ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES SCHOOL OF

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The Effect Of Inter-personal Psychotherapy On Treatment Outcome Among Breast Cancer Patients With Common Mental Disorder: A Randomized Control Trial At Tikur Anbessa Specialized Hospital

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RESEARCH PROPOSAL

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APPROVED BY THE BOARD OF EXAMINERS

This thesis, by Ejigayehu Belay, is accepted in its present form by the board of examiners as fulfilling for the degree of master's in Health System Management.

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ABBREVIATIONS AND ACRONYMS

ANCOVA	Analysis of Covariance
BT	Behavioral therapy
CA	Cancer
CBT	Cognitive Behavioural therapy
CMD	Common mental disorder
GLM	General linear model
CCT	Client-Centered therapy
GLM	General Linear Model
EORTC-QLQ-C-30	European organization for research and treatment of cancer quality of life questionnaire core 30-items.
IPT-E	Interpersonal Psychotherapy adapted for Ethiopian use
PP	Per protocol analysis
HADS	Hospital Anxiety and Depression Scale
PDT	Psychodynamic therapy
PSA	Psychoanalysis therapy
QOL	Quality of Life
STPP	Short term Psychodynamic Psychotherapy
TAU	Treatment as usual

ABSTRACT

Background: Cancer is a serious and life-threatening disease with negative effects on physical and psychological well-being of patients. Depression and anxiety are the commonest co-morbidities that adversely affects how people feel, the way they think and how they act and it is common among cancer patients. The impact of common mental disorder (CMDs) on cancer patients is not well recognized and managed in Ethiopia while there is a dearth of evidence on the effect of Psychotherapy on depression, anxiety and treatment outcome among cancer patients. Interpersonal psychotherapy is one therapy technique used to treat common mental disorders.

Objectives:-To determine the Effect of Interpersonal Psychotherapy On treatment outcome among Breast Cancer patients with a common mental disorder at Tikur Anbessa specialized teaching Hospital (TASH), Addis Ababa, 2018/19.

Methods: A parallel randomized control trial was employed on 124 breast cancer patients with CMD that are randomly selected from TASH oncology unit Out-patient department in weeks. Then study participants was randomly assigned as Intervention group (n=62) and control group (n=62) randomly in weeks and also single blinding was employed so as the outcome assessors are blinded of the belongingness of individuals to specific study group.To avoid information contamination patients were randomized in weeks.As an outcome measure we hypothesized treatment outcome as the dependent variable and it was assessed using a 30 item questionnaire of quality of life measurement scale. Depression and anxiety were the independent variables that are measured with hospital anxiety and depression measurement scale. Both tools were validated for use in Ethiopia.Psychotherapy was given for a month in a weekly basis. Then outcome was measured two weeks after the final therapy with similar tool that were used at baseline.Data was analysed using GLM (ANCOVA) to control the effect of confounders. With 95% confidence interval and P-value < 0.05 was used to declare the statistical significance.

Result: Interpersonal Psychotherapy for Ethiopian use (IPT-E) had an effect on treatment outcome. IPT-E had a significant effect in decreasing anxiety, -5.76 with 95% CI (-7.10, -2.90) and depression, -4.74 with 95% (-6.44, -3.10) and with an IPT-E had also a significant effect on quality of life domains of physical, role, cognitive, emotional and social functioning with ($p<0.05$). And from the symptom scales insomnia and fatigue were decreased ($p<0.05$) also health-related quality of life was significantly improved ($p<0.001$).

Conclusion and recommendation: Interpersonal psychotherapy had an effect on treatment outcomes, among breast cancer patients with common mental disorders. So health programmers may consider incorporating it as a treatment option in the oncology unit.

1. INTRODUCTION

1.1 Background

Cancer is a serious and life-threatening disease, which has adverse effects on physical and psychological well-being of patients(1); also it is indicated that depression and anxiety were two of the common psychological distress among cancer patients and depression is a common as well as serious medical illness that adversely affects people's emotion, the way they think and how they act. It can lead to different emotional and physical problems and can hinder a person's ability to function at work and at home (2). Some of the causes of depression can be Biochemistry, Genetics, Personality, Environmental factors(Continuous exposure to physical and psychological abuse, neglect, poverty may make some people more prone to depression), diagnosis of some disease condition can also lead to depression (3). The occurrence of depression is common among cancer patients and has been found to be significantly associated with impaired quality of life (4).

Anxiety in cancer patients produces a number of typical signs and symptoms such symptoms as autonomic over-activity include palpitation and sweating, restlessness and reassurance-seeking are its typical features and also cognitive changes including apprehension, worry, and poor focus, and physical manifestations such as muscle tension or fatigue may occur(5).

Quality Of Life(QOL) is one of the common patient-reported treatment outcome measures(6) that strongly associated with psychological distress in a way that when Psychological distress gets treated, the aspects of quality of life will improve(7).

Depression and anxiety are among the most treatable mental disorders in which more than 80 percent of people with depression and anxiety respond well to treatment, additionally almost all patients gain some relief from their symptoms after receiving the appropriate treatment(8).The assessment and management of common mental disorders (depression, anxiety) are widely recognized as crucial components of care in oncology and also several psychotherapeutic interventions have focused on Psychological problems of patients at end-stage of Cancer (9).

Psychotherapy is termed a series of interrelated techniques or interventions designed to improve mental health, emotional, behavioral, psychological, and/or psychiatric disorders based on the verbal and/or nonverbal communication with an identified therapist or practitioner (10). Psychotherapy becomes a major addition to standard oncological treatment by reducing the severity of somatic and psychic symptoms, furthermore psychotherapy may also contribute to reducing the

number of medications used by a patient and eventually to lower costs of pharmacological treatment(11).

The most well-known individual psychotherapies include cognitive behavioural therapy, behavioural therapy, psychodynamic therapy, expressive, supportive, psychoanalysis, interpersonal therapy, Gestalt therapy, Humanistic/Existential, experiential, client-Centered, and derivative therapies such as emotion-focused therapy (12).Studies suggested the use of Psychotherapy for depressive and anxiety disorder as an adjuvant treatment(13).And also studies has established the efficacy of Interpersonal psychotherapy as an acute and chronic treatment for patients with major depressive disorder among cancer patients(14).

The need for psychological interventions among cancer patients is highly important particularly in Africa with regard to the frequently stated misconceptions in the origin of cancer due to spiritual or supernatural cause and curses such misconceptions tend to affect mood and feel negatively and may lead to depression and anxiety, as a result of such beliefs women with breast cancer may experience depression due to feeling mutilated, losing sense of femininity, mourning the loss of the breast, or worrying about the possibility of still retaining their husbands' affection after mastectomy(15).

Interpersonal Psychotherapy for Ethiopia (IPT-E) is a brief manualized psychotherapy that has been adapted for Ethiopia and low-income countries through a series of trials that have demonstrated its relevance and efficacy across cultures, Also it helps patients who struggle with psychological distress of common mental health disorders that are Depression, Anxiety and Somatoform problems or medically unexplained symptoms that mostly occur together (16).The goal of IPT is to help patients solve a crisis in her or his role functioning or social environment, which leads to improvement in depression and anxiety symptoms (17).

1.2 Statement of the Problem

Cancer is a major health care challenge and leading cause of disease and death globally(18). It is estimated that there will be 18.1 million new cases and 9.6 million cancer deaths worldwide in 2018 and Breast cancer is the most frequently diagnosed cancer and the leading cause of cancer death in females ;globally, it is estimated that there will be about 2.1 million newly diagnosed female breast cancer cases ,this accounts for almost 1 in 4 cancer cases among women, also in Africa mortality due to cancer is estimated to be 7.3 % according to GLOBCAN 2018 report (19). Despite the limited data on the epidemiology of cancer in Ethiopia, in 2015, it was estimated that the number of new cases of cancer were reported to be 21,563 and with 42,722 in males and females respectively. Breast and cancer of the cervix are being the commonest (20). In Ethiopia at Tikur Anbessa Hospital it is indicated that the prevalence of Breast and Cervical Cancer is found to be 29.5% and 22.7% respectively (21).

Several factors determine the occurrence of cancer, among those determinants of cancer; Behavioural factors, Occupation (occupational exposure), Educational status, Environment, Reproductive risk factors (lower rates of breastfeeding, and higher use of hormone replacement therapy), and socio-economic factors determines cancer in general(22). Also several factors determine the treatment outcome of cancer patients, among those determinants Socio-economic status, communication with the health care provider and family, general health condition of the patient and also depression and Anxiety potentially affect the treatment outcome of cancer patients(23-26).

Depression and Anxiety are the most frequent mental co-morbidities in 22% of cancer patients leading to substantial decrements of quality of life, adherence to treatment, work ability and prognosis in Canada(27). Also in Iran, anxiety and depression are prevalent mental comorbidities among cancer patients. As they have investigated in their study among breast and gastro-intestinal cancer patients, the prevalence of anxiety and depression is to be 46% and 43% respectively. In this study the source for anxiety and depression among breast cancer patients is known to be loss of body image due to mastectomy and its related effect on sexual motive, whereas among gastrointestinal cancer patients the source of depression and anxiety is fatigue, weight loss and colostomy due to the disease condition (28).

Depression and anxiety may be experienced by breast cancer patient at any stage of their illness from pre-diagnosis to the terminal phase of the illness; as studies in the Western countries showed, that the prevalence of depression among breast cancer patients ranges from 1% to 56%(29) whereas

the prevalence of depression from Asian studies is between 12.5% and 31% (30). As a study conducted in Nigeria indicates, depression and anxiety are common among cancer patients(31). According to a study done in Ghana among breast cancer patients, the prevalence of depression and anxiety is found to be 84.2% and 92.5% respectively(32).

Despite the very limited studies done in Ethiopia, studies have been done on investigating problems of Cancer patients; like the Estimates of the incidence of cancer, the prevalence of anxiety and depression among cancer patients, Depression and pain complaints of Cancer patients, Prevalence and Correlates of anxiety and depression among cancer patients has been investigated (20, 33, 34). For instance a study done in Addis Ababa in a tertiary hospital states that the prevalence of depression to be 12.6% compared with the general population (33) and also a study done in Gondar university hospital indicated that Anxiety and depression are prevalent among cancer patients, here the result showed that the prevalence of anxiety and depression is 51% and 58.44% respectively (34).

In spite of the fact that these studies have been conducted in Ethiopia, the effect of psychotherapy on treatment outcome among Breast cancer patients with a common mental disorder is not investigated. Studies are scarce in this area. The previous studies are conducted in developed countries, as far as my knowledge there is one pilot study done in Nigeria (from developing countries) about the Effectiveness of Psychological intervention among cancer patients with common mental disorder (31). Therefore the main purpose of this randomized control trial (RCT) is to determine the effect of Inter-personal psychotherapy on treatment outcome among Breast cancer patients' with common mental disorders.

1.3 Rationale and Significance of the study

The rationale of the study

In Tikur Anbessa Specialized Hospital oncology center, there is no set up to diagnose, treat and combat those co-morbid mental disorders. And this becomes an additional burden on cancer patients. The occurrence of common mental disorder among cancer patients has an adverse effect on their daily life and affect their treatment outcome (Quality of Life) in advance.

So this study is expected to improve the quality of cancer care by giving an insight into the effect of psychotherapy on treatment outcomes on cancer patients for policymakers and for those concerned with improving the health system as a whole.

This study is also expected to point out how it is possible to improve the treatment outcome, amongst the mentioned cancer patients' and also cancer patients as a whole by incorporating psychotherapy as routine care in oncology unit. This study with its approach will help cancer patients to combat Psychological disorders that they are facing due to the disease burden.

Significance of the study

This study is also expected to play an important role by showing health programmers the effect of incorporating Psychotherapy as an adjuvant treatment for cancer patients. Psychotherapy is expected to reduce depression and anxiety, in turn it is possible to increase the quality of life among cancer patients on the respective cancer departments. It is also expected to help the research community by identifying the effect of the mentioned therapy and its consecutive impact, so as it can be a grand point of reference. In turn it will help the community, the region and the nation as a whole.

2. LITERATURE REVIEW

2.1 Cancer Burden

Non-communicable diseases (NCDs) are now responsible for the majority of global deaths (35), and cancer is expected to rank as the leading cause of death and the single most important barrier to increasing life expectancy. According to estimates from the World Health Organization (WHO) in 2015, cancer is the first or second leading cause of death before age 70 years and Cancer incidence and mortality are rapidly growing worldwide(36).

According to GLOBOCAN 2018 projection. There will be an estimated 18.1 million new cancer cases and 9.6 million cancer deaths in 2018. According to this estimation for both sexes combined, 1 in 5 men and 1 in 6 women will develop the disease and 1 in 8 men and 1 in 10 women will die from it.

In both sexes combined, lung cancer is the most commonly diagnosed cancer and the leading cause of cancer death (18.4% of the total cancer deaths), closely followed by female breast cancer (11.6%), prostate cancer (7.1%), and colorectal cancer (6.1%). Worldwide, lung cancer remains the leading cause of cancer incidence and mortality, with 2.1 million new lung cancer cases and 1.8 million deaths predicted in 2018, representing close to 1 in 5 (18.4%) cancer deaths in other contrast Worldwide, there will be about 2.1 million newly diagnosed female breast cancer cases in 2018, accounting for almost1 in 4 cancer cases among women(19).

And in Africa there were 847,000 new cancer cases (6% of the world total) and 591,000 deaths (7.2% of the world total) in the 54 countries of Africa in 2012, the most common cancers in men were prostate (16.4% of new cancers), liver (10.7%), and Kaposi sarcoma (6.7%); in women, by far the most important are cancers of the breast (27.6% of all cancers) and cervix uteri (20.4%)(37).

And in Ethiopia according to a study done in Tikur Anbessa hospital over a period of sixteen years, 1997-2012, more than 50 cancer types, a total of 16,622 new cases were registered in Tikur Anbessa Specialized Hospital. Out of this, 3460 (prevalence=20.8%) were new cases of breast cancer representing approximately 216 cases per annum(38).

2.2 Prevalence of Depression and Anxiety (Common Mental Disorder) among Breast Cancer Patients

A study done by F L Sotelo states that the prevalence of depressive symptoms in patients with cancer exceeds that observed in the general population and depression is associated with a poorer prognosis in cancer patients (39).

According to a research done by Lueboonthavatchai indicates, having breast cancer or receiving treatment has been seen as a traumatic experience to women due to its impacts 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(40).

According to a systematic review done by Zainal, the prevalence of depression is high during the first year after breast cancer diagnosis(29).

According to a study done in Iran by Novin Nikbakhsh among 150 cancer patients forty-four (29.3%), patients had mild anxiety, 25 (16.7%) symptomatic anxiety but mild and symptomatic depression were seen in 40 (26.7%) and 32 (21.3%) patients, respectively. Here there were significant relationships between anxiety, depression and the age group of the patients with higher frequency in older ages. There were significant relationships between anxiety and depression with the type of cancer and type of treatment(28).

A Cross-sectional study done by Saniah and Zanial found that among 141 breast cancer patients showed that prevalence for depression was 19.1% and prevalence for anxiety was 24.1%. In this study, Anxiety is stated to be related to practical, family and emotional problems though depression is stated as to be associated with practical problems as transportation, financial and work problems(41).

Another cross-sectional study done in Malaysia on 205 women who were diagnosed with breast cancer by Mohd Rohaizat Hassan, the prevalence of anxiety was 31.7% (n=65) and of depression was 22.0% (n=45) among the breast cancer patients(42).

A Descriptive cross-sectional study done in Greece by Konstantinos Tsaras with a sample size n=170 breast cancer patients states that a large percentage of study subjects found to be classified as depressed (38.2%) and anxious (32.2%) (43).

As a study done in Egypt by Hanan Yousif Aly and colleagues among 96 breast cancer patients it is reported that the prevalence of depression, anxiety, or both is (46.87%, 49.96%, and 32.29%, respectively). Here one-third reported as having an advanced degree of depression, anxiety or both (33.34%; 33.33%, and 32.29% respectively)(44).

2.3 The Effect of Psychotherapy on Cancer patients with a common mental disorder

A multicentre randomized control trial done in German on 157 breast cancer patients with co-morbid depression by Beutel with the tempt to treat depression states that 44% of the Short-term Psychodynamic Psychotherapy group(Intervention group) overcome highly significant more remission(lessening amount of the disease condition) with $p<0.001$ after the therapy than that of the treatment as usual group(TAU) which is 23%.So this study has proved that Short term Psychodynamic Psychotherapy is an effective treatment for depressed breast cancer patients in improving depression and functional Quality of life (45).

Whereas another randomized control trial study done in Germany by Goerling on 45 gynecological cancer patients to examine the Efficacy of Short-term Psycho-oncological intervention in anxiety, depression and psychological stress found that psycho-oncological therapy for anxiety and depression significantly decrease both anxiety and depression with $p<0.001$ (46).

A randomized control study done in France by Dolbeault on the effectiveness of a psycho-educational therapy group intervention after early-stage breast cancer treatment on 203 patients states that a significant reduction in anxiety among group Participants, a reduction in anger, depression, and fatigue, a significant improvement in energy and interpersonal relationships, in emotional and role functioning, in health Status and fatigue level was achieved (47). Also another randomized control trial done in China on 178 cancer patients by Guo found that Patients randomly assigned to the intervention group showed significant improvements in symptoms of depression ($p < 0.05$) and anxiety ($p < 0.05$), health-related QOL ($p < 0.05$) (i.e. better global health status, and physical and emotional functioning, and less insomnia) when compared with controls. Here Compared to control group patients, patients who had received a psychosocial intervention showed significantly lower scores of anxiety and depression ($p < 0.001$)(48).

A systematic review done by Chen and Ahmed to investigate the effectiveness of adjunct psychotherapies for newly diagnosed cancer patients who have not received any cancer treatment revealed that adjunct psychotherapy groups or intervention groups showed a better outcome as decreased emotional distress, decreased anxiety and depression and improved quality of life(49).

Another pilot study done in Nigeria on 33 female cancer patients on the Effect of cognitive restructuring therapy intervention on depression in female breast and cervical cancer patients by Asuzu found that after the therapy a significant difference between participants in their pre and

post-intervention depression scores (M= 23.71, SD= 10.11 and M= 13.18, SD= 8.07 for pre and post-intervention depression scores, respectively (31).

2.4 The Effect of Depression and Anxiety on Quality of Life among Cancer Patients

A comparative-Cross-sectional study done by Simone S.M. Ho on 269 breast cancer with common mental disorder found that women with higher levels of anxiety are associated with poorer physical and functional well-being, and especially with reduced emotional wellbeing during and after treatment whereas breast cancer patients with higher levels of depression are associated with poorer physical, social/family, emotional and functional well-being during and after treatment(50).

Another cross-sectional descriptive study done by Winnie K.W. So on 218 breast cancer patients revealed that patients with depression experienced overall a poorer level of QOL and other domains of QOL than those in the non-case group also those in the anxiety case group had significantly poorer overall QOL, Physical Well Being, Emotional Well Being, Functional Wellbeing than those in the non–case group, the explanation for these is that depression and anxiety may lead to physical symptoms (e.g. fatigue, anorexia, and/or weight loss) in such manner a depressed mood will probably have a negative influence on self-reported QOL(51).

2.5 The Effect of Psychotherapy on Quality of Life among cancer patients with a common mental disorder

A study done by Ewa Wojtyna on the influence of cognitive-behavior therapy on quality of life and self-esteem in women suffering from breast cancer states an improvement in general QoL, general health status and self-esteem were observed in the period following the therapy among CBT patients in Comparison with the control group(52).

Another randomized control trial study done by Zhen Guo on the benefits of psychosocial interventions for cancer patients undergoing radiotherapy found that psychosocial intervention significantly reduced levels of depression, anxiety, and improvement in elements of QOL, such as global health status, physical functioning, and emotional functioning, compared to a control group(48).

Similarly, another randomized control trial study done by Fatemeh Moghaddam Tabrizi1 on the effects of supportive-expressive discussion groups on loneliness, hope and quality of life in breast

cancer survivors revealed that positive changes from pre to post-intervention occurred in QoL in the intervention group(53).

A randomized control trial study done by D. MANOS on studying the results of a multi-componential psychosocial intervention program for women with early-stage breast cancer on Quality of life and mental adjustment, the result states that the intervention benefits these patients in terms of both quality of life and mental adjustment(54).

A meta-analysis done by Alejandro states that quality of life is improved by psychological interventions, especially when patients have to cope with medical treatment or with adjustment after the disease is treated, which means psychological treatments that promoted greater reductions in depressive symptomatology yielded greater benefits on QoL(55).

Another study by Barbara Rehse favours the overall hypothesis that psychosocial interventions reveal a positive impact on QoL in adult cancer patients(56).

2.6 Factors that affect the treatment Outcome of Cancer patients

Several factors have been reported to affect the treatment outcome of cancer patients. These factors can be stated as demographic and disease-related factors.

Amongst those factors studies have reported that race is not associated with the treatment outcome of cancer patients. In another way Socio-economic status tends to affect cancer treatment outcome significantly. Here environment, diet, education, behavior, and access to treatment can contribute their part(57). A study done by Bradley suggests, that low-income women tend to have late-stage cancer at diagnosis, less likely to receive radiation therapy and more likely to die sooner than that of the other contrast. This association might be because of that those low-income groups are less likely to receive standard care for diagnosis and treatment due to the issue of financial difficulty to seek and get the intended care. Additionally the poor treatment outcome among low-income groups is due to the fact that physicians are reluctant to recommend routine screening and cancer treatment for these low socio-economic groups. So those factors affect the treatment outcome of low-income cancer patients(23).

The other factor that could possibly affect the treatment outcome of cancer patients is communication (communication with a health care providers, within the family).Through better physician-patient interaction; it is possible to increase the health outcome of cancer patients. It is due to that patient-physician communication will lead to increase patient knowledge and understanding, it also builds trust and help them to reach on consensus. This in other way increases

the likelihood of adherence to treatment, higher quality medical decision, ability to deal with emotions and better care for self. This in turn helps to achieve good treatment outcome(24).

The General health condition of the patient is the other factor that seemingly affects the treatment outcome of cancer patients, in some cases for instance, patients who have chronic medical conditions like dementia, the treatment outcome of the patients will be affected. The explanation for this could be that patients with such a condition might be limited even to access cancer screening and follow-up due to the typical characteristics of the disease condition (dementia). In case they might even forget that they should attend their follow up and treatment(23).

Studies also suggest that tumor size tend to affect the treatment outcome of cancer patients. A study done in UK states that 25% of patients with small size tumor has adequately low recurrence rate and even have a probability to be treated. Whereas the other 25% has high recurrence of cancer with significantly poor treatment outcome as indicated(58).

Depression and anxiety are also found to affect the treatment outcome of cancer patients. As studies have revealed higher depression may favor faster cancer progression. And also depression could lower adherence to treatment which in turn fastens up cancer progression. Another biomarker of depression which is serum cortisol (glucocorticoid hormone) that circulates glucose in the blood for emergency condition, though if it happens to exist highly in bloodstream, it will potentially be immunosuppressant. So it will critically influences the cancer patients' adherence to any treatment given and also they will not be able to combat the disease due to the low immune status, these, in turn, will affect the treatment outcome of cancer patients who develop this co-morbid health threat(26).

2.7 Factors that affect the Quality of Life of Cancer patients

An Institutional based study done by Abdel W Awadalla on 181 patients with breast cancer and gynecologic cancers and their family caregivers states that higher QOL was associated with patients being married, as well as having higher levels of employment and higher educational attainments in a way that marriage, higher educational attainment, and employment will increase the potential for awareness of disease, social support and the use of positive coping methods, all of which can contribute to higher QOL(59).

A systematic review done by Martin Fortin and Lise Lapointe states that there is an inverse relationship between the number of medical conditions (Co-morbidity) and QOL, here co-morbidity mostly affects physical dimensions of QOL(60).

Another descriptive study done by Winnie K.W. So revealed that type of treatment affect QOL; in this study it is indicated that there were poorer QOL among participants undergoing chemotherapy; the study explained that this finding is due to the result of more severe treatment side effects and poorer self-esteem because treatment side effects often involve changes in physical appearance(61).

2.8 Factors that affect the treatment outcome of Breast cancer Patients

Several factors are reported to affect the treatment outcome (prognosis) of breast cancer patients. Some of the factors are:-

Stage of the disease at diagnosis

If breast cancer is diagnosed at an early stage which means before the metastasis of the tumor, it will have a good prognosis. Whereas if the diagnosis of the tumor is at late stage, it is unlikely to have a good prognosis or treatment outcome (62).

Size of the tumor

If tumor size is large at the time of diagnosis, it will result in unfavorable prognosis. In another way if the tumor size is small, it will result in good prognosis(63).

Tumor Grade

If the grade of the tumor is low, it is less likely to advance quickly. Whereas high-grade tumor is more likely to advance aggressively and tends to result in poor treatment outcome(64).

Age at the time of diagnosis

Breast cancer in younger women is less likely to have a favorable prognosis due to the aggressive nature of the tumor (65).

Different factors were reported to affect treatment outcome of breast cancer patients.Due to the limited access to research, the reference population that we used in our study was the population in China and that of in Germany. That might not be comparable.

2.9 Conceptual Framework

The conceptual framework that was used for this study is originally prepared for the purpose of explaining factors affecting the treatment outcome of cancer patients focusing on common mental disorders. The Framework in these studies tried to explain the factors affecting the treatment outcome of cancer patients especially those of breast cancer patients by focusing on the effect of anxiety and depression among those specific patients and it tried to show the association of the factors and their respective effect towards treatment outcome. The variables that are placed in the right and left of the middlebox with single arrow were those variables that explain the factors affecting the treatment outcome of cancer patients whereas the other which is indicated with a bold arrow is the main objective of the study that will be intervened.

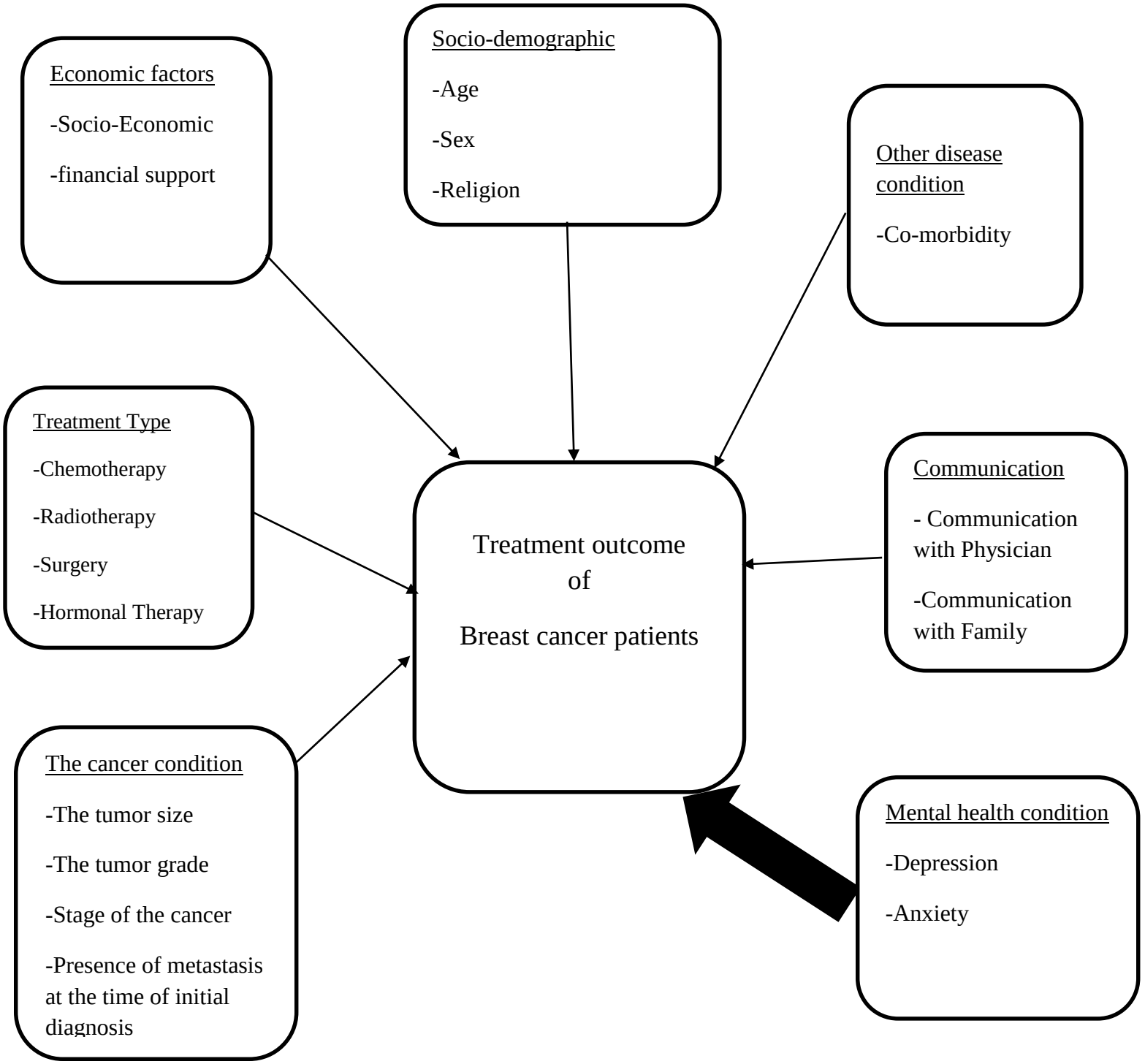

Figure 1: Conceptual framework for factors affecting treatment outcome of breast CA patients focussing on common mental disorder. Diagram developed for: Factors affecting the treatment outcome of breast cancer patients 2018/19.

2.10 Research Question

1. Does Inter-personal Psychotherapy has an effect on treatment outcome among Breast cancer patients with common mental disorder?

3. HYPOTHESIS

Null Hypothesis- Inter-personal Psychotherapy has no Effect on Treatment Outcomes among Breast Cancer patients' with common mental disorders.

4. OBJECTIVES

4.1 General Objective

To determine the Effect of Interpersonal Psychotherapy-E on treatment outcome among Breast Cancer patients with common mental disorder at Tikur Anbessa Specialized Hospital, Addis Ababa.

4.2 Specific Objectives

1. To determine the effect of interpersonal psychotherapy on the level of depression and anxiety reduction among breast cancer patients of Intervention and control group at Tikur Anbessa Specialized Teaching Hospital, Addis Ababa, 2018/19.
2. To determine the effect of interpersonal psychotherapy on quality of life of Intervention and control group at Tikur Anbessa Specialized Hospital, Addis Ababa, 2018/19.

