PREVALENCE AND FACTORS ASSOCIATED WITH DEPRESSION AMONG PATIENTS WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET.

BY

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A RESEARCH PROPOSAL SUBMITTED TO THE SCHOOL OF
MEDICINE, IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE AWARD OF THE DEGREE OF
MASTER OF MEDICINE IN PSYCHIATRY

Date.....

DECLARATION

DECLARATION BY CANDIDATE

Signature.....

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DEDICATION

The research thesis is dedicated to My Husband and the children Javan, Maxwell, Shamim, Emma, Valarie, and Asbel for always being there for me.

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LIST OF ABBREVIATIONS

DSM 5 Diagnostic and Statistical Manual-5

HADS Hospital Anxiety and Depression Scale

HAMD Hamilton Rating Scale for Depression

HPV Human PapillomaVirus

KEMRI Kenya Medical Research Institute

MDD Major Depressive Disorder

MTRH Moi Teaching and Referral Hospital

WHO World Health Organization

DEFINITION OF KEY TERMS.

Major Depressive Episode: - Is a period lasting at least two weeks in which the mood is low most of the time almost every day or loss of interest in pleasurable activities and is clinically significant to cause distress or impairment plus at least five of the following: Association (A.P 2013 DSM-5)

- Hypersomnia/insomnia
- Change in weight
- Psychomotor retardation/agitation
- Feeling of worthlessness
- Fatigue
- Recurrent suicidal thoughts

Breast Cancer- Is the development of malignant cells in the breast. The malignant cells originate in the lining of the milk glands or ducts of the breast

Cancer cells are characterized by uncontrolled division leading to abnormal growth and the ability of these cells to invade normal tissue locally or to spread throughout the body, -metastasis.

Adjuvant Chemotherapy-Adjuvant means **additional**. Adjuvant chemotherapy is given to patients after primary treatment when there is a high risk of cancer will return. After a primary treatment of surgery or radiation, adjuvant chemotherapy reduces the risk of recurrence.

Neoadjuvant chemotherapy-Neoadjuvant chemotherapy refers to medicines that are administered before surgery for the treatment of breast cancer. This kind of chemotherapy may be recommended due to the size of the tumor, since the drugs may shrink the tumor and give more surgical options.

Palliative chemotherapy-Is treatment is designed for terminal cancer patients to prolong survival and ease symptoms but not cure disease.

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PREVALENCE AND FACTORS ASSOCIATED WITH DEPRESSION AMONG PATIENTS WITH BREAST CANCER AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET

ABSTRACT

Background: Major Depression is the presence of sadness, empty or irritable mood, accompanied by somatic and cognitive changes. It is often unrecognized and untreated among patients with breast cancer, which causes amplification of physical symptoms, increased functional impairment, and poor treatment outcome. Factors associated with having depression among patients with breast cancer include age at diagnosis, tumor stage, surgery, and chemotherapy. There is limited data on depression among patients with breast cancer at Moi Teaching and Referral Hospital (MTRH).

Objective: To determine the prevalence and factors associated with depression among patients with breast cancer at MTRH.

Methods: This was a cross-sectional study, involving a total of seventy-nine patients, in which the Hamilton Depression Rating Scale (HAM-D) was used to diagnose and measure the severity of depression. A researcher-designed questionnaire was used to obtain socio-demographic and clinical information. The study was done at the breast cancer clinic, medical and surgical wards of MTRH, in which seventy-nine random consenting patients were interviewed from January to December 2017. Descriptive statistics were used for continuous data and categorical data. Chi-square and Fisher's exact tests were used to measuring for associations. Multivariate analysis by logistic regression was used to measure an independent association.

Results: of all the participants 98% of them were females. The mean age was 40±7.8 years. The prevalence of depression among patients with breast cancer was 59.5%. Those who were employed were 3 times more likely to have depression compared with the unemployed (AOR=3.7, 95% CI: 1.07, 17.27; p=0.047). Patients on neoadjuvant and palliative therapy were 9 times more likely to have depression (AOR=9.43, 95% CI: 1.5, 185.32; p=0.044 and AOR =9.5, 95% CI: 1.62, 181.81; p=0.039) respectively than those on adjuvant therapy. Patients with late-stage breast cancer had 61% increased odds of having depression (AOR=1.61, 95% CI: 0.63, 4.17; p=0.319) than patients with early-stage breast cancer.

Conclusion: There was a high prevalence of depression among patients with breast cancer. Being employed, the use of chemotherapy, and the late stage of cancer were significantly associated with having depression.

Recommendation: Screening and interventions for depression should be initiated for all patients with breast cancer especially late stages of cancer, those on chemotherapy, and employed.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Depression is the psychological syndrome that receives the most attention in individuals with cancer. Major depression is a frequent but unrecognized and untreated condition among breast cancer patients, which causes amplification of physical symptoms, increased functional impairment, and poor treatment adherence (Massie, 2004).

Breast cancer is reported to be a leading cancer diagnosis among women worldwide with more than 210,000 new cases and 40,000 deaths per year in the U.S.A.According to various studies carried out, it's been noted that the prevalence of depression among cancer patients ranges from 10%-58% (Massie2004 and Ballantyne et-al., 2009and Qiu et-al., 2012). Major depression was found to be as high as 38% (Massie, 2004). Many factors may contribute to depression including age at diagnosis, cancer stage, surgery, and chemotherapy (Hopwood et-al, 2010 and Hardouin et-al., 2011). The biological factors include the tumor burden, treatment morbidity, pain, and physical sensation. While the psychosocial factors impacting an individual functioning include, loss of control, increased dependency, change in the role of functioning, appearance, and identity(Ballantyne et al., 2009).

Diagnosis of breast cancer might no longer be regarded as fatal but has been increasingly acknowledged as treatable. Nevertheless, cancer diagnosis and its treatment are recognized to be stressful times that underscore the need for clinicians to actually identify its psychological sequelae such as depression in vulnerable patients.

Early detection and treatment of depression in cancer patients not only significantly improves their quality of life but also increases their survival rates (Weinberger et al., 2010).

According to a report by the Kenya Medical Research Institute (KEMRI), about 80% of cases of cancer are diagnosed at advanced stages, when very little can be achieved in terms of curative treatment (National Cancer Control Strategy 2011-2016.)

In the reports of the Eldoret Cancer Registry (2009), cancer of the cervix is the most common among females followed by those of the breast and esophagus. In males, cancer of the esophagus at 16.5% is the commonest and it is followed by cancer of the skin 9.2%, Non-Hodgkin Lymphoma 8.8%, and prostate cancer6.3% respectively. In females cervical cancer is the most common at 17.4% followed by breast cancer at 13.6%, esophagus at 9.2% and the least was colon-rectal cancer at 3.1% (Tenge et al., 2009). MTRH is currently handling a big number of patients with cancer (2000) in a year. The hospital has satellite clinics in North Rift and Western Kenya that help with early detection of cancer and follow-up.

