtests were created clinically according to the domains of QoL identified in Phase 1. After this attempt the subtests fitted the model, except for the chi-square (0.000054) that still indicated a misfit. The PSI dropped to 0.788,

which indicated that the data of this sample were less reliable. The mean item location and standard deviation were not close to the suggested criteria of 0.00 and 1.0 respectively.

After several attempts to resolve the misfit issues, a solution could not be found. It seemed that the combination of negative and positive factors in one questionnaire could have led to misinterpretation of the questions, thus making the questions in Questionnaire 3 difficult to endorse for the participants in this sample.

6.3   DISCUSSION

The uniqueness and contribution of this study is that it developed a QoL instrument for cancer patients in South Africa using public health care for cancer treatment. The assessment instrument which was developed and validated will in future be called the South African Quality of Life Instrument for Cancer patients (SAQOLI-Ca). In addition, this was a patient-directed instrument, as the researcher first investigated what QoL means to these patients where after the instrument was developed. As discussed in Chapter 1, the meaning of QoL differs from person to person, as individuals place subjective priorities on their own value and what constitutes QoL to them (Chippendale, 2001). Experience of QoL depends on the perspective of the individual and not the perspective of the health care provider. Bennett and Closs (2008) describe QoL as a broad, complex and highly individual concept, which involves the total assessment of all aspects of daily life. Mitera, Zeiadin, Sahgal and Finkelstein et al. (2011) agree that QoL assessment should be done from the patient's perspective and not as perceived by health care providers.

When reflecting on possible reasons for the two questionnaires (Questionnaires 2 and 3) which showed poor fit to the Rasch model, the researcher realised that Questionnaire 2 and 3 did not test what she intended to test. The aim with developing the QoL instrument was to identify and manage problems which have a negative influence on QoL. Questionnaire 2 and 3 determined what had a positive influence on QoL, which was not the intention of the researcher.

Even though Questionnaire 1: *What makes life hard for you?* met the expectations of the Rasch model, the structure of the questions could be changed to make the questionnaire easier for persons with a low educational level and cancer patients to complete, as was attempted in

Questionnaire 3. An example is: Question 3: *Not being able to work: yes/no* in Questionnaire 1 was changed to: *Life is hard because I am not able to work: yes/no* in Questionnaire 3. The researcher hoped that the questions would be clear and easy to answer, but, when looking at the answers and during the validation process realised that the questions could be simpler. The format of the questions was changed in Questionnaire 3 and appeared to be more understandable to the respondents.

The combination of negative and positive factors in one questionnaire, like in Questionnaire 3, seemed to have led to misinterpretation of the questions. Questions about factors which make life good and hard were mixed. For instance, Question 6 asked whether *Life is hard because I cannot eat,* whilst Question 23 asked whether *Life is good because my symptoms are controlled well by the medication.* A possibility is that respondents, who were experiencing distressing symptoms such as pain or adverse social- or financial factors such as a lack of income, could have answered questions about good QoL differently than when they did not have such problems. It is quite possible that respondents with a low educational level or language difficulty could have misunderstood the questions and given different answers than intended. Twenty-eight percent of respondents who completed Questionnaire 1, 30% of respondents who completed Questionnaire 2 and 31% of respondents who completed Questionnaire 3 had less than a secondary school education.

During validation of the three questionnaires, creating subtests improved the fit of the data to the Rasch model. When further validation of the QoL instrument is done in future, the researcher proposes that the questions in the questionnaire be grouped according to domains of QoL, like in the WHOQOL-BREF, the FACT-G and the Ferrans conceptual model for QoL (Ferrans, 2011).

Even though Questionnaire 3 did not test what was intended, the researcher was interested to see what the difference in respondents' evaluation of QoL issues was during treatment and six or twelve months after treatment. When comparing QoL of respondents who were receiving active treatment with the QoL of respondents during follow up visits six or twelve months after treatment (Table 6.8), it was clear that the QoL of the respondents on treatment was much worse than during follow up, which suggested that symptoms might not have been assessed

and managed effectively. Therefore, it might have been quite possible that the QoL of the patients on treatment could have been better if QoL had been assessed during the patient's

Table 6.8: **Comparison of problems identified by the treatment- and follow up group**

Domain	Treatment group %	Follow up group %
Physical	48.2	32.6
Financial	54.5	47.7
Psychosocial	26.5	18.4
Spiritual	13.2	8.4
Existential	16.3	14.8
Emotional	31.7	27.0

first visit to the oncology unit and during subsequent visits, in order to identify and address problems timeously. This could have led to early identification of the patients' problems and also guided the manner in which these problems were addressed.

