# EFFECTS OF A PSYCHOSOCIAL INTERVENTION ON THE QUALITY OF LIFE OF PRIMARY CAREGIVERS OF WOMEN WITH BREAST CANCER IN ABUJA, NIGERIA

**ISRAEL OLATUNJI GABRIEL**

**STUDENT NUMBER: GBRISR002**

A DISSERTATION SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

*In fulfilment of the requirements for*

**Master of Science in Nursing**

**MM002**

**Faculty of Health Sciences**

**UNIVERSITY OF CAPE TOWN**

**Supervisor: Associate Professor Pat Mayers, Department of Health and Rehabilitation Sciences, University of Cape Town**

# Declaration

I, **Israel Olatunji Gabriel**, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and have used the Harvard UCT style of referencing. I declare that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: Signed by candidate

Date: 4th June, 2017

# Acknowledgements

I will like to thank the Authority in Heaven, the God of the universe for the grace and mercy He permitted me to freely access throughout my study. Lord, you have helped me thus far, I feel like singing continually for your faithfulness in my life. My heartfelt thanks go to my indefatigable supervisor, Associate Professor Pat Mayers, I want to say thank you for choosing to supervise me and for your patience, understanding, assistance, and spontaneous response each time I submitted work to you. These have enabled me to complete this project.

I will like to salute the staff members and students of the Department of Health and Rehabilitation Sciences for the administrative assistance, educational mentoring/guidance and moral support you made available and accessible to me. Worthy of note are: Associate Professor Sinegugu Duma, Dr Nicki Fouche, Dr Una Kyriacos, Dr Helen Buchanan, Abimbola Eunice Ojo, and Mamotlatsi Caroline Lefunyane, your contribution towards the realisation of this dream is highly appreciated.

To my editor, Leverne Gething, I must confess you are indeed a wonderful being. Thank you for investing your precious time and energy on my dissertation. Your expertise is worthy of note. Thank you for being prompt at such short notice.

My heartfelt thanks go to my HOD/Assistant Director (Nursing Education) Mrs Salamatu Hassan of the School of Post Basic Nursing Programme, Ahmadu Bello University Teaching Hospital (ABUTH), Zaria for her absolute support of my career progression, may Allah bless you ma. Worthy of note are my superior in the office, Mr Joshua Oscar and Mr Mohammed Okeme and the members of staff of the School of Post Basic Nursing Programme, Ahmadu Bello University Teaching Hospital (ABUTH) Zaria. I hope to bring to bear the knowledge I acquired during my study.

How can I forget my one and only family? My lovely wife, you became a father and mother to our daughters Marvellous, Victoria and Shalom. Your sacrifice is second to none; you are indeed my rare gem. I love you so much.

# Dedication

To my Heavenly Father,

In whom I live and have my being. To Him be the glory for ever and ever, and

To my wife,

Ruth Gabriel,

For her unfailing love, support and encouragement in all my endeavours

## Contents

## CHAPTER ONE

## CHAPTER TWO

## CHAPTER THREE

## CHAPTER FOUR

## CHAPTER FIVE

## List of Figures

## List of Tables

# Abstract

Studies have shown that limited attention has been paid to the psychosocial wellbeing of caregivers of patients undergoing care and treatment for breast cancer in Nigeria. There are no interventions in place to cater for their needs despite, the psychological problems faced by this group of people. This study investigated the effectiveness of a psychosocial intervention in term of impact on the quality of life (QOL) of primary caregivers of women with breast cancer in Abuja, Nigeria. Using a quasi-experimental design, sample of 108 participants assigned to the intervention and control groups, the study made use of the Zarit Burden Interview (ZBI) and Caregiver Quality of Life Index-Cancer (CQOLC) to measure caregiver burden and QOL respectively. The hypothesis for the study was that the primary caregivers of women with breast cancer who receive a psychosocial intervention programme will report improved QOL compared with caregivers who do not attend a psychosocial intervention programme. The study established that there were a negative linear relationship between caregiver burden and QOL ($R = -0.45$, $p < 0.001$) as a basis for intervention, and also that 29% variance of QOL could be explained by caregiver burden.

The intervention results showed that at baseline 51.9% participants reported moderate to severe burden and 48.1% reported severe burden. These figures reduced to 22.3% and 12.6% for moderate to severe and severe burden respectively at 6 weeks after intervention, and further reduced to 18.6% and 4.9% respectively at 12 weeks after intervention. Comparing the QOL of the intervention and control groups, the results showed a significant difference on the score at baseline, 6 and 12 weeks. However, looking at performance of the intervention group, there was no significant different at baseline and 6 weeks ($t=0.83$, $p < 0.05$), and baseline and 12 weeks ($t=1.65$, $p < 0.05$). With reference to the caregiver burden of the intervention and control groups, it was found that a significant difference existed at baseline ($t=9.33$, $p < 0.001$). In respect of the impact of the intervention on caregiver burden of the intervention group, results showed a significant difference between baseline and 6 weeks ($t=30.34$, $p < 0.001$) and between baseline and 12 weeks ($t = 36.80$, $p < 0.001$) after intervention.

The study concluded that the psycho-education intervention significantly affected caregiver burden but did not affect caregivers' QOL. Therefore, there is a need for a psycho-education intervention for caregivers of patients with breast cancer, in order to reduce the burden and help them cope with the work of caregiving. Appropriate supportive interventions should be made available to support the close family members of patients with breast cancer in order to reduce caregiver burden. Relevant stakeholders in the healthcare sector especially in palliative care should promote awareness of carer needs. The provision of intervention programmes for caregivers requires further research to develop contextually specific programmes and services which will improve the QOL of caregivers.

**Keywords:** Caregiver burden, Quality of life, Psycho-education intervention, Psychosocial, and breast cancer.

## List of abbreviations

| | |
|---|---|
| CBT | Cognitive Behavioural Therapy |
| CCP | Caring for the Caregiver Programme |
| COPE | Creativity, Optimism, Planning and Expert Information |
| CQOLC | Caregiver Quality of Life Index- Cancer |
| ECOG | Eastern Co-operative Oncology Group |
| FACT:G | Functional Assessment of Cancer Therapy- General |
| GHQ | General Health Questionnaire |
| POS | Palliative Outcome Scale |
| QOL | Quality of Life |
| RCT | Randomised Controlled Trial |
| WHOQOL | World Health Organization Quality of Life Instruments |
| ZBI | Zarit Burden Interview |

# CHAPTER ONE

## OVERVIEW OF THE STUDY

### 1 Introduction

Breast cancer is the leading type of cancer among women in Nigeria. It affects the middle and older age groups more than women below the age of 40 years (Ntekim, Nufu & Campbell, 2009:242; Nggada et al., 2008:285; Oluwatosin, 2006:461). The incidence of the disease has risen significantly between 1960 and 2010 in Nigeria; it was 13.7 per 100 000 in 1960-1969; 24.7 per 100 000 in 1998-1999; and 54.3 per 100 000 between 2009 and 2010. This represents a 100% increase (Jedy-Agba et al., 2012:274; Adebamowo & Adekunle, 1999:665). About 24.5 million women in Nigeria were at risk of breast cancer in 1990, and this increased to about 40 million in 2010. It has been projected that by 2020, about 50 million women would be at risk of having this disease (Akarolo-Anthony, Ogundiran & Adebamowo, 2010:1).

Despite the rise in breast cancer incidence, there has been improvement in its diagnosis and management. According to Parkin and Fernandez (2006:73,77-78), 89% of breast cancer patients survive beyond 5 years after diagnosis. This high survival rate is attributed to early detection and improved treatment. The treatment of breast cancer has improved which has led to more persons with breast cancer living longer than ever before (Vos et al., 2006:212). Another development in breast cancer management is the shift from the acute care cancer centre (hospital in-patient care) to outpatient and community settings for continued care (Wadhwa et al., 2013:403; Northouse, 2012:500; Adams, Boulton & Watson, 2009:179). Consequently, the burden of care has now been shifted from health workers to family members, who often serve as primary caregivers (Frambes et al., 2017:2; Sklenarova et al., 2015:1513; Aoun et al., 2005:551-552).

If persons with breast cancer are living longer and treatment of the condition is now situated in community settings, it implies that this results in more responsibilities for the primary caregivers, particularly those always with the person with breast cancer (Chih et al., 2013:534; Williams & Bakitas, 2012:775; Chiquelho et al., 2011:337; Aranda & Hayman-White, 2001:301). However, most primary caregivers are not prepared for the caregiving role but suddenly find themselves having to take this on. The result is that they cannot deliver proper care because of little or no knowledge of caregiving (Chih et al., 2013:534; Northouse, 2012:500), and in the attempt to provide care for their loved ones, often neglect their own health care needs (Lapid et al., 2016:1400), causing deterioration in their quality of life (QOL).

Although studies have given attention to the QOL of persons with breast cancer (Bonnaud-Antignac et al., 2012:320), little is known about the predictors of QOL (physical, social and psychological wellbeing) of primary caregivers in Nigeria (Yusuf, Adamu & Nuhu, 2011:902). Therefore, this study aimed to implement and evaluate the effectiveness of a psychosocial intervention programme on the QOL of primary caregivers of women with breast cancer.

The theoretical framework for this study is the Lazarus and Folkman transactional model of stress and coping. This acknowledges personal, social, and illness-related factors as antecedent conditions that can constitute harm and affect the QOL of primary caregivers of women with breast cancer (Lazarus & Folkman, 1987).

## 1.1 Background to the study

A woman with breast cancer may develop psychopathological disturbances such as depression and anxiety with negative effects on her QOL, and therefore needs physical, psychological, and social support (Govina et al., 2015:81; Li & Loke, 2014:731; Shahi et al., 2014:332; Fann et al., 2008:112-113). Due to improvements in cancer treatments over the past few decades, many patients are living long after their original diagnoses; this comes with an associated increase in caregiving demands which must be met by the primary caregivers (Chih et al., 2013:534; Deeken et al., 2003:922-923).

The primary caregivers do many things that used to be done in the hospital by health workers (Mitnick, Leffler & Hood, 2010:255); they can help plan treatment, make decisions, and carry out treatment plans all through the different phases of managing the condition (Lkhoyaali et al., 2015:2; Waldron et al., 2013:1200). As most of them begin caregiving without training and are expected to meet many demands without much help, they face anxiety and other psychological problems (Dionne-Odom et al., 2016:854). They are often overwhelmed with the tasks of caregiving and may neglect their own physical, psychological, and social needs, if this persists; it will negatively affect their QOL (Kent et al., 2016:1989; Effendy et al., 2015:585; Turkoglu & Kilic, 2012:4141-4142; Cameron et al., 2004:137).

Previous studies have shown that caregivers experience a high level of stress that has a detrimental effect (Mahendran et al., 2017:2; Amir et al., 2012:1167; Hagedoorn et al., 2008:1-2; Hodges, Humphris & Macfarlane, 2005:9) on their psychological wellbeing (Northouse et al., 2012:237). A review and meta-analysis conducted by Hodges et al. (2005:9) reported that there was a significant relationship between the distress reported by cancer patients and the distress reported by their caregivers. When cancer patients experience distress, their caregivers share the distress (Rottmann et al., 2015:486). In another meta-analysis, Hagedoorn et al. (2008:6,18) reported that spouses who provide care to their partners with cancer experience equal levels of distress as the partner with cancer. Bevans and Sternberg (2012:398-402) documented a case study to show the nature of psychological distress experienced by a caregiver of a spouse with cancer. This study showed that a caregiver is likely to experience anxiety, depression, worry and extreme loneliness, fatigue, and sleep problems.

Possible sources of distress for caregivers include workload associated with caregiving, overwhelming feelings of powerlessness about how to reduce the suffering of the patient, social isolation and uncertainty about the outcome of the illness (Din et al., 2017:465-466; Northouse et al., 2012:237). Sometimes the caregiver may also be coping with a health problem prior to taking up the caregiving role and will experience difficulties in maintaining habits and behaviours such as exercise and healthy eating to improve their wellbeing.

Although the QOL of primary caregivers of women with breast cancer has been investigated in other continents of the world (Wadhwa et al., 2013:404; Waldron et al., 2013:1200; McMillan & Small, 2007:313; McMillan et al., 2006:214), no information on the condition in Nigeria was found in the course of reviewing literature related to this study.

However, from the numerous studies done in the developed world, meta-analyses indicate that the primary caregivers of persons with breast cancer benefit from psycho-educational interventions (Yoon et al., 2014:1244; O'Hara et al., 2010:2; Stenberg, Ruland & Miaskowski, 2010:1013; Badger et al., 2004:24-25; Samarel, Tulman & Fawcett, 2002:466-467; Sandgren et al., 2000:686). A variety of these interventions have been used to assist caregivers in managing the effects that caregiving burdens have on their QOL (Tan et al., 2015:3403; Dolbeault et al., 2009:648).

## 1.2 Research problem

The prevalence of the breast cancer-related death is on the increase in Nigeria. Patients and their primary caregivers are negatively affected (Haun et al., 2014:384; Ovayolu et al., 2014:424-425). Despite the psychological problems faced by primary caregivers of persons with breast cancer, limited attention has been paid to their physical, social, and psychological wellbeing (Yusuf, Adamu & Nuhu, 2011:902). Most interventions have been on persons with breast cancer, with few on cancer patient/family caregiver dyads (Northouse et al., 2014:321; McMillan et al., 2006:215). The situation is, however, worse in Nigeria because no published studies have been found which investigated the psychosocial burden faced by primary caregivers or effectiveness of interventions on the QOL of primary caregivers of women with breast cancer. Therefore, this study will address the problem by assessing the effectiveness of a psychosocial intervention on the QOL of primary caregivers of women with breast cancer in Abuja, Nigeria.

## 1.3 Rationale for the study

A review of the literature shows that both persons with cancer such as breast cancer and primary caregivers experience distress and psychosocial problems associated with the illness (Girgis et al., 2013:1557; Harding et al., 2012:7; Girgis, Lambert & Lecathelinais, 2011:387; Caress, Chalmers & Luker, 2009:1517). There is therefore a need to provide the primary caregivers with psychosocial interventions that will improve their physical, social, and psychological wellbeing, as well as QOL. This study provided an intervention for the primary caregivers of persons with breast cancer who receive treatment at the National Hospital, Abuja, Nigeria.

## 1.4 Research question

The following was the research question investigated in this study:

What are the effects of a psychosocial intervention programme on the QOL of primary caregivers of women with breast cancer?

## 1.5 Aim of the study

The aim of the study was to implement and evaluate the effectiveness of a psychosocial intervention programme on caregiver burden and self-reported QOL of primary caregivers of women with breast cancer in Abuja, Nigeria.

## 1.6 Objectives of the study

The objectives of the study were:

1. To determine the self-reported psychosocial burden associated with caregiving of women living with breast cancer using the Zarit Burden Interview (ZBI) tool (Section B of Appendix C);
2. To compare the QOL and caregiving burden in the control and intervention groups.
3. To evaluate the impact of the intervention on the psychosocial burden of the intervention group using the ZBI (Section B of Appendix C).
4. To evaluate whether the intervention improved primary caregivers' QOL using the Caregiver Quality of Life Index-Cancer (CQOLC) (Appendix D).

## 1.7 Hypothesis

The primary caregivers of women with breast cancer who attend a psychosocial intervention programme will report an improved QOL and decreased caregiving burden compared with caregivers who do not attend a psychosocial intervention programme.

## 1.8 Definition of terms

### 1.8.1 Primary caregiver

This is a person who may or may not be family member but who is in a close supportive role and shares in the illness experience of the patient, as well as undertakes vital work and emotional management of the patient (Schildmann & Higginson, 2011:345; Mitnick, Leffler & Hood, 2010:255).

### 1.8.2 Psychosocial interventions

These are structured, time-limited, non-medical support services that consist of health education, enhancement of problem-solving skills, stress management, and psychological support that facilitate resilience within individuals, families and communities (Boesen et al., 2007:5698).

### 1.8.3 Breast cancer

This is a heterogeneous disease of the breast with distinct intrinsic subtypes that are associated with diverse clinical outcomes and treatment responses (Bae et al., 2015:269).

### 1.8.4 Quality of life (QOL)

"Quality of life is defined as a multidimensional construct that includes, at a minimum, physical, functional, psychological and social well-being. Other dimensions include spirituality, sexuality, occupational functioning, treatment satisfaction and the overall rating of the QOL" (Montazeri, 2009:2), *OR* "QOL is the perception of individuals of their own status within their cultures and value systems. It includes the person's physical functions, psychological status, family and social relations, environmental influences, and beliefs" (Alptekin et al., 2010:608).

### 1.8.5 Appraisal

Appraisal is how an individual perceives and forms the 'meaning' of a stressor. It is a key determinant of the individual's ability to adapt to that stressor (Lazarus & Folkman, 1987).

### 1.8.6 Antecedent factor

The Stress-Coping Model used for this study has two antecedent factors: personal and social; the personal factor is conceptualised as demographics, while the social factor is conceptualised as social support and communication (Shaw et al., 2008:393).

### 1.8.7 Caregiving

Caregiving refers to attending to an individual's health needs (such as bathing, dressing, and transporting), provided by a family member or friend rather than by a professional who is reimbursed for services (Gaugler et al., 2013:385; Schulz & Sherwood, 2008:23).

### 1.8.8 Caregiving burden

Caregiving burden is defined as "a multidimensional response to the negative appraisal and perceived stress resulting from taking care of an ill individual, or the distress that caregivers feel as a result of providing care. It is specific to the care and varies from anxiety and depression to other emotional and more general responses" (Rha et al., 2015:376; Kim et al., 2012:846; Papastavrou, Charalambous & Tsangari, 2009:129).

### 1.8.9 Palliative care

Palliative care is "an approach that improves the QOL of patients and their families facing problems associated with serious illness, through the prevention and relief of suffering" (Kanach, Brown & Campbell, 2014:342).

## 1.9 Theoretical framework

There are a number of theories and models relating to stress and coping with stress. The model selected for this study is Lazarus and Folkman transactional model of stress and coping. "This has been widely advocated as a useful framework to guide caregiver research. This framework acknowledges the importance of positive psychological states and intervention outcomes relevant to caregiving" (Hudson, 2003:354; Shaw, 1999:1247; Lazarus and Folkman 1987:141).

Lazarus and Folkman (1987:141-169) contended that "stress is a result of a transaction between a person and his/her environment. As such, stress encompasses a set of cognitive, affective, and coping factors".

This model argues that the primary mediator of person-environmental transactions is appraisal. Three types of appraisal were identified: primary, secondary, and reappraisal (Figure 1.1).

- "Primary appraisal is a judgment about how a person perceives a situation to be a potential source of harm, as well as what harm occurred as a result of the situation. This perception of harm triggers secondary appraisal" (Figure 1.1).
- "Secondary Appraisal is the process of determining what coping options or behaviours are available to deal with any harm and how effective these options might be. Often, primary and secondary appraisals occur simultaneously and interact with each other".
- "Reappraisal is the process of continuously evaluating and changing earlier primary or secondary appraisal as the situation evolves; what was initially perceived as harm may now be viewed as irrelevant. Often, reappraisal results in the cognitive elimination of a perceived threat" (Shaw, 1999:1247).

The factors that influence appraisals of harm include a person's values, commitments, nature of the harm, social support, availability of resources, coping skills, and duration of harm.

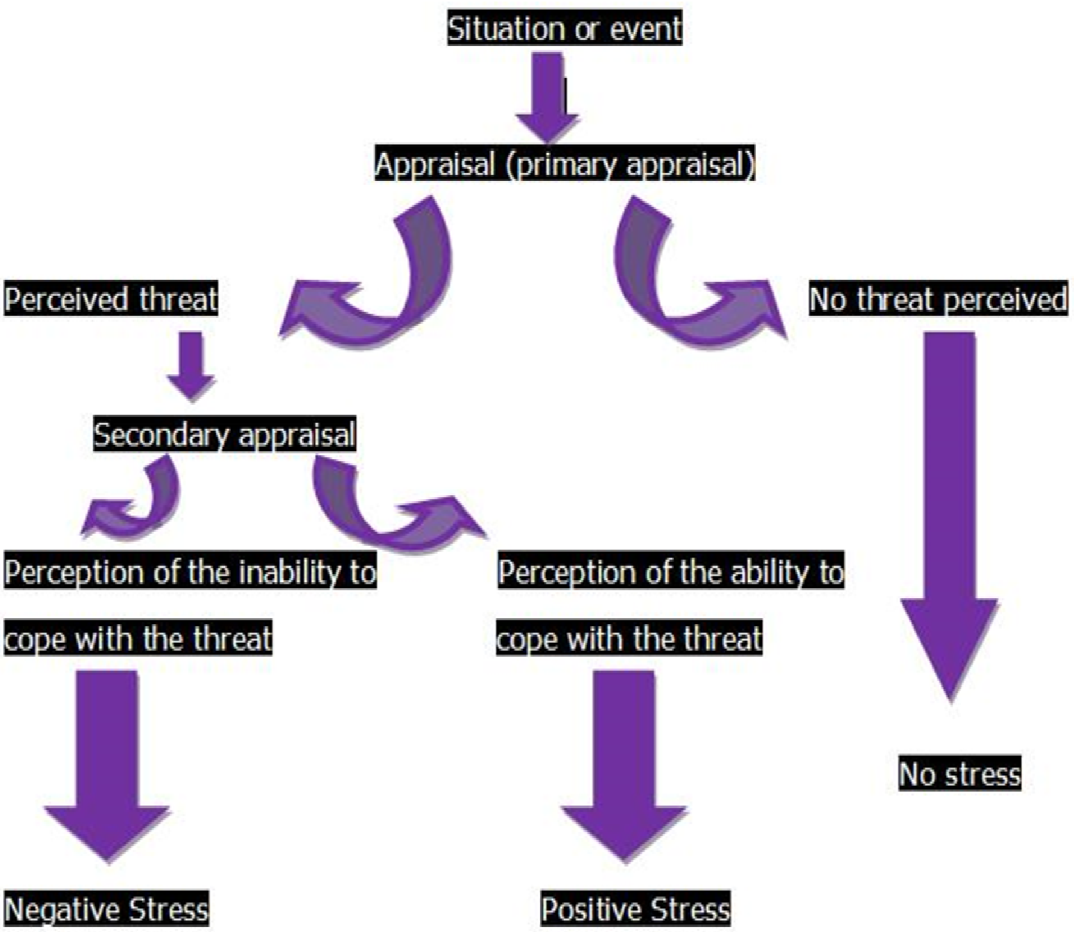


**Figure 1.1: Lazarus and Folkman's transactional model of stress and coping (Shaw, 1999).**

According to this model, personal, social, and illness-related factors are antecedent conditions that can constitute harm and affect the QOL of cancer caregivers. The transaction between a person and his/her social or illness-related factors such as breast cancer can influence how individuals appraise and cope with the illness (Shaw, 1999:1247) (Figure 1.2).

A number of studies on cancer caregivers have used this model as a guide (Hudson, Aranda & Hayman-White, 2005:330; Northouse et al., 2005:479; Northouse, Templin & Mood, 2001:116; Northouse et al., 2000:272). LeSeure and Chongkham-Ang (2015:413) reported that primary caregivers perceive illness as harm. Therefore, as the number of stressors such as work stress, family stress, and the challenge of caregiving increase, it may negatively affect their QOL (Figure 1.1).

The variables identified in the Lazarus and Folkman transactional model of stress and coping are predictors of psychosocial outcomes of primary caregivers of patients with breast cancer. Therefore, they provide a strong conceptual basis for an intervention to improve QOL.

## 1.10 Conceptual framework

Lazarus and Folkman’s transactional model of stress and coping is a conceptual framework developed for evaluating the process of coping with numerous stressors, such as work stress, family stress, and the challenge of caregiving. This has been widely advocated as a useful framework to guide caregiver research (Hudson, Aranda & Kristjanson, 2004:21). The conceptual underpinning of the model is that when people are faced with a stressor such as breast cancer, they experience appraisal processes which, in turn, direct their adaptation to the stressor. If they cannot adapt, it affects their QOL.

This framework provides a testable theoretical approach to assessing change in QOL. The theoretical model depicted in Figure 1.2 was used to clarify and predict changes in perceived QOL that results from the interaction of these factors.

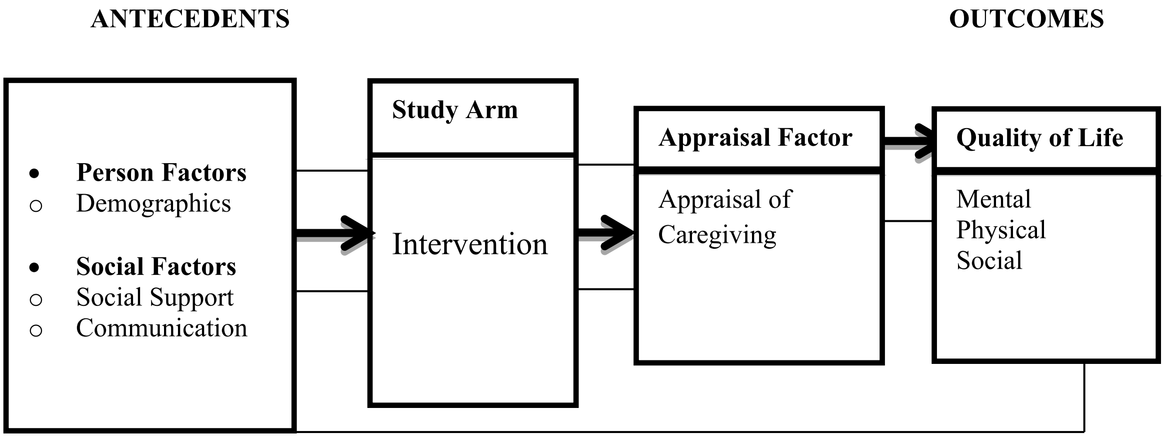


**Figure 1.2: Theoretical model of factors affecting Primary Caregiver QOL.**

Bold arrows (➡) indicate hypothesised direct and indirect effects of intervention on outcome. Light lines (-) indicate significant relationships among study variables observed from previous studies.

## 1.11 Outline of the dissertation

This dissertation is structured as outlined below.

**Chapter One:** This chapter introduces the background to and rationale for the study, research problem, aim and objectives of the study, research question, and operational definition of terms that are related to the study. It concludes with the conceptual framework that guided the study.

**Chapter Two:** This chapter discusses the literature related to breast cancer survival, incidence of caregiver burden, caregiver burden and caregivers' QOL, and provides an overview of psychosocial interventions, effectiveness of such interventions, outcome measures reported, evaluations of the outcome measurement tools, and critical appraisal of study instruments used by reviewed articles.

**Chapter Three:** This chapter presents the methodology of the study, which includes the study design, study setting and population, inclusion and exclusion criteria, sample, measurement instrumentation, pilot study, data analysis, and data collection procedures. The ethical considerations and issues of, data management and storage conclude this chapter.

**Chapter Four:** This chapter presents the baseline characteristics of the sample and the results of the study.

**Chapter Five:** This chapter includes the discussion of the results, recommendations, limitations of the study, and conclusion.

## 1.12 Conclusion

This chapter outlined the introduction to and background of the study, rationale for the study, research problem, research question, aim and objectives of the study, hypothesis and definition of basic terms. The conceptual framework used to guide the research was also outlined.

The next chapter outlines a review of literature pertaining to impact of psychosocial interventions on the QOL of primary caregivers of women with breast cancer.

# CHAPTER TWO

# LITERATURE REVIEW

## 2.1 Introduction

This chapter discusses the published literature that was included in the study. Most of the published work refers to research conducted in developed countries, namely the: United Kingdom (UK), Australia, United States of America (USA), China, Iran, France, Canada and Singapore. The study settings in the reviewed literature varied from specialist oncology centres to home- or community-based palliative care centres. There is a paucity of literature on the effects of a psychosocial intervention on the QOL of the caregivers of women with breast cancer in Africa; no previous published studies have investigated this in Nigeria.

The chapter also provides details of breast cancer survival, incidence of caregiver burden, and caregiver burden/caregivers' QOL. It further provides an overview of psychosocial interventions, effectiveness of such interventions, outcome measures reported, evaluations of the outcome measurement tools, and critical appraisal of study instruments used by reviewed articles.

## 2.2 Search strategies and inclusion criteria

The first publication identified on the QOL of primary caregivers of patients with cancer was a study carried out in 1996 (McMillan, 1996), and in 1998 a description of psycho-educational intervention for family caregivers of persons with cancer was reported (Barg et al., 1998). Searches were therefore conducted for the period 1996 to 2016 using MEDLINE-via EBSCO HOST, CINAHL, Psych INFO, Google search, and PubMed. Search key terms were combined using a Boolean search: effectiveness OR efficacy OR effect AND education OR health education OR psychosocial intervention OR psycho-educational intervention AND family caregivers OR primary caregivers OR carers AND cancer AND quality of life AND clinical trials OR non-randomised trials OR randomised controlled trials OR treatment outcome OR random allocation. The search results are tabulated in Table 2.1.

A total of 172 studies were identified. Criteria for inclusion in the review were:

- caregiver's age not less than 18 years;
- assessed caregiver QOL;
- employed a psychosocial/psycho-educational intervention aimed specifically to target family/primary caregivers' needs without a primary focus on the cancer patients; and
- used a random or a quasi-experimental method.

The titles and abstracts were screened. Based on the screening, 118 did not meet the criteria for inclusion. Full text articles were then retrieved for the remaining 54 studies, of which 42 were excluded. Twelve studies were included, which discussed primary caregivers' psychological problems and interventions (Figure 2.1).

**Table 2.1: Databases searched, using search terms***

| **Databases searched** | **Search terms** | **Results** | **Relevant items** |
|---|---|---|---|
| CINAHL | Effect, Effectiveness-<br>Psychosocial Intervention, Psycho-educational Intervention-<br>Quality of Life-<br>Family Caregivers, Carers-<br>Cancer, Breast Cancer-<br>Randomised Control Trial-<br>Quasi-experimental Method | 21 | 4 |
| MEDLINE | | 46 | 0 |
| Psych INFO | | 71 | 3 |
| PubMed | | 21 | 5 |
| Google Scholar | | 13 | 0 |
| **Total** | | **172** | **12** |

Search terms used: Effect, effectiveness-psychosocial intervention, psycho-educational intervention-quality of life-family caregivers, carers-cancer, breast cancer-randomised control trial-quasi-experimental method.

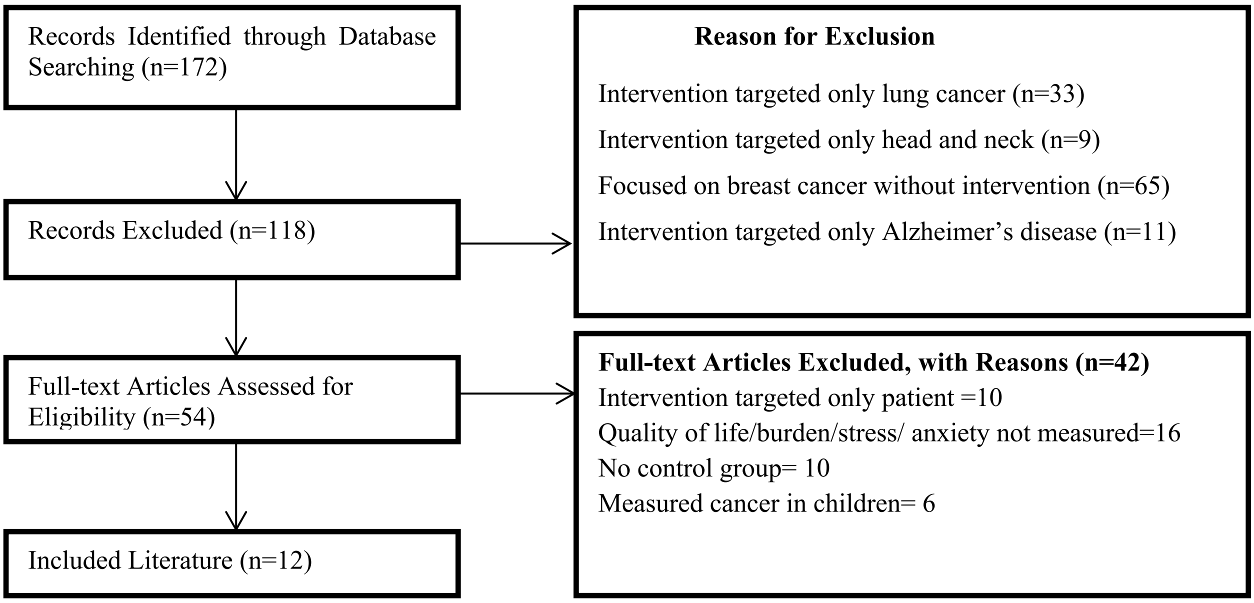


**Figure 2.1: Selection of published studies included in this study.**

## 2.3 Overview of breast cancer and its effect on primary caregivers

This section discusses an overview of breast cancer, breast cancer staging, breast cancer and survival, incidence of caregiver burden, caregiver burden and caregiver QOL.

### 2.3.1 Overview of breast cancer

Cancer is the world number one terminal illness with an estimated 14.1 million people affected as at 2012, affecting both males and females. This figure, according to World Cancer Research Fund International, is expected to grow to 24 million in 2035. Of the over 14 million cancer worldwide, breast cancer accounts for 1.7 million or, 11.9% (Ferlay et al., 2015:363-364). It has been reported that about half of the breast cancer and 60% of the deaths occur in the developing countries (Jemal et al., 2011:71).

In 2008, the estimated cancer burden in Africa stood at 681,000; Nigeria makes up 20% of Africa's population, and contributed 15% of this incidence rate (Sylla & Wild, 2012:2). The increased incidence of cancer in Nigeria, as is the case in every developing country is the result of an increase in population, life expectancy, infectious diseases and lifestyle factors (Sylla & Wild, 2012:2).

Available statistics in Nigeria from 2012 showed that 102,100 cases are diagnosed yearly; however, as the country's overall cancer estimate is not available, studies are based on estimates (Jedy-Agba et al., 2012:272). In a study of two cancer registries in Nigeria, in Ibadan and Abuja, Jedy-Agba et al. (2012:273) reported that the most common cancer among women of all age group is breast cancer (40%), the next highest incidence being cervical cancer (24%).

Against this background, cancer burden in general and breast cancer in particular poses a great burden for both patients and significant others (Budin et al., 2008:200). This manifests in both physical and psychological stress and strain on caregivers and the care recipients in taking care of patients with chronic and severe health challenges (Krug et al., 2016:4; Turner et al., 2013:12). Physical burdens emanate from physical activities that are carried out in the course of taking care of the patient, resulting in stress, fatigue and exhaustion, while on the other hand, psychological burdens are emotional issues, attitudes and feelings which are brought to bear in taking care of the patient resulting in psychological issues such as anxiety and depression (Rinaldi et al., 2005:169). Because of the physical and psychological burden which caregiving places on caregivers, caregivers' QOL is threatened (Morimoto, Schreiner & Asano, 2003:218).

### 2.3.2 Breast cancer stage grouping

Breast cancer staging is usually expressed as a number on a scale of 0 through IV-with stage 0 indicating non-invasive cancers that remain within their original location and stage IV indicating invasive cancers that have spread outside the breast to other parts of the body.

The classifications for breast cancer is shown in Table 2.2

**TABLE 2.2: Tumour, node and metastasis classifications for breast cancer from the American Joint Committee on Cancer Staging Manual, 6th edition (Singletary & Connolly, 2006)**

| Classification | Definition |
|---|---|
| TX | Primary tumour cannot be assessed |
| T0 | No evidence of primary tumour |
| Tis | Carcinoma *in situ* |
| Tis (DCIS) | Ductal carcinoma *in situ* |
| Tis (LCIS) | Lobular carcinoma *in situ* |
| Tis (Paget) | Paget disease of the nipple with no tumour (Paget disease associated with a tumour is classified according to the size of the tumour) |
| T1 | Tumour <_2 cm in greatest dimension |
| T1mic | Micro invasion <_ 0.1 cm in greatest dimension |
| T1a | Tumo(van Maaren et al., 2016:1164)ur > 0.1 cm but <_0.5 cm in greatest dimension |
| T1b | Tumour > 0.5 cm but <_ 1 cm in greatest dimension |
| T1c | Tumour > 1cm but <_ 2 cm in greatest dimension |
| T2 | Tumour > 2cm but <_ 5 cm in greatest dimension |
| T3 | Tumour > 5 cm in greatest dimension |
| T4 | Tumour of any size with direct extension to chest wall or skin, only as described below |
| T4a | Extension to chest wall, not including pectoralis muscle |
| T4b | Oedema (including peau d'orange) or ulceration of the skin of the breast, or satellite skin nodules confined to the same breast |
| T4c | Both T4a and T4b |
| T4d | Inflammatory carcinoma |

### 2.3.3 Breast cancer and survival

The stage of breast cancer at diagnosis will determine treatment options, prognosis, and has a strong influence on the length of survival. If it is presented and diagnosed at an early stage when the disease is still localised (stage 1), the prognosis will almost always be positive, but if it has spread (metastasis- stage IV) to other parts of the body, the chance of survival/ length of survival is low. Therefore, the earlier that breast cancer is detected, the better chance a person has of surviving 5 years after being diagnosed (Van Maaren et al., 2016:1164).

However, this has not been the case in Africa, particularly in Nigeria, where patients are presenting themselves for treatment in hospitals at an advanced stage of the disease process (stage III and IV) (Anarado et al., 2017:38; Singletary & Connolly, 2006:38), after they have spent time and money on religious or traditional treatment alternatives (Odigie et al., 2010:894).

### 2.3.4 Incidence of caregiver burden

Caregiver burden has been defined by Applebaum, Kulikowski, and Breitbart (2015:2) as “multidimensional bio-psychosocial reaction resulting from an imbalance of care demands relative to caregivers’ personal time, social roles, physical and emotional states, financial resources, and formal care resources given the other multiple roles they fulfil”. The burden includes psychological and physical complications.

Several studies have been conducted on caregiving burden and caregiver QOL and findings from such studies have been documented in family and palliative research (Leow, Chan & Chan, 2015:69; Rha et al., 2015:376; Bevans & Sternberg, 2012:398). The general essence of caregiving is to provide support and care in order to reduce the illness burden on the patient. However, it has been widely acknowledged in palliative research literature that such caregiving has shifted an enormous health burden both physical and psychological, onto the caregiver, this being termed ‘caregiver burden’.

Incidences of caregiver burden have been reported from caring for people with dementia (Kim et al., 2012:853), hospice patients (Lau et al., 2010:1085), breast cancer (Grunfeld et al., 2004:1795), and stroke patients (Morimoto, Schreiner & Asano, 2003:218), to mention but a few. Caregiver burden is conceptualised as a multidimensional reaction to the negative appraisal and/or assessment of caregiving and the perception of stress as a result of caring for a care recipient (Kim et al., 2012:847). This is because caregiving burden threatens the physical, psychological, emotional and functional health of caregivers (Carretero et al., 2009:75-76; Etters, Goodall & Harrison, 2008:425). As a result of the multidimensional perspective of caregiver burden, which cuts across the psychological and physical domain of health, it has been categorised into subjective and objective burdens (Honea et al., 2008:508). Objective burdens are caregivers' health and personal time away from the care recipient and include privacy, income, personal time and freedom, vacation time, energy, and relationships with others. Subjective burdens include issues such as feelings and attitudes about the caregiving experience (Govina et al., 2015:81-82; Honea et al., 2008:508). Govina et al. (2015:81) explained that the objective burden of caregiving is the amount of time a caregiver spends on caregiving, the task of giving the care or the tasks of caregiving that are performed, and the likely financial burdens that result. For instance, in informal caregiving for medication management for hospice patients, such objective burdens are "management skills such as the ability to store, organise, and discard medications, and technical skills such as the ability to recognise symptoms and administer different types of medications" (Lau et al., 2010:1086).

According to Govina et al. (2015:82) subjective caregiver burdens are the perception of the impact of objective burdens on the caregiver arising from the process of caregiving. This aspect of caregiving burden is the psychological dimension of caregiving burden which is rooted in social support and coping ability. Subjective caregiver burdens deplete the psychological resources of the caregiver in the process of caregiving. Researchers argue that although it is important and necessary to assess the objective burden of caregiving, it does not show how the caregivers carry out caregiving tasks (Brouwer et al., 2004:571).

They further explain that some caregivers may enjoy caring for a loved one, whereas others may find it a difficult and heavy duty, resulting in changes in subjective burden over time due to changes in the caregiving situation, and future prospects of the patient.

Several studies have looked at correlates, predictors and outcomes of caregiver burden (Tang et al., 2013:1312; Kim et al., 2012:846; Pinquart & Srensen, 2007:126). Lau et al.(2010:1086) explored the possible influence of caregiving on medication management for home hospice patients. Adopting a semi-structured interview with open-ended questions with 23 informal caregivers and 22 hospice providers from four hospital programmes in the Chicago metropolitan areas, this qualitative study identified themes which facilitate and/or impede caregiving burden in informal caregiving. Issues that were identified were caregivers' assets, caregivers' limitations, competing responsibilities, patient-driven demands, relationship with patients and social networks. The findings show that Caregivers highlighted life experiences, such as employment background, as assets that facilitated medication management. Unlike core knowledge/skills specific to medication management that hospital workers would teach, life experience encompassed broader background knowledge that caregivers acquired in other life events and that they drew upon while managing medications. These assets work to reduce objective caregiving burden (Lau et al., 2010:1087).

Self-confidence was also identified as an asset which works to reduce the high subjective burden and impedes caregivers' performance, which increases the subjective burden when it is low. Other factors which increased subjective burden were negative emotional states, such as grief and fatigue, cognitive and physical impairments, low literacy and poor communication skills. Competing responsibilities, which include, employment, housekeeping, and care of other dependents, acted as impediments to caregiving. With reference to the patient-driven demands, Lau et al. (2010:1086) reported that patients’ negative emotional states challenged caregivers' ability to administer medications due to patients' resistance to medication regimens. The study reported that, caregiving demands were affected by patients’ resistance to or difficulty in taking drugs.

Finally, referring to social context, the study found that ability to establish and maintain a good relationship with the patient was important in caregiving as well as availability of support networks.

Similarly, Grunfeld et al. (2004:1795) investigated family caregiver burden among caregivers of breast cancer patients. This longitudinal study over a period of 3 years included 89 participants. The study focused on three broad perspectives of caregiver burden: psychological burden, occupational burden and economic burden. The study reported that the causes of psychological burden were caregiver burden, patient anxiety, patient physical functioning as well as patient emotional support, resulting in caregiver anxiety and depression. The study found that caregiver psychological burden increases as patient functional ability decreases. It was found with respect to occupational burden, that although there was no change in employment status of caregivers as they progressed from the palliative to the terminal period, a greater percentage of them (77%) reported missing work, inability to work regular hours and work lost during the terminal period than during the palliative period. Economic burden was also reported to have increased. The study found that psychological, occupational and economic burdens related to caregiving increase as patients' functional status declines, as well as the outcomes of these burdens such as caregiver anxiety and depression.

Studies by Grunfeld et al. (2004:1798) and, Kim et al. (2012:852-853) have reported that caregiver burden increases as the impairment/disability of the care recipient increases. In a study which examined the predictors of caregiver burden among caregivers of dementia patients, Kim et al. (2012:851-852) established both correlates and predictors of caregiver burden. The researchers reported that socio-demographic factors such as age, gender, spousal status and co-residential status were positively related to caregiver burden. Other disease-related factors and caregiving-related factors were also positively related, for instance, longer hours of caregiving were related to increased caregiving burden and higher coping strategies indicated higher level of caregiving burden. Using a hierarchical multiple regression model, the study reported that nine identified factors; caregiver age, caregiver gender, marital status, living with the care recipient, daily activities, instrumental activities of daily living, number of carers, coping strategies, and number of hours were all predictors of caregiver burden, accounting for 40% of caregiver burden.

Daily activities of caregiving, instrumental activities of daily living and coping strategies as well as numbers of hours spent on caregiving were the greatest contributors to caregiver burden prediction, accounting for 18%, 34%, 27% and 32% respectively. By implication, patients with significant functional decline place serious demands on the caregiver in terms of time devoted to the care recipient who requires increased help with daily activities, which in turns results in high levels of both objective and subjective caregiver burden. This finding supported those from other studies including Conde-Sala et al. (2010:1266-1268), Sussman and Regehr (2009:35-37), Molyneux et al. (2008:1193,1197) and, Rinaldi et al. (2005:168,172), that reported similar findings on the predictors of caregiver burden, especially as regards daily activities of caregiving and instrumental activities of daily living.

Stajduhar et al. (2008:77) investigated factors influencing family caregivers' ability to cope with providing end-of-life cancer care at home. Adopting a mix of qualitative and quantitative methods, the researchers identified five broad themes: “(1) the caregiver's approach to life, (2) the patient's illness experience, (3) the patient's recognition of the caregivers' contribution to his or her care, (4) the quality of the relationship between the caregiver and the dying person, and (5) the caregiver's sense of security” (Stajduhar et al., 2008:80). According to the study findings, caregivers with a positive approach to life tend to cope better with caregiving demands than those who do not, indicating that a positive approach to life tends to reduce subjective caregiving burden. Consistent with prior findings, which reported that personality traits such as hardiness, resilience, and optimism are likely to reduce the negative effect of life's difficult experiences and serve as protective mechanisms against the harmful effects of stress, Stajduhar and colleagues opined that individualised approaches to assessing the coping abilities of family caregivers would assist in predicting how they might cope with home-based caregiving. Care recipient and caregiver relationship was also cited as an important factor in creating an effective coping environment for caregivers. The study found that caregivers reported ill treatment from care recipients, which made coping difficult. Social support was further shown to be an important element in caregiving as care recipients were reported to be appreciative of support received from family and friends. This acted as a good booster of caregivers' coping strength. Finally, the study revealed that healthcare systems and institutions acted as caregivers to the caregivers when they provide support to them in the process of caregiving. Findings showed that institutional support influenced caregivers coping abilities in a positive way and acted as an encouragement.

The findings of Stajduhar et al. (2008), although plausible, do have some identified gaps which place some constraints on generalisation. The major issue is the subjective nature of the study, which is purely descriptive. The five thematic domains upon which the findings are based as possible influencers of caregiver ability to cope cannot be measured. Caregiving burden was found to be subjective as well as objective.  Other situational variables need to be considered to be able to assess the objective nature of caregiving burden.

### 2.3.5 Caregiver burden and caregiver QOL

Caregiver QOL is an important outcome of the caregiver burden. Caregiving outcomes are seen in caregivers' psychological, physical, and social health in terms of QOL (Park et al., 2013:2802-2804). A study conducted in China showed that the psychological health of caregivers of persons with cancer was seriously affected, followed by their social, spiritual and physical health (Lu et al., 2010:508-510). Psychological health effects of the caregiving burden have been reported to include anxiety, depression, stress and burnout (Eisdorfer et al., 2003:1-2). Physical health effects include physiological abnormalities and dysfunctions such as skeletal injury, muscle strain, arthritis, and physical discomfort (Pinquart & Srensen, 2007:126). Both psychological and physical aspects of caregiver burden determine the QOL of the caregiver. According to Bevans and Sternberg (2012:399), caregiver burden is complex and complicated by multiple competing priorities, often resulting in negative psychological, behavioural, and physiological experiences which affect the caregiver's daily life and health.

Although quality of life has different definitions, due to its multidimensional and multifaceted nature, Zacharopoulou, Zacharopoulou, and Lazakidou (2015:52), state that it is a complicated evaluation of health status filtered by the subjective perception and expectation of the individuals themselves.

Notwithstanding its nature, Kaplan and Ries (2007) conceptualised it as a blend of physical function, work, socioeconomic status, network supporting, housing, income, self-esteem, life satisfaction, happiness, and health. Due to its multidimensional nature, various measurement tools have been developed to measure and capture QOL in various domains (Vickrey et al., 2009:2-3; Thomas et al., 2002:1034-1035; McMillan & Mahon, 1994:437).

The imperative of examining the impact of caregiving burden on the health quality of caregivers was first presented in the 1980s in a seminal paper by George and Gwyther (1985). They argued that it was not enough to study caregivers’ burden alone, arguing that studies should also assess the comparative impact of such burden on the wellbeing of both caregiver and care recipient (George & Gwyther, 1985). Wellbeing in this context was defined by these authors as physical health, mental health, financial resources, and social participation. They found that caregivers taking care of adult dementia patients were likely to experience problems with physical health, mental health, financial resources, and social participation.