5. METHODS AND MATERIALS

5.1 Study Area and Period

This study was conducted at Tikur Anbessa Specialized Teaching Hospital (TASH) oncology unit, Addis Ababa Ethiopia. It is located in the capital city of Ethiopia. One of the well-known teaching hospitals and only central referral hospital and Cancer treatment and diagnostic Centre of the country with both radiotherapy and chemotherapy. It also gives service to the population in Addis and to the population all over the country by receiving a referral from all over the region (21). TASH is a large referral teaching hospital, under the administration of Addis Ababa University, located in Addis Ababa, Ethiopia. It has divisions such as internal medicine, surgery, gynecology and obstetrics, pediatrics, radiotherapy, adult oncology, pediatrics oncology /hematology, nuclear medicine, psychiatry, laboratory, orthopedics, pharmacy, etc. The hospital has 700 beds and gives diagnostic and treatment service for about 370,000-400,000 patients per year. The oncology unit of TASH is the only oncology unit with radiation therapy for the country and has an outpatient department that gives service to new and follow-up patients and an in-patients department which has 21 beds(38).

Of the 201 physicians at the hospital, only two are hematologists, four are medical oncologists, four are radiotherapists, two are surgical oncologists, and one is a pediatric oncologist. Three palliative pain specialists also work at the hospital. Only 26 of the Black Lion's 627 nurses are dedicated Oncology nurses. Treatments offered at the Black Lion Hospital cancer center include anticancer drugs, surgery, and radiotherapy (66).This study was conducted from January 1st 2019 to August 30 2019.All Eligible Breast Cancer patients diagnosed with Common mental disorder will be incorporated in the study.

Black Lion Hospital, Addis Ababa, houses Ethiopia's only cancer referral center with radiation therapy

5.2 Study Design

A parallel randomized control clinical trial was conducted at Tikur Anbessa Specialized hospital Oncology centre out-patient department. The study was conducted to determine the effect of Interpersonal Psychotherapy on treatment outcome among Breast cancer patients' with common mental disorder.The effect of interpersonal psychotherapy was determined by applying Psychotherapy for the intervention group while the routine treatment was carried out to the control group. Participants were randomized in weeks of their visit to minimize the issue of information contamination. Since psychotherapy was a talk therapy, it would be affected if the participants exchanged information with each other. Due to the characteristics of the study base-line assessors were not blinded of the allocation status of groups. Also psychotherapists were not blinded of the allocation status of the groups. But outcome assessors were blinded of the allocation status of the groups. This made our study to employ Single blinding.

5.2.1 Randomization and Blinding

To avoid information contamination, individuals were randomized in weeks of their visits of the oncology unit. The randomization technique started considering the pre-determined data collection period which was 16 weeks These weeks were randomized which led us to have 8 weeks for Intervention and 8 weeks for the control groups. After having these pre-determined weeks; patients were enrolled to the intervention or to the control groups in their order of visits of the oncology unit. Randomization of weeks was employed so that we could get potential participants that would come for their routine follow up and care in the respective oncology unit and also to reduce potential information contamination. So patients that would fall on the intervention week received the intervention and those who fall in the control week received the usual care. And the order of the sequential assignment for the two groups of participants in weeks was done using random sequence generator from Excel 2016 program available on Office 2016 package software (Microsoft Corporation).

The principal investigator (PI) prepared an appointment card that are identically colored. Right after screening, the professional who was assigned to do the screening appointed the patient to get psychotherapy or treatment as usual as per their respective week and the principal investigator allocated a code on the patients appointment card so as it became possible to differentiate those of the intervention group to that of the control groups.

5.2.1.1 Unit of Randomization

To reduce information contamination; in this study, the units of randomization were not individuals rather we utilized weeks of the data collection period as units of randomization. In this study the participants in the respective week could not be considered as true clusters because of the fact that these groups did not full fill a characteristics of a true cluster. The justification for this could be that the individuals in the intervention and control group in weeks were not different due to the different weeks that they were at. And the patients in the respective week were similar in their clinical features, clinical presentation, socio-demographic as well as socio-economic variation, also in treatment kind that they take and also in the hospital that they attend their routine follow up and treatment. Even if there was a little variation that were by chance. Due to this fact, we consider the characteristics of the individuals in the respective week were sufficiently homogeneous.

5.2.1.2 Unit of Analysis

In this study for the purpose of analysis, we took our unit of Analysis individual participants in the treatment and control groups.

Univariate and multivariate regression was computed before fitting the domains and the independent variables into ANCOVA. Additionally General linear model (ANCOVA) was used to measure the Effect of Interperonal-psychotherapy on treatment outcome after controlling the effect of covariates on determining the effect of the psychotherapy on treatment outcome (Quality of Life).

5.2.2 Blinding

The therapists were not blnded of the allocation status of the group, since they are the one who administer the therapy.The participants also were not blinded of the specific study group since they knew that they were getting additional treatment. Base-line assessors also were not blinded of the allocation status of the group since they appointed the patients for psychotherapy. But post intervention outcome assessors in this study were not told about the allocation status of the group. And that make the intervention single blinding.

5.2.3 Information Contamination

Psychotherapy is mainly a talk therapy, so information contamination were an issue. After randomizing the patients in their respective weeks; those patients that would fall on the intervention week became intervention groups and those who fall in the control week, became control groups. These reduced information contamination in a way that groups wouldn’t meet and

share therapeutic information and procedures since they differ in their follow up and appointment weeks.

5.3 Situational Assessment

This study had five phases that are Situational assessment, screening and , intervention (Psychotherapy), post intervention assessment and that of Post-trial beneficence. Situational assessment was done at the Oncology centre on 10 key informant health care providers about the status of the set-up, about their routine care in the set-up (weather they screen cancer patients for depression and anxiety, if they did routine screening; what kind of professional conduct the screening process, what their management was and weather they had appropriate linkage system with the responsible department for this condition. This assessment helped the study to gain an insight about the condition of the set-up and what the routine (usual) care was for cancer patients.

5.3.1 Base-line assessment and screening

Patients on their arrival at the oncology department was briefed about the aim of the study and after delivering the necessary information about the study, informed consent was obtained from those willing to participate. If they agreed to participate, they would be enrolled in the Screening procedure. The screening procedure was conducted using a standardized 14 item Hospital Anxiety and depression measurement scale (HADS) questionnaire. Those participants with HADS score of >=8 were enrolled in the study. Right after screening those patients who agreed to participate in the study were assessed for other base-line characteristics (socio-demographic,economic and clinical characteristics) and quality of life.

5.3.2 Intervention

After having ethical approval from the Institutional review board (IRB) of AAU SPH and Addis Ababa health bureau Ethical review board, the eligible participants were enrolled into two groups' 1.Interpersonal psychotherapy group and 2.treatment as usual group.

Following the random assignment of eligible participants, the assigned therapists provided adjuvant psychotherapy for the treatment group whereas the control groups were taking their usual treatment ; which is the treatment they were taking for their routine care (radiotherapy, chemotherapy and hormonal therapy).

Therapists were clinical Psychology professionals that were trained and certified for delivering IPT-E. Study therapists were supervised daily by supervisor using check-list (treatment tracking form)

to ensure adherence and competence. Because the study was conceived more as effectiveness than a pure efficacy trial.

The therapist delivered IPT-E based on the guideline: BEGINNING TASKS: At the beginning (sessions #1-2) the therapist asked the patient questions to understand their problems, symptoms, explanatory model and psychosocial supports. We establish a therapy relationship, provide feedback, and choose the IPT problem area (**loss, change or disagreements**) for the focus of the middle phase sessions.

MIDDLE PHASE TASKS: In this phase (#2 session) of IPT the therapist focuses on working through aspects of underlying interpersonal problems and on helping patients to connect with supports. It is recommended to focus on one problem area, but sometimes the therapeutic focus can extend to another area if it is also saliently linked to current distress.

ENDING PHASE TASKS: During the final session (# 1 session), the patient's efforts and progress are reviewed. Contingency plans are made in case symptoms worsen. In the ending phase old losses may be processed and `symptoms` from these may be mistaken for a reoccurrence of the original symptoms that brought the patient to treatment. The therapist will meet the patient every week for 30-60 minute per session for the predetermined period of time(67).

5.3.3 Post Intervention Assessment

The outcome assessors were trained on how to administer the assessment tool which was HADS and EORTIC QLQ C-30. Outcome assessment was done two weeks after the intervention. And the outcome assessors were different professionals from the baseline assessors, this helped us to avoid the bias that could possibly arise from baseline assessors (adjustment of post-assessment score which is in favour of the study). And the outcome assessors were blinded so as we can prevent intentional adjustment of participant's outcome.

5.3.4 Post-trial Beneficence

Here the control groups were told about the purpose of the study and its probable side-effects as described in the consent form. Though, since the process of delivering an adjuvant treatment (Psychotherapy) for one group and denying for the other might bring Ethical issue. So in order to fill these Ethical Bridge the control groups in this study got post-trial beneficence.Which is psychotherapy with equal duration and content with that of the intervention group.

5.3.5 The therapeutic Process and Set-up

After getting informed conscentnt patients were screened for common mental disorder at base-line , and those who met the inclusion criteria were taken to the therapy room. The therapy room was situated in a separate area from the oncology unit. It was placed apart from the oncology unit for the ease of creating noise free atmosphere for the therapeutic process. The room had a window for us to get enough light during the therapeutic process, the chairs for the therapist and the individual patient were placed as the therapeutic process requests, there was no permanent barrier between the patient and the therapist, and there was a waiting area for patients to wait for their turn around the therapy room. Also patients were appointed in an hourly interval from the other patient so as we can avoid long waiting times. Patients were contacted through their mobile phone. On their arrival patients were being communicated by the supervisor and taken to the therapy room on their order.

5.4 Population

5.4.1 Source Population

All women with Breast Cancer at Tikur Anbessa Specialized Teaching Hospital that are on Treatment and follow up.

5.4.2 Study Population

All Breast Cancer patients who were aged 18 and above and those that are diagnosed with common mental disorder at Tikur Anbessa Specialized Teaching Hospital outpatient department, Addis Ababa, Ethiopia.

5.4.3 Study Unit

The study unit was an individual breast cancer patient available during data collection.

5.5 Variables and Measurement

5.5.1 Outcome Measures

Dependent variable

Treatment outcomes can be measured subjectively and objectively. The subjective treatment outcome measures are the patients' responses about the effect of treatment while the objective ones are carried out using certain standard clinical measures like laboratory finding and as such.

In this study treatment outcome is the dependent variable and it was assessed using a 30 item question of quality of life measurement scale.

Quality of Life

Quality of life is an important indicator in measurements of treatment outcome among cancer patients because the treatment can affect the patient's everyday life and can cause serious harm to the patient, which can outweigh the advantages it is supposed to give. QOL will be assessed using The Amharic version of EORTC QLQ-C30 that is found to be reliable and had an acceptable validity to assess the QOL among cancer patients.

The Amharic version of EORTC QOL-C30 is composed of 30 questions. Of the 30 items, 24 are organized into nine scales: Physical functioning (5 items; questions from 1 to 5), Role functioning (2 items; question 6 and 7), Emotional functioning(4 items; questions from 21 to 24),Cognitive functioning(2 items; question 20 and 25), Social functioning(2 items; question 26 and 27), GHS/quality of life(2 items; question 29 and 30), Fatigue(3 items; questions 10, 12 and 18), Nausea and vomiting(2 items; question 14 and 15), and Pain(2 items; question 9 and 19)and 6 single items assessing financial impact and various physical symptoms such as dyspnea, insomnia, appetite loss, constipation and diarrhea(questions 28, 8, 11, 13, 16 and 17 respectively(68).

Scoring

In practical terms, if items I_1, I_2, I_n... are included in a scale, the procedure is as follows:

Raw score

Calculate the raw score

Raw Score = RS $\left(I_1 + I_2 \ldots I_n \right)/n$

Linear transformation

Apply the linear transformation to 0-100 to obtain the score *S*, the individual score for each domain is as follows. So for domains under functional scale, we use the first formula and for the domains under the symptom scale, we will use the second and likewise.

Functional scales: $S = \left\{ 1 - \frac{(RS-1)}{\text{Range}} \right\} * 100$

Symptom scales/items: $S = \{(RS - 1)\ \text{range}\} * 100$

Global health status / QoL: $S = \{(RS - 1)\ \text{range}\} * 100$

Range is the difference between the maximum possible value of RS and the minimum possible

Value. A high score for a functional scale represents a high/healthy level of functioning and a high score for the global health status / QoL represents a high QoL, whereas a high score for a symptom scale or item represents a high level of symptomatology or problems(69).

Independent Variable

Behavioral Factors: -Depression and anxiety score is measured using the HADS measurement scale.

Depression and Anxiety are measured with an Ethiopian validated HADS measurement scale. The instrument is validated by Ayalu Aklilu(70). The Hospital Anxiety and Depression Scale (HADS) is a widely used health-related quality of life instrument for measuring psychological distress. The HADS is a questionnaire intended for the diagnosis and evaluation of anxiety and depression in non-psychiatric patients (71-73).

The items are rated on a four-point Likert scale ranging from 0 to 3 giving maximum and minimum scores of 0 and 21 respectively for each subscale. Sub-scores on the anxiety or depression subscales ranging from 0 to 7 are considered normal; while 8 to 10 and 11 to 21 are considered 'cause for concern' and 'probable cases of anxiety or depression' respectively. The Ethiopian version of the HADS is an easy to administer instrument for measuring emotional distress. It showed good consistency between the items and high test-retest reliability(70).

HADS measurement of

0 to 7--- normal

8 to 10----- mild

11 to 14 ----- moderate and those 15 to 21----- severe.

5.5.3 Cofounding Variables

Socio-demographic Factors

Age: - is measured in years.

Religion: - will be categorized into four as 1) Orthodox Christian 2) Muslim 3) Catholic 4) protestant.

Educational status:-will be assessed as

(1).No Formal Schooling (2). Read and Write (3). Primary (4). Secondary (5). College and some University

Economic status: - is measured by Wealth index indicator

Cancer related Factors

-Tumor size (1) < 2cm (2) 2-5 cm (3) > 5cm

-Tumour grade (1) Low grade (2) Intermediate grade (3) High grade

-Stage of the cancer (1) Stage 1 (2) Stage 2 (3) Stage 3

- Metastasis at the time of initial diagnosis (1) Metastasis present (2) Metastasis Absent

Treatment Type (1) Radiotherapy (2) Chemotherapy (3) Surgery

5.6 Sampling

5.6.1 Sample size determination

The sample size was determined using Epi info version 7.2.2.6 software (United-states center for disease prevention and control, Atlanta, GA) using double population proportion mean formula, from a study done in China on the Benefit of Psychosocial intervention for cancer patients with depression and Anxiety(48) and using a study done in Frankfurt Germany on comparing Efficacy of Interpersonal Psychotherapy and Cognitive Behavioural Psychotherapy in comparison with the waiting list group(74), using

$$n = \frac{2[(\partial + \beta)^2 * (SD1)^2 + (SD2)^2]}{(\mu_1 - \mu_2)^2}$$ formula, with the assumption of significance level ((α=5%),Power 90% and 95% confidence level, ratio of intervention and control groups(R) 1:1.The computation that had larger sample size were taken as the final sample of the study. In this study we considered the cultural, economical, and awareness differences of the reference group to that of our community. Aside from that we took under consideration the professional skill and knowledge gap that the therapists in our set-up might had in delivering the proposed therapy in comparison with the reference population. So we assumed that we would find 10% lessen effect of the therapy in our intervention group in comparison with the reference population and also we assumed that our control groups had 15% higher anxiety and depression level and 15% lessen quality of life than our reference population (We took studies done in China- Guilin and German- Frankfurt) for sample size determination. We have calculated the sample size for all the domains and we have taken the largest. From the sample sizes calculated the largest sample size was taken, that was 113 and 10% loss to follow up is added and the final sample size was turned out to be 124. Detail description of the sample size determination is mentioned in table one below.

Table 1: Sample size determination procedure to identify the Effect of Interpersonal Psychotherapy on treatment Outcome among Breast Cancer Patients with Common Mental disorder at TASH 2018/2019.

Specific Objective	Variable considered	Assumption Previous studies	Means	Standard Deviations	Estimated sample size with 10% non-response rate
1.	Physical Functioning	Those who received Psychotherapy(Intervention group)	71.73	9.80	77
		Those who receive treatment as usual (Control group)	64.05	9.71	
	Emotional Functioning	Those who received Psychotherapy(Intervention group)	66.762	11.43	71
		Those who receive treatment as usual (Control group)	56.12	14.00	
	Cognitive Functioning	Those who received Psychotherapy(Intervention group)	73	12.36	123
		Those who receive treatment as usual (Control group)	66.01	10.01	
	Social Functioning	Those who received Psychotherapy(Intervention group)	67.015	10.67	123
		Those who receive treatment as usual (Control group)	60.00	11.88	
	Health-related Quality of	Those who received Psychotherapy(Intervention group)	52.92	12.20	

	life/General health status	Those who receive treatment as usual (Control group)	43.452	12.82	84
2.	Depression	Those who received Psychotherapy	4.499	4.0	63
		Those who do not receive Psychotherapy(control)	9.23	6.13	
3.	Anxiety	Those who received Psychotherapy	52.976	22.36	124
		Those who do not receive Psychotherapy(control)	68.885	29.05	

Sample size of group 1=62
Sample size of group 2=62 } -Both groups are those who are diagnosed with depression and anxiety. And they will be assigned randomly as Intervention and control group respectively.

5.6.2 Sampling Technique and Procedure

The study area was selected for the of the site being the only cancer treatment and therapy center with both radiotherapy and chemotherapy in Ethiopia; so in order to find those patients that are both on radiotherapy and chemotherapy treatment, the site is selected. The total number of patients on treatment at TASH from each cancer type based on the last year data. Which was in similar fiscal year with our data collection period three month report was totally 1042: for breast cancer 327, cervical cancer 250, gastrointestinal cancer 235, non-Hodgkin lymphoma (NHL) 132 and prostate cancer 98.Breast Cancer is selected because it is the leading cancer and most frequently diagnosed cancer type as per report. Selection of the study participants were done consecutively using the inclusion criteria and they will receive an informed consent and if they agreed they were randomly assigned into either of the two comparative groups equally in weeks. The recruitment of participants were continued until it reaches the required sample size.

5.6.3 Inclusion Criteria

All women who are aged 18 and above with all Stage Breast cancer and those that are diagnosed for a common mental disorder with HADS measurements which is HADS>=8 at Tikur Anbessa specialized teaching Hospital and those who were willing to be enrolled in the study.

5.6.4 Exclusion Criteria

Those with severe physical illness, severe mental illness (psychosis & mania), functionally impairing substance abuse, and Patients who are acutely suicidal were excluded from the study.

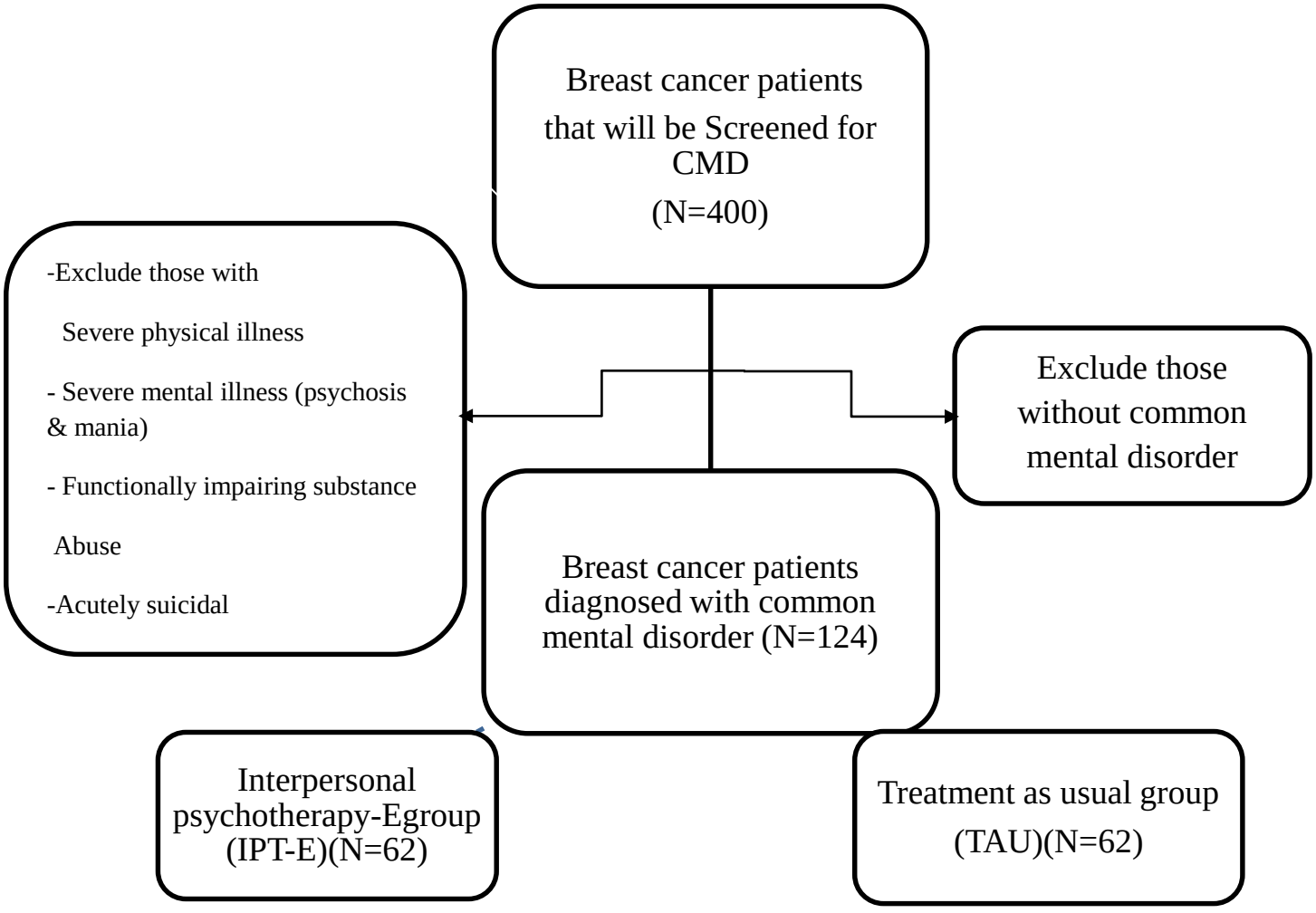

Figure 2: Schematic presentation of the effect of Interpersonal psychotherapy on treatment outcome among breast cancer patients with a common mental disorder at Tikur Anbessa specialized hospital study design flow 2018/19.

5.7 Data Collection procedure

Data were collected through a structured questionnaire. One-day training theoretical and practical was given for data collectors to collect data relating to Socio-demographic status, disease related, quality of life related and concerning Depression and Anxiety score.The detail training manual is annexed on **Annex 16**. Therapists that do already have a training on IPT-E were briefed and trained about the intention and goal of the study to deliver Psychotherapy. At base line depression, anxiety and quality of life of the patients were assessed and at the end of the therapy; anxiety, depression and quality of life were assessed in the same manner. The tools that were utilized in this study are standard tools that are already validated. But those tools that are developed for the purpose of this study was pre-tested for suitability before data collection in other Hospitals that had no chance of being included in this study. After completing filling the questionnaires, trained therapists delivered the Psychotherapy. The data collectors were nurses that have a training on collecting related data. At arrival, patients were taken to the nurses' room and screened for the presence of anxiety and depression. If they were possible cases and if they met the inclusion criteria, they were taken to the therapy room that is placed in a separate area from the oncology unit. Therapists were waiting for the patients at the therapy room where one to one session for about an hour is held.

5.8 Data Collection Tool

Data regarding age, sex, marital status (Demographic data) and data regarding socio-economic status of patients was adopted from the demographic data questionnaire which is adapted from the EDHS(75)by the trained data collectors. Then data regarding their cancer related factors, were obtained using tools adapted from different literatures (23-25, 62-65). Whereas data regarding the study participants depression and Anxiety status; was obtained using HADS measurement scale(70), additionally data regarding the patients treatment outcome was obtained using EORTC QOL-C-30(68).

5.9 Operational Definitions and Standard Definition

5.9.1 Standard Definition

Cognitive function- Had a lot of difficulty concentrating and remembering things when the score is 0 and no difficulty of concentrating and remembering things when score is 100(76).

Emotional functions- felt intense, irritable, depressed and worried a lot when the score is 0 and don't feel intense, irritable and do not worry when the score is 100(77).

Fatigue-did not feel at all weak or tired and did not need to rest at all when the score is 0 and did feel very weak and tired and needed to rest a lot when the score is 100(78).

Pain-didn't have pain and pain did not interfere with daily activities when the sore is 0 and had a lot of pain; interfere very much with daily activities of the day when the score is 100(78).

Physical function- Was confined to bed, needed help dressing, washing and eating when the score is 0 and able to do strenuous activities when the score is 100(78).

QoL - a multidimensional construction that measures patients' perception of the positive and negative aspects associated with their disease and its treatment, in at least 4 aspects: physical, emotional, psychological, and treatment-related(78).

Role functions- is completely unable to work at a job or do household jobs when the score is 0 and able to do work at household and at work when the score is 100(78).

Social Function- when physical function and medical treatment interfered very much with family life and social activities when the score is 0 and physical function and medical treatment do not interfere with family and social activities when the sore is 100(78).

5.9.2 Operational Definition

Treatment Outcome: Treatment outcome can be measured subjectively and objectively. The subjective treatment outcome measures are the patients' responses about the effect of treatment while the objective ones are carried out using certain standard clinical measures like laboratory finding and as such. But in this study is treatment outcome is measured through patient-reported treatment outcome measures as the quality of life and that of reduction in depression and anxiety.
Treatment as usual: In this study treatment, as usual, is considered as the existing treatment that Cancer patients receive routinely at this care center. So we refer those groups who take the routine treatment at the oncology unit as treatment as usual groups (Controls).

Common mental disorder: Common mental disorder encompasses three main kind of disorders such as anxiety, depression and that of somatoform problems or medically unexplained problems. But in this study we consider anxiety and depression as common mental disorder.

5.10 Data quality assurance

The data quality assurance followed a series of activities at every level of the data management and started initially by random assignment of participant and masking as much as possible in order to minimize selection biases. The measurement of the investigations was conducted using a similar measurement scale and the outcome assessment was done with these professionals and assessed by experienced health professionals in the hospital with known ethical care provision. For the data collection tool, translation in to Amharic before starting the data collection process and the data collectors and supervisor also received an adequate training on the standard operating procedures (SOPs). The supervisor supported and supervised the data collectors on a daily basis. The PI overlooked and supervised the data collections and therapy process every day. Training manual and SOP is annexed on **Annex 15**.

5.11 Data Management and Analysis

After the data were collected, the completeness and consistency of the questionnaire were checked manually, missing values and outliers was checked by the principal investigator. Then both the questionnaires and the variables were coded. After this, Epi DATA version 4.4.2.1 were used to enter, clean the collected data. Per-protocol analysis was considered to analyse data.

Also, the Analysis ranges from simple descriptive to Analysis of Covariance Model. The analysis was done using Minitab 18 software.

Descriptive statistics of numeric variables are presented in means and standard deviation. The assumption was checked for normal distribution using normal probability plot, versus fits, histogram, and versus order on Minitab. Per protocol, analysis was assumed to analyze the data.Assumption graphs are annexed on **Annex 13**.

Baseline comparison for categorical variables

Chi-square was done to identify the base-line difference between the intervention and control concerning the categorical variables as Age, wealth index, religion, educational status, communication, tumor size, tumor grade, metastasis, and treatment kind. And also independent t-test was employed to compare groups' in terms of anxiety, depression and that of quality of life domains. This helped us to identify the comparability of the two groups' interms of the observed characteristics.

Wealth Index

Principal component analysis (PCA) was conducted by first asking all study participants about their household fixed asset and housing condition questions a score "1" given to those who own/have and score of "0" given to those who did not . Then, all the items asked were assessed for internal consistency to transfer the asset information into latent factors and the first PCA explaining most of the variation based on the objective of the study was taken as a wealth score. Wealth index was by rank ordered into quintiles to give poorest, poor, medium, wealthy and wealthiest status or lowest, second, medium, fourth and highest quintiles.

Depression and anxiety

Depression and anxiety were measured with a 14-item Likert scale each having a range of 0 up to 3 choice. Anxiety and depression separately have 7 item questionnaire scored out of 21. Groups were compared for base-line anxiety and depression score difference using independent t-test.

Quality of life

Quality of life is a multidimensional scale with three scales named as functional, symptom and general health status which incorporated 15 domains in it. The domain was calculated using Standardized Likert scale summated score to mark EORTIC QOL-C30 according to Quality of life scoring manual. The score has possible values ranging from 0 to 100, a high score for a functional scale represents a high/healthy level of functioning and a high score for the global health status represents a high QoL, whereas a high score for a symptom scale or item represents a high level of symptomatology or problems.To compute standardized score we have to calculate Raw score as,

Raw Score = RS $(I_{1+} I_{2...} In)/ n$.

I_1 indicating item 1 and the others as is. And we will compute the standardized score for each domain as

Functional scales: $S= \left\{ 1- \frac{(RS-1)}{Range} \right\} *100$

Symptom scales / items: $S= \{(RS-1) \text{ range}\}*100$

Global health status / QoL: $S = \{(RS-1) \text{ range}\}*100$

Groups were compared for base-line difference in these domains using Independent t-test.

Evaluation of the effect of IPT on common mental disorder among breast cancer patients

The effect of inter-personal psychotherapy on common mental disorder is evaluated using general linear model (ANCOVA). Before fitting the response variables, factors and covariates into the ANCOVA model; univariate linear regression was done to check the presence of association between the dependent and the independent variables. Here finding from literatures were used as a principal guide.Detailed ANCOVA result is annexed on **Annex 14.**

Evaluation of the effect of IPT on treatment outcome among breast cancer patients

The effect of inter-personal psychotherapy on treatment outcome by each domain is evaluated using general linear model (ANCOVA). Before fitting the response variables, factors and covariates into the ANCOVA model; univariate linear regression was done to check the presence of association between the dependent and the independent variables. Here finding from literatures were used as a principal guide. Detailed ANCOVA result is annexed on **Annex 14.**

Index (composite) score of over-all quality of life

Cronbach's alpha

Principal Component Analysis (PCA) is done so as we can get the factor scores (Index score) for Quality of life, which is a 30-Item Questionnaire that are sub-divided in three scales and different sub-domains. Reliability test for each item domain is done. And it is found that they have good reliability with most of the domain have good reliability with a cut-off point 0.7 and above except some of the domains under the symptom scale with reliability of 0.58 and Health related quality of life domain with reliability of 0.59. The scores that were found using PCA were used for GLM (ANCOVA) model in both pre and post intervention groups. The reliability of the item in each domain is indicated in the table below (**Table 2**).