When the researcher reflected on the sample size for Phase 2 of the study she realised it was relatively small when compared with other studies which developed new instruments. For instance, the study on meaning on life conducted in South Africa, Australia and New Zealand (Schutte et al., 2016), which used a sample of 601 and a study on nutrition literacy (Guttersrud et al., 2013), which used a sample of 473. However, none of the samples included sick people; the sample for the meaning of life study consisted of members of the general public and the study on nutrition literacy used respondents who were nursing students. The smaller sample sizes of 47, 44 and 195 for the three questionnaires respectively, were used due to the fact that the instrument was still in the developmental phase. Also, respondents were cancer patients known to experience side-effects related to their disease and treatment, therefore, the researcher did not want to burden too many cancer patients with completion of the questionnaires which still contained too many questions.

However, the sample size of 195 for Questionnaire 3 compares positively to other studies involving cancer patients, such as a study for the validation of the EuroQol Five-dimension

(EQ5D) instrument for an Indian population (Tripathy et al., 2015), which used a sample of 150 cancer patients. Other studies for the validation of the University of Washington Quality of Life Questionnaire for patients with head and neck cancer (Adnane et al., 2016), and for the association of coping styles with QoL in cancer patients (Shakeri et al., 2015), used a sample of 104 and 150 cancer patients respectively.

It was clear that of the three questionnaires Questionnaire 1: *What makes life hard for you*? (Addendum G) fitted the Rasch model best. Questionnaire 2: *What makes life good for you?* (Addendum H) and Questionnaire 3: *What makes your life good or hard?* (Addendum I) did not fit the model. In Questionnaire 2 the chi-square was constantly below 0.05 and the PSI indicated that the instrument did not distinguish between high and low QoL (Table 6.4). In Questionnaire 3 the chi-square (0.000054) indicated a misfit. The PSI of 0.788 indicated that the data of the sample were less reliable. The mean item location and standard deviation were not close to the suggested criteria of 0.00 and 1.0 respectively.

The suggestion of the researcher is that Questionnaire 1: *What makes life hard for you?* (Addendum G) be tested in the clinical field to determine the effectiveness to assess QoL of cancer patients in South Africa who access public health care for cancer treatment.

6.4   SUMMARY

In Chapter 6 the findings of Phase 2 of the study were discussed with regards to the development and validation of three QoL assessment questionnaires. After the validation of the questionnaires, Questionnaire 1: *What makes life hard?* conformed to the expectations of the Rasch Measurement Model and the researchers propose that the instrument be tested for applicability for the assessment of QoL of South African cancer patients. The demographic data of the respondents who completed the three questionnaires were presented before presenting the results of the Rasch analysis of the different questionnaires. Thereafter the researchers reflected on the findings of Phase 2. Chapter 7 will present the justification, limitations and recommendations for further research.

CHAPTER 7

JUSTIFICATION, LIMITATIONS AND RECOMMENDATIONS

7.1   INTRODUCTION

The focus of Chapter 7 is the justification of the study, in terms of the purpose and aims, the research process, limitations and recommendations for further research. Through the exploration of QoL from the perspective of cancer patients in South Africa, the domains of QoL applicable to them were identified. A new instrument was developed for the assessment of QoL of cancer patients in South Africa.

7.2   JUSTIFICATION OF THE STUDY

The study focused on the quality of life of cancer patients in South Africa who access public health care for treatment and aimed to add to the body of knowledge of cancer care, in an attempt to develop and validate a patient-directed QoL instrument.

A mixed methods study was conducted. Qualitative interviews were conducted in order to identify domains of QoL which are applicable to South African cancer patients who access public health care for treatment. After transcribing the interviews and analysing the data, the following domains were identified as being applicable: physical-, financial-, social-, spiritual-emotional- and existential. When comparing these domains with the domains included in QoL instruments which are commonly used for cancer patients, such as the EORTC QLQ-C30, the WHOQLQ-BREF and the FACT-G, the domains were not the same, especially with regards to the financial-, spiritual- and existential domains.

It was clear that most of the study participants had to cope with financial difficulties as well as the effects of cancer and treatment. These findings can be compared to a study in the United States of America, which indicated that Latino-, Chinese- and African American cancer patients with a low income also suffered from severe financial strain while having to cope with a cancer diagnosis and that patients' needs with regards to an income, employment and transport are

often not met, just like in this study (Gany et al., 2015). The authors confirm that health care providers need to identify financial problems of cancer patients and provide support by referring patients to social services in order to improve QoL. The findings are also confirmed by a study on coping styles of cancer patients, which confirms the negative influence of a low income on QoL (Shakeri et al., 2015).

The quantitative part of the study developed and validated a new QoL assessment instrument. After analysing the data gathered in Phase 1 of the study, the categories were operationalised into questions and two questionnaires were compiled. The researcher divided the questions into two questionnaires to limit the number of questions and not place a too high burden on cancer patients when completing the questionnaires.