Attention has subsequently shifted to issues of caregiver burdens and the QOL of caregivers as seen in various studies in this area (Deeken et al., 2003:923; Hughes et al., 1999:534). For instance, Rivera-Navarro et al. (2009:1347-1351) established a relationship between caregiver burden and all the dimensions of QOL of caregivers. Working with caregivers of multiple sclerosis patients from 19 clinics in 13 Spanish cities, the researchers investigated the relationship between caregivers' burden and caregivers' QOL and possible predictors of QOL among this group. The study reported that caregiver burden (as measured by the Zarit Caregiver Burden Interview) correlated with all the dimensions of QOL (as measured by the 36-SF Short Item Form Health Survey). Rivera-Navarro et al. (2009:1353) further reported that the aspects of health-related QOL most affected by caregiving burden were general health status, mental health, bodily pain, and role-emotional functioning. According to them, the major predictors of QOL of caregivers were gender, caregiver comorbidities, caregiver's age and level of illness or disability of the care recipient. They established that these factors significantly predicted low QOL of caregivers.

However, the study reported that the majority of the study participants reported low caregiving burden (85%), compared to other studies which focused on caregivers of patients with Parkinson's disease and dementia (Serrano-Aguilar, Lopez-Bastida & Yanes-Lopez, 2006:6). Explaining this position, Rivera-Navarro et al. (2009:1353) believed that caregivers of persons with multiple sclerosis felt less burden compared to caregivers of patients with dementia and Parkinson's disease, as the latter place more behavioural and cognitive demands on the caregiver. Collaborating this finding, Leroi et al. (2012:212) reported a significantly poorer QOL among caregivers of patients with Parkinson's disease and dementia compared to other groups with mild cognitive impairment. In addition, Leroi et al. (2012:212) found that caregiver burden was higher for caregivers of patients with Parkinson's disease and dementia.

Examining the demands placed on caregivers' mental health arising from caregiving, Wright et al. (2010:4461-4462) demonstrated that caregivers who are bereaved of their cancer patients are at risk of developing a psychiatric illness. For example, they found that caregivers of patients who died of cancer in a hospital were more likely to develop Post-traumatic Stress Disorder and Prolonged Grief Disorder than caregivers of those who died at home. Similarly, Song et al. (2011:1524-1525) found that health-related QOL was significantly lower among caregivers of patients with terminal cancer. They reported that more than 36% of caregivers experienced frequent occurrences of depression; factors such as caregiver’s level of self-perceived stress, financial problems and lack of family support had a negative impact on their physical and mental health.

In a study that investigated constituents of caregiver burden and its possible effect on QOL of husbands of breast cancer patients, Wagner, Bigatti, and Storniolo (2006:113,116) found that severity of illness and treatment of the wife, stage of illness, duration of diagnosis, and type of surgery were all aspects of caregiver burden. Others were need for help in activities of daily living and instrumental activities of daily living no longer carried out by the wife, due to the illness. The study reported a negative relationship between caregiver burden and QOL. Wagner, Bigatti and Storniolo. (2006:113-114) noted that husbands of breast cancer patients reported a lower level of QOL in terms of general health, vitality, and mental health compared to husbands of wives without breast cancer.

Turkoglu and Kilic (2012:4142-4144) conducted a survey study which examined the effect of care burdens of caregivers of cancer patients on their QOL. This study included 290 family caregivers of cancer patients in Turkey, and utilised the standardised instruments- the Zarit Burden Interview (ZBI) and the Caregiver Quality of Life Index-Cancer (CQOLC) Scale to measure both caregiver burden and QOL of caregivers. The results showed a significant negative linear relationship between care burden and caregiver QOL, indicating that as caregiving burden increases, QOL of caregivers decreases (Turkoglu & Kilic, 2012:4142). The study further revealed that caregiving burden accounted for 60% variance in QOL, suggesting that 60% of QOL of caregivers of cancer patients is predicted by caregiving burden experience. Aside from the caregiving burden, other psycho-demographic variables identified as having a possible effect on caregivers' QOL were age, gender, income status, relationship with the patient, and the perception level of the patient regarding their health.

Caregiving burden is therefore seen to affect caregivers QOL psychologically, socially, physically, as well as spiritually (Helseth & Misvaer, 2010:1455). Psychological distress is the most common effect of caregiving on the caregiver's QOL (Hudson et al., 2015:19; Northouse et al., 2012:237).

In addition, patients with cancer often need physical help and practical assistance during the course of their illness. This assistance is provided by the primary caregivers, who are on duty 24 hours a day. This is physically demanding for the caregiver, who may need to help the patient with many activities during the day, such as: using the toilet, eating, changing position in bed, using medical equipment, and moving from one place to another (Cui et al., 2014:562-563; Hudson et al., 2008:271). If this continues for a long period of time without adequate rest, cumulative sleep disruption and fatigue become obvious (Carter, 2006:96). Also, as caregivers try to meet the physical demands of caregiving, they may not take care of their own health, and may neglect healthy habits such as exercise, a healthy diet, and regular medical check-ups. This could worsen any health problems the caregiver already has, or cause a new health problem (Northouse et al., 2010:318). "Social roles and relationships are profoundly affected by cancer. The nature and quality of the pre-existing patient-caregiver relationship are important considerations in the assessment and treatment of caregiver burden" (Hodges, Humphris & Macfarlane, 2005:9).

In summary, related studies reviewed above have presented similar trends and patterns of findings, indicating that caregiving has a burden, irrespective of the domain from which care is being provided. The studies have also shown what constitutes caregiver burden, ranging from type of illness, perception of illness by the caregiver, duration of illness, activities of daily living and time demands of instrumental activities of daily living. It has also been established that caregiver burden negatively affects the QOL of caregivers. Studies reviewed all agreed that caregiver burden affects the caregiver's psychological, behavioural, physiological and mental health as well as economic and financial resources.

## 2.4 Design of reviewed articles and effectiveness of intervention programme

This section provides details of the different study designs used in the reviewed articles, an overview of psychosocial interventions, types of interventions used in the articles, a critical appraisal of the interventions and, outcome measures, with evaluation of outcome measurement tools, and critical appraisal of study instruments used by the reviewed articles.

### 2.4.1 Study design of reviewed articles

Twelve studies were included, 11 of which were randomised controlled trials (RCTs), and one a non-randomised trial (Table 2.3).

The eleven articles that used an RCT design had different study arms and time-points.

Leow, Chan and Chan. (2015:63); Walsh et al. (2007:143); Hudson, Aranda and Hayman-White. (2005:330-331); Northouse et al. (2005:480); and Bultz et al. (2000:306-307) used a two-arm design with pre-test and repeated post-tests (three time-points), while Bahrami and Farzi. (2014:4) used a two-arm, with two-step; before-after clinical trial (two time-points), and Meyers et al. (2011:466) employed a two-arm study with six time-points. Four studies, (Hudson et al., 2013:1988-1989; Northouse et al., 2013:556; McMillan & Small, 2007:315,317; McMillan et al., 2006:216-217) were three-arm RCTs with three time-points, while the only non-randomised controlled trial was the study of Harding et al. (2004:397-405) with two-arms and three time-points (baseline, post- intervention and follow-up).

**Table 2.3: Design of Reviewed Articles**

| Study design | Authors |
|---|---|
| i) Non- RCT | Harding et al., 2004 |
| ii) RCT | Leow, Chan and Chan. 2015; Bahrami and Farzi 2014; Northouse et al. 2013; Hudson et al. 2013; Meyers et al. 2011; McMillan and Small 2007; Walsh et al. 2007; McMillan et al. 2006; Hudson, Aranda & Hayman-White. 2005; Northouse et al. 2005; Bultz et al. 2000. |

### *2.4.1.1 Non-RCT*

A non-RCT is where participants have been assigned to the treatment, procedure, or intervention alternatives by a method that is not random. It is a type of quasi-experimental design.

The basic structure of a non-RCT is shown in Figure 2.2.

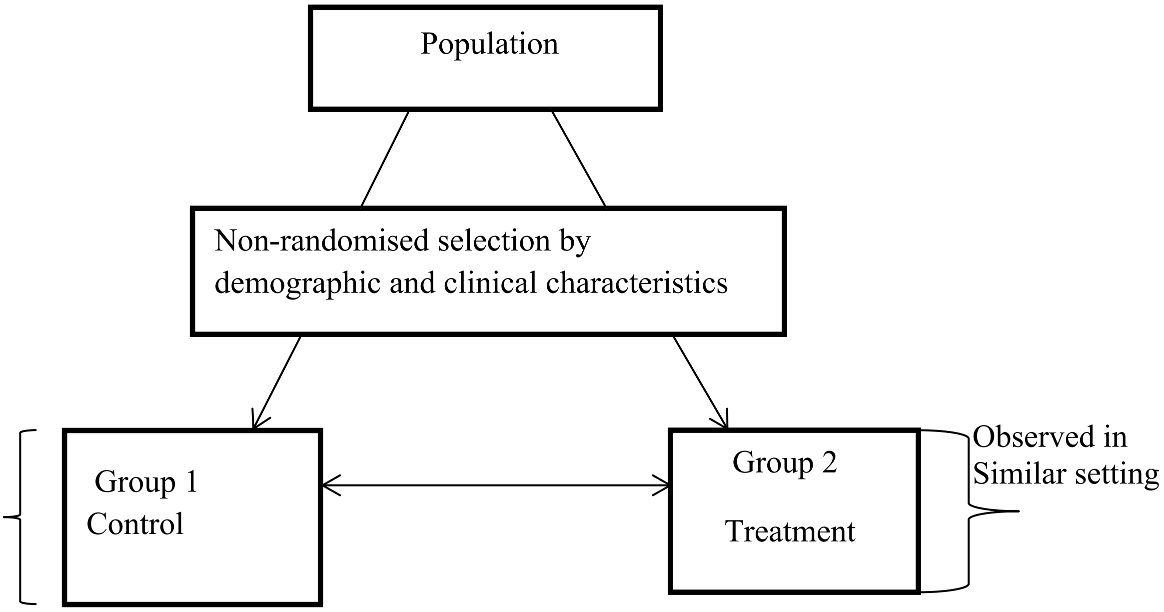


**Figure 2.2: Basic structure of a non-RCT.**

#### *2.4.1.2 RCT*

An RCT is a type of study in which participants are randomly allocated to either the treatment or standard groups. Participants are given the same standard treatment, apart from those in the treatment group, who receive the intervention. Both groups are analysed at the end of the study. The RCT is regarded as the gold standard for evaluating the effectiveness of interventions and the most effective method of testing hypotheses in medical intervention (Akobeng, 2005:840).

The basic structure of an RCT is shown in Figure 2.3.

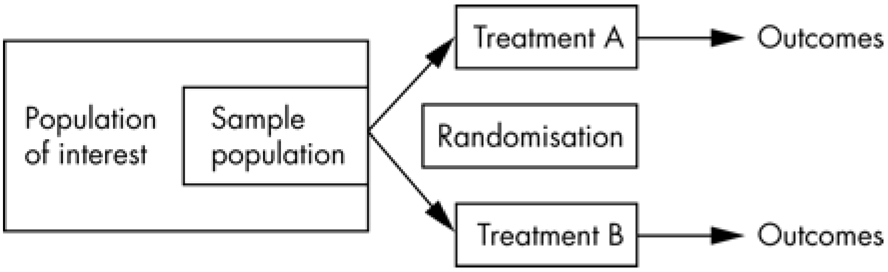


**Figure 2.3: Basic structure of an RCT (Akobeng, 2005:841).**

##### *2.4.1.2.1 Methods of randomisation*

Kim and Shin (2014:103) grouped randomisation into three categories, namely: simple randomisation, block randomisation, and stratified randomisation.

**Simple randomisation** is based on a single sequence of random assignments; the participants are assigned to a particular group (Altman & Bland, 1999:1209). Basic methods of simple randomisation include flipping a coin, computer-generated random numbers, or throwing a dice. This randomisation is most trusted to generate similar numbers of subjects among groups in large clinical research study (Suresh, 2011:8).

**Block randomisation** is designed to "randomise subjects into groups that result in equal sample sizes. It ensures a balance in sample size across groups over time. Blocks are best used with a limited number of participants, and more than two study arms" (Kim & Shin, 2014:103).

**Stratified randomisation** is used to "achieve balance among groups in terms of subjects' baseline characteristics (covariates). The researcher must first identify the specific covariates and understand the potential influence each has on the dependent variable. Stratification is achieved by generating a separate block for each combination of covariates, and subjects are assigned to the appropriate block of covariates. After all subjects have been identified and assigned into blocks, simple randomisation is performed within each block to assign subjects to one of the groups" (Kim & Shin, 2014:104).

### 2.4.2 Overview of psycho-educational interventions

Although a wide range of psycho-educational interventions are used to treat chronic diseases such as mental health disorder, diabetes mellitus and, acquired immunodeficiency syndrome (AIDS), this study discussed psycho-educational interventions used in the reviewed articles to assist primary caregivers who rendered care to family members experiencing cancer. An overview of psycho-educational interventions is now provided.

Schildmann and Higginson (2011:346) defined a psycho-educational intervention as "a structured programme geared toward providing information about the care receiver's disease process and about resources and services, as well as training caregivers to respond effectively to disease-related problems". "The psycho-educational intervention generally includes providing patients/caregivers with information about treatments, symptoms, resources, and services; training to provide care and respond to disease-related problems; problem-solving strategies for coping with cancer; and supportive therapy" (Applebaum & Breitbart, 2013:234; Hudson et al., 2008:271). This may be delivered to a group of people or individually by using "booklets, videos, audiotapes, and computers, and the formats may be interactive among healthcare professionals and patients and caregivers, self-directed via the use of CDs and other materials, or delivered online or telephonically" (Northouse et al., 2014:323-324; Budin et al., 2008:202; Cunningham, Edmonds & Williams, 1999:178).

#### *2.4.2.1 Information about treatments, symptoms, resources, and services*

Adams, Boulton and Watson. (2009:181-182) categorised information which is provided to patients with cancer into 11 types: treatment-related information, diagnosis/prognosis-related information, coping information, information on self-care/home care, cancer-specific information, information about impact on the family, information on support, information about impact on the relationship with a partner, information on practical issues, information on hospital care, and follow-up/rehabilitation information. This information can only be obtained through the delivery of psycho-educational interventions. Pasacreta et al. (2000:5) offered a "6-hour group psycho-educational programme for caregivers, called the Family Caregiver Cancer Education Programme which addressed symptom management, improving technical competence, and administering medication to patients in the home" as well as psychosocial reactions to caregiving.

#### *2.4.2.2 Training to provide care and respond to disease-related problems*

This is a vital aspect of psycho-educational intervention, and one of the ways to achieve this is through administration of Cognitive-Behavioural Therapy (CBT). CBT is a short-term, goal-oriented intervention with a practical approach to problem-solving (Vereenooghe & Langdon, 2013:4087). "It aims to change patterns of thinking or behaviour that are behind people's difficulties, and so change the way they feel. It is used to help treat a wide range of issues in a person's life, from anxiety, depression, and sleeping difficulties or relationship problems, to drug and alcohol abuse". The target of this therapy is changing people's attitudes and their behaviours by focusing on the thoughts, images and beliefs that are held (a person's *cognitive processes*), and how these processes relate to the way a person behaves, as a way of dealing with emotional problems. CBT has been helpful in treating mental health disorders such as depression and eating disorder, but not everyone who benefits from CBT has a mental health condition.

#### *2.4.2.3 Problem-solving strategies for coping*

Good problem-solving skills are what enable people to cope with major life challenges such as cancer. The aim of problem-solving/skill building interventions is to develop the ability to assess and manage patients' symptoms and caregiving skills (Caress, Chalmers & Luker, 2009:1524).

Cameron et al. (2004:138) administered an intervention to 34 family caregivers of people with advanced cancer using the COPE (Creativity, Optimism, Plan, and obtain Expert information) to meet the challenges of caregiving. In another study, a 16-week supportive nursing intervention, focused on symptom management, surveillance, training on disease and treatment, emotional support, and caregiver preparedness was given to 125 patient-carer dyads to assist patients and carers to manage symptoms and caregiving tasks (Kozachik et al., 2001:1151-1152). McMillan and Small (2007:316) and McMillan et al. (2006:216) used the COPE framework to assist with symptom management.

#### *2.4.2.4 Supportive therapy*

Supportive therapy involves the "provision of emotional support through structured interventions, which include activities such as general counselling related to emotional and other issues. The interventions can be one-on-one individualised sessions, support group sessions, or specific interventions with caregivers that may be provided by healthcare professionals or may be structured as peer group support. This may be provided via telephone, physical presence, or online groups" (Chih et al., 2013:537).

### 2.4.3 Types of interventions used in reviewed articles

A group of six studies (Leow, Chan & Chan, 2015:65; Hudson et al., 2013:1988; Walsh et al., 2007:143; Hudson, Aranda & Hayman-White, 2005:332; Harding et al., 2004:398; Bultz et al., 2000:307) was identified that utilised psycho-educational interventions to assist caregivers to provide support to the cancer patient. These interventions involved the use of trained counsellors to provide education and instructions to caregivers. Caregivers were taught how to assess their clients' needs. These interventions also provided information that prepared caregivers on how to cope with their caregiving roles, as well as strategies they could use to reduce psychological distress.

Four studies (Bahrami & Farzi, 2014:3; Meyers et al., 2011:466; McMillan & Small, 2007:316; McMillan et al., 2006:216) had interventions that focussed on problem-solving strategies for coping using the COPE framework to investigate the effects of a psycho-educational programme. This approach aimed at teaching caregivers the nature of the medical problem the patient is facing and also how to identify the psychological needs of the patients. It also provides caregivers with creative caregiving strategies, and information that will enable caregivers to maintain a positive and realistic approach in caregiving and how to plan for future caregiving goals. In the reviewed articles COPE was delivered in weekly sessions.

Another two studies were identified (Northouse et al., 2013:556-557; Northouse et al., 2005:481) which addressed interventions (FOCUS programme) to reduce negative appraisals and improve QOL.

#### *2.4.3.1 Studies of interventions with a learning focus*

Leow, Chan and Chan. (2015:63-64) conducted "an RCT trial with pre- and post-intervention measures. This intervention evaluated the effectiveness of a psycho-educational intervention, the Caring for the Caregiver Programme (CCP), to enhance the QOL of family caregivers. Development of the CCP was guided by self-efficacy theory, which aimed to help caregivers cope with stress, frustration, depression, and anticipatory grief. The training consisted of a one-hour face-to-face session, a video clip, two follow-up phone calls, and an invitation to an online social support group". The CCP had positive effects on caregivers of patients with advanced cancer. The findings showed better social support satisfaction, closeness with patient and self-efficacy in self-care among the intervention group, and they reported significantly higher QOL scores.

Hudson et al. (2013:1987) conducted "a three-arm RCT in which two versions of the intervention (one face to face visit versus two visits) plus standard care was compared to a control group with only standard care. The aim was to prepare caregivers for the role of supporting a patient with advanced cancer". The intervention was guided by a well-documented theory of a transactional model of stress and coping, which focused on the information and resources given to family caregivers to promote psychological wellbeing. There was no significant change in the primary outcome (psychological wellbeing) (Hudson, Aranda & Hayman-White, 2005:330; Northouse et al., 2005:479; Nijboer et al., 1998:6).

Walsh et al. (2007:142-143) evaluated the effectiveness of an intervention to reduce symptoms of anxiety, depression, caregiver burden, and improved QOL of patients receiving palliative care, which was carried out by seven specialist palliative care teams in three London cancer networks. Advisors made six visits over a 6-week to provide individualised information on patient care, psychological health, relationships and psychological health, relationships and social networks, relationships with health and social service providers. Advisors were experienced in community nursing and social work. Data were collected at 4 weeks, 9 weeks and 12 weeks after randomisation.

Hudson, Aranda and Hayman-White. (2005:329) conducted a two group RCT with 106 family caregivers of patients dying of cancer at home (n=52control, n=54 intervention). The study aimed to determine if primary caregivers who received the psycho-educational intervention would report higher levels of preparedness, self-awareness and self-efficacy, competence and reduced anxiety compared to caregivers who did not receive the intervention. The learning tool was a guide-book, aimed to provide caregivers with information related to caring for a dying person, and audiotape focussed on self-care strategies. The intervention was delivered in two scheduled home visits, complemented by a follow-up phone call between the visits.

Harding et al. (2004:396) conducted a two-group prospective, observational evaluation, combining qualitative and quantitative methods, which aimed to evaluate a short-term group intervention for primary caregivers. Caregivers of patients attended six sessions of 90 minutes per week training, aimed to promote self-care. Feedback from participants was positive, particularly regarding support and knowledge gains from the training.

Bultz et al. (2000:303) conducted an RCT of a brief psycho-educational support group for partners of early-stage breast cancer patients. The study had two groups: the intervention group (n=15) and the control group (n=19), who were assessed at baseline, 6 weeks, and 3 months post-intervention. The psycho-educational intervention had two components: education and support.

There were six sessions: the first two sessions were educational in nature, while the remaining four were unstructured and, focused on helping partners with their mood disturbance. The partners had less mood disturbance after the intervention (see Table 2.4).

#### *2.4.3.2 Studies of interventions of problem-solving processes*

Bahrami and Farzi (2014:1) conducted a pre-post two-group intervention study that determined the effect of a supportive educational programme based on the COPE framework. Support included provision of information and psychological support in the form of counselling sessions. Caregivers' physical, mental, spiritual and, environmental domains and overall QOL increased significantly. No significant differences were found in the social domain of QOL.

Meyers et al. (2011:466) examined the effect of a standardised cognitive-behavioural problem-solving educational intervention on the QOL of patients/caregivers. Baseline data were collected and then follow-up data at 30, 60, 90, 120 and 180 days after the randomisation. Findings showed no significant difference in patient QOL between the intervention and control groups, while caregiver QOL scores declined in the intervention arm.

Another study was identified with caregivers of hospice home care patients that also used the COPE intervention in a three-group comparative design with repeated measures. In an RCT of 329 caregivers, patients' symptom distress improved from baseline to 16 and 30 days, while QOL was not significantly different (McMillan & Small, 2007:313). McMillan et al. (2006:214) reported caregivers with less distress and less burden from caregiving.

#### *2.4.3.3 Interventions to enhance care through managing symptoms*

Northouse et al. (2013:555) reported on data from 484 patient/caregiver dyads who had attended a FOCUS programme intervention. The aim was to determine whether a brief or extensive FOCUS intervention has better intermediary and primary outcomes, and whether risk for distress and other antecedent factors moderated the effect of the brief or extensive programme on intermediary and primary outcomes. Intermediary outcomes were appraisals and resources, and the primary outcome was QOL. Brief and extensive FOCUS programmes were offered at four cancer centres.

The brief FOCUS programme consisted of three contacts (two 90-minute home visits and one 30-minute phone session). The extensive FOCUS programme consisted of six contacts (four 90-minute home visits and two 30-minute phone sessions).

Northouse et al. (2005:478) examined the effects of the intervention (FOCUS programme) on the proximal and distal outcomes (appraisal of illness/caregiving, uncertainty, hopelessness, coping, and QOL) of women with recurrent breast cancer. The FOCUS programme consists of five core content areas: family involvement, optimistic attitude, coping effectiveness, uncertainty reduction, and Symptom management.

### Table 2.4: Studies of interventions with learning focus

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| Leow, Chan and Chan, 2015. | A pilot RCT of the effectiveness of a psycho-educational intervention on family caregivers of patients with advanced cancer. | 80 caregivers. | A psycho-educational intervention, the CCP, consisted of a one-hour face-to-face session, a video clip, two follow-up phone calls, and an invitation to an online social support group. | Standard care group (control) received routine home hospice care.<br>The intervention group received the CCP and routine home hospice care.<br>Questionnaires were administered at baseline, week four and eight after the intervention. | QOL was measured by the CQOLC.<br>Social support was measured by the Social Support Questionnaire.<br>Stress and depression was measured using the Depression Anxiety Stress Scale.<br>Self-efficacy was measured by the Self-care Scale.<br>Closeness with the patient was measured by General Closeness Scale.<br>Rewards were measured by the Rewards of Caregiving Scale.<br>Knowledge was measured by the six questions rated on a five-point Likert-type scale developed by the nurse researchers. | The CCP had positive effects on caregivers of patients with advanced cancer.<br>The intervention group reported significantly higher QOL scores. They also showed better social support satisfaction, closeness with patient and self-efficacy in self-care. | Exclusion of older adults who are non-English-speaking caregivers.<br>Inability to randomise all caregivers.<br>Research settings were chosen by convenience.<br>The study used a small sample size. |
| Hudson et al., 2013 | Reducing the psychological distress of family caregivers of home-based palliative care patients: short-term effects from an RCT. | 298 family caregivers. | The training manual was developed from a family caregiver guidebook. The psycho-educational programme was delivered over 4 weeks with four steps:<br>Step 1- preparing caregivers for the intervention.<br>Step 2- assessing caregiver needs and preparing a care plan.<br>Step 3- reassessing the needs and evaluating the care plan.<br>Step 4- assisting the caregivers with bereavement. | Caregivers were randomised to three groups:<br>Control group (n=148) received standard care.<br>Intervention one (n=57) received one visit and three phone calls plus standard care.<br>Intervention two (n=93) received two visits and two phone calls plus standard care.<br>Data were collected at baseline, one week post-intervention, and 8 weeks post patient death. | Primary outcome was psychological well-being measured with the General Health Questionnaire (GHQ)-12.<br>Other outcomes included:<br>Caregiver competence measured with Caregiver Competence Scale (CCS).<br>Preparedness for caregiving measured with Preparedness for Caregiving Scale (PCS).<br>Unmet needs and positive aspects of caregiving. | There was no significant change in the primary outcome (psychological well-being). | Large proportion of caregivers declined to participate.<br>Attrition between T1 and T2 (25 loss in the intervention one, 39 loss in the intervention two, and 65 loss in the control).<br>Routine implementation of the intervention was not guaranteed.<br>Economic implications of the intervention were not explored. |

**Table 2.4: (Continued)**

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| Walsh et al., 2007 | Reducing the emotional distress in people caring for patients receiving specialist palliative care | 271 caregivers | The intervention was made up of six weekly visits by trained advisors.<br>The visit consisted of an assessment of caregivers' emotional needs, provision of advice and support to the caregiver. | There were two groups:<br>Intervention group (n=137) received usual care plus visits from trained advisors.<br>Control group (n=134) received only usual care.<br>Study participants completed questionnaires which were posted to them at 4, 9 and 12 weeks after randomisation. | Primary outcome was caregiver distress, the General Health Questionnaire (GHQ).<br>Secondary outcomes were Caregiver strain, Caregiver QOL, satisfaction with care Core bereavement index. | No significant difference between both groups in terms of GHQ and care giver QOL.<br>Caregivers in the intervention group reported benefits qualitatively. | Management of missing data; not completely at random owing to death of the patients.<br>Not certain that all distressed carers were invited.<br>Service providers might influence the recruitment. |
| Hudson, Aranda and Hayman-White. 2005 | A psycho-educational intervention for family caregivers of patients receiving palliative care: an RCT. | 106 family caregivers. | A psycho-educational intervention delivered through two home visits, and two phone calls by a nurse. Complemented by a caregiver guidebook and audiotape. The intervention programme content included caregivers' preparation, access to information, caregivers' needs, psychosocial support, and future planning and goals. | Participants were randomised into control group (n=52), and experimental group (n=54).<br>Data were collected at baseline, 5 weeks later, and then 8 weeks following patient's death. | Caregivers' preparedness. Caregivers' competence. Mastery. Self-efficacy. Anxiety. Rewards of caregiving. | There was positive effect of the intervention on perceptions of caregiving rewards. No other significant effects on preparedness to care, competence, self-efficacy, and anxiety. | Insufficient power to detect differences.<br>Highly functioning caregivers, making it difficult to produce intervention effects.<br>The impact of participants' pre-palliative care characteristics on the success of the intervention remains unknown. |

**Table 2.4: (Continued)**

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| Harding et al., 2004. | Evaluation of a Short-Term Group Intervention for Informal Carers of patients attending a Home Palliative Care Service. | 73 caregivers | The intervention is a programme of six weekly sessions of 90-minute group training. The training provided information about issues faced by the patient and to address the source of distress.<br>The intervention combined informal professional teaching with peer support and exchange. | The study had two groups: the group that accepted the intervention (n=36) and the group that declined the intervention (n=37) in a specialised home palliative care programme. | Palliative Outcome Scale (POS)<br>Eastern Cooperative Oncology Group performance scale<br>Coping response inventory<br>General Health questionnaire-12<br>State Anxiety Scale shortened version. | The intervention improved Zarit Burden scores of caregivers and general health scores.<br>Intervention participants reported that they gained positively from the intervention. | Small sample size. |
| Bultz, et al., 2000 | An RCT of a brief psycho-educational support group for partners of early-stage breast cancer patients. | 34 couples | The psycho-educational intervention had two components: education and support. There were six sessions, the first two sessions were educational in nature while the remaining four were unstructured, and focused on helping partners in the area of their mood disturbance. | The study had two groups: the intervention group (n=15) and the control group (n=19).<br>They were assessed at baseline, 6 weeks, and 3 months. | The patient’s adjustment to illness.<br>Mood disturbance.<br>Marital satisfaction | The partners had less mood disturbance after the intervention. | There was self- selection which resulted in a participation rate of 31%.<br>Small sample size |

## Table 2.5: Studies of interventions of problem-solving processes

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| Bahrami and Farzi, 2014 | The effect of a supportive educational programme based on COPE model on caring burden and QOL in family caregivers of women with breast cancer. | 64 family caregivers | A psycho-educational programme based on COPE.<br>The training also included two hospital visits and two telephone sessions. | 64 family caregivers were assigned to control group and intervention group.<br>Participants were assessed at baseline, and a month after the intervention. | QOL was measured by the CQOLC and WHO brief questionnaire.<br>Caring burden was measured by the Zarit Burden Interview. | Intervention showed a significant effect on the physical, mental, spiritual, environmental domains and overall QOL.<br>There was no change in the social domain of QOL.<br>There was a significant decrease in caring burden in the intervention group. | Small sample |
| Meyers et al., 2011. | Effect of a problem-solving intervention (COPE) on QOL for patients with advanced cancer on clinical trials and their caregivers; Simultaneous Care Educational Intervention (SCEI): linking palliation and clinical trial. | 476 patient-caregiver pairs | The intervention consisted of:<br>A copy of the book "*The Home Care Guide for Cancer.*"<br>A 7-day educational session focused on the COPE model.<br>A 30-day instructional sessions reinforcing how to practice COPE. | Patient-caregiver pairs were randomised into the intervention group (n=348) and control group (n=128).<br>The intervention group received usual care + COPE.<br>The control group received only usual care.<br>Baseline data were collected and then follow-up data were collected at 30, 60, 90, 120 and 180 days after the randomisation. | Primary outcome measure was the City of Hope QOL instruments for patients or caregivers (COH QOL).<br>The social problem solving inventory (SPSI-R). | There was no significant difference in patients' QOL between the intervention and control groups.<br>Caregiver QOL scores declined in the intervention arm. | Limited enrolment of ethnic minorities.<br>English language requirement.<br>Slower than anticipated accrual. |

**Table 2.5: (Continued)**

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| McMillan and Small, 2007 | Using the COPE intervention for family caregivers to improve symptoms of hospice homecare patients: A clinical trial. | 329 primary caregivers | The COPE intervention, which supports caregivers to solve problems associated with pain management, dyspnoea and constipation. | 329 care givers were randomised into three groups:<br>Control group (n=109) received only standard care;<br>Experimental group A (n=109) received standard care and friendly visits;<br>Experimental group B (n=111) received standard care and COPE intervention. | Intensity of pain, dyspnoea, overall symptom distress and QOL. | There was no change in intensity of symptoms but there was a significant improvement in symptom distress. No change observed in caregivers' and patients' QOL. | The protocol did not audit the behaviours of caregivers to determine whether their symptom management changed and whether any changes that were made were appropriate and effective. |
| McMillan et al., 2006 | Impact of coping skills intervention with family caregivers of hospice patients with cancer. | 354 family caregivers | Problem-solving intervention with four components: creativity, optimism, planning, and expert information (COPE). | 354 caregivers were randomised into three groups. (1) a control group (n=109); (2) a group who received standard care + three supportive visits (n=109); (3) a group who received standard care + three visits to teach a coping skills intervention (n=111).<br>Data were collected at baseline, 1 and 2 weeks post-intervention. | Caregivers' QOL<br>Caregivers' burden<br>Caregivers' mastery<br>Caregivers' coping | At the 30-day follow-up the COPE intervention showed significant improvement in caregiver's QOL, burden of patient symptoms, and caregiving task burden compared to the other two conditions. None of the groups showed any change in caregiving mastery and coping. | The authors did not report limitations. |

## Table 2.6: Interventions to enhance care through managing symptoms

| AUTHOR(S) | TITLE | STUDY POPULATION | INTERVENTION DESCRIPTION | EVALUATION DESIGN | OUTCOME VARIABLES | FINDINGS/ TREATMENT EFFECTS | LIMITATIONS |
|---|---|---|---|---|---|---|---|
| Northouse et al., 2013 | RCT of a brief and extensive dyadic intervention for advanced cancer patients and their family caregivers. | 484 patient/caregiver dyads | Brief and extensive FOCUS programme conducted at four cancer centres. The brief FOCUS programme consists of three contacts (two 90-min home visits and one 30-min phone session). The extensive FOCUS programme consists of six contacts (four 90-min home visits and two 30-min phone sessions). | Patient/caregiver dyads were randomised to three groups:<br>Control group (n=163 dyads) received only usual care.<br>Intervention group one (n=159 dyads) received usual care plus brief FOCUS programme.<br>Intervention group two (n=162 dyads) received usual care plus extensive FOCUS programme.<br>Data were collected at baseline, at 3 and 6 months from baseline. | Intermediary outcome was the appraisal of illness and caregiving. This was assessed with the Appraisal of Illness Scale (patients and caregivers).<br>Primary outcome was QOL which was measured with the General Functional Assessment of Cancer Therapy. | There were no differential changes among groups on appraisal variables (appraisal of illness, uncertainty, and hopelessness).<br>Significant group by time showed that there was an improvement to dyads' coping and social QOL and in caregivers' emotional QOL.<br>Most effects were found at 3 months only. | The study measured risk for distress instead of current distress.<br>The study did not collect information on patients' performance status over time.<br>Patients' risk status was used as a stratification variable. |
| Northouse et al., 2005 | Effects of family intervention on the QOL of women with recurrent breast cancer and their family caregivers. | 134 patients and their family caregivers | The FOCUS intervention programme with five core content areas, with the first letter of each area forming the acronym FOCUS: family involvement, optimistic attitude, coping effectiveness, uncertainty reduction, and symptom management. | 134 patients and their family caregivers were assigned to control group and experimental group.<br>Dyads were assessed at baseline, 3 and 6 months later. | Appraisal of illness/caregiving Uncertainty. Hopelessness. Coping. QOL. | Patients in the family intervention reported significantly less hopelessness and less negative appraisal of illness compared to the other condition (control); their family caregivers showed significantly less negative appraisal of caregiving. Intervention effects were evident at 3 months, but not sustained at 6 months. None of the groups showed any difference in QOL. | No cost-effectiveness measures included.<br>A number of analyses conducted which increased the possibility that some findings may have occurred by chance.<br>Exclusion of variables that could have been affected by the intervention. |

### 2.4.4 Critical appraisal of the articles

Twelve articles were critically appraised to identify strengths and weaknesses in order to assess the usefulness and validity of research findings.

Leow, Chan and Chan. (2015:64-65) conducted an RCT with pre-and post-test measures. Allocation of the participants into the intervention and control group was achieved through a computerised random number table. Randomisation was concealed as the research assistants were not part of the study team and were blinded to group allocation, but it was not reported whether the research team and clinicians were blinded to the allocation. The groups were similar as there were no statistically significant differences in the caregivers' socio-demographic data at baseline. Apart from the CCP received by the intervention group, both groups were treated the same, and both received routine care (regular weekly to monthly visits for about 30 minutes, and psychosocial support). Of 80 participants that were recruited, six dropped out between T2 and T3 due to the death of their patients. There was significant improvement in all of the caregivers' outcomes when compared to the control group ($p=0.00$); however, the result may not be generalisable because of the small sample size. The greater the sample size, the more generalisable the results. Tipton et al (2016:29-30) have noted that the benchmark for generalisability differs markedly in small samples.

The CCP intervention was not frequently utilised in the published intervention studies. Furthermore, there is a chance of bias as it was reported that not all of the caregivers were randomised. Schildmann and Higginson (2011:346) argued that only randomised allocation can prevent selection bias. Many instruments (seven questionnaires) were used and this could promote attrition as a result of discouragement.

Bahrami and Farzi (2014:2) investigated the effect of a supportive educational programme based on COPE, on the family caregivers' burden and QOL. The aim was clearly stated and the study used a standard intervention programme (COPE) (Meyers et al., 2011:466; McMillan & Small, 2007:315; McMillan et al., 2006:216; Houts et al., 1996:68-69). The target population, intervention and comparison groups and the outcomes were clearly defined, but the sample size (64) was too small for the results to be generalised.

Randomisation was carried out even though it is not explained how this was achieved. No blinding was reported to have been done. The groups were similar at baseline and received similar standard care. The study participants were accounted for, and there was a significant increase in the physical, mental and spiritual domains, as well as in overall QOL, but no change in the social domain.

Northouse et al. (2013:555) carried out a clinical trial of a brief and extensive dyadic intervention, using the FOCUS programme, aimed at determining whether a brief or extensive FOCUS intervention has better intermediary and primary outcomes, and to determine whether risk for distress and other antecedent factors moderated the effect of the brief or extensive programme. Intermediary outcomes were appraisals and resources and the primary outcome was QOL. Dyads were randomised to three arms: (i) control group with usual care; (ii) intervention group one with brief FOCUS programme; and (iii) intervention group two with extensive FOCUS programme. Data were collected at three points: at baseline, following the intervention at 3 months, and at 6 months after baseline. The groups received similar usual care such as psychosocial support and cancer treatment. Standardised instruments were used to measure the outcome variables, with an improvement in dyads' coping, self-efficacy and social QOL, with most effects found at 3 months.

However, no blinding of outcome assessors was reported, so the chance of selection bias was possible. The study recorded a high level of attrition (more than 16%), which could affect the reliability of the study. This concurs with Dumville, Torgerson, and Hewitt (2006:969) that losses of between 5% and 20% may be a source of bias.

Hudson et al. (2013:1987) conducted a three-arm RCT in which two versions of the intervention (one face-to-face visit versus two visits) plus standard care were compared to a control group with only standard care. The aim was to prepare caregivers for the role of supporting a patient with advanced cancer. The problem and outcome measures were clearly stated. Randomisation was achieved using a computer-generated random list, and the research assistants were blinded to group allocation. Data were collected at baseline, one week post- intervention (5 weeks from intervention), and 8 weeks post-patient death (not part of the study).

Despite the fact that the intervention programme was adapted from the initial intervention and guided by a well-documented theory of a transactional model of stress and coping (Hudson, Aranda & Hayman-White, 2005:330; Northouse et al., 2005:479; Nijboer et al., 1998:9), the intervention was not detailed, and the authors failed to report the source of initial intervention programme. There was a high attrition rate between T1 and T2, (n=116), and the reasons for this were concealed.

Meyers et al. (2011:465) reported on a prospective randomised study that was carried out in five oncology supportive care centres. In each of these centres patient/caregiver dyads were allocated to either an intervention group or control group. The objective was to examine the effect of a problem-solving intervention on the QOL of patients and their caregivers. Randomisation to the intervention group or control group was achieved using a three-to-one weighted randomisation scheme, blocked by site. The primary outcomes were QOL and problem-solving skills. Primary outcomes were measured repeatedly over 6 months after the intervention, using follow-up data collected at 30, 60, 90, 120, and 180 days after randomisation. The study participants were accounted for. Missing data and attrition were reported.

There was, however, no blinding of trained health educators who delivered the intervention programme. It was not reported whether the groups received similar usual care. Also, 51% of those with usual care and 46% in the intervention did not complete their follow-up as a result of withdrawal of consent or death, which might affect the validity of the results.

McMillan and Small (2007:313) tested an intervention for caregivers to better manage symptoms experienced by cancer patients. The target population, intervention and comparison groups as well as outcomes were clearly defined. The authors presented useful and well organised information on using the COPE intervention for family caregivers to improve symptoms of hospice homecare patients. Randomisation was achieved using a computer-generated random list. The groups were similar at baseline as the characteristics revealed no statistically significant differences. Both groups received similar usual care and all participants were accounted for; however, the study failed to explain if blinding was done and if so how it was achieved.

Walsh et al. (2007:142) evaluated the effectiveness of increased support for distressed primary caregivers of patients receiving palliative care, carried out by seven specialist palliative care teams in three London cancer networks. Participants were randomised using a block randomisation design. Although the process was systematically explained, with aim clearly stated and outcome variables reported using standard instruments, the intervention programme that was developed by the research team was neither piloted and nor was it reported that it was adapted from any standard intervention programme.

McMillan et al. (2006:214) aimed to "determine whether hospice plus COPE intervention improved family caregivers' QOL, burden coping and mastery, compared with hospice plus emotional support and usual hospice care". A widely published intervention (COPE) (Bahrami & Farzi, 2014:2; Meyers et al., 2011:466; McMillan & Small, 2007:316) was used. All groups participated in data collection; standard care was offered to group one, group two received standard care plus supportive visits, and group three had the COPE intervention in addition to the standard care. The outcome measures were caregivers' QOL, and general caregiver mastery, which was measured at baseline, 16, and 30 days from baseline. However, it was not reported whether intervention nurses and home health aides were blinded to the allocation.

Hudson, Aranda and Hayman-White. (2005:329-330) conducted an RCT to determine if caregivers who received the psycho-educational intervention would report higher levels of preparedness, self-awareness and self-efficacy, competence and reduced anxiety compared to caregivers who did not receive the intervention. Randomisation was achieved through a computer-generated software system. The process of data collection and the intervention programme were explicit. However, the study did not report whether the research assistants that participated in the study were blinded to the allocation.

Northouse et al. (2005:478) determined the effects of a family-based intervention on the QOL of patients with breast cancer and their family caregivers. A well-known FOCUS intervention programme was used and all the outcomes (proximal and distal) were clearly mentioned. All missing data were reported. This helped to account for all the patients and their family caregivers. However, the study did not report how randomisation was achieved and no blinding of outcome measures was reported.

Harding et al. (2004:397-398) aimed to evaluate a short-term group intervention for primary caregivers. The intervention and comparison groups were similar at baseline in terms of age, sex, months of caring, depression, anxiety and coping scales. However, it was not clear how the allocation sequence was generated and concealed, and how randomisation was achieved. Also, it was not clear if there was blinding, but the study reported that research staff were not involved in the intervention delivery and invitations but that they collected the data.

Bultz et al. (2000:303-307) carried out an RCT with the target population, intervention and comparison groups, and the outcomes were clearly stated. Randomisation was done by drawing six of the 12 names from an envelope; the intervention group received a psycho-educational intervention with two components, education and support, even though the source was not mentioned. The groups were similar at baseline, but blinding of the participants and research assistants was not reported. Also, it was not reported whether the intervention group received usual care apart from the intervention programme.

Table 2.7 presents a critical appraisal of the included articles.

## TABLE 2.7: Critical appraisal of the reviewed articles

| **Study ID** | **Did the trial address a clearly focused issue?** | **Was the assignment of patients to treatments randomised?** | **Were patients, health workers and study personnel blinded?** | **Were the groups similar at the start of the trial?** | **Aside from the experimental intervention, were the groups treated equally?** | **Were all of the patients who entered the trial properly accounted for at its conclusion?** | **How large was the treatment effect?** | **How precise was the estimate of the treatment effect?** | **Can the results be applied in your context (or to the local population)?** | **Were all clinically important outcomes considered?** | **Are the benefits worth the harms and costs?** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Leow, Chan and Chan, 2015 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly defined. | A computerised table of random numbers was used to generate the allocation sequence and randomised study participants into the control and intervention groups. | Outcomes were assessed by a research assistant who was blinded to the allocation. | Yes, the groups were similar at baseline and as a result showed no statistically significant differences in socio-demographic data between the two groups. | The two groups received similar routine care which included regular weekly to monthly visits (about 30 minutes) with psychosocial support such as counselling from a home hospice nurse. | All study participants were accounted for. Missing data were reported, such as patient's death, caregiver being too busy, patient no longer receiving home hospice care. | The intervention group reported significantly higher QOL, social support satisfaction and number of supported people, closeness with the patient, self-efficacy in self-care, rewards of caregiving, and knowledge, and lower stress and depression. | Confidence intervals were reported | No. It was carried out in Singapore, a high-income country with advanced technology compared to Nigeria. | Yes | Yes |
| Bahrami and Farzi, 2014 | Yes, the target population, the intervention and the comparison groups and the outcomes were clearly defined. | Participants were randomised but the study did not explain how it was carried out. | No blinding was reported to have been done. | The groups were similar at baseline. | The groups received similar standard care. | The study participants were accounted for. | There was significant increase in physical, mental and spiritual domains, as well as overall QOL. However, social domain did not change. Also, caring burden of intervention group recorded a decrease compared to the control group. | Confidence intervals were reported. | No, because it was done in a different context. | Yes | Yes |

| **Study ID** | **Did the trial address a clearly focused issue?** | **Was the assignment of patients to treatments randomised?** | **Were patients, health workers and study personnel blinded?** | **Were the groups similar at the start of the trial?** | **Aside from the experimental intervention, were the groups treated equally?** | **Were all of the patients who entered the trial properly accounted for at its conclusion?** | **How large was the treatment effect?** | **How precise was the estimate of the treatment effect?** | **Can the results be applied in your context (or to the local population)?** | **Were all clinically important outcomes considered?** | **Are the benefits worth the harms and costs?** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northouse et al., 2013 | Yes, the target population, the intervention and the comparison groups and the outcomes were clearly defined. | Dyads randomly assigned in blocks of three. They were stratified by risk status, type of cancer and research site. | No blinding of outcome assessors was reported. | The groups were similar at baseline. | The groups received similar usual care such as psychosocial support. | All missing data were reported. This helped to account for all the patients. | There was improvement in dyads' coping, self-efficacy, and social QOL, and in caregivers' emotional QOL in the intervention group. | Confidence intervals were reported. | No, it was carried out in the USA, which is a high-income country with developed technology. | Yes | Yes |
| Hudson et al., 2013 | Yes, the target population, the intervention and the comparison groups and the outcomes were clearly defined. | Block randomisation was achieved using computer generated random list. | There was blinding. The research assistants were blinded to group allocation. | Yes, the intervention and the comparison groups were similar at baseline. | Yes, the groups received the same usual care such as initial assessment, scheduled home visits, and access to a health care professional. | Yes, all the study participants were accounted for and analysed in the group they were assigned to. Intention to treat analysis was used. | No significant reduction in unmet needs or improvements in positive aspects of caregiving among the intervention groups were identified. However, both interventions demonstrated significant improvements in participants’ levels of preparedness, and competence for intervention 2. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |

| Study ID | Did the trial address a clearly focused issue? | Was the assignment of patients to treatments randomised? | Were patients, health workers and study personnel blinded? | Were the groups similar at the start of the trial? | Aside from the experimental intervention, were the groups treated equally? | Were all of the patients who entered the trial properly accounted for at its conclusion? | How large was the treatment effect? | How precise was the estimate of the treatment effect? | Can the results be applied in your context (or to the local population)? | Were all clinically important outcomes considered? | Are the benefits worth the harms and costs? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Meyers et al., 2011 | Yes, the target population, the intervention and the comparison groups and the outcomes were clearly defined. | Randomisation was achieved using a three-to-one weighted randomisation scheme, blocked by site. | No blinding was reported to have been done. | The groups were similar at baseline. | It was not reported if the groups received similar usual care. | The study participants were accounted for. Missing data and attrition were reported. | Caregivers' QOL showed moderately statistically significant on the intervention arm but not significant in the usual care arm. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |
| McMillan and Small, 2007 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly defined. | Randomisation was achieved using a computer-generated random list. | No, blinding was done. | The groups were similar at baseline as the characteristics revealed no statically significant differences. | The groups received similar usual care. | All participants were accounted for. | Symptom distress was significantly improved in the intervention but there was no improvement in QOL. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |

| Study ID | Did the trial address a clearly focused issue? | Was the assignment of patients to treatments randomised? | Were patients, health workers and study personnel blinded? | Were the groups similar at the start of the trial? | Aside from the experimental intervention, were the groups treated equally? | Were all of the patients who entered the trial properly accounted for at its conclusion? | How large was the treatment effect? | How precise was the estimate of the treatment effect? | Can the results be applied in your context (or to the local population)? | Were all clinically important outcomes considered? | Are the benefits worth the harms and costs? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Walsh et al., 2007 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly defined. | Participants were randomized using a block randomisation design. | Outcome assessors were blinded to the intervention groups. | The groups were similar at baseline. | The groups received similar usual care such as specialist palliative care with specialist medical support. | Attrition and deaths were recorded. | Mean scores in the intervention group were lower at all-time points but these differences were not significant. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |
| McMillan et al., 2006 | Yes, the target population, the intervention and the comparison groups and the outcomes were clearly defined. | Computerised randomisation procedure was used to achieve randomisation. | No blinding was done. | The groups were similar at baseline. | The groups received similar usual care. | All participants were accounted for. A longitudinal attrition analysis was conducted. | The intervention led to significantly greater improvement in caregiver QOL, and decline in burden related to caregiving task. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |

| Study ID | Did the trial address a clearly focused issue? | Was the assignment of patients to treatments randomised? | Were patients, health workers and study personnel blinded? | Were the groups similar at the start of the trial? | Aside from the experimental intervention, were the groups treated equally? | Wereall of the patients who entered the trial properly accounted for at its conclusion? | How large was the treatment effect? | How precise was the estimate of the treatment effect? | Can the results be applied in your context (or to the local population)? | Were all clinically important outcomes considered? | Are the benefits worth the harms and costs? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Hudson, Aranda and Hayman-White, 2005 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly defined. | Randomisation was achieved through a computer-generated software system. There is no information as to how allocation was concealed. | There was no blinding done. There was no blinding of outcome assessors. | Yes, the intervention and the comparison groups were similar at baseline. | Yes, the groups received the same usual care besides the intervention group that received intervention programme. | Yes, all the study participants were accounted for and analysed in the group they were assigned to. Intention to treat analysis was used. | No intervention effects were identified with respect to preparedness to care, self-efficacy, competence, and anxiety. However, participants who received the intervention reported a significantly more positive caregiver experience than those who received standard care. | P-values were reported but confidence intervals were not reported. | No, it was carried out in a high-income country. | Yes | Yes |
| Northouse et al., 2005 | Yes<br>The target population, the intervention and the comparison groups, and the outcomes were clearly defined. | The study did not report how randomisation was achieved. | No blinding of outcome measures was reported. | The groups were similar at baseline. | The groups received similar usual care | All missing data were reported. This helped to account for all the patients. | The intervention group reported significantly less negative appraisal of caregiving at 3-month assessment but not sustained at 6 months.<br>No difference was found in the quality of life of dyads in experimental or control conditions. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |

| Study ID | Did the trial address a clearly focused issue? | Was the assignment of patients to treatments randomised? | Were patients, health workers and study personnel blinded? | Were the groups similar at the start of the trial? | Aside from the experimental intervention, were the groups treated equally? | Were all of the patients who entered the trial properly accounted for at its conclusion? | How large was the treatment effect? | How precise was the estimate of the treatment effect? | Can the results be applied in your context (or to the local population)? | Were all clinically important outcomes considered? | Are the benefits worth the harms and costs? |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Harding et al., 2004 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly defined. | It is not clear how allocation sequence was generated or how randomisation was achieved. | It is not clear if there was blinding, but the study reported research staff who were not involved in the intervention delivery and invitations but who collected the data. | Yes, the intervention and the comparison groups were similar at baseline in terms of age, sex, months of caring, POS family score, depression, anxiety and coping scales. | Yes, the groups received the same usual care besides the intervention group that received an additional intervention programme. | Yes, all the study participants were accounted for and analysed in the group they were assigned to. The level of attrition was reported. | There is no significant change in the outcome measures. | Confidence intervals were reported. | No, it was carried out in a high-income country. | Yes | Yes |
| Bultz, et al., 2000 | Yes, the target population, the intervention and the comparison groups, and the outcomes were clearly stated. | Randomisation done by drawing six of the 12 names from an envelope. | Blinding was not clearly defined. | The groups were similar at baseline. | It was not clearly defined if there was other treatment beside the psychosocial programme for the intervention group. | Yes, all the study participants were accounted for and analysed in the group they were assigned to. The level of attrition was reported at 3 months. | Partner has less mood disturbance (anxiety, tension) after 3 months of intervention. | Confidence intervals were reported. | No, because of the location where the study was carried out. | Yes | Yes |

### 2.4.5 Outcomes measures reported

Out of eight studies that reported on QOL, four reported a positive effect of a psychosocial intervention (Leow, Chan & Chan, 2015:69; Bahrami & Farzi, 2014:6; Northouse et al., 2013:562; McMillan et al., 2006:219). Three reported no significant effect of the intervention (McMillan & Small, 2007:313; Walsh et al., 2007:145; Northouse et al., 2005:478). Meyers et al. (2011:465) reported that caregivers' QOL scores in the intervention arm declined, but at less than half the rate of the control arm. The study did not improve the caregivers' QOL scores.