Table 2: Reliability test of Quality of life domains by the sub-group of items

No	Domains	Item	Reliability
1	Physical functioning	Q1,Q2,Q3,Q4,Q5	0.7759
2	Role Functioning	Q6,Q7	0.8868
3	Cognitive Functioning	Q20,Q25	0.6870
4	Emotional Functioning	Q21,Q22,Q23,Q24	0.8559

5	Social Functioning	Q26,Q27	0.8364
Symptom scale-1			
6	(Dyspnea, Insomnia, Appetite Loss, Constipation, Diarrhea and Financial difficulties)	Q8,Q11,Q13,Q16,Q17,Q28	0.5858
Symptom scale-[5]			
7	Pain	Q9,Q19	0.6869
8	Fatigue	Q10,Q12,Q18	0.8232
9	Nausea/Vomiting	Q14,Q15	0.8820
10	Health related quality of life/General health status	Q29,Q30	0.5904

5.11 Ethical Considerations

This research was conducted to act in the best interests of study participants. In which ethical approval was obtained from the school of public health, Addis Ababa University and Research Ethical Committee. After the ethical approval, formal letter of cooperation was written to the department of oncology to review records for the enrolment purpose. Oral and written consent was also requested from all the participants during data collection. Only approved study personnel had access to this information. After completion of the study, identifier information were set aside and only study identification numbers (ID no.) was used during analysis. At the time of enrolment, study participants and their family members was encouraged to contact the data collectors in the unlikely event of any adverse occurrence. The right to withdraw from the research process at any point in time were respected. Regarding safety of intervention, since psychotherapy is a talk therapy there was no expected severe complication due to the therapeutic process but the Ethical Bridge of assigning one group as Intervention and the other as Control were filled by informing participants that they had equal chance of being allocated as intervention and control group. And even during the intervention period, control groups were told that they can withdraw anytime from the study and get treatment of their preference. Aside from that in order to fill the Ethical Bridge the control groups in this study got post-trial beneficence based on their preference.

5.12 Dissemination of the results

The result of this study will be disseminated to Addis Ababa University School of Public Health, Federal Ministry of Health, non-governmental organizations (NGOs) who are currently working on cancer care, other stakeholders and local and international journal.

6. Result

Among the 400 patients that were available during the data collection period at TASH oncology unit, 124 met the inclusion criteria whereas 268 of them did not met the inclusion criteria and 8 of the patients refuse to participate in the study. After excluding 268 of the patients that do not meet the inclusion criteria and 8 of the patients that refused to participate in the study; the 124 patients that met the inclusion criteria were allocated to the intervention and control groups according to the week that they visited the oncology.From those allocated in the intervention and control groups, 10 of them lost to follow up.These made our response rate to became 91.9%.

The reason for the patients loss to follow-up were:-

Reason for loss-to-follow up

- Three of the patients were lost to follow up because they were not comfortable with the therapeutic procedure. These patients reported that they were not comfortable with the therapeutic procedure.

Proposed Solution

- These patients were contacted and discussed about the arised problem.Possible solutions were proposed to them, such as changing therapist but they refused to proceed in the therapeutic procedure.

Reason for losss-to-follw-up

- Two patients reported that they didn't perceive therapy would be helpful for them.

Proposed Solution

- They were contacted and discussed about their reason to lost to follow up.They were briefed about the burden of common mental disorder and the respective influence on quality of life and also how the therapy would play its part.

Reason for loss-to-follow up

- Three patients became physically deteriorated and we were un-able to trace them back for re-evaluation.

Reason for loss-to-follow up

- We were un able to know about our two patients reason for lost-to- follow-up since we couldn't contact this patients via their telephone.

Among the intervention and control groups those who didn't progress well were linked to the psychiatry department for further evaluation and management.

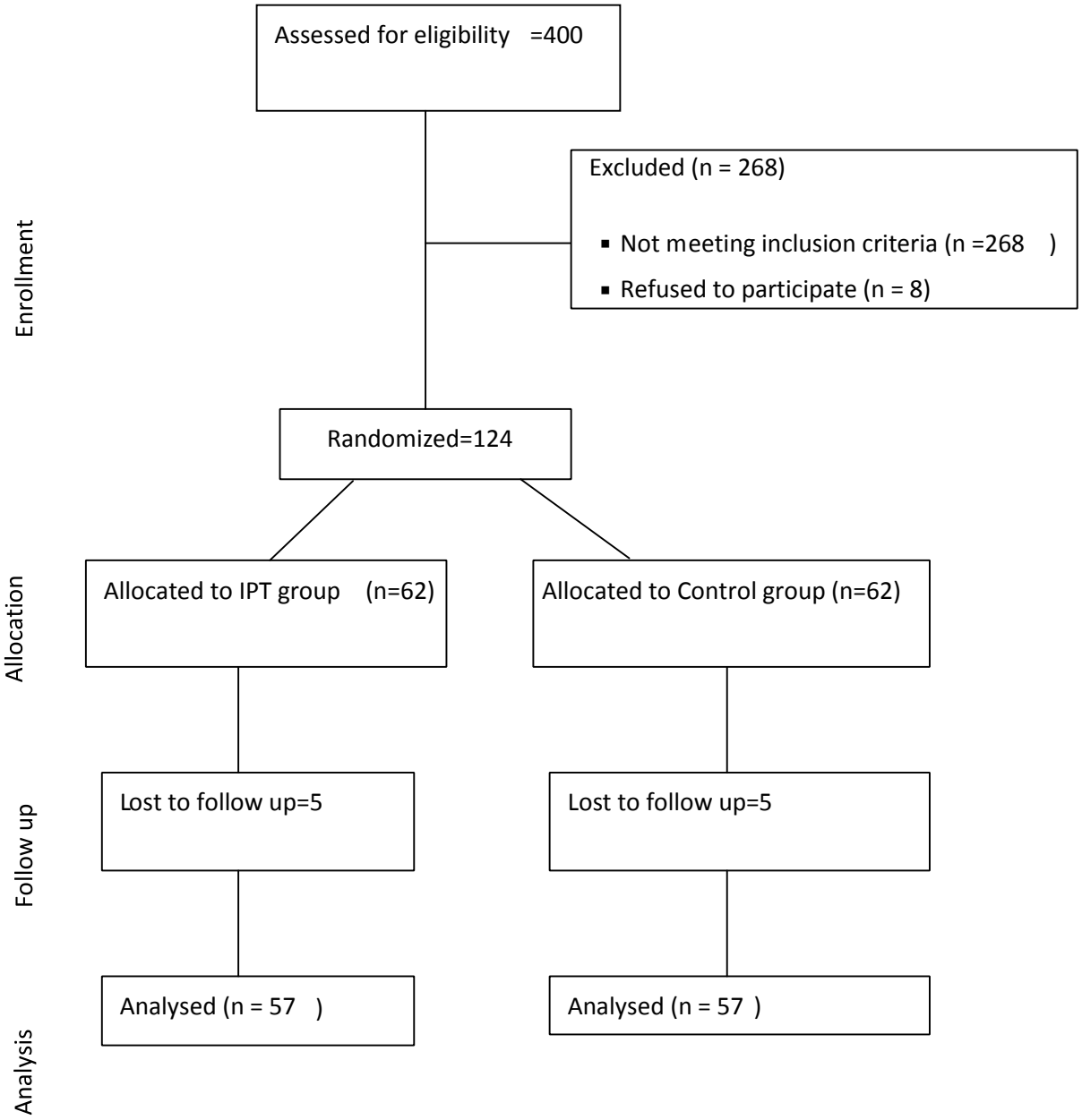

Figure 3**: CONSORT flowchart for the study "**The Effect of Inter-Personal Psychotherapy on Treatment Outcome among Breast Cancer Patients with Common Mental Disorder: A Randomized Control Trial at Tikur Anbessa Specialized Hospital Oncology unit 2018/19."

6.1 Base-line characteristics of the study participants

Among the participants 71.9% intervention and 63.2% of the control groups of the study participants were orthodox Christians. Also 46.9% of the intervention and 46.8% of the control groups attained secondary school. Among the total 114 study participants 27(47.4%) of the intervention and 37(64.9%) of the control groups were married. Significance difference was observed between the intervention and control groups in the communication that they have with their physician. (**Table 3**)

Table 3: Socio-demographic, Economic and Communication related condition of patients of both group at TASH oncology unit Addis Ababa, Ethiopia 2018/19

Background Characteristics	**Intervention Groups(IPT) N=57 N (%)**	**Control groups (TAU) N=57 N (%)**	**P-value**
Age			
19-28	5(8.7%)	6(10.5%)	
29-38	19(33.3%)	18(31.5%)	
39-48	24(42%)	22(38.6%)	0.970
49-58	5(8.7%)	7(12.3%)	
>58	4(7.01%)	4(7.01%)	
Mean±SD			
Wealth Quintiles			
Lowest	17(29.8%)	23(40.3%)	
Second	6(10.5%)	2(3.5%)	
Middle	9(15.7%)	12(21.05%)	0.400
Fourth	20(35.08)	15(26.31%)	
Highest	5(8.7%)	5(8.7%)	
Religion			
Orthodox	41(71.9%)	36(63.2%)	0.397
Catholic	0(0)	2(3.5%)	
Protestant	10(17.5%)	11(19.3%)	

Muslim	5(8.75)	8(14%)	
Other	1(1.7%)	0(0)	
Educational status			
No Formal Education	9(15.7%)	13(22.8%)	
Primary School	13(26.5%)	10(21.3%)	
Secondary School	23(46.9%)	22(46.8%)	0.07
Technical school and above	12(24.5%)	12(25.5%)	
Marital status			
Single	30(52.6%)	20(35.1%)	
Married	27(47.3%)	37(64.9%)	0.06
Communication with Physician			
Good Communication	28(49.1%)	8(14%)	0.000
Poor Communication	29(50.8%)	49(85.9%)	
Communication with Family			
Good Communication	43(75.4%)	40(70.2%)	0.528
Poor Communication	14(24.6%)	17(29.8%)	

6.2 Base-line clinical Characteristics of Breast Cancer patients at TASH Oncology Unit

No significant difference was observed among the clinical characteristics of the patients except that of the treatment kind that the patients were on. Significant difference was observed on kind of the treatment that the patient is on between the intervention and control groups. 29(50.8%) of the Intervention and 48(84.2%) of the control groups are on chemotherapy and had mastectomy. (**Table 4**)

Table 4: Clinical Characteristics of Breast Cancer patients of both groups at TASH Addis Ababa, Ethiopia 2018/19

Clinical Characteristics	**Intervention Groups(IPT) N=57 N (%)**	**Control groups (TAU) N=57 N (%)**	**P-value**
Tumor size			
<2cm	9(15.7%)	6(10.5%)	
2cm-5cm	30(52.6%)	31(54.3%)	0.32
>5cm	18(31.5%)	20(35.08%)	
Stage of the cancer			
Stage 1	5(8.7%)	1(1.75%)	
Stage 2	14(24.1%)	15(26.3%)	0.36
Stage 3	20(35.08%)	22(38.59)	
Stage 4	18(31.5%)	19(33.3)	
Metastasis at diagnosis			
Metastasis present	18(31.5%)	19(33.3%)	0.743
Metastasis absent	39(68.3%)	38(22.8%)	
Kind of treatment			
Chemotherapy	3(5.2%)	7(12.2%)	
Radiotherapy	1(1.7%)	0(0)	
Chemotherapy and Radiotherapy	0(0)	1(1.7%)	
Chemotherapy and surgery	29(50.8%)	48(84.2%)	0.000
Chemotherapy, Radiotherapy and surgery	12(21.1%)	0(0)	
Radiotherapy and surgery	1(1.7%)	0(0)	

Hormonal therapy	11(19.3%)	1(1.7%)	
Other disease condition			
Present	12(21%)	6(10.5%)	0.123
Absent	45(79%)	51(89.4%)	

6.3 Base-line depression and anxiety status of Breast cancer Patients at TASH Oncology unit

There was a significant difference in depression level of the patients. The patients in the intervention groups were found to be more depressed than that of the control groups. Whereas patients both in the intervention and control groups are not different in their Anxiety level.

Table 5: Anxiety and Depression status of the Breast cancer patients among both groups at TASH, oncology unit Addis Ababa, Ethiopia 2018/19

Characteristics	**Intervention Group(IPT)** Mean(SD)	**Control groups (TAU)** Mean(SD)	**P-value**
Anxiety	12.61(3.67)	12.22(2.73)	0.2630
Depression	13.87(3.48)	11.75(3.45)	0.0014

6.4 Base-line quality of Life of Breast cancer Patients at TASH Oncology unit

Breast cancer patients with common mental disorder at TASH oncology unit exhibited certain difference in few domains of quality of life both in the intervention and control group. Cognitive functioning, Emotional functioning, social functioning and insomnia were the domains that had exhibited a certain significant baseline difference. The intervention groups were having a lessen Cognitive, Emotional and Social functioning. Whereas insomnia was observed to be less among the control groups. **(Table 6)**

Table 6: Quality of life of participants in all domains at Baseline among the two groups among breast cancer patients at TASH, oncology unit Addis Ababa, Ethiopia 2018/19

Quality Of Life Domains	**Intervention Group(IPT)** Mean(SD)	**Control groups (TAU)** Mean(SD)	**P-value**
Physical Functioning	66.08(20.32)	59.29(26.74)	0.1302
Role Functioning	57.60(32.59)	59.94(39.06)	0.7292
Cognitive Functioning	60.23(29.16)	76.90(26.30)	0.0018
Emotional Functioning	40.20(23.68)	55.70(26.91)	0.0015
Social Functioning	50.29(35.28)	64.03(36.56)	0.0435
QOL Symptom Scales			
Dyspnea	26.31(27.98)	23.39(29.52)	0.5884
Pain	44.44(30.42)	40.35(31.95)	0.4851
Fatigue	45.41(28.81)	48.53(29.21)	0.567
Insomnia	44.44(36.36)	28.07(31.36)	0.0114
Appetite Loss	46.19(34.93)	47.95(39.34)	0.8017
Nausea/Vomiting	19.59(25.02)	26.60(31.94)	0.1944
Constipation	29.23(32.77)	29.82(34.89)	0.9267
Diarrhea	5.84(17.95)	4.67(14.69)	0.7042
Financial Difficulties	67.83(35.61)	60.23(41.99)	0.2995
GHS/HRQOL	46.92(15.64)	50.29(17.24)	0.2779

6.5 The Effect of Interpersonal Psychotherapy on Common Mental Disorder among Breast Cancer patients

Inter-personal Psychotherapy was associated with post-intervention mean anxiety score; which indicated that due to the intervention, the post-intervention anxiety score became 5.726 unit lesser in the intervention group than that of the control group [p<0.01 ,coefficient -5.76 and 95%CI(-7.696,-3.756)]. Participants base-line anxiety score was also associated with post-intervention anxiety score [p<0.01, coefficient 0.590, and 95%CI (0.332, 0.849)], which means that participants who had a unit higher base-line anxiety score before the intervention were found to have 0.590 unit higher post-intervention anxiety score when compared with the other participants with a unit lower score. Being in the highest quintile was inversely associated with post-intervention anxiety score. Which means that being in the highest quintile resulted in a decreased anxiety score [p=0.006, 95%CI (-7.60,-1.30)]. On the other hand patient being on radiotherapy and having mastectomy found to increase anxiety [p=0.029, 95%CI (1.10, 20.19)]. Here the effect that being on the highest quintile had on post-intervention anxiety score depends on the patient's treatment kind, which is the patient being on radiotherapy and having mastectomy. Thus, the effect that being in the highest quintile had on post-intervention anxiety score was mediated by the patient being on radiotherapy and having mastectomy. This result underlines that the protective effect of being in the highest quintile on post-intervention anxiety score was no longer effective when the patient is on radiotherapy and had mastectomy.

Inter-personal Psychotherapy was also associated with post-intervention mean depression score, even if the base-line depression level of the intervention group was higher than that of the control groups. It was found that due to the intervention, post-intervention depression was decreased by 4.784 unit in the intervention group than that of the control group [p<0.01, coefficient -4.784 and 95%CI (-6.466, -3.103)].Participants base-line depression level was also found to associate with post-intervention depression score [p<0.01 coefficient 0.599 and 95%CI (0.363, 0.835)], which means that participants who had a unit higher base-line depression before the intervention were found to have 0.599 unit higher post-intervention depression score when compared with the other participants with a unit lower score.

Table 7: ANCOVA result of the effect of IPT-E on common mental among breast cancer patients at TASH oncology unit Addis Ababa, Ethiopia 2018/19

Symptoms	Exposure status	Baseline Mean(SD)	Outcome Mean(SD)	Coefficient	95% CI	t value	P value
Anxiety	Intervention	12.61(3.68)	6.78(5.09)	-5.76	(-7.10,-2.90)	-4.73	<0.01**
	Control	12.28(2.73)	11.98(4.62)	-	-	-	-
Depression	Intervention	13.87(3.485)	8.28(4.74)	-4.784	(-6.44,-3.103)	-5.64	<0.01**
	Control	11.754(3.445)	12.228(4.48)	-	-	-	-

**p<0.01 Referent groups: - Tumor size :< 2cm, Tumor grade: low grade, Cancer stage: stage I, Treatment kind: Chemotherapy, Metastasis: Metastasis present, any other disease: Yes, Wealth Quintile: Lowest

The above tables is number of ANCOVA model that is done separately for anxiety and depression. We displayed the outcomes in this table for presentation simplicity. The detailed ANCOVA model is annexed on **Annex-14**.

6.6 The Effect of Interpersonal Psychotherapy on treatment Outcome among Breast Cancer patients with Common mental disorder

The result showed that inter-personal psychotherapy had an effect in improving quality of life domains such as; Physical, role, cognitive, emotional and social functioning. Among the symptom scales; the result showed that there was a significant decrease in insomnia and fatigue where as an improvement in general health status/health related quality of life. The result of individual domain ANCOVA analysis revealed that there was a significant difference between the intervention and control groups after the intervention interms of certain quality of life domains.

In this study psychotherapy was found to be associated with post-intervention physical functioning. It was found that due to the intervention, post-intervention mean physical functioning level increased by 10.61 unit in the intervention group [p=0.005, coefficient 10.61 and 95%CI (3.19, 18.03)] when compared with control group. Another remarkable result to emerge from the data was that participants base-line physical functioning level was also found to be associated with post-intervention physical functioning score post-intervention [p<0.01, coefficient 0.472 and 95%CI (0.312, 0.632)], which means that patients who had a unit higher base-line physical functioning score before the intervention were found to have an increased post-intervention physical functioning by 0.472 unit when compared with other participants with a unit lower score. Interestingly the participant's age was found to crucially affect the post-intervention physical functioning with [p=0.019 and 95%CI (-0.798, -0.073)]. It was found that a year increase in the patient's age found to decrease post-intervention physical functioning by 0.436 unit. It was also fundamental to note that base-line depression was found to significantly associate with post-intervention physical functioning with [p=0.022 and 95%CI (-2.44, -0.191)], which means a unit increase in base-line depression level found to decrease post-intervention physical functioning by 1.317 unit.

The intervention was also remarkably associated with outcome role functioning. Which means that due to IPT, post-intervention role functioning was 24.46 unit higher in the intervention group than that of the control group [p<0.01, coefficient 24.46 and 95%CI (13.67, 35.25)]. Particpants baseline role functioning found to be associated with post-intervention role functioning, which means that patient who had a unit higher base-line role functioning score before the intervention were found to have an increased post-intervention role functioning by 0.195 unit when compared with other

participants with a unit lower score. The association between age of the patient and post-intervention role functioning was interesting in a way that when age increase by 1 year, role functioning decreased by 0.659 unit [p=0.017 and 95%CI (-1.195, -0.123].Being married is also positively significantly related with post-intervention role functioning (p=0.004) but this depends on the interventional group that the patient is on.The effect that being married had on post-intervention role functioning depends on the interventional group that the patient is on, which means that patients who are married and in the intervention group had better post-intervention role functioning than patients who are married and on the control group. This underlines that the protective effect of being married had on post-intervention role functioning was no longer effective when the patients' were on the control group.

Interestingly the intervention was associated with a 16.26 unit increase in cognitive functioning in the intervention group than that of the control group with [p=0.002, coefficient 16.26 and 95%CI (6.11, 26.40)]. Paticipants base-line cognitive functioning was associated with post-intervention cognitive functioning in a way that unit increase in base-line cognitive functioning resulted in an increase in post-intervetion cognitive functioning with [p<0.01 and 95%CI (0.183, 0.531)], which means that participants who had a unit higher base-line cognitive functioning score before the intervention were found to have an increased post-intervention cognitive functioning by a 0.357 unit when compared with other participants with a unit lower score. It was worth mentioning that base-line depression was also associated with post-intervention cognitive functioning with [p=0.002, coefficient -2.251 and 95%CI (-3.642, -0.861)] in a way that a unit increase in base-line depression found to decrease post-intervention cognitive functioning by 2.251. Another important factor that significantly affect outcome cognitive functioning was the treatment kind that the patient was on. Here being on radiotherapy and having mastectomy affect post-intervention cognitive functioning negatively but this finding depends on the interventional group that the patient is on. The effect that being on radiotherapy and having mastectomy had on post-intervention cognitive functioning score was influenced by the interventional group that the patient were following, which means that patients who were on radiotherapy and had mastectomy in the IPT group had better post-intervention cognitive functioning than patients who were taking similar treatment and were on the non-IPT group(controls).This means that the exposure effect that being on radiotherapy and having mastectomy had on post-intervention cognitive functioning was no-longer a factor when the patients attend the intervention (IPT) group.

Most importantly IPT was again associated with a 34.80 unit increase in post-intervention emotional functioning in the intervention group than that of the control group [p<0.01,coefficient 34.80 and 95%CI (24.73, 44.88)].Participants base-line emotional functioning was observed to associate with post-intervention emotional functioning 95%CI (0.266, 0.675), which means that participants who had a unit higher base-line emotional score before the intervention were found to have an increased post-intervention emotional functioning score by 0.470 unit when compared with other participants with a unit lower score. Being in the highest quintile also significantly positively affect outcome emotional functioning with (p=0.004) and 95%CI (8.28, 41.93) but this finding depends on the interventional group that the patients were found, which means that patients that were in the highest quintile and in the intervention group had better emotional functioning than those who were in the same quintile and on the control group. This means that the protective effect of being in the highest quintile had on post-intervention emotional functioning was no longer effective when the patients were on the control group.

Inexplicably, IPT was associated with outcome social functioning. It was indicated that after the intervention social functioning of the intervention group increased by 18.51 unit with [p=0.007, coefficient 18.51 and 95%CI (4.55, 27.62)].Participants base-line social functioning was observed to affect post-intervention social functioning [p=0.004, coefficient 0.234 and 95%CI (0.075, 0.393)] , which means that participants who had a unit higher base-line social functioning before the intervention were found to have an increased post-intervention social functioning by a 0.234 unit when compared with other participants with a unit lower score. Base-line depression also found to affect post-intervention social functioning in a way that a unit increment in base-line depression tend to decrease post-intervention social functioning by 1.801 unit [p=0.03 and 95% CI (-3.419, -0.183)].Being in the highest quintile also positively associates with post-intervention social functioning but this finding depends on the presence or absence of another disease condition.This means that the protective effect of being in the highest quintile had on post-intervention social functioning was no longer effective when the patient had other disease condition.

There were no significant differences in baseline and post-intervention dyspnea symptom between the intervention and control groups due to psychotherapy (p=0.197).Though base-line dyspnea found to significantly affect outcome dyspnea [p<0.001 and 95%CI (0.3244, 0.6512)], as it was revealed in this result; a unit increase in base-line dyspnea increased post-intervention dyspnea score with a 0.488 unit.

Our results showed that Psychotherapy did not affect pain symptom (p=0.072).Here base-line pain symptom significantly affect post-intervention pain symptom with (p=0.001) and 95%CI (0.125, 0.481), a unit increase in base-line pain tends to increase post-intervention pain by 0.303.Being stage IV also found to significantly affect the post-intervention pain with [p=0.031 and 95%CI (2.7, 54.9)] but this finding is highly dependent on the wealth quintile that the patient is on.

The asociation between psychotherapy and post-intervention fatigue score was worth mentioning because we found psychotherapy to be associated with a decrease in post-intervention fatigue score in 11.37 unit [p=0.028, coefficient -11.37 and 95%CI (-21.49, -1.24)]. Participants base-line fatigue score was associated with post intervention fatigue score [p<0.01, coefficient 0.389 and 95%CI (0.209, 0.569)], which means that patient who had a unit higher base-line fatigue score before the intervention were found to have an increased post-intervention fatigue by 0.389 unit when compared with other participants with a unit lowe score. Breast cancer stage also found to significantly affect outcome fatigue; which was the patient's being stage IV highly increased the post-intervention fatigue score [p=0.015 and 95%CI (5.7, 51.21)] but this finding inevitably depended on the intervention group that the patient was on. The effect that being stage IV had on post-intervention fatigue depended on the patient being on the intervention or control group, patients that were stage IV and on the intervention group had lessen fatigue score than those in the same stage of cancer thus found in the control group. This again means that the exposure effect that being stage IV had on post-intervention fatigue was no longer effective when the patient is in the intervention group.

The result in this study offered compelling finding on showing the effect of psychotherapy on outcome insomnia score.It was found that psychotherapy to be associated with a decreased post-intervention insomnia score by 19.56 unit [p=0.002, coefficient -19.56 and 95%CI (-31.87, -7.25). Participants base-line insomnia score was associated with post intervention insomnia [p<0.001, coefficient 0.403 and 95%CI (0.229, 0.0576)], which means that patient who had a unit higher base-line insomnia before the intervention were found to have an increased post-interventioninsomnia by 0.403 unit when compared with other participants. Being in the highest quintile also found to negatively affect outcome insomnia with (p=0.04) but this finding highly relied on the patient's interventional group. Patients that were in the intervention and also on the highest quintile found to have a decreased insomnia than those who were found on the same quintile and found on control group. This means that the protective effect of being in the highest quintile had on post-intervention insomnia was no longer effective when the patients' were on the control group.

The analysis did not confirm any significant differences between psychotherapy and post-intervention appetite loss score. Base-line appetite loss score also found to significantly affect post-intervention appetite loss score [p<0.001 and 95%CI (0.137, 0.461)], which indicates that a unit base-line increase of appetite loss score had increased outcome appetite loss score by 0.299. Here age of the respondents was found to positively influence post-intervention appetite loss score with [p=0.004 and 95%CI (0.29, 1.495)].

No significant difference had observed between the intervention and control group on post-intervention nausea and vomiting score (p=0.126).But base-line nausea and vomiting found to associate with post-intervention nausea and vomiting score [p<0.001 and 95%CI (0.183, 0.524)]. Also treatment kind found to associate with outcome nausea and vomiting symptoms as in being both on chemotherapy and radio-therapy found to increase outcome nausea and vomiting symptoms.

Our intervention ddn't significantly associate with post-intervention constipation symptoms (p=0.326).Base-line constipation symptom found to associate with the post-intervention constipation symptom score with [p<0.001 and 95%CI (0.316, 0.646)]. Inexplicably depression also found to affect outcome constipation with (p=0.002).

No significant difference was highlighted between post-intervention and base-line diarrheal symptom due to the intervention. This result indicated that there was no association between IPT and post-intervention diarrheal symptom. Base-line diarrheal symptom found to be associated with post-intervention diarrheal symptom in a way that a unit rise in baseline diarrheal symptom score found to increase the outcome diarrhea by 0.272 [p=0.022) and 95%CI (0.039,0.505)].

Psychotherapy was not associated with post-intervention financial difficulty.There was no significant relationship between post-intervention and base-line financial difficulties between the intervention and control group (p=0.419). Base-line financial difficulty significantly positively affect outcome financial difficulty (p<0.001). Most importantly here being in the highest quintile found to negatively affect outcome financial difficulty (p=0.05) and 95%CI (-46.7, 0.0).

The most striking result to emerge from these experimental study was that psychotherapy strongly positively associated with 21.85 increase in post-intervention health related quality of life score in the intervention group than that of the control group [p<0.001, coefficient 21.85 and 95%CI (14.10, 29.59)].Being in the highest quintile positively associated with health related quality of life [p=0.05

and 95%CI (0.02, 24.59)] but this finding depends on the patient being on radio-therapy. Here radio-therapy found to negatively associate with post-intervention health related quality of life (p=0.013).Thus, the effect that being in the highest quintile had on post-intervention health related quality of life was mediated by the patient being on radiotherapy. This means that the protective effect that being in the highest quintile had on post-intervention health related quality of life was no longer effective when the patient was on radiotherapy.

Table 8: ACOVA result of the effect of Psychotherapy on treatment outcome among breast cancer patients with CMD; all domains of quality of life result Addis Ababa, Ethiopia 2018/19.

Scales	**Quality of life Domains**	**Exposure status**	**Baseline Mean(SD)**	**Outcome Mean(SD)**	**Coefficient**	**95% CI**	**t value**	**P value**
Functional Scales	Physical functioning	Intervention	66.08(20.33)	73.57(22.00)	10.61	(3.19, 18.03)	3.01	0.005*
		Control	59.30(26.75)	62.81(25.54)	-			
	Role functioning	Intervention	57.60(32.59)	78.36(30.37)	24.46	(13.67, 35.25)	4.49	0.000*
		Control	59.94(39.07)	61.11(33.08)	-			
	Cognitive Functioning	Intervention	60.23(29.17)	73.39(29.19)	16.26	(6.11, 26.40)	3.18	0.002*
		Control	76.90(26.31)	69.01(26.06)	-			
	Emotional Functioning	Intervention	40.20(23.68)	76.46(28.92)	34.80	(24.73, 44.88)	6.85	0.000*
		Control	55.70(26.92)	52.19(29.40)	-			
	Social Functioning	Intervention	50.29(35.28)	73.68(31.65)	18.51	(7.00, 30.03)	3.19	0.002*
		Control	64.04(36.57)	58.19(32.14)	-			
	Dyspnea	Intervention	26.32(27.99)	19.88(28.07)	-6.10	(-15.43, 3.22)	-1.30	0.197
		Control	23.39(29.52)	24.56(29.23)	-			
	Pain	Intervention	44.44(30.43)	29.53(31.02)	-10.47	(-21.89, 0.94)	-1.82	0.072
		Control	40.35(31.96)	40.35(30.20)	-			

Symptom Scales	Fatigue	Intervention	45.42(28.81)	30.99(29.90)	-11.37	(-21.49, -1.24)	-2.23	0.028*
		Control	48.54(29.22)	44.25(30.32)	-			
	Insomnia	Intervention	44.44(36.37)	21.05(27.91)	-19.56	(-31.87, -7.25)	-3.15	0.002*
		Control	28.07(31.36)	35.09(36.42)	-			
	Appetite Loss	Intervention	46.20(34.93)	28.65(35.88)	-6.98	(-19.63, 5.66)	-1.10	0.276
		Control	47.95(39.35)	43.27(35.05)	-			
	Nausea/Vomiting	Intervention	19.59(25.02)	10.82(19.54)	-9.50	(-21.71, 2.71)	-1.54	0.126
		Control	26.61(31.94)	28.36(32.27)	-			
	Constipation	Intervention	29.24(32.78)	20.47(33.78)	-5.92	(-17.80, 5.97)	-0.99	0.326
		Control	29.82(34.89)	33.92(35.35)	-			
	Diarrhea	Intervention	5.85(17.95)	4.09(14.18)	-7.26	(-16.23, 1.72)	-1.60	0.112
		Control	4.68(14.69)	15.20(24.45)	-			
	Financial difficulties	Intervention	67.84(35.62)	43.27(40.81)	-5.54	(-19.06, 7.99)	-0.81	0.419
		Control	60.23(41.99)	56.14(36.27)	-			
General Health Status	Health related quality of life/General health status	Intervention	46.93(15.64)	65.79(17.51)	21.85	(14.10, 29.59)	5.60	0.000**
		Control	50.29(17.25)	44.30(16.90)				

*p<0.05 **p<0.01 Referent groups: -Status: control, Tumor size :< 2cm, Tumor grade: low grade, Cancer stage: stage I, Treatment kind: Chemotherapy, Metastasis: Metastasis present, any other disease: Yes, Wealth Quintile: Poorest, Marital Status: Single, Communication: Good

The above tables is number of ANCOVA model that is done separately for each 15 quality of life domains separately but we displayed the main outcomes in this table for simplicity. The detailed ANCOVA model with each independent variable is annexed on **Annex-14**.