Diagnosis of cancer, and subsequent treatment for the disease, can be an upsetting and harrowing experience that profoundly affects how the patient feels. Firstly, finding out that one has cancer can, in and of itself, make one depressed – for reasons we can all understand and empathize with. A second reason could be the unpleasant side-effects of cancer therapy. Chemotherapy, radiotherapy, and surgery, despite saving lives, all have effects that can alter our mental well-being. But the US researchers propose that chemicals produced by cancer itself could be involved. Cancer cells secrete a range of chemicals that affect how our bodies work, so it is not that far-fetched to think that they could affect how we think and feel. The study done by

Pyter et al., (2010) found that Sickness behaviors were caused by chemicals called cytokines, produced by the immune system during infection. As the researchers point out in their paper, raised levels of cytokines, at even moderate levels, have been linked to learning difficulties and emotional problems in humans. (Pyter et al., (2010) found that low-level increases in cytokines over the period of time it takes for cancer to grow (months or weeks) could be enough to significantly change our emotional state. Cortisol hormones can weaken the activity of the immune system. It also has a negative-feedback effect on interleukin-1which is useful in combating some diseases (Besedovsky et al., 1986).

Potential sources in the gap and inconsistencies of current knowledge include differences in the study methods (e.g. variable measures in screening or diagnosing depression), the variable definition of study populations i.e. survivors, sample selection, sampling time points, and the quality of reporting. A good review of this topic was conducted systematically (Fann et al., 2008) but did not focus on depression during survivorship; rather it looked at depression at no specific point of the disease.

1.2 Problem Statement

The number of depression cases among patients with breast cancer at The MTRH has been rising in recent years. Depression is among the leading causes of disability worldwide. Untreated depression leads to personal suffering and increased mortality. Although the prevalence of depression varies considerably globally, the most common symptoms of depression are depressed mood, insomnia, and fatigue. Based on (Globocan, 2008 and 2010)estimates about 12.7 million cancer cases and 7.6 million cancer deaths are estimated to have occurred in 2008; of these, 56% of the cases and 64% of the deaths occurred in the economically developing world

(Jemaletal, 2011). Cancer survival tends to be poorer in developing countries, most likely because of a combination of a late-stage at diagnosis and limited access to timely and standard treatment.

A decade ago in East Africa, an estimated 175,000 persons were living with cancer, and that number has dramatically increased, with cancer projected to become a leading cause of death in sub-Saharan Africa over the next few years. Unfortunately, as the threat of early death and disability from chronic diseases like cancer grows in sub-Saharan Africa, it is clear that countries like Kenya have very little in place to meet this challenge (Mutuma and Korrir 2003). According to the Eldoret cancer registry, cancer of the cervix (17.4%) is the most common among females followed by breast (13.6%) and esophagus (9.2%). In males, cancer of the esophagus (16.5%) is the commonest and it is followed by cancer of the skin (9.2%), Non-Hodgkin Lymphoma(8.8%), and prostate cancer (6.3%) respectively (Tenge et al, 2009). Therefore this brings in the fact that MTRH is handling many patients with cancer. Apart from the hospital set up they also have satellite clinics in North Rift and Western Kenya where they follow up and treat patients with cancer on specific days.

In Kenya, cancer ranks third as a cause of death after infectious diseases and cardiovascular diseases. It causes 7% of total national mortality every year. Although population-based data does not exist in the country, it is estimated that the annual incidence of cancer is about 28,000 cases, and the annual mortality to be over 22,000. Over 60% of those affected are below the age of 70 years. In Kenya, the risk of getting cancer before the age of 75 years is 14% while the risk of dying of cancer is estimated at 12%.

1.3 Study Justification

There is a high degree of variation among people with depression in terms of symptoms, course of illness, and response to treatment, indicating that depression may have several complex and interacting causes. However, recent advances in research technology are bringing scientists closer than ever before to characterizing the biology and physiology of depression in its different forms and to the possibility of identifying effective treatments for individuals based on symptom presentation. One of the most challenging problems in depression research and clinical practice is the treatment of depression among cancer patients in the advanced stage of the disease. Even among treatment responders, many do not have complete or lasting improvement, and adverse side effects are common. Thus, an important goal of the research is to advance the development of more effective treatments for depression among cancer patients. New figures and projections of the global cancer burden report the incidence of cancer has increased from 12.7 million to 14.1 million in 2012. This will bring the number of cancer cases close to over 25 million next two decades.

The greatest impact will unquestionably be in low and middle-income countries which are ill-equipped to cope with the escalation in the number of people with cancer. As a result, prevention is central to reducing or reversing the rise in cancer burden. In the past few years, we were privileged to have a center opened at MTRH: Chandaria cancer and chronic disease management center. It is a multidisciplinary center. This has made access to treatment for various departments easily available. Chemotherapy is available and very soon the radiotherapy department will be functioning. Secondly, the study on the prevalence of depression among cancer patients was last carried out in 2009. I would like to find out the current prevalence

rate of depression among patients with breast cancer at MTRH. To contribute to global knowledge and source of local data for comparison in the future.

1.4 Research Questions

- What is the prevalence of depression among breast cancer patients at MTRH?
- What are the factors associated with the development of depression among patients with breast cancer at MTRH?

1.5 Objectives of the Study

1.5.1 Broad Objectives

The main objective of the study is to establish the prevalence and factors associated with the development of depression among patients with breast cancer at MTRH

1.5.2 Specific objectives of the Study

- To determine the prevalence of depression among patients with breast cancer at MTRH.
- 2. To determine the factors associated with the development of depression among patients with breast cancer at MTRH.

CHAPTER TWO

2.1 LITERATURE REVIEW

2.2 Prevalence of Depression among Patients with Breast Cancer in Developed

Countries

Major depression is a frequent but under-recognized and undertreated condition among breast cancer patients, which causes amplification of physical symptoms, increased functional impairment, and poor treatment adherence. Being diagnosed and living with breast cancer can take its toll not only on your body but also on your mind. Depression in women with breast cancer is common, but is often overlooked and therefore, undertreated. The reported prevalence ranges from 1.5% to 46% (Massie, 2004). Breast cancer is the leading cancer diagnosis among women worldwide with more than 210,000 new cases and 40,000 deaths per year. In the United States of America, depression can be a significant factor during the course of breast cancer (United States statistic 1999-2008).

Research studies have been carried out to determine the duration of psychological distress in breast cancer patients and survivors in a prospective study of 160 women awaiting breast surgery. Morris and colleagues (2000) found a 22% prevalence of depression in women who had a mastectomy for breast cancer. This prevalence persisted at 2 years compared with an 8% prevalence of depression in those with benign disease. Meyer and Aspergren (2005) found a 30% rate of anxiety or depressive symptoms in a study of 58 ambulatory women who were 5 years post-treatment for breast cancer. Women who had a partial mastectomy followed by radiation had better body image but a similar amount of anxiety and depression symptoms and fear of recurrence as did women who had modified radical mastectomy. Maguire and colleagues found a 26% moderate or severe depression

among women who had mastectomy compared with a 12% prevalence of depression in women with benign disease. Grandi and colleagues reported a 22% prevalence of depression and post lumpectomy hospitalized stage II or III breast cancer patients. Maraste and colleagues found low levels of depression (1.5%) but higher levels of anxiety (14%) in 133 ambulatory breast cancer patients receiving radiotherapy after mastectomy or lumpectomy. From the various research group analyses, it showed that there was no significant difference in depression between mastectomy patients and those who had conservative surgery either preoperatively or at 6 and 12 months postoperatively.