During the validation of the first two questionnaires by means of the Rasch model, some of the questions were problematic. When looking at the questions, the researchers found that some of the questions were asked in a positive way, such as: *Being too tired to carry out your normal activities of daily living* and other questions were asked in a negative way, such as: *Not being able to enjoy life.* The questions could have been confusing to respondents who had a low literacy level. Twenty-seven percent of the respondents who completed Questionnaire 1 and 29.5% of the sample who completed Questionnaire 2 did not have a secondary school education. The three response options: *yes/no/unsure* also appeared to be confusing for some of the respondents. After removing response option *unsure*, the questionnaire fitted the Rasch model better.

After removing categories which were problematic or duplicated, subtests were created according to domains of QoL. Questionnaire 1: What makes life hard for you? conformed to Rasch model expectations.

For Questionnaire 3 the format of the questions was changed and duplicated questions were removed. The researcher expected the questionnaire to work well and tested it with a larger sample of 195 respondents. This questionnaire did not conform to Rasch model expectations. When reflecting on possible reasons why the questionnaire did not fit the model, the researcher realised that the questionnaire did not only test what was intended, namely which

factors had a negative influence on QoL, in order to identify problems timeously. Clinical evaluation of the questions was needed to understand why certain questions were problematic.

Questionnaire 1: *What makes life hard for you?* fitted the Rasch model best and was accepted for testing in the clinical field. After testing the instrument further and validating it for other populations in South Africa, the questionnaire will be known as the South African Quality of Life Instrument for Cancer Patients (SAQOLI-Ca).

The study met all the objectives of the study as described in Chapter 1. The aims of the study as described in Chapter 1 were to explore QoL from the perspective of cancer patients in South Africa who access public health services for treatment and to develop and validate a patient-directed QoL assessment instrument. Chapter 2 presented a literature review and Chapter 3 the methods of Phase 1 of the study. Chapter 4 presented the findings of Phase 1 of the study and discussed QoL from the perspective of cancer patients in South Africa who accessed public health care for cancer treatment.

Chapter 5 presented the methods of the quantitative phase of the study, Phase 2, including the development of the questionnaires and the Rasch Measurement Model, which was used for validation of the instrument. Chapter 6 discussed the validation of the questionnaires and presented the findings of Phase 2.

7.3   LIMITATIONS OF THE STUDY

The limitations of the study were:

The study population consisted of patients who received treatment for cancer at one public health care facility in one province in South Africa; however the expectation of the researcher is that the findings will be the same for cancer patients treated in other public health facilities in South Africa.

The sample size for Phase 2 of the study was relatively small, (n=47, n=44 and n=195), but compared favorably with the samples in other studies which developed and validated QoL instruments for cancer patients (Tripathy et al., 2015; Adnane et al., 2016).

The structuring of the questions in the instrument is regarded as a limitation, as the questions could be confusing, especially for a person with a low literacy level. It is proposed that the questions all be asked the same way, for example: *Life is hard because I cannot sleep* yes/no and *Life is hard because I have severe pain* yes/no.

7.4   RECOMMENDATIONS

7.4.1   Recommendations for further research

The researcher recommends that the questions be revised to ensure that all the questions are structured the same way. The questions could be grouped according to domains of QoL found in Phase 1 of the study. It is further suggested that factors which have a positive influence on QoL not be included in a questionnaire which determines factors which have a negative influence on QoL, as it could be confusing to patients with a low educational level. If feasible, the number of questions should be further reduced to lessen the burden placed on cancer patients when completing the questionnaire. In addition, it is recommended that further research be done into the psychometric properties of the instrument and investigation be continued to refine the instrument.

It is proposed that the instrument be tested further for internal consistency, convergent and discriminative validity. Internal consistency is a reliability issue and will determine the stability of the questions in the new instrument. Convergent and discriminant validity will be helpful to show how well the new instrument correlate with similar QoL instruments for cancer patients.

Once validated for a population, it is proposed that the instrument be validated for other populations, for instance in other provinces in South Africa, and for other developing sub-Saharan countries.

In future the researcher proposes that the instrument be tested in the clinical field in public health facilities, as well as in private hospitals and clinics where patients are treated who have medical insurance. The researcher would like to determine what the difference in QoL is of patients treated in public- and private health facilities and if the support needs of cancer patients treated in private facilities are the same as patients' who are treated in public health facilities.

Once the instrument is validated for African countries, the researcher suggests that it be tested in first world countries for applicability.

7.4.2   Recommendations for nursing practice

The researcher recommends that the instrument be used by oncology nurses to assess QoL of cancer patients during first- and subsequent visits to health care facilities, in order to identify problems which have a negative influence on QoL timeously. By identifying problems early and throughout the illness trajectory, nurses can develop and implement care plans tailored for the individual needs of patients. In addition, early identification would also allow patients to be referred to other members of the multi-disciplinary team such as psychologists and social workers for additional support. When problems are managed effectively, the QoL of cancer patients can be improved and maintained while having to cope with cancer and the treatment thereof.