6.7 Over-all Quality of Life

As it was described in the methodology section an index score for quality of was computed using principal component analysis. And this index score for both base-line and post-intervention were analysed with the predictors using General linear model (ANCOVA). And the result of ANCOVA model revealed that there was no association between Psychotherapy and over-all quality of life (p=0.413). From these result we concluded that it is better to analyse quality of life as per each domain than computing an index score. Thus computing index score might not reveal the effect of the therapy on individual scores and infact may introduce an error.

Table 9: ANCOVA result of the effect of Psychotherapy on Over-all Quality of Life of Breast Cancer Patients with Common mental disorder at TASH oncology unit Addis Ababa, Ethiopia 2018/19. (Result of Index score of Quality of Life)

Domain	Exposure status	Baseline Mean(SD)	Outcome Mean(SD)	Coefficient	95% CI	t value	P value
*Overall Quality of Life	Intervention	-0.156(0.914)	-0.05(0.95)	-0.162	(-0.546,0.222)	-0.84	0.413
	Control	0.156(1.06)	0.05(1.05)	-	-	-	-

7. Discussion

This study was conducted to determine the effect of psychotherapy on treatment outcome among breast cancer patients with common mental disorder. The finding in this study showed that, IPT-E has an effect on certain domains of quality of life. It was also identified that IPT-E had an effect in reducing anxiety and depression. We found that Interpersonal Psychotherapy that was adapted for Ethiopian use had significantly improved physical, role, cognitive, emotional and social functioning. It also decreases some symptoms (fatigue and insomnia) and improved global quality of life.

As hypothesized in our study IPT was found to be effective in reducing anxiety and depression significantly. Studies suggested the use of Psychotherapy for depressive and anxiety disorder as an adjuvant treatment(13).Our experiment is consistent with previous studies results (47, 79, 80). One study indicates usefulness of individual cognitive behavioural therapy (CBT) for cancer survivors with depression and anxiety with an approach that typically employ weekly, goal oriented visits(79).Also our study is in good agreement with another randomized control trial study done in Germany on gynaecological cancer patients to examine the Efficacy of Short-term Psycho-oncological intervention on anxiety , depression and psychological stress, in this study they found that psycho-oncological therapy for anxiety and depression significantly decrease both anxiety and depression(80).Similarly randomized control study done in France on the effectiveness of a psycho-educational therapy group intervention after early-stage breast cancer treatment on 203 patients states that a significant reduction in anxiety, a reduction in anger and depression were observed in the intervention group when compared with that of the control group(47). Our ANCOVA model showed that there is a significant positive association between post-intervention anxiety score and the patient being in the highest quintile. Similarly a study done in India indicated that those patients with low-monthly income and less financial support were tend to be more anxious than the other contrast(81). This might be due to the intolerable cost of cancer treatment. Here the more economically established the patients are, the less they worry about the cost of cancer treatment, so being in the highest quintile clearly had an impact on their anxiety score. In our study we also found that a significant association between post-intervention anxiety score

and that of radiotherapy and mastectomy. Similarly one study found that radiotherapy led to an increased emotional distress such anxiety and depression(82).

Our study showed that the manualized Interpersonal Psychotherapy for Ethiopian use (IPT-E) had significantly improved quality of life specifically in certain domains as physical, role, cognitive, emotional, social and in some symptom scales(Fatigue and insomnia). Also the therapy improves general health status/ global quality of life. In this study IPT-E significantly positively affect physical functioning.

Physical functioning of patients in the IPT group in this study was improved significantly when compared with that of the control group. Here physical functioning was found to be increased significantly in the intervention group than that of the control group. This finding is supported by different randomized control trial studies(83-86). As it has been shown in the results of this randomized control trials; psychosocial intervention significantly reduced levels of depression and anxiety compared to a control group. Further, the result in this studies revealed that the intervention was effective for improving elements of QOL, such as global health status and physical functioning; it also increased emotional functioning, significantly decreased insomnia in comparison with usual care(48). Similarly another study clearly indicated that psycho-educational Interventions have been developed to enhance patient resilience by helping patients with breast cancer promote more positive psychosocial outcomes on cancer treatment(84).As the study indicated soothing of depressive symptoms may serve as a mechanism for positive adaptation, which increases positive psychosocial functioning, protects against psychological distress during cancer treatment, and protects quality of life after completion of therapy in women with breast cancer(87). As the studies indicated face-to-face discussion as a method of treatment has been proven to be successful in resolving psychological distress and in turn it is known in improving physical side effects or physical symptoms(85, 86). Our ANCOVA analysis showed, age and depression were negatively associated with physical functioning. This finding was consistent with an observational transversal study done in Germany in which they found that age was negatively associated to physical functioning(88). The possible explanation for this could be, the impact of the sudden cancer episode in addition to other chronic conditions in old age patients increased the likelihood

of diminished social support and also social isolation with aging, that results to deterioration in physical functioning since that is a part of normal aging(89). Another important association was observed between depression and postintervention physical functioning in our study. It is possible to increase physical well-being by decreasing depression. So as proven by studies that by reducing depressive symptoms, we can improve physical functioning. The possible explanation for increasing physical functioning by decreasing anxiety and depression symptoms could probably be is due to that depression and anxiety may lead to physical symptoms (e.g. fatigue, anorexia, and/or weight loss)(51). So it is possible to improve physical functioning by reducing depressive symptoms.

Role functioning was significantly positively affected by IPT. This finding goes in line with studies done in other settings. Our ANCOVA model showed that there is a significant negative association between age and role functioning whereas positive association with the patient being married. The possible explanation for this could be that marriage will increase the potential of getting social support and the use of positive coping methods, all of which can contribute to higher QOL (59). A study done in France indicated that Psycho-educational intervention clearly had an effect on patients' anxiety and some aspects of mood and QOL, in this study role functioning significantly improved while fatigue significantly decreased(47). In contrast with our finding in a study done in china role functioning was not improved by their intervention(48). This might be due that our therapy technique had a focus area that role functioning could be enhanced. As reported in other study, most women with breast cancer were unable to continue their employment and were on prolonged sick leave or forced to retire. The ability to perform domestic work was also often limited. For many the change from being needed to needing someone was difficult to accept and lead to decreased feelings of autonomy(76) which is similar to our finding. This results in distress, so one way to overcome that limitation through the therapy was to change internal standards; for many patients being able to do something useful for the family was important. So in our therapy the patients were encouraged to do little things at a time at home and in their work place as required. This results in increase of their feeling of being in charge of something or as person who have role in day to day activity. As is role functioning were maintained.

Cognitive functioning was also another quality of life domain that was improved significantly by the intervention administered. Our finding seem to confirm observation in other studies that the effect of cognitive behavioural psychotherapy on cognitive functioning was proved in a way that the intervention group patients demonstrated a higher opinion concerning their ability to remember things, concentrate on a given course of action and to demonstrate intelligence in comparison with the women who did not undergo therapy(11).Our study was congruent with other studies in noting that the patients' complaints of difficulties in concentrating on things, while beginning things was especially difficult(76). So here patients were given home taken exercise and were asked to tell how it works in progress.Also our ANCOVA model has revealed that depression had association with post-intervention cognitive functioning in a way that acting up on depressive symptoms would enhance cognitive functioning. One study indicated that depressive illness was associated with some degree of cognitive deficits(90). So reducing depressive symptomatology might help improve cognitive functioning.

Emotional Functioning was significantly positively associated with IPT. The intervention groups were found to have significant improvement than that of the control groups. This finding was in line with other studies in which supportive-expressive group therapy had an effect on quality of life as in Emotional functioning and other domains. In this study it is worth noting that the observed reduction of somatic symptoms and the improvement of emotional functioning allow patients to regain a sense of control over their disease, this leads to seeking constructive solutions to various problems and has a positive impact on cooperation during the treatment(53). In line with this finding in our study after the intervention administered; the patients in our intervention group became concerned about their illness and they were entitled to ask their physicians about their condition, possible treatment option and the recommended nutrition that goes with their treatment and the like. This indicates that the patients became in need of constructive solution for their disease condition. Another study indicated that increased sense of control over the symptoms of the disease and one's own emotions help them regain a sense of being able to control events and a belief in the possibility for the patient to control the disease. This leads to better adaptation to the disease. Improved functioning was also observed if the patient sense of control was deceptive(misleading) (91, 92).And our finding is also consistent with a psycho-

educational intervention study done among breast cancer patients in France that results in significant improvement in the patients emotional functioning(47). As one study indicated, emotional functioning meant the ability to enjoy life, which also gave them the strength to commit themselves to treatment. There were times when they felt that they had lost their will to live. Most patients reported feeling bad-tempered, feeling down, depressed and being less tolerant than the usual. This feelings are an indicator of emotional instability(76). So our therapy did its part in enhancing hope in the patients' day to day activity and also by soothing this symptoms towards the normal.

Social Functioning is also another domain that has shown to be affected by the intervention. Similar to our finding, in other studies, cancer patients reported that on one hand they missed the normal mutual social relationships, while on the other they retreated from social relationships with colleagues, neighbours and distant friends. The meaning of keeping on equal mutual relationships had a great importance in controlling the illness experience and dignity(76). So here patients were advised to interact with friends, neighbours and colleagues. Since the more they interact with the support system, the less they will enumerate about their cancer condition. Our finding is also in line with a study in Iran on effects of supportive-expressive discussion groups on loneliness, hope and quality of life in breast cancer survivors(53).Social support is one of the most common and most prominent states to deal with loneliness and hopelessness. The results of the qualitative study conducted in Iran(93) revealed that women with breast cancer experienced separation from the community, and were prone to hopelessness and depression(94, 95). The good thing about IPT is that it had a specific focus area that address the issue of role transition. Which is; patients being diagnosed for cancer and becoming ill is a role transition, this results in a change in relationship with spouse, family, and the community and so on. This life changes results in social role changes, which means that expectation in relation changes. Role transitions, with their demands and stresses, can precipitate or worsen states of mental illness such as depression(96). So this issue was addressed in our IPT sessions by exploring where the problem of participants was and later on by acting accordingly. In our study; the social problem of the intervention groups were assessed and important members of their social support were invited to the therapy sessions with the participants consent. This helped us to intervene on the route cause of the problem. And the

therapist held a session with the near family member or relatives that was in charge of care for the patients. The therapist discussed the main issue that the patient needs support on with the concerned person also important stressors were being discussed. This has been done with the preference of our study participants which is; by including our study participants with their family member or with their family members only. In this way we tried to address the patients' main concern and stressors. That probably be the crucial component of our intervention which helped us to enhance the social functioning of patients in the intervention group.

Among the symptom scales our experiments confirm that dyspnea, pain, appetite loss, nausea and vomiting, constipation, diarrhea and financial difficulties were not found to be affected by the intervention. This findings are in good agreement with other experimental studies (45, 48, 87). In this studies they found that different type of psychotherapies were un-able to soothe certain symptoms scales of quality of life.This might be because of that these scales are not the one to be influenced by the therapeutic technigues that we used in our study and also it might be due to that psychotherapy was unable to influence this domains since they do not have psychometric nature rather they are more of directly related to the disease condition.

While certain symptom scales were not affected by IPT in our study, we found insomnia to be significantly affected by IPT. Our results shared number of similarities with other studies, like those who found improved self-rated sleep parameters among breast cancer patients(97); and that of the others who found reduced incidence of sleep disturbances among their participants(98).Similarly another study that implemented 12 weeks of mindfulness based stress reduction technique found improved sleep quality in patients with breast cancer(99). Also another study done on investigating the effect of cognitive behavioural psychotherapy for insomnia revealed that the short-term effects of the intervention found on self-reported sleep measures are pertinent. On average, treated patients increased their sleep efficiency from 69% to 84% at post-treatment(100).Other studies consistent with the above that are done mainly on insomnia (101-103) implied that sleep difficulties can be alleviated by psychotherapeutic intervention this could be an alternative strategy or even stop the use of soporific medications.

Similarly results in another study indicated that greater sleep efficiency and less sleep disturbance in mindfulness based stress reduction among breast cancer participants were attained compared with usual care participants, as they proposed this was probably due to improved self-regulation of emotional bias and increased openness to the current experience often decreases negative cyclic thinking or recurrent persistent worrying over fears of recurrence that plague patients. All these processes may contribute to improvements in falling asleep, staying asleep, and undesired waking(99).Additionally patients in our therapy sessions that were having complaints of insomnia were given sleep hygiene and were followed for the progress. That might be the reason for reduction in insomnia symptoms.

Fatigue is also another symptom scale that was found to be affected by IPT. This finding was consistent with other studies, that studied the effect of mindfulness based stress reduction technique on reducing fatigue in cancer survivors (104). Here our ANCOVA model revealed that there is a significant association between fatigue and cancer stage. We found that being stage IV highly predict fatigue. The possible explanation for this could be that as the stage of the cancer increases physical deterioration becomes inevitable, patients also will start experiencing severe pain and fatigue in advance.

Health related quality of life/general health status is also another important domain that is affected by IPT. Our ANCOVA model revealed that there was a significant association between the patient being in the highest quintile and health related quality of life. The possible explanation for this could be that income levels are positively associated with better "nutrition, housing, schooling, and recreation,"(105) all elements relevant to an individual's HRQOL. Individuals either living in poverty or near the poverty line are more likely to have problems with access to health care in line with that fewer financial barriers to accessing health services might result in higher rates of preventative care and ultimately a healthier population(106).

Also we found that the patient being on radiotherapy and having mastectomy was significantly associated with health related quality of life.Our finding was in line with a study done in china(48). As studies indicated this might be due to radiotherapy often has a strong negative impact on cancer patients: it commonly leads to long-term physical effects (e.g. pain, and decreased physical functioning) and emotional distress (e.g. anxiety and depression)(82). Various studies have demonstrated that anxiety

and depression are important and prevalent problems that affect QOL in patients with cancer (107-112).Here the effect of the one factor was found to be highly dependent with the other. Our finding is in line with other studies, in those studies what they found was that all of the patients' overall quality of life (measured by the Global Index of Quality of Life) improved with the passing of time, yet this improvement was more emphasized for the patients in the intervention group than that of the control group(54).

8. Strength and Limitation of the study

8.1 Strength of the study

- The study used a validated tool to assess Depression, anxiety and quality of life of the study participants.HADS is an Ethiopian validated screening tool that is used for assessment of anxiety and depression.Also the EORTIC-QLQ C-30 is a validated tool that incorporates different domain that measures multidimensional functional and symptom scales.
- The study used a strong study design.
- We included only one cancer type. Since the groups are homogenous, we can represent the finding for this cancer type.

8.2 Limitation of the study

The result of this study should be interpreted with caution due to the following limitations.

- In this study, we measured post-intervention outcome two weeks after the final psycho-therapy session. So this might influence our outcome.
- In this study we used the patients' response for outcome assessment. So it's some what subjective.
- Also in this study we were un-able to control the therapist-to-therapist difference that could influence our outcome.

9. Conclusion and recommendation

9.1 Conclusion

In this study, we showed that interpersonal psychotherapy for Ethiopian use had an effect on treatment outcome, among breast cancer patients with common mental disorder. IPT had an effect in reducing anxiety and depression as well as in improving certain domains of quality of life.Yet, more studies should have to be done on determining the length of stay of this effect and studies should also identify these effect in a different therapy technique.

9.2 Recommendation

9.2.1 Recommendation for health care provider

- Being diagnosed and treated for cancer is a very traumatic experience. Thus, it is highly recommended the health care providers know how to break bad news. Since this might influence the way that the patient handles the incidence and also the treatment process.
- Depression and anxiety are the most prevalent comorbid disorders. Thus, the health professionals should have to be very cautious about the occurrence of this disorders while patients are on treatment and follow up.
- It is highly recommended that the health care providers comfort the patients during the treatment and follow up periods since that influence the treatment adherence and in turn the treatment outcome.

9.2.2 Recommendation for policy makers

- It is recommended that policy makers to prepare national assessment and management tool for depression, anxiety and quality of life specifically for cancer patients and this should be included in curriculums and cancer related trainings.
- Common mental disorders (depression and anxiety) assessment is not well addressed in our health system. So it is recommended to give training concerning their assessment and management for every oncology units in the country.

- It is highly recommended to give training for oncology unit professionals, concerning on the assessment and management of common mental disorder among cancer patients. Thus, acting up on anxiety and depression will result in improved quality of life.

9.2.3 Recommendation for Researchers

- For researchers who have planned to conduct similar studies, it is recommended to use individual randomization or to consider multicentre trial to overcome individual differences among the study participants.
- For future, it is recommended that researchers conduct similar studies with other therapeutic techniques. Thus, selecting the effective one for oncology units.

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9. ANNEXES

Annex 1: Data collection Tools

9.1.1 Study informant sheet-1

Introduction and objective: Hello My name is _____.You are invited to participate in a research study on the effect of Inter-personal psychotherapy on treatment outcome among cancer patients with common mental disorder. From the information collected and studied in this project we hope to learn more about the most beneficial Effect of Psychotherapy for potentially anxious and depressed breast cancer patients and also the factors affecting treatment outcome of cancer patients.

Procedures: With your permission, we would like to collect information about you, including information about your (Age, sex, Educational status, monthly income and marital status) and question related to current medical history (The Tumor size, Stage of the cancer, Age at the time of diagnosis, metastasis at the time of diagnosis) will be obtained from your chart. Important information including religion, financial support your communication with your family and physician will be obtained by asking you. And question related to your mental status (anxiety and depression) will be obtained from you by administering certain questions using the standard anxiety depression measurement questionnaire. And questions related to quality of life will be obtained from you using a standard quality of life questionnaire. The study will have two groups with different observations that; Group 1) receive an adjuvant therapy which is Interpersonal psychotherapy-E, Group 2) receive treatment as usual. You will be assigned to any of the groups randomly. Before, during and after the psychotherapy you will receive the Essential treatment with the usual standard. After the psychotherapy you will continue to follow your standard treatment closely as the protocol of the hospital. Finally you will be evaluated concerning your mental status (anxiety and depression and quality of life) level with the same questionnaire that was used in the beginning of the study.

Risk and benefits

There will not be a very complicated risk. Since Psychotherapy is an adjuvant talk therapy which is given for those with co-morbid mental disorder, it will not compromise the original treatment that

has been given to you. You might be a bit psychologically distressed due to the discussion of your personal matter in the therapy session. Also it might take some of your time due to your availability in the four therapy sessions. From your participation, you will get an understanding about cancer, anxiety and depression. It also assist you to gain some skills of the therapy in other areas of life. You might not receive a direct benefit from participation and additionally your participation could highly benefit your current situation and future cancer patients with anxiety and depression that are found in Ethiopia.

Rights and confidentiality

All of the procedures will be carried out by trained health professionals, nurses and clinical psychologists that are trained for a case as yours. You are allowed to stay at the oncology unit until the data collection process is completed. Your medical information and other related information that will be accessed for this study are going to remain confidential. The necessary data will be documented only using unique codes for each participant and no names or card numbers will be recorded. You have full right of accepting or denying of participating in this study without being forced by someone. You are free to cease the procedure at any time if you feel discomfort or due to any other reasons. Failure to participate or withdrawing from the study will not prevent you from receiving the best medical care that the hospital provides. If you have any question regarding the information I gave you, please fill free to ask me.

For further clarifications you can contact the coordinator of the research using the following phone number.

Research coordinator: EJIGAYEHU BELAY
Telephone: 0921388192

Advisors: Dr Ababi Zergaw

Telephone: 0911-69-59-36

Mr. Werisaw Haileselassie

Telephone: 0912-00-57-18

Based on the information provided about the study, Are you willing to participate in the study?

1. YES **2. NO**

If the answer is **YES** please continue to the informed consent form below.

Informed Consent Form

I agreed to voluntarily participate in this study after fully understand the procedures that will be conducted.

Participant Signature_____Date_____

Annex 2: Hospital Anxiety and depression measurement scale scoring sheet

Please check you have answered all the questions

D	A		D	A	
		I feel tense or 'wound up'			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Not at all

Scoring:

Total score: Depression (D) _____Anxiety (A) _____

(1) 0-7 = Normal

(2) 8-10 = Mild case

(3) 11-14 =Moderate

(4) 15-21 = Severe case

Annex 3: Socio-Demographic Data Questionnaire

Part 2. Background information

Please Circle your possible answer in the response box.

No.	Questions	Responses	
201	Age of respondent in years	----------	
202	What is your religion?	1. Orthodox 2. Catholic 3. Protestant 4. Muslim 5.Other (Specify) _____	
203	What is your educational status?	1. Illiterate (can't read and write) 2. Can read and write 3. Primary school (grade 1-8) 4. Secondary school (grade 9-12) 5. Some college or technical school 6. College graduate or above	
204	How much is your household family size including you?	----------	

205	With whom do you live now?	1. With both of my parents 2. With my mother only 3. With my father only 4. With brothers/sisters 5. With grandparents 6. With cousins 7. With mother/father and a stepfather or stepmother 8. With my partner and children 9. With my children	
206	Marital status	1.Singe/divorced/widowed/ separated 2.Married	
207	What is your partner's educational status?	1. Illiterate (can't read and write) 2. Can read and write 3. Primary school (grade 1-8) 4. Secondary school (grade 9-12) 5. Some college or technical school 6. College graduate or above 7. I don't know 8.partner is not alive	
208	What is your father's educational status?	1. Illiterate (can't read and write) 2. Can read and write	

		3. Primary school (grade 1-8) 4. Secondary school (grade 9-12) 5. Some college or technical school 6. College graduate or above 7. I don't know 8. Father is not alive	
209	What is your mother's educational status?	1. Illiterate (can't read and write) 2. Can read and write 3. Primary school (grade 1-8) 4. Secondary school (grade 9-12) 5. Some college or technical school 6. College graduate or above 7. I don't know 8. Mother is not alive	

Part 3. Household socio-economic status (Wealth Index).The next questions ask about your household assets, services and housing conditions .please circle your possible answer within the response box.

No.	Questions	Responses	Skip
1. Household assets & services – In answering the questions below please think of assets & services available in your household			
301	Television	1. Yes 2. No	

302	Radio/tape recorder	1. Yes 2. No	
303	Mobile telephone	1. Yes 2. No	
304	Non-mobile/fixed telephone	1. Yes 2. No	
305	Electric stove	1. Yes 2. No	
306	Refrigerator	1. Yes 2. No	
307	Laundry machine	1. Yes 2. No	
308	Sofa	1. Yes 2. No	
309	Bicycle/motorcycle	1. Yes 2. No	
310	Car	1. Yes 2. No	
311	Domestic servant	1. Yes 2. No	
312	Do you own any agricultural land?	1. Yes 2. No	
313.	How many (LOCAL UNITS) of agricultural land do members of this household own? LOCAL UNITS	Local units |__|__|	
314	Do you own Cattles at your house-hold?	1. Yes 2. No	
315.	How many of the following animals do you keep?	1.Milk cows, oxen or bulls |__|__|	

	(Interviewer: if household does not own a particular item, record "00" against that item.)	2.Chickens |__|__| 3. Goats |__|__| 4. Sheep |__|__| 5. Horses ,donkey, or mule |__|__| 6. Beehives |__|__|	

2. Housing Condition – please answer the following questions thinking about the housing condition of your household and circle your possible answer.			
314	Home ownership	1. Private 2. Government 3. Rent 4. Other (specify) ——	
315	Number of rooms	----------	
316	Number of individuals per sleeping room	----------	
317	Roofing material	1. Natural material 2. Corrugated iron 3. Tiles 4. Other (specify) ——	
318	Flooring material	1. Mud 2.Parquet/polished wood 3. Cement 4. Ceramic tiles 5. Carpet 6. Other (specify) ——	

Annex 4: Life Style related questionnaire

No	**Question**	**Response**	**Skip**
401.	Have you ever smoked cigarette?	1. Yes sometimes 2.Yes I still smoke	

		3.I have never smoked	
402.	If Your answer is yes for the above Question, how long it has been? If the answer is no for the above question, mark on skip.		
403.	Do you frequently Exercise?	1. Yes 2.No	
404.	If your answer is yes, how frequent do you exercise?	1.Twice a week 2.Three times a week 3.Four times a week 4.Everyday	

Annex 5: Financial Support related questionnaire

No.	**Question**	**Response**	**Skip**
501.	Do you have any source of income?	1. Yes 2.No	
502.	Do you have any financial support?	1. Yes 2.No	
503.	If your answer is yes, from whom do you get the support?	1. Family member 2. From relative 3. From neighbor 4. From health professional 5. Other	
504.	If your answer is yes for question 1, do you get the support regularly?	1. Yes 2.No	

505.	Do you think the support that you get is enough?	1.Not Enough 2.Fair 3.Enough	

Annex 6 : Nutritional Support related questionnaire

No	Question	Response	skip
601.	Do you get food provision from your house-hold?	1. Yes 2.No	
603.	Do you get the food in time?	1.Yes 2.No	
603.	Do you think it's Enough?	1.Yes 2.No	

Annex 7: Communication related questionnaire

No	Question	Response	skip
701	How is your communication with your physician? Do you talk about?	1.Everything concerning your disease condition A. Treatment type, B. All my worries C. Medical expenses D. How I feel every day) 2.Few things (concerning about treatment type and expense) A. Treatment type B. Expense 3. About my medical condition Only	
702.	How is your communication with your family? Do you talk about?	1. Everything concerning your disease condition A. Treatment type	

		B. All my worries, C .Medical expenses, D. How I feel every day 2.Few things concerning about A. Treatment type B. Expense) 3. About my medical condition Only	
703.	Do You have any emotional support when you are sad, angry, or feeling down from your surrounding?	1.Yes I have a support 2. I don't have a support	
704	From whom do you get the emotional support?	1.Family 2.Friend 3. Neighbor	

Annex 8: Relationship related Questionnaire

No.	Question	Response	Skip
801.	How do express your relationship with your spouse?	1.Bad 2.Not Bad 3.Fair 4.Good 5.I have no spouse/single/divorced/separated	
802.	Do you think your current medical condition affect your relationship with your spouse?	1.Yes 2.No	

Annex 9: Cancer related condition of the patient

No.	Question	Response	Skip
901.	The tumor size	(1) < 2cm (2) 2-5 cm (3) > 5cm (4) unknown	

902	The tumor grade	(1)Low grade (2)Intermediate grade (3) High grade (4) unknown	
903.	Stage of the cancer	1. Stage 1 2.Stage 2 3. Stage 3 4.Stage 4	
904.	Presence of metastasis at the time of initial diagnosis	1.Metastasis present 2. Metastasis absent	
905.	Kind of treatment that the patient is on	1. Chemotherapy 2. Radiotherapy 3. Chemotherapy and Radiotherapy 4. Chemotherapy and surgery 5. Chemotherapy, Radiotherapy and surgery 6.Radiotherapy and surgery 7.Hormonal therapy	

Annex 10: Other disease condition related questionnaire

No.	Question	Response	Skip

1001.	Have the patient been diagnosed with any other disease condition recently?	1.Yes 2.No	
1002	If the answer is yes please state the disease in the space provided	----------	

Annex 11: Quality of life related Questionnaire

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: □□□□

Your birthdate (Day, Month, Year): □□□□□□□□
Today's date (Day, Month, Year): □□□□□□□□

No	Questionnaire	Not at all	A little	Quite a bit	Very much
1101.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	**1**	**2**	**3**	**4**
1102.	Do you have any trouble taking a long walk?	**1**	**2**	**3**	**4**
1103.	Do you have any trouble taking a short walk outside of the house?	**1**	**2**	**3**	**4**
1104.	Do you need to stay in bed or a chair during the day?	**1**	**2**	**3**	**4**
1105.	Do you need help with eating, dressing, washing yourself or using the toilet?	**1**	**2**	**3**	**4**
During the past week		**Not at all**	**A little**	**Quite a bit**	**Very much**

1106.	Were you limited in doing either your work or other daily activities?	**1**	**2**	**3**	**4**
1107.	Were you limited in pursuing your hobbies or other leisure time activities?	**1**	**2**	**3**	**4**
1108.	Were you short of breath?	**1**	**2**	**3**	**4**
1109.	Have you had pain?	**1**	**2**	**3**	**4**
1110.	Did you need to rest?	**1**	**2**	**3**	**4**
1111.	Have you had trouble sleeping?	**1**	**2**	**3**	**4**
1112.	Have you felt weak?	**1**	**2**	**3**	**4**
1113.	Have you lacked appetite?	**1**	**2**	**3**	**4**
1114.	Have you felt nauseated?	**1**	**2**	**3**	**4**
1115.	Have you vomited?	**1**	**2**	**3**	**4**
1116.	Have you been constipated?	**1**	**2**	**3**	**4**
During the past week:		**1**	**2**	**3**	**4**
1117.	Have you had diarrhea?	**1**	**2**	**3**	**4**
1118.	Were you tired?	**1**	**2**	**3**	**4**
1119.	Did pain interfere with your daily activities?	**1**	**2**	**3**	**4**
1120.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	**1**	**2**	**3**	**4**
1121.	Did you feel tense?	**1**	**2**	**3**	**4**
1122.	Did you worry?	**1**	**2**	**3**	**4**
1123.	Did you feel irritable?	**1**	**2**	**3**	**4**
1124.	Did you feel depressed?	**1**	**2**	**3**	**4**
1125.	Have you had difficulty remembering things?	**1**	**2**	**3**	**4**

1126.	Has your physical condition or medical treatment interfered with your family life?	**1**	**2**	**3**	**4**
1127.	Has your physical condition or medical treatment interfered with your social activities?	**1**	**2**	**3**	**4**
1128.	Has your physical condition or medical treatment caused you financial difficulties?	**1**	**2**	**3**	**4**
For the following questions please circle the number between 1 and 7 that best applies to you					
1129.	How would you rate your overall health during the past week? Very poor 1 2 3 4 5 6 Excellent 7				
1130	How would you rate your overall quality of life during the past week? Very poor 1 2 3 4 5 6 Excellent 7				

Annex 12: Amharic version of the Information sheet

Informed Consent and/or Ascent form (Amharic version)

በአዲስ አበባ ዩኒቨርስቲ ጤና ሣይንስ ፋኩሌቲ የህብረተሰብ ጤና አጠባበቅ ትምህርት ክፍል የተጠያቂው / መላሾች የመረጃ ቅፅ

ጤና ይስጥልን እንደምን ነዎት!