2.2 Prevalence of Psychological Distress among patients with breast Cancer

Studies have shown that the prevalence of psychological distress among breast cancer patients is high, and they are at higher risk of developing severe anxiety, depression, and mood disorders (Mehnert and Koch et al., 2008). Depression and anxiety are the two most common psychiatric comorbidities encountered in breast cancer patients (Baumeister et al.,2010). Recently, more attention has been paid to the rapidly increasing prevalence of psychiatric disorders happening in breast cancer patients. As we know, diagnosis and treatment of breast cancer patients can be a very stressful issue during and after the treatment. Nearly 30% of those who survived cancers have reported having some sort of psychological problems (Maed, 2008). Cancer may induce the development of psychological disorders especially in women who have breast cancer and the effects can be on both the patients and their family members. It is very important to take early measures to treat these psychosocial problems for breast cancer patients and their partners as this will improve their quality of life later (UmutVarol et al., 2014).

Few researchers have noted the time of onset of depression or correlated patients' history of depression with current depression or functioning. In a cross-sectional study of 303 relatively young (mean age 46 years) women with early (stage I or II) breast cancer at 3 months after breast surgery using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire and Hospital Anxiety and Depression Scale (HADS), Kissane and colleagues found that history of depression was associated with depression in breast cancer patients. They also noted that women with few psychological symptoms and good emotional adjustment to cancer may have refused participation in this study because these women were also being recruited into an intervention study. In Kenya cancer is the third most common cause of death after infectious and cardiovascular diseases with breast cancer contributing to 23.3 % of cancer deaths, cervical cancer 20%, and prostate cancer 9.4%. Cancer is estimated to be responsible for 7% of the total annual deaths in Kenya.

Psychosocial stress has been related to impaired immunity in cancer patients. The long-term activation of the stress-response system and the subsequent overexposure to cortisol hormone and other stress hormones can disrupt almost all body processes. Cortisol hormones can weaken the activity of the immune system. It also has a negative-feedback effect on interleukin-1which is useful in combating some diseases (Besedovsky et al., 1986). Psychosocial factors, such as social support and distress, are associated with changes in the cellular immune response, not only in peripheral blood but also at the tumor level (Lutgendorf., 2005).

2.3 Biological Factors That Contribute to the Development of Depression among patients with breast cancer.

Increasing evidence has suggested that cytokines may play a role in the pathophysiology of mood disorders. Circulating cytokines and tumor necrosis factor can stimulate the hypothalamic-pituitary axis and corticotrophin-releasing factor (Reichlin S 1993, Blalock Je., 1989 & Besedovsy Ho et al., (1996)

Breast cell growth is stimulated by the estrogen and prolonged continuous exposure of estrogen can enhance the risk of breast cancer (Zhang et al., 2012). Certain conditions are uncontrollable like early menarche and late menopause which cause prolonged exposure to estrogen. The more estrogen your body has made over time, the higher your risk for developing depression. Getting a period before age 12, starting menopause after age 55, and never being pregnant raises one's lifetime exposure to estrogen and breast cancer risks.

Biological components associated with the disease itself, as well as with its treatment, could be responsible for depressive symptoms often observed in cancer patients. Thus, hormonal changes (*e.g.* abrupt changes in steroid levels) occurring for various reasons appear to be associated with symptoms of mood disorders in a subgroup of women. (Deecher et al., 2008)

Following a cancer diagnosis, patients report challenges in coping with work, caring for their family as well as severe pain that interferes with their general social life (Bailiff, 2000. A forced regression occurs requiring an individual to surrender at least temporarily the autonomy and environmental mastery that characterizes the psychologically mature adult (Proshansky et al., 1979).

2.4 Psychosocial Factors Contributing to Depression among patients with breast cancer in Kenya

A study on Psychological and social profiles among cancer patients was carried out by (Ndetei et al., 2012) at Kenyatta National Hospital. The results showed a high prevalence of depression (44%) disorders among patients. The prevalence rate of depression was much higher than in the general population. The study found 93% of cancer respondents who had stage 3 and 4 cancers had a severe depressive disorder. These results, therefore, confirmed that much of the psychiatric morbidity experienced by respondents with cancer goes unrecognized, and thus untreated, by healthcare providers.

Kenyatta National Hospital oncology clinic carried out a study and they found out that there was strong social-emotional support from contact persons for whom they not only talked to frequently but also had their contact persons and also shared frequently when they had problems. This showed that the social integration of the cancer respondents was an important part of their treatment. This was an indication of good psychosocial support for these cancer respondents (Ndetei et al., 2011).

Social and familial challenges occur in terminal illness. The effect of such a diagnosis reaches every facet of life including work, family, the will to live (or die), and one's coping mechanisms that limit interaction in cancer patients. This may make one not to interact with others on the same level as before the diagnosis. An individual diagnosed with advanced cancer may worry about financial concerns, death anxiety, and emotional welfare of family members (Kristjanson and Aoun, 2004).

A decade ago in East Africa, an estimated 175,000 persons were living with cancer, and that number has dramatically increased, with cancer projected to become the

leading cause of death in sub-Saharan Africa over the next few years. Unfortunately, as the threat of early death and disability from chronic diseases like cancer grows in sub-Saharan Africa, it is clear that countries like Kenya have very little in place to meet this challenge (Mutuma G.Z, and Korrir A.R, 2003).

There is a stigma associated with seeking mental health services for cancer patients (Jimmie C. H, 2002). They feel bad that they have to expose themselves physically and psychologically to their families, community, and the health workers and consider their illness as a sign of weakness. When these patients are referred to a psychiatrist to seek help, they feel traumatized to be associated with mental illness. They may want to keep their issues to themselves not to be exposed to be too sick or weak (Charmaz K., 2000).

Cancer survival tends to be poorer in developing countries, most likely because of a combination of a late-stage at diagnosis and limited access to timely and standard treatment. Clinicians, public health professionals, and policymakers can play an active role in accelerating the application of such interventions such as psychosocial alongside medical care globally. Estimates show that the burden may hit 21 million deaths by the year 2030, with nearly two-thirds of all cancer diagnoses occurring in low- and middle-income countries (Jemal et al., 2011).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

The study was a descriptive crossectional. All patients with a confirmed diagnosis of breast cancer and who meet the inclusion criteria were recruited for the study. Data obtained from the study were included, demographic and clinical data, and was to be addressed individually according to the study objectives for this study. Patients who were found to have depression were sent for review by a psychiatrist and further follow up. MTRH was chosen for the study because it's a national teaching and referral hospital that has an oncology clinic that covers the western Kenya region and parts of eastern Uganda.

3.2 Study area and background of the study area

Recruitment of the study subjects was carried out at the breast cancer out-patient clinic at Chandaria cancer and chronic disease management center and in-patients unit (surgical, medical wards) at MTRH.

Background of the study area

MTRH is located in Uasin-Gishu County; it is the second national referral hospital covering the western Kenya region with a population of about 16 million. It is a teaching and referral hospital used by Moi University. The hospital serves patients from western Kenya, north rift, and south rift regions. The hospital provides both inpatient and outpatient services. It handles all emergencies in the accident and emergency unit and has many specialties. These include medical, surgical, gynecological, psychiatric, pediatrics services among others. The inpatient has a bed capacity of approximately 800 patients. All types of cancer patients both pediatrics and adult (gynecological, surgical, and medical) are attended to at the center. The

oncology clinic is run on Mondays and Wednesdays between 8.00 am to 2.00 pm, but remains open for patients who come on any other day of the week. Patients are booked for the clinic by the record clerks. The number of patients seen with cancer in a week is 150 and a year the number of patients is approximately 2000. Patients with breast cancer seen in a year are about 100.