The researcher further recommends that the findings of the study be incorporated in the curriculum of Oncology Nursing Education to enhance evidence-based practice with regards to QoL of cancer patients.

7.5   CONCLUSION

This study supports the opinion that QoL is a complex, highly individual phenomenon. As seen in the study, QoL was influenced by various factors such as social- physical-, spiritual-, financial-, existential- and emotional factors. Using a patient-directed approach allowed the researcher to develop and pilot test a new QoL assessment instrument which includes all the relevant

domains of QoL for South African cancer patients. After validating the three questionnaires, the researchers found that Questionnaire 1: *What makes life hard for you?* (Addendum G) fitted the Rasch model best. In future the instrument will be referred to as the South African Quality of Life Instrument for Cancer Patients (SAQOLI-Ca).

7.6   FINAL NOTE

Through this study I, the researcher, learnt that the development of an instrument is a process which requires hard work and dedication and a learning curve with regards to the validation process. I sincerely hope that the QoL instrument which was developed will in future contribute to better QoL of cancer patients in South Africa.

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QUESTIONNAIRE FOR PATIENT DEMOGRAPHIC DATA

			Office use
1. How old are you?	yrs		**Q1=**
2. What is your gender?	Male	1	**Q2=**
	Female	2	
3. Which cultural group do you belong to?		1	**Q3=**
4. Which grade did you complete at school?			**Q4=**
5. Are you			
	Married customary	1	**Q5=**
	Married culturally	2	
	Single	3	
	Divorced	4	
	Widowed	5	
	Separated	6	
	Living with a partner	7	
6. What kind of cancer do you suffer from?		1	**Q6=**
7. How long have you been ill?	months/years		**Q7=**
8. What treatment do you receive?	Chemotherapy	1	**Q8=**
	Radiation therapy	2	
	Chemotherapy and radiation	3	
9. Which medication are you using?			**Q9=**
10. Who takes care of you?			**Q10=**

ADDENDUM B

<div align="center">

TOPIC GUIDE

</div>

The following themes will be explored:

What makes life good

- Generally

- Physically

- Psychosocially

- Spiritually

What makes life hard

- Generally

- Physically

- Psychosocially

- Spiritually

How patient feels about current life

ADDENDUM C
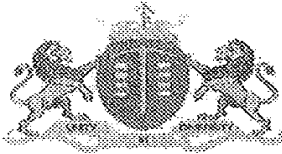
GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. L. Mngomezulu
Tel: (011): 488-3793
Fax: (011): 488-3753
Date: 15th April 2013

Ms. Rontie Jansen van Rensburg
Department of Nursing Education
University of the Witwatersrand

Dear Ms. Jansen van Rensburg

RE: "Development and validation of a Quality of Life assessment instrument for cancer patients in
        South Africa"
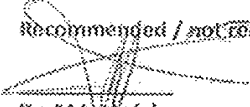
Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a
    result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister In-Charge to agree on the dates and
time that would suit all parties.
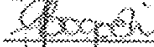
Kindly forward this office with the results of your study on completion of the research.

Recommended / not recommended

Dr. M.J. Mofokeng
Clinical Director   15/04/2013

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
16 | 04 | 2013

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ADDENDUM D

Nursing Education

CONFIDENTIALITY AGREEMENT: INTERPRETER

I, _____, ID number _____ hereby declare that I am willing to assist Mrs Kotie Jansen van Rensburg during interviews for her PhD study, by interpreting in case a participant in the study does not understand a question asked in Afrikaans or English. I understand that all information obtained during the interviews has to be kept confidential.

Signature: _____ Date: _____

Witness: _____ Date: _____

Witness: _____ Date: _____

Nursing Education

INFORMATION LEAFLET AND INFORMED CONSENT

TITLE: DEVELOPMENT AND VALIDATION OF A QUALITY OF LIFE ASSESSMENT INSTRUMENT FOR CANCER PATIENTS IN SOUTH AFRICA

Dear Patient

My name is Kotie Jansen van Rensburg. I am a student at the University of the Witwatersrand, Department of Nursing Education. I would like to invite you to take part in a study that I am conducting in this Oncology Unit where you are receiving your treatment for cancer. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in the study, you should fully understand what is involved. If you have any questions which are not fully explained in this leaflet, do not hesitate to phone me, Kotie Jansen van Rensburg at 082 822 7989 or my supervisor, Professor Lize Maree at 011 488 4196 during office hours. You should only agree to take part if you are completely satisfied with all the procedures involved.

What is the study all about?