One of the studies measured burden in caregivers. Two of the studies measured other caregiver issues such as perception of caregiving rewards and preparedness for caregiving. Harding et al. (2004:401) reported an increase in ZBI scores for caregivers who participated in the intervention. Hudson, Aranda and Hayman-White. (2005:336) and Hudson et al. (2008:277) reported an improvement in perception of caregiving and preparedness for caregiving respectively.

Each of the included studies used a different outcome measurement tool and a different intervention design; therefore, the findings of each of these studies are not comparable. This makes it difficult to draw conclusions about the effectiveness of the interventions under review.

The outcomes measured by Leow, Chan and Chan. (2015:67) include QOL, social support, caregivers' stress and depression, closeness with the patient, self-efficacy, positive gains of caregiving, and caregivers' perceived knowledge. The intervention group reported significant improvement in all seven outcome variables at three points (baseline, 4 weeks, and 8 weeks) ($p<0.05$); they all reported significantly higher results, with a p-value of 0.00.

Bahrami and Farzi. (2014:4) measured QOL and caring burden at two points (baseline, and a month after the intervention). The intervention group reported a significant increase in physical domain ($p<0.001$), psychological and spiritual domains ($p=0.017$), environmental domain ($p=0.047$), and overall QOL ($p<0.001$). The group also showed a decrease in caring burden ($p<0.001$); however, the social domain showed no significant difference after intervention ($p=0.845$).

Northouse et al. (2013:557) measured intermediary and primary outcomes. Intermediary outcomes were appraisal (appraisal of illness/caregiving, uncertainty, hopelessness) and resources (coping, interpersonal relationship, self-efficacy). Primary outcome was QOL; both were measured at baseline, and 3 and 6 months from baseline.

The brief and extensive interventions did not improve appraisal variables (appraisal of illness, uncertainty, and hopelessness) and interpersonal variables (communication and dyadic support). The brief intervention did not show any effect on self-efficacy throughout the period, while extensive intervention has a significant effect on self-efficacy at 3 months (p=0.041); however, this was not maintained at 6 months.

Both interventions reduced the use of avoidant coping significantly from baseline to 3 months (p=0.001 and p=0.033). This effect was maintained only for brief intervention at 6 months. The social and emotional QOL of intervention groups showed significant effects at 3 and 6 months (all p <0.05).

Hudson et al. (2013:1989) measured psychological well-being, preparedness for caregiving, caregiver competence, unmet needs, and positive aspects of caregiving at baseline, 5 weeks post recruitment, and 8 weeks post patient death). The interventions had a non-significant effect on unmet needs (p>0.19), positive aspects of caregiving (p>0.28), and psychological well-being (p>0.18), even though there was an improvement. However, there were significant improvements in participants' levels of preparedness and competence for intervention two.

Meyers et al. (2011:466) measured patients' or caregivers' QOL and problem solving skills at baseline, and 30, 60, 90, 120 and 180 days after the randomisation. The caregivers' QOL showed a significant decline while patients' QOL was not significantly different. Patients showed a decline in problem-solving skills, but caregivers did not show any difference.

McMillan and Small (2007:315) measured intensity of pain, dyspnoea, constipation, overall symptom distress and QOL, at baseline, 16 and 30 days. Symptom intensity for three target symptoms (pain, dyspnoea, constipation) did not decrease, but symptom distress was significantly improved (p=0.009). QOL was not significantly different.

In the study by Walsh et al. (2007:142), caregivers' distress, carer strain and QOL were the primary and secondary outcomes measured at 4, 9 and 12 weeks. None of the variables showed significant changes.

In the study conducted by McMillan et al. (2006:215), caregivers' QOL, burden, mastery and coping were measured. The intervention had significant effects on the caregivers' QOL (p=0.054), burden related to patient symptoms (p=0.001), and caregivers' burden (p=0.021). The caregivers' feelings of mastery were not affected by the intervention.

In Hudson, Aranda and Hayman-White. (2005:332) study, caregivers' preparedness, competence, mastery, self-efficacy, anxiety and rewards of caregiving were measured at three time points. There were no intervention effects on caregivers' preparedness to care, self-efficacy, competence, and anxiety, but there was a significantly more positive caregiver experience in the intervention group.

In Northouse et al. (2005:482) study, appraisal of illness/caregiving, uncertainty, hopelessness, coping, and QOL were measured at baseline, 3 and 6 months. The intervention had effects on the negative appraisal of illness and hopelessness from baseline to 3 months (p=0.008, p=0.03), but the effect did not last till 6 months (p=0.13, p=0.19). The intervention decreased the negative appraisal of caregiving from baseline to 3 months (p=0.046), but was not sustained till 6 months (p=0.37). Other variables such as QOL, coping and uncertainty were not different.

Harding et al. (2004:398) measured psychological status and patients' physical status at baseline, 8 and 20 weeks. Intervention was not found to improve the psychological measures, but it did improve the Zarit Burden scores of caregivers and general health scores.

### 2.4.6 Critical appraisal of study instruments used by reviewed articles

Eight of the included studies reported on QOL, but the instruments used to measure it were not uniform. QOL instruments used were City of Hope QOL, FACT-G, Hospice QOL index and Caregiver QOL-Cancer (CQOLC) index.

General Functional Assessment of Cancer Therapy (FACT-G): The test-retest reliability of this instrument as reported in (Lyons et al., 2009:25) is 0.92.

The domains measured by the FACT-G include physical well-being, emotional well-being, functional well-being and social and family well-being. The tool has 27 items.

SF-36 Health Survey: The domains measured by this instrument include “physical health, physical functioning, physical role limitation, general health, mental health, emotional role limitation, vitality, mental health and social functioning”. This tool has a shortened form with 12 items and a standard version with 36 items.

World Health Organization QOL (WHOQOL): This instrument has a Cronbach α score of 0.73-0.85. The test-retest reliability is 0.66-0.87. The domains covered by this instrument include physical domain, psychological domain, social domain and environmental domain. The tool has 100 items.

Palliative Outcome Scale (POS): Domains covered by this tool include emotional, social, psychological and spiritual problems. The test-retest score is 22.3 (Pelayo-Alvarez, Perez-Hoyos & Agra-Varela, 2013:871).

Leow, Chan and Chan. (2015:67) used the CQOLC to measure the QOL and a social support questionnaire to measure social support available to caregivers.

Northouse et al. (2013:557) used a social support questionnaire to measure social support available to patient-caregiver dyads, a general functional assessment tool and FACT-G to measure QOL of caregivers.

Hudson et al. (2013:1989) used the following measurement tools: (1) General Health Questionnaire-12; (2) Caregiver Competence Scale (CCS); (3) Preparedness for Caregiving Scale; (4) Family Inventory of Need; and (5) Rewards for Caregiving Scale.

Meyers et al. (2011:466) used the City of Hope QOL tool to measure QOL and social problem solving inventory-revised tool to measure positive problem orientation, rational problem solving, negative problem orientation, impulsivity/carelessness style and avoidance style.

Hudson et al. (2008:273) used the following measurement tools: (1) Caregiver Competence Scale to measure perceived competence; (2) Preparedness for Caregiving Scale to measure perceived preparedness for caregiving; (3) Family Inventory of Need to measure unmet informational needs of caregivers; (4) Rewards for Caregiving Scale to measure positive aspects of the caregiving role; (5) Social Support Questionnaire to measure social support for caregivers; (6) Brief Assessment Scale for Caregivers to measure burden; and (7) Life Orientation Test to measure optimism.

McMillan et al. (2006:215-216) and McMillan and Small (2007:316) used a CQOLC and HQLI to measure QOL among caregivers and short mental status questionnaire to measure the ability to complete a serial subtraction task.

Northouse et al. (2005:482-483) used the "Appraisal of Illness Scale, Appraisal of Caregiving Scale, Mishel Uncertainty in Illness Scale, Beck Hopelessness Scale, Brief COPE, the FACT scale, and the SF-36 Health Survey". Walsh et al. (2007:142) used the 28-item General Health Questionnaire (GHQ-28).

Hudson, Aranda and Hayman-White. (2005:332-333) used the Preparedness for Caregiving Scale to measure perceived competence and hospital anxiety, Caregiver Competence Scale, Rewards of Caregiving Scale, and Depression Scale to measure anxiety in caregivers.

Harding et al. (2004:398-399) used outcome measurement tools which included: (1) POS to measure social, psychological and spiritual domains and provision of information; (2) Eastern Co-operative Oncology Group (ECOG) Performance Scale to measure patient performance; (3) ZBI to measure stress among carers; (4) Coping Responses Inventory to measure approach coping and avoidance coping among caregivers; (5) General Health Questionnaire-12 (GHQ-12) to measure psychological morbidity that relates to inability to carry out one's normal healthy functioning; and (6) the State Anxiety Scale, shortened version, to measure qualities of anxiety such as apprehension, tension, nervousness, and worry.

Tables 2.8 and 2.9 present the outcome measurement tools and evaluation of the instruments used in the included studies

### TABLE 2.8: Outcome measurement tools

| **Outcome measurement tool** | **Leow Chan and Chan. (2015)** | **Bahrami and Farzi. (2014)** | **Northouse et al. (2013)** | **Hudson et al. (2013)** | **Meyers et al. (2011)** | **McMillan and Small. (2007)** | **Walsh et al. (2007)** | **McMillan et al. (2006)** | **Hudson, Aranda & Hayman -White. (2005)** | **Northouse et al. (2005)** | **Harding et al. (2004)** | **Bultz et al. (2000)** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| POS | | | | | | | | | | | **X** | |
| ZBI | | **X** | | | | | | | | | **X** | |
| Coping Responses Inventory | | | | | | | | | | | **X** | |
| GHQ | | | | **X** | | | **X** | | | | **X** | |
| State Anxiety Scale-shortened version | | | | | | | | | | | **X** | |
| ECOG Performance Scale. | | | | | | | | | | | **X** | |
| Appraisal of Caregiving Scale | | | **X** | | | | | | | **X** | | |
| Mishel Uncertainty Index Scale. | | | **X** | | | | | | | **X** | | |
| Beck Hopelessness Scale | | | **X** | | | | | | | **X** | | |
| Index of Marital Satisfaction | | | | | | | | | | | | **X** |
| Functional Social Support Scale | | | | | | | | | | | | **X** |
| Brief COPE Scale | | | **X** | | | | | **X** | | **X** | | |
| FACT-G | | | **X** | | | | | | | **X** | | |
| SF-36 Health survey | | | | | | | | | | **X** | | |
| CQOLC | **X** | **X** | | | | | **X** | **X** | | | | |

| **Outcome measurement tool** | **Leow Chan and Chan. (2015)** | **Bahrami and Farzi. (2014)** | **Northouse et al. (2013)** | **Hudson et al. (2013)** | **Meyers et al. (2011)** | **McMillan and Small. (2007)** | **Walsh et al. (2007)** | **McMillan et al. (2006)** | **Hudson, Aranda & Hayman -White (2005)** | **Northouse et al. (2005)** | **Harding et al. (2004)** | **Bultz et al. (2000)** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Social Support Questionnaire | **X** | | **X** | | | | | | | | | |
| Appraisal of Illness Scale | | | **X** | | | | | | | **X** | | |
| Depression Anxiety Stress Scale | **X** | | | | | | | | | | | |
| Rewards of Caregiving Scale | **X** | | | **X** | | | | | **X** | | | |
| City of Hope QOL | | | | | **X** | | | | | | | |
| Social Problem-solving Inventory-Reversed | | | | | **X** | | | | | | | |
| Mental Adjustment to Cancer Scale | | | | | | | | | | | | **X** |
| Profile of Mood States | | | | | | | | | | | | **X** |
| Caregiver Demands Scale | | | | | | | | **X** | | | | |
| General Caregiver Scale | | | | | | | | **X** | | | | |
| Short Portable Mental State Questionnaire | | | | | | | | **X** | | | | |
| CCS | | | | **X** | | | | | **X** | | | |
| Preparedness for Caregiving Scale | | | | **X** | | | | | **X** | | | |
| Family Inventory of Need | | | | **X** | | | | | | | | |
| Numeric Rating Scale | | | | | | **X** | | | | | | |
| Hospice QOL Index | | | | | | **X** | | | | | | |
| Dyspnoea Intensity Scale | | | | | | **X** | | | | | | |

| **Outcome measurement tool** | **Leow Chan and Chan. (2015)** | **Bahrami and Farzi. (2014)** | **Northouse et al. (2013)** | **Hudson et al. (2013)** | **Meyers et al. (2011)** | **McMillan and Small. (2007)** | **Walsh et al. (2007)** | **McMillan et al. (2006)** | **Hudson, Aranda & Hayman-White. (2005)** | **Northouse et al. (2005)** | **Harding et al. (2004)** | **Bultz et al. (2000)** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Constipation Assessment Scale | | | | | | **X** | | | | | | |
| Memorial Symptom Assessment Scale | | | | | | **X** | | **X** | | | | |
| Hospital Anxiety and Depression Scale | | | | | | | | | **X** | | | |
| Mastery Scale | | | | | | | | | **X** | | | |
| Self-Care Scale | **X** | | | | | | | | **X** | | | |
| WHOQOL | | **X** | | | | | | | | | | |

### Table 2.9: Evaluation of instruments used in the reviewed articles

| S/N | Instruments | What does it measure? | Reliability | Validity | Comments |
|---|---|---|---|---|---|
| 1. | POS (12 items) | Addresses emotional, social, psychological, and spiritual problems, information and practical support. | Good test/retest reliability. Internal consistency of the different versions of the measure was also good (Cronbach alpha = 0.65) | Good construct validity (Spearman rho = 0.43–0.80) | It was designed for use with advanced cancer patients and in palliative care (Collins et al., 2015:843) |
| 2. | ZBI (22 items) | Stress among caregivers, caring burden. | Good<br>Cronbach's alpha; a value of ≥0.7 | Good<br>(correlation coefficient = 0.73, $p<0.0001$) | The ZBI was developed to measure subjective burden among caregivers of adults with dementia; however, it has been used in cancer patients (Seng et al., 2010:761; Higginson & Gao, 2008:3; Grunfeld et al., 2004:1795). |
| 3. | Coping Responses Inventory (48 items) | Evaluated eight different types of coping responses to stressful life situations. | Good<br>The internal consistency (Cronbach α-coefficients for the eight subscales of the CRI-A (logical analysis = 0.785; positive reappraisal = 0.739; seeking guidance = 0.734; problem-solving = 0.821; cognitive avoidance = 0.721; acceptance or resignation = 0.711; seeking alternative rewards = 0.744; emotional discharge = 0.713) (Pretorius, Walker & Esterhuyse, 2010:2). | Good | It is useful in counselling, stress management education, also monitors coping strategies to develop better clinical case descriptions, and to plan and evaluate the outcome of treatment. |
| 4. | GHQ (12 item and 28 item) | Psychological morbidity, psychological well-being. | Good.<br>12-items: Cronbach'sreliability of 0.70.<br>28 item: Cronbach's alpha 0.922 (De Almeida Vieira Monteiro, Ana,Paula Teixeira, 2011; Ip & Martin, 2006). | Good<br>12- items: correlation of 0.57 | It is the most extensively used instrument for mental disorders, and psychological well-being. |
| 5. | State Anxiety Scale-shortened version (6-items). | Quality of anxiety in physically and cognitively debilitated patients. | Good<br>Cronbach α for the scale was 0.79 (Perpi-Galva, Cabaero-Martnez & Richart-Martnez, 2013). | Good<br>Pearson coefficient of correlation of 0.77 (P = .01) | It is a potent tool for anxiety related illness. |
| 6. | ECOG performance scale. | Measured how the disease impacts a patient's daily living abilities | Good | Good<br>(coefficient 0.91) (Blagden et al., 2003) | The tool describes a patient's level of functioning in terms of their ability to care for themselves in daily activities and physical ability. |

| S/N | Instruments | What does it measure? | Reliability | Validity | Comments |
|---|---|---|---|---|---|
| 7. | Appraisal of Caregiving Scale (27 -items) | Caregivers' views of tasks and problems associated with caregiving | Good<br>Cronbach's alpha for all subscales exceeded the minimal value of 0.70 (Lambert et al., 2015). | Good<br>Correlation between the Benefit subscale and the Benefit Finding Scale exceeded the minimal accepted value of 0.30 (r = 0.557). | It measures the positive and negative appraisals of caregiving including general stress, and benefit appraisals |
| 8. | Mishel Uncertainty Index scale (29-items) | Uncertainty | Good<br>Cronbach's coefficient alpha was 0.82 and 0.88 (Lambert et al., 2015). | Good<br>Coefficients were 0.71 and 0.86 | It measures uncertainty among chronically ill patients or their caregivers. |
| 9. | Beck Hopelessness Scale (20 -items) | Hopelessness | Good reliability (test-retest, r = 0.81) and a good internal consistency (alpha = 0.97) | Good | It measures negative attitudes about the future and inability to stop negative life occurrences (Neufeld, O'Rourke & Donnelly, 2010; Bouvard et al., 1992). |
| 10. | Index of Marital Satisfaction | Marital satisfaction and social support | Good<br>Cronbach's alpha was 0.97 | Good<br>Validity coefficient (correlation between total score and group membership) was 0.82. Concurrent validity coefficient was -0.94 (Torkan & Moulavi, 2009) | It was designed to measure the marital dissatisfaction among partners. |
| 11. | Functional Social Support Scale | Satisfaction with the functional and affective support | Good<br>Cronbach's alpha of 0.83 |  | It measures perceived social support. The original version had 14-items that was reduced to eight after reliability testing (Isaacs & Hall, 2011). |
| 12. | Brief COPE Scale (24 - items) | Coping | Good<br>Cronbach's alpha scores were: 0.72 and 0.84 (Cooper, Katona & Livingston, 2008) | Good | It measures various coping strategies among caregivers of chronic illness. |
| 13. | FACT-G (27- items) | Family caregivers' QOL | Good<br>Internal consistency was considered adequate when α ≥ 0.70 | Good | It is a widely used instrument in clinical practice for the evaluation of QOL of cancer patients or their caregivers (Campos, Juliana Alvares Duarte Bonini et al., 2016) |

| S/N | Instruments | What does it measure? | Reliability | Validity | Comments |
|---|---|---|---|---|---|
| 14. | CQOLC (35 items) | Caregivers' QOL | Good<br>Internal consistency, Cronbach's alpha was > 0.80 (Bektas & Ozer, 2009) | Good | A widely used instrument to measure QOL in cancer caregivers; it has been used in many countries. |
| 15. | WHOQOL-Brief | Physical, psychological, spiritual, social, and environmental domains of the QOL | Good<br>Internal consistency of 0.63-0.84 | Good<br>Content validity r = 0.39-0.65 (p < 0.01) and criterion-related validity r = 0.28-0.65 (p < 0.05 | It is a better tool to measure the physical domain of the QOL (Gau et al., 2010). |
| 16. | SF-36 Health Survey | Physical and mental QOL | Good<br>Cronbach's alpha coefficient was 0.70 (Sinha, Van den Heuvel & Arokiasamy, 2013) | Good | It measures physical health, physical functioning, physical role limitation, general health, mental health, emotional role limitation, vitality, mental health, and social functioning. |
| 17. | Self-efficacy in Self-care scale | Self-efficacy. | Good<br>Cronbach's alpha coefficient above 0.70 (Gustafsson, Svenstedt & Vikman, 2013) | Good | It consists of 10 items, rated on a 10-point Likert-type scale. |
| 18. | Social Support Questionnaire | Dyadic social support. | Good<br>Cronbach's alpha of 0.89 (Van et al., 2004). | Good<br>Pearson correlation of 0.72 (P < 0.001) | It measures caregivers' satisfaction level. It also helps the nurses in determining if a patient's need for social support is fulfilled. |
| 19. | Appraisal of Illness Scale | Appraisals of illness | Good<br>The reliability (coefficient alpha) was 0.867 (Kao & Liu, 2010) | Good | It measures patients' awareness of his symptoms, his need for treatment, and the consequences of his illness. |
| 20. | Depression and Stress Subscale from the Depression Anxiety Stress Scale (14-items) | Caregivers' stress and depression | Good<br>Internal consistency reliability was assessed using Cronbach's coefficient alpha. For the total scales, alpha was 0.91. | Good<br>Significant negative correlation was found between scores on the Depression Anxiety Stress Scales and the Satisfaction with Life Scale (r = −0.27, p < 0.001. | The Depression Anxiety Stress Scales have 42 items. One of the subscales is Depression which has 14 items. This scale evaluates dysphonic mood states like self-depreciation, low self-esteem, hopelessness, and lack of incentive (Bayani, 2010). |

| S/N | Instruments | What does it measure? | Reliability | Validity | Comments |
|---|---|---|---|---|---|
| 21. | Rewards of Caregiving Scale | Positive gains of caregiving, positive aspects of caregiving | Good<br>It demonstrated alpha values of 0.9. | Good | It is valid and reliable for use in family members of persons with life-threatening illness (Henriksson et al., 2012). |
| 22. | Mental Adjustment to Cancer Scale | Psychological responses. | Good<br>Reliability (Cronbach's α = 0.67-0.88) (Fong & Ho, 2015) | Good | It is widely used to evaluate cancer patients' psychological responses. |
| 23. | Profile of Mood States | Tension, depression, anger, vigour, fatigue. | Good<br>Reliability coefficients (Cronbach's alpha) were 0.779-0.926 (Yokoyama et al., 1990). | Good | It consists of 65 items and six factors have been derived from this: tension-anxiety, depression, dejection-hostility, fatigue-inertia, vigour-activity, confusion. |
| 24. | CCS | Caregiver competence | Good<br>Cronbach's alpha was good; all scales demonstrated alpha values of 0.9 (Henriksson et al., 2012). | Good | It measures the caregiver's evaluation of their performance in the caregiving role. |
| 25. | Preparedness for Caregiving Scale | Preparedness for caregiving | Good<br>Cronbach's alpha was good; all scales demonstrated alpha values of 0.9. | Good<br>Convergent validity was supported. | The instrument assesses caregivers' readiness to provide care (Henriksson et al., 2012). |
| 26. | Family Inventory of Need | Unmet needs | Good.<br>Cronbach's α for the entire questionnaire was 0.924 on the importance scale and 0.912 for the satisfaction scale; for all domains (Bužgová & Kozáková, 2016). | Good | It measures the care needs of families of advanced cancer patients. |
| 27. | Hospital Anxiety and Depression Scale | Clinically significant anxiety and depression. | Good<br>The internal consistency was 0.78 for the anxiety subscale, 0.76 for depression subscales and 0.87 for the full scale of HADS (Reda, 2011). | Good | It measures anxiety and depression of patient and the caregiver. |
| 28. | Mastery Scale | How much control a person perceives he/she has over an event. | Good<br>Cronbach's alpha (criterion>0.7) (Chen et al., 2013) | Good | It is an essential instrument to measure mastery in a valid and reliable way. |

## 2.5 Conclusion

Currently breast cancer form a serious health issue globally, with more than one million new cases diagnosed every year, resulting in over 400 000 annual deaths and about 4.4 million women living with the disease. In sub-Saharan Africa about 94 000 new cases of breast cancer and 48 000 deaths occurred in 2012. This is projected to double by 2030 (McKenzie et al., 2016:1). Journal articles for the period 1996 to 2016 were searched for in databases. A total of 172 studies were identified, but only 12 studies met the inclusion criteria while 160 were excluded from the study. The 12 discussed three main types of psychosocial intervention; 11 of these used RCTs, and one was a non-randomised experimental study. Eight of the intervention studies reported QOL. However, the outcome measurement tools used to measure QOL were not uniform across the studies; one study measured Zarit Burden in caregivers and two other studies measured caregiver issues such as preparedness for caregiving and perception of caregiving rewards.

Out of eight studies that reported on QOL, four reported a positive effect of psychosocial intervention, three reported no significant effect of the intervention, and one reported a negative effect of the intervention. The study reported that caregiver QOL scores in the intervention arm declined – but at less than half the rate in the control arm. Harding et al. (2004:400) reported an improvement in Zarit Burden scores for caregivers who participated in the intervention. Hudson, Aranda and Hayman-White. (2005:336) and Hudson et al. (2008:270) reported an improvement in perception of caregiving and preparedness for caregiving respectively. It should be noted that none of these included studies was conducted in a low-middle-income or low-income country. There is therefore a need to investigate whether these interventions will work in low-middle-income countries and low-income countries.

# CHAPTER THREE

# METHODOLOGY

## 3.1 Introduction

This chapter focuses on the overview, study design, study setting, study population and sample, instruments, recruitment, inclusion and exclusion criteria, data collection procedures, data management and analysis and ethical considerations pertaining to the study. The aim of the study was to implement and evaluate the effectiveness of a psychosocial intervention programme on the QOL of primary caregivers of women with breast cancer in Abuja, Nigeria.

## 3.2 Overview of the study design

This research implemented and evaluated the effectiveness of a psychosocial intervention programme on the QOL of primary caregivers of women with breast cancer. A quasi-experimental design with intervention and control groups was chosen in order to evaluate the effectiveness of a psychosocial intervention programme on the QOL of the primary caregivers of women with breast cancer. The choice of a longitudinal design was motivated by the interest in investigating changes in QOL over a 12-week period (Northouse et al., 2005:480).

The quantitative and descriptive study design examined the relationships among the dependent variables, QOL, and the independent variables, which include demographics and caregiving burden. Caregivers were assessed at baseline and reassessed at 6 and 12 weeks following the baseline. The study was a non-randomised control study with two arms (control group that received standard care only, and intervention group that received an intervention programme plus standard care). The intervention was introduced to observe its effect. A number of variables were examined across three time periods:

Time 1: Before commencement of the caregiver intervention programme (baseline); this involved the administration of demographic data (Appendix C, Section A), ZBI (Appendix C, Section B), and CQOLC (Appendix D).

Time 2: After the caregiver intervention programme (6 weeks from baseline); the ZBI and CQOLC were re-administered.

Time 3: Six weeks following the last caregiver intervention session; the ZBI and CQOLC were re-administered.

This research design was appropriate because it allowed for examination of the interrelationships among variables. In addition, the design has the strength of realism which may allow for practical problem solving (Polit & Beck, 2008:31).

The data collection process is described in Figure 3.1.

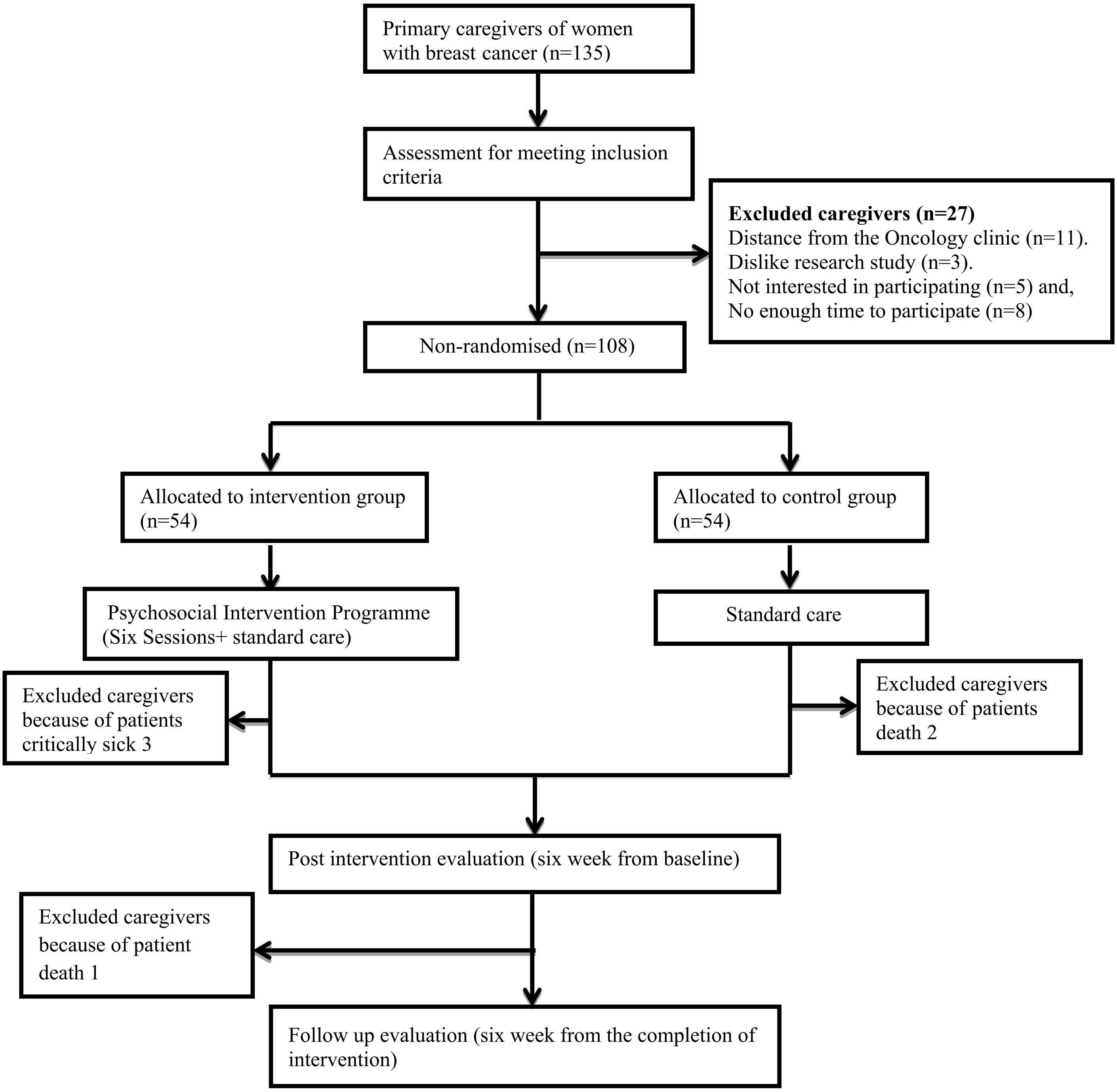


Figure 3.1: Design of the data collection process.

### 3.2.1 Pre-test/post-test with quasi-experimental design

The study used pre-test/post-test quasi-experimental design and data were collected before and after the intervention. The allocation of participants to the intervention and control groups was non-random; hence it was not possible to assume equivalence between the study groups. The researcher assessed the differences at baseline and account for any demographic or behavioural differences in the analysis.

The basic structure of a classic quasi-experimental design is shown in Figure 3.2.

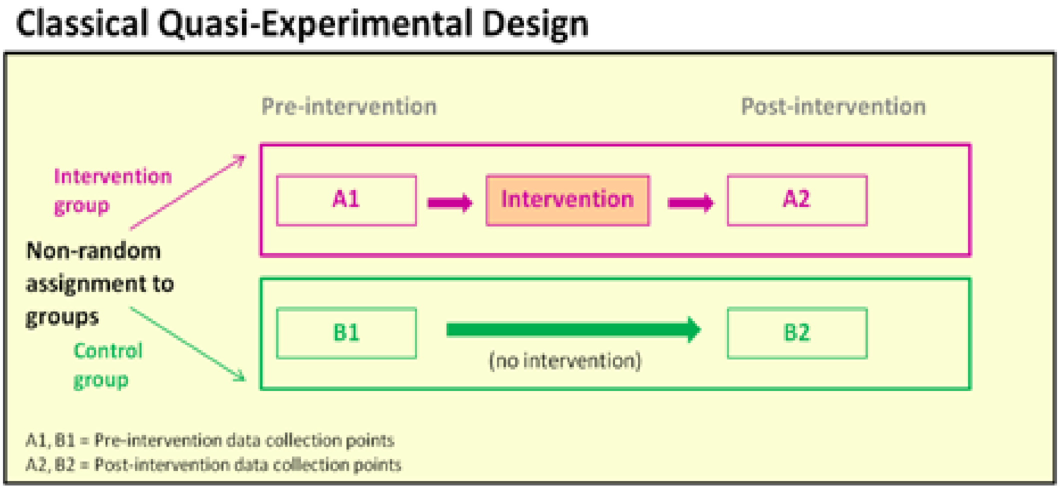


**Figure 3.2: Classical Quasi-experimental Design**

### 3.3 Study setting

The study was conducted at the National Hospital, Abuja, Nigeria. The National Hospital is a tertiary health institution and one of the two centres with a radiotherapy facility in the northern region of Nigeria. It is situated in the central area of Abuja; Nigeria's Federal Capital Territory. It is a public hospital, serving as a referral centre for all medical/surgical conditions. Patients are referred to the hospital from all over the northern region and beyond.

The hospital was established to cater for women and children with a view to reducing morbidity and mortality rates in Nigeria, and to conduct research into the causes of women and children- related diseases in Africa. The hospital started operations on 1 September 1999. In the year 2000 the scope of its operations was expanded in order for all Nigerians including male patients to benefit from the services and modern equipment in the hospital. Initially named ‘National Hospital for Women and Children’, it was later renamed the National Hospital Abuja on 10 May 2000. The hospital is used as a clinical teaching and learning facility for doctors and nurses.

Abuja is a planned capital city of Nigeria which was built in the 1980s and officially became Nigeria's capital on 12 December 1991. It is home to the country's Executive, Legislative and Judicial arms of government at the central level. The city is located in the centre of Nigeria, within a territory called the Federal Capital Territory.

Figure 3.3 presents a map of Nigeria showing Abuja where the National Hospital is situated.

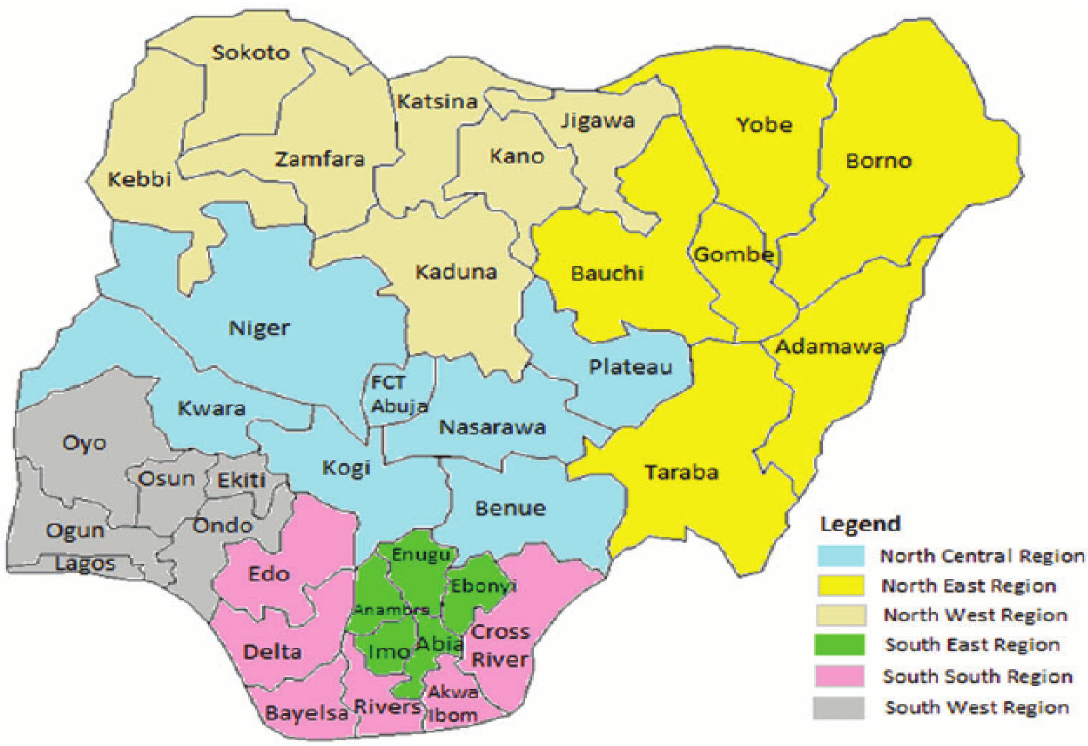


**Figure 3.3: Map of Nigeria showing the 36 states and the Federal Capital Territory (adapted from Ministry of the Federal Capital Territory).**

## 3.4 Study population

Study population refers to the total number of elements from which the sample is selected. The target population of the study was all accessible adult unpaid primary caregivers of women with breast cancer who received care and treatment at the National Hospital Abuja at the time of the study.

### 3.4.1 Inclusion criteria

- Adults of age 18 years or older. The physician and the care/treatment team identified the primary caregivers.
- The person being cared for should not be immediately terminal, and should have a more than 6-month survival prognosis as indicated by their health care team. The reason for this was to minimise the extra stress of coping with a dying relative while participating in a research project (Cameron et al., 2004:139).
- Literate with a minimum of ninth grade education (junior secondary school level) in order to be able to complete the questionnaire.

### 3.4.2 Exclusion criteria

- Professional health caregivers, as their knowledge and information could influence their participation.
- Caregivers who, at the time of the study, were receiving treatment for breast cancer or a condition which increased their physical and/or psychological vulnerability as defined by the physician.
- Caregivers who, after being given information, declined to participate.

## 3.5 Sample

The primary caregivers of women with breast cancer were the subjects of this study. In order to determine the sample size, the researcher utilised the findings of the study of Bachner and O'Rourke (2007). ZBI score was generated as a sum of relevant item scores obtained from the preliminary run. The score had a mean of 40 and a standard deviation of 16. A test-retest correlation value of 0.30 was assumed. For the main study it was desired that the power of the test be about 80%, and the preferred significance level is 5%.

The power of a test is the ability of the test to correctly reject the null hypothesis. The significance level of a test is the probability of rejecting the null hypothesis when it is actually true. The primary null hypothesis of the statistical analyses to be carried out in this study states that: The psychological intervention programme has no effect on the QOL of primary caregivers of patients with breast cancer.

The sample size calculations using the data from the previous study, based on the desired power and significance level, yielded 90 participants. That is, at least 90 subjects must participate in the main study to achieve about 80% power and 5% significance level. The study reported that there was an approximately 20% drop-out rate during the preliminary study (Bachner & O'Rourke, 2007). To adjust for this, at least 20% of 90=18 persons would be recruited; therefore 108 participants were required for this study.

### 3.6 Measurement instrumentation

The study utilised three questionnaires:
(a) A researcher-developed, closed-ended socio-demographic questionnaire (Appendix C, Section A);
(b) ZBI (Appendix C, Section B); and
(c) CQOLC (Weitzner et al., 1999:55) (Appendix D).

The instruments were selected because they are recommended standard instruments that have been used in studies of cancer caregivers' burden and QOL; they have established validity and reliability (Leow, Chan & Chan, 2015:67; Tamayo et al., 2010:52; Lai, 2007:45).

#### 3.6.1 Socio-demographic questionnaire

This comprised nine questions relating to age, gender, ethnicity, marital status, level of education completed, religion, employment status, relationship to the patient, and impact of caregiving on the primary work/employment (Appendix C, Section A).

#### 3.6.2 ZBI

The ZBI has 22 items and is identified as a one-factor scale, reflecting areas of concern, namely health, finances, social life, emotional well-being, personal life, and interpersonal relationships (Ozer, Yurttas & Akyil, 2012:66). It has been widely used among caregivers for assessing burden. The ZBI was designed to measure subjective burden among caregivers of adults with dementia. However, Higginson and Gao (2008:3) and Grunfeld et al. (2004:1796) used it in cancer patients. It has also been used in Nigeria in a study on "caregiver burden among poor caregivers of patients with cancer in an urban African setting" (Yusuf, Adamu & Nuhu, 2011:903). "Items were generated based on clinical experience with caregivers and prior studies, resulting in a 22-item self-report inventory that examines burden associated with functional/behavioural impairments and the home care situation. The items are worded subjectively, focusing on the affective response of the caregiver" (Kumar & Gupta, 2014:52) (Appendix C, Section B). The ZBI instrument was divided into three domains (Bianchi et al., 2016:5; Harding et al., 2004:403): role strain, personal strain, and competencies and expectations.

#### 3.6.2.1 Scoring/interpretation

The ZBI is scored on a 5 point Likert scale. Each item is scored from 0 to 4, where 0= never, 1= rarely, 2= sometimes, 3= quite frequently, and 4 = nearly always. The total ZBI was obtained by adding the scores for the 22 items with a range of 0 to 88, higher scores indicating greater burden (Zarit, Reever & Bach-Peterson, 1980).

Interpretation of score:

0 - 20 little or no burden
21- 40 mild to moderate burden
41- 60 moderate to severe burden
61- 88 severe burden

#### 3.6.2.2 Validity and reliability

Validity can be defined as the extent to which an instrument measures the variable that it is intended to measure (Kimberlin & Winterstein, 2008:2278).

Reliability refers to the consistency and dependability of a research instrument to measure a variable, including stability, equivalence and internal consistency (Kimberlin & Winterstein, 2008:2277).

The ZBI has been validated in a number of countries, including Turkey, Singapore and China. In Turkey, it was used to measure the caregiving burden among family caregivers of in-patients in medical and surgical clinics. It has an overall coefficient alpha of 0.82. The Cronbach alpha ranged between 0.81 and 0.83 (Ozer et al., 2012:67).

The ZBI was used to measure the level of burden experienced by caregivers in Singapore (Seng et al., 2010:759). Validity scores were highly correlated with the Burden Assessment Scale score (correlation coefficient = 0.73, $p<0.0001$); consistency reliability was assessed using Cronbach's alpha; a value of ≥0.7 and was considered satisfactory.

In China it was used in measuring caregivers’ burden, and the internal consistency was high (Cronbach’s alpha 0.875). The Kaiser–Meyer–Olkin measure of sampling adequacy was 0.867 and the Bartlett test of sphericity was 3487.085 ($p < 0.001$) (Lu et al., 2009:731-732).

No translation or modification was done before using the tool, because English is the official national language and the language of conversation in Nigeria. Most people can read and communicate in English.

### 3.6.3 CQOLC

The CQOLC (Appendix D) is one of the most commonly used and recommended standard instruments to measure cancer caregivers’ QOL. The CQOLC has been used in numerous types of cancer studies and in many parts of the world such as the USA, Canada, France, Turkey, and Singapore (Mahendran et al., 2017:1; Lapid et al., 2016:1402; Effendy et al., 2015:587; Leow, Chan & Chan, 2015:67; Lafaye et al., 2013:119; Wadhwa et al., 2013:404; Bektas & Ozer, 2009:3003; McMillan et al., 2006:215); and in QOL cancer research with diverse populations of Hispanic, Taiwanese subjects (Chen, Chu & Chen, 2004:470).

The primary focus of this instrument is the QOL of primary caregivers of patients with cancer, capture most theoretical dimensions of caregiver QOL. The CQOLC scale was developed by Weitzner using groups of cancer patients and their caregivers in 1997 (Duan et al., 2015:2-3). This study sample included caregivers of patients with breast, lung, gastro-intestinal, and genito-urinary cancers. The instrument has a test–retest reliability correlation coefficient of 0.95 and a Cronbach’s alpha coefficient of 0.91 (Weitzner et al., 1999:57,60).

#### *3.6.3.1 Scoring/interpretation*

The CQOLC is a 35-item self-report questionnaire; it is scored on a five-point Likert-type scale that yields a single QOL, ranging from 0 = Not at all to 4 = Very much: 10 items relate to burden; 7 to disruptiveness; 7 to positive adaptation; 3 to financial concerns and 8 single items to additional factors such as day-to-day focus, mental strain satisfaction with sexual sleep disruption, management of patient's pain and family interest in caregiving (Son et al., 2012:218). The questionnaire is scored by adding up the score on each item to yield a total score for the instrument, and scores can range from 0 to 140. The maximum total score on the CQOLC is 140, the higher the score on the CQOLC, the better the QOL (Duan et al., 2015:3; Edwards & Ung, 2002:344).