3.3 Study population

The study populations were patients above 18 years seen at the out-patient clinic at MTRH, and those admitted to the medical ward with confirmed cancer of the breast and also the surgical ward admitted for surgical procedures. They should all meet the inclusion criteria

3.4 Eligibility Criteria

3.4.1Inclusion Criteria

- Be adults (aged 18 or older) with a definite breast cancer diagnosis
- Patients in the medical/surgical wards with a definite breast cancer diagnosis.
- Patients at chandaria cancer and chronic disease management center outpatient clinic with a definite diagnosis of breast cancer.

3.4.2Exclusion criteria

- Patients in coma
- Patients with impaired cognition

3.5 Sampling procedures

For this study, a census sampling procedure was used. A census study occurs if the entire population is very small or it is reasonable to include the entire population (for other reasons). It is called a census sample because data is gathered on every member of the population till you attained the desired sample size.

3.6 Sample size

For this study we used census sampling, the number of patients seen with cancer is approximately 2000 per year. The number of patients with a histological diagnosis of breast cancer was 102 from January2016-December 2016. My first participant was the first patient seen at the outpatient clinic and that was in January of 2017 and using the next was consequiestive sampling. The study recruitment was completed by end of December 2017. For the given period of the study, I interviewed 79 participants who met the inclusion criteria for this study.

3.7 Clinical procedures.

Patients were recruited for the study within 72 hours of admission. The principal investigator recruited and trained 2 research assistants on how to carry out the study. Their main responsibility was to assist with the identification of the new patients, retrieving their files, and getting all the required information from the participants. Demographic data such as age, sex, and residential areas, level of education, and occupation achieved were recorded. A 17-item Hamilton Depression Rating Scale (HAM-D) was used to assess depression severity among patients. The total score is obtained by summing the score of each item, 0–4 (symptom is absent, mild, moderate, or severe) or 0–2 (absent, slight or trivial, clearly present). For the 17-item version, scores can range from 0 to 54. Since its development in 1960 by Dr. Max Hamilton of the University of Leeds, England, the scale has been widely used in clinical practice

and became a standard in research trials. The Hamilton Depression Rating Scale has proven useful for determining the level of depression before, during, and after treatment (Bagby et al., 2004). The Ham-D has demonstrated reliability, validity, and efficiency in adults (Stukenberg&Kiecolt-Glaser, 1990). A major review of 70 studies suggested that the internal, inter-rater, and retest reliability estimates are adequate for the global score (Bagby et al., 2004). The questionnaire is designed for adults and is used to rate the severity of their depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation or retardation, anxiety, weight loss, somatic and symptoms. The scale has been translated into several languages including French, German, Italian, Thai, and Turkish. In comparison to the Beck Depression Inventory, a meta-analysis suggested that after treatments, the HAM-D was more 'sensitive to change' on retesting (Edward BC et al.,1984) and this is probably why it has been so widely used in clinical trials.

3.8 Data Collection and Analysis

Data was collected using a formatted questionnaire that contained patient unique numbers for identification. The data collection forms were checked at the end of each day for completeness and inconsistencies were ruled out before data entry. Data obtained was maintained in the study computer under a password for protection. On completion of the study, data was transferred to a computer database for analysis. Descriptive statistics were used; for continuous data, means median and mode were used and categorical data frequencies and percentages were used. Data were analyzed using STATA version 14. Descriptive statistics were done for continuous data and categorical data. Inferential statistics such as Chi-square and Fisher's exact tests were used to measure associations of categorical variables. Two samples t-tests were used

to compare means of continuous variables. Logistic regression was used to measure the association between depression and socio-demographic variables

3.9 Ethical consideration.

Approval was sought from the institutional research and ethics committee to carry out the study. Permission and approval were sought from the chief executive officer MTRH. Patients were fully informed on all the procedures of the study and informed consent was sought from the entire study population before enrolment. The procedures involved in the study and the length of the interview was explained to each patient and their guardians. All patients' records will remain confidential and patients will receive all necessary and indicated care regardless of their willingness or unwillingness to participate in the study.

CHAPTER FOUR

4.1 RESULTS

This chapter provides the analyzed results of the study. The first part will describe the sociodemographic characteristics of the participants. The second will be the objectives of this study.

4.2Sociodemographic Characteristics

A total of 79 respondents participated in the study. The mean age was 40 (SD=7.8) years. Of those who responded 98.7% were females and the majority were married 86.1%. More than half of the respondents had achieved a tertiary level of education at 58.2%. 79.7% had some form of employment (**Table 4.1**)

Table4.1: Socio-Demographic Characteristics

Variables	Levels	N(%)
		Mean + SD
Age years		40+7.8
Sex	Female	78(98.7)
	Male	1(1.3)
Marital status	Married	68(86.1)
	Never married	11(13.9)
Education levels	Primary	4(5.1)
	Secondary	29(36.7)
	Tertiary	46(58.2)
Employment	Employed	63(79.7)
	Unemployed	16(20.3)
Substance use	Alcohol	14(17.7)
	Opiate	4(5.1)
	Khat	1(1.3)
	Others	16(20.3)

4.3 Prevalence of Depression

The prevalence of depression among patients with breast cancer at MTRH was shown to be 59.4% had depression. (**Table. 4.2**)

Table 4.2 Depression status based on the Hamilton Depression Scale

HAM-D	SEVERITY
>24 Severe depression	5(6.3)
17- 23 Moderate	14(17.7)
8-16 Mild	28 (35.4)
0-7 Normal	32(40.5)

4.4 Factors Associated with Depression

The second objective of the study was to determine the factors associated with depression among patients with breast cancer. From the results, it was shown that age, marital status, chemotherapy, surgical treatments, hormonal therapy, cancer stages, employment, and level of education are some of the factors associated with depression. The results obtained from this study showed that the late stage of cancer, employment, and use of chemotherapy was statistically significant (0.002, 0.047, and 0.048) respectively(**Table4.3**).