I would like to find out how you feel about your life at present: what makes life good for you and what makes life hard for you. Talking to me about your life will help me to understand what is important for cancer patients to live a good life and then I will be able to help to improve the lives of cancer patients in South Africa.

What will you need to do in the study?

If you agree to take part in the study, I will first ask you to sign a consent form. This form is to show that you will allow me to talk to you and use the information that you give me. If you agree, I will use a voice recorder during the interview, so that I can listen to what you said when

I am at home and can type everything you said. If you do not agree, I will not record the interview and will make notes during the interview. I would ask you to tell me a little of yourself like how old you are, who takes care of you and what type of cancer you are suffering from. After that I will talk to you about your experience of life at present. This will take about one hour of your time. If you get very upset or tired during the interview, you may ask me to stop for a while or you may refuse to continue with the interview.

Are there any conditions that may exclude you from the study?

You have to be a patient at the Oncology unit, receiving chemotherapy or radiation therapy or both for cancer and be older than 18 years.

What are the risks involved in this study?

You might become sad when you tell me about your experience of having cancer and receiving treatment. Unfortunately this is the only way that I can find out how you feel about your life at present. If you are upset I will be able to refer you to a very experienced counselor who will help you discuss your distress or anxiety and give you some assurance about your illness and the treatment you are undergoing. As mentioned previously, you may decide at any time during the interview that you don't want to be in the study, or that you need a break before continuing with the interview. You are perfectly within your rights and, if you do decide to withdraw, your decision will not have any effect on the normal treatment you would receive at the Oncology unit.

What are the potential benefits that may come from the study?

By participating in this study you will help me to understand how cancer patients in South Africa experience cancer and the treatment for cancer and what is important for them in their lives. This would help me find a way to serve patients better. There are, however, no benefits for you personally and you will not be paid to participate in the study.

What are your rights as a participant in this study?

You can choose if you want to take part in the study. You can also, during the interview, say that you do not want to take part any more. You can even tell me that I cannot use the information after you have talked to me. Once I have taped what you have said, I will wipe out your name and nobody will know that this is what you said. I will not share your personal information and your name with anybody and will use a pseudonym when talking about the information that you shared with me. A pseudonym is another name that I will call you that nobody else knows about.

How will confidentiality and anonymity be ensured for the study?

What you say to me is strictly confidential and only I would be able have access to your information. I will not identify you in any way on my records – your information will be given a code number which cannot be traced back to your name. When I type what you said, I will remove your name and use the pseudonym which I told you about previously. Your real name will not be used when I write the report.

Has the study received ethical approval?

Before asking you to take part in the study, the Human Research Ethics Committee of the University of the Witwatersrand and the Ethics Committee of the Gauteng Health Department will approve the study. Should you have any questions regarding the ethical aspects of the study, you can contact the chairperson of the Ethics Committee Prof Peter Cleaton-Jones on 011-7172100.

Thank you for taking the time to consider joining the study. If you have any further questions, please contact me.

Yours sincerely,

Kotie Jansen van Rensburg

Cell: 082 822 7989

Informed consent

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 my personal details will be anonymously processed into a research report. I understand that I may withdraw my consent and participation in the study. I had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant's name   _____   (Please print)

Participant' signature   _____   Date _____

Investigator's name   _____   (Please print)

Investigator's signature   _____   Date _____

I, …………………………………………. (field worker) herewith confirm that the above participant has been informed fully about the nature, conduct and risks of the above study.

Witness's name*   _____   (Please print)

ADDENDUM F

Nursing Education

INFORMATION LEAFLET AND INFORMED CONSENT

TITLE: DEVELOPMENT AND VALIDATION OF A QUALITY OF LIFE ASSESSMENT INSTRUMENT FOR CANCER PATIENTS IN SOUTH AFRICA

Dear Patient

My name is Kotie Jansen van Rensburg. I am a student at the University of the Witwatersrand, Department of Nursing Education. I would like to invite you to take part in a study that I am conducting in this Oncology Unit where you are receiving your treatment for cancer. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in the study, you should fully understand what is involved. If you have any questions which are not fully explained in this leaflet, do not hesitate to phone me, Kotie Jansen van Rensburg at 082 822 7989 or my supervisor, Professor Lize Maree at 011 488 4196 during office hours. You should only agree to take part if you are completely satisfied with all the procedures involved.

What is the study all about?

I would like to find out how you feel about your life at present: what makes life good for you and what makes life hard for you. Talking to me about your life will help me to understand what is important for cancer patients to live a good life and then I will be able to help to improve the lives of cancer patients in South Africa.

What will you need to do in the study?