#### *3.6.3.2 Validity and reliability*

Reliability was 0.95 and internal consistency was 0.91 (Weitzner et al., 1999:60). The CQOLC possesses adequate validity, test-retest reliability and internal consistency. The CQOLC has been utilised with family caregivers of patients with cancer (McMillan et al., 2006:215).

### 3.6.4 Pilot study

A pilot study was conducted on a small population who gave their consent to be part of the study to identify potential practical problems and test the quality of the instruments in the research procedure. Viechtbauer et al. (2015:1376) found that a sample size of at least 9% of the sample size for the main study is a reasonable number of participants to consider enrolling in a pilot study. Therefore 10 caregivers (n=10) from another hospital in Abuja (Asokoro District Hospital) were recruited. It was determined that the procedures, recruitment strategy and instrument questions were satisfactory. These data were not used in the study and were destroyed (Leon, Davis & Kraemer, 2011:627).

## 3.7 Data analysis

The programme specifically targeted primary caregivers of women who were suffering from breast cancer. It was expected that the intervention programme would improve the QOL of the target group (intervention group). QOL was measured with two instruments, namely the CQOLC and the ZBI. A relatively higher QOL and a lower ZBI correspond to improved QOL of the target group. The collected data also included some demographic information.

The analysis contains some quantitative and some visual exploration of the data sets and details of the inferential statistical analyses that were used to investigate the degree of the impact of the intervention programme, if any. A number of variables were examined across three time periods (Time 1- before commencement of the caregiver intervention programme, Time 2- after the caregiver intervention programme, and Time 3- 6 weeks after the last caregiver intervention session). All analyses were carried out using the Statistical Package for Social Sciences (SPSS) version 20.

### 3.7.1 Statistical methods

To attain the objectives of this study, different statistical methods were used, which are outlined below.

#### *3.7.1.1 Independent sample t test*

The independent t test also known as the Student t test or the independent sample t test is an inferential statistical procedure used in determining if there is a statistically significant difference between two unrelated groups (Kim, 2015:540). It was used to assess if there was a significant difference between the QOL and ZBI of the control and intervention groups. It assumes that the population is normally distributed with equal variances.

#### *3.7.1.2 Paired sample t test*

The paired t-test, also called to as the paired-samples t-test or dependent t-test, is used to determine whether the mean of an outcome variable is the same in two related groups, that is two groups of participants that are measured at two different time points or who underwent two different conditions. The paired t test was done to evaluate the impact of the intervention on the psychosocial burden and QOL of the intervention group as compared to the control group by using ZBI and CQOLC.

#### *3.7.1.3 Pearson’s and spearman’s correlation coefficients*

Correlation coefficients are used to measure the extent to which two different variables change together. It describes the strength and the direction of the relationship. The Pearson’s correlation coefficient examines the linear relationship between two continuous variables. In other words, when a change in one variable is associated with a proportional change in the other variable, then the relationship is said to be linear. The Spearman’s correlation, on the other hand, examines the monotonic relationship between two continuous or ranked (ordinal) variables. A relationship is said to be monotonic when the variables change together, but this change is not necessarily at a constant rate (Hauke & Kossowski, 2011:1). The two correlation coefficients were used to determine whether the ZBI affected the QOL.

#### *3.7.1.4 Multiple linear regressions*

Multiple linear regression is an extension of the normal linear regression. It is basically a linear regression but with two or more indicator variables. Multiple linear regressions have some assumptions which are important. The population mean of the outcome variable within strata defined by the predictor variables follows an additive linear pattern and is normally distributed. Also, the dependent observations are assumed to be statistically independent (Brandt & Williams, 2007:1-2). In our study, the multiple linear regressions were used to assess the effect of burden of caregiving on the QOL of caregivers using the domains of the ZBI and CQOLC.

## 3.8 Data collection procedures

Prior to implementation of the intervention programme the processes outlined below were completed.

### 3.8.1 Preparation for the intervention

Following ethics approval from Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (HREC REF: 243/2016) (Appendix E) and the Ethics Committee, National Hospital Abuja (NHA/EC/043/2016) (Appendix G), the researcher scheduled meetings with the people to be recruited as research assistants at the recruitment site (Oncology Unit, National Hospital, Abuja) to provide information on the study purpose and, inclusion and exclusion criteria, and to answer any questions they had regarding the study.

Six volunteers were recruited to work as research assistants. They are registered nurses who were trained by the researcher in the ethical conduct of research, and their roles in the study process. They were recruited from nurses working at the National Hospital who were not working on allocated shifts (i.e. in off- duty time) at the time of data collection so that patients' care would not be compromised. It should be noted that nurses working in the oncology team of the hospital were not used as research assistants to minimise bias.

The research assistants helped in recruiting the caregivers, administration of questionnaires, and training of the intervention group. They were blinded to allocation of participants to each arm of the study; the researcher performed this role. No compensation was given, except for costs incurred. It was, however, anticipated that the volunteers would gain from the experience of being involved in this research study.

### 3.8.2 Recruitment

Primary caregivers were recruited when they accompanied their relatives or persons with breast cancer for whom they were caring to out-patient consultations. The researcher and research assistants approached the health staff working in the Oncology Unit where women with breast cancer are being treated; information about the study was explained to the staff working in this Unit in order for them to serve as mediators between the researcher and the primary caregivers. Flyers (Appendix L) were posted in the clinic waiting areas and distributed by oncology nurses. Staff were requested to give the information sheet (Appendix A) to potential participants identified by the oncology team.

A total of 135 primary caregivers were approached within 2 weeks (from 1 to 12 August, 2016). Of these, 108 agreed to participate in the study and were referred to the research assistants, while 27 chose not to participate. Reasons for declining included:

- distance from the Oncology Clinic (n=11);
- dislike of the research study (n=3);

- lack of interest in participating (n=5); and
- lack of enough time to participate (n=8).

This information was obtained through phone calls and visits to the clinic. Those who showed interest in participating in the study were asked to provide their names and contact details to a staff member. The researcher then made an appointment to meet them at the National Hospital, Abuja on Saturday 13 August, 2016 (first contact). The purpose and process of the research were explained to them and they were asked to sign a written informed consent form (Appendix B). The researcher was responsible for getting informed consent from potential participants. This process took place in one of the halls of Oncology Unit. The choice of the venue was because the hospital is centrally located and easily accessible from any part of the city.

### 3.8.3 Allocation

At a meeting participants were quasi-randomised to each study arm. Each participant was allocated using sequential numbers (1-108). Those with even numbers were assigned to the intervention group (n=54), and those with odd numbers were assigned to the control group (n=54). None of the oncology staff or the participants knew which group each participant was assigned to (Hadgu, Nordb & Skjeldestad, 2012:503).

### 3.8.4 Baseline data collection

All participants were asked to complete the self-report questionnaires, which included the baseline demographic data of study participants, ZBI and the CQOLC, which they completed within 30 minutes at the first meeting. Research assistants were responsible for the collection of these data, which was carried out in an enclosed room in the Oncology Unit to ensure privacy. The data collected were stored in a locked cupboard to which only the researcher had access.

## 3.9 Adaptation of the training manual

The training manual (Appendix J) was adapted from the following sources after permission had been granted by the publishers (Appendix M).

- *"Supporting a Person Who Needs Palliative Care: A Guide for Family and Friends"* written by Peter Hudson (PhD) and Rosalie Hudson (PhD), well-known scholars in psycho-educational intervention studies for cancer patients and their family members. The book was a compendium of various intervention studies they have conducted over the years (Hudson et al., 2008; Hudson et al., 2013; Hudson et al., 2015; Hudson, Aranda & Hayman-White., 2005; Hudson et al., 2004; Hudson et al., 2010).

- Publications from the National Cancer Institute, United States Department of Health and Human Services, including: *"When Someone You Love is Being Treated for Cancer", "What you need to know about Breast Cancer", and "Support for People with Cancer Coping with Advanced Cancer".*

No translation was required as English is spoken and understood by the Nigerian population. The manual was piloted among the 10 participants involved in the pilot study at Asokoro District Hospital, Abuja, and the outcome was satisfactory. This manual was used after permission had been granted by the author (Appendix M).

## 3.10 Intervention phase

This section discusses the six-session training programme which was offered to the intervention group, which lasted for 6 weeks. The training was conducted in the hall of the Oncology Unit of the hospital and was coordinated by the research assistants. The themes were: (1) introduction and information about breast cancer, (2) helping the participants adjust to being a caregiver, (3) communication on preventing misunderstanding and promoting positive interaction, (4) the emotions experienced by members of the group, (5) information about the importance of self-care and how caregivers can practice self-care, and (6) tips on helping caregivers to give practical care, how to deal with common symptoms and the patient's emotions (Appendix J).

The weekly sessions (six in total) were offered on consecutive Saturdays, and each was 60-90 minutes in length. The training programme was carefully structured. Each session included a PowerPoint presentation which was complemented by written material. The objectives for each session are listed below, and the full programme appears in Appendix K.

### 3.10.1 Session one

The first session began with introduction of the researcher, research assistants and, the participants, the training expectations and objectives.

The objectives were:

- to understand their personal expectations of the training;
- to understand the topics of the training;
- to have knowledge of breast cancer; and
- to understand the various ways of managing breast cancer.

The session lasted for 85 minutes, with 54 participants in attendance.

### 3.10.2 Session two

Beginning with this session, all of the remaining sessions began with participants discussing what they learned in the previous session and sharing their experiences. The objectives were:

- to gain a deeper understanding of caregiving;
- to understand the basic concept and meaning of caregiving; and
- to help the participants adjust to being caregivers.

The session lasted for an hour, with 54 participants in attendance.

### 3.10.3 Session three

The session had the following objectives:

- to discuss the importance of good communication in cancer caregiving; and
- to identify basic communication skills.

The presentation lasted for 95 minutes (5-minutes beyond the normal duration), with 54 participants present.

### 3.10.4 Session four

The objectives of this session were:

- to help families improve their emotion-management strategies; and
- to know how to manage stress.

The session lasted for 80 minutes, with 49 participants in attendance.

### 3.10.5 Session five

The objectives of session five were:

- to know the importance of self-care; and
- how to practice self-care.

The session lasted for 90 minutes, with 50 participants in attendance,

### 3.10.6 Session Six

The objectives of the last session were:

- to have knowledge of practical care; and
- to know what to do when a patient presents certain symptoms and emotions.

Being the last day, the training lasted for 100 minutes, with 51 participants in attendance.

## 3.11 Post-intervention data collection

Post-intervention data collection comprised the data collected immediately after the training (6 weeks from baseline). The ZBI and CQOLC were administered to 51 participants in the intervention group on the last day of the training, while 52 participants in the control group came on the evening of same day to complete the same questionnaires.

## 3.12 Post-intervention phase (follow-up)

This comprised the data collected 6 weeks after completion of the intervention. It involved 50 participants in the intervention group and 52 participants in the control group. The participants in both groups completed the ZBI and CQOLC at follow-up. After the study had been completed the participants in the control group were also trained for 6 days; however, this information was not included in the study.

## 3.13 Control group

The participants in this group received the 'standard care', which includes the routine care received by the primary caregivers such as clinical counselling and information prior to the study. Participants in this group will be offered the intervention programme after completion of the study.

### 3.14 Ethical considerations

The researcher was guided by the principles for ethical research as stated in the Declaration of Helsinki (World Medical Association, 2013). Ethical approval was obtained from the Human Research Ethics Committee of the Faculty of Health Sciences (HREC REF: 243/2016), University of Cape Town, and Ethics Committee of the National Hospital Abuja (NHA/EC/043/2016).

#### 3.14.1 Autonomy/respect of persons

The participants were treated with respect in terms of their individual autonomy, dignity, freedom of choice and human rights. They were asked to give voluntary informed consent and informed of their right not to participate, and that should they wish to withdraw at any point, this would not affect their usual care in any way. They would be given a copy of research findings on request.

#### 3.14.2 Beneficence

The principle of beneficence refers to the obligation to act for the benefit of others (Bell, McDonald & Hobson, 2016). To uphold this principle, all study details were disclosed to potential participants to enable them to give informed consent for voluntary participation. At all times the researcher aimed to maximise benefits and reduce risk.

#### 3.14.3 Confidentiality and anonymity

The researcher respected the participants' right to confidentiality through the following measures: participant questionnaires were coded and their identity was known to the researcher only; their names will not be linked to any results which would be published at the completion of the study; all information on electronic devices was kept safely in the possession of the researcher; and no names were used at any stage of the study.

#### 3.14.4 Justice and fairness

The researcher ensured that all participants were treated equally and impartially, by ensuring that each had equal opportunity with regard to engagement in the programme. After the study was completed the researcher offered the control group the same six session intervention to ensure fairness and equity.

### 3.14.5 Risks and benefits of the study for participants

There was no foreseeable physical harm to the participants as this is a non-invasive study. As there might be some psychological distress evoked during the training sessions, such as emotional issues raised or recall of previous traumatic experiences participants may have in the course of caregiving, participants who reported such experiences were referred to a clinical psychologist for psychosocial support and counselling within the National Hospital. The intervention programme will hopefully enable the caregiver participants to cope with their responsibilities and care for themselves. No direct benefit in relation to other types of caregiving support (e.g. material support) was provided.

### 3.14.6 Non-maleficence

The researcher provided the necessary information about the study prior to recruiting participants was sensitive towards the participants and endeavoured to minimise any emotional risk as a result of participation in the study.

## 3.15 Data management and storage

All documents such as demographic data, consent forms, written notes, field notes and a summary of the analysed data were stored in a secure cupboard; only the researcher has access to it. Electronic data were entered into a password-protected Excel template.  Data collected were checked for missing values and outliers to ensure consistency. These data will be kept for a period of 5 years before it is destroyed by the researcher.

## 3.16 Conclusion

This chapter provided information regarding the methodology and design used to collect the data. The intervention, training, and instruments for collecting and analysing data were analysed. The ethical issues were also discussed.

# CHAPTER FOUR

# RESULTS

## 4 Introduction

This chapter discusses the results of this study and is organised in such a way that it aligns with the study design in the previous chapter. The results were achieved using socio-demographic information and two questionnaires (ZBI and CQOLC).

### 4.1 Socio-demographic characteristics of participants

A total of 108 participants were included in the study. Most of the participants were female (51.9%) with 36.1% being within the ages of 30-39 years. Of the participants 45.5% were married and 37% were graduates and 52% were not employed. Of all participants (including the unemployed and most of the employed), 83.3% reported that caregiving does not affect their primary work or employment (Table 4.1).

## Table 4.1: Socio-demographic distribution of respondents (n=108)

| Variable | | Frequency | % |
|---|---|---|---|
| **Gender** | | | |
| | *Male* | 52 | 48.1 |
| | *Female* | 56 | 51.9 |
| **Age (years)** | | | |
| | *18-29* | 29 | 26.9 |
| | *30-39* | 39 | 36.1 |
| | *40-49* | 24 | 22.2 |
| | *50 and above* | 16 | 14.8 |
| **Ethnicity** | | | |
| | *Yoruba* | 18 | 16.7 |
| | *Igbo* | 30 | 27.8 |
| | *Hausa* | 25 | 23.1 |
| | *Others* | 35 | 32.4 |
| **Religion** | | | |
| | *Christianity* | 66 | 61.1 |
| | *Islam* | 31 | 28.7 |
| | *Traditional worshipper* | 9 | 8.3 |
| | *Others* | 2 | 1.9 |
| **Marital status** | | | |
| | *Married* | 49 | 45.4 |
| | *Divorced* | 10 | 9.3 |
| | *Single* | 44 | 40.7 |
| | *Widowed* | 5 | 4.6 |
| **Level of education completed** | | | |
| | *Grade 6 (Primary)* | 14 | 13.0 |
| | *12 years of school (High school)* | 26 | 24.1 |
| | *Undergraduate* | 19 | 17.6 |
| | *Graduate* | 40 | 37.0 |
| | *Postgraduate* | 9 | 8.3 |
| **Employment status** | | | |
| | *Permanent* | 21 | 19.4 |
| | *Temporary* | 22 | 20.4 |
| | *Retired* | 9 | 8.3 |
| | *Not working* | 56 | 51.9 |
| **Relationship to patient** | | | |
| | *Parents* | 17 | 15.7 |
| | *Spouse* | 33 | 30.6 |
| | *Sibling* | 19 | 17.6 |
| | *Child* | 23 | 21.3 |
| | *Friend* | 16 | 14.8 |
| **Has caregiving affected your primary work/employment?** | | | |
| | *Yes* | 18 | 16.7 |
| | *No* | 90 | 83.3 |

## 4.2 Psychosocial burden associated with caregiving for women living with breast cancer using the ZBI tool

At baseline a larger proportion (51.9%) of the participants reported having moderate to severe burden while 48.1% reported having severe burden. After 6 weeks of administering the intervention programme, most of the participants (44.7%) reported having mild to moderate burden, 22.3% reported moderate to severe burden, 12.6% reported severe burden, and 20.4% reported having little or no burden. At 12 weeks 25.5% of the participants reported little or no burden, 51% reported mild to moderate burden, 18.6% reported moderate to severe burden, and 4.9% reported severe burden. Table 4.2 shows these results.

**Table 4.2: Determination of psychosocial burden associated with caregiving for women living with breast cancer using the ZBI tool (Baseline n=54, Week 6 n=51, Week 12 n=50)**

| Study time | Little or no burden (%) | Mild to moderate burden (%) | Moderate to severe burden (%) | Severe burden (%) |
|---|---|---|---|---|
| **Baseline** | - | - | 51.9 | 48.1 |
| **Week 6** | 20.4 | 44.7 | 22.3 | 12.6 |
| **Week 12** | 25.5 | 51.0 | 18.6 | 4.9 |

## In Figure 4.1

The QOL and ZBI means for different age groups at baseline are shown. Caregivers within the age group of 30-39 years had the highest QOL mean score (103.9), while caregivers within the age group of 18-29 years had the highest ZBI mean score (61.9).

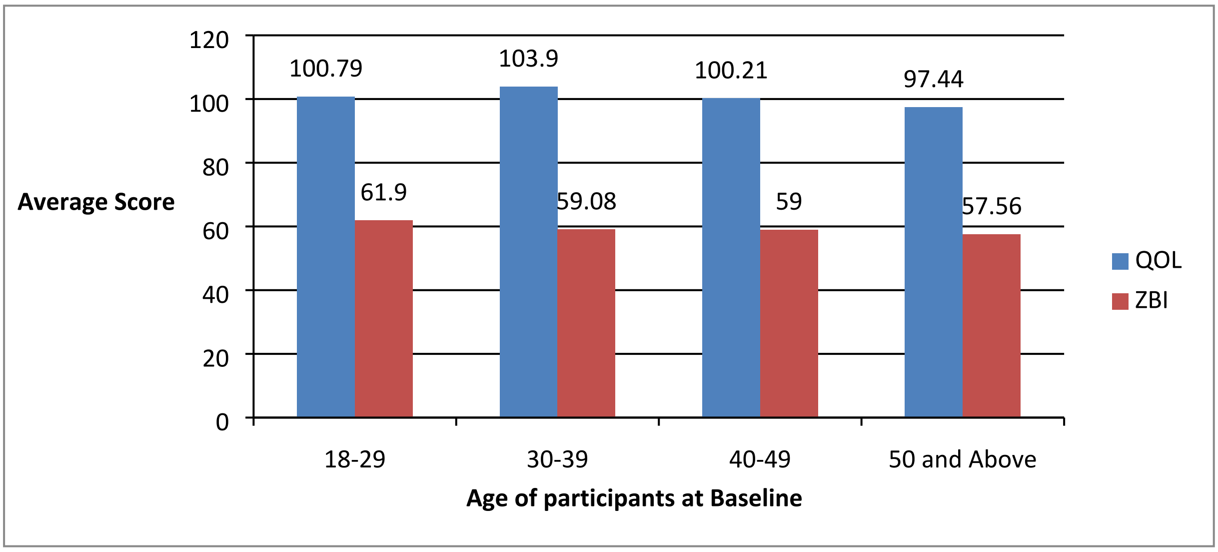


**Figure 4.1: QOL and ZBI of caregivers at baseline.**

## Figure 4.2

This figure presents the QOL and ZBI means in different age groups at week 6. Caregivers within the age group of 40-49 years had the highest QOL mean score (72.87), while those within the age group of 50 years and above had the highest ZBI mean score (41.8).

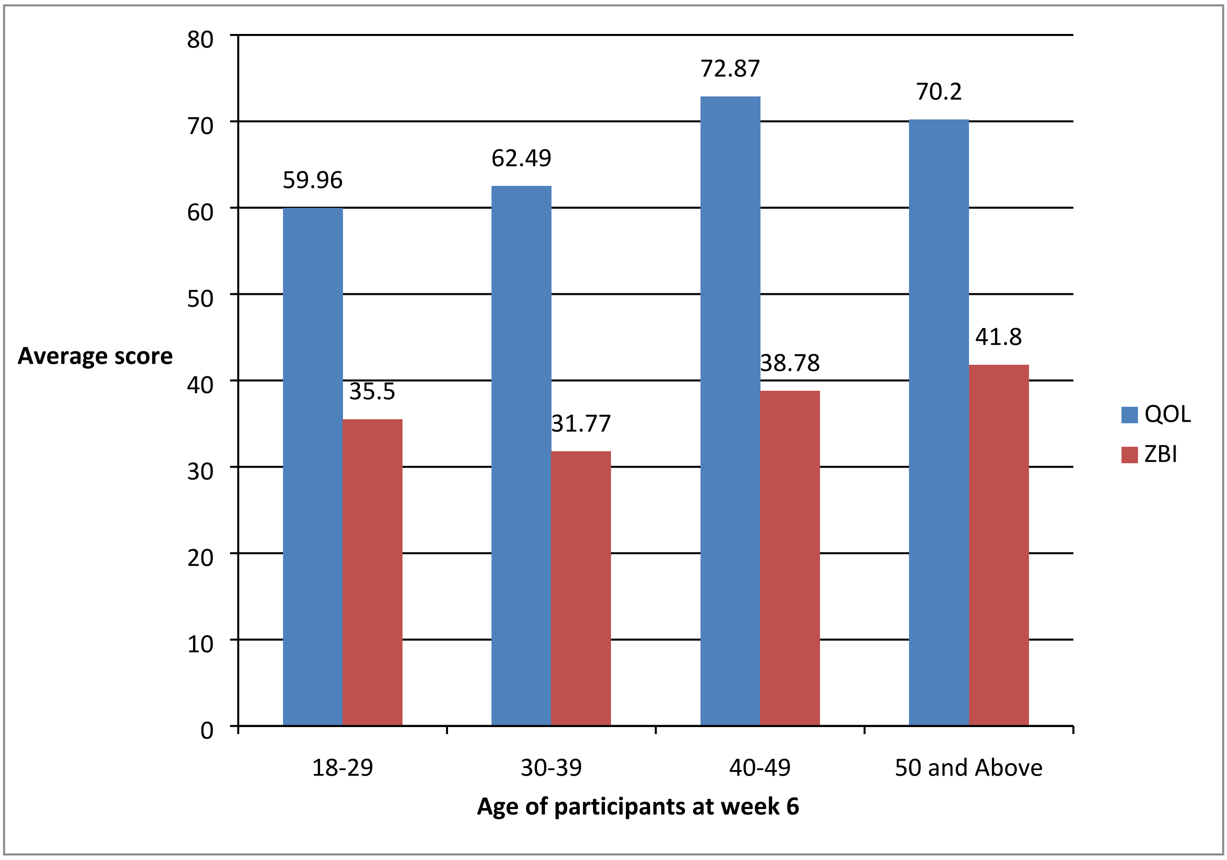


**Figure 4.2: QOL and ZBI of caregivers at week 6.**

### Figure 4.3

This figure presents the QOL and ZBI means in different age groups at week 12. Caregivers within the age group of 50 years and above had the highest QOL mean score (70.73), while those within the age group of 40-49 years had the highest ZBI mean score (34.09).

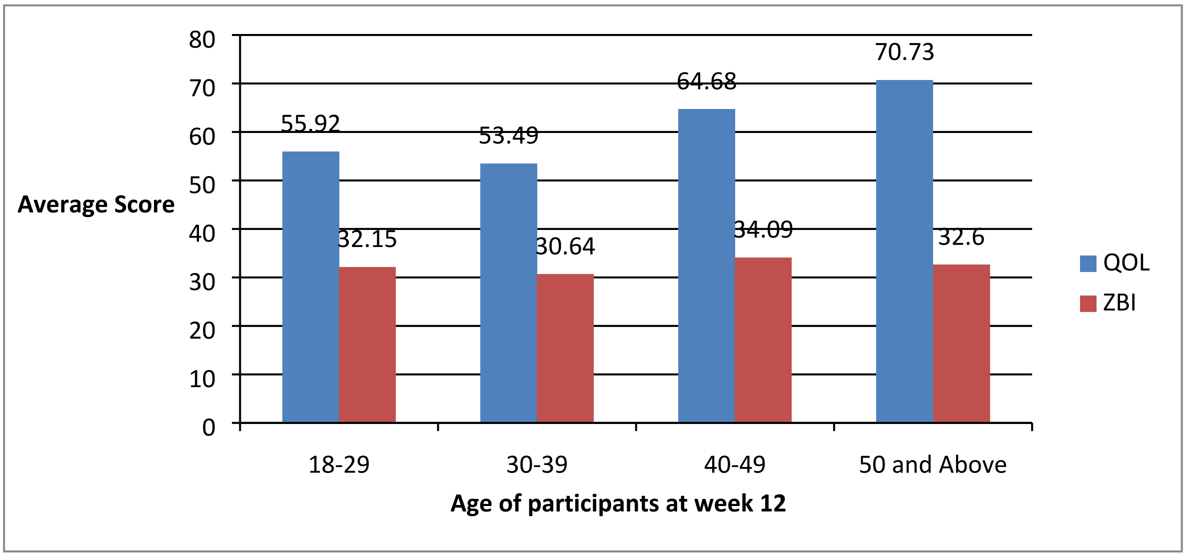


**Figure 4.3: QOL and ZBI of caregivers at week 12 by age group.**

## Figure 4.4

This figure presents the QOL and ZBI means according to categories of the caregiver's relationship with the patient at baseline. Caregivers who were the children of the patients had the highest QOL (108.35) and ZBI (62.17) mean scores.

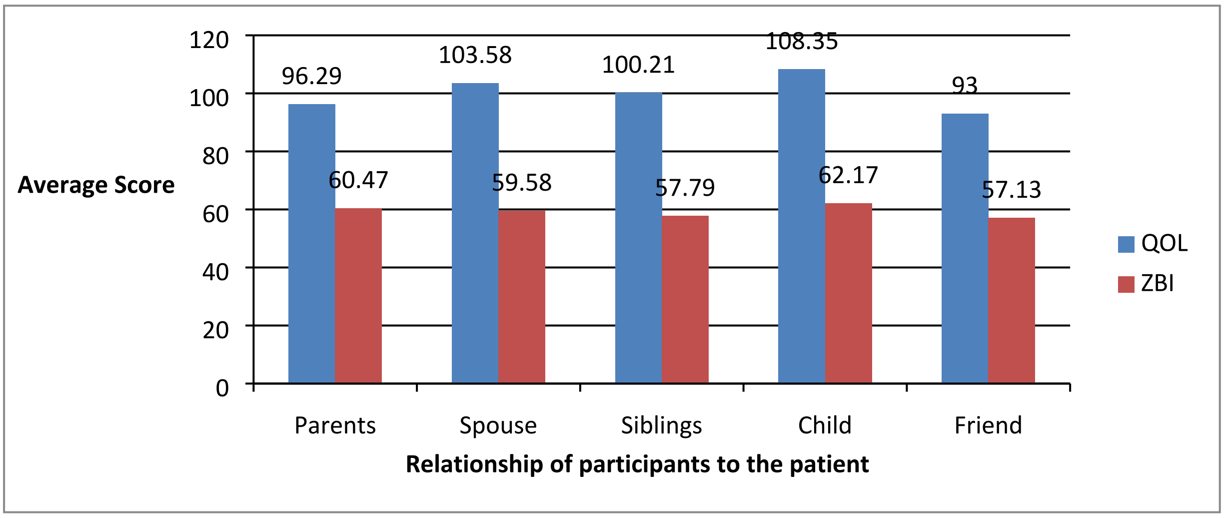


**Figure 4.4: QOL and ZBI of the caregivers at baseline according to relationship with the patient.**

### Figure 4.5

This figure presents the QOL and ZBI means according to the caregiver's relationship with the patient at week 6. Caregivers who were siblings of the patients had the highest QOL mean score (71.44), while those who were spouses of the patients had the highest ZBI mean score (62.87).

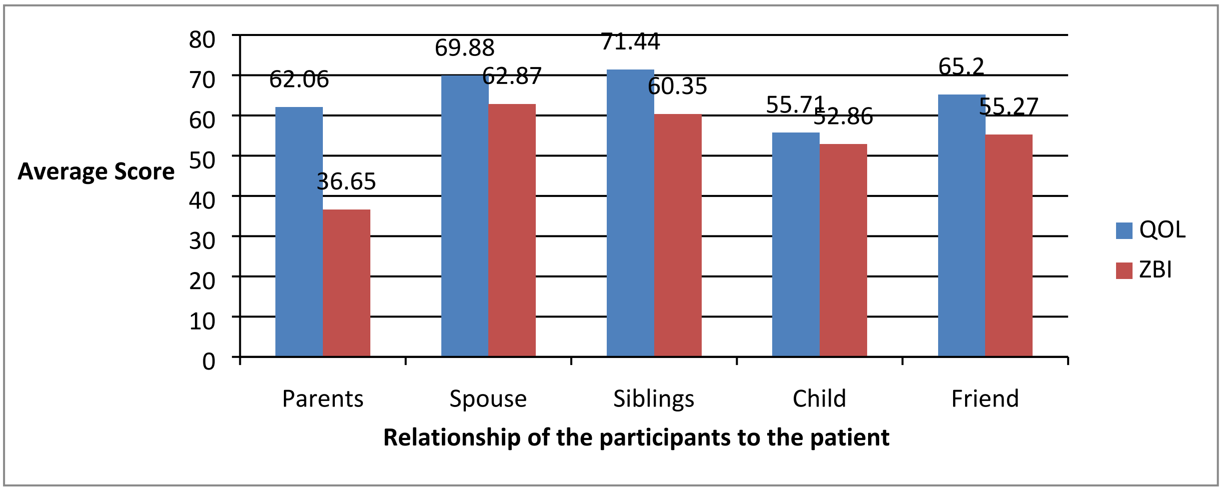


**Figure 4.5: QOL and ZBI of caregivers at week 6 according to relationship with patient.**

## Figure 4.6

This figure presents the QOL and ZBI means with categories of the caregiver's relationship with the patient at week 12. Caregivers who were the spouses of the patient had the highest QOL mean score (62.87), while those who were the parents of the patients had the highest ZBI mean score (35.59).

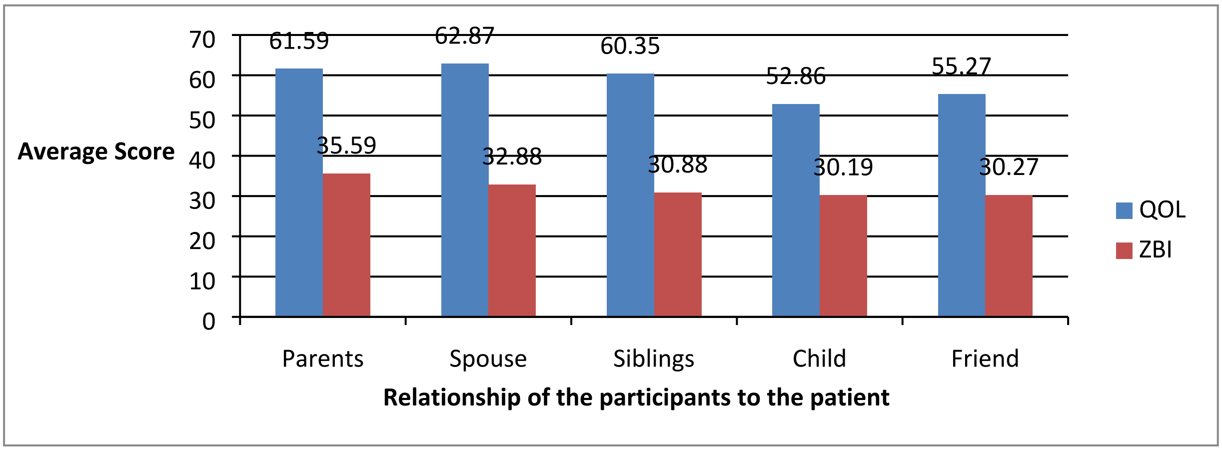


**Figure 4.6: QOL and ZBI of caregivers at week 12 according to relationship with patient.**

## 4.3 Comparison of QOL in the intervention and control groups

Table 4.3 shows the results of the independent t test. The results showed that at baseline the QOL for the control group (113.22±89.35) was significantly better than that for the intervention group (89.35±14.04) (t = 9.97, p <0.001). Furthermore, after week 6 the QOL for the intervention group (87.20±15.16) was significantly better than that for the control group (43.81±18.55) (t = -12.98, p<0.001), and in week 12 the QOL of the intervention group (83.90±20.40) was significantly better than in the control group (35.17±13.18) (t= -14.38, p<0.001). These results suggest that the intervention had an effect on the QOL of the participants.

**Table 4.3: Comparison of QOL of the intervention and control groups. Intervention group (Baseline n=54, Week 6 n=51, Week 12 n=50). Control group (Baseline n=54, Week 6 n=52, Week 12 n=52)**

| **Study time** | **Intervention group (M±SD)** | **Control group (M±SD)** | **T** | **P-value** |
|---|---|---|---|---|
| QOL baseline | 89.35±14.04 | 113.22±89.35 | 9.97 | <0.001 |
| QOL week 6 | 87.20±15.16 | 43.81±18.55 | -12.98 | <0.001 |
| QOL week 12 | 83.90±20.40 | 35.17±13.18 | -14.38 | <0.001 |

## 4.4 Comparison of the caregivers' burden in the intervention and control groups

Table 4.4 shows the results of the independent t test, which showed that at baseline the ZBI of the intervention group was significantly higher (65.11±6.37) than that in the control group (54.07±5.91) (t = -9.33, p <0.001). Furthermore, after week 6 the intervention group's ZBI was significantly lower (24.44±7.19) than that in the control group (47.25±14.45) (t =10.18, p<0.001). In week 12 the ZBI for the intervention group was significantly lower (22.40±6.45) compared to that in the control group (42.10±12.08) (t = 10.33, p<0.001). These results suggest that the intervention reduced the caregiver's burden.

**Table 4.4: Comparison of caregivers' burden in the intervention and control groups. Intervention group (Baseline n=54, Week 6 n=51, Week 12 n=50). Control group (Baseline n=54, Week 6 n=52, Week 12 n=52)**

| Study time | Intervention group (M±SD) | Control group (M±SD) | t | P-value |
|---|---|---|---|---|
| Caregivers' burden baseline | 65.11±6.37 | 54.07±5.91 | -9.33 | <0.001 |
| Caregiver' burden week 6 | 24.44±7.16 | 47.25±14.45 | 10.18 | <0.001 |
| Caregivers' burden week 12 | 22.40±6.45 | 42.10±12.08 | 10.33 | <0.001 |

## 4.5 Effect of intervention on QOL of the intervention group using CQOLC

Table 4.5 shows the results of the paired t test. A paired-samples t-test was applied to compare the QOL at baseline and 6 weeks after the intervention. There was no significant difference in the QOL scores at baseline (89.75±14.04) and 6 weeks after intervention (87.20±15.16) (t = 0.83, p = 0.41). Furthermore, there was also no significant difference in the QOL scores at baseline (89.70±14.17) and 12 weeks after the intervention (83.90±20.40) (t = 1.65 p= 0.11). The results suggest that the intervention does not have an effect on QOL.

**Table 4.5: Effect of intervention on QOL of intervention group using CQOLC (Baseline n=54, Week 6 n=51, Week 12 n=50)**

| Study time | M±SD | T | P-value |
|---|---|---|---|
| Baseline | 89.75±14.04 | 0.83 | 0.41 |
| Week 6 | 87.20± 15.16 | | |
| Baseline | 89.70±14.17 | 1.65 | 0.11 |
| Week 12 | 83.90±20.40 | | |

## 4.6 Effect of intervention on caregivers’ burden in intervention group using ZBI

Table 4.6 shows the result of the paired t test. A paired-samples t-test was conducted to compare ZBI at baseline and 6 weeks after the intervention. There was a significant difference in ZBI scores at baseline (64.88±6.38) and 6 weeks after intervention (24.44±7.19) (t = 30.34, p = <0.001). Furthermore, there was a significant difference in ZBI scores at baseline (64.88±6.38) and 12 weeks after the intervention (22.40±6.45) (t = 36.80 p<0.001). The results suggest that the intervention does have an effect on the ZBI.

**Table 4.6: Effect of intervention on caregivers’ burden in intervention group using ZBI (Baseline n=54, Week 6 n=51, Week 12 n=50)**

| Study time | M±SD | T | P-value |
|---|---|---|---|
| Baseline | 64.88±6.38 | 30.34 | <0.001 |
| Week 6 | 24.44± 7.19 | | |
| Baseline | 64.88±6.38 | 36.80 | <0.001 |
| Week 12 | 22.40±6.45 | | |

## 4.7 Effect of caregivers' burden on their QOL

In Table 4.7 the burden of caregivers, which was assessed by the ZBI, instrument was divided into three domains (Bianchi et al., 2016:5; Harding et al., 2004:403): role strain, personal strain and competencies and expectations. Also, the CQOLC instrument was divided into domains, which are burden, disruptiveness, positive adaptation, financial concerns and independent items (Duan et al., 2015:3; Son et al., 2012:218). The domains of the ZBI were tested on each of the domains of the CQOLC at baseline to assess if it had any significant effect on QOL. Results showed that for the burden QOL domain, only competencies and expectations had a significant effect on the QOL of caregivers (p=0.03). In addition, for the disruptiveness QOL domain, only personal strain had a significant effect on the QOL of caregivers (p=0.02). Furthermore, for the financial concerns domain only role strain had a significant effect on the QOL of caregivers (p=0.02). However, none of the ZBI domains had significant effects on the positive adaptation and independent items domains of the QOL. For the overall QOL, only the competencies and expectations domains had a significant effect on the QOL of the caregivers (p=0.02).

**Table 4.7: Effect of the caregivers' burden on their QOL**

| | **ZBI domains** | | | | | | |
|---|---|---|---|---|---|---|---|
| **QOL** | **Role strain** | | **Personal strain** | | **Competencies and expectations** | | **R$^2$** |
| | **$\beta$ (95%CI)** | **P** | **$\beta$ (95%CI)** | **P** | **$\beta$ (95%CI)** | **P** | |
| **Burden QOL** | 0.08(-0.19,0.38) | 0.52 | 0.10(-0.23, 0.49) | 0.47 | 0.29(0.08,1.14) | 0.03 | 0.17 |
| **Disruptiveness QOL** | 0.18(-0.05,0.41) | 0.12 | 0.33(0.06,0.63) | 0.02 | -0.03(-0.47,0.37) | 0.81 | 0.20 |
| **Positive adaptation QOL** | 0.11(-0.14,0.38) | 0.37 | 0.25(-0.06,0.60) | 0.10 | -0.05(-0.57,0.39) | 0.71 | 0.09 |
| **Financial concerns QOL** | 0.30(0.03,0.31) | 0.02 | 0.07(-0.13,0.22) | 0.61 | -0.01(-0.27,0.24) | 0.91 | 0.12 |
| **Independent items QOL** | 0.21(-0.02,0.45) | 0.07 | 0.11(-0.18,0.42) | 0.43 | 0.14(-0.20,0.68) | 0.28 | 0.16 |
| **Overall** | -0.11(-1.32,0.45) | 0.33 | -0.22(-2.04,0.19) | 0.10 | -0.29(-3.67, -0.40) | 0.02 | 0.29 |

## 4.8 Correlation between caregivers' burden and their QOL

Table 4.8 shows the relationship between the burden of caregivers and their QOL using the Pearson's and Spearman's correlation coefficients. The results showed that at baseline there was a significant relationship between the burden and QOL of caregivers for both Pearson's ($r = 0.45$, $p < 0.001$) and Spearman's ($r = 0.50$, $p < 0.001$) correlation.

**Table 4.8 Correlation coefficient of caregivers' QOL and their burden (ZBI) (n=54)**

| | **ZBI baseline** | **QOL baseline** |
|---|---|---|
| ZBI baseline | | |
| Pearson's | 1.00 | 0.45 |
| P | | <0.001 |
| Spearman's | 1.00 | 0.50 |
| P | | <0.001 |
| QOL baseline | | |
| Pearson's | 0.45 | 1.00 |
| P | <0.001 | |
| Spearman's | 0.50 | 1.00 |
| P | <0.001 | |

### 4.9 Summary of results

The results were achieved using socio-demographic information and two questionnaires (ZBI and CQOLC). Most of the participants were female, Christian and unemployed, and 83.3% reported that caregiving does not affect their primary work or employment.

At baseline 51.9% of the participants reported having moderate to severe burden while 48.1% reported having severe burden. Immediately after the intervention programme (6 weeks), 22.3% of the participants reported moderate to severe burden, 12.6% reported severe burden, 20.4% reported having little or no burden, and 44.7% reported having mild to moderate burden. At follow up (12 weeks) 18.6% of the participants reported moderate to severe burden, 4.9% reported severe burden, 25.5% reported little or no burden, and 51% reported mild to moderate burden.

Comparing the QOL of the intervention and control groups showed that at baseline the control group's QOL was significantly better than that of the intervention group. At week 6 the QOL of the intervention group was significantly better than that of the control group, and by week 12 the QOL of the intervention group was significantly better than that of the control group.

Evaluation of the effect of the intervention on the caregivers' burden in the intervention group showed a significant difference in ZBI scores at baseline and 6 weeks after intervention, as well as a significant difference in ZBI scores at baseline and 12 weeks after the intervention. However, the effect of the intervention on the QOL of the intervention group showed no significant difference between the QOL scores at baseline and 6 weeks, and there was also no significant difference in the QOL scores at baseline and 12 weeks. The results suggest that the intervention did not have an effect on the QOL of the participants.

# CHAPTER 5

# DISCUSSION, RECOMMENDATIONS, LIMITATIONS AND CONCLUSION

## 5.1 Introduction

This chapter provides the discussion, limitations and, conclusion to this study, as well as recommendations for further study. This study assessed the effect of a psychosocial programme (intervention) on the QOL and the burden of caregiving of primary caregivers of women with breast cancer. The CQOLC was used to assess the QOL of primary caregivers in the intervention and control groups while the ZBI was used to assess the caregiving burden in these groups. The study also aimed to determine whether there was a significant relationship between caregiving burden and the QOL of carers.

## 5.2 Demographic analysis

The study sample was distributed across demographic characteristics such as gender, age, ethnicity, religion, marital status, education and employment. The three major ethnic groups in Nigeria were adequately represented in the sample. The results show that participants' relationship with the patients ranged from friend to spouse, and more than half of the participants were full-time caregivers with no paid employment, which may explain the participants' responses to the question on the effect of caring on employment: over 80% reported no impact of caregiving on work or primary employment. Gender and, marital status were evenly distributed, but the participants' religion was skewed, with 61% being Christians and the remaining 39% from Islam, traditional and other religions. Of the participants 37% were post-secondary school graduates, which is typical for the population in Abuja, as the city attracts professionals from various parts of the country (Table 4.1).

### 5.2.1 Caregiver burden across the demographic characteristics

The results show that participants reported a high burden at baseline across all age groups, with the highest being among those between the ages of 18 and 29 years, followed by those aged 30 to 39 years.

Participants aged 50 years and above reported the least amount of burden (Figure 4.1). A reduction in the caregiving burden was reported across all age groups after six weeks of intervention (Figure 4.2). At six weeks after intervention, the burden dropped by almost half for participants within the 30-39 years age group (down from 59% to 31.8%). Participants aged between 18 and 29 years also reported a 42% decrease in caregiving burden. This reduction was sustained at 12 weeks after intervention (Figure 4.3).

The reported caregiving burden differed with respect to the relationship of the caregiver to the patient. At baseline, caregiving burden was highest for the caregivers of parents with breast cancer. Parent caregivers reported slightly less burden, and friends who were caregivers experienced the least amount of burden (Figure 4.4). This result was in concordance with that of Yusuf et al. (2011:904), who reported that the burden of caregiving was higher among sons of patients with cancer, because the burden and economic hardship fell heavily on them. Lowenstein and Gilbar (2000:342), however, reported that spouses of patients with cancer reported a significantly higher burden than the children. At 6 weeks after intervention reduction of burden was not reported equally: a significant reduction only occurred with the parents of the patient. At 12 weeks, a significant reduction was reported across all the categories of caregivers. This seems to indicate that the longer the intervention, the more the benefit that was experienced.

The high incidence of caregiving burden reported by patients' relatives at baseline in this study has been reported in other studies. It is clear that the caregiver’s burden has a direct effect on family members. Parents, children, siblings and, spouses are those directly involved in taking care of patients with breast cancer and therefore experience first-hand caregiving burden. The burden experience may be attributed to factors such as financial burden, personal care, medical care and the general management of the patient. Patients with breast cancer, particularly in the late stages, may require dietary management, lifestyle changes, and management of medication, among others. It is the task of the caregiver to perform these effectively to ameliorate the effect of the illness on the patient. Lu et al. (2010:506) also reported that patients' relations are most likely to experience high caregiver burden. The current study found that age, spousal status and co-residential status were positively related to caregiver burden, which was also reported by Kim, Baker and Spillers (2007:300).

Palliative care is more informal than formal, and this has implications for the caregivers. More attention needs to be devoted to the needs and support of caregivers in order to facilitate the caregiving tasks and minimise the caregiving burden.

### 5.2.2 Caregivers' QOL across the demographic characteristics

With respect to the caregivers' QOL across all age groups at baseline, the highest QOL score was reported among people between 30 and 39 years of age (Figure 4.1). The ratings for QOL after the intervention, at 6 and 12 weeks, showed a decline for all age groups. Of interest is that the QOL rating for caregivers with different relationships to the patients did not follow the same pattern as that for caregiver burden. Children of patients with breast cancer reported the highest QOL, followed by spouses, and the QOL rating for friends who were caregivers was the lowest (Figure 4.4). A reduction in the QOL score across all categories of caregivers was reported 6 and 12 weeks after intervention. Although the intervention seemed to alleviate the experience of burden, it did not have any effect on the caregivers' QOL scores (Figures 4.5 and 4.6).

## 5.3 Psychosocial burden associated with caregiving

The profiling of the burden of caregiving as reported by the participants indicated that at baseline, prior to the intervention programme, almost 52% of the participants reported moderate to severe burden while more than 48% reported severe burden. At 6 weeks and 12 weeks after intervention, the percentage of caregivers with moderate to severe burden dropped to 22.3% and 18.6% respectively while those with severe burden dropped to 12.6% and 4.9% respectively. The percentage of participants who reported little or no burden increased from 20.4% to more than 25% between 6 weeks and 12 weeks after intervention, and those who reported mild to moderate burden increased from 44.7% to 51% over the same period. The significant decrease in the number of people who reported moderate to severe burden and severe burden in the course of caregiving could be a result of the intervention (Table 4.2).

## 5.4 Comparison of QOL between intervention and control groups

The comparison of QOL scores between the intervention and control groups shows that there was a significant difference in these between the two groups at baseline, 6 weeks after intervention and 12 weeks after intervention.

At baseline the control group's score for QOL was significantly higher than that of the intervention group, whereas at 6 and 12 weeks after intervention the intervention group score was significantly higher than that of the control group (Table 4.3). However, the overall QOL scores show a decline from baseline to 12 weeks after intervention. This is in contrast with what would be expected after such an intervention (Table 4.5); the expected pattern should be an increase in reported QOL.