Table 4.3. Factors associated with depression

Variables	Total N=79	Depre =yes	Depre =NO	P-
		N=32	N=47	VALUE
Age	40±7.8	39.5±6.8 40.4±8.5		0.599
Cancer_stg_2	11(13.9)	0(0)	11(23.4)	0.002
Cancer_stg_3	27(34.2)	13(40.6)	14(29.8)	0.319
Cancer_stg_4	41(51.9)	19(59.4)	22(46.8)	0.272
Surgical treatment	35(44.3)	12(37.5)	23(48.9)	0.315
Hormonal therapy	58(78.4)	21(65.6)	37(78.7)	0.196
Gender female	78(98.7)	32(100)	46(97.9)	0.406
Marital status Married	68(86.1)	29(90.6)	39(83)	0.335
Employment Employed	63(79.7)	29(90.6)	34(72.3)	0.047
Substance use	16(20.3)	4(12.5)	12(25.5)	0.167
Alcohol	14(17.7)	4(12.5)		0.107
Opiate	4(5.1)	0(0)	10(21.3)	0.38
Tobacco	6(7.6)	2(6.2)	10(21.3)	
Khat	1(1.3)	0(0)	4(8.5)	0.143
			4(8.5)	1
			1(2.1)	1
Educational levels				
Primary	4(5.1)	2(6.2)	2(4.3)	0.42
Secondary	29(36.7)	9(28.1)	20(42.6)	
Tertiary	46(58.2)	21(65.6)	25(53.2)	
Chemotherapy	1			
	12(15.2)	1(3.1)	11(23.4)	0.048
Adjuvant chemotherapy	26(32.9)	12(37.5)	14(29.8)	
Neoadjuvant chemother		19(59.4)	22(46.8)	
Palliative Chemothera		17(37.1)	22(10.0)	

4.5: Results of the unadjusted and adjusted analysis of depression among patients with breast cancer

Table 4.4:Results of the unadjusted analysis of depression among patients with breast cancer

Variable	Unadjusted ORs (95%	P-
	CIs)	Value
Age	0.98(0.93,1.04)	0.609
Marital Status: Married	1.98(0.52,9.65)	0.342
Employment Status:	3.7(1.07,17.27)	0.058
Employed		
Substance Use	0.4(0.1,1.31)	0.152
Alcohol	0.53(0.13,1.76)	0.321
Tobacco	0.72(0.09,3.92)	0.711
Cancer Stage 3	1.61(0.63,4.17)	0.32
Cancer Stage 4	1.66(0.67,4.19)	0.274
Surgical_Treatment	0.63(0.25,1.55)	0.316
Hormonal Therapy	0.52(0.18,1.42)	0.199
Chemotherapy		
Adjuvant Chemotherapy	Ref	
Neoadjuvant	9.43(1.5,185.32)	0.044
Chemotherapy		
Palliative Chemotherapy	9.5(1.62,181.81)	0.039
Education Level		
Primary	Ref	
Secondary	0.45(0.05,4.23)	0.459
Tertiary	0.84(0.09,7.49)	0.867

Findings of the unadjusted odds ratio

Unadjusted OR showed that there was a 98% increased odds of a diagnosis of depression among patients with breast cancer among married participants, compared to the unmarried, [OR: 1.98 (95% CI: 0.52,9.65),] and a 60% reduced odds of depression among patients with breast cancer diagnosis among participants who used substances compared with those who didn't, [OR: 0.4(95% CI 0.1,1.31)].

Compared to those with a primary level of education, the participants with a secondary and tertiary level of education had 55%, and 16% reduced odds of a diagnosis of depression; [OR: 0.45 (95% CI: 0.05, 4.23), and OR 0.84 (95% CI: 0.09, 7.49)] respectively.

The odds of being diagnosed with depression among patients with breast cancer in the employed had an increased odds of 270%, compared to the unemployed, [OR: 3.7(95% CI: 1.07, 17.27)].

Compared to the participants who had received hormonal therapy, there was a reduced odds of 48% of being diagnosed with depression among patients with breast cancer than those not receiving hormonal therapy, [OR: 0.52(95% CI: 0.18, 1.42)].

The findings for using chemotherapy as a mode of treatment were as follows; compared to adjuvant chemotherapy, the participants on neoadjuvant chemotherapy and palliative chemotherapy had 830% and 850% increased odds of having a diagnosis of depression among patients with breast cancer. [OR: 9.43(95% CI: 1.5, 185.32) and OR 9.5(95% CI: 1.62, 181.81)] respectively. This finding was statistically significant.

The odds of being diagnosed with depression among patients with breast cancer among participants who had surgical treatment had a reduced odds of 37% compared to those who did not have surgical treatment, [OR: 0.63(95% CI: 0.25, 1.55)].

Compared to the early stage of cancer, the participants with late stage of cancer had 61% increased odds of having a diagnosis of depression among patients with breast cancer, [OR: 1.61(95% CI: 0.63, 4.17)] shown in **Table.4.4**

Table 5: Multivariate logistic regression

Variable	Adjusted ORs (95% CIs)	P-Value
Age	0.95(0.87,1.03)	0.216
Surgical_Treatment	1.73(0.33,9.54)	0.516
Hormonal_Therapy	0.87(0.24,3.22)	0.839
Marital Status : Married	4.08(0.7,28.94)	0.13
Employment Status:	4.29(0.84,33.51)	0.107
Employed		
Education Level		
Primary	Ref	
Secondary	0.23(0.01,3.55)	0.3
Tertiary	0.52(0.02,8.97)	0.656
Chemotherapy		
Chemotherapy.1	Ref	
Chemotherapy.2	16.55(2,377.23)	0.024
Chemotherapy.3	20.85(1.46,658.69)	0.041

^{*} Predictors **adjusted** for Age, surgical treatment, hormonal therapy, marital status, employment status, education level, and chemotherapy.

Findings of adjusted analysis

Finding showed that there was a 329% increased odds among the employed of having depression among patients with breast cancer compared to the unemployed [OR: 4.29(95% CI: 0.84, 33.51)], and a reduced odds of 13% among those who receive hormonal therapy compared to those who did not, [OR: 0.87(95%CI: 0.24, 3.22)].

^{**}Large CIs due to low cell sizes.

There was a 73% increased odds of having depression among those who had surgical treatments, compared to those who did not have surgical treatment [OR: 1.73(95% CI: 0.33, 9.54)]. compared to chemotherapy 1(adjuvant), the participants with chemotherapy 2(non-adjuvant) and chemotherapy 3 (palliative) had 1550% and 1950% increased odds of having a diagnosis of depression among patients with breast cancer [OR:16.55(95%CI:2,377.23)]and[OR:20.85(95%CI:1.46,658.69)] respectively. This finding was statistically significant. Compared to those with a primary level of education, the participants with a secondary and tertiary level of education had 77% and 48% reduced odds of a diagnosis of depression, [OR: 0.23(95% CI: 0.01, 3.55) and [OR:0.52(95%CI: 0.02, 8.97)] respectively.

CHAPTER FIVE

5.0 DISCUSSION

5.1 Prevalence of depression among patients with breast cancer

Breast cancer is the most commonly diagnosed cancer worldwide and the leading cause of cancer death, with roughly 1.4 million new breast cancer cases and 458,000 deaths in 2008. (Jemal A et al., 2010). The different modalities for treatment of primary breast cancer include surgery, chemotherapy, radiotherapy, and hormonal therapy, all four of which can be used alone or in combination (Jones and Bartle 2004). The number of people who survive breast cancer has significantly increased in recent years due to advances in detection and treatment. However, the aggressiveness of the treatment exposes the patients to various treatment side-effects. In fact, cancer and treatment-related symptoms can be major stressors in a patient with breast cancer who is undergoing treatment for the disease Jim et al., (2007). The adverse effects of breast cancer or treatment-related symptoms and types of treatment have been associated with different domains of quality of life Gavric et al., (2016). High levels of depression in breast cancer can also influence coping with cancer and quality of life adversely. Gorken et al., (2010).