If you agree to take part in the study, I will first ask you to sign this consent form. This form is to show that you will complete a short questionnaire and allow me to use the information that

you give me. I would ask you to tell me a little of yourself like how old you are, which cultural group you belong to and what type of cancer you are suffering from. You will be asked to fill in a questionnaire, which will take about 20 minutes of you time. If you get very upset or tired while completing the questionnaire, you may ask to stop for a while or you may refuse to continue with the questionnaire.

Are there any conditions that may exclude you from the study?

You have to be a patient at the Oncology unit, receiving chemotherapy or radiation therapy or both for cancer and be older than 18 years.

What are the risks involved in this study?

You might become sad when filling in the questionnaire about your experience of having cancer and receiving treatment. Unfortunately this is the only way that I can find out how you feel about your life at present. If you become upset I will be able to refer you to a very experienced counselor who will help you to discuss your distress or anxiety and give you some assurance about your illness and the treatment you are undergoing. As mentioned previously, you may decide at any time during the completion of the questionnaire that you don't want to be in the study, or that you need a break before continuing. You are perfectly within your rights and, if you do decide to withdraw, your decision will not have any effect on the normal treatment you would receive at the Oncology unit.

What are the potential benefits that may come from the study?

By participating in this study you will help me to understand how cancer patients in South Africa experience cancer and the treatment for cancer and what is important for them in their lives. This would help me find a way to serve patients better. There are, however, no benefits for you personally and you will not be paid to participate in the study.

What are your rights as a participant in this study?

You can choose if you want to take part in the study. You can also, during the completion of the questionnaire, say that you do not want to take part any more. You can even tell me that I cannot use the information after you have completed the questionnaire.

How will confidentiality and anonymity be ensured for the study?

What you say to me is strictly confidential and only I would be able have access to your information. I will not identify you in any way on my records – your questionnaire will not contain your name, but will be given a number which cannot be traced back to your name.

Has the study received ethical approval?

The Human Research Ethics Committee of the University of the Witwatersrand and the Ethics Committee of the Gauteng Health Department have approved the study. Should you have any questions regarding the ethical aspects of the study, you can contact the chairperson of the Ethics Committee Prof Peter Cleaton-Jones on 011-7172100.

Thank you for taking the time to consider joining the study. If you have any further questions, please contact me.

Yours sincerely,

Kotie Jansen van Rensburg

Department of Nursing Education   Tel: 011 488 4268 or Cell: 082 822 7989

Informed consent

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 my personal details will be anonymously processed into a research report. I understand that I may withdraw my consent and participation in the study. I had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

Participant's name   _____   (Please print)

Participant's signature   _____ Date _____

Investigator's name   _____   (Please print)

Investigator's signature   _____   Date _____

I, ……………………………………………. (field worker) herewith confirm that the above participant has been informed fully about the nature, conduct and risks of the above study.

Witness's name*   _____   (Please print)

ADDENDUM G

Questionnaire 1: What makes life hard for you?

General information:

Question	Answer		Office use
1. How old are you?	years		Q1=
2. What is your gender	Male	1	Q2=
	Female	2	
3. Which cultural group do you belong to?		1	Q3=
4. What is your highest qualification?		1	Q4=
5. What kind of cancer do you have?			Q5=

Which of the following make life hard for you?

No	Question	Yes	No	Unsure
1.	Not being able to do what you did before the cancer			
2.	Being too tired to carry out your normal activities of daily living			
3.	Not being able to work			
4.	Not being able to enjoy life			
5.	Not being able to keep busy			
6.	Not being able to have a sexual relationship			
7.	Being told to eat different foods			
8.	Experiencing physical problems like:			
	• Not being able to eat			
	• Not being able to sleep			
	• Losing your hair			
	• Having diarrhea			
	• Having constipation			
	• Suffering from nausea and vomiting			
	• Experiencing changes in smell sensation			
	• Experiencing changes in taste sensation			
	• Suffering from bleeding			
	• Having pain			

No	Question	Yes	No	Unsure
	• Suffering from piles			
	• Feeling dizzy			
	• Experiencing skin changes			
	• Experiencing swelling of your legs and feet			
	• Getting cramps			
	• Seeing stars before your eyes			
	• Feeling tired most of the time			
	• Suffering from hot flushes			
9.	Not being able to do what others do			
10.	Having to get up very early to go to the hospital			
11.	Having to travel far to the hospital			
12.	Not feeling good about your body			
13.	Losing weight			
14.	Not being able to be as active as before			
15.	Not being able to take part in religious activities like prayer, singing, attending church and worshipping			
16.	Being separated from your family			
17.	Experiencing changes in your relationships with others			
18.	Not being able to care for yourself			
19.	Not getting support from your friends and family			
20.	Experiencing difficulties with traveling to the hospital			
21.	Not being able to manage your work			
22.	Having to keep on working while sick			
23.	Not being able to visit your friends			
24.	Struggling to come to hospital due to lack of money			
25.	Not having money for the right foods			
26.	Losing your job because of the illness			
27.	Being financially dependent on others			
28.	Not having enough money for food for your family			
29.	Having to cope with the diagnosis of cancer			
30.	Having to face negative people			
31.	Being upset about losing weight			
32.	Feeling embarrassed about your symptoms			