The t-test scores indicated that between baseline and 6 weeks after intervention there was no statistically significant difference in the QOL scores of the intervention group. This was also evident when comparing the QOL scores of the intervention group between baseline and 12 weeks after intervention, confirming that the intervention did not have a significant impact on the QOL of participants. It is difficult to explain this finding, which differs from similar studies which utilised intervention programmes such as COPE, CCP and FOCUS, which reported significant effects of a psycho-education intervention on the QOL of caregivers (Belgacem et al., 2013:873-874; Leow, Chan & Chan, 2015:68; Northouse et al., 2013:555). This results of the study, are similar to those of McMillan and Small (2007:313) (using the COPE intervention programme), who reported a significant decline in caregivers' QOL while patient QOL did not show any significant difference. Walsh et al. (2007:145) also reported no significant difference in the QOL of caregivers 12 weeks after administering the Carer Advisor Intervention, developed by the research team.

## 5.5 Comparison of caregivers' burden in the intervention and control groups

The comparison of caregiver burden scores in the intervention and control group showed that there was a significant difference between the groups at baseline, 6 weeks and 12 weeks after intervention (Table 4.4). At baseline the caregiver burden score of the intervention group was higher than that of the control group, whereas at 6 and 12 weeks after intervention the control group scores were higher than those of the intervention group. As expected, the general pattern in the score of caregiver burden showed a decline from baseline to 12 weeks after intervention, and this decline was significant – an almost 50% reduction, indicating an improvement in the reported caregiver burden after the intervention. The findings are in accordance with those of Bahrami and Farzi. (2014:2) and Belgacem et al. (2013:875); both studies reported that caregiver burden was significantly decreased in the intervention group after intervention compared to the control group.

Further examination of the impact of intervention on the caregiver burden of the intervention group revealed that there was a significant difference in the caregiver burden score between baseline and 6 weeks as well as between baseline and 12 weeks after intervention.

## 5.6 Effects of the psychosocial intervention on the caregivers' burden and caregivers' QOL

This study has demonstrated that a psychosocial intervention has an effect on caregiver burden, reducing reported caregiving burden (Table 4.6). This finding is in line with those of Bahrami and Farzi. (2014:2), who found that psycho-education decreased caregiver burden, and Hudson et al. (2005:336), who reported that a psycho-educational intervention improves caregiving experience such as competence and mastery. Northouse et al. (2005:485) reported that the Brief COPE intervention programme significantly reduced the negative appraisal of illness and hopelessness from baseline to 3 months, but this effect was not lasting.

It is evident from the literature that the impact and/or effects of psychosocial interventions on the QOL of caregivers and caregiver's burden are mixed. A possible reason for this is that such programmes do not necessarily take into account (or report on) factors such as culture and, personality and some social factors. These factors may not have been fully explored and incorporated into these intervention programmes. In the present study the performance of the intervention on caregivers' burden followed an *apriori* expectation of a reduction of caregiving burden among caregivers and improved caregiving experience to cope better with the job of providing help and care for care recipients. The intervention did not improve the caregivers' QOL, and the anticipated relationship between caregiving burden and QOL was inverted. The effect of the intervention on QOL was not significant.

This finding requires further examination. Caregiving burden comprises both subjective and objective aspects. Caregiver burden can be objectively perceived and measured; however, QOL is subjective in nature as it relates to a person's subjective perception of wellbeing and coping ability. Therefore, interventions that do not incorporate subjective aspects of psycho-education that work with caregiver emotions, feelings, perceptions and experiences are less likely to have a significant effect on the QOL of caregivers. Psycho-education interventions that focus more on objective caregiving, such as amount of time a caregiver spends on caregiving, tasks of caregiving, financial burden and management of medication regimens, are more likely to show a reduction in objective burden but may not show an effect on subjective QOL. This is because caregiver distress emanates not only from the practical demands of the caregiver role but also the emotional demands, such as seeing the patient suffer (Northouse, 2012:237). The fact that a caregiver is able to take care and manage the care recipient is not enough; the caregiver continues to see the patient go through pain and suffering, and knowledge that the patient will eventually die will affect a caregiver's psychological, social and physical health.

### 5.7 Correlation between caregivers' burden and their QOL

One of the objectives of the study was to establish whether there was a relationship between caregiver burden and the QOL of primary caregivers. To determine this, correlation analysis and linear regression were conducted (Table 4.8). The study found that a relationship exists between caregiver burden and the QOL of primary caregivers of patients with breast cancer. The relationship between caregiver burden and the QOL implies that a change in one would lead to a change in the other. It was also established that the relationship between caregiver burden and caregiver QOL was statistically significant. The regression analysis results indicate that the three domains of caregiver burden (role strain, personal strain and competencies and expectation) significantly and jointly predicted caregiver QOL (Table 4.7). From the findings, it could be seen that 29% of caregiver QOL could be explained by these three aspects of caregiver burden. However, only the competencies and expectation domain of caregiver burden made a significant contribution to the prediction of QOL accounting for the 29% variance (see Table 4.7). The negative sign of the prediction coefficient is useful, as this signifies that a unit increase in caregiver burden score will lead to a unit decrease in QOL, and vice versa.

Therefore, as caregiving burden increases, QOL decreases. This finding supports the findings of earlier studies in this area (Turkoglu & Kilic, 2012:4143; Wagner et al., 2006:109). For instance, Wagner et al. (2006:116) reported that caregiving burden accounted for more than 26% variance in QOL of husbands of patients with breast cancer, while Turkoglu and Kilic (2012:4144) found that caregiving burden explained 60% variance in QOL of cancer patients' caregivers and that a negative linear relationship exists between caregiver burden and QOL.

The current study also demonstrated that the different domains of caregiving burden were associated with different domains of QOL. For instance, the competencies and expectations domains of ZBI affect the burden domain of the CQOLC, and the personal strain aspect of the ZBI affects disruptiveness aspects of the CQOLC, while role strain burden affects financial concern and the independent aspect of the CQOLC (Table 4.7).

## 5.8 Recommendations

A number of recommendations emanate from the findings of this study:

- It is recommended that this type of intervention programme should target younger caregivers of between 18 and 39 years, who are primarily the children and siblings of patients. Close family members of the patients should be given more attention with interventions for reducing caregiver burden.
- In a country such as Nigeria, with few non-governmental organisations which serve the needs of breast cancer patients, there is a need for effective advocacy on the issue of caregiving burden. This will strengthen the social support of families and create more room for effective family networks and bonding. This would contribute to strengthening of the traditional collective culture in Nigeria.
- The need for effective advocacy on the issue of caregiver's burden is vital, as there has been an increase in the incidence of all forms of cancer in Nigeria. Relevant stakeholders in the healthcare sector, especially in palliative care, should conduct advocacy campaigns to promote the culture of caring and support for the person with cancer and the caregiver. This will enable families of cancer patients to know that even though cancer is a life-threatening and, for many in Nigeria, a terminal illness, it is possible for care recipients and caregivers to enjoy a meaningful life within the period that the illness allows through effective palliative care.

- As the intervention did not impact on the QOL of caregivers, there is a need to reconsider the nature of psycho-education interventions that are aimed at improving QOL of caregivers. Such interventions need to address the emotional aspects of caregiving in more detail.
- Further studies, including an RCT, should be done to assess the effect of psychosocial interventions. Further research in Nigeria should investigate the incorporation into psycho-education programmes of cultural aspects of care for patients with breast cancer, taking into account local conditions, beliefs and rituals.

## 5.9 Limitations

This study has several limitations that should be considered. Firstly, there could be some degree of bias because the study design used a non-randomised control trial. Secondly, the study involved primary caregivers of women with the most common type of cancer in Nigeria (breast cancer); therefore, the interventions cannot be said to have effects on primary caregiver's QOL in relation to other forms of cancer. Thirdly, the psychosocial intervention dwelled more on objective caregiving, with the results more likely to show a reduction in objective burden and no effect on subjective burden. Fourthly, a larger sample size would have provided a better result in identifying the effect of the intervention programme on the intervention group. Furthermore, this study was conducted in just one area of Nigeria, so cultural variations in different areas might have an influence on caring for a patient with breast cancer and thus on the QOL of the primary caregiver. The study also, involved an urban, relatively well-educated group of caregivers, and for that reason, generalisation of the results is not possible. It should be noted, however, that one cannot exclude the effects of variables not known to the researcher which may have affected the participants' wellbeing.

## 5.10 Conclusion

This study has been able to show that caregiver burden and caregiver QOL are related, and caregiver burden is associated with caregiver QOL for caregivers of patients with breast cancer. The caregiver burden in the study participants ranged from moderate to severe. Against this background, a psychosocial intervention given to the intervention group was only effective in relation to caregiver burden, but was not effective regarding the QOL of caregivers. However, in testing the hypothesis, the QOL for the intervention group after intervention (week 6 and 12) was significantly better than that for the control group, and the caregiver’s burden of the intervention group was significantly lower than that in the control group after intervention (week 6 and 12). These results suggest that the intervention had an effect on the QOL and reduced the caregiver’s burden of the participants. Therefore, the hypothesis is accepted.

# REFERENCES

Adams, E., Boulton, M. & Watson, E. 2009. The information needs of partners and family members of cancer patients: a systematic literature review. *Patient Education and Counseling.* 77(2):179-186. DOI:10.1016/j.pec.2009.03.027.

Adebamowo, C.A. & Adekunle, O.O. 1999. Case-controlled study of the epidemiological risk factors for breast cancer in Nigeria. *British Journal of Surgery.* 86(5):665-668.

Akarolo-Anthony, S., Ogundiran, T.O. & Adebamowo, C.A. 2010. Emerging breast cancer epidemic: evidence from Africa. *Breast Cancer Research:* 12 Suppl 4:S8. DOI:10.1186/bcr2737.

Akobeng, A.K. 2005. Understanding randomised controlled trials. *Archives of Disease in Childhood.* 90(8):840-844.

Alptekin, S., Gnll, G., Ycel, I. & Yaris, F. 2010. Characteristics and quality of life analysis of caregivers of cancer patients. *Medical Oncology.* 27(3):607-617. DOI:10.1007/s12032-009-9256-2.

Altman, D.G. & Bland, J.M. 1999. Statistics notes. Treatment allocation in controlled trials: why randomise? *British Medical Journal (Clinical Research Ed.).* 318(7192):1209.

Amir, Z., Wilson, K., Hennings, J. & Young, A. 2012. The meaning of cancer: implications for family finances and consequent impact on lifestyle, activities, roles and relationships. *Psycho-Oncology.* 21(11):1167-1174. DOI:10.1002/pon.2021.

Anarado, A.N., Ezeome, E.R., Ofi, O.B., Nwaneri, A.C. & Ogbolu, Y. 2017. Experiences and desired nursing assistance of women on out-patient breast cancer chemotherapy in Southeastern Nigeria. *Psycho-Oncology.* 26(3):385-391. DOI:10.1002/pon.4034.

Aoun, S.M., Kristjanson, L.J., Currow, D.C. & Hudson, P.L. 2005. Caregiving for the terminally ill: at what cost? *Palliative Medicine.* 19(7):551-555.

Applebaum, A.J. & Breitbart, W. 2013. Care for the cancer caregiver: a systematic review. *Palliative & Supportive Care.* 11(3):231-252. DOI:10.1017/S1478951512000594.

Applebaum, A.J., Kulikowski, J.R. & Breitbart, W. 2015. Meaning-Centered Psychotherapy for Cancer Caregivers (MCP-C): Rationale and Overview. *Palliative & Supportive Care.* 13(6):1631-1641. DOI:10.1017/S1478951515000450.

Aranda, S.K. & Hayman-White, K. 2001. Home caregivers of the person with advanced cancer: an Australian perspective. *Cancer Nursing.* 24(4):300-307.

Bachner, Y.G. & O'Rourke, N. 2007. Reliability generalization of responses by care providers to the Zarit Burden Interview. *Aging & Mental Health.* 11(6):678-685.

Badger, T.A., Braden, C.J., Mishel, M.H. & Longman, A. 2004. Depression burden, psychological adjustment, and quality of life in women with breast cancer: patterns over time. *Research in Nursing & Health.* 27(1):19-28.

Bae, M.S., Seo, M., Kim, K.G., Park, I. & Moon, W.K. 2015. Quantitative MRI morphology of invasive breast cancer: correlation with immunohistochemical biomarkers and subtypes. *Acta Radiologica (Stockholm, Sweden: 1987).* 56(3):269-275. DOI:10.1177/0284185114524197.

Bahrami, M. & Farzi, S. 2014. The effect of a supportive educational program based on COPE model on caring burden and quality of life in family caregivers of women with breast cancer. *Iranian Journal of Nursing and Midwifery Research.* 19(2):119-126.

Barg, F.K., Pasacreta, J.V., Nuamah, I.F., Robinson, K.D., Angeletti, K., Yasko, J.M. & McCorkle, R. 1998. A description of a psychoeducational intervention for family caregivers of cancer patients. *Journal of Family Nursing.* 4(4):394-413.

Bayani, A.A. 2010. Reliability and preliminary evidence of validity of a Farsi version of the depression anxiety stress scales. *Perceptual and Motor Skills.* 111(1):107-114.

Bektas, H.A. & Ozer, Z.C. 2009. Reliability and validity of the caregiver quality of life index-cancer (CQOLC) scale in Turkish cancer caregivers. *Journal of Clinical Nursing.* 18(21):3003-3012. DOI:10.1111/j.1365-2702.2009.02915.x.

Belgacem, B., Auclair, C., Fedor, M., Brugnon, D., Blanquet, M., Tournilhac, O. & Gerbaud, L. 2013. A caregiver educational program improves quality of life and burden for cancer patients and their caregivers: a randomised clinical trial. *European Journal of Oncology Nursing:* 17(6):870-876. DOI:10.1016/j.ejon.2013.04.006.

Bell, A., McDonald, F. & Hobson, T. 2016. The Ethical Imperative to Move to a Seven-Day Care Model. *Journal of Bioethical Inquiry.* 13(2):251-260. DOI:10.1007/s11673-016-9708-2.

Bevans, M. & Sternberg, E.M. 2012. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. *Journal of the American Medical Association.* 307(4):398-403. DOI:10.1001/jama.2012.29.

Bianchi, M., Flesch, L.D., Alves, Erika Valeska da Costa, Batistoni, S.S.T. & Neri, A.L. 2016. Zarit Burden Interview Psychometric Indicators Applied in Older People Caregivers of Other Elderly. *Revista Latino-Americana De Enfermagem.* 24:e2835. DOI:10.1590/1518-8345.1379.2835.

Blagden, S.P., Charman, S.C., Sharples, L.D., Magee, L.R.A. & Gilligan, D. 2003. Performance status score: do patients and their oncologists agree? *British Journal of Cancer.* 89(6):1022-1027.

Boesen, E.H., Boesen, S.H., Frederiksen, K., Ross, L., Dahlstrm, K., Schmidt, G., Naested, J., Krag, C. et al. 2007. Survival after a psychoeducational intervention for patients with cutaneous malignant melanoma: a replication study. *Journal of Clinical Oncology:* 25(36):5698-5703.

Bonnaud-Antignac, A., Hardouin, J., Leger, J., Dravet, F. & Sebille, V. 2012. Quality of life and coping of women treated for breast cancer and their caregiver. What are the interactions? *Journal of Clinical Psychology in Medical Settings.* 19(3):320-328. DOI:10.1007/s10880-012-9300-9.

Bouvard, M., Charles, S., Gurin, J., Aimard, G. & Cottraux, J. 1992. [Study of Beck's hopelessness scale. Validation and factor analysis]. *L'Encephale.* 18(3):237-240.

Brandt, P. & Williams, J.T. 2007. Multiple time series models. Thousand Oaks, CA, US: Sage Publications, Inc.

Brouwer, W.B.F., Van Exel, N.J.,A., Van, d.B., Dinant, H.J., Koopmanschap, M.A. & Van den Bos, G.,A.M. 2004. Burden of caregiving: evidence of objective burden, subjective burden, and quality of life impacts on informal caregivers of patients with rheumatoid arthritis. *Arthritis and Rheumatism.* 51(4):570-577.

Budin, W.C., Hoskins, C.N., Haber, J., Sherman, D.W., Maislin, G., Cater, J.R., Cartwright-Alcarese, F., Kowalski, M.O. et al. 2008. Breast cancer: education, counseling, and adjustment among patients and partners: a randomized clinical trial. *Nursing Research.* 57(3):199-213. DOI:10.1097/01.NNR.0000319496.67369.37.

Bultz, B.D., Speca, M., Brasher, P.M., Geggie, P.H. & Page, S.A. 2000. A randomized controlled trial of a brief psychoeducational support group for partners of early stage breast cancer patients. *Psycho-Oncology.* 9(4):303-313.

Bužgová, R. & Kozáková, R. 2016. Psychometric evaluation of a Czech version of the Family Inventory of Needs. *Palliative and Supportive Care.* 14(02):142-150.

Cameron, J.I., Shin, J.L., Williams, D. & Stewart, D.E. 2004. A brief problem-solving intervention for family caregivers to individuals with advanced cancer. *Journal of Psychosomatic Research.* 57(2):137-143.

Campos, Juliana Alvares Duarte Bonini, Spexoto, M.C.B., Serrano, S.V. & Maroco, J. 2016. Psychometric characteristics of the Functional Assessment of Cancer Therapy-General when applied to Brazilian cancer patients: a cross-cultural adaptation and validation. *Health and Quality of Life Outcomes.* 14:8-8. DOI:10.1186/s12955-015-0400-8.

Caress, A., Chalmers, K. & Luker, K. 2009. A narrative review of interventions to support family carers who provide physical care to family members with cancer. *International Journal of Nursing Studies.* 46(11):1516-1527. DOI:10.1016/j.ijnurstu.2009.03.008.

Carretero, S., Garcs, J., Rdenas, F. & Sanjos, V. 2009. The informal caregiver's burden of dependent people: theory and empirical review. *Archives of Gerontology & Geriatrics.* 49(1):74-79. DOI:10.1016/j.archger.2008.05.004.

Carter, P.A. 2006. A brief behavioral sleep intervention for family caregivers of persons with cancer. *Cancer Nursing.* 29(2):95-103.

Chen, M., Chu, L. & Chen, H. 2004. Impact of cancer patients' quality of life on that of spouse caregivers. *Supportive Care in Cancer.* 12(7):469-475.

Chen, Y., Hsiung, P., Chung, L., Chen, S. & Pan, A. 2013. Psychometric properties of the Mastery Scale-Chinese version: Applying classical test theory and Rasch analysis. *Scandinavian Journal of Occupational Therapy.* 20(6):404-411. DOI:10.3109/11038128.2013.838999.

Chih, M., Dubenske, L.L., Hawkins, R.P., Brown, R.L., Dinauer, S.K., Cleary, J.F. & Gustafson, D.H. 2013. Communicating advanced cancer patients symptoms via the Internet: A pooled analysis of two randomized trials examining caregiver preparedness, physical burden, and negative mood. *Palliative Medicine.* 27(6):533-543. DOI:10.1177/0269216312457213.

Chiquelho, R., Neves, S., Mendes, Relvas, A.P. & Sousa, L. 2011. proFamilies: a psycho-educational multi-family group intervention for cancer patients and their families. *European Journal of Cancer Care.* 20(3):337-344. DOI:10.1111/j.1365-2354.2009.01154.x.

Collins, E.S., Witt, J., Bausewein, C., Daveson, B.A., Higginson, I.J. & Murtagh, F.E.M. 2015. A Systematic Review of the Use of the Palliative Care Outcome Scale and the Support Team Assessment Schedule in Palliative Care. *Journal of Pain and Symptom Management.* 50(6):53.e19. DOI:10.1016/j.jpainsymman.2015.07.015.

Conde-Sala, J., Garre-Olmo, J., Turr-Garriga, O., Vilalta-Franch, J. & Lpez-Pousa, S. 2010. Differential features of burden between spouse and adult-child caregivers of patients with Alzheimer's disease: an exploratory comparative design. *International Journal of Nursing Studies.* 47(10):1262-1273. DOI:10.1016/j.ijnurstu.2010.03.001.

Cooper, C., Katona, C. & Livingston, G. 2008. Validity and reliability of the brief COPE in carers of people with dementia: the LASER-AD Study. *Journal of Nervous and Mental Disease.* 196(11):838-843. DOI:10.1097/NMD.0b013e31818b504c.

Cui, J., Song, L.J., Zhou, L.J., Meng, H. & Zhao, J.J. 2014. Needs of family caregivers of advanced cancer patients: a survey in Shanghai of China. *European Journal of Cancer Care.* 23(4):562-569. DOI:10.1111/ecc.12174.

Cunningham, A.J., Edmonds, C.V. & Williams, D. 1999. Delivering a very brief psychoeducational program to cancer patients and family members in a large group format. *Psycho-Oncology.* 8(2):177-182.

De Almeida Vieira Monteiro, Ana,Paula Teixeira 2011. Assessment of the factor structure and reliability of the Portuguese version of the General Health Questionnaire-28 among adults. *Journal of Mental Health.* 20(1):15-20. DOI:10.3109/09638237.2010.492414.

Deeken, J.F., Taylor, K.L., Mangan, P., Yabroff, K.R. & Ingham, J.M. 2003. Care for the caregivers: a review of self-report instruments developed to measure the burden, needs, and quality of life of informal caregivers. *Journal of Pain and Symptom Management.* 26(4):922-953.

Din, S.H.S., Jaafar, N.R.N., Zakaria, H., Saini, S.M., Ahmad, S.N.A. & Midin, M. 2017. Anxiety disorders in family caregivers of breast cancer patients receiving oncologic treatment in Malaysia. *Asian Pacific Journal of Cancer Prevention.* 18(2):465-471.

Dionne-Odom, J., Hull, J.G., Martin, M.Y., Lyons, K.D., Prescott, A.T., Tosteson, T., Li, Z., Akyar, I. et al. 2016. Associations between advanced cancer patients' survival and family caregiver presence and burden. *Cancer Medicine.* 5(5):853-862. DOI:10.1002/cam4.653.

Dolbeault, S., Cayrou, S., Brdart, A., Viala, A.L., Desclaux, B., Saltel, P., Gauvain-Piquard, A., Hardy, P. et al. 2009. The effectiveness of a psycho-educational group after early-stage breast cancer treatment: results of a randomized French study. *Psycho-Oncology.* 18(6):647-656. DOI:10.1002/pon.1440.

Duan, J., Fu, J., Gao, H., Chen, C., Fu, J., Shi, X. & Liu, X. 2015. Factor analysis of the Caregiver Quality of Life Index-Cancer (CQOLC) scale for Chinese cancer caregivers: a preliminary reliability and validity study of the CQOLC-Chinese version. *Plos One.* 10(2):e0116438. DOI:10.1371/journal.pone.0116438.

Dumville, J.C., Torgerson, D.J. & Hewitt, C.E. 2006. Reporting attrition in randomised controlled trials*: British Medical Journal (International Edition).* 332(7547):969-971. DOI:10.1136/bmj.332.7547.969.

Edwards, B. & Ung, L. 2002. Quality of life instruments for caregivers of patients with cancer: a review of their psychometric properties. *Cancer Nursing.* 25(5):342-349.

Effendy, C., Vernooij-Dassen, M., Setiyarini, S., Kristanti, M.S., Tejawinata, S., Vissers, K. & Engels, Y. 2015. Family caregivers' involvement in caring for a hospitalized patient with cancer and their quality of life in a country with strong family bonds. *Psycho-Oncology.* 24(5):585-591. DOI:10.1002/pon.3701.

Eisdorfer, C., Czaja, S.J., Loewenstein, D.A., Rubert, M.P., Argelles, S., Mitrani, V.B. & Szapocznik, J. 2003. The effect of a family therapy and technology-based intervention on caregiver depression. *The Gerontologist.* 43(4):521-531.

Etters, L., Goodall, D. & Harrison, B.E. 2008. Caregiver burden among dementia patient caregivers: a review of the literature. *Journal of the American Academy of Nurse Practitioners.* 20(8):423-428. DOI:10.1111/j.1745-7599.2008.00342.x.

Fann, J.R., Thomas-Rich, A., Katon, W.J., Cowley, D., Pepping, M., McGregor, B.A. & Gralow, J. 2008. Major depression after breast cancer: a review of epidemiology and treatment. *General Hospital Psychiatry.* 30(2):112-126. DOI:10.1016/j.genhosppsych.2007.10.008.

Ferlay, J., Soerjomataram, I., Dikshit, R., Eser, S., Mathers, C., Rebelo, M., Parkin, D.M., Forman, D. et al. 2015. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. *International Journal of Cancer.* 136(5):E386. DOI:10.1002/ijc.29210.

Fong, T.C.T. & Ho, R.T.H. 2015. Re-examining the factor structure and psychometric properties of the Mini-Mental Adjustment to Cancer Scale in a sample of 364 Chinese cancer patients. *Supportive Care in Cancer: Official Journal of the Multinational Association of Supportive Care in Cancer.* 23(2):353-358. DOI:10.1007/s00520-014-2367-0.

Frambes, D., Given, B., Lehto, R., Sikorskii, A. & Wyatt, G. 2017. Informal Caregivers of Cancer Patients: Review of Interventions, Care Activities, and Outcomes. *Western Journal of Nursing Research.* : DOI:10.1177/0193945917699364.

Gau, B., Chen, Y., Lo, L., Chang, M., Chao, Y.Y., Chiang, B. & Yao, G. 2010. Clinical applicability of the World Health Organization Quality of Life Scale Brief Version (WHOQOL-BREF) to mothers of children with asthma in Taiwan. *Journal of Clinical Nursing.* 19(5-6):811-819. DOI:10.1111/j.1365-2702.2009.02934.x.

Gaugler, J.E., Eppinger, A., King, J., Sandberg, T. & Regine, W.F. 2013. Coping and its effects on cancer caregiving. *Supportive Care in Cancer:* 21(2):385-395. DOI:10.1007/s00520-012-1525-5.

George, L.K. & Gwyther, L.P. 1985. Family caregivers of Alzheimer patients: Correlates of burden and the impact of self-help groups. *Unpublished Manuscript, Duke University, Center for the Study of Aging and Human Development, Durham, NC.*

Girgis, A., Lambert, S.D., McElduff, P., Bonevski, B., Lecathelinais, C., Boyes, A. & Stacey, F. 2013. Some things change, some things stay the same: a longitudinal analysis of cancer caregivers' unmet supportive care needs. *Psycho-Oncology.* 22(7):1557-1564. DOI:10.1002/pon.3166.

Girgis, A., Lambert, S. & Lecathelinais, C. 2011. The supportive care needs survey for partners and caregivers of cancer survivors: development and psychometric evaluation. *Psycho-Oncology.* 20(4):387-393. DOI:10.1002/pon.1740.

Govina, O., Kotronoulas, G., Mystakidou, K., Katsaragakis, S., Vlachou, E. & Patiraki, E. 2015. Effects of patient and personal demographic, clinical and psychosocial characteristics on the burden of family members caring for patients with advanced cancer in Greece. *European Journal of Oncology Nursing.* 19(1):81-88. DOI:10.1016/j.ejon.2014.06.009.

Grunfeld, E., Coyle, D., Whelan, T., Clinch, J., Reyno, L., Earle, C.C., Willan, A., Viola, R. et al. 2004. Family caregiver burden: results of a longitudinal study of breast cancer patients and their principal caregivers*: Canadian Medical Association Journal/Journal De L'Association Medicale Canadienne.* 170(12):1795-1801.

Gustafsson, S., Svenstedt, S. & Vikman, I. 2013. Psychometric evaluation of a Swedish Self-Efficacy scale and Recovery Locus of Control scale in the context of minor illness. *Scandinavian Journal of Caring Sciences.* 27(3):765-772. DOI:10.1111/j.1471-6712.2012.01084.x.

Hadgu, A., Nordb, S.A. & Skjeldestad, F.E. 2012. One in 16 Quadrillion: Importance of Blinding in Research Reproducibility. *Epidemiology.* 23(3):503-504.

Hagedoorn, M., Sanderman, R., Bolks, H.N., Tuinstra, J. & Coyne, J.C. 2008. Distress in couples coping with cancer: a meta-analysis and critical review of role and gender effects. *Psychological Bulletin.* 134(1):1-30. DOI:10.1037/0033-2909.134.1.1.

Harding, R., Higginson, I.J., Leam, C., Donaldson, N., Pearce, A., George, R., Robinson, V. & Taylor, L. 2004. Evaluation of a short-term group intervention for informal carers of patients attending a home palliative care service. *Journal of Pain and Symptom Management.* 27(5):396-408.

Harding, R., List, S., Epiphaniou, E. & Jones, H. 2012. How can informal caregivers in cancer and palliative care be supported? An updated systematic literature review of interventions and their effectiveness. *Palliative Medicine.* 26(1):7-22. DOI:10.1177/0269216311409613.

Hauke, J. & Kossowski, T. 2011. Comparison of values of Pearson’s and Spearman’s correlation coefficient on the same sets of data. Quaestiones Geographicae. 30(2)

Haun, M.W., Sklenarova, H., Brechtel, A., Herzog, W. & Hartmann, M. 2014. Distress in cancer patients and their caregivers and association with the caregivers' perception of dyadic communication. *Oncology Research and Treatment.* 37(7-8):384-388. DOI:10.1159/000364885.

Helseth, S. & Misvaer, N. 2010. Adolescents' perceptions of quality of life: what it is and what matters. *Journal of Clinical Nursing.* 19(9-10):1454-1461. DOI:10.1111/j.1365-2702.2009.03069.x.

Henriksson, A., Andershed, B., Benzein, E. & Arestedt, K. 2012. Adaptation and psychometric evaluation of the Preparedness for Caregiving Scale, Caregiver Competence Scale and Rewards of Caregiving Scale in a sample of Swedish family members of patients with life-threatening illness. *Palliative Medicine.* 26(7):930-938.

Higginson, I.J. & Gao, W. 2008. Caregiver assessment of patients with advanced cancer: concordance with patients, effect of burden and positivity. *Health and Quality of Life Outcomes.* 6:42. DOI:10.1186/1477-7525-6-42.

Hodges, L.J., Humphris, G.M. & Macfarlane, G. 2005. A meta-analytic investigation of the relationship between the psychological distress of cancer patients and their carers. *Social Science & Medicine.* 60(1):1-12.

Honea, N.J., Brintnall, R., Given, B., Sherwood, P., Colao, D.B., Somers, S.C. & Northouse, L.L. 2008. Putting Evidence into Practice: nursing assessment and interventions to reduce family caregiver strain and burden. *Clinical Journal of Oncology Nursing.* 12(3):507-516. DOI:10.1188/08.CJON.507-516.

Houts, P.S., Nezu, A.M., Nezu, C.M. & Bucher, J.A. 1996. The prepared family caregiver: a problem-solving approach to family caregiver education. *Patient Education and Counseling.* 27(1):63-73.

Hudson, P. 2003. A conceptual model and key variables for guiding supportive interventions for family caregivers of people receiving palliative care. *Palliative & Supportive Care.* 1(4):353-365.

Hudson, P.L., Aranda, S. & Kristjanson, L.J. 2004. Meeting the supportive needs of family caregivers in palliative care: challenges for health professionals. *Journal of Palliative Medicine.* 7(1):19-25.

Hudson, P.L., Aranda, S. & Hayman-White, K. 2005. A psycho-educational intervention for family caregivers of patients receiving palliative care: a randomized controlled trial. *Journal of Pain and Symptom Management.* 30(4):329-341.

Hudson, P., Quinn, K., Kristjanson, L., Thomas, T., Braithwaite, M., Fisher, J. & Cockayne, M. 2008. Evaluation of a psycho-educational group programme for family caregivers in home-based palliative care. *Palliative Medicine.* 22(3):270-280. DOI:10.1177/0269216307088187.

Hudson, P., Trauer, T., Kelly, B., O'Connor, M., Thomas, K., Summers, M., Zordan, R. & White, V. 2013. Reducing the psychological distress of family caregivers of home-based palliative care patients: short-term effects from a randomised controlled trial. *Psycho-Oncology.* 22(9):1987-1993. DOI:10.1002/pon.3242.

Hudson, P., Trauer, T., Kelly, B., O'Connor, M., Thomas, K., Zordan, R. & Summers, M. 2015. Reducing the psychological distress of family caregivers of home based palliative care patients: longer term effects from a randomised controlled trial. *Psycho-Oncology.* 24(1):19-24. DOI:10.1002/pon.3610.

Hughes, S.L., Giobbie-Hurder, A., Weaver, F.M., Kubal, J.D. & Henderson, W. 1999. Relationship between caregiver burden and health-related quality of life. *The Gerontologist.* 39(5):534-545.

Ip, W.Y. & Martin, C.R. 2006. Factor structure of the Chinese version of the 12-item General Health Questionnaire (GHQ-12) in pregnancy. *Journal of Reproductive and Infant Psychology.* 24(02):87-98.

Isaacs, K.B. & Hall, L.A. 2011. A psychometric analysis of the functional social support questionnaire in low-income pregnant women. *Issues in Mental Health Nursing.* 32(12):766-773. DOI:10.3109/01612840.2011.610561.

Jedy-Agba, E., Curado, M.P., Ogunbiyi, O., Oga, E., Fabowale, T., Igbinoba, F., Osubor, G., Otu, T. et al. 2012. Cancer incidence in Nigeria: a report from population-based cancer registries. *Cancer Epidemiology.* 36(5):e278. DOI:10.1016/j.canep.2012.04.007.

Jemal, A., Bray, F., Center, M.M., Ferlay, J., Ward, E. & Forman, D. 2011. Global cancer statistics. *CA: A Cancer Journal for Clinicians.* 61(2):69-90. DOI:10.3322/caac.20107.

Kanach, F.A., Brown, L.M. & Campbell, R.R. 2014. The role of rehabilitation in palliative care services. *American Journal of Physical Medicine & Rehabilitation.* 93(4):342-345. DOI:10.1097/PHM.0000000000000005.

Kao, Y. & Liu, Y. 2010. The clinical applicability of the Self-Appraisal of Illness Questionnaire (SAIQ) to chronic schizophrenic patients in Taiwan. *Psychiatric Quarterly.* 81(3):215-225. DOI:10.1007/s11126-010-9131-5.

Kaplan, R.M., & Ries, A.L. 2007. Quality of life: concept and definition. *COPD: Journal of Chronic Obstructive Pulmonary Disease.* 4(3), 263-271.

Kent, E.E., Rowland, J.H., Northouse, L., Litzelman, K., Chou, W.S., Shelburne, N., Timura, C., O'Mara, A. et al. 2016. Caring for caregivers and patients: Research and clinical priorities for informal cancer caregiving. *Cancer.* 122(13):1987-1995. DOI:10.1002/cncr.29939.

Kim, Y., Baker, F. & Spillers, R.L. 2007. Cancer caregivers' quality of life: effects of gender, relationship, and appraisal. *Journal of Pain and Symptom Management.* 34(3):294-304.

Kim, H., Chang, M., Rose, K. & Kim, S. 2012. Predictors of caregiver burden in caregivers of individuals with dementia. *Journal of Advanced Nursing.* 68(4):846-855. DOI:10.1111/j.1365-2648.2011.05787.x.

Kim, J. & Shin, W. 2014. How to do random allocation (randomization). *Clinics in Orthopedic Surgery.* 6(1):103-109. DOI:10.4055/cios.2014.6.1.103.

Kim, T.K. 2015. T test as a parametric statistic. *Korean Journal of Anesthesiology.* 68(6):540-546. DOI:10.4097/kjae.2015.68.6.540.

Kimberlin, C.L., & Winterstein, A.G. 2008. Validity and reliability of measurement instruments used in research. *American Journal of Health-System Pharmacy: AJHP*: 65(23):2276-2284. DOI: 10.2146/ajhp070364.

Kozachik, S.L., Given, C.W., Given, B.A., Pierce, S.J., Azzouz, F., Rawl, S.M. & Champion, V.L. 2001. Improving depressive symptoms among caregivers of patients with cancer: results of a randomized clinical trial. *Oncology Nursing Forum.* 28(7):1149-1157.

Krug, K., Miksch, A., Peters-Klimm, F., Engeser, P. & Szecsenyi, J. 2016. Correlation between patient quality of life in palliative care and burden of their family caregivers: a prospective observational cohort study. *BMC Palliative Care.* 15:4. DOI:10.1186/s12904-016-0082-y.

Kumar, K. & Gupta, M. 2014. Clinical and socio-demographic determinants of psychological health and burden in family caregivers of patients with unipolar depression. *Asian Journal of Psychiatry*. 9:51-56. DOI:10.1016/j.ajp.2014.01.002.

Lafaye, A., De Chalvron, S., Houédé, N., Eghbali, H. & Cousson-Gélie, F. 2013. The Caregivers Quality of Life Cancer index scale (CQoLC): an exploratory factor analysis for validation in French cancer patients' spouses. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation.* 22(1):119-122. DOI:10.1007/s11136-012-0113-y.

Lai, D.W.L. 2007. Validation of the Zarit Burden Interview for Chinese Canadian caregivers. *Social Work Research.* 31(1):45-53.

Lambert, S.D., Yoon, H., Ellis, K.R. & Northouse, L. 2015. Measuring appraisal during advanced cancer: psychometric testing of the appraisal of caregiving scale. *Patient Education and Counseling.* 98(5):633-639. DOI:10.1016/j.pec.2015.01.009.

Lapid, M.I., Atherton, P.J., Kung, S., Sloan, J.A., Shahi, V., Clark, M.M. & Rummans, T.A. 2016. Cancer caregiver quality of life: need for targeted intervention. *Psycho-Oncology.* 25(12):1400-1407. DOI:10.1002/pon.3960.

Lau, D.T., Berman, R., Halpern, L., Pickard, A.S., Schrauf, R. & Witt, W. 2010. Exploring factors that influence informal caregiving in medication management for home hospice patients. *Journal of Palliative Medicine.* 13(9):1085-1090. DOI:10.1089/jpm.2010.0082.

Lazarus, R.S. & Folkman, S. 1987. Transactional theory and research on emotions and coping. *European Journal of Personality.* 1(3):141-169.

Leon, A.C., Davis, L.L. & Kraemer, H.C. 2011. The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research.* 45(5):626-629. DOI:10.1016/j.jpsychires.2010.10.008.

Leow, M., Chan, S. & Chan, M. 2015. A pilot randomized, controlled trial of the effectiveness of a psychoeducational intervention on family caregivers of patients with advanced cancer. *Oncology Nursing Forum.* 42(2):E72. DOI:10.1188/15.ONF.E63-E72.

Leroi, I., McDonald, K., Pantula, H. & Harbishettar, V. 2012. Cognitive impairment in Parkinson disease: impact on quality of life, disability, and caregiver burden. *Journal of Geriatric Psychiatry and Neurology.* 25(4):208-214. DOI:10.1177/0891988712464823.

LeSeure, P. & Chongkham-Ang, S. 2015. The Experience of Caregivers Living with Cancer Patients: A Systematic Review and Meta-synthesis. *Journal of Personalized Medicine.* 5(4):406-439. DOI:10.3390/jpm5040406.

Li, Q. & Loke, A.Y. 2014. A systematic review of spousal couple-based intervention studies for couples coping with cancer: direction for the development of interventions. *Psycho-Oncology.* 23(7):731-739. DOI:10.1002/pon.3535.

Lkhoyaali, S., El Haj, M.A., El Omrani, F., Layachi, M., Ismaili, N., Mrabti, H. & Errihani, H. 2015. The burden among family caregivers of elderly cancer patients: prospective study in a Moroccan population. *BMC Research Notes.* 8:347. DOI:10.1186/s13104-015-1307-5.

Lowenstein, A. & Gilbar, O. 2000. The perception of caregiving burden on the part of elderly cancer patients, spouses and adult children. *Families, Systems & Health: The Journal of Collaborative Family HealthCare.* 18(3):337-346.

Lu, L., Wang, L., Yang, X. & Feng, Q. 2009. Zarit Caregiver Burden Interview: development, reliability and validity of the Chinese version. *Psychiatry and Clinical Neurosciences.* 63(6):730-734. DOI:10.1111/j.1440-1819.2009.02019.x.

Lu, L., Pan, B., Sun, W., Cheng, L., Chi, T. & Wang, L. 2010. Quality of life and related factors among cancer caregivers in China. *Psychiatry and Clinical Neurosciences.* 64(5):505-513. DOI:10.1111/j.1440-1819.2010.02131.x.

Lyons, K.D., Bakitas, M., Hegel, M.T., Hanscom, B., Hull, J. & Ahles, T.A. 2009. Reliability and validity of the Functional Assessment of Chronic Illness Therapy-Palliative care (FACIT-Pal) scale. *Journal of Pain and Symptom Management.* 37(1):23-32. DOI:10.1016/j.jpainsymman.2007.12.015.

Mahendran, R., Lim, H.A., Tan, J.Y.S., Ng, H.Y., Chua, J., Lim, S.E., Kua, E.H. & Griva, K. 2017. Evaluation of a brief pilot psychoeducational support group intervention for family caregivers of cancer patients: a quasi-experimental mixed-methods study. *Health and Quality of Life Outcomes.* 15(1):17. DOI:10.1186/s12955-017-0595-y.

McKenzie, F., Zietsman, A., Galukande, M., Anele, A., Adisa, C., Cubasch, H., Parham, G., Anderson, B.O. et al. 2016. African Breast Cancer-Disparities in Outcomes (ABC-DO): protocol of a multicountry mobile health prospective study of breast cancer survival in sub-Saharan Africa. *British Medical Journal Open.* 6(8):e011390. DOI:10.1136/bmjopen-2016-011390.

McMillan, S.C. 1996. Quality of life of primary caregivers of hospice patients with cancer. *Cancer Practice.* 4(4):191-198.

McMillan, S.C. & Mahon, M. 1994. Measuring quality of life in hospice patients using a newly developed Hospice Quality of Life Index. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation.* 3(6):437-447.

McMillan, S.C., Small, B.J., Weitzner, M., Schonwetter, R., Tittle, M., Moody, L. & Haley, W.E. 2006. Impact of coping skills intervention with family caregivers of hospice patients with cancer: a randomized clinical trial. *Cancer.* 106(1):214-222.

McMillan, S.C. & Small, B.J. 2007. Using the COPE intervention for family caregivers to improve symptoms of hospice homecare patients: a clinical trial. *Oncology Nursing Forum.* 34(2):313-321.

Meyers, F.J., Carducci, M., Loscalzo, M.J., Linder, J., Greasby, T. & Beckett, L.A. 2011. Effects of a problem-solving intervention (COPE) on quality of life for patients with advanced cancer on clinical trials and their caregivers: simultaneous care educational intervention (SCEI): linking palliation and clinical trials. *Journal of Palliative Medicine.* 14(4):465-473. DOI:10.1089/jpm.2010.0416.

Mitnick, S., Leffler, C. & Hood, V.L. 2010. Family caregivers, patients and physicians: ethical guidance to optimize relationships. *Journal of General Internal Medicine.* 25(3):255-260. DOI:10.1007/s11606-009-1206-3.

Molyneux, G.J., McCarthy, G.M., McEniff, S., Cryan, M. & Conroy, R.M. 2008. Prevalence and predictors of carer burden and depression in carers of patients referred to an old age psychiatric service. *International Psychogeriatrics.* 20(6):1193-1202. DOI:10.1017/S1041610208007515.

Montazeri, A. 2009. Quality of life data as prognostic indicators of survival in cancer patients: an overview of the literature from 1982 to 2008. *Health and Quality of Life Outcomes.* 7:102. DOI:10.1186/1477-7525-7-102.

Morimoto, T., Schreiner, A.S. & Asano, H. 2003. Caregiver burden and health-related quality of life among Japanese stroke caregivers. *Age and Ageing.* 32(2):218-223.

Neufeld, E., O'Rourke, N. & Donnelly, M. 2010. Enhanced measurement sensitivity of hopeless ideation among older adults at risk of self-harm: Reliability and validity of Likert-type responses to the Beck Hopelessness Scale. *Aging & Mental Health.* 14(6):752-756. DOI:10.1080/13607860903421052.

Nggada, H.A., Yawe, K.T., Abdulazeez, J. & Khalil, M.A. 2008. Breast cancer burden in Maiduguri, North eastern Nigeria. *Breast Journal.* 14(3):284-286. DOI:10.1111/j.1524-4741.2008.00576.x.

Nijboer, C., Tempelaar, R., Sanderman, R., Triemstra, M., Spruijt, R.J. & van den Bos, G A 1998. Cancer and caregiving: the impact on the caregiver's health. *Psycho-Oncology.* 7(1):3-13.

Northouse, L.L. 2012. Helping patients and their family caregivers cope with cancer. *Oncology Nursing Forum.* 39(5):500-506. DOI:10.1188/12.ONF.500-506.

Northouse, L.L., Mood, D., Templin, T., Mellon, S. & George, T. 2000. Couples' patterns of adjustment to colon cancer. *Social Science & Medicine (1982).* 50(2):271-284.

Northouse, L., Templin, T. & Mood, D. 2001. Couples' adjustment to breast disease during the first year following diagnosis. *Journal of Behavioral Medicine.* 24(2):115-136.

Northouse, L., Kershaw, T., Mood, D. & Schafenacker, A. 2005. Effects of a family intervention on the quality of life of women with recurrent breast cancer and their family caregivers. *Psycho-Oncology.* 14(6):478-491.

Northouse, L.L., Mood, D.W., Schafenacker, A., Montie, J.E., Sandler, H.M., Forman, J.D., Hussain, M., Pienta, K.J. et al. 2007. Randomized clinical trial of a family intervention for prostate cancer patients and their spouses. *Cancer.* 110(12):2809-2818.

Northouse, L.L., Katapodi, M.C., Song, L., Zhang, L. & Mood, D.W. 2010. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. *CA: A Cancer Journal for Clinicians.* 60(5):317-339. DOI:10.3322/caac.20081.

Northouse, L.L., Katapodi, M.C., Schafenacker, A.M. & Weiss, D. 2012. The impact of caregiving on the psychological well-being of family caregivers and cancer patients. *Seminars in Oncology Nursing.* 28(4):236-245. DOI:10.1016/j.soncn.2012.09.006.

Northouse, L.L., Mood, D.W., Schafenacker, A., Kalemkerian, G., Zalupski, M., LoRusso, P., Hayes, D.F., Hussain, M. et al. 2013. Randomized clinical trial of a brief and extensive dyadic intervention for advanced cancer patients and their family caregivers. *Psycho-Oncology.* 22(3):555-563. DOI:10.1002/pon.3036.

Northouse, L., Schafenacker, A., Barr, K.L.C., Katapodi, M., Yoon, H., Brittain, K., Song, L., Ronis, D.L. et al. 2014. A tailored Web-based psychoeducational intervention for cancer patients and their family caregivers. *Cancer Nursing.* 37(5):321-330. DOI:10.1097/NCC.0000000000000159.

Ntekim, A., Nufu, F.T. & Campbell, O.B. 2009. Breast cancer in young women in Ibadan, Nigeria. *African Health Sciences.* 9(4):242-246.

Odigie, V.I., Tanaka, R., Yusufu, L.M.D., Gomna, A., Odigie, E.C., Dawotola, D.A. & Margaritoni, M. 2010. Psychosocial effects of mastectomy on married African women in Northwestern Nigeria. *Psycho-Oncology.* 19(8):893-897. DOI:10.1002/pon.1675.

O'Hara, R.,E., Hull, J.G., Lyons, K.D., Bakitas, M., Hegel, M.T., Li, Z. & Ahles, T.A. 2010. Impact on caregiver burden of a patient-focused palliative care intervention for patients with advanced cancer. *Palliative & Supportive Care.* 8(4):395-404. DOI:10.1017/S1478951510000258.

Oluwatosin, O.A. 2006. Rural women's perception of breast cancer and its early-detection measures in Ibadan, Nigeria. *Cancer Nursing.* 29(6):461-466.

Ovayolu, O., Ovayolu, N., Tuna, D., Serçe, S., Sevinç, A. & Pirbudak Çöçelli, L. 2014. Quality of life of caregivers: a cross-sectional study. *International Journal of Nursing Practice.* 20(4):424-432. DOI:10.1111/ijn.12147.

Ozer, N., Yurttas, A. & Akyil, R.e. 2012. Psychometric evaluation of the Turkish version of the Zarit Burden Interview in family caregivers of inpatients in medical and surgical clinics. *Journal of Transcultural Nursing:* 23(1):65-71. DOI:10.1177/1043659611423830.

Papastavrou, E., Charalambous, A. & Tsangari, H. 2009. Exploring the other side of cancer care: the informal caregiver. *European Journal of Oncology Nursing:* 13(2):128-136. DOI:10.1016/j.ejon.2009.02.003.

Park, B., Kim, S.Y., Shin, J., Sanson-Fisher, R., Shin, D.W., Cho, J. & Park, J. 2013. Prevalence and predictors of anxiety and depression among family caregivers of cancer patients: a nationwide survey of patient-family caregiver dyads in Korea. *Supportive Care in Cancer:* 21(10):2799-2807. DOI:10.1007/s00520-013-1852-1.