ስሜ---------- ይባላል፡፡ እርስዎ በዚህ ጥናት ውስጥ እንዲሳተፉ ተጋብዘዋል፡፡ጥናቱም የድብርትና የጭንቀት ችግር ያለባቸው የካንሰር በሽታ ህሙማን ፤ የድብርት እና የጭንቀት ህክምና ማግኘት በካንሰር ህክምና ውጤት ላይ የሚኖረውን አስተዋጽኦ የሚመለከት ነው፡፡ከዚህ ጥናት ከሚገኝ መረጃ እና ውጤት ለድብርትና ለጭንቀት የተጋለጡ የካንሰር ህሙማን የስነልቦና ህክምና ማግኘታቸው የሚኖረውን ጠቃሚታ ብሎም የካንሰር ህሙማን የህክምና ውጤት ላይ ተፅእኖ የሚያመጡ ነገሮችን ለይተን እናውቃለን የሚል ተስፋ አለን፡፡

ተግባራት፡ በፍቃድዎ፤ የእርስዎን መረጃዎች ማለትም (እድሜዎን ፣የትምህርት ደረጃዎን፤የወር ገቢዎን ፤የጋብቻ ሁኔታዎን) እናም የአሁን የህክምና ሁኔታዎን የሚመለከት መጠይቅ ማለትም (የእባጩ መጠን፤የካንሰሩ ደረጃ፤የመጀመሪያ የካንሰር ምርመራዎ ጊዜ እድሜዎ ስንት እንደነበር፤የመጀመሪያ የካንሰር ምርመራዎ ወቅት የካንሰሩ የስርጭት ሁኔታ) በተመለከተ ከህክምና ማህደርዎ ላይ መረጃ የሚወሰድ ሲሆን ሌሎች ጠቃሚ መረጃዎች ማለትም ሃይማኖት፤የድጋፍ ሁኔታ፤ከሃኪምዎ ብሎም ከቤተሰብዎጋር የህክምና ሁኔታዎን በተመለከተ ያሎት ግንኙነት እርሶን በመጠየቅ እናገኛለን፡፡የስነልቦና ሁኔታዎን የሚመለከትም መረጃ (ስለድብርትና እና የጭንቀት ሁኔታዎ) ለዛ በተዘጋጀ የሆስፒታል የድብርትና የጭንቀት መለኪያ መጠይቅ እርስዎን በመጠየቅ መረጃ እንወስዳለን፡፡ እርስዎንና የጤንነት ሁኔታዎንም በተመለከተ በእርሶ የሚሞላ ለዛ የተዘጋጀ መጠይቅ አለ፡፡በተጨማሪም ጥናቱ ሁለት ቡድን ይኖረዋል፡፡ይህም ቡድን -1 ተጨማሪ የስነልቦና ህክምና የሚያገኝ ቡድን ሲሆን ሌላኛው ቡድን -2 ደግሞ የተለመደውን ህክምና የሚያገኝ ቡድን ይሆናል ማለት ነው፡፡እርስዎ በዚህ ጥናት ላይ እንዲሳተፈ የተመረጡት በተደጋጋሚ በተደረገ የኢጋጣሚ የናሙና አወሳሰድ ስሌት መሰረት ነው፡፡ከጥናቱ በፊት በጥናቱ ጊዜም ሆነ ከጥናቱ በኋላ መጀመሪያ ሲከታተሉ የነበረውን ህክምና ያገኛሉ፡፡ በመጨረሻም የስነልቦናዎ ሁኔታ(የድብርትና የጭንቀት መጠንዎ)ብሎም የእርስዎ የጤናዎ ሁኔታ በጥናቱ መጀመሪያ በመጠይቅ በተለካበት ሁኔታ ይለካል ማለት ነው፡፡

ጥቅምና ጉዳትን በተመለከተ

ይህ ጥናት ያን ያህል ጉዳት አይኖረውም፡፡ይህም የሆነው የስነልቦና ህክምና የድብርትና እና የጭንቀት ችግር ወይም የስነልቦና ችግር ላለባቸው የሚሰጥ ተጨማሪ ህክምና ስለሆነ ነው፡፡ይህ የስነልቦና ህክምና በቀዳሚነት ሲሰጣቹ የነበረው ህክምና ላይ ተፅእኖ የሚያደርግ አይደለም፡፡ምናልባት ህክምናውን በባለሙያ ሲያገኙ ከባለሙያው ጋር ስለግል ጉዳይዎ ከማውራትዎ አንጻር ትንሽ የመረበሽ ስሜት ሊሰማዎ ይችላል፡፡በተጨማሪም ይህ የስነልቦና ህክምና የተወሰነ ጊዜዎን ሊወስድ ይችላል፡፡ በዚህ ጥናት ተሳታፊ በመሆንዎ ፤ስለ ካንሰር፤ስለጭንቀት እና ድባቴ ፤ብሎም የስነልቦና ችግሮች በካንሰር ህክምና ውጤትዎ ላይ ስለሚኖረው ተፅእኖ ግንዛቤ ይኖርዎታል፡፡ምናልባት ቀጥተኛ ተጠቃሚ ላይሆኑ ይችሉ ይሆናል፤ ነገር ግን ተሳትፎዎ የአሁን የህክምና ሁኔታዎን ብሎም የወደፊት የካንሰር ህሙማንን የህክምና ውጤት በከፍተኛ ሁኔታ የሚቀይር እና የሚጠቅም ሊሆን ይችላል፡፡

መብትንና ሚስጥርን መጠበቅን በተመለከተ

ሁሉም ተግባር ወይንም ህክምና ብቃቱና ስልጠናው ባላቸው የጤና ባለሙያዎች ማለትም በስነልቦና ህክምና ሙያ እና እንደርሶ አይነት የስነ ልቦና ችግር ላለባቸው ሰዎች ህክምና ለመስጠት ስልጠናውን በወሰዱ ባለሙያዎች ይካሄዳል፡፡በህክምና መስጫ ቦታው አስፈላጊ መረጃዎች እስኪሰበሰብ ድረስ መቆየት ይችላሉ፡፡የህክምናም ሆነ የስነልቦና ሁኔታዎን ለማወቅ ለሚጠየቁት ጥያቄ የሚሰጡት መረጃ በሚስጥርነት የሚያዝ ይሆናል፡፡አስፈላጊው መረጃ ከተወሰደ በኋላ የእርሶዎ መረጃ በተሰጠው የሚስጥር ቁጥር መሰረት ተመዝግቦ የሚቀመጥ ይሆናል፡፡በዚህ ጥናት ውስጥ የመካተትም ሆነ ጥናቱ ውስጥ ያለመካተት ሙሉ መብትዎ የተጠበቀ ነው፡፡በማንኛውም ምክነያት በጥናቱ ውስጥ መቆየት ካልፈለጉ ወይም ምቾት ካልተሰማዎ የማቋረጥ መብትዎ ሙሉ በሙሉ የተጠበቀ ነው፡፡አለመሳተፍ ወይም ተሳትፎን ማቋረጥ የሚያገኙ የነበረውን ህክምና አይከለክልም(ተፅእኖ) አያረግም፡፡የሰጠዎትን መረጃ በሚመለከት ጥያቄ ካልዎ እባክዎ ነፃ ሆነው ይጠይቁ፡፡

ለተጨማሪ ማብራርያ የጥናቱን ዋና አስተባባሪ የሚከተለውን አድራሻ በመጠቀም ማነጋገር ይችላሉ፡፡

የጥናቱ አስተባባሪ ፡ እጅጋየሁ በላይ

ስልክ ፡ 0921-38-81-92

አማካሪዎች፡ ዶ/ር አባቢ ዘርጋው

ስልክ :0911-69-59-36

አ/ቶ ወሪሳው ኃይለስላሴ

ስልክ:0912-00-57-18

የተሰጠውን መረጃ መሰረት በማድረግ ፤ጥናቱ ውስጥ ለመሳተፍ ፍቃደኛ ነዎት?

ነ.ፍቃደኛ ነኝ

2.ፍቃደኛ አይደለሁም

የፍቃደኝነት መጠየቂያ ቅፅ

የጥናቱን ተግባራት ሙሉ በሙሉ ከተረዳው በኋላ በጥናቱ ውስጥ በፍቃዴ ለመሳተፍ ተስማምቻለው፡፡

የተሳታፊ

ፊርማ ----------ቀን----------

የሆስፒታል የጭንቀትና የድባቴ መለኪያ

ክፍል-1 :የሆስፒታል ውስጥ የጭንቀትና የድብርት መለኪያ መጠይቆች

ስነልቦና ብ□ በሽ□ዎች ላ□ □ራሱ □ሆነ ሚና እንቋለ□ □□ወቃል እናም ሀኪምዎ □ሚሰማዎትን ስሜት ካወቁ በ□ንብ ሊረ□ዎት ይችላሉ።ባለ□ው ሣምንት □ተሰማዎን ትክክለኛ ስሜት መሠረት በማትረፅ □□ና ባለሙ□□ ቀ□ሎ ለሚ□□ቁዎት □□ቁ ተ□ዊ□ን መልስ □ስ□።በተቻለ መ□ን ሲመልሱ ብ□ ቂ□ አይ□ ሰ□ ፣ ምናልባትም እን□ተ□□ቁ ወቂ□ው□ □መ□ልዎት መልስ ትክክለኛ ስሜትዎን ሊ□ልን □ችላል።

ት	□		ት	□	
		□መ□ ነቅ ወ□ም □መወ□ር ስሜት ምን □ህል □ሰማዎ□ል?			□ስተኛ ነዎት?
	3	በ□ም ብ□ ቂ□	3		ምንም □ስተኛ አ□□ለሁም
	2	ብ□ ቂ□	2		ብ□ ቂ□ □ስተኛ አይ□ለሁም
	1	አል□ አል□	1		ብ□ም ባ□ሆን □ስተኛ ነኝ
	0	ምንም አ□ሰማኝም	0		አብ□ኛውን ቂ□ □ስተኛ ነኝ
		ቀ□ም ሲል □ስ□ሰቱዎ □ገበሩ ነቂሮች አሁን ምን □ህል □ሰ□ስቱዎ□ል?			ተረ□ፅተዉ መቀመ□ እና □ና ማለት □ችላሉ?
0		አሁንም እን□ትሮዉ □ሰ□ስቱኛ ል		0	ሁሌም እችላለሀ
1		ከድሮዉ ትንሽ ቀንሷ.ል		1	አብ□ኛውን ቂ□ እችላለሁ
2		በ□ቂቱ □ሰ□ስቱኛል		2	ብዙውን ቂዜ አልችልም
3		□ ራሽ አ□ሰ□ስቱኝም		3	ምንም አልችልም

		አንድ መ□□ ነ‹ር ሊ□□□ምዎ □ተቃረበ □ሚመስል □አ ርሀት ስሜት □ሰማዎተል?			ስራዎን ሲያከናውኑ ወ□ተ አ□ነትዎ ምን □ህል □ቀነሰ □መስልዎ□ል?
	3	እ□ፅ በ□ም □ሠማኛል	3		እ□ፅ በ□ም ብ□ ቂ□
	2	በ□ም □ሠማኛል	2		በ□ም ብ□ ቂ□
	1	በ□ቂቱ □ሠማኛል	1		አል□ አል□
	0	ምንም አ□ሠማኝም	0		ምንም አልቀነሰም
		መሳቅና □ነ‹ሮችን አስቂኝ □ነ ማየት □ችላሉ?			ሆት አካባቢ □ሚሰማ □መ□ንቹ□ ወ□ም □መሸበር ስሜት □ሰማዎ□ል?
0		አብ□ኛውን ቂ□ እችላለሁ		0	ምንም አ□ሰማኝም
1		እን□ትሮዉ ባ□ሆንም እችላለሁ		1	አል□ አል□
2		በ□ቂቱ እችላላሁ		2	ብ□ ቂ□
3		ምንም አልችልም		3	በ□ም ብ□ ቂ□
		ጭንቀትን □ሚ□□ ሩ ሀሳቦች በአምሮዎ ምን □ህል ቂ□ □መላለሳሉ?			ለአለባበስዎ ትኩረትን መስ□ት አቁመኻል?
	3	በ□ም ብ□ ቂ□	3		አዎን ምንም ትኩረት እ□ሠ□ሁ አይ□ለም
	2	ብ□ ቂ□	2		□ም□ልቶውን □ህል ትኩረት እ□ሰ□ሁ አይ□ለም

	1	አብ□ኛውን ቂ□ ባ□ሆንም አል□ አል□	1		ትሮ ከምሰ□ዉ ትኩረት በ□ቂቱ □ካሰ ትኩረትን እሰ□ለሁ
	0	አንቲንዴ ብቻ	0		ሁሌም □ምሰ□ውን ትኩረት እሰ□ለሁ
		አንድ ቦ□ መዜት □ለብዎ □መስል ተረ□ግቶ መቀመ□ □ችዅርዎ□ል ?			በትንገት □መ□ንገጥ ወ□ም □መሸበር ስሜት □ሰማዎ□ል?
	3	በ□ም ብ□ ቂ□ □ቸፅረኛል		3	በ□ም ብ□ ቂ□ □ሰማኛል
	2	ብ□ ቂ□ □ቸፅረኛል		2	ብ□ ቂ□ □ሰማኛል
	1	ብ□ም አ□ቸፅረኝም		1	አል□ አል□ □ሰማኛል
	0	ምንም አ□ቸፅረኝም		0	ምንም አ□ሰማኝም
		መቸ ነዅሮችን በ□ስ□ □□ብቃሉ?			በራቴ□ ወ□ም □ቴሌቪዯ□ን ኘ ሮግራሞች ራስዎን □ሰ□ስ□ሉ?
0		አዎ ሁሌም በተለመ□ዉ ወ□ም በትሮዉ መ□ን □ብቃለሀ	0		አዎን ብ□ ቂ□
1		ከድሮዉ ወ□ም ከተለመ□ዉ በ□ቂቱ ባነሰ መ□ን □ብቃለሀ	1		ብ□ም ባ□ሆን አዎ
2		ከድሮዉ ወ□መ ከተለመ□□ ባነሰ መ□ን □ብቃለሀ	2		አል□ አል□
3		ምንም በ□ስ□ አል□ብቅም	3		በ□ም አል□ አል□

(1) 0-7 Normal (የድብርት እና የጭንቀት ምልክቶች የሉም)
(2) 8-10 Mild (በትንሹ የድብርትና የጭንቀት ምልክቶች አለ)
(3) 11-14 Moderate(በመጠኑ » » »)
(4) 14-21 Severe (በከፍተኛ ደረጃ » » »)

ይህንን የምናገኘው ለድብርት ለብቻ ብሎም ለጭንቀት ለብቻ ምላሻቸው ላይ በማከበብ እና በመደመር ይሆናል ማለት ነው::

ውጤቱን እንደሚከተለው ያስቀምጡ::

A=----------
D=----------

ክፍል-2 :ማህበረሰባዊ መረጃዎችን የተመለከተ መጠይቅ መሠረታዊ መረጃ
እባኮ ትክክለኛ መልስዎን ያክብቡ

ቁጥር	ጥያቄ	መልስ	
201	እድሜ በአመት		
202	ሀይማኖት	**1.**ኦርቶዶክስ **2.** ካቶሊክ **3.**ፕሮቴስታንት **4.** ሙስሊም **5.** ሌላ ይቅስ----------	
203	የትምህርት ደረጃ	**1.**ያልተማረ (ማንበብና መፃፍ የማይችል) **2.**ማንበብና መፃፍ የሚችል **3.**የመጀመሪያ ደረጃ ያጠናቀቀ(ክፍል**1-8)** **4.**ሁለተኛ ደረጃ ያጠናቀቀ **(9-12)** **5.**ኮሌጅ ወይም የሙያ ት/ት **6.**የኮሌጅ ምሩቅ ወይም ከዛበላይ	
204	እርሶን ጨምሮ ቤትዎ ውስጥ ስንት ሰው ይኖራል ?	----------	
205	አሁን ከማን ጋር ነው የሚኖሩት	**1.**ከሁለቱም ወላጆቼ ጋር **2.** ከ እናቴ ጋር ብቻ	

		3. ከ አባቴ ጋር ብቻ **4.** ከ እናቴ ወንድም ጋር **5.** ከ አያቴ ጋር **6.** ከ አክስቴ ጋር **7.**ከአሳዳጊዎቼ ጋር እና ከእንጀራ እናቴ ወይም አባቴ ጋር **8.** ከጓደኞቼ ጋር **9.** ሌላ ካለ ጥቀስ	
206	የትዳር ሁኔታ	***1.***ያላገባ ***2.*** ያገባ	
207	የትዳር አጋርሽ የትምህርት ደረጃ	***1.***ያልተማረ (ማንበብና መፃፍ የማይችል) ***2.***ማንበብና መፃፍ የሚችል ***3.***የመጀመሪያ ደረጃ ያጠናቀቀ(ከፍል***1-8***) ***4.***ሁለተኛ ደረጃ ያጠናቀቀ (***9-12***) ***5.***ኮሌጅ ወይም የሙያ ት/ት ***6.***የኮሌጅ ምሩቅ ወይም ከዛበላይ ***8.***አላውቅም ***9.***በህይወትየለም	
207	የወላጅ አባት/ሽ የትምህርት ደረጃ	***1.***ያልተማረ (ማንበብና መፃፍ የማይችል) ***2.***ማንበብና መፃፍ የሚችል ***3.***የመጀመሪያ ደረጃ ያጠናቀቀ(ከፍል***1-8***) ***4.***ሁለተኛ ደረጃ ያጠናቀቀ (***9-12***) ***5.***ኮሌጅ ወይም የሙያ ት/ት ***6.***የኮሌጅ ምሩቅ ወይም ከዛበላይ ***8.***አላውቅም ***9.***በህይወትየለም	
208.	የወላጅ እናትሽ/ህ የትምህርትደረጃ	***1.***ማንበብና መፃፍ የማትችል ***2.***ማንበብና መፃፍ የምትችል ***3.***የመጀመሪያ ደረጃ ያጠናቀቀች (ከፍል***1-8***) ***4.*** ሁለተኛ ደረጃ ያጠናቀቀች (***9-12***) ***5.*** ኮሌጅ ወይም የሙያ ት/ት ***6.*** የኮሌጅ ምሩቅ ወይም ከዛበላይ ***7.*** አላውቅም	

		8.በህይወትየለችም	

ክፍል-3 :የቤት ውስጥ ማህበራዊና ኢኮኖሚያዊ ደረጃ (wealth index)
የሚቀጥለው መጠየቅ የቤተሰብ ንብረት አገልግሎትና የቤት ሁኔታን የሚቃኝ ይሆናል፡፡ እባእዎ መልስን በተሰጠው መልስ ሳጥን ውስጥ ያክብቡ፡፡

ቁጥር	**ጥያቄ**	**መልስ**	
301	ቴሌቪዥን	1.አዎ 2. የለም	
302	ሬድዮ /ቴፕሬኮርደር	1.አዎ 2.የለም	
303	ሞባይል ስልክ	1.አዎ 2.የለም	
304	ሞባይል የለም/የገመድ ስልክ	1.አዎ 2.የለም	
305	የኤሌትሪክ ምድጃ	1 አዎ 2.የለም	
306	ፍሪጅ	1.አዎ 2. የለም	
307	ላውንደሪ (የልብስማጠቢያ	1.አዎ 2.የለም	
308	ሶፋ	1.አዎ 2.የለም	
309	ሳይክል/ሞተር ሳይክል	1.አዎ 2. የለም	
310	መኪና	1 አዎ 2.የለም	
311	የቤት ውስጥ ሰራተኛ	1.አዎ 2.የለም	
312	ቤተሰቡ የእርሻ መሬት አለው?	1.አዎ 2.የለም	**ይዘለል**
313	የቤተሰቡ አባል ምን ያህል የእርሻ መሬት አለው በአካባቢው መለኪያ----------(ይገለጽ)	1.የአካባቢው መለኪያ ___	
314	የቤተሰቡ አባል እንስሳ አለው?	1.አዎ 2.የለም	
315	ከተዘረዘሩት የእንስሳ መሀል የቤተሰቡ አባል ምን ያህል አለው(የቤተሰቡ አባል እንስሳ የሌለው ከሆነ በሳጥን ውስጥ 00 ይጻፉ)	1.የወተት ላም፣ በሬ፣ኮርማ ___ 2. ዶሮ___ 3. ፍየል___ 4. በግ___ 5.ፈረስ፣አህያ፣በቅሎ___ 6. የንብ ቀፎ___	

2.የቤት ሁኔታ፣የሚከተለው መጠየቅ የእርሶን የቤት ሁኔታ የሚቃኝ ይሆናል እባኮዎ መልስዎን በትክክለኛው መልስ ላይ ያክብቡ

314	የመኖሪያ ቤት ባለቤትነት	1.የግል 2.የመንግስት 3.ኪራይ 4.ሌላ ጥቅስ
315	የክፍል ቁጥር	--------
316	በአንድ ክፍል ውስጥ የሚተኛው የሰው ብዛት	--------
317	የጣራው ሁኔታ	1.ተፈጥራዊቁስ (ሣር) 2.ቆርቆሮ 3.ሽክላ 4.ሌላ ጥቅስ
318	የወለሉ ሁኔታ	1. ጭቃ 2. ጣውላ 3. የሲሚንቶወለል 4. ሴራሚክ 5. ምንጣፍ 6. ሌላ (ጥቅስ) –––

ክፍል-4: ከአኖኖር ዘይቤ ጋር በተያያዘ በተያያዘ የሚሰጥ ጥያቄዎች

ተ.ቁ	**ጥያቄ**	**መልስ**	**ይዘለል**
401.	ሲጋራ አጭሰው ያውቃሉ?	1.አዎ አልፎ አልፎ አጨስ ነበር 2.አሁንም አጨሳለው 3.አይ በፍጹም አጭሼ አላውቅም	
402.	ከላይ ለተጠየቁት ጥያቄ አዎ ብለው ከመለሱ ምን ያህል ጊዜ ሆንዎት ከላይ ለተጠየቁት ጥያቄ መልሶ አጭሼ አላውቅም ከሆነ ምልክት አድርገው ይለፉ		
403.	አዘውትረው እንቅስቃሴ ያደርጋሉ ?	1. አዎ 2.አይ አላደርግም	
404.	ከላይ ለተጠየቁት ጥያቄ አዎ ብለው ከመለሱ በየስንት ጊዜ እንቅስቃሴ ያደርጋሉ?	1.በሳምንት ሁለት ጊዜ 2.በሳምንት ሶስት ጊዜ	

		3.በሳምንት አራት ጊዜ 4.በየቀኑ	

ክፍል-5:ከገንዘብ ድጋፍ ጋር በተያያዘ የሚሰጥ ጥያቄዎች

ቁጥር	ጥያቄዎች	መልስ	ይዘለል
501.	ማንኛውም አይነት የገቢ ምንጭ አለዎት?	1.አለኝ 2.የለኝም	
502	የገንዘብ ድጋፍ ያገኛሉ?	1.አዎ 2.የለም	
503	መልሶ አዎ ከሆነ ከማንነው ድጋፍ የሚያገኙት?	1.ከቤተሰብ አባል 2.ከዘመድ 3.ከ ጎረቤት 4.ከጤና ባለሙያ 5.ሌላ	
504	መልሱ አዎ ከሆነ የሚያገኙት ድጋፍ ቋሚ ነው?	1.አዎ 2.የለም	
505.	የሚያገኙት ድጋፍ በቂ ነው ብለው ያስባሉ?	1. በቂ አይደለም 2. ምንም አይልም 3.በቂ ነው	

ክፍል-6 : ስለ ስነ-ምግብ ድጋፍ በተያያዙ የሚሰጥ ጥያቄዎች

ቁጥር	ጥያቄዎች	መልስ	ይዘለል
601.	የሚመገቡትን ምግብ ከቤቶ ያገኛሉ ?	1. አዎ 2. የለም	
603.	የሚመገቡትን ምግብ በሰአቱ ያገኛሉ ?	1. አዎ 2. የለም	
603.	የሚመገቡትን ምግብ በቂ ነው ብለው ያስባሉ ?	1. አዎ 2. የለም	

ክፍል-7፡ ግኙነትን ወይም ንግግርን የተመለከተ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
701	ከሀኪም ጋር ያሎት ግንኙነት ምን ይመስላል ምንን በተመለከተ ንግግር ያደርጋሉ?	ነ.ከህመሙ ጋር የተገናኙ ነገሮችን በሙሉ A.ስለህክምናው ኣይነት B.የሚያስጨንቁኝን ነገሮች C.የህክምና ወጪ ፣ D.ስለስሜቶቼ 2. ጥቂት ነገሮች A.ስለህክምናው ኣይነት እንዲሁም B. ወጪ) 3. ጥቂት ነገሮችን A. ስለህክምና ሁኔታ	
702	ከቤተሰቦት ጋር ያሎት ግንኙነት ምን ይመስላል ምንን በተመለከተ ንግግር ያደርጋሉ?	ነ.ከህመሙ ጋር የተገናኙ ነገሮችን በሙሉ A.የመድሃኒት ኣይነት B.የሚያስጨንቁኝን ነገሮች C.የህክምና ወጪ ፣ D.ስለስሜቶቼ 2.ጥቂት ነገሮች A.ስለህክምናው ኣይነት እንዲሁም B. ወጪ) 3. ጥቂት ነገሮችን A.ስለህክምና ሁኔታ	
703	በአካባቢዎ ሲያዝኑ፤ሲናደዱ ወይም በህመምዎ ሁኔታ ሲጨነቁ ስሜቶን የሚካፈሎት(የሚያጋሩት) ሰው አለ?	ነ. አዎ የማካፍለው ሰው አለ 2. የለም ምንም ኣይነት ስሜቴን የሚጋራኝ ሰው የለም	
704	ስሜቶን የሚያጋሩት ለማን ነው?	ነ.ቤተሰብ 2.ጓደኛ 3.ዘመድ 4.ሌላ	

ክፍል-8: ከግንኙነት ጋር በተያያዘ የሚሰጥ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
801.	ከትዳር አጋርዎ ጋር ያልዎትን ግንኙነት እንዴት ይደልጹታል ?	1.መጥፎ 2.መጥፎ ያልሆነ 3.ምንም አይልም 4.ጥሩ 5. ያላገባ/የተለያየ/የተፋታ	
802.	አሁን ያጋጠሞት ህመም ከትዳር አጋርዎ ጋር ያልዎት ግንኙነት ላይ ተጽእኖ ያለው ይመስልዎታል ?	1. አዎ 2. የለም	

ክፍል-9 :ከህመምተኛው የካንሰር ሁኔታ ጋር በተያያዘ የሚሰጥ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
901	የእባጩ መጠን	1.<2 ሴ.ሜ 2.2-5 ሴ.ሜ 3.>5 ሴ.ሜ	
902	የእባጩ ክፍል	1.ትንሽ 2. መካከለኛ 3. ከፍተኛ	
903	የእባጩ ደረጃ	1.ደረጃ 1 2.ደረጃ 2 3.ደረጃ 3 4.ደረጃ 4	
904	መጀመሪያ ያወቁ ጊዜ የስርጭት ሁኔታ	1.ተሰራጭቶ ነበር 2.ስርጭት አልነበረም	
905.	የህመምተኛው የህክምና አይነት	1.Chemotherapy 2.Radiotherapy 3. Chemotherapy and Radiotherapy 4. Chemotherapy and Surgery 5. Chemotherapy, Radiotherapy and Surgery 6. Radiotherapy and Surgery 7.Hormonal therapy	

ክፍል-10: ሌሎች የህመም ሁኔታዎችን የተመለከተ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
1001.	ህመምተኛው ለሌላ የበሽታ ሁኔታ በቅርብ ተመርምረው ያውቃሉ?	1. አዎ 2. የለም	
1002.	መልስዎ አዎ ከሆነ የበሽታው አይነት ይገለጥ	----------	

ክፍል-11 :EORTC QLQ-C30 (እትም 3)

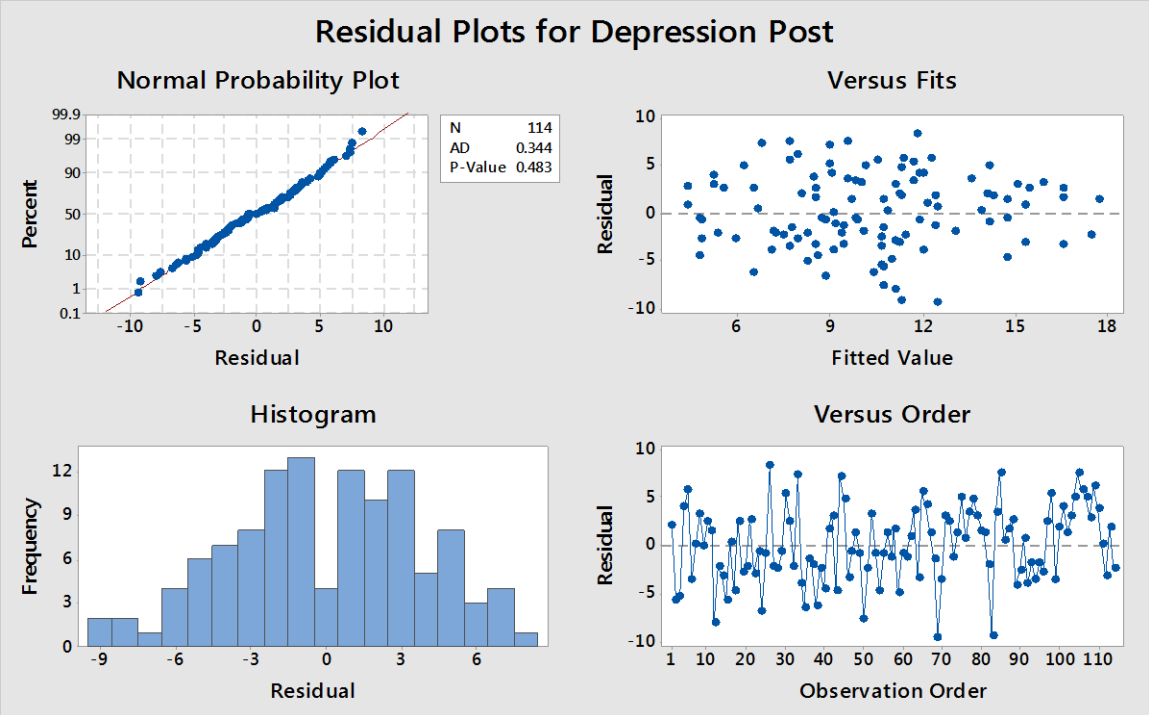
እርስዎንና ጤንነትዎን በተመለከተ የተወሰኑ ነገሮችን ለማወቅ እንፈልጋለን። እባክዎትን የሚከተሉትን ጥያቄዎች በሙሉ እርስዎ ትክክለኛ ነው ብለው ያመኑበትን ይመልሱ። «ትክክለኛ» መልስ ወይም «የተሳሳተ» መልስ የሚባል የለም። የሚሰጡት መረጃ ሁሉ ምስጢራዊነቱ በደንብ የተጠበቀ ይሆናል። እባክዎን የእርስዎን የአባትዎንና የአያትዎን የስም መጀመሪያ ፊደል ይጻፉ። ----------፣ የዛሬው ዕለት (ቀን ፣ወር፣ ዓም)፦ ----------