No	Question	Yes	No	Unsure
33.	Feeling depressed			
34.	Feeling angry			
35.	Feeling unsure about the future			
36.	Feeling hopeless			
37.	Being scared of death			
38.	Not having hope for the future			
39.	Worrying about what will happen to your children and family			
40.	Feeling like ending your life			
41.	Not being able to enjoy life			
42.	Not being informed about cancer and the treatment			
43.	Being scared of the unknown			
44.	Feeling worried about your work			
45.	Feeling like less of a woman / man			
46.	Being scared of people's reactions when they hear that you have cancer			
47.	Missing your children and family			
48.	Feeling you have too much to cope with			
49.	Not being able to plan for the future			
50.	Not being able to fulfill your role as a parent / partner			

ADDENDUM H

Questionnaire 2: What makes life good for you?

General information:

Question	Answer		Office use
1. How old are you?	years		Q1=
2. What is your gender	Male	1	Q2=
	Female	2	
3. Which cultural group do you belong to?		1	Q3=
4. What is your highest qualification?		1	Q4=
5. What kind of cancer do you have?			Q5=

Please tell me which of the following make life good for you?

No	Question	Yes	No	Unsure
1.	Being able to eat			
2.	Not losing weight			
3.	Not having pain			
4.	Being able to keep busy			
5.	Getting relief of symptoms through medication			
6.	Learning through the experience of cancer			
7.	Being able to make peace with having cancer			
8.	Being able to do what you did before the cancer (cooking, cleaning, working)			
9.	Being able to take care of yourself and your family			
10.	Finding ways of earning money at home			
11.	Being able to enjoy activities like reading, watching TV, singing and dancing			
12.	Not having difficulties to come to the hospital			
13.	Being able to maintain your relationships with your friends			
14.	Being able to talk to other patients about cancer			
15.	Getting support from members of your church			
16.	Having a good relationship with your partner and family			
17.	Being able to spend time with your family			

No	Question	Yes	No	Unsure
18.	Being informed about your illness and treatment			
19.	Receiving treatment from caring staff			
20.	Being able to be positive despite of your illness			
21.	Not being afraid of the future			
22.	Being able to enjoy life			
23.	Receiving support from your partner, family and friends			
24.	Being able to talk to somebody about your illness			
25.	Feeling in control of your life			
26.	Being able to take part in spiritual activities like prayer, song, worshipping, reading the Bible and going to church			
27.	Feeling closer to God because of the cancer			
28.	Growing spiritually			
29.	Believing God is in control of the cancer and your life			
30.	Feeling blessed despite having cancer			
31.	Believing in eternal life			
32.	Experiencing the love and grace of God during your illness and treatment			
33.	Accepting suffering and death as part of life			
34.	Not being afraid of death			
35.	Experiencing love and friendliness when you are with members of your church			
36.	Being able to support other patients with cancer			
37.	Having hope to live a normal life in future			
38.	Being able to use your experience of cancer to encourage others to live close to God			
39.	Being able to believe that your illness is part of God's plan for your life			
40.	Being able to be strong for your family			
41.	Having hope for a better future without pain and suffering			
42.	Being able to see death as part of life			
43.	Being able to get your matters in order			
44.	Being able to pay for your own and your family's expenses			
45.	Having a job			

No	Question	Yes	No	Unsure
46.	Having financial support from your partner / family			
47.	Having an income			
48.	Having a job to return to after your treatment			
49.	Being able to live one day at a time and be grateful			
50.	Being able to fulfill your roles as a mother / father / spouse / friend			

ADDENDUM I

Questionnaire 3: What makes your life good or hard?

General information:

Question	Answer		Office use
1. How old are you?	years		Q1=
2. What is your gender	Male	1	Q2=
	Female	2	
3. Which cultural group do you belong to?		1	Q3=
4. What is your highest qualification?		1	Q4=
5. What kind of cancer do you have?			Q5=

Please answer all the questions

No	Question	Yes	No
1.	Life is hard because I am too tired to do what I did before the cancer		
2.	Life is hard because I am not able to work		
3.	Cancer is making life difficult for me at the moment		
4.	Life is hard because I am not able to keep busy		
5.	Life is hard because I have to eat different foods		
6.	Life is hard because I cannot eat		
7.	Life is hard because I cannot sleep		
8.	Life is hard because I am losing my hair		
9.	Life is hard because I have diarrhea		
10.	Life is hard because I have a problem with constipation		
11.	Life is hard because I am suffering from nausea and vomiting		
12.	Life is hard because I cannot taste the food or the food tastes different		
13.	Life is hard because I am bleeding a lot		
14.	Life is hard because I have severe pain		
15.	Life is hard because I often feel dizzy		
16.	Life is hard because I am experiencing changes in my skin		
17.	Life is hard because I suffer from cramps		
18.	Life is hard because I suffer from hot flushes		
19.	Life is hard because I cannot do what others do		