Parkin, D.M. & Fernndez, L.,M.G. 2006. Use of statistics to assess the global burden of breast cancer. *Breast Journal.* 12 Suppl 1:S80.

Pasacreta, J.V., Barg, F., Nuamah, I. & McCorkle, R. 2000. Participant characteristics before and 4 months after attendance at a family caregiver cancer education program. *Cancer Nursing.* 23(4):295-303.

Pelayo-Alvarez, M., Perez-Hoyos, S. & Agra-Varela, Y. 2013. Reliability and concurrent validity of the Palliative Outcome Scale, the Rotterdam Symptom Checklist, and the Brief Pain Inventory. *Journal of Palliative Medicine.* 16(8):867-874. DOI:10.1089/jpm.2012.0625.

Perpi-Galva, J., Cabaero-Martnez, M.J. & Richart-Martnez, M. 2013. Reliability and validity of shortened state trait anxiety inventory in Spanish patients receiving mechanical ventilation. *American Journal of Critical Care:* 22(1):46-52. DOI:10.4037/ajcc2013282.

Pinquart, M. & Srensen, S. 2007. Correlates of physical health of informal caregivers: a meta-analysis. *Journals of Gerontology. Series B, Psychological Sciences and Social Sciences.* 62(2):P137.

Polit, D.F. & Beck, C.T. 2008. *Nursing research: Generating and assessing evidence for nursing practice.* Philadelphia, PA: Wolters Kluwer/ Lippincott Williams & Wilkins.

Pretorius, C., Walker, S.P. & Esterhuyse, K.G.F. 2010. Coping responses as predictors of satisfaction with life amongst a group of patients diagnosed with diabetes mellitus. *Health SA Gesondheid.* 15(1):127-131. DOI:10.4102/hsag.v15i1.513.

Reda, A.A. 2011. Reliability and validity of the Ethiopian version of the hospital anxiety and depression scale (HADS) in HIV infected patients. *Plos One.* 6(1):e16049. DOI:10.1371/journal.pone.0016049.

Rha, S.Y., Park, Y., Song, S.K., Lee, C.E. & Lee, J. 2015. Caregiving burden and the quality of life of family caregivers of cancer patients: the relationship and correlates. *European Journal of Oncology Nursing:* 19(4):376-382. DOI:10.1016/j.ejon.2015.01.004.

Rinaldi, P., Spazzafumo, L., Mastriforti, R., Mattioli, P., Marvardi, M., Polidori, M.C., Cherubini, A., Abate, G. et al. 2005. Predictors of high level of burden and distress in caregivers of demented patients: results of an Italian multicenter study. *International Journal of Geriatric Psychiatry.* 20(2):168-174.

Rivera-Navarro, J., Benito-Len, J., Oreja-Guevara, C., Pardo, J., Dib, W.B., Orts, E. & Bell, M. 2009. Burden and health-related quality of life of Spanish caregivers of persons with multiple sclerosis. *Multiple Sclerosis.* 15(11):1347-1355. DOI:10.1177/1352458509345917.

Rottmann, N., Hansen, D.G., Larsen, P.V., Nicolaisen, A., Flyger, H., Johansen, C. & Hagedoorn, M. 2015. Dyadic coping within couples dealing with breast cancer: A longitudinal, population-based study. *Health Psychology.* 34(5):486-495. DOI:10.1037/hea0000218.

Samarel, N., Tulman, L. & Fawcett, J. 2002. Effects of two types of social support and education on adaptation to early-stage breast cancer. *Research in Nursing & Health.* 25(6):459-470.

Sandgren, A.K., McCaul, K.D., King, B., O'Donnell, S. & Foreman, G. 2000. Telephone therapy for patients with breast cancer. *Oncology Nursing Forum.* 27(4):683-688.

Schildmann, E.K. & Higginson, I.J. 2011. Evaluating psycho-educational interventions for informal carers of patients receiving cancer care or palliative care: strengths and limitations of different study designs. *Palliative Medicine.* 25(4):345-356. DOI:10.1177/0269216310389223.

Schulz, R. & Sherwood, P.R. 2008. Physical and mental health effects of family caregiving. *American Journal of Nursing.* 108(9):23-27. DOI:10.1097/01.NAJ.0000336406.45248.4c.

Seng, B.K., Luo, N., Ng, W.Y., Lim, J., Chionh, H.L., Goh, J. & Yap, P. 2010. Validity and reliability of the Zarit Burden Interview in assessing caregiving burden. *Annals of the Academy of Medicine, Singapore.* 39(10):758-763.

Serrano-Aguilar, P., Lopez-Bastida, J. & Yanes-Lopez, V. 2006. Impact on health-related quality of life and perceived burden of informal caregivers of individuals with Alzheimer's disease. *Neuroepidemiology.* 27(3):136-142.

Shahi, V., Lapid, M.I., Kung, S., Atherton, P.J., Sloan, J.A., Clark, M.M. & Rummans, T.A. 2014. Do age and quality of life of patients with cancer influence quality of life of the caregiver? *Journal of Geriatric Oncology.* 5(3):331-336. DOI:10.1016/j.jgo.2014.03.003.

Shaw, B.R., Dubenske, L.L., Han, J.Y., Cofta-Woerpel, L., Bush, N., Gustafson, D.H. & McTavish, F. 2008. Antecedent characteristics of online cancer information seeking among rural breast cancer patients: an application of the Cognitive-Social Health Information Processing (C-SHIP) model. *Journal of Health Communication.* 13(4):389-408. DOI:10.1080/10810730802063546.

Shaw, C. 1999. A framework for the study of coping, illness behaviour and outcomes. *Journal of Advanced Nursing.* 29(5):1246-1255.

Singletary, S.E. & Connolly, J.L. 2006. Breast cancer staging: working with the sixth edition of the AJCC Cancer Staging Manual. *CA: A Cancer Journal for Clinicians.* 56(1):37-47.

Sinha, R., Van den Heuvel, W.,J.A. & Arokiasamy, P. 2013. Validity and Reliability of MOS Short Form Health Survey (SF-36) for Use in India. *Indian Journal of Community Medicine: Official Publication of Indian Association of Preventive & Social Medicine.* 38(1):22-26. DOI:10.4103/0970-0218.106623.

Sklenarova, H., Krmpelmann, A., Haun, M.W., Friederich, H., Huber, J., Thomas, M., Winkler, E.C., Herzog, W. et al. 2015. When do we need to care about the caregiver? Supportive care needs, anxiety, and depression among informal caregivers of patients with cancer and cancer survivors. *Cancer.* 121(9):1513-1519. DOI:10.1002/cncr.29223.

Son, K.Y., Lee, C.H., Park, S.M., Lee, C.H., Oh, S.I., Oh, B., Tak, S.H., Cho, B. et al. 2012. The factors associated with the quality of life of the spouse caregivers of patients with cancer: a cross-sectional study. *Journal of Palliative Medicine.* 15(2):216-224. DOI:10.1089/jpm.2011.0305.

Song, J.I., Shin, D.W., Choi, J.Y., Kang, J., Baik, Y.J., Mo, H., Park, M.H., Choi, S.E. et al. 2011. Quality of life and mental health in family caregivers of patients with terminal cancer. *Supportive Care in Cancer: Official Journal of the Multinational Association of Supportive Care in Cancer.* 19(10):1519-1526. DOI:10.1007/s00520-010-0977-8.

Stajduhar, K.I., Martin, W.L., Barwich, D. & Fyles, G. 2008. Factors influencing family caregivers' ability to cope with providing end-of-life cancer care at home. *Cancer Nursing.* 31(1):77-85. DOI:10.1097/01.NCC.0000305686.36637.b5.

Stenberg, U., Ruland, C.M. & Miaskowski, C. 2010. Review of the literature on the effects of caring for a patient with cancer. *Psycho-Oncology.* 19(10):1013-1025. DOI:10.1002/pon.1670.

Suresh, K. 2011. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *Journal of Human Reproductive Sciences.* 4(1):8-11. DOI:10.4103/0974-1208.82352.

Sussman, T. & Regehr, C. 2009. The influence of community-based services on the burden of spouses caring for their partners with dementia. *Health & Social Work.* 34(1):29-39.

Sylla, B.S. & Wild, C.P. 2012. A million africans a year dying from cancer by 2030: what can cancer research and control offer to the continent? *International Journal of Cancer.* 130(2):245-250. DOI:10.1002/ijc.26333.

Tamayo, G.J., Broxson, A., Munsell, M. & Cohen, M.Z. 2010. Caring for the caregiver. *Oncology Nursing Forum.* 37(1), E50-57. DOI: 10.1188/10.onf.e50-e57

Tan, J.Y.S., Lim, H.A., Kuek, N.M.Y., Kua, E.H. & Mahendran, R. 2015. Caring for the caregiver while caring for the patient: exploring the dyadic relationship between patient spirituality and caregiver quality of life. *Supportive Care in Cancer:* 23(12):3403-3406. DOI:10.1007/s00520-015-2920-5.

Tang, S.T., Chang, W., Chen, J., Wang, H., Shen, W.C., Li, C. & Liao, Y. 2013. Course and predictors of depressive symptoms among family caregivers of terminally ill cancer patients until their death. *Psycho-Oncology.* 22(6):1312-1318. DOI:10.1002/pon.3141.

Thomas, P., Chantoin-Merlet, S., Hazif-Thomas, C., Belmin, J., Montagne, B., Clment, J., Lebruchec, M. & Billon, R. 2002. Complaints of informal caregivers providing home care for dementia patients: the Pixel study. *International Journal of Geriatric Psychiatry.* 17(11):1034-1047.

Tipton, E., Hallberg, K., Hedges, L. V. & Chan, W. 2016. Implications of Small Samples for Generalization: Adjustments and Rules of Thumb. *Evaluation Review*. DOI: 10.1177/0193841x16655665

Torkan, H. & Molavi, H. 2009. Psychometrical properties of the Index of Marital Satisfaction (IMS). Journal of Psychology. 13(1):3-19.

Turkoglu, N. & Kilic, D. 2012. Effects of care burdens of caregivers of cancer patients on their quality of life. *Asian Pacific Journal of Cancer Prevention:* 13(8):4141-4145.

Turner, D., Adams, E., Boulton, M., Harrison, S., Khan, N., Rose, P., Ward, A. & Watson, E.K. 2013. Partners and close family members of long-term cancer survivors: health status, psychosocial well-being and unmet supportive care needs. *Psycho-Oncology.* 22(1):12-19. DOI:10.1002/pon.2050.

Van, d.A., Stevens, M., Spriensma, A. & van Horn, J.,R. 2004. Groningen Orthopaedic Social Support Scale: validity and reliability. *Journal of Advanced Nursing.* 47(1):57-63.

Van Maaren, M.,C., de Munck, L., de Bock, G.,H., Jobsen, J.J., Van Dalen, T., Linn, S.C., Poortmans, P., Strobbe, L.J.A. et al. 2016. 10 year survival after breast-conserving surgery plus radiotherapy compared with mastectomy in early breast cancer in the Netherlands: a population-based study. *The Lancet.Oncology.* 17(8):1158-1170. DOI:10.1016/S1470-2045(16)30067-5.

Vereenooghe, L. & Langdon, P.E. 2013. Psychological therapies for people with intellectual disabilities: a systematic review and meta-analysis. *Research in Developmental Disabilities.* 34(11):4085-4102. DOI:10.1016/j.ridd.2013.08.030.

Vickrey, B.G., Hays, R.D., Maines, M.L., Vassar, S.D., Fitten, J. & Strickland, T. 2009. Development and preliminary evaluation of a quality of life measure targeted at dementia caregivers. *Health and Quality of Life Outcomes.* 7:56. DOI:10.1186/1477-7525-7-56.

Viechtbauer, W., Smits, L., Kotz, D., Bud, L., Spigt, M., Serroyen, J. & Crutzen, R. 2015. A simple formula for the calculation of sample size in pilot studies. *Journal of Clinical Epidemiology.* 68(11):1375-1379. DOI:10.1016/j.jclinepi.2015.04.014.

Vos, P.J., Visser, A.P., Garssen, B., Duivenvoorden, H.J. & de Haes, H.,C.J.M. 2006. Effects of delayed psychosocial interventions versus early psychosocial interventions for women with early stage breast cancer. *Patient Education and Counseling.* 60(2):212-219.

Wadhwa, D., Burman, D., Swami, N., Rodin, G., Lo, C. & Zimmermann, C. 2013. Quality of life and mental health in caregivers of outpatients with advanced cancer. *Psycho-Oncology.* 22(2):403-410. DOI:10.1002/pon.2104.

Wagner, C.D., Bigatti, S.M. & Storniolo, A.M. 2006. Quality of life of husbands of women with breast cancer. *Psycho-Oncology.* 15(2):109-120.

Waldron, E.A., Janke, E.A., Bechtel, C.F., Ramirez, M. & Cohen, A. 2013. A systematic review of psychosocial interventions to improve cancer caregiver quality of life. *Psycho-Oncology.* 22(6):1200-1207. DOI:10.1002/pon.3118.

Walsh, K., Jones, L., Tookman, A., Mason, C., McLoughlin, J., Blizard, R. & King, M. 2007. Reducing emotional distress in people caring for patients receiving specialist palliative care. Randomised trial. *British Journal of Psychiatry:*190:142-147.

Weitzner, M.A., Jacobsen, P.B., Wagner, H., J., Friedland, J. & Cox, C. 1999. The Caregiver Quality of Life Index-Cancer (CQOLC) scale: development and validation of an instrument to measure quality of life of the family caregiver of patients with cancer. *Quality of Life Research:*8(1-2):55-63.

Williams, A. & Bakitas, M. 2012. Cancer family caregivers: a new direction for interventions. *Journal of Palliative Medicine.* 15(7):775-783. DOI:10.1089/jpm.2012.0046.

World Medical Association 2013. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Journal of the American Medical Association.* 310(20):2191.

Wright, A.A., Keating, N.L., Balboni, T.A., Matulonis, U.A., Block, S.D. & Prigerson, H.G. 2010. Place of death: correlations with quality of life of patients with cancer and predictors of bereaved caregivers' mental health. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology.* 28(29):4457-4464. DOI:10.1200/JCO.2009.26.3863.

Yokoyama, K., Araki, S., Kawakami, N. & Tkakeshita, T. 1990. Production of the Japanese edition of profile of mood states (POMS): assessment of reliability and validity. *[Nihon Koshu Eisei Zasshi] Japanese Journal of Public Health.* 37(11):913-918.

Yoon, S., Kim, J., Jung, J., Kim, S. & Kim, S. 2014. Modifiable factors associated with caregiver burden among family caregivers of terminally ill Korean cancer patients. *Supportive Care in Cancer: Official Journal of the Multinational Association of Supportive Care in Cancer.* 22(5):1243-1250. DOI:10.1007/s00520-013-2077-z.

Yusuf, A.J., Adamu, A. & Nuhu, F.T. 2011. Caregiver burden among poor caregivers of patients with cancer in an urban African setting. *Psycho-Oncology.* 20(8):902-905. DOI:10.1002/pon.1814.

Zacharopoulou, G., Zacharopoulou, V. & Lazakidou, A. 2015. Quality of Life for Caregivers of Elderly Patients with Dementia and Measurement Tools: A Review. *International Journal of Health Research Innovatio.* 3:49-64.

Zarit, S.H., Reever, K.E. & Bach-Peterson, J. 1980. Relatives of the impaired elderly: correlates of feelings of burden. *The Gerontologist.* 20(6):649-655.

# APPENDICES

## Appendix A: The Information Sheet

**Researcher**: ISRAEL OLATUNJI GABRIEL **Supervisor:** Associate Professor Pat Mayers

**MSc Candidate**

Division of Nursing & Midwifery

Department of Health & Rehabilitation Sciences

Faculty of Health Sciences

University of Cape Town

OBSERVATORY 7925

Telephone Number: +2348035660412, +27622414091

e-mail: gbrisr002@myuct.ac.za, israelchristson@gmail.com

**Title of Study: The effects of a psychosocial intervention on the quality of life of primary caregivers of women with breast cancer in Abuja, Nigeria.**

### Invitation

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear. Take time to decide whether or not to take part.

### Why is this study being done?

The purpose of this study is to implement and evaluate the effectiveness of a psychosocial intervention programme on the quality of life of primary caregivers of women with breast cancer who are attending the oncology clinic, National Hospital, Abuja.

**Does the study have ethics approval?**

Ethics approval has been obtained from the UCT Faculty of Health Sciences' Human Research Ethics Committee **(HREC Ref: 243/2016).** Approval has also been obtained from the research committee of the National Hospital, Abuja **(NHA/EC/043/2016).**

**Why are you being asked to take part?**

This study is about the effects of a psychosocial intervention on the quality of life of primary caregivers of women with breast cancer. You have been selected to participate in the study because you are taking care of a woman with breast cancer.

**What do we do to decide if you are eligible to take part?**

You are eligible to take part in this study because you are:

Adult (age 18 or older) primary caregiver.

Literate as it involves reading of information and self-administered questionnaire.

Not living with breast cancer yourself, or have a serious illness which may make it difficult to participate.

**What will happen if you decide to take part in the study?**

If you agree to participate in the study after I have explained to the primary caregivers of women with breast cancer what the study is about, you will be asked to sign a consent form that is at the end of the Information Sheet. I will keep this and give you a copy. This will indicate that your participation is voluntary and you may withdraw from the study at any stage, that there will be no foreseeable risks and that your information is confidential and anonymous as you will be given a code number.

**Do you need to complete any questionnaire?**

Once you agree to participate; you will be asked to complete the following questionnaires:

General information about yourself e.g. age, gender, ethicity, religion, marital status,, level of education completed.

A questionnaire dealing with the psychosocial burden associated with caregiving, and a questionnaire dealing with quality of life of caregivers.

**How do we keep your identity?**

The questionnaires will have a code number for you that will be known only to me the researcher. You will place your completed questionnaire in a specially marked box *"Mr Gabriel: Research"* in the venue. I will be in the venue and will seal and remove the box to a secure location. Once I have analysed the questionnaires I will place them in a locked cupboard and only I will have the key. I will enter the data onto software on my computer and only I will have the password. Data will be copied onto a CD and stored in a locked cupboard for five years as this is a legal requirement. Your name will not be linked to any results that are published at the completion of the study.

**How long will it take to complete the questionnaires?**

It should take about 45 minutes to complete the questionnaires.

**How does the study work?**

The study will have two groups; the intervention and the control groups.

*The intervention group*: those in this group will receive usual care and attend the six week caregiver training programme which will be offered in one of the oncology clinic halls. This training will comprise six educational modules/sessions. Each session will be 60–90 minutes (one session per week) that will last for six weeks without repetition. If you are in this group, and at any time feel distressed, you will be asked to inform the trainers, who will refer the person for further support. Participants in this group should attend all the sessions.

*Control group*: If you are allocated to the control group, you will be asked to complete the questionnaires and will attend the training programme after the first group have completed. The information will not be included in the study. You will continue to attend the hospital with the person for whom you care.

**How do you know which of the study group do you belong?**

Once all voluntary participants have completed the questionnaires, the researcher will allocate the participants to each study arm by giving them numbers sequentially; starting with number one and continuing until 108, the one with even numbers will receive usual care and attend the programme (intervention), and those with odd numbers will receive usual care.

**What will happen when the training is over?**

Immediately after the training, group one and two will be asked to complete the second and third questionnaire again, and once again six week later.

**Do you have a choice?**

In the event that you are selected it is still required of you to indicate your willingness to participate in the study. Should you choose not to participate this will be respected.

**How long will this study last?**

The study will take 12 weeks to train, and collect the information.

**Confidentiality/Anonymity:** You have the right to remain anonymous or to use a pseudonym of your choice when completing the questionaires. All information is confidential and participants' names will not appear on the data emerging from the study. Confidentiality and anonymity will therefore be maintained throughout the study by using a code number for you.

**What are the risks and discomforts of this study?**

There are minimal risks involved in the study. No physical risks are involved. There are no known or anticipated risks. Information offered by participant is confidential and protected, however, should there be any risk such as stigmatisation that may follow interaction within group training session or feelling any distress as a result of your participation in the study, counselling will be made available for you by the trainers or if necessary you may be referred to a psychologist, who will provide psychosocial support.

### Who do I speak to (or contact) if I have any questions about the study?

If you have any further questions regarding the study, you may contact me directly or my supervisor, Associate Professor Pat Mayers on **+27824672302.** You may also contact the Human Research Ethics Committee for more information about your rights and welfare as a research participant at telephone number **+27214066338.**

### What if you decide not to take part?

Your participation is voluntary and you have the right to withdraw from the study at any stage without penalties. Your participation will not affect the treatment of the person for whom you care.

### Are there any benefits to you for being in this study?

The information you give is of utmost importance and may contribute significantly to assisting caregivers in caregiving. If you are in the training (intervention) group, it is anticipated that this experience will be beneficial. If you are not included in the intervention group of the study, you will be invited to join the next training programme after completion of the study.

### What will happen when the study is over?

If you agree to participate voluntarily in the study then once you have completed the questionnaire (and participated voluntarily in the interview if you are selected) then nothing else will be required of you. The anonymised research results will be published in peer reviewed nursing journals at the completion of the study and a copy of the dissertation will be given to the Chief Medical Director, National Hospital, Abuja for the library, and copy will be given to you on request.

### What will happen to the data when study is over?

All documents will still be kept in a secure cupboard and only the researcher will have access to it, while electronic data will still be in a password-protected Excel template. These data will be kept for the period of five years before the researcher destroys it.

**Human Research Ethics Committee Contact:**

Human Research Ethics Committee,

E 52 Room 24, Old Main Building, Groote Schuur Hospital, Observatory

Cape Town, South Africa.

Telephone: +27 21 406 6338

## Appendix B (i) - CONSENT: INTERVENTION GROUP.

I………………………………………….. ***(Name and Surname),*** hereby agree to participate in the study. I have read the information sheet and understand that I will be permitted to withdraw at any time and that I will in no way be penalised should I wish to do so. I have had an opportunity to raise questions and concerns and am satisified with the answers given regarding the study. I understand that taking part in this study is voluntary. I consent to the research staff collecting and processing my information.

______________________________ ______________________________

**Participant** **Date**

______________________________ ______________________________

**Researcher** **Date**

**Human Research Ethics Committee Contact:**
Human Research Ethics Committee,
E 52 Room 24, Old Main Building, Groote Schuur Hospital, Observatory
Cape Town, South Africa.
Telephone: +27 21 406 6338

***Thank you for your assistance.***

## Appendix B (ii) - CONSENT FORM: CONTROL GROUP

**Confidentiality/Anonymity:** The researcher has explained that all information is confidential and that my name will not appear on the data emerging from the study. The researcher has also explained that he is the only person who will have a copy of my name and the number assigned to my data.

**Risks:** The researcher has explained that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks, and if anyone occurs measures have been put in place to manage it.

**Benefits:** The information you give is of utmost importance and may contribute significantly to assisting caregivers in caregiving. If you are in the intervention group, it is anticipated that this experience will be beneficial. If you are not included in the intervention group of the study, you will be invited to join the next training programme after completion of the study.

**Autonomy/Right to withdraw:** The researcher has explained that participation is voluntary and that I have the right to withdraw from the study at any stage without penalties. All my questions will be answered by the research staff.

| | |
|---|---|
| ________________________ | ______________________ |
| **Participant** | **Date** |
| ________________________ | ______________________ |
| **Researcher** | **Date** |

**Human Research Ethics Committee Contact:**
Human Research Ethics Committee,
E 52 Room 24, Old Main Building, Groote Schuur Hospital, Observatory
Cape Town, South Africa.
Telephone: +27 21 406 6338

***Thank you for your assistance.***

## APPENDIX C

## THE CAREGIVER PSYCHOSOCIAL ASSESSMENT QUESTIONNAIRE (ZARIT BURDEN INTERVIEW)

**INSTRUCTIONS:** I am conducting research on the effects of a psychosocial intervention on the quality of life of primary caregivers of women with breast cancer. Please tick the appropriate response and fill in where applicable.

### SECTION A: DEMOGRAPHIC DATA

1) Age

| 18-29 | 30-39 | 40-49 | 50 and above |
|---|---|---|---|
| | | | |

2) Gender

| Male | Female |
|---|---|
| | |

3) Ethnicity

| Yoruba | Igbo | Hausa | Other |
|---|---|---|---|
| | | | |

If other please explain______________________________

4) Marital status

| Married | Divorced | Single | Widowed | Other |
|---|---|---|---|---|
| | | | | |

If others please explain______________________________

5) Level of education completed

| Grade six (Primary) | 12yrs of schooling (High School) | Undergraduate | Graduate | Post Graduate |
|---|---|---|---|---|
| | | | | |

6) Religion

| Christianity | Islam | Traditional Worshipper | Other |
|---|---|---|---|
| | | | |

If other please explain______________________________

7) Employment status

| Permanent | Temporary | Retired | Not working |
|---|---|---|---|
| | | | |

8) Relationship to the patient

| Parent | Spouse | Sibling | Child | Friend | Other |
|---|---|---|---|---|---|
| | | | | | |

If other please explain______________________________

9) Has caregiving affected your primary work/employment?

| Yes | No |
|---|---|
| | |

***The demographic data was designed by the researcher with the help of his supervisor.***

## Section B

| | ITEMS | 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|---|
| | | NEVER | RARELY | SOMETIMES | QUITE FREQUENTLY | NEARLY ALWAYS |
| 1 | Do you feel that your patient asks for more help than she needs? | | | | | |
| 2 | Do you feel that because of the time you spend with your patient that you don’t have enough time for yourself? | | | | | |
| 3 | Do you feel stressed between caring for your patient and trying to meet other responsibilities for your family or work? | | | | | |
| 4 | Do you feel embarrassed over your patient’s behaviour? | | | | | |
| 5 | Do you feel angry when you are around your patient? | | | | | |
| 6 | Do you feel that your patient currently affects your relationship with other family members or friends in a negative way? | | | | | |
| 7 | Are you afraid what the future holds for your patient? | | | | | |
| 8 | Do you feel strained when you are around your patient? | | | | | |
| 9 | Do you feel your patient is dependent on you? | | | | | |
| 10 | Do you feel your health has suffered because of your involvement with your patient? | | | | | |
| 11 | Do you feel that you don’t have as much privacy as you would like because of your patient? | | | | | |
| 12 | Do you feel that you will be unable to take care of your patient much longer? | | | | | |
| 13 | Do you feel that your social life has suffered because you are caring for your patient? | | | | | |
| 14 | Do you feel uncomfortable about having friends over because of your patient? | | | | | |
| 15 | Do you feel that your patient seems expect you to take care of her as if you were the only one she could depend on? | | | | | |
| 16 | Do you feel that you don’t have enough money to take care of your patient in addition to the rest of your expenses? | | | | | |
| 17 | Do you feel you have lost control of your life since your patient become ill? | | | | | |
| 18 | Do you wish you could leave the care of your patient to someone else? | | | | | |
| 19 | Do you feel uncertain about what to do about your patient? | | | | | |
| 20 | Do you feel you should be doing more for your patient? | | | | | |
| 21 | Do you feel you could do a better job in caring for your patient? | | | | | |
| 22 | Overall, are you overwhelmed with the care you are rendering for your patient? | | | | | |

**Bedard, M., Molloy, D.W., Squire, L., Dubois, S., Lever, J.A & O’Donnell, M. 2001. The Zarit Burden Interview: a new short version and screening version. Gerontologist, 41, 652-7.**

# APPENDIX D

## CAREGIVER QUALITY OF LIFE- CANCER QUESTIONNAIRE

Below is a list of statements that other people caring for loved ones with cancer have said are important. Please indicate how true each statement has been for you during the past 7 days.

**During the past 7 days:**

| | | **0 NOT AT ALL** | **1 A LITTLE BIT** | **2 SOMEWHAT** | **3 QUITE A BIT** | **4 VERY MUCH** |
|---|---|---|---|---|---|---|
| 1 | It bothers me that my daily routine is altered. | | | | | |
| 2 | My sleep is less restful. | | | | | |
| 3 | My daily life is imposed upon. | | | | | |
| 4 | I am satisfied with my sex life. | | | | | |
| 5 | It is a challenge to maintain my outside interests. | | | | | |
| 6 | I am under a financial strain. | | | | | |
| 7 | I am concerned about our insurance coverage. | | | | | |
| 8 | My economic future is uncertain. | | | | | |
| 9 | I fear my loved one will die. | | | | | |
| 10 | I have more of a positive outlook on life since my loved one's illness. | | | | | |
| 11 | My level of stress and worries has increased. | | | | | |
| 12 | My sense of spirituality has increased. | | | | | |
| 13 | It bothers me, limiting my focus on my loved one. | | | | | |
| 14 | I feel sad. | | | | | |
| 15 | I feel under increased mental strain. | | | | | |
| 16 | I get support from my friends and neighbours. | | | | | |
| 17 | I feel guilty. | | | | | |
| 18 | I feel frustrated. | | | | | |
| 19 | I feel nervous. | | | | | |
| 20 | I worry about the impact my loved one's illness has had on my children or other family members. | | | | | |
| 21 | I have difficulty dealing with my loved one's changing eating habits. | | | | | |
| 22 | I have developed a closer relationshipwith my loved one | | | | | |

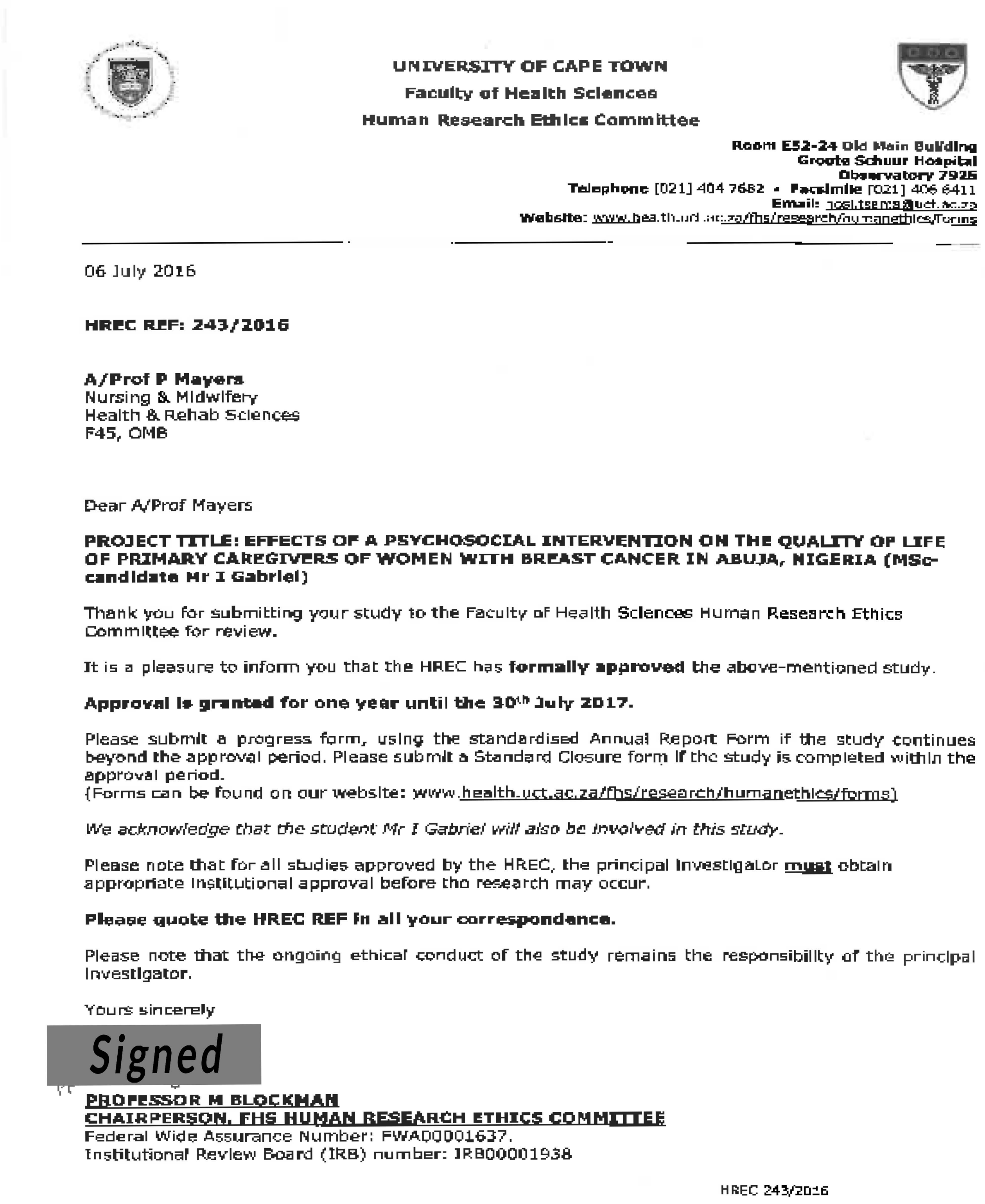
**Appendix D continued**

## CAREGIVER QUALITY OF LIFE- CANCER QUESTIONNAIRE

| | | | | | | |
|---|---|---|---|---|---|---|
| 23 | I feel adequately informed about my loved one’s illness | | | | | |
| 24 | It bothers me that I need to be available to accompany my loved one to appointments. | | | | | |
| 25 | I fear the adverse effects of treatment on my loved one. | | | | | |
| 26 | The responsibility I have for my loved one's care at home is overwhelming. | | | | | |
| 27 | I am glad that my focus is on getting my loved one well | | | | | |
| 28 | Family communication has increased. | | | | | |
| 29 | It bothers me that my priorities have changed. | | | | | |
| 30 | The need to protect my loved one bothers me. | | | | | |
| 31 | It upsets me to see my loved one deteriorate. | | | | | |
| 32 | The need to manage my loved one's pain is overwhelming. | | | | | |
| 33 | I am discouraged about the future. | | | | | |
| 34 | I am satisfied with the support I get from my family. | | | | | |
| 35 | It bothers me that other family members have not shown interest in taking care of my loved one. | | | | | |

**WEITZNER, M. A. & MCMILLAN, S. C. 1999. The Caregiver Quality of Life Index-Cancer (CQOLC) Scale: Revalidation in a home hospice setting. *J Palliative Medicine,* 15, 13-20.**

## Appendix E: Ethical clearance from Human Research Ethics Committee, Faculty of Health Sciences.



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
**Telephone** [021] 404 7682 • **Facsimile** [021] 406 6411
**Email:** nosi.tsema@uct.ac.za
**Website:** www.health.uct.ac.za/fhs/research/humanethics/forms

06 July 2016

**HREC REF: 243/2016**

**A/Prof P Mayers**
Nursing & Midwifery
Health & Rehab Sciences
F45, OMB

Dear A/Prof Mayers

**PROJECT TITLE: EFFECTS OF A PSYCHOSOCIAL INTERVENTION ON THE QUALITY OF LIFE OF PRIMARY CAREGIVERS OF WOMEN WITH BREAST CANCER IN ABUJA, NIGERIA (MSc-candidate Mr I Gabriel)**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**Approval is granted for one year until the 30th July 2017.**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

*We acknowledge that the student Mr I Gabriel will also be involved in this study.*

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

**Please quote the HREC REF in all your correspondence.**

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signed

**PROFESSOR M BLOCKMAN**
**CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE**
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 243/2016

## Appendix F: National Hospital Request Letter

**Division of Nursing and Midwifery,**
**Department of Health and Rehabilitation Sciences, Faculty of Health Sciences,**
**University of Cape Town,**
**South Africa.**

**Date: 8th July, 2016**

**The Chairman,**
**Health Research Ethics Committee,**
**National Hospital,**
**Abuja.**

**Dear Sir/ Madam,**

**PERMISSION TO USE YOUR FACILITY FOR RESEARCH STUDY.**

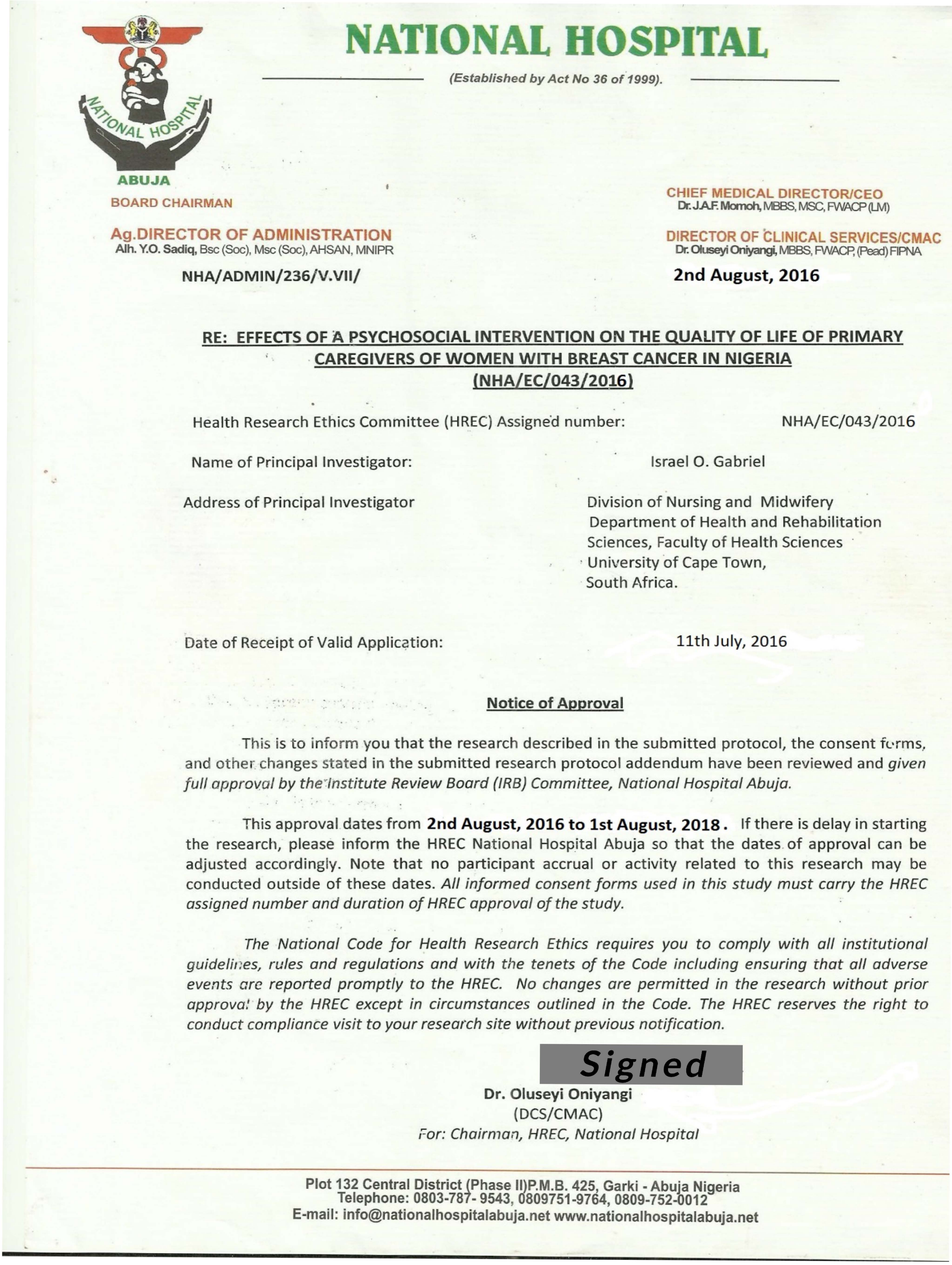
I am a Postgraduate nursing student (Masters by dissertation) of the University of Cape Town, South Africa, I am carrying out research on the ***"Effects of a Psychosocial intervention on the Quality of Life of Primary Caregivers of Women with Breast Cancer in Nigeria",*** the study will involve primary caregivers who follow patients to the hospital, they will be grouped into the intervention and control groups; intervention group will undergo six weeks training, while both groups will fill questionnaires on the psychosocial burden and quality of life before the intervention, immediately after the intervention and six weeks following the intervention. Therefore, your institution has been chosen for research setting. Ethics approval has been obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town **(REC Ref: 243/2016).** I shall be grateful if my application is favourably granted. Attached are the copies of research proposal, appendices, and the University ethics approval.

**Yours faithfully,**

_______________________

**ISRAEL O. GABRIEL.**
**GBRISR002**

## Appendix G: Ethical clearance from Hospital under study



NATIONAL HOSPITAL

(Established by Act No 36 of 1999).

NATIONAL HOSPITAL
ABUJA

BOARD CHAIRMAN

Ag.DIRECTOR OF ADMINISTRATION
Alh. Y.O. Sadiq, Bsc (Soc), Msc (Soc), AHSAN, MNIPR

CHIEF MEDICAL DIRECTOR/CEO
Dr. J.A.F. Momoh, MBBS, MSC, FWACP (LM)

DIRECTOR OF CLINICAL SERVICES/CMAC
Dr. Oluseyi Oniyangi, MBBS, FWACP, (Pead) FIPNA

NHA/ADMIN/236/V.VII/

**2nd August, 2016**

**RE: EFFECTS OF A PSYCHOSOCIAL INTERVENTION ON THE QUALITY OF LIFE OF PRIMARY CAREGIVERS OF WOMEN WITH BREAST CANCER IN NIGERIA (NHA/EC/043/2016)**

| | |
|---|---|
| Health Research Ethics Committee (HREC) Assigned number: | NHA/EC/043/2016 |
| Name of Principal Investigator: | Israel O. Gabriel |
| Address of Principal Investigator | Division of Nursing and Midwifery<br>Department of Health and Rehabilitation Sciences, Faculty of Health Sciences<br>University of Cape Town,<br>South Africa. |
| Date of Receipt of Valid Application: | 11th July, 2016 |

**Notice of Approval**

This is to inform you that the research described in the submitted protocol, the consent forms, and other changes stated in the submitted research protocol addendum have been reviewed and *given full approval by the Institute Review Board (IRB) Committee, National Hospital Abuja.*

This approval dates from **2nd August, 2016 to 1st August, 2018**. If there is delay in starting the research, please inform the HREC National Hospital Abuja so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study.*

*The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the Code. The HREC reserves the right to conduct compliance visit to your research site without previous notification.*

Signed

**Dr. Oluseyi Oniyangi**
(DCS/CMAC)
*For: Chairman, HREC, National Hospital*

Plot 132 Central District (Phase II)P.M.B. 425, Garki - Abuja Nigeria
Telephone: 0803-787- 9543, 0809751-9764, 0809-752-0012
E-mail: info@nationalhospitalabuja.net www.nationalhospitalabuja.net

## Appendix H: Head Oncology Unit, National Hospital, Abuja

**Division of Nursing and Midwifery,**
**Department of Health and Rehabilitation Sciences, Faculty of Health Sciences,**
**University of Cape Town,**
**South Africa.**

**Date: 5th August, 2016**

**Head, Oncology Unit,**
**National Hospital, Abuja.**

**Dear Sir/Madam,**

### REQUEST TO CARRY OUT RESEARCH IN THE ONCOLOGY UNIT.

I am a Postgraduate nursing student (Masters by dissertation) of the University of Cape Town, South Africa, I am carrying out research on the ***"Effects of a Psychosocial Intervention on the Quality of Life of Primary Caregivers of Women with Breast Cancer in Nigeria"***, the study will involve primary caregivers who follow patients to the Oncology Unit, they will be grouped into the intervention and control groups; intervention group will undergo six weeks training, while both groups will fill questionnaires on the psychosocial burden and quality of life before the intervention, immediately after the intervention and six weeks following the intervention. Ethics approval has been obtained from the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town **(REC Ref: 243/2016)**, and the National Hospital, Abuja **(NHA/EC/043/2016).**

Your cooperation will be highly appreciated. Attached are the necessary documents.

**Yours faithfully,**

_________________________

**ISRAEL O. GABRIEL**
**GBRISR002**

## Appendix I: The Nurses/Doctors Oncology Unit, National Hospital, Abuja

**Division of Nursing and Midwifery,**
**Department of Health and Rehabilitation Sciences, Faculty of Health Sciences,**
**University of Cape Town,**
**South Africa.**

**Date: 5th August, 2016**

**The Nurses/Doctors,**
**Oncology Unit,**
**National Hospital, Abuja.**

**Dear Sir/Madam,**

**REQUEST**

I am a Postgraduate nursing student (Master's by dissertation) of the University of Cape Town, South Africa, I am carrying out research on the ***"Effects of a Psychosocial Intervention on the Quality of Life of Primary Caregivers of Women with Breast Cancer in Nigeria",*** the study will involve primary caregivers who accompanying patients to the Oncology Unit, they will be grouped into the intervention and control groups; intervention group will undergo six weeks training, while both groups will fill questionnaires on the psychosocial burden and quality of life before the intervention, immediately after the intervention and six weeks following the intervention. Therefore, I am requesting that the patient caregivers should be referred to the study. This study has received the ethics approval from the Faculty of Health Sciences' Human Research Ethics Committee of the University of Cape Town **(REC Ref: 243/2016),** and the National Hospital, Abuja **(NHA/EC/043/2016).**

Your cooperation is highly appreciated. I shall be grateful if my request is granted. Attached are the necessary documents.

**Yours faithfully,**

______________________

**ISRAEL O. GABRIEL**
**GBRISR002**

## Appendix J: Training Manual

# Psychosocial Intervention Programme

Faculty of Health Sciences,
Department of Health and Rehabilitation,
Division of Nursing and Midwifery,
University of Cape Town, South Africa.

# Training Guide for Primary Caregivers of Women with Breast Cancer

**Compiled by: ISRAEL OLATUNJI GABRIEL**

**Date: 8th March, 2016.**

## OPENING AND WELCOME SPEECH.

**Dear; distinguished participants of the training,**
**Ladies and Gentlemen,**

It is my distinct pleasure, honour and privilege to welcome you all to this momentous and historic occasion in the life of primary caregivers of women with breast cancer.

Let me briefly introduce for the benefit of participants the purpose of our gathering; participants to this training program will learn basic information about cancer, its treatment and evolution, adjusting to being a caregiver, community resources that can help cancer caregivers, how to help families improve their emotion-management strategies, the variety of internal and external resources to assist caregivers in this role among others.

The training is made up of six educational modules/sessions; the duration of each session is 60–90 minutes (one session per week) that will last for six weeks.

Finally, this is an opportune time for me to declare the official opening of the training of caregivers on the "Effects of a psychosocial intervention on the quality of life of primary caregivers of women with breast cancer in Abuja, Nigeria''.

We look forward to a successful training programme over the next six weeks and I strongly encourage you all to become actively engaged in the various course sessions and discussions on subject matter. I wish all six fruitful weeks of interesting and beneficial programme and also that you have a pleasant stay in the National Hospital, Abuja.

**I warmly welcome you again.**

***ISRAEL OLATUNJI GABRIEL***

## OBJECTIVES OF THE TRAINING

**At the end of the training, the participants are expected to:**

- Have a general idea about caregiving and psychosocial intervention for women with breast cancer.
- Gain a deeper understanding of breast cancer.
- Acquire basic skills needed for caregiving.
- Identify the psychosocial needs of primary caregivers.
- Have knowledge on how to meet their emotional needs and those of the patients.