Our study comprised of 79 participants with breast cancer. The study found out that the prevalence of depression was 59.4%. Studies have shown that nearly a third to a half of female breast cancer patients are likely to experience psychological distress. Knobt et al.,(2007). The variation in estimates of the prevalence of depression among patients with breast cancer can be attributed to differences in the study time frame, criteria for depression, disease stage, and study population. Kim et al.,(2008), Burgess et al., (2005) & Bardwellet et al., (2006). Findings from a study in Iran showed that 42.3% of patients with breast cancer suffered from moderate to severe depression

shakeri et al.,(2009). A study done in Nairobi found a prevalence of 44%. Ndetei et al., (2012). This finding was almost similar to our study. For this study, the population was all cancer patients, had a larger population compared to my study and it was a longitudinal study. Studies in western countries reported a prevalence ranging from 1-56%. Baumeister et al.,(2010). From the report, it is clear that the prevalence is similar to our findings. The study was a longitudinal study with a large population followed up for a period of 5years. Findings from a study done in Croatia had a prevalence of 36.5% Aukst-Margetic et al., (2005) which was slightly lower compared to our study. This is a developed country, and the population was slightly lower than our study and used a PHQ 9 for their study. A study done in Nigeria had a prevalence of 37.2% Nuhu. F et al., (2009), findings were lower compared to our study because the sample size was smaller and it was a longitudinal study. Studies have shown that the prevalence of psychological distress among breast cancer is high, and they are at higher risk of developing severe depressive disorders. (Hehnert et, al 2008), Deshied.Det, al. (2006) and Burgess.C. et al., (2005). A study conducted by Hassan et al. (2015), found that the prevalence of depression was 22.0% this finding was lower than what we got from our study. In Asian studies, the prevalence was between 12.5%-31% among patients who had breast cancer. The prevalence of depression among breast cancer patients in developing countries was 42% from moderate to severe by Shakeri et al. (2009). These findings were associated with the socio-economic status of developing countries compared to the developed counties. In most developing countries the health systems are not well placed with poor funding from their government this was from a survey done in Geneva WHO (2002). A study done in Athens had a prevalence of depression of 38.2% Konstantinos et al., (2018). These findings were lower compared to my study because of the difference in

economic status, and the government provides funding that assists the patients with their treatment and they also have good, functioning health systems. In Eldoret, a study done by Tenge et al. (2009) reported a prevalence of 13.6%. This figure is lower than that found in our study. This was because the population was all cancer patients seen in Eldoret, and it was a longitudinal study. The prevalence of depression among breast cancer patients 9.1% this was a study done in Ethiopia. Halemariam et al.,(2012). This study had a very small population of 50 participants and used PHQ 9 which is different from HAM-D.

The possible causes of the difference in these studies are the difference in demographic variables such as age, marital status, duration of cancer, type of treatment, and the number of treatment sessions Rajabizadeh et al., (2005), as well as locational and cultural diversity that can affect the mental and psychological conditions of patients. On the one hand, in justifying the differences in the results of these studies, the type of instruments used and how the scores obtained from these instruments for assessing depression in participants in studies were interpreted should not be ignored.

5.2 Association of socio-demographic factors and depression among breast patients with breast cancer

In our study age, education, substance abuse, and marital status were found not to be associated with depression among patients with breast cancer. From our study, we found an association between depression and employment with a p-value (0.047). In our study, the mean age was 40 years. Studies by Hassan et al., (2015) showed the commonest age of breast cancer ranges from 40-49 with a mean age of 50 years. A recent study in Germany found older patients were 1.2 times likely to experience

depression than younger patients. Engelhand et al.,(2015). Growing older is one of the major risk factors for breast cancer. In a study in North India mean age of cases and controls was 54.0 years with S.D. ± 9.7 and 53.8 years with S.D. ± 9.3 years respectively and the range was 30-80 years. It is also comparable to many of the previous studies. In a study by Afsaneh et al.,(2010) the mean age of those with breast cancer was 47.63 years and 49.18 years by Zare et al., and 51.3 years by Mosavi et al., (2006) and 48.9 years. Eva S. Eva Singletaryet al. (2003) concluded that if all women less than 65 years of age compared with women aged 65 or older, the relative risk of breast cancer associated with increased age is 5.8.

In our study, the majority of the participants had a tertiary level of education. Low levels of education were found to be a predictor of psychological comorbidity in patients with breast cancer. This somehow might be explained by the fact that patients with higher educational levels have a greater opportunity to be aware of their disease and its related aspects, Menhert et al.,(2008). In a study in South Africa, Kagee et al.,(2017) reported that the less education the higher the risk of depression among breast cancer patients. A similar finding was reported by Osborne et al., (2003). Our findings reinforce findings from the existing literature and support the assumption that education can be a protective factor in the occurrence of depression and anxiety among women dealing with breast cancer (Hopwood et al., 2010; Bener et al., 2017). This finding can be attributable to the fact that women with higher educational status can have better access to information regarding their health conditions and be fully aware and understand the treatment plans and what is expected.

Marital status was one of the associated factors with depression. These findings were not statistically significant in our study. Similar findings were reported in studies were done by Hassan et al., (2015) and Aass et al. (2014). A study in North India by Vivex

et al.,(2016), reported that single women showed a higher prevalence of depression compared to married. A study done in Lagos Nigeria reported that being married is a protective factor and is less likely to develop depression Akechi et al., (1999). Studies have shown that the advantages of employment are weaker in married women, more so if they have children and in preschool. Roberts et al (1982). A study done in Malaysia reported that women who were single and unmarried compared to married had better global health status. Chui et al.,(2015) & Edib et al., (2016).

5.3 Other factors associated with depression among patients with breast cancer

The problems experienced by survivors include physical symptoms, psychological reactions, and existential concerns, which potentially disrupt their well-being Würtzen et al., (2013). The wide range of rates may be due to several factors, including the use of different instruments to assess depression with different psychometric properties, the use of different criteria for defining depression, and differences between included cancer populations concerning cancer type, stage, and treatment modality Krebber et al., (2014). Having breast cancer or receiving treatment has been seen as a traumatic experience to people due to its impact on their self-image and sexual relationship, so most of the breast cancer patients have psychological reactions such as denial, anger, or intense fear toward their disease and treatment process, and many of have psychiatric morbidities Lueboonthavatchai et al. (2007). Many of the breast cancer patients experience fatigue, depression, and/or anxiety months to years after their breast cancer diagnosis with these symptoms being associated with greater disability and a poorer quality of life Rogers et al., (2017). Adjuvant chemotherapy may lead to an increased risk of depression, anxiety, or both during but not after treatment Burgess et al., (2005).

The study we carried out at MTRH, found that chemotherapy, employment, and cancer stage had an association with the development of depression among patients with breast cancer. Employment had a p-value of 0.047. Being employed was associated because of various factors: trying to adjust their financial uses in anticipation of treatment, care for their families and periods of being unwell and being out of work and fear of losing their jobs contributed to the distress in this population. A study done in Malaysia reported that the employed had better health globalyEdib et al., (2016), Chui et al., (2015), found that the unemployed or with low income had better health globally. This will in turn help reduce mortality and improve the quality of life of these patients. Studies by Ell et al., (2005) and Hassan et al., (2015) found that MDD is more prevalent among the ethnic minority and low income. Those who were unemployed were unlikely to receive psychiatric treatment and supportive counseling. They felt burdened by cancer treatment and expenses. Being employed has beneficial effects on psychological health. It brings interest, income, fulfillment, social contacts, and status, and provides structure and a sense of control Jahoda et al., (1982).