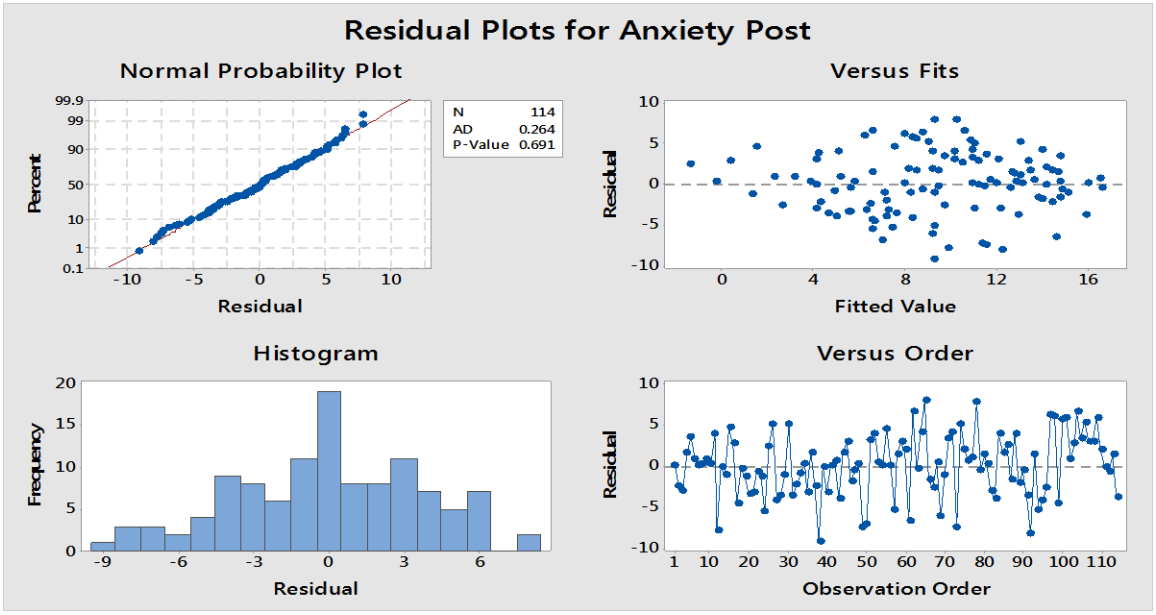
		በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
1101.	እንደ ከባድ ዘንቢል ወይም ሻንጣ መሸከም የመሳሰሉ ጉልበት የሚጠይቁ እንቅስቃሴዎችን ለማድረግ ችግር አለብዎት?	1	2	3	4
1102.	ረዥም የእግር ጉዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
1103.	ከቤትዎ ውጭ አጭር የእግር ጎዞ ለማድረግ ችግር አለብዎ?	1	2	3	4
1104.	በህመምዎ የተነሳ በቀን አልጋ ላይ ወይም ወንበር ላይ ሆነው ረዘም ላለ ሰዓት ያሳልፋሉ?	1	2	3	4
1105.	ሲመገቡ፣ ሲለብሱ፣ ሲታጠቡ ወይም ሽንት ቤት ሲጠቀሙ እገዛ ያስፈልግዎታል?	1	2	3	4
ባለፈው ሳምንት ውስጥ፦		በጭራሽ	በትንሹ	በመጠኑ	በጣም በብዛት
1106.	ስራዎትን ወይንም የዕለት ተለት እንቅስቃሴዎትን ለማከናወን ተገድበው ነበር?	1	2	3	4

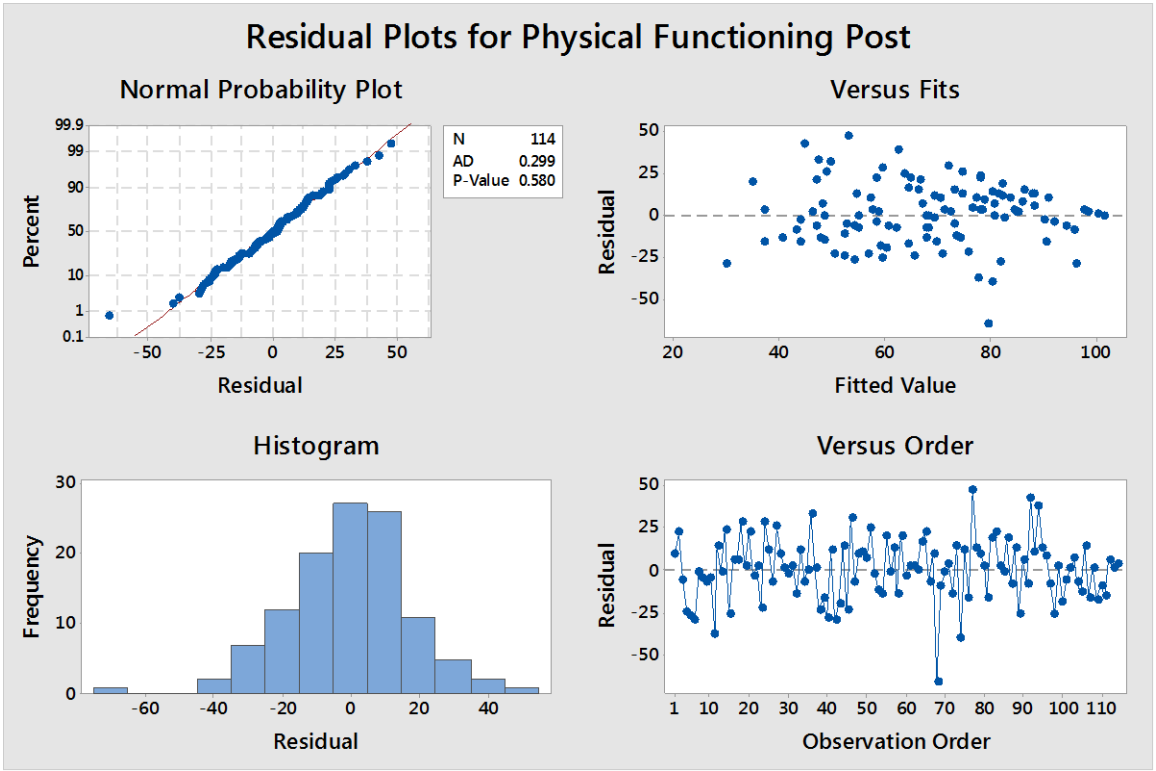
1107.	በትርፍ ጊዜ የሚከናወኑ ስራዎችን ወይንም ሌሎች የመዝናኛ ጊዜዎችን ለማሳለፍ ገድቦዎት ነበር?	1	2	3	4
1108.	ሲተነፍሱ የትንፋሽ ማጠር አጋጥሞት ነበር?	1	2	3	4
1109.	የህመም ስሜት ነበረብዎ?	1	2	3	4
1110.	ከወትሮው የተለየ ዕረፍት አስፈልጎዎት ነበር?	1	2	3	4
1111.	የዕንቅልፍ ችግር ነበረብዎ?	1	2	3	4
1112.	አቅም ያንስዎት ነበር?	1	2	3	4
1113.	የምግብ ፍላጎትዎ ቀንሷል?	1	2	3	4
1114.	የማቅለሽለሽ ስሜት ነበረብዎ?	1	2	3	4
1115.	አስመልሶዎት ነበር?	1	2	3	4
1116.	የሰገራ ድርቀት ነበረብዎ?	1	2	3	4
ባለፈው ሳምንት ውስጥ፦					
1117.	ተቅማጥ ነበረብዎ?	1	2	3	4
1118.	የድካም ስሜት ነበረዎ?	1	2	3	4
1119.	ህመሙ የዕለት ተዕለት እንቅስቃሴዎትን ያውክብዎ ነበር?	1	2	3	4
1120.	አንድ አንድ ነገሮችን ትኩረት ሰጥተው ለመስራት ያውክዎት ነበር (ለምሳሌ፤ ጋዜጣ ለማንበብ፣ ራዲዮ ለማዳመጥ)?	1	2	3	4
1121.	የውጥረት ስሜት ነበረብዎ?	1	2	3	4
1122.	የመጨነቅ ስሜት ነበረብዎ?	1	2	3	4
1123.	የመጨነቅ ስሜት ነበረብዎ?	1	2	3	4
1124.	የመደበር ስሜት ነበረብዎ?	1	2	3	4
1125.	ነገሮችን የማስታወስ ችግር ነበረብዎ?	1	2	3	4
1126.	አካላዊ ሁኔታዎ ወይም የሚከታተሉት ህክምና በቤተሰባዊ ህይወትዎ ላይ ያሳደረው ተጽዕኖ ነበር?	1	2	3	4
1127.	የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና በማህበራዊ ሕይወትዎ	1	2	3	4

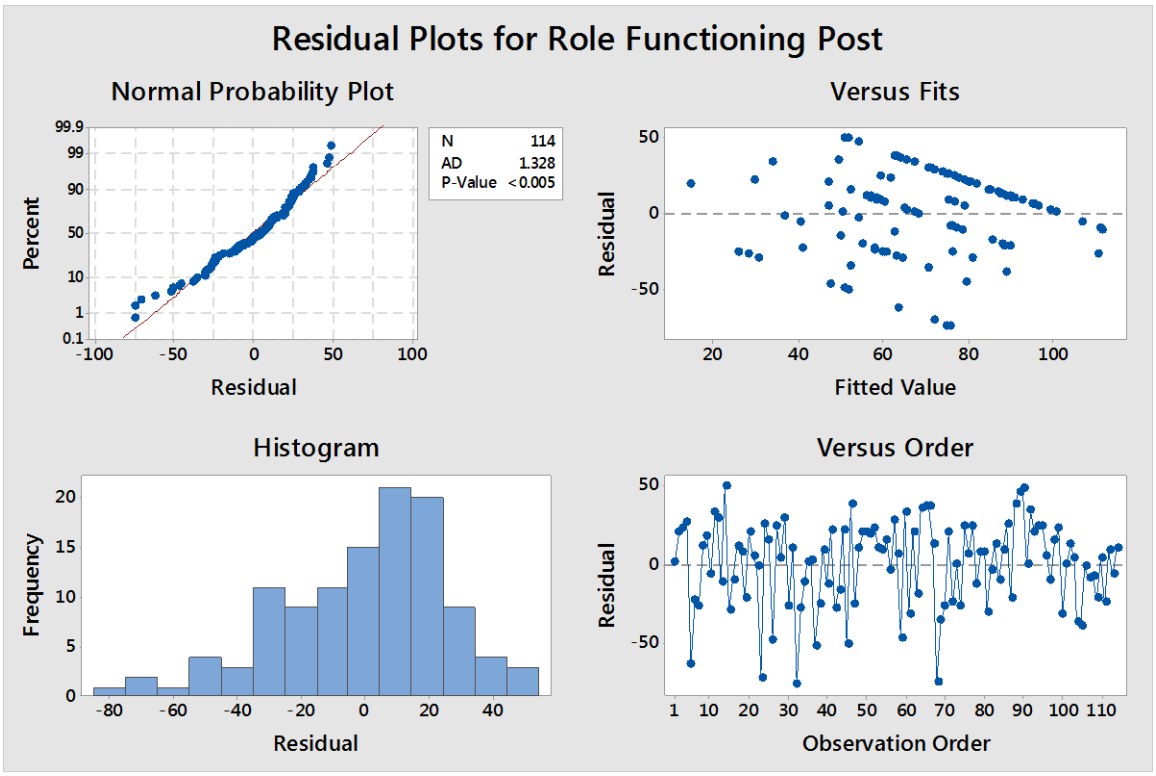
	በሚደርጉት እንቅስቃሴዎ ላይ ያሳደረው ተጽዕኖ ነበር?				
ዘ28.	የጤናዎ ሁኔታ ወይም የሚከታተሉት ህክምና ገንዘብ እንዲያጥርዎ /እንዲቸግርዎ/ አድርጓል?	1	2	3	4
ለሚከተሉት ጥያቄዎች ከ 1-7 ካሉት ቁጥሮች ውስጥ እርስዎን በደንብ የሚገልጽዎን አንዱን ቁጥር ያክብቡ					
ዘ29.	በአጠቃላይ ባለፈው ሳምንት የነበረዎን የጤንነት ሁኔታ እንዴት ይመዝኑታል? በጣም መጥፎ 1 2 3 4 5 6 7 እጅግ በጣም ጥሩ				
ዘ30.	በአጠቃላይ ባለፈው ሳምንት የነበረዎን የኑሮ ሁኔታ ጥራት እንዴት ይመዝኑታል? በጣም መጥፎ 1 2 3 4 5 6 7 እጅግ በጣም ጥሩ				

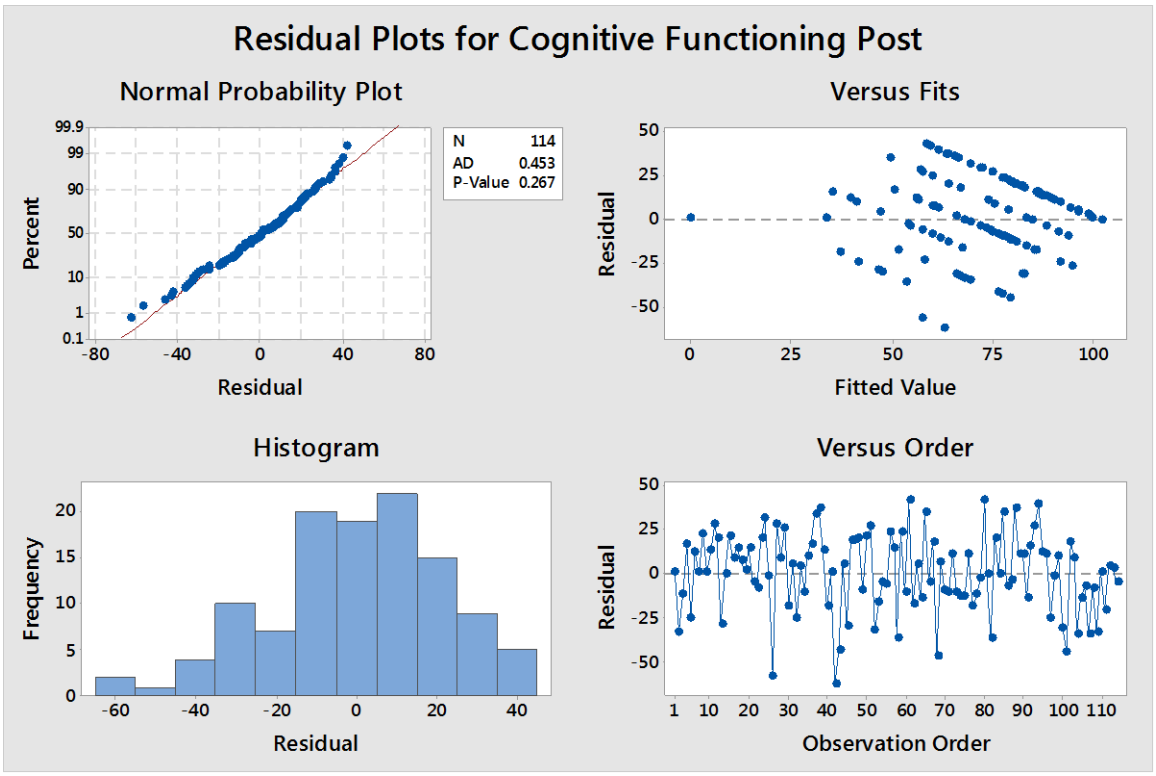
Annex 13 : Assumptions for Depression, anxiety and quality of life domains

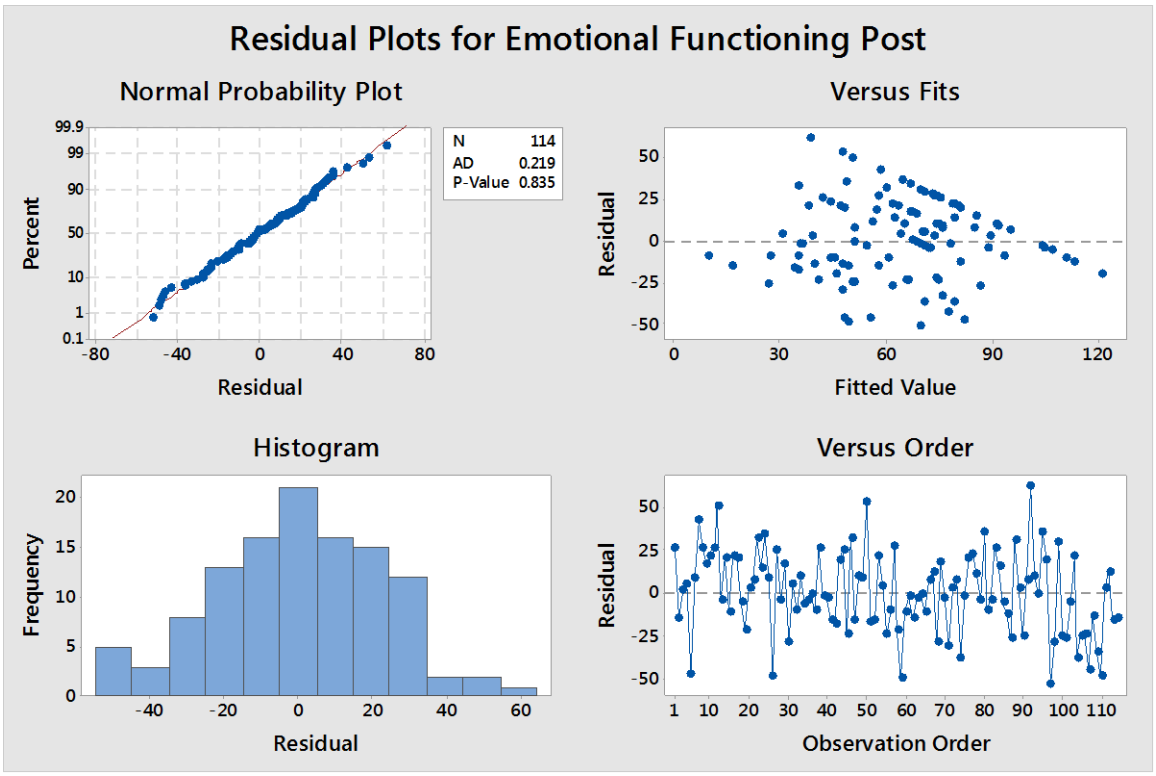


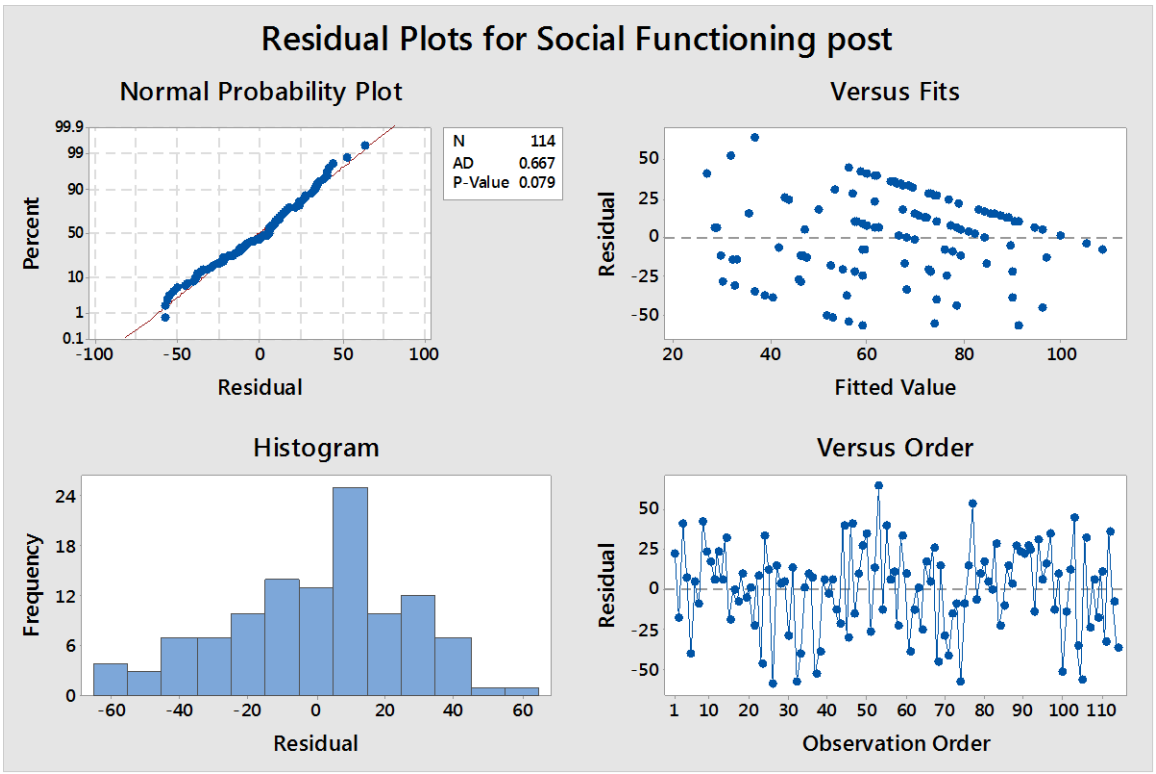

Residual Plots for Anxiety Post
Normal Probability Plot
N 114
AD 0.264
P-Value 0.691
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

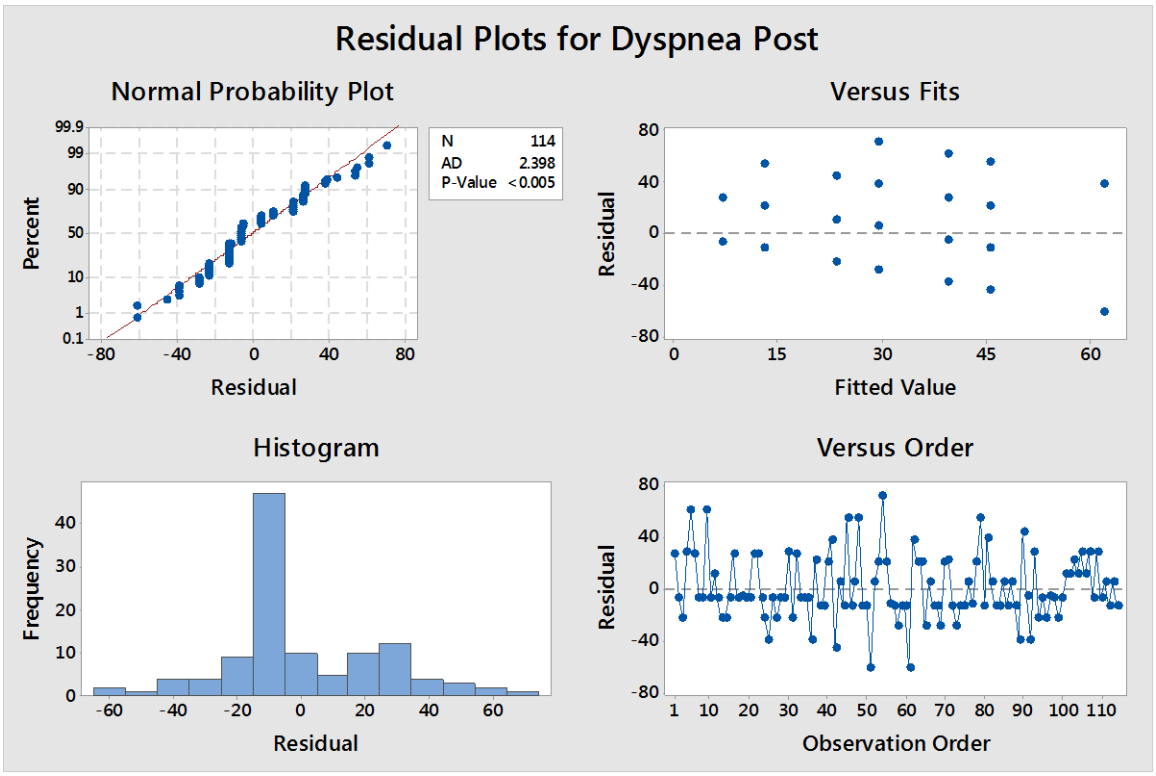

Residual Plots for Physical Functioning Post
Normal Probability Plot
N 114
AD 0.299
P-Value 0.580
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

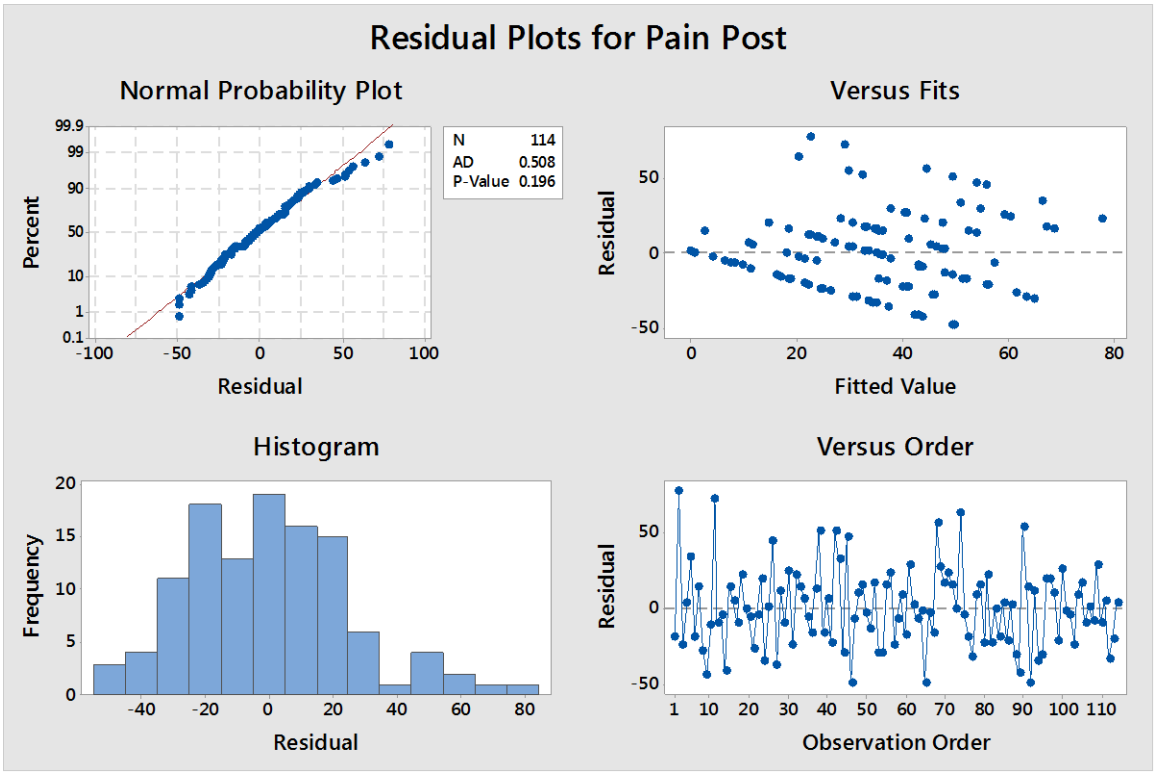

Residual Plots for Role Functioning Post
Normal Probability Plot
N 114
AD 1.328
P-Value <0.005
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

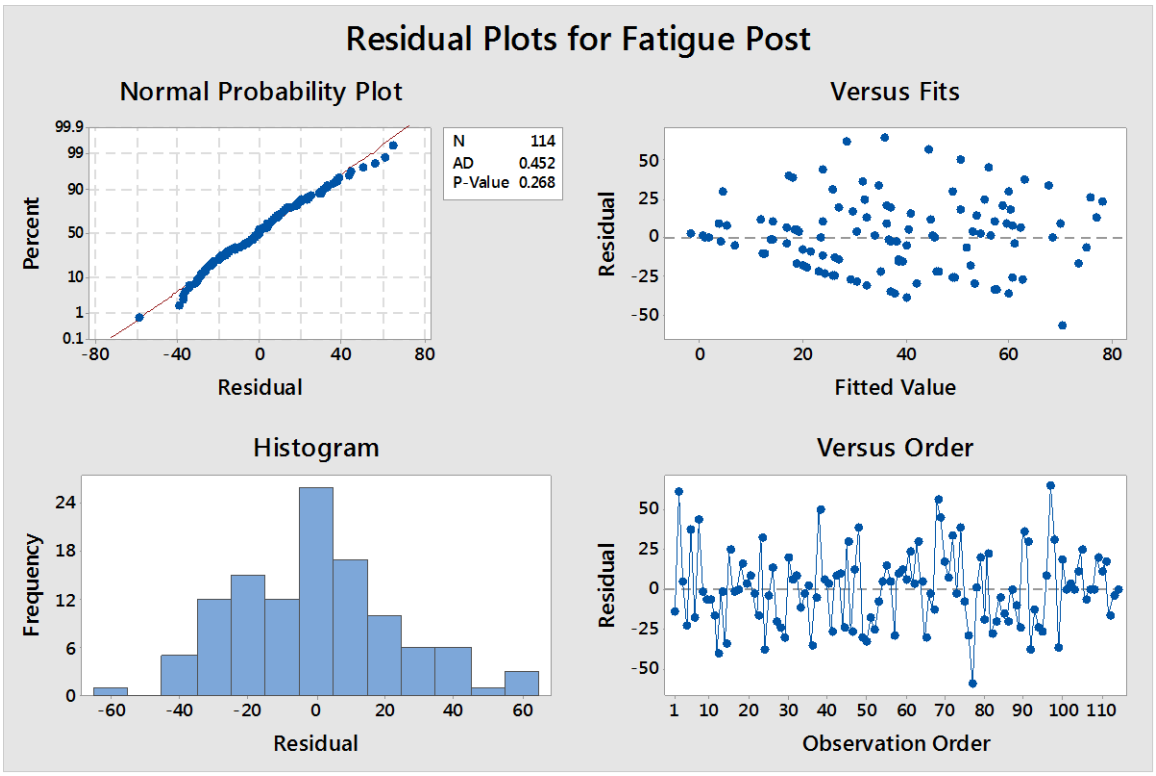

Residual Plots for Cognitive Functioning Post
Normal Probability Plot
N 114
AD 0.453
P-Value 0.267
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