# AGENDA

## MODULE I: INTRODUCTION AND INFORMATION ABOUT CANCER.

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9-9:20AM | Welcome and Introductions of participants | -Make them familiar with one another.<br>-Provide an opportunity to express their ideas, views, and experiences.<br>-Facilitate creating a working atmosphere. | Markers, board, flip charts, projector, and computer. |
| Session Two | 9:20-9:30AM | Expectations and objectives of the training | -Understand their personal expectations of the training.<br>-Understand the topics of the training.<br>-Explain the objectives of the training. | Markers, board, flip charts, projector, and computer. |
| Session Three | 9:30-10:30AM | Basic information about cancer, it treatment and evolution | -Have knowledge of breast cancer.<br>-Understand the various management of breast cancer. | Markers, board, flip charts, projector, computer, and training guide. |

## MODULE II: HELPING THE PARTICIPANTS ADJUSTING TO BEING A CAREGIVER

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9-10AM | Explanation of caregiving and adjusting to being a caregiver | -To gain a deeper understanding of caregiving.<br>-Understand the basic concept and meaning of caregiving.<br>-Helping the participants adjusting to being a caregiver. | Markers, board, flip charts, projector, computer, and training guide. |
| Session Two | 10-10:30AM | Interactive session | -Brainstorming of what have been discussed.<br>-Share ideas and personal experience.<br>-Ask questions where necessary.<br>-Create inter-personal relationship. | Markers, board, flip charts, projector, and computer. |

## MODULE III: COMMUNICATION IN PREVENTING MISUNDERSTANDING AND PROMOTING POSITIVE INTERACTION.

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9AM–9:30AM | Importance of communication | -Discuss the importance of good communication in cancer caregiving.<br>-Identify basic communication skills. | Markers, board, flip charts, projector, computer, and training guide. |
| Session Two | 9:30–10:30AM | Keeping the lines of communication open | -Know how to get information from their patients.<br>-Know about information that is available from other participants. | Markers, board, flip charts, projector, computer, and training guide. |

## MODULE IV: THE EMOTIONS EXPERIENCED BY THE MEMBERS OF THE GROUP.

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9- 9:40AM | Coping with your feelings and Stress | -Help families improve their emotion-management strategies.<br>-Know how to manage stress. | Markers, board, flip charts, projector, computer, and training guide. |
| Session Two | 9:40-10:30AM | Interactive session | -Sharing personal experiences among the participants.<br>-Allow to ask any question regarding caregiving. | Markers, board, flip charts, projector, and computer. |

## MODULE V: INFORMATION ABOUT THE IMPORTANCE OF SELF-CARE AND HOW CAREGIVERS CAN PRACTICE SELF-CARE.

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9-10AM | Self-care and the practice of self-care | -Know the importance of self-care.<br>-We able to practice self-care. | Markers, board, flip charts, projector, computer, and training guide. |
| Session Two | 10-10:30AM | Questions and Answers | -Share ideas and personal experience.<br>-Ask question where necessary.<br>-Create inter-personal relationship. | Markers, board, flip charts, projector, and computer. |

## MODULE VI: PROVIDE TIPS ON HELPING CAREGIVERS TO GIVE PRACTICAL CARE, HOW TO DEAL WITH COMMON SYMPTOMS AND PATIENT'S EMOTIONS

| | TIME | ACTIVITY | AIM OF ACTIVITY | EQUIPMENT NEEDED |
|---|---|---|---|---|
| Session One | 9-9:40AM | Practical care, how to deal with common patient's symptoms/emotions. | -Have the knowledge of practical care.<br>-Know what to do when patient presents certain symptoms and emotion. | Markers, board, flip charts, projector, computer, and training guide. |
| Session Two | 9:40-10:30AM | Review of previous modules | -Recall those things that have been taught.<br>-Participant interaction. | Markers, board, flip charts, projector, and computer. |

## MODULE I: INTRODUCTION AND INFORMATION ABOUT CANCER

Session 1: Introduction of Participants…………………………..….9AM – 9:20AM

Session 2: Expectations and Objectives of the Training………..9:20 – 9:30AM

Session 3: Basic information about cancer, its treatment and evolution…9:30-10:30AM

### MODULE 1

**General Objective:**
Participants develop a basic understanding of the overall content of the training.

**Specific Objectives:**
At the end of the module, the participants will be able to:

- Develop a clear understanding of the objectives of the training.
- Share overall views about the training and be ready to begin.

### Session 1: Introduction of Participants

**Objectives**

This session:

- Welcome the participants to the training.
- Make them familiar with one another.
- Provide an opportunity to express their ideas, views, and experiences.
- Facilitate creating a working atmosphere.

**Activities**

**Time:** 20 minutes

**Materials:** markers, flipchart, white board.

### Session 2: Expectations and Objectives of the Training

**Objectives**

At the end of the session participants are expected to:

- Understand their personal expectations of the training.
- Understand the topics of the training.
- Explain the objectives of the training.

**Activities**

**Time:** 10 minutes

**Materials:** flipchart, markers, board, projector, and computer.

## Session 3: Basic information about cancer, its treatment and evolution

### Objectives

At the end of the session participants are expected to:

- Have knowledge of breast cancer.
- Understand the various management of breast cancer.

### Activities

**Time:** 1hour

Materials: flipchart, markers, board, projector, computer, and handout.

**Resource Material:** *What You Need to Know About Breast Cancer*- National Cancer Institute.

### The Breasts

Inside a woman's breast are 15 to 20 sections (lobes). Each lobe is made of many smaller sections (lobules). Lobules have groups of tiny glands that can make milk. After a baby is born, breast milk flows from the lobules through thin tubes (**ducts**) to the nipple. **Fibrous tissue** and fat fill the spaces between the lobules and ducts.

### CANCER CELLS

Cancer begins in cells, the building blocks that make up all tissues and organs of the body, including the breast.

Normal cells in the breast and other parts of the body grow and divide to form new cells as they are needed. When normal cells grow old or get damaged, they die, and new cells take their place.

Sometimes, this process goes wrong. New cells form when the body doesn't need them, and old or damaged cells don't die as they should. The build-up of extra cells often forms a mass of tissue called a lump, growth, or **tumour**.

Tumours in the breast can be **benign** (not cancer) or **malignant** (cancer):

**Benign tumours:** Are usually not harmful

Rarely invade the tissues around them

Don't spread to other parts of the body

Can be removed and usually don't grow back

**Malignant tumours:** May be a threat to life

Can invade nearby organs and tissues (such as the chest wall)

Can spread to other parts of the body

Often can be removed but sometimes grow back

Breast cancer cells can spread by breaking away from a breast tumour. They can travel through **blood vessels** or **lymph vessels** to reach other parts of the body. After spreading, cancer cells may attach to other tissues and grow to form new tumours that may damage those tissues.

For example, breast cancer cells may spread first to nearby lymph nodes. Groups of lymph nodes are near the breast under the arm (axilla), above the collarbone, and in the chest behind the breastbone.

When breast cancer spreads from its original place to another part of the body, the new tumour has the same kind of abnormal cells and the same name as the primary (original) tumour. For example, if breast cancer spreads to a lung, the cancer cells in the lung are actually breast cancer cells. The disease is metastatic breast cancer, not lung cancer. For that reason, it's treated as breast cancer, not lung cancer.

### Types

The most common type of breast cancer is ductal carcinoma. This cancer begins in cells that line a breast duct. About 7 of every 10 women with breast cancer have ductal carcinoma.

The second most common type of breast cancer is **lobular carcinoma**. This cancer begins in a lobule of the breast. About 1 of every 10 women with breast cancer has lobular carcinoma.

Other women have a mixture of ductal and lobular type or they have a less common type of breast cancer.

### TESTS

After you find out that you have breast cancer, you may need other tests to help choose the best treatment for you.

### Lab Tests with Breast Tissue

The breast tissue that was removed during your biopsy can be used in special lab tests:

**Hormone receptor tests:** Some breast cancers need hormones to grow. These cancers have **hormone receptors** for the hormones **oestrogen**, **progesterone**, or both. If the hormone receptor tests show that the breast cancer has these receptors, then **hormone therapy** is often recommended as part of the treatment plan.

**HER2 test:** Some breast cancers have large amounts of a protein called **HER2**, which helps them to grow. The HER2 test shows whether a woman's breast cancer has a large amount of HER2. If so, then **targeted therapy** against HER2 may be a treatment option.
It may take several weeks to get the results of these tests. The test results help your doctor decide which cancer treatments may be options for you.

**Staging Tests**
Staging tests can show whether cancer cells have spread to other parts of the body.

When breast cancer spreads, cancer cells are often found in the underarm lymph nodes (**axillary lymph nodes**). Breast cancer cells can spread from the breast to almost any other part of the body, such as the lungs, liver, bones, or brain.

Your doctor needs to learn the stage (extent) of the breast cancer to help you choose the best treatment. Staging tests may include…
**Lymph node biopsy:** If cancer cells are found in a lymph node, then cancer may have spread to other lymph nodes and other places in the body. Surgeons use a method called **sentinel lymph node biopsy** to remove the lymph node most likely to have breast cancer cells. If cancer cells are not found in the sentinel node, the woman may be able to avoid having more lymph nodes removed. The method of removing more lymph nodes to check for cancer cells is called **axillary dissection**.
**CT scan:** An **x-ray** machine linked to a computer takes a series of detailed pictures of your chest or abdomen. You may receive contrast material by mouth and by injection into a blood vessel in your arm or hand. The **contrast material** makes abnormal areas easier to see. The pictures from a **CT scan** can show cancer that has spread to the lungs or liver.

**MRI:** A strong magnet linked to a computer is used to make detailed pictures of your chest, abdomen, or brain. An **MRI** can show whether cancer has spread to these areas. Sometimes contrast material makes abnormal areas show up more clearly on the picture.

**Bone scan:** The doctor injects a small amount of a **radioactive** substance into a blood vessel. It travels through the bloodstream and collects in the bones. A machine called a scanner detects and measures the **radiation**. The scanner makes pictures of the bones. Because higher amounts of the substance collect in areas where there is cancer, the pictures can show cancer that has spread to the bones.

**PET scan:** You'll receive an injection of a small amount of radioactive sugar. The radioactive sugar gives off signals that the **PET** scanner picks up. The PET scanner makes a picture of the places in your body where the sugar is being taken up. Cancer cells show up brighter in the picture because they take up sugar faster than normal cells do. A PET scan can show cancer that has spread to other parts of the body.

**Stages**

The stage of breast cancer depends on the size of the breast tumour and whether it has spread to lymph nodes or other parts of the body.

Doctors describe the stages of breast cancer using the Roman numerals 0, I, II, III, and IV and the letters A, B, and C.

A cancer that is Stage I is **early-stage breast cancer**, and a cancer that is Stage IV is **advanced cancer** that has spread to other parts of the body, such as the liver.

The stage often is not known until after **surgery** to remove the tumour in the breast and one or more underarm lymph nodes.

**Stage 0:** Stage 0 is **carcinoma in situ**. In **ductal carcinoma in situ** (DCIS), abnormal cells are in the lining of a breast duct, but the abnormal cells have not invaded nearby breast tissue or spread outside the duct.

**Stage IA:** The breast tumour is no more than 2 centimetres (no more than 3/4 of an inch) across. Cancer has not spread to the lymph nodes.

**Stage IB:** The tumour is no more than 2 centimetres across. Cancer cells are found in lymph nodes.

**Stage IIA:** The tumour is no more than 2 centimetres across, and the cancer has spread to underarm lymph nodes.

Or, the tumour is between 2 and 5 centimetres (between 3/4 of an inch and 2 inches) across, but the cancer hasn't spread to underarm lymph nodes.

**Stage IIB:** The tumour is between 2 and 5 centimetres across, and the cancer has spread to underarm lymph nodes. Or, the tumour is larger than 5 centimetres across, but the cancer hasn't spread to underarm lymph nodes.

**Stage IIIA:** The breast tumour is no more than 5 centimetres across, and the cancer has spread to underarm lymph nodes that are attached to each other or nearby tissue. Or, the cancer may have spread to lymph nodes behind the breastbone.

Or, the tumour is more than 5 centimetres across. The cancer has spread to underarm lymph nodes that may be attached to each other or nearby tissue. Or, the cancer may have spread to lymph nodes behind the breastbone but not spread to underarm lymph nodes.

**Stage IIIB:** The breast tumour can be any size, and it has grown into the chest wall or the skin of the breast. The breast may be swollen or the breast skin may have lumps. The cancer may have spread to underarm lymph nodes, and these lymph nodes may be attached to each other or nearby tissue. Or, the cancer may have spread to lymph nodes behind the breastbone.

**Stage IIIC:** The breast cancer can be any size, and it has spread to lymph nodes behind the breastbone and under the arm. Or, the cancer has spread to lymph nodes above or below the collarbone.

**Stage IV:** The tumour can be any size, and cancer cells have spread to other parts of the body, such as the lungs, liver, bones, or brain.

## TREATMENT

Women with breast cancer have many treatment options. Treatment options include…

Surgery

Radiation therapy

Hormone therapy

Chemotherapy

Targeted therapy

You may receive more than one type of treatment.

The treatment that's best for one woman may not be best for another. The treatment that's right for you depends mainly on…

i. The stage of breast cancer
ii. Whether the tumour has hormone receptors
iii. Whether the tumour has too much HER2
iv. Your general health

In addition, your treatment plan depends on…

The size of the tumour in relation to the size of your breast

Whether you have gone through menopause

At any stage of disease, care is available to control pain and other symptoms, to relieve the side effects of treatment, and to ease emotional concerns.

## SURGERY

Surgery is the most common treatment for breast cancer. There are several kinds of surgery. Your surgeon can describe each kind of surgery, compare the benefits and risks, and help you decide which kind might be best for you:

**Removing part of the breast: Breast-sparing surgery** is an operation to remove the cancer and a small amount of the normal tissue that surrounds it. This is also called breast-conserving surgery. It can be a **lumpectomy** or a **segmental mastectomy** (also called a **partial mastectomy**). A woman usually has radiation therapy after breast-sparing surgery to kill cancer cells that may remain in the breast area. Some women will have more tissue removed but not the whole breast. For these women, the surgeon will remove lymph nodes under the arm and some of the lining over the chest muscles below the tumour.

**Removing the whole breast:** Surgery to remove the whole breast (or as much of the breast tissue as possible) is a **mastectomy**. In some cases, a skin-sparing mastectomy may be an option. For this approach, the surgeon removes as little skin as possible. In **total** (simple) **mastectomy**, the surgeon removes the whole breast but not the underarm lymph nodes.

In **modified radical mastectomy**, the surgeon removes the whole breast and most or all of the lymph nodes under the arm. Often, the lining over the chest muscles is removed. A small chest muscle may also be taken out to make it easier to remove the lymph nodes.

The choice between breast-sparing surgery and mastectomy depends on many factors:

The size, location, and stage of the tumour

The size of the breast

Certain features of the cancer

How you feel about how surgery will change your breast

How you feel about radiation therapy.

Ability to travel to a radiation treatment centre for daily treatment sessions.

The surgeon usually removes one or more lymph nodes from under the arm to check for cancer cells. If cancer cells are found in the lymph nodes, other cancer treatments will be needed.

After mastectomy, you may choose to have breast reconstruction. This is **plastic surgery** to rebuild the shape of the breast. If you're considering breast reconstruction, talk with a plastic surgeon before having cancer surgery. It's common to feel tired or weak for a while after surgery for breast cancer. The time it takes to heal is different for each woman.

Surgery causes pain and tenderness, and the skin where your breast was removed may feel tight. Your arm and shoulder muscles may feel stiff and weak, and your neck and back may hurt. Medicine can help control your pain. Before surgery, discuss the plan for pain relief with your health care team. After surgery, they can adjust the plan if you need more pain control.

Any kind of surgery carries a risk of infection, bleeding, or other problems. Tell your health care team right away if you develop any problems.

Removing the underarm lymph nodes slows the flow of lymph fluid. The fluid may build up in your arm and hand and cause swelling. This swelling is called **lymphedema**. It can develop soon after surgery or months or even years later.

## RADIATION THERAPY

Radiation therapy uses high-energy rays to kill cancer cells. It affects cells only in the part of the body that is treated.

Radiation therapy may be used after surgery to destroy breast cancer cells that remain in the chest area. Women usually have radiation therapy after breast-sparing surgery, but it's sometimes used after mastectomy too.

You can get radiation therapy to treat breast cancer in two ways:

**Machine outside the body** (**external radiation therapy**): The radiation comes from a large machine outside the body. You'll go to a hospital or clinic for treatment. Usually, women get treatment once a day, 5 days a week for 3 to 6 weeks. Each treatment session lasts only a few minutes. External radiation is the most common type used for breast cancer.

**Material inside the body** (**brachytherapy**): The doctor will place one or more thin tubes inside the breast through a tiny incision. A radioactive substance is loaded into the tube. The treatment session may last for a few minutes, and the substance is removed. When it’s removed, no radioactivity remains in your body. This method of radiation therapy may be repeated every day for a week.

Side effects depend mainly on the type of radiation and how much is given. Ask your health care team to describe what you can expect.

## HORMONE THERAPY

Hormone therapy can also be called anti-hormone treatment. If lab tests show that your breast cancer cells have hormone receptors, then hormone therapy may be an option. Hormone therapy keeps the cancer cells from getting or using the natural hormones (oestrogen and progesterone) they need to grow.

If you have not gone through **menopause**, the options for hormone therapy include…

**A drug that blocks oestrogen’s activity in the body** (**tamoxifen**)

**Surgery to remove your ovaries** (which make oestrogen)

**A drug that reduces the amount of oestrogen made by the ovaries** (**LH-RH agonist**) If you have gone through menopause, the options include…

**A drug that prevents the body from making oestrogen** (**aromatase inhibitor**)

**Tamoxifen**

The side effects of hormone therapy depend on the type used. The most common side effects are hot flashes, vaginal discharge, and nausea.

## CHEMOTHERAPY

Chemotherapy uses drugs to kill cancer cells. It may be given to women with Stage I, II, III, or IV breast cancer. Chemotherapy may be given before or after surgery.

The drugs for breast cancer are usually given directly into a vein (intravenously) through a thin needle or as a pill. You may receive a combination of drugs.

You may receive chemotherapy in a clinic, at the doctor’s office, or at home. It’s unusual for a woman to need to stay in the hospital during treatment.

The side effects depend mainly on which drugs are given and how much. Chemotherapy kills fast-growing cancer cells, but the drugs can also harm normal cells that divide rapidly:

**Blood cells:** When drugs lower the levels of healthy blood cells, you’re more likely to get infections, bruise or bleed easily, and feel very weak and tired. Your health care team will check for low levels of blood cells. If your levels are low, your health care team may stop the chemotherapy for a while or reduce the dose of the drug. There are also medicines that can help your body make new blood cells.

**Cells in hair roots:** Chemotherapy may cause hair loss. If you lose your hair, it will grow back after treatment, but the colour and texture may be changed.

**Cells that line the digestive tract:** Chemotherapy can cause a poor appetite, nausea and vomiting, diarrhoea, or mouth and lip sores. Your health care team can give you medicines and suggest other ways to help with these problems.

Some drugs used for breast cancer can cause tingling or numbness in the hands or feet. This problem often goes away after treatment is over.

Other problems may not go away. For example, some of the drugs used for breast cancer may weaken the heart. Your doctor may check your heart before, during, and after treatment. A rare side effect of chemotherapy is that years after treatment, a few women have developed **leukaemia** (cancer of the blood cells).

If you have not yet gone through menopause, some anticancer drugs may damage the **ovaries** and cause hot flashes, vaginal dryness, and other menopause symptoms. Your **menstrual periods** may no longer be regular or may stop, and you may lose the ability to become pregnant. The older you are, the more likely that this damage to the ovaries will be permanent. Women who may want to get pregnant later on should ask their health care team about ways to preserve their eggs before treatment starts.

On the other hand, other anticancer drugs don’t damage the ovaries and you may remain able to become pregnant during chemotherapy. Before treatment begins, talk with your doctor about birth control because many anticancer drugs given during the first trimester are known to cause birth defects.

## TARGETED THERAPY

Women whose lab tests show that their breast cancer cells have too much HER2 protein may receive targeted therapy. The targeted therapies used to treat breast cancer block cancer cell growth by blocking the action of the extra HER2 protein.

These drugs may be given intravenously or as a pill. The side effects depend mainly on which drug is given. Possible side effects include nausea, vomiting, and diarrhoea.

The drugs may also cause heart damage, heart failure, and serious breathing problems. During treatment, your doctor will watch for signs of heart and lung problems.

***Adapted from* What you need to know about cancer*, National Cancer Institute Publication.***

## MODULE 11: HELPING THE PARTICIPANTS ADJUSTING TO BEING A CAREGIVER

Session 1: Explanation of caregiving and adjusting to being a caregiver……9AM – 10AM
Session 2: Interactive session……………………………………………...10 – 10:30AM

### Session 1: Explanation of caregiving and adjusting to being a caregiver

**Objectives**
This session:

- To gain a deeper understanding of caregiving.
- Understand the basic concept and meaning of caregiving.
- Helping the participants adjusting to being a caregiver.

**Activities**
**Time:** 1hr
**Materials:** projector, computer, flip-cards, markers, and board.

### THE EDUCATIONAL COMPONENT

A caregiver is someone who gives basic care to a person who has a medical condition, such as cancer, that prevents him or her from independently doing activities of daily living. The caregiver helps the person with tasks such as preparing meals and feeding, taking medicine, bathing and dressing.

Caregiving can mean helping with day-to-day activities such as doctor visits or preparing food, coordinating care and services for your loved one by phone or email. Caregiving can also mean giving emotional and spiritual support. You may be helping your loved one cope and work through the many feelings that come up at this time. Talking, listening, and just being there are some of the most important things you can do.

Giving care and support during this challenging time isn’t always easy. The natural response of most caregivers is to put their own feelings and needs aside. They try to focus on the person with cancer and the many tasks of caregiving. This may be fine for a short time. But it can be hard to keep up for a long time. And it’s not good for your health. If you don’t take care of yourself, you won’t be able to take care of others. It’s important for everyone that you give care to you.

## Adjusting to Being a Caregiver

### Changing Roles

Whether you're younger or older, you may find yourself in a new role as a caregiver. You may have been an active part of someone's life before cancer, but perhaps now the way you support that person is different. It may be in a way in which you haven't had much experience, or in a way that feels more intense than before. Even though caregiving may feel new to you now, many caregivers say that they learn more as they go through their loved one's cancer experience. Common situations that they describe:

Your spouse or partner may feel comfortable with only you taking care of him.

Your parent may have a hard time accepting help from you (her adult child) since she's always been used to caring for you.

Your adult child with cancer may not want to rely on his parents for care.

You may have health problems yourself, making it hard physically and emotionally to take care of someone else.

Whatever your roles are now, accepting the changes may be tough. It's very common to feel confused and stressed at this time. If you can, try to share your feelings with other loved ones or join a support group. Or you may choose to seek help from a counselor or psychologist. Many caregivers say that talking with a counselor helped them. They feel they were able to say things that they weren't able to say to their loved ones.

### Coping with Your Feelings

You've probably felt a range of feelings as you care for your loved one. They can be quite strong and may come and go as you go through treatment with the patient. Many caregivers describe it as being "like a rollercoaster." You may feel sad, afraid, angry, and worried. There is no right or wrong way to feel or react. These feelings are all normal.

You may relate to all of the feelings on the next page, or just a few. You may feel them at different times, with some days being better than others. It may help to know that other caregivers have felt the same way that you do. One of the first steps in coping with feelings is to recognize that they exist and that having them is normal. Try to give yourself time to understand and work through your range of emotions.

**Anger:** Many caregivers say they often feel angry with themselves, their family members, or the patient. Sometimes anger comes from feelings that are hard to show, such as fear, panic, or worry. Or it may come from resentment of all that you're going through. If you can, try to avoid lashing out at others because of these emotions. Anger can be healthy if you handle it the right way. It can help motivate you to take action, find out more, or make positive changes in your life. But if these feelings persist and you remain angry at those around you, seek help from a counselor or other mental health professional. *"It's emotionally exhausting, and I never know what to expect. One minute, things are looking up. Then a couple of hours later, something happens and I don't have the answers."* —David

**Grief:** You may be mourning the loss of what you hold most dear—your loved one's health or the life you had with each other before cancer. It's important to give yourself permission to grieve these losses. It takes time to work through and accept all the changes that are occurring.

**Guilt:** Feeling guilty is a common reaction for caregivers. You may worry that you aren't helping enough, or that your work or distance from your loved one is getting in the way. You may even feel guilty that you're healthy. Or you may feel guilty for not acting upbeat or cheerful. But know that it's okay. You have reasons to feel upset, and hiding these feelings may keep other people from understanding your needs.

**Anxiety and depression:** Anxiety means you have extra worry, you can't relax, you feel tense, or you have panic attacks. Many people worry about how to pay bills, how the cancer
will affect the family, and of course, how their loved one is doing. Depression is a persistent sadness that lasts more than two weeks. If any of these symptoms start affecting your ability to function normally, talk with your health care provider. Don't think that you need to tough it out without any help. There are ways your symptoms can be eased during this hard time.

**Hope or hopelessness:** You may feel hope or hopelessness to different degrees throughout your loved one's cancer treatment. And what you hope for may change over time. You may hope for a cure most of all. But you may also hope for other things, such as comfort, peace, acceptance, and joy. If you're not able to get rid of a feeling of hopelessness, talk to a trusted family member, friend, health provider, or spiritual or faith leader. As a caregiver, feelings of hope can get you through the next 5 minutes or the next 5 days. *"There are times when you don't know how to help. You can't take away the pain. You can't take away the frustration. All you can do is be there, and it's a very helpless feeling."* —Cecile

**Loneliness:** You can feel alone in your role as a caregiver, even if you have lots of people around you. It's easy to feel like no one understands what you're going through. You may feel lonely because you have less time to see people and do things that you used to. Whatever your situation, you aren't alone. Other caregivers share your feelings.

### Other Ways to Cope

**Let go of mistakes-** You can't be perfect. No one is. The best we can do is to learn from our mistakes and move on. Continue to do the best you can. And try not to expect too much from yourself.

**Cry or express your feelings-** You don't have to be upbeat all the time or pretend to be cheerful. Give yourself time to cope with all the changes you're going through. It's okay to cry and show that you are sad or upset.

**Put your energy into the things that matter to you-** Focus on the things you feel are worth your time and energy. Let the other things go for now. For example, don't fold the clothes when you're tired. Go ahead and take time to rest.

**Understand where anger comes from-** Your loved one may get angry with you. It's very common for people to direct their feelings at those who are closest. Their stress, fears, and worries may come out as anger. Try not to take it personally. Sometimes patients don't realize the effect their anger has on others. So it may help to share your feelings with them when they're calm. Try to remember that the anger isn't really about you.

**Forgive yourself-** This is one of the most important things you can do. Chances are that you are doing what you can at this moment. Each new moment and day gives you a new chance to try again.

### Knowing Your Strengths and Limits

One way that caregivers cope is to focus their energy on things they can control. This can mean:

Helping schedule doctor visits

Helping with daily needs such as meals and errands

Taking on your loved one's tasks

Learning more about cancer and treatment options

Doing whatever else you can do

Many caregivers say that, looking back, they took on too much themselves. Or they wish they had asked for help sooner. Take an honest look at what you can and can't do. What things do you need or want to do yourself? What tasks can you give to or share with others? Be willing to let go of things that aren't essential for you to do.

### Setting Your Priorities

Make a list of your weekly tasks and activities. Figure out how much time you spend on each one and how important it is. Scratch things off your to-do list if they aren't important. That will give you more time for the things you really want and need to do. This may mean disappointing someone else. But you need to take care of what's important to you, regardless of what others may think. Most people will understand if you tell them what is going on.

*"You have to learn that if people offer, let them do something. Ask for what you need, because they don't know. You have to be willing to let go of your pride and let them help you."* —Chevonne

### Why Getting Help Is Important

Accepting help from others isn't always easy. When tough things happen, many people tend to pull away. They think, "We can handle this on our own." But things can get harder as the patient goes through treatment. You may need to change your schedule and take on new tasks. As a result, many caregivers have said, “There’s just too much on my plate.”

Remember that getting help for yourself can also help your loved one because:
You may stay healthier.

Your loved one may feel less guilty about all the things that you’re doing.

Some of your helpers may offer time and skills that you don’t have.

### How Can Others Help You?

Would you find it helpful if someone made dinner for you or ran some of your errands? If so, yo may benefit from having people help with tasks you don t have time to do.

People want to help, but many don’t know what you need or how to offer it. It’s okay for you to take the first step. Ask for what you need and for the things that would be most helpful to you. For example, you may want someone to:
Help with household chores, such as cooking, cleaning, shopping, yard work, and childcare or eldercare

Talk with you and listen to your feelings

Drive your loved one to appointments

Pick up a child from school or activities

Set up a website where people can find out what support you need or receive updates on your loved one

Look up information that you need

Be the contact person and help keep others updated on your loved one’s situation

### Who Can Help?

Think about people who can help you with tasks. Think of all the people and groups you know, including family, friends, neighbors, and coworkers. Members of your faith community, civic groups, and associations may also be able to help. The hospital or cancer center may also be able to tell you about services they offer, or have a list of agencies to call.

### Finding Respite Help

Respite (RES-pit) helpers spend time with your loved one. They can be paid or may volunteer their time. Many caregivers say they wish they had gotten respite help sooner. It can leave you free to rest, see friends, run errands, or do whatever you'd like to do. Respite caregivers can also help with physical demands, such as lifting the patient into a bed or a chair. If this service appeals to you, you may want to:

Talk with your loved one about having someone come into your home to help out from time to time.

Get referrals from friends, health care professionals, or your local agency on aging.

Ask respite helpers what types of tasks they do.

You can get respite help from family and friends, but also government agencies or nonprofit groups. Whatever you do, remember that it isn't a failure on your part as a caregiver if you need some help and time to yourself. *"We've gotten lots of support, and some of it comes from people we expected it from. But a lot has come from those we don't know very well. And others we do know well have stayed away. You just never know with people."* —Jessie

### Be Prepared for Some People to Say No

Sometimes people may not be able to help. This may hurt your feelings or make you angry. It may be especially hard coming from people that you expected help from. You might wonder why someone wouldn't offer to help you. Some common reasons are:

Some people may be coping with their own problems, or a may not have the time.

They are afraid of cancer or may have already had a bad experience with cancer. They don't want to get involved and feel pain all over again.

Some people believe it's best to keep a distance when people are struggling.

Sometimes people don't realize how hard things really are for you. Or they don't understand that you need help unless you ask them for it directly.

Some people feel awkward because they don't know how to show they care.

If someone isn't giving you the help you need, you may want to talk to them and explain your needs. Or you can just let it go. But if the relationship is important, you may want to tell the person how you feel. This can help prevent resentment or stress from building up. These feelings could hurt your relationship in the long run.

### Tips on how to ask for help

| **Roadblock** | **what others have done** |
|---|---|
| **“Her cancer is a private thing. I’d have to tell people about it to get any support.”** | You and your loved one can decide who to tell, what to tell them, and when and how. Some options are to:<br>Tell only a few people close to you for now.<br>Limit specifics about what you share. You can say, “He’s sick,” or “She isn’t feeling well today.”<br>Ask another family member, friend, or member of your faith or spiritual community to share the news.<br>Get help from services or agencies in your area instead of from people you know. |
| **“Everyone has a lot going on. I don’t want to bother them or put them out.”** | If you’re worried about being a burden to others, here are some things to think about:<br>Many people probably want to help.<br>If you let more people help, it can ease your workload.<br>Would you want to help someone else who was in a similar situation? Would you mind if they asked you to lend a hand? |
| **“I can’t explain it, but I just don’t feel up to reaching out right now.”** | Many people don’t want support when they need it most. You may often back away from your regular social life and from people in general. You may feel that it’s just too much work to ask for help.<br>Talk with someone you trust, such as a friend, member of your faith community, or counselor. This person can help you sort out your thoughts and feelings. They can also help you find ways to get support. |
| **“It’s my duty to take care of my family, not someone else’s.”** | Having a support system is a way of taking care of your family. Giving some tasks to others lets you focus on those that you feel you should do yourself. |

*Adapted from* **When Someone You Love Is Being Treated For Cancer*, National Cancer Institute.***

### Session 2: Interactive session

**Objectives**

- Brainstorming of what have been discussed.
- Share ideas and personal experience.
- Ask question where necessary.
- Create inter-personal relationship.

**Activities**

**Time:** 30 minutes

**Materials:** flip-chats, markers, board

## MODULE 111: COMMUNICATION IN PREVENTING MISUNDERSTANDING AND PROMOTING POSITIVE INTERACTION.

Session 1: Importance of communication…………………………9AM – 9:30AM

Session 2: Keeping the lines of communication open……………9:30 – 10:30AM

### Session 1: Importance of communication

**Objectives:**

After completing this session, participants will be able to:

- Discuss the importance of good communication in cancer caregiving.
- Identify basic communication skills.

**Activities**

**Time:** 30 minutes

**Materials:** computer, hand-out, flip charts, projector, markers, and board.

### THE EDUCATIONAL COMPONENT

The educational component of this session begins with a presentation, made by the facilitators, about community resources that can help cancer caregivers. It focuses on the importance of communication in preventing misunderstandings and promoting positive interaction.

### Talking with Family and Friends

Talking about serious issues is never easy. It’s hard to face an uncertain future and the potential death of your loved one. Often people are uncomfortable talking about it, or just don’t know what to say. But you will need to talk to your loved one or others about a number of issues. These might include the seriousness of the cancer, preparing for the future, fears of death, or wishes at the end of life.

Some families talk openly about things. Others don’t. There is no right or wrong way to communicate. But studies show that families who talk things out feel better about the care they get and the decisions they make.

### Talking with Your Loved One Who Has Advanced Cancer

It’s likely that you and your loved one are both having the same thoughts and fears about the end of life. It’s natural to want to protect each other. But talking about death does not cause someone to die. And keeping things to yourself doesn’t make them live longer.

You and your loved one can still have hope for longer life or an unexpected recovery. But it’s also a good idea to talk about what’s happening and the fact that the future is uncertain. And keeping the truth from each other isn’t healthy. Avoiding important issues only makes them harder to deal with later. You may find that you both are thinking the same things. Or you may find you’re thinking very different things. This makes it all the more important to get them out in the open. Talking over your concerns can be very healing for all involved.

**Often the best way to communicate with someone is to just listen.** This is one of the main ways of showing that you’re there for them. It may be one of the most valuable things you can do. And it’s important to be supportive of whatever your loved one wants to say. It’s his life and his cancer. He needs to process his thoughts and fears in his own time and his own way. You can always ask whether he is willing to think about the issue and talk another time. He may even prefer to talk to someone else about the topic.

## Bringing Up Hard Topics

Bringing up challenging subjects is draining. You may think, for example, that your loved one needs to try a different treatment or see a different doctor. Or she may be worrying about losing independence, being seen as weak, or being a burden to you.

“Ever since Audrey was diagnosed, we’ve danced around the subject. No one really wants to talk about the end. Now that her cancer has advanced, we really have no other choice. We have to discuss how she wishes to spend her final days. For our family, it’s the hardest thing in the world to do.” —Robert

What is important to remember is that your loved one has the right to choose how to live the rest of her life. Although you may have strong opinions about what she should do, the decision is hers to make. Here are some tips on how to bring up hard topics:

Practice what you’ll say in advance.

Find a quiet time. Ask if it’s an okay time to talk.

Be clear on what your aims are. What do you want as the result?

Speak from your heart.

Allow time for your loved one to talk. Listen and try not to interrupt.

Don’t feel the need to settle things after one talk.

You don’t always have to say, “It’ll be okay.”
Some people won’t start a conversation themselves, but may respond if you start first. Also, you can ask other caregivers how they have handled hard topics.

If you continue to have trouble talking about painful issues, ask for professional advice. A mental health expert may be able to help you explore issues that you don’t feel you can yourselves. But if your loved one doesn’t want to go, you can always make an appointment to go alone. You may hear some ideas for how to bring up these topics. You can also talk about other concerns and feelings that you are dealing with right now.

Your own daily stresses and fears can affect how you act with your patient. You may be torn between wanting to give time to your kids, and knowing your loved one with cancer also needs your time. That’s why it’s good to let patient know how you’re feeling, as well as to find out how they’re feeling. And never assume you know what your patient is thinking. You can’t predict how she will react to information, either. Experts say that telling patient the truth about the cancer is better than leaving their imaginations free to worry about the worst.

Although it’s a very hard chapter in a family’s life. Dealing with cancer honestly and openly can teach them how to handle uncertainty for the rest of their lives. Making the most of the present is an important lesson for everyone to learn.

### Session 2: Keeping the lines of communication open

**Objectives**

After completing this session, participants will:

- Know how to get information from their patients.
- Know about information that is available from other participants.

**Activities**

**Time:** 1hr

**Materials:** marker, board, flip charts, computer, projector.

## THE EDUCATIONAL COMPONENT

## KEEPING THE LINES OF COMMUNICATION OPEN

### Understand Your relation Actions and Feelings

Patient with breast cancer react to their loved ones in many different ways. They may: Seem confused, scared, angry, lonely, or overwhelmed.

Feel scared or unsure how to act when they see the treatment's effects on the patient

Act clingy or miss all the attention they used to get

Feel responsible or guilty

Get angry if they're asked to do more chores around the house

Get into trouble at school and neglect their homework

Have trouble eating, sleeping, keeping up with schoolwork, or relating to friends

Be angry that someone else is taking care of them now

No matter how your relation is reacting, it's usually easier to deal with their feelings before problems appear. If they don't open up to you, they may prefer talking to someone outside the family. If you notice changes or problems, you may want to ask for help from other family members who knows your patient already. Any of these may be able to suggest a mental health professional for your children, if needed.

### Other Behaviours

It's normal for some children to show signs of regression. They may begin acting younger than their years, resuming behaviors that they had stopped, such as baby talk or bedwetting. Or they may lose skills they had mastered recently. This is usually a sign of stress. Regression indicates that your children need more attention. It's a way for them to express their feelings and, in their own way, ask for support. Recognize that they are needier right now. Be patient as you work with them to get them back to their normal behavior. But don't hesitate to seek help from a social worker or other professional if you need more advice or support.

### Try to Ask Open-Ended Questions

For some families, talking about serious issues is very difficult. As challenging as it may be, *not* talking about it can be worse. Try to ask open-ended questions, instead of "yes" or "no" questions. Here are some ideas you might want to share with children of any age:

"No matter what happens, you will always be taken care of."

"Nothing you did caused the cancer. And there is nothing you can do to take it away either."

"People may act differently around you because they're worried about you or worried about all of us."

"You can ask me anything anytime."

"Are you okay talking with me about this? Or would you rather talk to Mrs. Jones at school?"

"It is okay to be upset, angry, scared, or sad about all this. You may feel lots of feelings throughout this time. You'll probably feel happy sometimes, too. It's okay to feel all those things."

### Encourage Your patient to Share Their Feelings and Questions

Let patient know they're not alone, and it's normal to have mixed emotions. Help them find ways to talk about their feelings. Keep encouraging them to ask questions throughout caregiving. Keep in mind that your patient may ask the same question over and over. This is normal, and you should calmly answer the question each time.

### Find Moments to Connect

Come up with new ways to connect. Make a point of tucking them in at bedtime, eating together, and reading to them, talking on the phone or by email. Talk to them while you fold clothes or do the dishes. Take a walk together. Going to the grocery store can even be "together time." Just 5 minutes alone with patient without interruptions can make a world of difference.

### Communicating With Your Partner with Cancer

Some couples feel more comfortable talking about serious issues than others. Only you and your partner know how you feel about it.

Some things that cause stress for you and your partner can't be solved right now. But sometimes talking about them can be helpful. You may want to say something like this up front, "I know we can't solve this today. But I'd like to just talk some about how it's going and how we're feeling."

Topics to explore may include how each person:

Copes with change and the unknown

Feels about being a caregiver or being cared for

Handles changing roles in the relationship or home

Would like to be connected to one another

Sees what issues may be straining the relationship

Feels, or would like to feel, cared for and appreciated

Feels thankful for the other person

*"I've noticed that my husband tries to stay really positive with everyone else, even his parents. He'll say he's doing great. This is frustrating for me because at home, I see that he isn't."* —Emily

As your loved one becomes sicker, you may also want to share more practical issues. These may include which decisions you should share together, and which you should make alone. Along with this, you may want to talk about the different tasks you can each handle right now.

**Find Ways to Say Thanks**

Maybe your partner used to do a lot to keep your family going. And now, because he's sick, you're trying to get used to less help. It may be hard to notice the small things your partner is still doing to help out. There's often too much going on. But when you can, try to look for these things and thank your partner for doing them.

Often it doesn't take much to put a bright spot in your loved one's day. Bringing your partner a cool drink, giving him a card, or calling to check in can show him that you care. Showing a little gratitude can make both of you feel better.

**Spend Time Together**

Many couples find that it helps to plan special time together. Some days may be better than others, depending on how your partner feels. So you may need to be okay with last-minute changes. You don't have to be fancy. It's about spending time together. That can mean watching a video, going out to eat, or looking through old photos. It can be whatever you both like to do. You also can plan occasions to include other people, if you miss that.

### Communication Troubles

Studies show that open and caring communication works best. Yet often caregivers run into:

Tension from different ways of communicating

Lack of sensitivity or understanding about appropriate ways to talk and share feelings

People who don’t know what to say, won’t communicate at all, or won’t be honest.

### Find Ways to Be Intimate

You may find that your sex life with your partner is different than it used to be. Many things could be affecting it:

Your partner is tired, in pain, or uncomfortable.

You’re tired.

Your relationship feels distant or strained.

You or your partner may not be comfortable with the way he or she looks.

You may be afraid of hurting your partner.

Your partner’s treatment might be affecting his or her interest in sex or ability to perform.

You can still have an intimate relationship in spite of these issues. Intimacy isn’t just physical. It also involves feelings. Here are some ways to keep your intimate relationship:

**Talk about it.** Choose a time when you both can talk. Focus on how you can renew your connection.

**Try not to judge.** If your partner isn’t performing, try not to read meaning into it. Let your partner tell you what he or she needs.

**Make space.** Protect your time together. Turn off the phone and TV. If needed, find someone to take care of the kids for a few hours.

**Reconnect.** Plan an hour or so to be together without trying to have sex. For example, you may want to play special music or take a walk. Take it slow. This time is about reconnecting.

**Try new touch**. Cancer treatment or surgery can change your partner's body. Areas where touch used to feel good may now be numb or painful. For now, you can figure out together what kind of touch feels good, such as holding, hugging, and cuddling.

### Communicating with Other Family Members and Friends

Any problems your family may have had before the cancer diagnosis are likely to be more intense now. This is true whether you are caring for a young child, an adult child, a parent, or a spouse. Your caregiver role can often trigger feelings and role changes that affect your family in ways you never expected. And relatives you don't know very well or who live far away may be present more often, which may complicate things.

It's very common for families to argue over a number of things at this time. These might include:

Treatment options for their loved one, or whether to continue treatment at all

When to use hospice care

What treatment the patient desires

Feelings that some family members help more than others

While everyone may be trying to do what's best for your loved one, some family members may disagree as to what this means. Everyone brings their own set of beliefs and values to the table, which makes these decisions hard. It is often during these times that families ask their health care team to hold a family meeting.

### Family Meetings

*"My sisters keep hoping for the magic bullet. I don't know how to get them to understand how serious things are."* —Verdell

Family meetings are necessary throughout cancer care. They become even more important as cancer progresses. In a family meeting, the health care team and family meet to discuss care. You can ask a social worker or counselor to be there if needed. Talk with your loved one to see if he wants a family meeting. Ask if he would like to be involved. Meetings can be used to:

Have the health care team explain the overall goals for care

Let the family state their wishes for care

Give everyone an open forum in which to express their feelings

Clarify caregiving tasks

If you need to, bring a list of issues to discuss. At the end of the meeting, ask the health care team to summarize decisions and plan next steps.

### How to Communicate When Support Isn’t Useful

Sometimes people are eager to help you because they want to feel useful. But at times you may not need the support, or you may simply want to spend time alone with your sick loved one.

If people offer help that you don’t need or want, thank them for their concern. Let them know that right now you have things under control, but you’ll contact them if you need anything. You can tell them that it always helps to send cards, letters, and emails. Or they can pray or send good thoughts.

Sometimes people offer unwanted advice on parenting, medical care, or any number of issues. It can be unpleasant to hear such comments. For example, some caregivers have shared:

“We have a problem with a member of my husband’s family. She doesn’t live here and keeps questioning all our decisions. It’s gotten so bad that we’ve had our doctor explain to her that she’s not here all day, and, therefore, doesn’t understand the situation. She has been a real pain.”

“I feel like people really want him to do the treatment they are suggesting, rather than what we feel is best. It’s making this harder than it needs to be.”

People often offer unwanted advice because they aren’t sure what else they can do. They may feel helpless to do anything, yet want to show their concern. While it may come from a good place, it can still seem judgmental to you.

It’s your decision on how to deal with these opinions. You don’t have to respond at all if you don’t want to. If someone has concerns about your kids that seem valid, talk to a counselor or teacher about what steps to take. Or if the concerns are about your loved one, you can talk to the medical team. Otherwise, thank them. And reassure them that you are taking the necessary steps to get your loved one and family through this tough time.

***Adapted from "when someone you love has advanced cancer" National Cancer Institute Publication.***

## MODULE IV: THE EMOTIONS EXPERIENCED BY THE MEMBERS OF THE GROUP.

Session 1: Coping with your feelings and Stress…………………………9 – 9:40AM

Session 2: interactive session……………………………………………..9:40 – 10:30AM

### Session 1: Coping with your feelings and Stress

**Objectives**

After completing this session, participants will be able to:

- help families improve their emotion-management strategies.
- Know how to manage stress.

**Activities**

**Time:** 40 minutes

**Materials:** computer, projector, markers, board, flip charts.

### THE EDUCATIONAL COMPONENT

This is support session which aims to help families improve their emotion-management strategies. It is emphasised that when facing the cancer of a family member, feelings of revote and blame are normal. The teaching is centred upon the emotions experienced by the members of the group.

**Stress**

**Your body may react to the stress and worry of caring for cancer patient. You may notice that:**

your heart beats faster

you have headaches or muscle pains

you don't feel like eating, or you eat more

you feel sick to your stomach or have diarrhea

you feel shaky, weak, or dizzy

you have a tight feeling in your throat and chest

you sleep too much or too little

you find it hard to concentrate

Stress can also keep your body from fighting disease as well as it should.

You can learn to handle stress in many ways, like:

exercising

listening to music

reading books, poems, or magazines

getting involved in hobbies such as music or crafts

relaxing or meditating, such as lying down and slowly breathing in and out

talking about your feelings with family and close friends

If you're concerned about stress, talk to your doctor. He or she can suggest a social worker or a counselor. You could also find a class that teaches people ways of dealing with stress. The key is to find ways to control stress and not to let it control you.

## Coping With Your Feelings

You've probably had a range of feelings as you care for your loved one. These emotions can be quite strong at times and less so at others. It takes a lot of energy to stay hopeful and cope with the ongoing waves of emotion. Now that the cancer has advanced, these feelings may be even more intense.

You may relate to all of the feelings below or just a few. You may feel them at different times, with some days being better than others. It may help to know that others have felt the same way that you do. Some of the things others have done to cope with their feelings may help you, too.

### Hope

You can feel a sense of hope, despite your role of caring for cancer patient. But what you hope for changes with time. If you have been told that remission may not be possible, you can hope for other things. These may include comfort, peace, acceptance, even joy. Hoping may give you a sense of purpose. This, in itself, may help you feel better.

To build a sense of hope, set goals to look forward to each day. Plan something to get your mind off the cancer. Here are some tips from others caring for cancer patient:

Plan your days as you've always done.

Don't stop doing the things you like to do just because your loved one has cancer.

Find small things in life to look forward to each day. You can also set dates and events to look forward to. Don't limit yourself. Look for reasons to hope, while staying aware of what's at hand.

**Inner Strength** *"My biggest struggle is that I need help, but I don't want people to give me too much of it. I want to do what I can for myself. If I have to work at something, there's a reason to live."* —Will

Caregivers find strength they didn't know they had. You may have felt overwhelmed when you first learned that doctors couldn't control your loved one cancer. And now you aren't coping as well as you did in the past. But your feelings of helplessness may change. You may find physical and emotional reserves you didn't know you had. Calling on your inner strength can help revive your spirit.

Some people find it helpful to focus on the present instead of the past or future. They start a new daily routine. They accept that it may have to be different from the old routine. Others like to plan ahead and set goals. With places to go and things to do, life stretches out before them. Others focus on the relationships they have with people close to them. Inner strength is different for each person. So draw on the things in your life that are meaningful to you.

### Sadness and Depression

It's normal to feel sad. You may have no energy or not want to eat. It's okay to cry or express your sadness in another way. You don't have to be upbeat all the time or pretend to be cheerful in front of others.

Pretending to feel okay when you don't doesn't help you feel better. And it may even create barriers between you and your loved ones. So don't hold it in. Do what feels natural to you.

Depression can happen if sadness or despair seems to take over your life. Some of the signs below are normal during a time like this. Some symptoms could be due to physical problems. It's important to tell someone on your health care team about them.

**Signs of Depression**

Feeling helpless or hopeless, or that life has no meaning

Having no interest in family, friends, hobbies, or things you used to enjoy

Losing your appetite

Feeling short-tempered and grouchy

Not being able to get certain thoughts out of your mind

Crying for long periods of time or many times each day

Thinking about hurting or killing yourself

Feeling "wired," having racing thoughts or panic attacks

Having sleep problems, such as not being able to sleep, having nightmares, or sleeping too much.