No	Question	Yes	No
20.	Life is hard because I have to get up early and travel far to the hospital for treatment		
21.	Life is hard for me because the cancer changed my body		
22.	Life is hard for me because I am losing weight		
23.	Life is good because my symptoms are controlled well by the medication		
24.	Life is hard because I cannot have a sexual relationship due to the cancer		
25.	Life is hard for me because I am separated from my family		
26.	Life is hard for me because my relationships with my friends and family have changed		
27.	Life is hard for me because I am not able to take care of myself and my family		
28.	Life is hard because I cannot visit my friends		
29.	Life is hard because I am worried about my work		
30.	Life is hard for me because I cannot fulfill my role as a parent / partner		
31.	Life is good because I can read, watch TV and sing		
32.	Talking to other patients about cancer makes life good for me		
33.	I have a good relationship with my partner and family		
34.	The staff at the hospital are friendly and caring		
35.	My partner, family and friends support me		
36.	Being able to work makes life good for me		
37.	Life is hard for me because I cannot go to church		
38.	Taking part in activities like prayer, song, reading the Bible and going to church makes life good for me		
39.	I feel closer to God because of the cancer		
40.	The support which I get from members of the church makes life good for me		
41.	I believe God is in control of the cancer and my life		
42.	Using my experience of cancer to encourage others to live close to God makes life good for me		
43.	Life is hard because I do not have money for transport to come to the hospital		

No	Question	Yes	No
44.	Life is hard because I have to keep on working while I am sick		
45.	Life is hard because I have to depend on my friends and family for financial support		
46.	I find it difficult to cope with having cancer		
47.	I find it difficult to face negative people		
48.	I feel embarrassed about my symptoms		
49.	I feel depressed most of the time		
50.	I feel angry most of the time		
51.	I feel hopeless most of the time		
52.	I am scared of dying		
53.	I am worried about my family and children		
54.	I feel scared because I do not know what is going to happen to me		
55.	I feel like less of a man / woman because of the cancer		
56.	I feel positive despite having cancer		
57.	I am not afraid of the future		
58.	I can still enjoy life despite having cancer		
59.	I feel in control of my life		
60.	I am able to be strong for my family		
61.	Life is hard because I cannot plan for the future		
62.	I feel I am learning through my experience of cancer		
63.	I have made peace with having cancer		
64.	I accept suffering and death as part of life		
65.	Being able to support other patients with cancer makes life good for me		
66.	I am able to get my matters in order		
67.	I have hope for a better future without pain and suffering		

Interview 1: 28 June

K   Good morning Poppy

P   How are you?

K   I'm fine and you?

P   I'm good, thanks

K   Thank you very much for agreeing to talk to me. What I would like to find out from you is: what makes life good for you?

P   Just living life. It's the best thing ever: living life as it comes.

K   So, are there things that you do... or relationships maybe that make life good for you?

P   Yes... having someone that's there for you...that cares for you and supports you...that makes it better.

K   So, who is supporting you?

P   My mom and my boyfriend

K   Is there anything about your body that makes life good for you.

P   Yes, it's a stable body. When I'm sick it doesn't drastically go down... I don't like to use weight...being thin, thin thin...it's just normal.

K   OK...so to keep your weight is important to you

P   Yes.

K   You don't want to be thin

P   No, I don't. (laughs).

K   Has the illness affected your body in any way?

P   Not really, it hasn't actually, no.

K   You are looking well. You look beautiful.

P   Thank you

K   Has the illness had any influence on you spiritually?

P   Yes, it taught me to kneel down more and concentrate on God more than I used to.

K   Can you tell me more about that?

ADDENDUM K

ETHICAL APPROVAL

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Kotie Jansen van Rensburg

CLEARANCE CERTIFICATE   M120919

PROJECT

Developnment and Validation of a Quality of
Life Assessment Instrument for Cancer
Patients in South Africa

INVESTIGATORS   Ms Kotie Jansen van Rensburg.

DEPARTMENT   Department of Nursing Education

DATE CONSIDERED   28/09/2012

DECISION OF THE COMMITTEE*   Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon
application.

DATE   07/12/2012   CHAIRPERSON ....
                                              (Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor :   Prof JE Maree

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor,
Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned
research and I/we guarantee to ensure compliance with these conditions. Should any departure to be
contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the
Committee. **I agree to a completion of a yearly progress report.**
       PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...