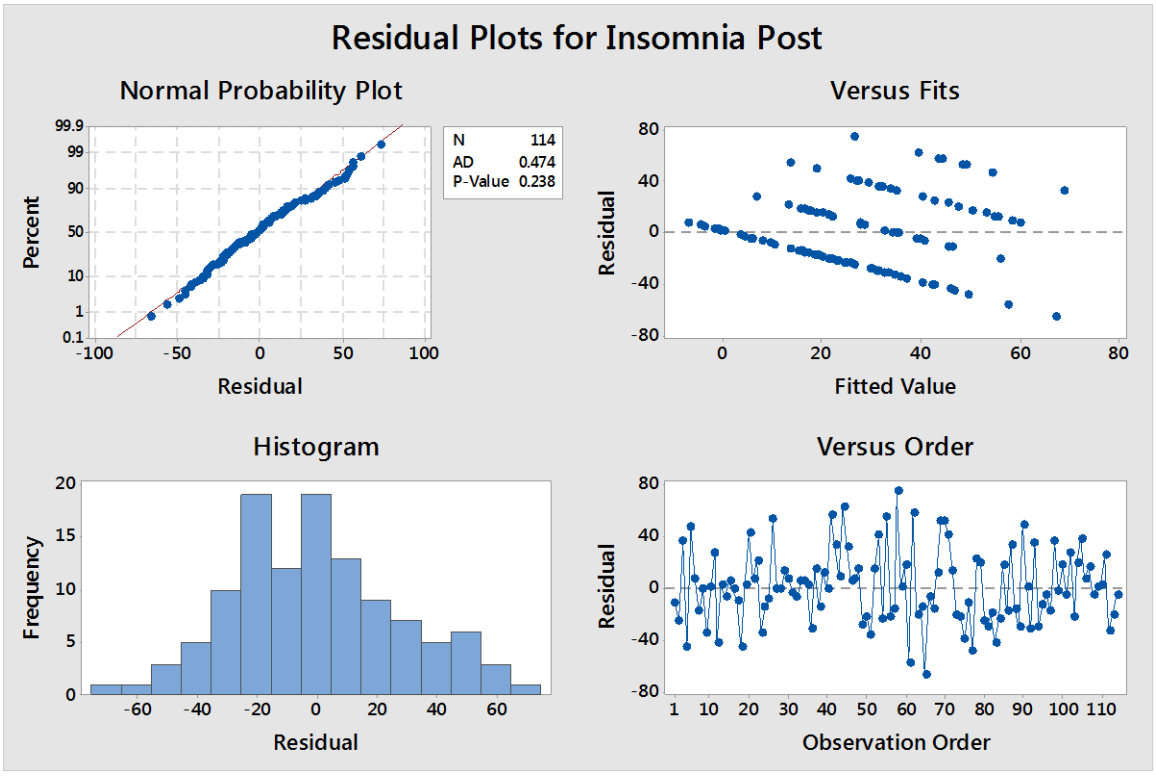

Residual Plots for Emotional Functioning Post
Normal Probability Plot
N 114
AD 0.219
P-Value 0.835
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

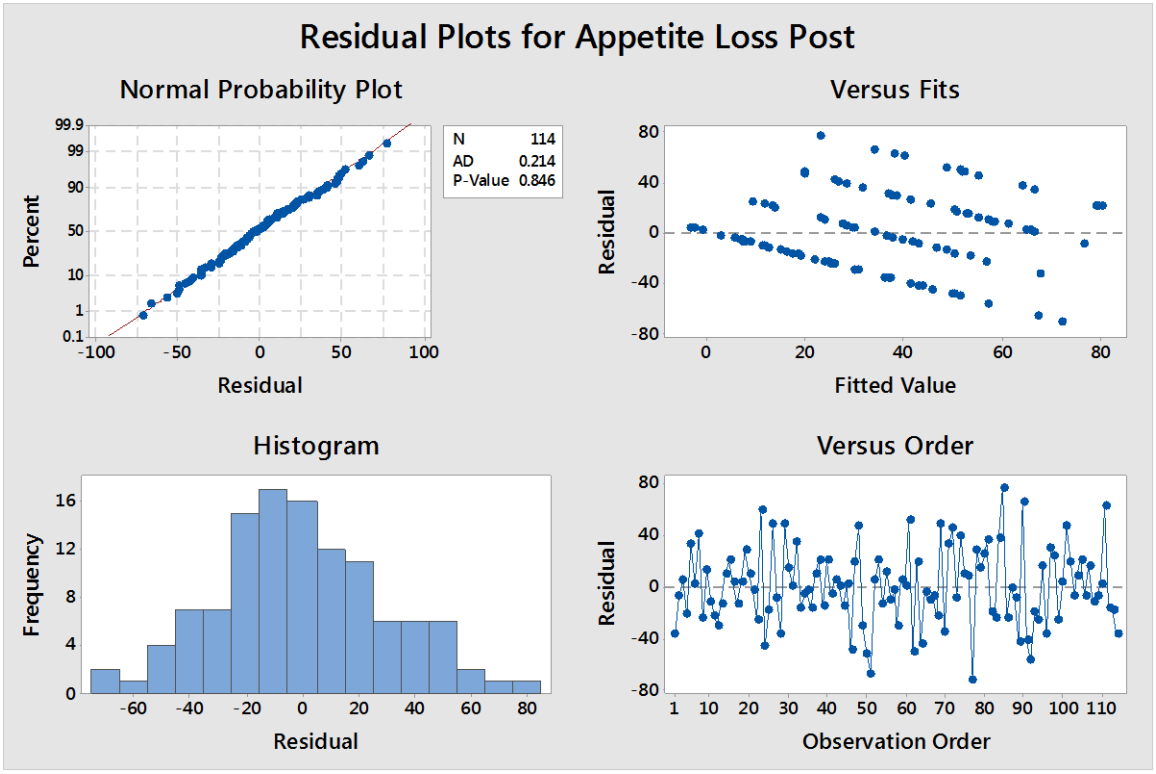

Residual Plots for Social Functioning post
Normal Probability Plot
N 114
AD 0.667
P-Value 0.079
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

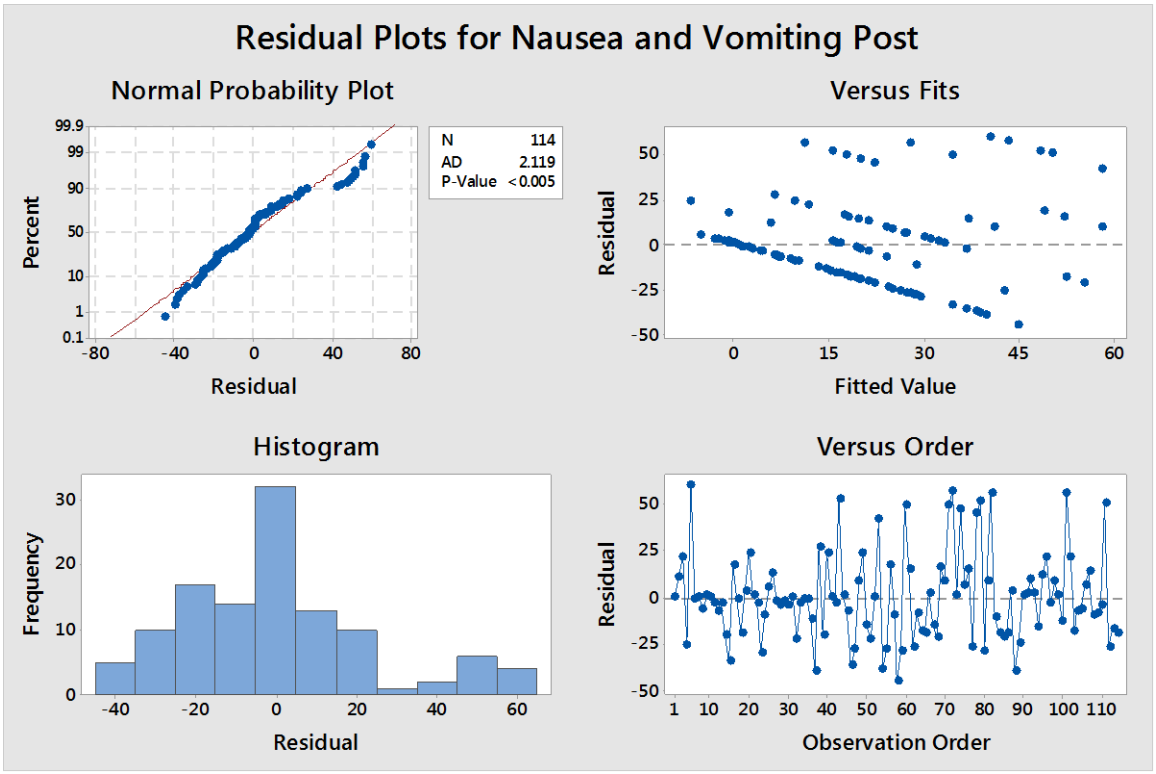

Residual Plots for Dyspnea Post
Normal Probability Plot
N 114
AD 2.398
P-Value <0.005
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

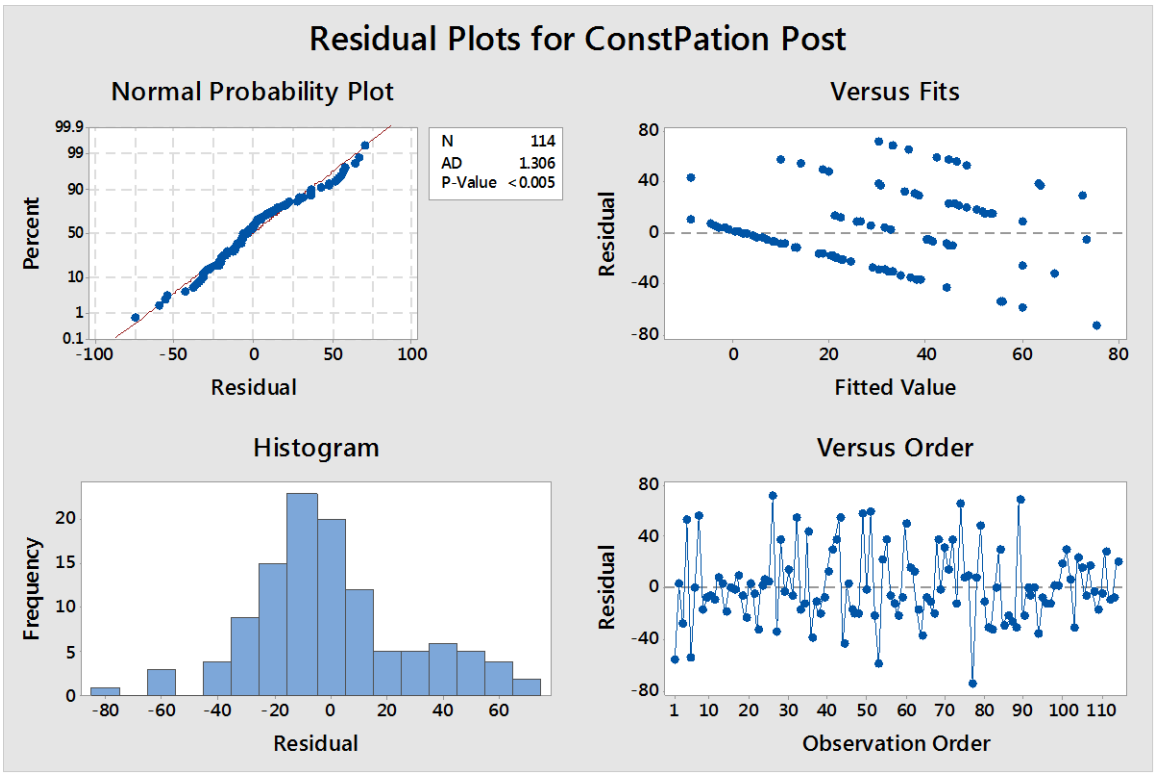

Residual Plots for Pain Post
Normal Probability Plot
N 114
AD 0.508
P-Value 0.196
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

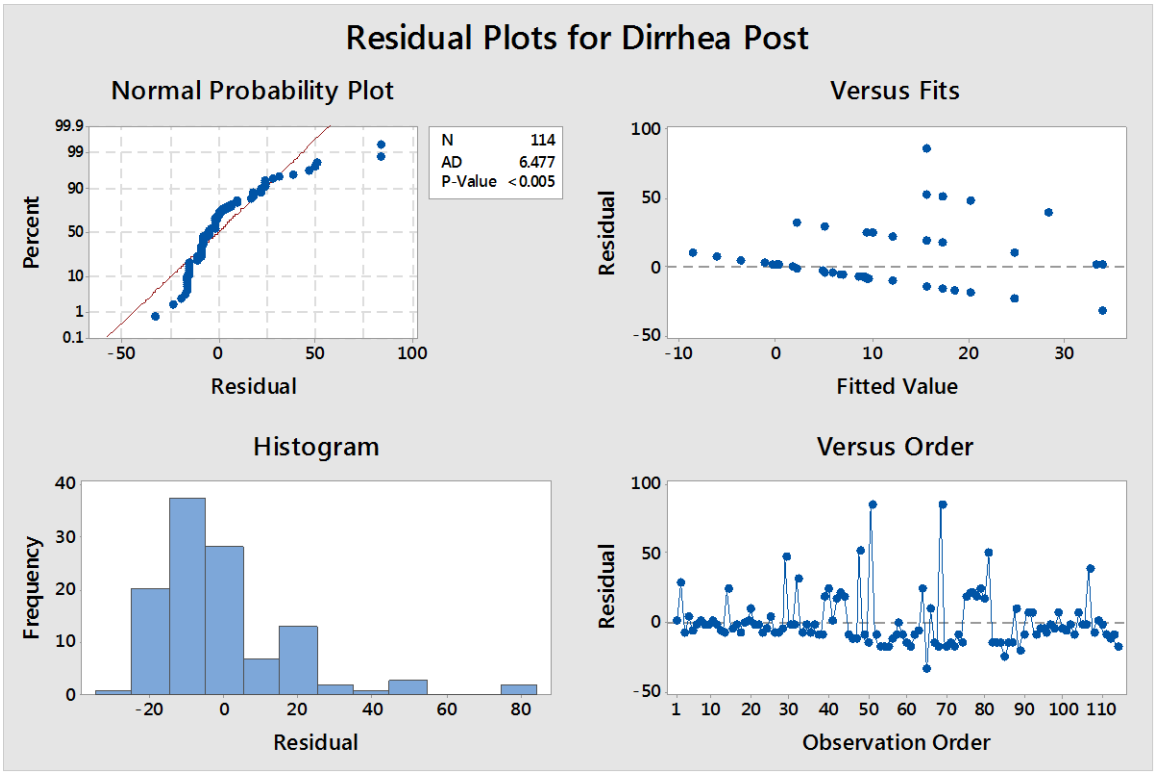

Residual Plots for Fatigue Post
Normal Probability Plot
N 114
AD 0.452
P-Value 0.268
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

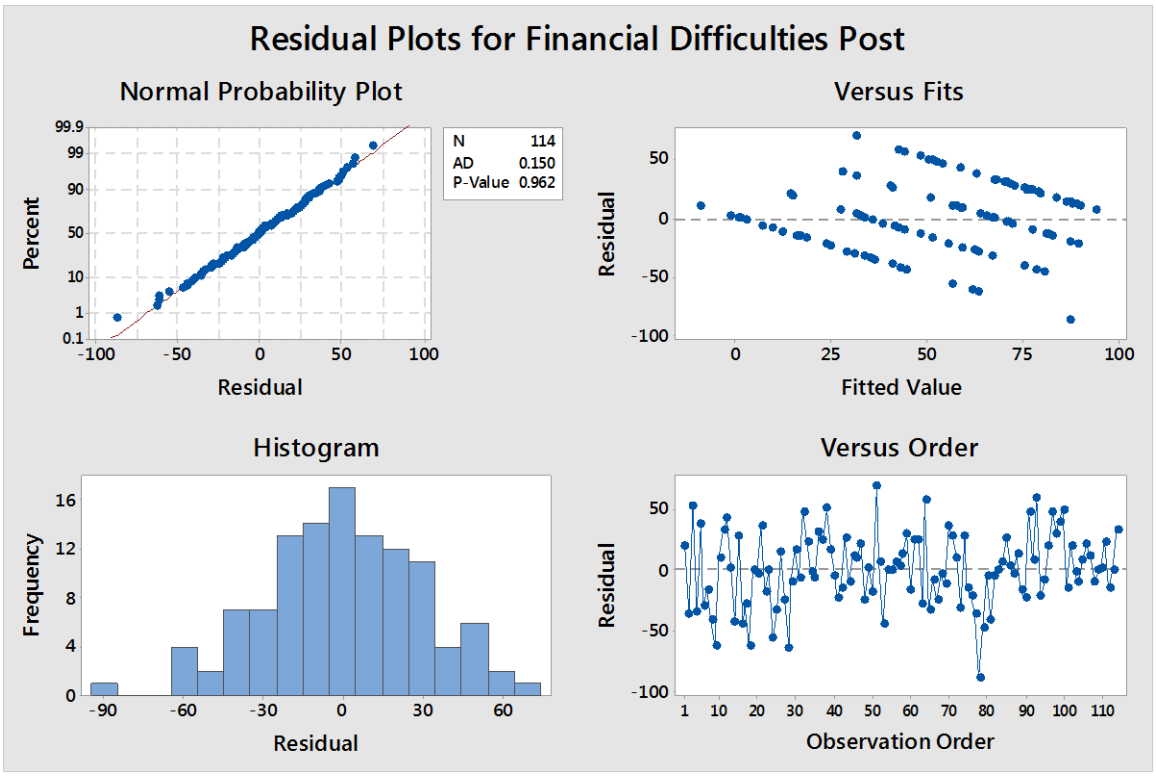

Residual Plots for Insomnia Post
Normal Probability Plot
N 114
AD 0.474
P-Value 0.238
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

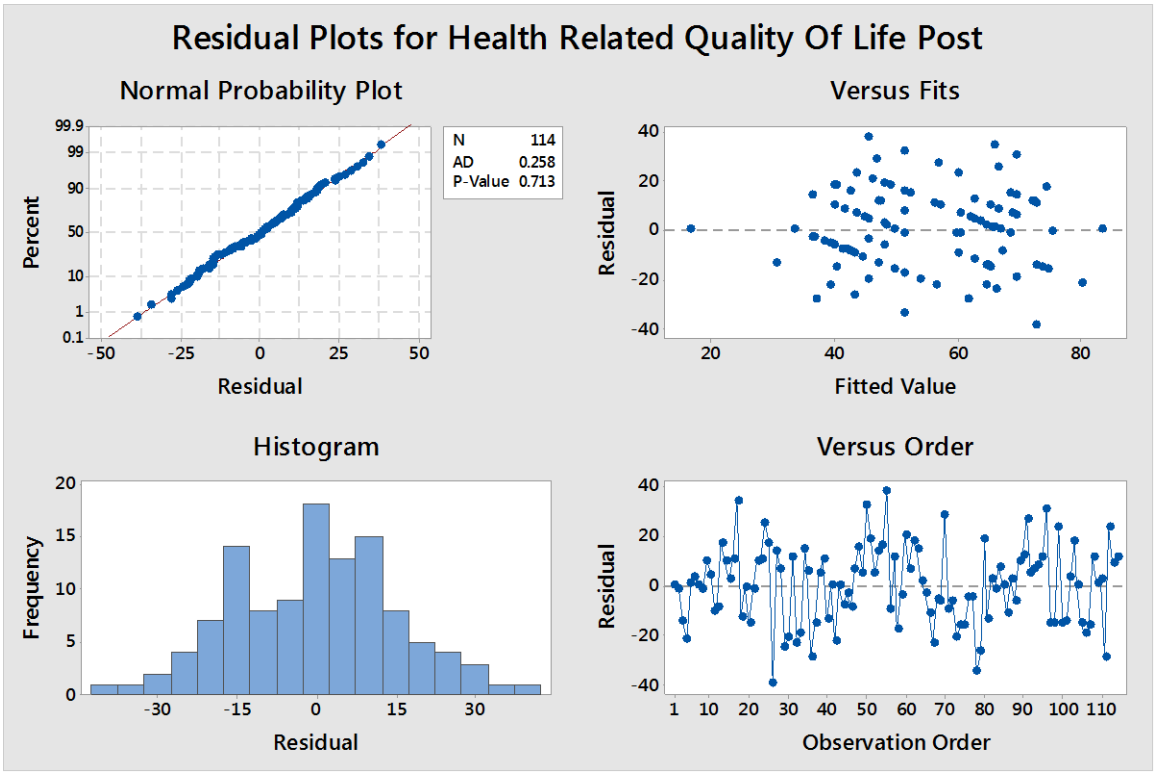

Residual Plots for Appetite Loss Post
Normal Probability Plot
N 114
AD 0.214
P-Value 0.846
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order


Residual Plots for Nausea and Vomiting Post
Normal Probability Plot
N 114
AD 2.119
P-Value < 0.005
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order


Residual Plots for ConstPation Post
Normal Probability Plot
N 114
AD 1.306
P-Value <0.005
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order


Residual Plots for Dirrhea Post
Normal Probability Plot
N 114
AD 6.477
P-Value <0.005
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order


Residual Plots for Financial Difficulties Post
Normal Probability Plot
N 114
AD 0.150
P-Value 0.962
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order


Residual Plots for Health Related Quality Of Life Post
Normal Probability Plot
N 114
AD 0.258
P-Value 0.713
Percent
Residual
Versus Fits
Residual
Fitted Value
Histogram
Frequency
Residual
Versus Order
Residual
Observation Order

Annex 14 Detailed result of ANCOVA model, outcomes with independent variables (Anxiety, depression and quality of life)

General Linear Model: Deppost versus Deppre, r_size, Cancer stage

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Tumor_size	Fixed	3	1, 2, 3
Cancer_stage	Fixed	4	1, 2, 3, 4

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Deppre	1	298.79	10.56%	411.07	411.070	25.32	0.000
intervention	1	750.09	26.51%	516.64	516.644	31.82	0.000
Tumor_size	2	42.09	1.49%	3.48	1.741	0.11	0.898
Cancer_stage	3	17.70	0.63%	17.70	5.901	0.36	0.779
Error	106	1720.95	60.82%	1720.95	16.235		
Lack-of-Fit	69	1086.03	38.38%	1086.03	15.740	0.92	0.629
Pure Error	37	634.92	22.44%	634.92	17.160		
Total	113	2829.62	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
4.02931	39.18%	35.16%	1961.71	30.67%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	3.58	2.13	(-0.64, 7.80)	1.68	0.095	
Deppre	0.599	0.119	(0.363, 0.835)	5.03	0.000	1.29
intervention						
1	-4.784	0.848	(-6.466, -3.103)	-5.64	0.000	1.26
Tumor_size						
2	0.10	1.37	(-2.62, 2.83)	0.07	0.941	3.11
3	0.68	1.80	(-2.88, 4.25)	0.38	0.704	4.20
Cancer_stage						
2	0.74	1.97	(-3.17, 4.65)	0.37	0.709	6.15
3	1.09	2.10	(-3.08, 5.25)	0.52	0.606	7.14
4	2.09	2.32	(-2.52, 6.69)	0.90	0.371	7.01

Regression Equation

intervention	Tumor_size	Cancer_stage			
0	1	1	Deppost	=	3.58 + 0.599 Deppre
0	1	2	Deppost	=	4.32 + 0.599 Deppre
0	1	3	Deppost	=	4.67 + 0.599 Deppre
0	1	4	Deppost	=	5.67 + 0.599 Deppre
0	2	1	Deppost	=	3.69 + 0.599 Deppre
0	2	2	Deppost	=	4.43 + 0.599 Deppre
0	2	3	Deppost	=	4.77 + 0.599 Deppre
0	2	4	Deppost	=	5.77 + 0.599 Deppre
0	3	1	Deppost	=	4.27 + 0.599 Deppre
0	3	2	Deppost	=	5.01 + 0.599 Deppre
0	3	3	Deppost	=	5.35 + 0.599 Deppre
0	3	4	Deppost	=	6.35 + 0.599 Deppre
1	1	1	Deppost	=	-1.20 + 0.599 Deppre
1	1	2	Deppost	=	-0.46 + 0.599 Deppre
1	1	3	Deppost	=	-0.11 + 0.599 Deppre
1	1	4	Deppost	=	0.89 + 0.599 Deppre
1	2	1	Deppost	=	-1.10 + 0.599 Deppre
1	2	2	Deppost	=	-0.36 + 0.599 Deppre
1	2	3	Deppost	=	-0.01 + 0.599 Deppre
1	2	4	Deppost	=	0.99 + 0.599 Deppre
1	3	1	Deppost	=	-0.52 + 0.599 Deppre
1	3	2	Deppost	=	0.22 + 0.599 Deppre
1	3	3	Deppost	=	0.57 + 0.599 Deppre
1	3	4	Deppost	=	1.57 + 0.599 Deppre

General Linear Model: Anxpost versus Anxpre, … ommP_new, quantile

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Metastasis	Fixed	2	1, 2
Treatment_kind	Fixed	7	1, 2, 3, 4, 5, 6, 7
quantie	Fixed	5	1, 2, 3, 4, 5
CommP_new	Fixed	2	1, 2

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Anxpre	1	429.06	12.67%	352.66	352.660	20.50	0.000
intervention	1	842.03	24.86%	572.13	572.127	33.26	0.000
Metastasis	1	54.25	1.60%	15.61	15.608	0.91	0.343
Treatment_kind	6	53.23	1.57%	134.01	22.335	1.30	0.265
quantie	4	303.52	8.96%	305.52	76.381	4.44	0.002
CommP_new	1	2.19	0.06%	2.19	2.190	0.13	0.722
Error	99	1702.74	50.27%	1702.74	17.199		
Lack-of-Fit	85	1511.08	44.61%	1511.08	17.777	1.30	0.302
Pure Error	14	191.67	5.66%	191.67	13.690		
Total	113	3387.02	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
4.14722	49.73%	42.62%	*	*

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	7.17	2.39	(2.43, 11.90)	3.00	0.003	
Anxpre	0.590	0.130	(0.332, 0.849)	4.53	0.000	1.17
intervention						
1	-5.726	0.993	(-7.696, -3.756)	-5.77	0.000	1.63
Metastasis						
2	-1.33	1.40	(-4.11, 1.44)	-0.95	0.343	1.57
Treatment_kind						
2	-0.46	4.54	(-9.46, 8.54)	-0.10	0.919	1.19
3	-2.50	4.40	(-11.23, 6.22)	-0.57	0.570	1.11
4	-1.24	1.65	(-4.51, 2.03)	-0.75	0.452	3.95
5	-0.50	2.11	(-4.68, 3.68)	-0.24	0.813	2.77
6	10.64	4.81	(1.10, 20.19)	2.21	0.029	1.33
7	-1.36	2.03	(-5.40, 2.68)	-0.67	0.506	2.58
quantie						
2	3.28	1.67	(-0.04, 6.60)	1.96	0.053	1.21
3	1.66	1.17	(-0.66, 3.99)	1.42	0.159	1.37
4	-0.16	1.02	(-2.19, 1.86)	-0.16	0.874	1.47
5	-4.45	1.59	(-7.60, -1.30)	-2.80	0.006	1.33
CommP_new						
2	-0.334	0.935	(-2.189, 1.522)	-0.36	0.722	1.25

Regression Equation

Anxpost = 7.17 + 0.590 Anxpre + 0.0 intervention_0 - 5.726 intervention_1 + 0.0 Metastasis_1
- 1.33 Metastasis_2 + 0.0 Treatment_kind_1 - 0.46 Treatment_kind_2
- 2.50 Treatment_kind_3 - 1.24 Treatment_kind_4 - 0.50 Treatment_kind_5
+ 10.64 Treatment_kind_6 - 1.36 Treatment_kind_7 + 0.0 quantie_1 + 3.28 quantie_2
+ 1.66 quantie_3 - 0.16 quantie_4 - 4.45 quantie_5 + 0.0 CommP_new_1
- 0.334 CommP_new_2

Descriptive Statistics: Anxpre

Statistics

Variable	intervention	N	N*	Mean	StDev	Minimum	Maximum
Anxpre	0	57	0	12.228	2.732	7.000	18.000
	1	57	0	12.614	3.678	2.000	18.000

Descriptive Statistics: Anxpost

Statistics

Variable	intervention	N	N*	Mean	StDev	Minimum	Maximum
Anxpost	0	57	0	11.982	4.612	0.000	18.000
	1	57	0	6.789	5.049	0.000	18.000

General Linear Model: Physical Functioning post versus PFpr, Deppre, Age respondent ... Intervention,

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
PFpr	1	24391.8	36.44%	11589.4	11589.4	34.10	0.000
Agerespondent	1	1384.9	2.07%	1931.5	1931.5	5.68	0.019
Deppre	1	1234.4	1.84%	1826.1	1826.1	5.37	0.022
Anxpre	1	493.8	0.74%	416.7	416.7	1.23	0.271
intervention	1	2728.9	4.08%	2728.9	2728.9	8.03	0.005
Error	108	36702.6	54.83%	36702.6	339.8		
Total	113	66936.5	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
18.4347	45.17%	42.63%	41252.7	38.37%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	75.8	14.2	(47.7, 103.9)	5.35	0.000	
PFpr	0.4723	0.0809	(0.3120, 0.6326)	5.84	0.000	1.24
Agerespondent	-0.436	0.183	(-0.798, -0.073)	-2.38	0.019	1.07
Deppre	-1.317	0.568	(-2.444, -0.191)	-2.32	0.022	1.40
Anxpre	-0.638	0.576	(-1.779, 0.504)	-1.11	0.271	1.15
intervention						
1	10.61	3.74	(3.19, 18.03)	2.83	0.005	1.17

Regression Equation

intervention			
0	PFpo	=	75.8 + 0.4723 PFpr - 0.436 Agerespondent - 1.317 Deppre - 0.638 Anxpre
1	PFpo	=	86.4 + 0.4723 PFpr - 0.436 Agerespondent - 1.317 Deppre - 0.638 Anxpre

General Linear Model: Role Functioning post versus RFpr, Deppre, Age respondent... l_status,

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Marital_status	Fixed	2	1, 2

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
RFpr	1	14643	12.06%	4458	4457.6	5.91	0.017
Agerespondent	1	2966	2.44%	4483	4483.5	5.94	0.016
Deppre	1	2353	1.94%	2778	2778.2	3.68	0.058
Anxpre	1	809	0.67%	1003	1003.3	1.33	0.251
intervention	1	13258	10.92%	15231	15231.3	20.18	0.000
Marital_status	1	6653	5.48%	6653	6653.5	8.82	0.004
Error	107	80743	66.50%	80743	754.6		
Total	113	121425	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
27.4701	33.50%	29.78%	92289.3	24.00%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	97.5	20.2	(57.4, 137.6)	4.82	0.000	
RFpr	0.1949	0.0802	(0.0359, 0.3538)	2.43	0.017	1.24
Agerespondent	-0.659	0.270	(-1.195, -0.123)	-2.44	0.016	1.05
Deppre	-1.663	0.867	(-3.381, 0.055)	-1.92	0.058	1.47
Anxpre	-1.000	0.867	(-2.719, 0.719)	-1.15	0.251	1.18
intervention						
1	24.46	5.44	(13.67, 35.25)	4.49	0.000	1.12
Marital_status						
2	16.09	5.42	(5.35, 26.83)	2.97	0.004	1.09