Your doctor can treat depression with medicine. He or she also may suggest that you talk about your feelings. You can do this with a psychologist or counselor. Or you may want to join a support group.

**Grief** *"I heard the doctor say, 'I'm so sorry, but . . .' and then I heard nothing else. My head was spinning, and I kept saying to myself, 'No, the doctor must be making a mistake. "* —Rosa. We all cope with loss or the threat of loss in different ways. You may feel sadness, loneliness, anger, fear, and guilt. Or you may find the way you think changes from time to time. For example, you may get easily confused or feel lost. Or your thoughts may repeat themselves over and over again. You may also find yourself low in energy. You may not want to do things or see people. These are all normal reactions to grief.

What you grieve for is as varied as how you think and feel. You may be grieving for the loss of your body as it used to be. You may grieve for the things you used to be able to do. You also may grieve losing what you have left: yourself, your family, your friends, and your future. It's okay to take time for yourself and look inward. It's also okay to surround yourself with people who are close to you. Let your loved ones know if you want to talk. Let them know if you just want to sit quietly with them. There is no right or wrong way to grieve.

Often people who go through major change and loss need extra help. You can talk with a member of your health care team, a member of your faith community, or a mental health professional. You don't have to go through this alone.

**Denial-** *"I feel like the reality of this cancer isn't going to go away if I deny it. If I did that, I might miss the comfort I get from sharing fears and concerns. I don't want to miss the sense of well-being I have knowing I have taken care of my loved ones."*—Carrie

It's hard to accept the news that your loved one cancer has spread or can no longer be controlled. And it's natural to need some time to adjust. But this can become a serious problem if it lasts longer than a few weeks. As time passes, try to keep an open mind. Listen to what others around you suggest for your care.

**Anger-** The feeling of "No, not me!" often changes to "Why me?" or "What's next?" You have a lot to deal with right now. It's normal and healthy to feel angry. You don't have to pretend that everything is okay. You may be mad at the doctor, family members, neighbours, and even yourself. Some people get angry with God and question their faith.

At first, anger can help by moving you to take action. You may decide to learn more about different treatment options. Or you may become more involved in the care you are getting. But anger doesn't help if you hold it in too long or take it out on others. Often the people closest to us are the ones who have to deal with our anger, whether we want that or not.

It may help to figure out why you are angry. This isn't always easy. Sometimes anger comes from feelings that are hard to show, such as fear, panic, worry, or helplessness. But being open and dealing with your anger may help you let go of it. Anger is also a form of energy. It may help to express this energy through exercise or physical activity, art, or even just hitting the bed with a pillow.

**Stress** *"Just because I love God and know where I'm going, doesn't mean I'm not stressed. I worry all the time about what's to come. I try to focus on the things I can control, but it's not always easy."* —David

Everyone has stress, but most likely you're having a lot more now. After all, you're dealing with many changes. Sometimes, you may not even notice that you're stressed. But your family and friends may see a change.

Anything that helps you feel calm or relaxed may help you. Try to think of things that you enjoy. Some people say it helps to:
Exercise or take a walk.

Write thoughts and feelings in a journal.

Meditate, pray, or do relaxation exercises.

Talk with someone about your stress.

Do yoga or gentle stretching.

Listen to soothing music.

Express yourself through art.

**Ways You Can Cope**

You may be able to keep doing many of your regular activities, even though some may be harder to do. Just remember to save your strength for the things you really want to do. Don't plan too many events for one day. Also, try to stagger things throughout the day.

***Adapted from "coping with advanced cancer" National Cancer Institute Publication***

**Session 2: interactive session**

**Objectives**

- Sharing personal experiences among the participants.
- Allow to ask any question regarding caregiving.

**Activities**

**Time:** 50 minutes

**Materials:** markers, flip charts, board, projetor, and computer.

## MODULE V: INFORMATION ABOUT THE IMPORTANCE OF SELF-CARE AND HOW CAREGIVERS CAN PRACTICE SELF-CARE

Session 1: Offers information about the importance of self-care and how caregivers can practice self-care…………………………………………………………9 – 10AM

Session 2: Questions and Answers……………………………………10 – 10:30AM

### SESSION 1: Self-care and the practice of self-care.

**Objectives**

- Know the importance of self-care.
- We able to practice self-care.

**Activities**

**Time:** 1hr

**Materials:** markers, board, flip chats, projector, and computer.

**How do I look after myself?**

Looking after yourself is important, so you should take time to do something for yourself every day. Don't feel guilty caring for yourself – you are important and deserve to be looked after. Your relative will also benefit if you are feeling a bit better about yourself. Even if it feels selfish to you, many patients feel less of a burden if they can see that the person caring for them is getting some enjoyment and rest. It may not be possible to take away all the stress but here are some things that might help:

- **Get some exercise.** Do something physical. Go for a walk and/or do some bending and stretching. There are exercise videos, DVDs and podcasts available for you to use at home if you find it difficult to leave the house. Exercise will help you maintain your energy. Try and choose an exercise you enjoy.
- **Get enough sleep.** It is common for carers to have some trouble sleeping. Limit coffee and alcohol in the evening. Consider herbal teas, a warm bath and/or some relaxing music to help you get off to sleep. If you can't fall asleep, get up for a little while, try to do something relaxing and then attempt to fall asleep again. If your night time sleep is disturbed, try to get a brief rest during the day. Most of us can manage with less sleep from time to time, but if you are finding it hard to sleep on a regular basis, discuss this with your nurse or doctor.

- **Maintain a healthy diet.** This can be hard at times, particularly if your relative has lost their appetite. However, you need your strength, so eat a balanced diet and don't forget to 'treat' yourself from time to time with food you enjoy.
- **Do something just for yourself everyday.** Make a list of 10 things you enjoy that would give you a short break and replenish your energy. Do at least one of these things each day. You may feel as though you are managing quite well; however, looking after yourself also helps prevent stress.
- Try and remain in contact with your friends as much as possible.
- Depending on your religious or spiritual beliefs and practices, you may find help in prayer, meditation, or discussion with a trusted pastoral counsellor. It may also be important for you to continue your involvement with your religious community or other community involvement**.**

### How do I maintain hope when the situation seems hopeless?

Maintaining hope while expecting the worst is a 'tough call' and your feelings of hopefulness and hopelessness may change many times. Some people have found help in hoping for small things, even in the face of death and loss.

*'I know I can't hope for her to be cured, but I can hope that she will have a good day today.'*

*'I hope I can keep my sense of humour even when things get pretty bad.'*

*'I hope she knows I'm here even though she's in pain.'*

### Accepting help

Some former carers did not seek help for themselves because they felt that their relative's needs were more important or that the palliative care team was too busy to offer additional assistance. Remember that your well-being is a vital part of being able to support your relative. It is the palliative care team's responsibility to help you, so don't be afraid to let them know if you need more support.

If you have relatives or friends who are willing to help, use them! Their assistance may take some of the strain off you. Keep handy a list of things that other people could do for you, such as preparing a meal, being with your relative while you go to an appointment or do some shopping, making phone calls or taking messages. That way, if you are talking to someone and they offer to help, you can make suggestions from your list.

Asking for help does not mean that you have failed or that you are not coping; it means that you are being smart, sensible and acting on your feelings.

### Family meetings

A family meeting may be arranged by the palliative care team and usually involves the patient (if well enough to attend), family carers and relevant health care professionals. The purpose of a family meeting is to involve you in developing a 'care plan' for your relative and clarifying the 'goals of care'. The care plan is based on your relative's specific needs and

includes your own needs. The care plan is regularly reviewed by the team, especially when your needs change, or your relative's needs change. Having a plan can help you to 'keep on track'.

### Juggling your needs, your relative's needs and life's usual duties

Some days you may feel as though all you have done is provide care and had no time for other things. Despite your relative's needs, life goes on around you and you may find it hard to manage. You may feel as though you are not in control. These are normal responses. You are reacting to a great deal of change and having to try and adapt very quickly. Here are some suggestions that may help you gain a greater sense of control of the situation:

- ***Prioritise tasks into lists:*** 'must do', 'would like to do', 'if I get a chance I'll do'. You may like to write down a list of things you would 'like to' achieve today, but don't make the list too long. Remind yourself that it is okay if you don't get everything done. At the end of the day think about the things you did achieve rather than the things you didn't.
- ***Take one day at a time.*** It is normal to think about the future but try to take the challenges of caring one day at a time.
- ***Consider writing care related issues down in a diary.*** You can keep track of things as they occur and you can use it as a reminder when asking questions or giving details to the palliative care team or other carers.
- ***Keep all written information about your relative in one place.*** For example place medication charts, palliative care team information, useful phone numbers and this guidebook all in one place.
- ***Get an answering machine.*** You don't have to pick up the phone if you are busy or having some time to yourself. Use this opportunity to have private time with your relative, time for an uninterrupted meal or just for time out.
- ***Get a mobile phone*** **if finances permit.** You can go out of the house knowing that if there is an urgent issue with your relative then you can be contacted.

• ***Make a list of friends/relatives you know you can ask for help.*** If there is no-one willing to help, speak with the palliative care team about a volunteer or see the social worker.

• ***Consider asking a friend/relative to stay overnight.*** This may allow you to get a good night's sleep and you might appreciate the extra company.

• ***Get someone else to do the household chores*** (unless you find these chores relaxing). Access the local council, private services in your local newspaper or ask a friend or relative to help.

• ***Ask your relatives/friends to bring over some prepared meals*** (soups, casseroles etc). If this is difficult, consider 'meals on wheels' or other home delivery food services.

• ***Ask one of your relatives/friends to phone or accept calls from 'others*** 'who need or want to know the latest information related to your relative. This saves you repeating the story over and over.

• ***If your work outside the home is making it stressful*** trying to juggle both roles, discuss the issue with your employer (or other people involved) to see how much flexibility you can have. You may also need to consider taking special leave.

• ***Consider sending a regular email to friends and families to keep them updated.*** This allows you to ensure relevant people are aware of how things are but saves you making lots of phone calls.

• ***Control the number of visitors.*** Relatives/friends may want to visit often; however, it is okay to say that the person you are caring for is very tired. You could put a note on the front door to say they are resting. If required, ask visitors to please always phone first. It may help to set up visiting hours to avoid a constant stream of visitors. Don't feel as though you always need to be the host. Ask others to make a cup of tea for you.

• ***If there is more than one person caring.*** Try and set up a roster system to share the load. Get family and friends together and ask what they would prefer to do, for example one person may prefer to offer emotional support rather than physical care. Another may want to act as the key contact with health professionals.

• ***Give yourself regular rewards.*** Take a break, have some nice food, do something special for yourself that makes you feel good and lifts your spirits.

**Feeling overwhelmed? It's time to relax!**

People respond to caring in different ways. Please understand it is very common to feel any or many of the following: anxious, down, angry, upset, grumpy, guilty or confused. Don’t ignore how you are feeling. Some carers also feel the strain physically; they might get very tired or get headaches from time to time. People deal with tension in different ways. There is no right or wrong way of managing the difficult emotions that arise. Here are some things that may help:

- *Plan to do something you enjoy* within the next few hours.
- *Discuss your feelings* with someone you feel comfortable with (a relative/friend, religious/spiritual professional or someone from the palliative care team).
- *Look for the positive* and find some benefits within your situation.
- *Plan to give yourself a big reward* in the next couple of days, for all your hard work so far.
- *Maintain hope* – that, even in the context of serious illness, things can get better.
- *Think of something funny* that you have experienced or heard, or tell some jokes.
- *Listen to a relaxation tape*
- *Remind yourself that:*

– You are doing the best you can.
– There are options (even if you can’t see them clearly at the moment).
– You are not alone.
– Your feelings are normal.
– There is help available.
– You will feel better.

- ***Try this relaxation exercise:* ‘10 steps to feeling calm’.**

It may take some practice, but it gets easier.

(1) Find yourself somewhere where you know you can have peace and quiet for at least 20 minutes.
(2) Take 10 deep breaths.
(3) Find a comfortable place: lie down on the floor. You may need to put something soft underneath you.
(4) Loosen your clothes and take your shoes off.
(5) Close your eyes.
(6) Take a deep breath and slowly breathe out.
(7) tense all your body muscles; count to five and then slowly release (do this 3 times).

(8) Begin tensing then relaxing muscles at the top of your head and work your way to your toes (take your time).
(9) Keep your eyes closed and imagine a real or fantasised place, which is peaceful. Imagine pleasant sounds or sights. Stay in this place until you feel ready to return.
(10) Count from 1–10 slowly, open your eyes. When you are ready stand up slowly
***Adapted from "Supporting a Person Who Needs Palliative Care"- A guide for family and friends by Peter Hudson***

## SESSION 2

Questions and answers

**Objective**

- Share ideas and personal experience.
- Ask question where necessary.
- Create inter-personal relationship

**Activities**

**Time:** 30 minutes.

**Materials:** flip charts, computer, projector, makers, board.

## MODULE VI: Provide tips on helping caregivers to give practical care, how to deal with common symptoms and how to deal with patient's emotions

**Session 1:** Practical care, how to deal with common patient's symptoms/emotions...9-9:40AM

**Session 2:** Review of previous modules………………………………………9:40–10:30AM

### Objectives

- Have the knowledge of practical care.
- Know what to do when patient present certain symptoms and emotion.

### Activities

**Times:** 40 minutes

**Materials:** computer, projector, board, markers, flip charts.

### Practical care

### Information about your relative's illness

A person's medical history is often a private matter. However, usually there are a couple of people in our lives that we don't mind sharing this information with. If possible, get your relative to write down the people who they will allow access to this medical information, and ask them to sign it and have someone sign as a witness. If you think that you are going to be a main carer for your relative, having their written permission to give and receive information about their medical situation may make it easier for you. This will make communication easier when you need to speak to nurses, doctors and other health professionals about your relative's condition from time to time.

### Providing practical care

Your relative may be quite independent with some tasks, or may require assistance. You will find it helps if you have some knowledge of these tasks, so you can assist when necessary. Remember, only do things you feel comfortable with. If you are unsure at any time, seek guidance from the palliative care team.

**Helping with medications**

- Always double-check the label on containers to ensure that you are giving the right medicine at the right time. Not all medicines are taken orally (by mouth), so check first. Not all medicines are in tablet form, some may be liquid and others may need to be given by injection or via a skin patch.
- Sometimes people are given a list, from the hospital, of what medicines are for and when to take them. If you haven’t got a list and you would like one, speak with the GP or palliative care team.
- Some medicines need to be given at certain times; others are given ‘as required’. For example, some pain medications should be taken only when the person gets pain, whilst other pain medications are given regularly at specific times of the day or night.
- Medicines should only be taken ‘as directed’. If your relative is not sure about this, speak to the doctor or nurse.
- If syringes and needles are being used, ask about safe disposal via a ‘sharps disposal’ container available from chemist or local council.
- It is quite common for medicines to change. When a medicine is no longer needed, it should be discarded to avoid accidental use. Unused medicines should be returned to the chemist for safe disposal. If there is a chance that a medicine may need to be used again in the future, store it in a safe, cool and dry place, away from the medicines that are being used every day.
- If you have only a few tablets (or other medicines) left, phone the doctor to arrange for another prescription. Try not to leave this too late. Where possible, avoid having to arrange this on a weekend.
- If swallowing is difficult, some tablets can be crushed and given with food or fluids. Check first, with the doctor or nurse, as some tablets should not be crushed, and an alternative form of the medication may need to be prescribed. Some people may need to take strong pain medicines, such as morphine. If a strong pain medicine is required, the doctor, chemist or palliative care team can explain why, how and when to use it. Written information is also available.
- In many cases the palliative care team may arrange for some medicines, in the form of injections, to be left in a safe place within the home. These are sometimes referred to as ‘emergency medications’ and are prescribed ‘just in case’ your relative has discomfort that isn’t relieved by medicines taken by mouth. For example, if a person

has nausea and can't take their pain medicine by mouth, the nurse or doctor may need to visit to give an injection to stop the nausea or to prevent the pain.

- Many drugs (medicines) given to relieve pain also have unwanted side effects. Speak with your nurse about this, so you know what to look for. Most side effects wear off within 24 or 48 hours as the body gets used to the drug. However, it's much better to *prevent* the side effects where possible; for example, by giving laxatives regularly to prevent constipation or having anti-nausea medications on hand to prevent vomiting.
- Some patients and families worry about the use of strong pain medicines (opioids such as morphine). They worry that the person may become addicted, or that the prolonged use of these powerful drugs may hasten death. You can rest assured that palliative care is based on the latest evidence. This shows that when given for pain, opioids do not cause addiction; and when used in prescribed doses, do not hasten death. In fact, many patients feel so much better when their pain is relieved; their appetite improves, they can move about more freely and can often resume pleasurable activities.

**Providing hygiene care**

- Assisting with hygiene care may be done in different ways: you might just be nearby to 'lend a hand', you may offer to wash your relative's face and hands, or you may want to assist with a complete shower or bed bath. Your relative may also need help to move out of bed and to the bathroom. The nurse can guide you with any of these tasks. If preferred, a nurse can provide the hygiene care and/or you can do it together.
- Safety is important. Consider having rails installed in the bathroom, and where there are steps. Talk to your palliative care team about hiring a shower/bath chair so that your relative does not have to stand. A hand held shower hose may also make things easier. A health professional can assess the bathroom set up in your home to improve safety. There are several other devices that help people move safely if they are unsteady on their feet.
- If incontinence, that is, loss of control over passing urine or faeces, is an issue there are a number of aids or products that can help your relative feel clean and comfortable. Don't be afraid to talk to one of the palliative care team or your doctor about this.

## Assisting with eating and drinking

- Many people with a life threatening illness lose their appetite This may be caused by the disease or a side effect of treatment and/or medications or through feeling sick, downhearted, constipated, tired or having a sore or dry mouth. Unrelieved pain can also result in loss of appetite.
- Despite the reason, caring for a person who is not interested in food and is losing weight can be very hard. Here are some suggestions you can offer:

– Smaller meals, more often, rather than three big meals. Serve food on smaller plates and don't fill drinks to the top of the glass.

– New types of foods. People's desire for certain food tastes may also change. For example, people may no longer like sweet tastes and may now prefer spicy food.

– Nutritious drinks. These can be bought from chemists and some supermarkets. You can also make your own juices or smoothies. If a person is not interested in solid food, offer drinks regularly.

– A glass of wine or other alcohol before a meal can help stimulate appetite. Alcohol should not be taken with some medicines so check with the doctor to see if it is okay.

– Good mouth care. Keep the mouth moist by encouraging regular teeth cleaning, drinks and mouth rinses. If you notice white 'flaky' spots in the mouth let the doctor or nurse knows. This is common and is usually easily treated with a special medication.

As your relative's illness progresses, you may notice they are eating less. It may not be so important at this stage to have 'well balanced meals' every day. It may be more important to concentrate on what your relative *enjoys*, as the following example shows.

*'I've always been so careful to give auntie her vegetables each day. Now that I have to feed her myself I see that she's constantly spitting them out. When I give her some ice cream or some chocolate, her eyes light up and she swallows the lot. The dietician told me it's better for her to have food she enjoys rather than no food at all!'*

## Help with other 'technical' care

Some patients cared for at home require special management of various tubes, wounds, drainage systems, injections, etc. Many relatives develop significant skills at managing this complex care. However, others are not so comfortable. As one carer said, *'I can do everything else, but I get all jittery with this technical equipment'.*

If you are concerned with any of this care, discuss it with the nurse. You may want to take time to learn some new skills, or you may prefer to leave all the technical care to the nurses.

**Use of special equipment**

The equipment you need depends on your situation. The use of equipment can increase your relative's independence, make it easier for you and promote a safer environment.

The following types of equipment may need to be used in the home:

- Shower chair – enables a person to safely sit down in the shower.
- Commode – portable toilet, looks like a chair
- Bath/shower hand rails – provides support for standing/sitting in a bath/shower
- Bath board – enables a person to safely get into and out of the bath
- Slipper pan/urinal – devices to allow toileting in bed
- Absorbent and plastic sheets – used on a bed or chair where incontinence (uncontrolled bladder or bowels) is an issue
- Dosette box – special medicine container that helps people to take the correct tablets at the right time
- Syringe driver – a device used to deliver medications under the skin rather than by mouth
- Sharps container for used syringes and needles
- Call bell or intercom
- Disposable gloves
- Hospital bed – a bed that can be raised or lowered and has sides to prevent falls.
- Bed stick – helps the person to sit up and get in or out of bed
- Urinary catheter – tube into the bladder to assist passing of urine
- Pressure relieving devices – special mattresses, sheepskins or cushions used for comfort in bed or a chair and to prevent bed sores
- Walking frame – a device used to help with walking
- Wheelchair – allows a person to be mobile if they are unable to walk easily
- Slide sheets – slippery sheets that make it easier to move your relative around when they are in bed. If you think you need any of the above the palliative care team can assist you in choosing what is required. They can also help you obtain the equipment

and show you how to use it. There may be some safety tips that you need to know. A hire charge usually applies.

### Dealing with common symptoms

The word symptom is used to describe an issue related to an illness. When a person has a serious illness, and where curative treatment has stopped, the focus of care is on relieving symptoms that may arise. Every person is different and so are the symptoms that might occur. It is important to highlight the common symptoms (pain, constipation, nausea, tiredness, breathlessness) and some basic ways of relieving them. Symptoms may not disappear completely, but in most cases symptoms can be controlled to a level that is comfortable. Your role in helping to recognise and manage the symptoms will depend on how independent your relative is, your relationship and what you feel comfortable doing. Remember that relief of symptoms is one of the major aims of the palliative care team, so help is available. If a symptom arises that is not mentioned here then speak with the palliative care team and they will provide you with more information. It may help to keep a diary or a daily journal to jot down the time and the words used by your relative to describe a particular symptom.

### Pain

Many carers worry about the comfort of their relative. This is very understandable. The first thing to be aware of is that not all people who need palliative care suffer ongoing pain. It is also important to realise that a person’s level of comfort is a very personal feeling. We all feel discomfort in different ways and at different levels. People often associate discomfort with pain; however, we may also feel uncomfortable if we feel sick, tired, worried or restless. The important thing is that if your relative says they are in pain then the palliative care team can help. Despite advances in treatment, pain may not always be completely removed. The palliative care team will help you with various strategies to reduce the pain as much as possible.

The ways of dealing with pain vary from person to person. Here are some common things you could do if your relative is in pain:

- Assess the pain. You may want to ask your relative these questions, and write down the answers. This will help you to describe the pain to the nurse or doctor and assist in the choice of treatment.

(1) Where is the pain? (Sometimes the pain may be more than one area).

(2) What does the pain feel like? (e.g. sharp, throbbing, burning).

(3) How long has the pain has been there?

(4) Is this a new type of pain?

(5) How would you rate the pain on a scale of one to ten? (1 being ‘no pain’ through to 10 being ‘excruciating pain’). If the answer is 7 or 8 out of 10 this would be regarded as a considerable amount of pain).

(6) Do you feel like vomiting?

(7) When did you last have your bowels open? (constipation can cause pain)

Alternatively, the palliative care nurse may give you a pain chart which either you or your relative can fill in. If your relative has dementia, or is unable to understand or answer the questions, it is important that you ask the nurse how to look for signs of pain (e.g., when your relative is moving from bed to chair, eating, walking, or being assisted to move in bed).

- Managing the pain:

(1) Ask your relative to lie on the bed or to sit down.

(2) Ask your relative to take 10 deep breaths.

(3) If your relative has been given some medicines to take (which are for the pain they are feeling) give the medicine as directed on the container. Check first to see what pain medicines have already been taken that day. If your relative has had as much as they are allowed phone the palliative care service.

(4) Ask your relative to try to take their mind off the pain by reading, watching TV or listening to some music.

(5) Offer a massage of feet, hands or shoulders.

(6) If nausea (feeling like vomiting) or constipation (no bowel action for several days) is an issue, this may be a possible cause of the pain (refer to sections on nausea and constipation below).

(7) If the discomfort has not eased after 30 minutes phone the palliative care team. They will be able to review the problem and suggest other ways to reduce the pain.

**Concern about opioids and hastening death**

Opioids are very strong pain killers which will only be prescribed if the pain is not managed with milder medicines. Some patients and relatives fear the use of opioids (like morphine for example) because they think it might hasten death. It’s important to remember that *what causes death is the underlying disease, not the drug.* The doctor will carefully reduce the medication if it is causing serious side effects. However, it is important that you know about the effect of these drugs and why they are used. Ask your palliative care nurse for a brochure which explains all about opioids.

### Nausea

This is the term used when someone feels the urge to vomit or feels sick at the thought or sight of food. The cause of nausea can be related to the disease, medications, chemotherapy, radiotherapy, constipation or an imbalance of chemicals within the body.

If your relative has nausea:

(1) Ensure a bowl or bucket is within easy reach in case they vomit.

(2) Ask how they rate the nausea on a scale from 1 to 5 (1 being 'very little' nausea and 5 being 'extreme' nausea).

(3) If anti-nausea medicines are prescribed check to see if they have been taken as directed. If the prescription allows, give the anti-nausea medication, unless the thought of trying to take a tablet makes your relative feel worse.

(4) Some people prefer not to eat or drink anything until the nausea passes; others find small amounts of food or drinks helpful.

(5) Ask when was the last time your relative had a good bowel motion. If it is longer than two days follow directions under the 'constipation' symptom below.

(6) encourage your relative to rest. Suggest deep breathing. Play some soft music. Offer a foot or neck massage. If your relative feels up to it, a bath or shower may help.

(7) If nausea is not relieved after one hour or if it gets worse, phone the palliative care team.

### Constipation

Constipation occurs when a person does not open their bowels for several days. This symptom can cause nausea, pain and tiredness. The cause of constipation can be related to decreased fluid intake, limited mobility, poor diet or the person's illness. Constipation is also related to side effects of strong pain medicines. In most cases constipation can be prevented.

To prevent constipation:

(1) Encourage drinks such as water and juices.
(2) If possible, have foods high in fibre, as well as plenty of drinks.
(3) suggest that your relative has a short walk each day if they feel up to it.
(4) Take note of the bowel actions: are they hard, soft, small, or liquid?
(5) Keep a record of when bowel actions occur.
(6) If your relative is prescribed strong pain medicines (such as morphine), make sure that laxatives have been ordered.
(7) There are many natural remedies for constipation that can be used in conjunction with prescribed medicines. Ask a member of the palliative care team for suggestions.
(8) If there is no bowel action for 2 days, speak with the palliative care team who will set up a plan specific to your relative's needs.
(9) Do not assume that if your relative is not eating that they do not need to use their bowels – constipation can still occur even when little food is eaten.

### Breathlessness

Breathlessness or difficulty breathing can be an unpleasant symptom. It is usually caused by disease of the lung, or asthma, emphysema, chest infection, and pressure from other body organs, or anxiety. While the specific treatment depends on the cause, here are some general tips which may help:

(1) Encourage your relative to sit in the upright position and stay with them.
(2) Put on a fan and/or open a window.
(3) Suggest that your relative wear loose fitting clothing.
(4) Put on some calming music, maintain a gentle, reassuring presence, offer a foot, hand or shoulder massage.
(5) If medicines for breathlessness have been prescribed, ensure they have been taken as directed.
(6) Oxygen via a mask or nasal prongs is not routinely needed and requires a doctor's order to be used.
(7) If breathlessness is not relieved and is causing distress, phone the palliative care team.

### Fatigue

Fatigue is very common in people with life threatening illness. It is a feeling of extreme tiredness that can be quite frustrating (or debilitating). There are a number of possible causes of fatigue. These include lack of sleep, low oxygen in the blood, poor diet, depression, effect of chemotherapy or radiotherapy, infection, or the effects of the disease itself.

Fatigue can be (not always) quite hard to manage. The following strategies may help:

(1) Encourage short naps during the day.

(2) Suggest regular gentle exercise.

(3) Encourage nutritious food and drinks.

(4) Plan to do the most energetic tasks (eg shower or bath) when energy levels are higher.

(5) encourage your relative to take up a hobby that does not require a lot of energy. For example: board games, talking books, listening to the radio and/or watching television or videos.

(6) If you think that fatigue has become worse, speak with the palliative care team.

### Delirium

This is a change in a person’s thinking, memory and behaviour and is common in patients who are receiving palliative care. The changes are caused by a disturbance in brain function due to illness or sometimes medication.

Patients receiving palliative care either in hospital or at home are often sicker than other patients; and are taking a variety of medicines. We know that patients who are seriously ill, taking several different medicines, and who may have infections or have had recent surgery may develop delirium. Also patients who are older, or who already have some memory problems are more likely to develop delirium.

Delirium can be very distressing for the person who has it, and for their family. People with delirium have difficulty remembering new information, trouble concentrating and paying attention, and sometimes have difficulty telling day from night. The person with delirium may be confused and not recognise familiar people, or they may become fixated on one thing, or become suspicious. Sometimes delirium causes hallucinations when people see things that are not there.

The doctors and nurses looking after your relative will look for causes and try to treat the cause so that the delirium will settle. Sometimes the patient may be prescribed tranquillising medicine to help them to feel calmer and to make sure they are safe.

The changes in the person’s thinking and behaviour when they have delirium are not usually permanent and do not mean that the person has an ongoing mental health problem. However it must be pointed out those patients in a palliative care setting may be very ill and close to death, and in this situation the thinking, memory and behaviour problems of delirium may not settle completely.

The best way of helping your relative with delirium is to make sure you have eye contact with them, speak slowly and calmly and remind them who you are, where they are and that you are there to help. If your relative is in hospital or another care facility it is very helpful for staff if family and friends can stay with the patient whenever possible, as patients with delirium respond better to familiar people than strangers.

It is best for the person with delirium not to have too many visitors at once, nor to have too much stimulation such as loud music or TV. It is also important to encourage them to drink fluids as they may get dry, especially if they are restless and not wanting to eat and drink.

Please advise health professionals if you think there are changes in your relative that might mean they are developing delirium. It is also helpful to give the staff as much information as you can about your relative's previous history as this may be important in diagnosing the cause of the delirium, and preventing delirium recurring.

### Complementary therapies

*Complementary* therapies are treatments used together with conventional medicine. *Alternative* treatments are often considered to be those used in place of conventional medicine and are sometimes referred to as unproven remedies.

Complementary physical and psychological therapies include massage, acupuncture, reiki, hypnosis and guided imagery. Complementary therapies can have beneficial outcomes in some circumstances. However, it is strongly recommended that you speak with a health professional for further information about what complementary therapy(s) might be suitable for your relative or for you. Other examples include aromatherapy, music therapy, art therapy, pet therapy. If you would like to find out more, ask the palliative care team. Here are two examples of complementary therapy:

*'I had no idea what music therapy was until the palliative care nurse asked whether I found music helpful in relaxing me and helping the pain. Within two days I had a visit from this beautiful harpist, and in one hour the pain just melted away.'*

*'The art therapist brought some paper and paints to help George express his feelings in ways other than words. One day he expressed his anger by painting the cancer cells invading his body. Another day he painted a soothing sunset.'*

It is quite common for people with life threatening illness to consider other medical treatments that are not routinely used by doctors. This is because people often want to explore all possible treatment options. It is highly recommended that before your relative uses alternative treatments that you discuss these options with your relative's doctor or medical specialist. While some of these alternative treatments may be promoted as being beneficial some might in fact be harmful. It is wise to talk with a medical specialist about the benefits of any alternative treatments.

## Emotional care

It is very hard to provide precise tips on dealing with your relative's emotions, as every relationship is different. It may help to be aware that your relative will have 'highs and lows' throughout the illness. At times they might feel angry, upset, grumpy or irritable and may even blame you for some of their emotions. However, sometimes they may even feel very positive.

Your relative may be thinking about a number of major issues about death and dying. Some of these things may be easier to talk about with someone else, perhaps someone from the palliative care team. The point is, you do not have to have all the answers.

Some things which may help include:

(1) Providing some time alone each day, if desired.

(2) Asking if there is anything that you can do to make things easier.

(3) Suggest some enjoyable things to do together.

(4) Asking if there is anything that they have a particular desire for.

(5) Remember that it is normal for your relative to feel downhearted from time to time.

(6) Encourage involvement in 'day to day' things such as the news and social activities.

(7) Remind your relative of the skills and different roles of the palliative care team.

(8) Tell them how much you care for them and want to help them.

In some instances patients and/or their carers become so worried about what is happening that they become depressed or anxious. Everyone has times where they feel a bit low or 'flat'. *Depression* usually means the person experiences the following symptoms for more than two weeks: feeling sad, down or miserable most of the time, lost interest or pleasure in most of their usual activities. While there are many types of *anxiety disorders* and the symptoms for each disorder are different, some general signs and symptoms include:

- feeling very worried or anxious most of the time
- finding it difficult to calm down
- feeling overwhelmed or frightened by sudden feelings of intense panic anxiety
- experiencing recurring thoughts that cause anxiety, but may seem silly to others
- avoiding situations or things which cause anxiety (e.g. social events or crowded places)
- experiencing ongoing difficulties (e.g. nightmares/flashbacks) after a traumatic event.

If you or your relative have these feelings please make the doctor or nurses aware. Then, a thorough assessment can be undertaken so that appropriate strategies can be used to try and lessen the depression and/or anxiety.

### Spiritual care at the end of life

Spiritual care is much broader than formal religious practices. It refers to any support related to questions about life's meaning, depending on the person's values and beliefs. The kind of spiritual care required will differ for every person. If you are unsure of your relative's spiritual needs, you (or someone else) can open up a conversation with questions such as:

'Is there any particular person, place, or object that gives you hope and strength at this stage of your illness?'

*'Is there a particular religious ritual you would like assistance with?*

*'Do you have any particular concerns as death is approaching?'*

*'Is there anyone you would like to talk to about spiritual matters?'*

If your relative is in the habit of attending religious services, and this is no longer possible, discuss the matter with the local minister, priest, rabbi, or other religious representative. For example, someone from the religious community may arrange to come to your home. It is important for these religious contacts to be maintained, as well as any familiar rituals. These visits may help you and your relative to feel less isolated, and to feel that you remain an important part of the religious community. Opportunities to receive Holy Communion or to participate in other rituals, to make confession or to seek religious ‘counsel’ are all a part of spiritual care, depending on your relative’s wishes and familiar practices. In times of crisis spiritual care can be very helpful, as in the following example.

*June was devastated when she learned there was no more curative treatment for her cancer. She had several operations and now the oncologist suggested ceasing the chemotherapy. June and her family felt the situation was hopeless.*

*The palliative care chaplain suggested June and her family might like a brief ritual to mark the transition from hospital to home. A prayer was offered, giving thanks for medical skills and acknowledging a different form of care would now be required to maintain June’s comfort.*

Other spiritual matters may include reminiscing or conducting a ‘life review’, with you and/or with another family member or friend. This provides opportunity to ‘tie up loose ends’, to laugh and to cry, and to tap into the ‘spirit’ of your relative. Some people choose to write the life review down so that it can be available as a memoir. Other ways of tapping into the ‘spirit’ or the ‘whole person’ may be through music, art, literature, photos or conversation. A way into this ‘spiritual realm’ may be to ask you relative:

‘What’s the most important issue for you at this time?’ Or ‘If you had one wish, what would it be?’

Remember, even if your relative has never been particularly ‘religious’ or ‘spiritual’ these issues may arise at some stage of the palliative care journey.

You can request assistance from the palliative care team at any time. For some people the formal services of a chaplain or pastoral care worker might be appropriate; for others, a friend or family member may become their ‘spiritual companion’. It is important for you, especially if you are the primary carer, to remember you may not be able to provide all the emotional and spiritual care as well as the physical care. It’s okay to seek help from others.

### Cultural care

We all have certain values, beliefs and customs and these are usually associated with our cultural backgrounds. It is important that you let the palliative care team know about any specific cultural practices that are important for you and your relative. These may include matters of diet, personal hygiene, clothing, special national or holy days, or other important rituals.

If you or your relative has difficulty understanding English the palliative care service can arrange for an interpreter. Although there might be family or friends who can help with interpreting from time to time it is recommended that a professional health interpreter be used when discussing important information about health care.

If you or your relative would prefer not to discuss issues of death and dying, because of your cultural beliefs, please let the palliative care team know, so that no offence or embarrassment is caused.

### How much should patients be told about their illness?

Your relative might have chosen not to be told of their serious illness, leaving you to obtain all the information and to make the decisions. Even though your relative may in fact 'know' that they have a life threatening illness, they may avoid any discussion on the subject. This may place a great burden on you, and seeking help from the palliative care team is essential. Depending on your relationship with your relative, and the way you have communicated difficult issues in the past, you may ask, 'Can we have a chat about this with someone else here?' A member of the palliative care team can help you with this discussion. Remember also, that some patients who have previously refused to speak about their terminal illness change their mind, so be prepared for the unexpected!

On some occasions family carers think that their relative should not be informed about their diagnosis. This may be because they think that their relative will not be able to cope with such news. Or, there may be specific cultural reasons why it is not appropriate to talk about death and dying.

However, people with a life threatening illness commonly want to plan and make decisions about their place of care, put their affairs in order, say their good-byes and be protected from unnecessary medical interventions. It is very difficult to keep information from relatives. As one person put it:

*"Truth may hurt but deceit hurts more."* The palliative care team are very experienced in having open discussions and answering family and patient queries about the impact of the illness.

### Forgoing medical treatment

Many patients and carers are keen to pursue 'just one more treatment' in the hope of a cure, or in the desire to postpone the person's death. Others think that 'stopping treatment' is 'giving up' or hastening the person's death. You may find reassurance in the palliative care principle that treatments should only be offered if they are going to improve the person's quality of life.

That's why treatment such as pain management will remain right until the end. Remember also, that palliative care focuses on comfort when cure is no longer possible. When no more specific medical treatment is likely to improve the person's condition, all aspects of palliative care (physical, psychological, spiritual, cultural and emotional) will continue, together with support for you and your relative.

***Adapted from "Supporting a Person Who Needs Palliative Care"- A guide for family and friends by Peter Hudson***

**Session 2:** Review of previous modules

**Objectives**

- Recall those things that have been taught.
- Participants interaction.

**Activities**

**Time:** 50 minutes

**Materials:** computer, projector, flip charts, markers, and board.

# **REFERENCES**

Health, N. I. of. (2012). When Someone You Love is Being Treated for Cancer, 2–4. http://doi.org/10.1037/e606232012-001

Tamayo, G. J., Broxson, A., Munsell, M., & Cohen, M. Z. (2010). Caring for the caregiver. Oncology Nursing Forum, 37(1), E50–7. http://doi.org/10.1188/10.ONF.E50-E57

Hudson, P, Hudson, R. (2012). Supporting a Person Who Needs Palliative Care: A Guide for Family and Friends. Retrieved from http://centreforpallcare.org/assets/uploads/PCV Supporting a person PC guide 2012.pdf

Support for People With Cancer Coping With Advanced Cancer. (n.d.).

National Cancer Institute, 2012. What You Need to Know About Breast Cancer. What You Need To Know About Breast Cancer, pp.1–46.

## Appendix K

## INTERVENTION SESSIONS

**Session one:** The first session begins with the introduction of the researcher, research assistants, the participants, the training expectations and objectives. The class governor was appointed whose duties were to link between the class and the researcher/research assistants, and also represents the interests of the participants.

The objectives include: understand their personal expectations of the training, understand the topics of the training, have knowledge of breast cancer, and understand the various management of breast cancer. The educational component involved in giving the primary caregivers basic information about cancer, its treatment and evolution. The presentation was delivered by one of the research assistants using power point which lasted for about an hour, and then the participants were given opportunity to ask questions. Some of the frequently asked questions include: why did God allow cancer to affect His people if indeed He loves them? How to detect cancer early, genetic factor in disease process, why poor prognosis? And side effects of the treatments. The participants confessed that it was easier to ask questions in this setting than during medical visit to the clinic where they feel anxious. All the questions were answered to the satisfactory of the participants, and they acknowledged that the information prepared them better to face the challenges of the breast cancer.

The participants were asked to identify the impacts of the breast cancer diagnosis on their family life. Some of the impacts mentioned include: depression, sadness, isolation, uncertainty, withdrawal from responsibilities, and fear of death.

At the end of the session, the participants and research assistants shared their contact details on a voluntary basis. The caregivers were given the task of interacting during the week by visitation and calling one another. The session lasted for 85 minutes.

**Session two:** Beginning with this session, all remaining sessions begins with participants discussing what they learned in previous session and as well as sharing experience.

The objectives of this session include: to gain a deeper understanding of caregiving, understand the basic concept and meaning of caregiving, and helping the participants adjusting to being a caregiver.

The educational component began with a presentation, made by another research assistant, about the explanation of caregiving and adjusting to being a caregiver, the presenter duelled on the following area: adjusting to being a caregiver-changing roles, coping with your feelings (anger, grief, guilt, hopelessness, loneliness, anxiety and depression), other ways to cope, knowing your strengths and limits, setting your priorities etc. The presentation lasted for an hour, followed by interactive session which includes: brainstorming of what have been discussed, share ideas and personal experience, ask question where necessary, and create inter-personal relationship. At the end of the session, the task was handed out: each participant should identify the area they have adjusted.

**Session three:** The session has the following objectives: discuss the importance of good communication in cancer caregiving, and identify basic communication skills. The educational component of this session began with a presentation, made by a research assistant, about the importance of communication and followed by keeping the lines of communication open. It discussed the importance of communication in preventing misunderstandings and promoting positive interaction. Good communication between patients and primary caregivers is important in cancer care as cancer patients have special communication needs. The presentation lasted for 95 minutes (five minutes beyond the normal duration); the participants that had questions were told to write them down till the following session because of the time, but they were encouraged to interact with one another during the week. The participants' body language and the numbers that turned up for each session of the training showed the level of acceptance of the training.

**Session 4:** The objectives of this session were to help families improve their emotion-management strategies and know how to manage stress. The activities of the day began with the interactive session; those that had question in session three were given opportunity to ask questions and appropriate answers were given to them satisfactorily.

The educational component of the day focussed on the emotions experienced by the members of the group.  It was a support session which aimed to help primary caregivers improve their emotion-management strategies. It was emphasised that when facing the cancer of a family member, feelings of revote and blame are normal. The teaching was centred upon the emotions experienced by the members of the group. Stress, possible sources and how to manage it were discussed. The participants were asked to explain how they reacted to stress, and what they do to manage it. Personal experiences where shared among the participants, and they were allow to ask any question regarding caregiving.

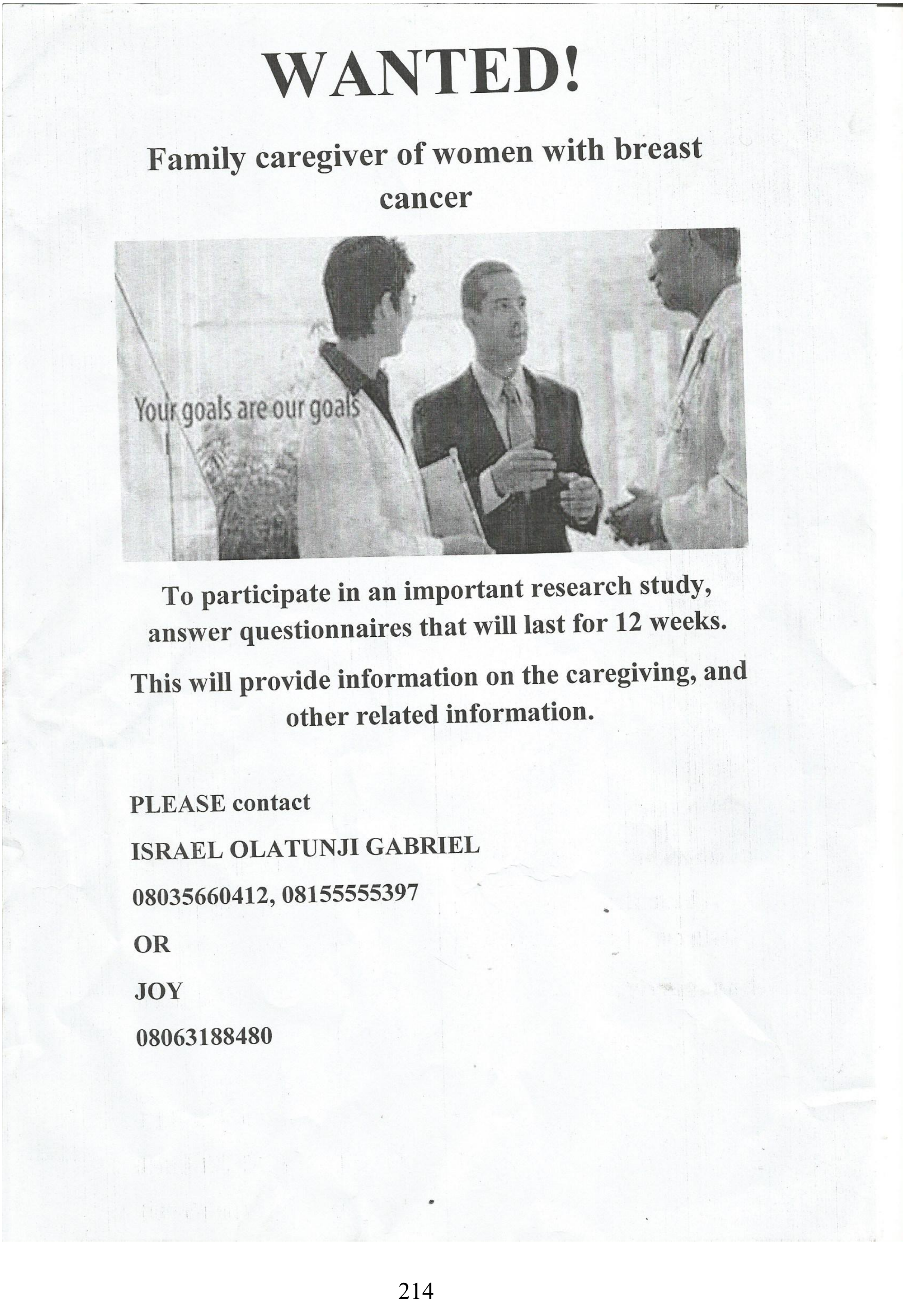
**Session 5:** The objectives of session five was to know the importance of self care, and how to practice self care. The educational component focussed on the information about the importance of self-care and how caregivers can practice self-care. The participants were made to know that if they do not take care of themselves, they would not be able to care for another, therefore, self-care practice for nourishment and replenishment must be taken very serious. “Only the healthy ones can take care of the sick”.  They were taken through how to look after themselves, maintain a healthy diet, exercise and movement, how to get enough sleep, and accepting help from others.

This was followed by interactive session with sharing of personal experience, questions and answers. As the next session will be the last meeting, the participants were asked to come on time and perhaps bring in something to share with one another. However, the researcher had made provision for food and drinks to celebrate the end of the training.

**Session 6:** The goals of the last session were to have the knowledge of practical care, and know what to do when patient present certain symptoms and emotion. The educational component provided tips on helping caregivers to give practical care, and how to deal with common symptoms and patient’s emotions. This segment was brief so as to have enough time for the end of training celebration.

Finally, a celebration took place; photographs were taken, those that brought things shared them among participants, food and soft drinks were given, participants exchanged their contact details. In fact, the class governor in his remark wished the programme could continue and expressed his gratitude for such opportunity to partake in the training.

## Appendix L: Flyer



# WANTED!

## Family caregiver of women with breast cancer

To participate in an important research study, answer questionnaires that will last for 12 weeks.

This will provide information on the caregiving, and other related information.

PLEASE contact

ISRAEL OLATUNJI GABRIEL

08035660412, 08155555397

OR

JOY

08063188480

## Appendix M: Guidebook Approval

# PERMISSION LETTER

Dear Israel,

Thank you for your email.

Extracts from the publication “Supporting a person who needs palliative care” may be used provided acknowledgement is made to Palliative Care Victoria.

It is unclear what ‘other tools” you are seeking permission to use.  Where copyright belongs to Palliative Care Victoria we provide permission for their use, again with appropriate acknowledgement.

Kind regards

Heather

**Heather Stevens**

Office & Members Services Manager

**T** 03 9662 9644

**M** 0400 903 803

**Palliative Care Victoria**

L2/182 Victoria Parade

East Melbourne VIC 3002

pallcarevic.asn.au

# PERMISSION LETTER

Dear Israel,

*This text may be reproduced or reused freely. Please credit the National Cancer Institute as the source. Any graphics may be owned by the artist or publisher who created them, and permission may be needed for their reuse.*