Chemotherapy as a mode of treatment for cancer was also found to have an association with the development of depression among patients with breast cancer. Chemotherapy has unpleasant side-effects, such as alopecia and nausea. After long periods of treatment, these side effects are significant and lead to psychological distress Polikandrioti et al., (2008) and Fann et al., (2008). The kinds of chemotherapy depending on the cancer stages are adjuvant, non-adjuvant, and palliative chemotherapy.

Our results show that the use of chemotherapy as a mode of treatment was associated with the development of depression among patients with breast cancer. This was an

expected finding and is similar to findings by other authors examining this association among patients with breast cancer. (Bower et al., 2000; 2011; Den Oudsten et al., 2009; Vahdaninia et al., 2010) found that the use of chemotherapy had adverse side effects and psychosocial effects on patients with breast cancer(p=0.003). A similar study done in Asia found an association between chemotherapy and depression among patients with breast cancer (Eversley et al., 2005; Morill et al., 2008). A similar finding was reported in a study in Iran (Novin et al., 2014).

Cancer stage was found to have an association with the development of depression among patients with breast cancer (p=0.002). This was an expected finding. Several studies reported that the stage of the cancer is strongly associated with depression and breast cancer patients with advanced-stage had a higher risk of depression as compared to those with early-stage cancer. Alemayehu et al., (2018), Akin-odanye et al., (2011) & Sheppard et al., (2013). This finding is similar to a study among breast cancer in Greece Fradelos et al. (2017) in which stage IV breast cancer patients were 1.9 (p=0.003) more likely to experience depressive symptoms. These findings are similar to a study by Inhenslern et al., (2017, Mustian et al., (2012). A similar result was reported in Iran by Novin et al., (2014). A study done in China found that there was no association between the breast cancer stage and the development of depression among patients with breast cancer (p=0.192) Hong JS et al. (2014).

Surgical treatment as a mode of treatment was found not to have an association with the development of depression among patients with breast cancer, this was the findings from our study, the results were unexpected finding P=0.315. Mastectomy can cause scars and disfigurement, which can lead to a perception of becoming less attractive, poor body image which is associated with depression. Begovic. et al., (2012). A study done in Karachi hospital found that going through mastectomy leads

to moderate to severe depression among patients with breast cancer, this was primarily because one feels incomplete and insecure after losing a part of themselves Sara Khan et al., (2016).

Hormonal therapy is one of the modes of treatment used to treat patients with breast cancer. Tamoxifen is mainly used in our setting. Tamoxifen is an estrogen hormone adjuvant used for more than 25 years to treat women with breast cancer with proven efficiency for the reduction of mortality and in preventing recurrences. The use of Tamoxifen, compared to no treatment, reduces the risk of recurrence for about 15 years Ma. Am et al., (2008). The factors usually indicated as those contributing to non-adherence in breast cancer patients include the therapy's adverse effects. Hormone therapy, including tamoxifen, may cause hot flashes, fluid retention, bleeding, skin rashes, vaginal itching, and dryness, the risk of endometrial cancer, joint pain, or deep vein thrombosis, among others (Early Breast Cancer Trialists' Collaborative Group (EBCTCG)(2005). The finding from our study was that there was no association with the development of depression among patients with breast cancer. This finding was unexpected. Several studies carried out in parts of the world found there was an association. Findings from a study done in China found that hormone receptor-positive tumors are generally associated with a better prognosis compared to the hormone negative receptors and that the incidence of depression was low Su JA et al., (2017).

During the study period, we found the participants at the first encounter (admission) had varied forms of depression, ranging from mild to severe forms of depression. These participants were immediately referred to a psychiatrist, some of the patients were started on antidepressants, while the majority were referred to a psychologist and were started on psychotherapies.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study sought to find the current prevalence of depression among breast cancer patients and the factors associated with MTRH to facilitate the diagnosis of depression among this population. The prevalence was reported to be 59.4%, a figure that is significantly higher compared to previous studies. Findings from our study showed that being employed, the use of chemotherapy and the cancer stage were significantly associated with having depression.

6.2 Recommendations

The findings obtained from this study have shown major clinical significance, mainly in the development of guidelines for early identification of depression among breast cancer patients at MTRH.

- Screening for depression should be initiated for a patient with cancer at all point s of interaction with patients.
- Early psychological support should be incorporated into the management of these patients
- More studies with a larger population to determine the associated factors with other psychiatric morbidities.
- More studies on the association between and chemotherapy as a mode of treatment should be done.

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APPENDICES

Appendix I: Consent Form

STUDY TITLE

PREVALENCE OF DEPRESSION AMONG BREAST CANCER PATIENTS AT MTRH

INVESTIGATOR: CHELAGAT SAINA

MOI UNIVERSITY, SCHOOL OF MEDICINE,

ELDORET.

EMAIL: csaina@yahoo.com

TEL: 0724292117

PURPOSE OF THE STUDY

The study aims at establishing the prevalence of depression among breast cancer patients and the risk factors associated with the development of depression among breast cancer patients at MTRH.

BENEFITS AND RISK

There may be no direct benefits to the participants but may gain more knowledge on the recommendation of the study. The study has no known risks to the participants during the study.

CONFIDENTIALITY

All information obtained in the study will be considered confidential and will be used only for academic purposes of the study. The identity of the respondent shall be kept confidential.

VOLUNTARY PARTICIPATION

Participation in the study is voluntary and if the participant refuses to comply it will not result in any penalties and have the right to withdraw from the study if he/she wishes at any time.

CONSENT

I have read and understood the nature of the study and voluntarily agree to participate in the study.

SIGNATURE
DATE
RESEARCHERS SIGN
DATE

APPENDIX II: DATA COLLECTION FORM. Patient study number						
Date of	Date of admission					
Date of	of discharge					
Age _						
Sex:	male	female				
1. Ma	rital status					
•	Married					
•	Single.					
•	Divorced.					
•	Separated.					
•	Not specified					
2. Edu	acation level:					
•	None					
•	Primary.					
•	Secondary.					
•	>secondary.					
4. Em	ployment.					
•	Employed					

• Unemployed

5. Substance use				
Yes				
No				
• Alcohol.				
• Bhang.				
• Tobacco.				
• Opiates.				
• Khat (Miraa)				
• Inhalants.				
 Hallucinogens 				
• Others (specify)				
6. Severity of the drug use.				
• No problem;				
• Minor problem;				
• Mild problem;				
Moderately severe problem;				
• Severe to a very severe problem;				
 Not known/Not applicable. 				
7. Hamilton depression scale score				
• At admission				
• At 6 months				
• At 12 months				

Appendix I11: Hamilton Depression Rating Scale. (HAM-D) HAM-D:

The 17-item Hamilton Depression Rating Scale(HAMD-17) is one of the most widely used instruments in depression assessment and research (Halmilton M.1960). It is a multiple item questionnaire used to indicate depression (hedlung 1979). In the last decade the psychometric properties of HAMD-17 in patients with stroke, Alzheimer's dementia, and Parkinson's disease and its concurrent validity with DSM-IV criteria for major depressive disorder in these patient groups have been investigated (Leentjens A.F et al, 2000 and Naarding P. et al, 2002). The questionnaire is designed for adults and is used to rate the severity of their depression by probing mood, feelings of guilt, suicide ideation, insomnia, agitation or retardation, anxiety, weight loss, and somatic symptoms. For the last 50 years, the Hamilton Depression Rating Scale (HDRS) has been regarded as a gold standard measure of the severity of depressive symptoms. 17-item version of the HAM-D has become the standard for clinical trials and, over the years, the most widely used scale for controlled clinical trials in depression. As the interviewer-rated HAM-D-17 is the most widely used and accepted measure for evaluating the severity of depression (Guy W. ECDEU (1976). Many of the psychometric properties of HAM-D are adequate and consistently meet established criteria. Sensitivity and specificity: In the Brazilian TBI study, a score of 7 or more led to a sensitivity of 92.9% and specificity of 78.1% (Schwarzbold et al., 2014). The HAM-D internal reliability is adequate. Convergent validity and discriminate validity are adequate (Bagby et al. 2004) .this was from a meta-review done in brazil. The total score is obtained by summing the score of each item, 0-4 (symptom is absent, mild, moderate, or severe) or 0–2 (absent, slight or trivial, clearly present). For the 17-item version, scores can range from 0 to 54. It is accepted by most clinicians that scores between 0 and 6 do not indicate the presence of depression,

scores between 7 and 17 indicate mild depression, scores between 18 and 24 indicate moderate depression and scores over 24 indicate severe depression.

DEPRESSED MOOD

(Sadness, hopelessness, helplessness, worthless)

Absent

These feelings are indicated only on questioning

These feelings are spontaneously reported verbally Communicates feelings non-verbally i.e., through facial expression, posture, voice, and tendency to weep. The patient reports VIRTUALLY ONLY these feelings in his spontaneous verbal and non-verbal communication

2. FEELINGS OF GUILT

Absent Self-reproach feels he has let people down

Ideas of guilt or rumination over past errors or sinful deed

Present illness is a punishment. Delusions of guilt

Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. SUICIDE

Absent Feels life is not worth living wishes he was dead or any thoughts of possible death to self-

Suicide ideas or gesture

Attempts at suicide (any serious attempt rates)

4. INSOMNIA EARLY

No difficulty falling asleep

Complains of occasional difficulty falling asleep - more than 1/2 hour Complains of nightly difficulty falling asleep

5. INSOMNIA MIDDLE

No difficulty patient complains of being restless and disturbed during the night waking during the night - and getting out of bed (except for purposes of voiding)

6. INSOMNIA LATE

No difficulty waking in the early hours of the morning but goes back to sleep Unable to fall asleep again if he gets out of bed

7. WORK AND ACTIVITIES

No difficult thoughts and feelings of incapacity, fatigue, or weakness related to activities (work or hobbies) Loss of interest in activities (hobbies or work) - either directly reported by the patient or indirectly in listlessness, indecision, and vacillation (feels he has to push himself to work or do activities) A decrease in actual time spent on activities or a decrease in productivity. In the hospital, if the patient does not spend at least three hours a day in activities (hospital job or hobbies) exclusive of ward chores Stopped working because of present illness. In the hospital, if the patient engages in no activities except ward chores, or if the patient fails to perform ward chores unassisted

8. RETARDATION: PSYCHOMOTOR

(Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

Normal speech and thought

Slight retardation at interview

obvious retardation at interview

Interview difficult

complete stupor

9. AGITATION

None

Fidgetiness Playing with hands, hair, etcMoving about, can't sit still and wringing, nail-biting, hair-pulling, biting of lips

10. ANXIETY: PSYCHIC

No difficulty

Subjective tension and irritability

Worrying about minor matters

Apprehensive attitude apparent in face or speech

Fears expressed without questioning

11. ANXIETY: SOMATIC

(Physiological concomitants of anxiety, such as - gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. - Cardiovascular: palpitations, headaches. -

Respiratory: hyperventilation, sighing. - Urinary frequency - Sweating)

Absent

Mild

Moderate

Severe

Incapacitating

12. SOMATIC SYMPTOMS: GASTROINTESTINAL

None Loss of appetite but eating without staff encouragement. Heavy feelings in the abdomen, Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastrointestinal symptoms

13. SOMATIC SYMPTOMS: GENERAL

None Heaviness in limbs, back, or head. Backaches, headache, muscle aches.

Loss of energy and fatigability

Any clear-cut symptom

14. GENITAL SYMPTOMS

(loss of libido, menstrual disturbances)

Absent

Mild

Severe

15. HYPOCHONDRIASIS

Not present

Self-absorption (bodily)

Preoccupation with health

Frequent complaints, requests for help, etc. ...

Hypochondriacal delusions

16. LOSS OF WEIGHT

No weight loss

Probable weight loss associated with present illness (>500g/week)

Definite weight loss(>1kg/week)

17. INSIGHT

Not depressed (based on above items) OR Acknowledges being depressed and

ill

Acknowledges illness but attributes cause to bad food, climate, overwork,

virus, need for rest, etc.

Denies being ill at all

Appendix IV: Estimated Study Budget.

	ITEM	UNIT	TOTAL
1.	Research computer	1	50,000
2.	Printer	1	10,000
3.	Stationary and printing costs	-	25,000
4.	Miscellaneous	-	15,000
5.	Research assistance costs	2	60,000

Appendix V: Proposed schedule for the study

Activity	Start	Complete.
Proposal concept development	October 2015	March 2016
Proposal writing	January 2016	May 2016
IREC approval	May 2016	August 2016
Research subjects' recruitment.	October 2016	December 2016
Data collection	January 2017	December 2017
Data cleaning and data analysis Thesis writing	December 2017 February 2019	February 2018 May 2019
	Proposal concept development Proposal writing IREC approval Research subjects' recruitment. Data collection Data cleaning and data analysis	Proposal concept development October 2015 Proposal writing January 2016 IREC approval May 2016 Research subjects' recruitment. October 2016 Data collection January 2017 Data cleaning and data analysis December 2017

Appendix VI: IREC Approval



INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC) MOI UNIVERSITY SCHOOL OF MEDICINE P.O. BOX 4606

MOI TEACHING AND REFERRAL HOSPITAL P.O. BOX 3 ELDORET Tel: 33471//2/3

Reference: IREC/2016/179

Dr. Chelagat Saina,

Moi University,

School of Medicine,

P.O. Box 4606-30100,

ELDORET-KENYA.

Dear Dr. Saina,

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE 13 SEP 2016 APPROVED O. Box 4606-30100 ELDORET

ELDORET

13th September, 2016

RE: PROVISIONAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Prevalence of Depression among Breast Cancer Patients at Moi Teaching and Referral Hospital, Eldoret."

Your proposal has been granted one month provisional approval from 13th September, 2016 subject to ratification by IREC Full Board. Note that this is a preliminary approval and you are only allowed to set-up in readiness for the study but no recruitment should take place within this period until formal approval is granted.

Sincerely

PROF. E. WERE CHAIRMAN

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

CC

CEO

MTRH

Dean

SOP

Dean

SOM

Principal

CHS

Dean

SON

Dean

SOD