Regression Equation

intervention	Marital_status			
0	1	RFpo	=	97.5 + 0.1949 RFpr - 0.659 Agerespondent - 1.663 Deppre - 1.000 Anxpre
0	2	RFpo	=	113.6 + 0.1949 RFpr - 0.659 Agerespondent - 1.663 Deppre - 1.000 Anxpre
1	1	RFpo	=	122.0 + 0.1949 RFpr - 0.659 Agerespondent - 1.663 Deppre - 1.000 Anxpre
1	2	RFpo	=	138.1 + 0.1949 RFpr - 0.659 Agerespondent - 1.663 Deppre - 1.000 Anxpre

General Linear Model: Cognitive Functioning Post versus CFpr, Deppre, ... n, Treatment kind

Method

Factor coding	(1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Treatment_kind	Fixed	7	1, 2, 3, 4, 5, 6, 7

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
CFpr	1	14574	16.89%	8701.0	8701.0	16.62	0.000
Deppre	1	4962	5.75%	5396.7	5396.7	10.31	0.002
Anxpre	1	1109	1.29%	418.9	418.9	0.80	0.373
intervention	1	5709	6.62%	5289.0	5289.0	10.10	0.002
Treatment_kind	6	5994	6.95%	5994.1	999.0	1.91	0.086
Error	103	53922	62.50%	53921.7	523.5		
Lack-of-Fit	101	51699	59.93%	51699.4	511.9	0.46	0.881
Pure Error	2	2222	2.58%	2222.2	1111.1		
Total	113	86269	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
22.8804	37.50%	31.43%	*	*

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	88.2	16.5	(55.4, 121.0)	5.34	0.000	
CFpr	0.3570	0.0876	(0.1833, 0.5307)	4.08	0.000	1.38
Deppre	-2.251	0.701	(-3.642, -0.861)	-3.21	0.002	1.39
Anxpre	-0.667	0.745	(-2.144, 0.811)	-0.89	0.373	1.25
intervention						
1	16.26	5.11	(6.11, 26.40)	3.18	0.002	1.42
Treatment_kind						
2	28.9	24.8	(-20.4, 78.1)	1.16	0.248	1.17
3	-9.4	24.3	(-57.6, 38.8)	-0.39	0.700	1.12
4	-13.75	7.90	(-29.42, 1.92)	-1.74	0.085	2.98
5	-10.9	10.5	(-31.7, 10.0)	-1.03	0.304	2.27
6	-62.2	24.6	(-111.0, -13.5)	-2.53	0.013	1.14
7	-15.7	10.6	(-36.7, 5.2)	-1.49	0.139	2.29

Regression Equation

intervention	Treatment_kind			
0	1	CFpo	=	88.2 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	2	CFpo	=	117.1 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	3	CFpo	=	78.8 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	4	CFpo	=	74.4 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	5	CFpo	=	77.3 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	6	CFpo	=	25.9 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
0	7	CFpo	=	72.4 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	1	CFpo	=	104.4 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	2	CFpo	=	133.3 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	3	CFpo	=	95.1 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	4	CFpo	=	90.7 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	5	CFpo	=	93.6 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	6	CFpo	=	42.2 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre
1	7	CFpo	=	88.7 + 0.3570 CFpr - 2.251 Deppre - 0.667 Anxpre

General Linear Model: Emotional Functioning post versus EFpr, Deppre, Anxpre, ... e, quantile

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
quantie	Fixed	5	1, 2, 3, 4, 5

Method

Factor coding (1, 0)

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
EFpr	1	14938	13.34%	11462.5	11462.5	20.91	0.000
Deppre	1	886	0.79%	2054.3	2054.3	3.75	0.056
Anxpre	1	3318	2.96%	843.6	843.6	1.54	0.218
intervention	1	31241	27.89%	25738.3	25738.3	46.94	0.000
Cancer_stage	3	683	0.61%	387.9	129.3	0.24	0.871
quantie	4	5026	4.49%	5026.1	1256.5	2.29	0.065
Error	102	55924	49.93%	55924.3	548.3		
Total	113	112015	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
23.4153	50.07%	44.69%	70272.3	37.27%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	56.2	18.5	(19.6, 92.8)	3.05	0.003	
EFpr	0.470	0.103	(0.266, 0.675)	4.57	0.000	1.52
Deppre	-1.442	0.745	(-2.920, 0.036)	-1.94	0.056	1.50
Anxpre	-0.997	0.804	(-2.591, 0.597)	-1.24	0.218	1.39
intervention						
1	34.80	5.08	(24.73, 44.88)	6.85	0.000	1.34
Cancer_stage						
2	-6.5	10.5	(-27.4, 14.3)	-0.62	0.537	5.18
3	-2.8	10.6	(-23.8, 18.2)	-0.27	0.789	5.37
4	-5.0	11.4	(-27.6, 17.5)	-0.44	0.658	4.97
quantie						
2	1.20	9.30	(-17.24, 19.64)	0.13	0.898	1.17
3	2.24	6.64	(-10.93, 15.41)	0.34	0.736	1.38
4	2.69	5.58	(-8.37, 13.76)	0.48	0.630	1.38
5	25.10	8.48	(8.28, 41.93)	2.96	0.004	1.20

Regression Equation

intervention	Cancer_stage	quantie			
0	1	1	EFpo	=	56.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	1	2	EFpo	=	57.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	1	3	EFpo	=	58.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	1	4	EFpo	=	58.9 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	1	5	EFpo	=	81.3 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	2	1	EFpo	=	49.7 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	2	2	EFpo	=	50.9 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	2	3	EFpo	=	51.9 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	2	4	EFpo	=	52.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	2	5	EFpo	=	74.8 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	3	1	EFpo	=	53.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	3	2	EFpo	=	54.6 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	3	3	EFpo	=	55.6 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	3	4	EFpo	=	56.0 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	3	5	EFpo	=	78.5 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	4	1	EFpo	=	51.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	4	2	EFpo	=	52.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	4	3	EFpo	=	53.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	4	4	EFpo	=	53.9 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
0	4	5	EFpo	=	76.3 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	1	1	EFpo	=	91.0 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	1	2	EFpo	=	92.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	1	3	EFpo	=	93.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	1	4	EFpo	=	93.7 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	1	5	EFpo	=	116.1 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	2	1	EFpo	=	84.5 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	2	2	EFpo	=	85.7 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	2	3	EFpo	=	86.7 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	2	4	EFpo	=	87.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	2	5	EFpo	=	109.6 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	3	1	EFpo	=	88.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	3	2	EFpo	=	89.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	3	3	EFpo	=	90.4 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	3	4	EFpo	=	90.8 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	3	5	EFpo	=	113.3 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	4	1	EFpo	=	86.0 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	4	2	EFpo	=	87.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	4	3	EFpo	=	88.2 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	4	4	EFpo	=	88.7 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre
1	4	5	EFpo	=	111.1 + 0.470 EFpr - 1.442 Deppre - 0.997 Anxpre

General Linear Model: Social Functioning post versus SF pre, Deppre ... r_disease, quantile

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
Any_other_disease	Fixed	2	1, 2
quantie	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
SFpr	1	15963	13.22%	6132	6132.1	8.49	0.004
Deppre	1	1340	1.11%	3520	3519.6	4.87	0.030
intervention	1	14745	12.21%	5531	5530.6	7.66	0.007
Cancer_stage	3	5211	4.31%	2648	882.5	1.22	0.306
Any_other_disease	1	4074	3.37%	6558	6558.0	9.08	0.003
quantie	4	5753	4.76%	5753	1438.2	1.99	0.102
Error	102	73687	61.01%	73687	722.4		
Lack-of-Fit	99	67437	55.84%	67437	681.2	0.33	0.968
Pure Error	3	6250	5.18%	6250	2083.3		
Total	113	120772	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
27.3758	34.22%	29.88%	91742.2	24.04%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	96.1	17.3	(61.7, 130.4)	5.54	0.000	
SFpr	0.2336	0.0802	(0.0746, 0.3927)	2.91	0.004	1.34
Deppre	-1.801	0.816	(-3.419, -0.183)	-2.21	0.030	1.36
intervention						
1	16.09	5.81	(4.55, 27.62)	2.77	0.007	1.33
Cancer_stage						
2	-17.7	12.1	(-41.7, 6.3)	-1.47	0.146	5.18
3	-13.5	12.2	(-37.6, 10.6)	-1.11	0.270	5.38
4	-23.0	13.1	(-48.9, 2.9)	-1.76	0.081	4.98
Any_other_disease						
2	-22.13	7.35	(-36.70, -7.56)	-3.01	0.003	1.13
quantie						
2	17.2	10.8	(-4.3, 38.7)	1.58	0.116	1.21
3	0.57	7.39	(-14.09, 15.22)	0.08	0.939	1.29
4	11.30	6.40	(-1.41, 24.00)	1.76	0.081	1.38
5	22.26	9.93	(2.57, 41.96)	2.24	0.027	1.24

Regression Equation

SFpo = 96.1 + 0.2336 SFpr - 1.801 Deppre + 0.0 intervention_0 + 16.09 intervention_1
+ 0.0 Cancer_stage_1 - 17.7 Cancer_stage_2 - 13.5 Cancer_stage_3 - 23.0 Cancer_stage_4
+ 0.0 Any_other_disease_1 - 22.13 Any_other_disease_2 + 0.0 quantie_1 + 17.2 quantie_2
+ 0.57 quantie_3 + 11.30 quantie_4 + 22.26 quantie_5

General Linear Model: Dyspnea post versus Dyspr, intervention

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Dyspr	1	21615	23.34%	22051	22050.8	35.01	0.000
intervention	1	1059	1.14%	1059	1059.3	1.68	0.197
Error	111	69918	75.51%	69918	629.9		
Lack-of-Fit	4	4717	5.09%	4717	1179.2	1.94	0.110
Pure Error	107	65201	70.42%	65201	609.4		
Total	113	92593	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
25.0976	24.49%	23.13%	75036.0	18.96%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	13.15	3.84	(5.54, 20.77)	3.42	0.001	
Dyspr	0.4878	0.0824	(0.3244, 0.6512)	5.92	0.000	1.00
intervention						
1	-6.10	4.71	(-15.43, 3.22)	-1.30	0.197	1.00

Regression Equation

intervention			
0	Dyspost	=	13.15 + 0.4878 Dyspr
1	Dyspost	=	7.05 + 0.4878 Dyspr

General Linear Model: Pain post versus Papr, Deppre, ... cer_stage, quantile

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
quantie	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Papr	1	17370	16.04%	8429.8	8429.8	11.43	0.001
Deppre	1	1604	1.48%	1194.7	1194.7	1.62	0.206
Anxpre	1	1044	0.96%	524.8	524.8	0.71	0.401
intervention	1	6441	5.95%	2443.8	2443.8	3.31	0.072
Cancer_stage	3	4781	4.41%	4153.2	1384.4	1.88	0.138
quantie	4	1834	1.69%	1833.6	458.4	0.62	0.648
Error	102	75244	69.47%	75243.5	737.7		
Total	113	108316	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
27.1603	30.53%	23.04%	92192.6	14.89%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	-11.3	16.5	(-44.0, 21.5)	-0.68	0.496	
Papr	0.3030	0.0896	(0.1252, 0.4808)	3.38	0.001	1.19
Deppre	1.086	0.854	(-0.607, 2.780)	1.27	0.206	1.46
Anxpre	0.746	0.885	(-1.009, 2.501)	0.84	0.401	1.25
intervention						
1	-10.47	5.76	(-21.89, 0.94)	-1.82	0.072	1.28
Cancer_stage						
2	19.8	12.2	(-4.3, 44.0)	1.63	0.107	5.15
3	16.7	12.3	(-7.7, 41.0)	1.36	0.178	5.37
4	28.8	13.1	(2.7, 54.9)	2.19	0.031	4.95
quantie						
2	-12.6	10.8	(-34.0, 8.8)	-1.17	0.246	1.17
3	-2.50	7.70	(-17.78, 12.77)	-0.33	0.746	1.38
4	-7.10	6.42	(-19.84, 5.63)	-1.11	0.271	1.36
5	-10.3	10.0	(-30.2, 9.6)	-1.03	0.306	1.24

Regression Equation

intervention	Cancer_stage	quantie			
0	1	1	Papo	=	-11.3 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	1	2	Papo	=	-23.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	1	3	Papo	=	-13.8 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	1	4	Papo	=	-18.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	1	5	Papo	=	-21.6 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	2	1	Papo	=	8.5 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	2	2	Papo	=	-4.1 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	2	3	Papo	=	6.0 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	2	4	Papo	=	1.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	2	5	Papo	=	-1.8 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	3	1	Papo	=	5.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	3	2	Papo	=	-7.2 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	3	3	Papo	=	2.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	3	4	Papo	=	-1.7 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	3	5	Papo	=	-4.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	4	1	Papo	=	17.5 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	4	2	Papo	=	4.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	4	3	Papo	=	15.0 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	4	4	Papo	=	10.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
0	4	5	Papo	=	7.2 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	1	1	Papo	=	-21.7 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	1	2	Papo	=	-34.3 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	1	3	Papo	=	-24.2 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	1	4	Papo	=	-28.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	1	5	Papo	=	-32.1 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	2	1	Papo	=	-1.9 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	2	2	Papo	=	-14.5 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	2	3	Papo	=	-4.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	2	4	Papo	=	-9.0 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	2	5	Papo	=	-12.3 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	3	1	Papo	=	-5.1 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	3	2	Papo	=	-17.7 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	3	3	Papo	=	-7.6 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	3	4	Papo	=	-12.2 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	3	5	Papo	=	-15.4 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	4	1	Papo	=	7.1 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	4	2	Papo	=	-5.5 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	4	3	Papo	=	4.6 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	4	4	Papo	=	-0.0 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre
1	4	5	Papo	=	-3.3 + 0.3030 Papr + 1.086 Deppre + 0.746 Anxpre

General Linear Model: Fatigue post versus Fatgpr, Deppre, Age respondent.....Cancer stage

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Fatgpr	1	30071	28.22%	10847.1	10847.1	18.46	0.000
Deppre	1	735	0.69%	1399.5	1399.5	2.38	0.126
Agerespondent	1	1824	1.71%	2441.9	2441.9	4.16	0.044
intervention	1	6052	5.68%	2911.7	2911.7	4.95	0.028
Cancer_stage	3	5571	5.23%	5570.8	1856.9	3.16	0.028
Error	106	62294	58.47%	62293.5	587.7		
Lack-of-Fit	105	62294	58.47%	62293.5	593.3	*	*
Pure Error	1	0	0.00%	0.0	0.0		
Total	113	106545	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
24.2420	41.53%	37.67%	72006.9	32.42%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	-26.8	16.1	(-58.7, 5.1)	-1.66	0.099	
Fatgpr	0.3899	0.0907	(0.2099, 0.5698)	4.30	0.000	1.33
Deppre	1.142	0.740	(-0.325, 2.609)	1.54	0.126	1.38
Agerespondent	0.506	0.248	(0.014, 0.998)	2.04	0.044	1.14
intervention						
1	-11.37	5.11	(-21.49, -1.24)	-2.23	0.028	1.26
Cancer_stage						
2	15.8	10.7	(-5.4, 37.1)	1.48	0.143	5.01
3	11.7	10.7	(-9.6, 33.0)	1.09	0.280	5.16
4	28.4	11.5	(5.7, 51.2)	2.48	0.015	4.72

Regression Equation

intervention	Cancer_stage			
0	1	Fatgpo	=	-26.8 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
0	2	Fatgpo	=	-11.0 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
0	3	Fatgpo	=	-15.1 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
0	4	Fatgpo	=	1.6 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
1	1	Fatgpo	=	-38.2 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
1	2	Fatgpo	=	-22.3 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
1	3	Fatgpo	=	-26.5 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent
1	4	Fatgpo	=	-9.7 + 0.3899 Fatgpr + 1.142 Deppre + 0.506 Agerespondent

General Linear Model: Insomnia post versus Inspr, Deppre, ... er_stage, quantile

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
quantie	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
Inspr	1	17934	14.52%	17641.8	17641.8	21.24	0.000
Deppre	1	170	0.14%	193.4	193.4	0.23	0.630
Anxpre	1	2902	2.35%	1047.9	1047.9	1.26	0.264
intervention	1	11073	8.97%	8254.1	8254.1	9.94	0.002
Cancer_stage	3	1383	1.12%	979.6	326.5	0.39	0.758
quantie	4	5310	4.30%	5310.0	1327.5	1.60	0.181
Error	102	84736	68.61%	84736.3	830.7		
Total	113	123509	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
28.8227	31.39%	23.99%	105565	14.53%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	18.1	17.6	(-16.8, 53.0)	1.03	0.306	
Inspr	0.4028	0.0874	(0.2294, 0.5762)	4.61	0.000	1.26
Deppre	-0.432	0.896	(-2.209, 1.344)	-0.48	0.630	1.43
Anxpre	1.094	0.974	(-0.838, 3.027)	1.12	0.264	1.35
intervention						
1	-19.56	6.21	(-31.87, -7.25)	-3.15	0.002	1.32
Cancer_stage						
2	-3.9	12.9	(-29.6, 21.8)	-0.30	0.765	5.18
3	-1.3	13.0	(-27.1, 24.6)	-0.10	0.922	5.37
4	4.4	14.0	(-23.3, 32.2)	0.32	0.751	4.97
quantie						
2	11.6	11.4	(-11.0, 34.3)	1.02	0.311	1.17
3	-2.38	8.23	(-18.72, 13.95)	-0.29	0.773	1.40
4	-2.20	6.81	(-15.71, 11.31)	-0.32	0.747	1.35
5	-21.8	10.5	(-42.5, -1.1)	-2.09	0.040	1.20

Regression Equation

intervention	Cancer_stage	quantie			
0	1	1	Inspo	=	18.1 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	1	2	Inspo	=	29.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	1	3	Inspo	=	15.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	1	4	Inspo	=	15.9 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	1	5	Inspo	=	-3.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	2	1	Inspo	=	14.2 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	2	2	Inspo	=	25.9 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	2	3	Inspo	=	11.8 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	2	4	Inspo	=	12.0 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	2	5	Inspo	=	-7.6 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	3	1	Inspo	=	16.8 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	3	2	Inspo	=	28.5 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	3	3	Inspo	=	14.4 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	3	4	Inspo	=	14.6 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	3	5	Inspo	=	-5.0 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	4	1	Inspo	=	22.5 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	4	2	Inspo	=	34.2 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	4	3	Inspo	=	20.2 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	4	4	Inspo	=	20.3 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
0	4	5	Inspo	=	0.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	1	1	Inspo	=	-1.5 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	1	2	Inspo	=	10.2 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	1	3	Inspo	=	-3.8 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	1	4	Inspo	=	-3.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	1	5	Inspo	=	-23.3 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	2	1	Inspo	=	-5.3 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	2	2	Inspo	=	6.3 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	2	3	Inspo	=	-7.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	2	4	Inspo	=	-7.5 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	2	5	Inspo	=	-27.1 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	3	1	Inspo	=	-2.7 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	3	2	Inspo	=	8.9 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	3	3	Inspo	=	-5.1 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	3	4	Inspo	=	-4.9 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	3	5	Inspo	=	-24.5 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	4	1	Inspo	=	3.0 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	4	2	Inspo	=	14.6 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	4	3	Inspo	=	0.6 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	4	4	Inspo	=	0.8 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre
1	4	5	Inspo	=	-18.8 + 0.4028 Inspr - 0.432 Deppre + 1.094 Anxpre

General Linear Model: Appetite Loss post versus ApLpr, intervention, Cancer stage, Com-P...

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
CommP_new	Fixed	2	1, 2

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
ApLpr	1	25215	17.15%	12569.5	12569.5	13.42	0.000
Agerespondent	1	7823	5.32%	8072.7	8072.7	8.62	0.004
intervention	1	5598	3.81%	1122.8	1122.8	1.20	0.276
Cancer_stage	3	7195	4.90%	7130.2	2376.7	2.54	0.061
CommP_new	1	1898	1.29%	1897.8	1897.8	2.03	0.157
Error	106	99259	67.53%	99259.3	936.4		
Lack-of-Fit	101	98704	67.15%	98703.7	977.3	8.80	0.011
Pure Error	5	556	0.38%	555.6	111.1		
Total	113	146988	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
30.6008	32.47%	28.01%	114239	22.28%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	-26.9	18.3	(-63.3, 9.4)	-1.47	0.145	
ApLpr	0.2991	0.0816	(0.1372, 0.4610)	3.66	0.000	1.10
Agerespondent	0.892	0.304	(0.290, 1.495)	2.94	0.004	1.07
intervention						
1	-6.98	6.38	(-19.63, 5.66)	-1.10	0.276	1.24
Cancer_stage						
2	4.6	13.5	(-22.2, 31.4)	0.34	0.734	5.01
3	5.8	13.6	(-21.2, 32.7)	0.42	0.673	5.18
4	23.9	14.1	(-4.1, 51.9)	1.69	0.094	4.51
CommP_new						
2	9.57	6.72	(-3.76, 22.89)	1.42	0.157	1.19

Regression Equation

intervention	Cancer_stage	CommP_new			
0	1	1	ApLpo	=	-26.9 + 0.2991 ApLpr + 0.892 Agerespondent
0	1	2	ApLpo	=	-17.4 + 0.2991 ApLpr + 0.892 Agerespondent
0	2	1	ApLpo	=	-22.3 + 0.2991 ApLpr + 0.892 Agerespondent
0	2	2	ApLpo	=	-12.8 + 0.2991 ApLpr + 0.892 Agerespondent
0	3	1	ApLpo	=	-21.2 + 0.2991 ApLpr + 0.892 Agerespondent
0	3	2	ApLpo	=	-11.6 + 0.2991 ApLpr + 0.892 Agerespondent
0	4	1	ApLpo	=	-3.0 + 0.2991 ApLpr + 0.892 Agerespondent
0	4	2	ApLpo	=	6.5 + 0.2991 ApLpr + 0.892 Agerespondent
1	1	1	ApLpo	=	-33.9 + 0.2991 ApLpr + 0.892 Agerespondent
1	1	2	ApLpo	=	-24.4 + 0.2991 ApLpr + 0.892 Agerespondent
1	2	1	ApLpo	=	-29.3 + 0.2991 ApLpr + 0.892 Agerespondent
1	2	2	ApLpo	=	-19.8 + 0.2991 ApLpr + 0.892 Agerespondent
1	3	1	ApLpo	=	-28.2 + 0.2991 ApLpr + 0.892 Agerespondent
1	3	2	ApLpo	=	-18.6 + 0.2991 ApLpr + 0.892 Agerespondent
1	4	1	ApLpo	=	-10.0 + 0.2991 ApLpr + 0.892 Agerespondent
1	4	2	ApLpo	=	-0.4 + 0.2991 ApLpr + 0.892 Agerespondent

General Linear Model: Nausea and Vomiting po versus NVpr, Anxpre, ... d, Cancer_stage

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Treatment_kind	Fixed	7	1, 2, 3, 4, 5, 6, 7
Cancer_stage	Fixed	4	1, 2, 3, 4

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value
NVpr	1	17636.8	19.94%	10338.5	10338.5	17.00
Anxpre	1	5233.8	5.92%	1247.4	1247.4	2.05
intervention	1	2514.7	2.84%	1447.7	1447.7	2.38
Treatment_kind	6	928.2	1.05%	575.0	95.8	0.16
Cancer_stage	3	744.3	0.84%	744.3	248.1	0.41
Error	101	61412.0	69.42%	61412.0	608.0	
Lack-of-Fit	88	57013.9	64.44%	57013.9	647.9	1.92
Pure Error	13	4398.1	4.97%	4398.1	338.3	
Total	113	88469.8	100.00%			

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
24.6585	30.58%	22.34%	*	*

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	4.3	15.1	(-25.6, 34.2)	0.28	0.776	
NVpr	0.3542	0.0859	(0.1838, 0.5246)	4.12	0.000	1.14
Anxpre	0.743	0.519	(-0.286, 1.773)	1.43	0.155	1.50
intervention						
1	-9.50	6.16	(-21.71, 2.71)	-1.54	0.126	1.78
Treatment_kind						
2	-21.3	26.9	(-74.7, 32.0)	-0.79	0.429	1.18
3	2.6	26.0	(-48.9, 54.1)	0.10	0.920	1.10
4	-3.63	9.56	(-22.60, 15.34)	-0.38	0.705	3.76
5	-0.8	12.1	(-24.7, 23.2)	-0.06	0.950	2.57
6	-12.6	27.2	(-66.6, 41.5)	-0.46	0.646	1.21
7	-3.1	11.5	(-26.0, 19.9)	-0.26	0.792	2.35
Cancer_stage						
2	5.9	11.3	(-16.5, 28.3)	0.52	0.605	5.39
3	8.8	11.2	(-13.5, 31.1)	0.78	0.436	5.46
4	11.6	12.1	(-12.3, 35.5)	0.96	0.339	5.04

Regression Equation

NVpo = 4.3 + 0.3542 NVpr + 0.743 Anxpre + 0.0 intervention_0 - 9.50 interven
+ 0.0 Treatment_kind_1 - 21.3 Treatment_kind_2 + 2.6 Treatment_kind
- 3.63 Treatment_kind_4 - 0.8 Treatment_kind_5 - 12.6 Treatment_kind
- 3.1 Treatment_kind_7 + 0.0 Cancer_stage_1 + 5.9 Cancer_stage_2
+ 8.8 Cancer_stage_3
+ 11.6 Cancer_stage_4

General Linear Model: Constipation Post versus ConstPr, Dep.... umor_size

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Tumor_size	Fixed	3	1, 2, 3

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-V
ConstPr	1	34173	24.58%	28130.5	28130.5	33.34	(
Deppre	1	12813	9.22%	8243.2	8243.2	9.77	(
intervention	1	747	0.54%	820.6	820.6	0.97	(
Tumor_size	2	189	0.14%	189.5	94.7	0.11	(
Error	108	91113	65.53%	91113.0	843.6		
Lack-of-Fit	83	81391	58.54%	81390.8	980.6	2.52	(
Pure Error	25	9722	6.99%	9722.2	388.9		
Total	113	139035	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
29.0455	34.47%	31.43%	103556	25.52%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	-5.7	10.3	(-26.2, 14.7)	-0.56	0.579	
ConstPr	0.4812	0.0833	(0.3160, 0.6464)	5.77	0.000	1.06
Deppre	1.946	0.622	(0.712, 3.179)	3.13	0.002	1.30
intervention						
1	-5.92	6.00	(-17.80, 5.97)	-0.99	0.326	1.22
Tumor_size						
2	2.76	8.32	(-13.73, 19.25)	0.33	0.741	2.20
3	0.04	9.89	(-19.55, 19.64)	0.00	0.996	2.45

Regression Equation

intervention	Tumor_size			
0	1	ConstPo	=	-5.7 + 0.4812 ConstPr + 1.946 Deppre
0	2	ConstPo	=	-2.98 + 0.4812 ConstPr + 1.946 Depre
0	3	ConstPo	=	-5.7 + 0.4812 ConstPr + 1.946 Deppre
1	1	ConstPo	=	-11.66 + 0.4812 ConstPr + 1.946 Deppost
1	2	ConstPo	=	-8.90 + 0.4812 ConstPr + 1.946 Deppre
1	3	ConstPo	=	-11.61 + 0.4812 ConstPr + 1.946 Deppre

General Linear Model: Diarrhea post versus DirPr, intervention, ...atment_kind

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Cancer_stage	Fixed	4	1, 2, 3, 4
Treatment_kind	Fixed	7	1, 2, 3, 4, 5, 6, 7

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-
DirPr	1	1886	3.91%	2133	2133.4	5.38	
intervention	1	3711	7.69%	1020	1020.4	2.57	
Cancer_stage	3	1205	2.50%	1287	428.9	1.08	
Treatment_kind	6	1031	2.14%	1031	171.9	0.43	
Error	102	40442	83.77%	40442	396.5		
Lack-of-Fit	18	6076	12.59%	6076	337.5	0.83	
Pure Error	84	34366	71.19%	34366	409.1		
Total	113	48275	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
19.9120	16.23%	7.19%	*	*

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	1.7	11.6	(-21.3, 24.6)	0.14	0.886	
DirPr	0.272	0.117	(0.039, 0.505)	2.32	0.022	1.05
intervention						
1	-7.26	4.52	(-16.23, 1.72)	-1.60	0.112	1.47
Cancer_stage						
2	2.48	9.13	(-15.64, 20.59)	0.27	0.787	5.40
3	8.78	9.05	(-9.17, 26.72)	0.97	0.334	5.42
4	10.40	9.63	(-8.70, 29.49)	1.08	0.283	4.94
Treatment_kind						
2	-3.2	21.7	(-46.3, 39.9)	-0.15	0.884	1.18
3	21.3	20.9	(-20.2, 62.8)	1.02	0.312	1.09
4	5.28	7.71	(-10.03, 20.58)	0.68	0.496	3.75
5	1.83	9.80	(-17.60, 21.27)	0.19	0.852	2.60
6	3.1	21.6	(-39.7, 45.9)	0.14	0.886	1.16
7	-3.04	9.30	(-21.49, 15.42)	-0.33	0.745	2.34

Regression Equation

Dirpo = 1.7 + 0.272 DirPr + 0.0 intervention_0 - 7.26 intervention_1 + 0.0 Cancer_stage_1
+ 2.48 Cancer_stage_2 + 8.78 Cancer_stage_3 + 10.40 Cancer_stage_4
+ 0.0 Treatment_kind_1 - 3.2 Treatment_kind_2 + 21.3 Treatment_kind_3
+ 5.28 Treatment_kind_4 + 1.83 Treatment_kind_5 + 3.1 Treatment_kind_6
- 3.04 Treatment_kind_7

General Linear Model: Financial Difficulties po versus FDpr, Deppost ... ation_pt, quantile

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Education_pt	Fixed	6	1, 2, 3, 4, 5, 6
quantie	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
FDpr	1	48921	28.50%	23610.3	23610.3	25.87	0.000
Deppre	1	16384	9.54%	9221.4	9221.4	10.11	0.002
intervention	1	1834	1.07%	601.4	601.4	0.66	0.419
Education_pt	5	6824	3.98%	3167.5	633.5	0.69	0.629
quantie	4	5530	3.22%	5529.8	1382.4	1.51	0.203
Error	101	92163	53.69%	92163.4	912.5		
Lack-of-Fit	98	91052	53.04%	91052.3	929.1	2.51	0.246
Pure Error	3	1111	0.65%	1111.1	370.4		
Total	113	171657	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
30.2078	46.31%	39.93%	115596	32.66%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	19.1	12.2	(-5.1, 43.3)	1.57	0.120	
FDpr	0.4277	0.0841	(0.2609, 0.5945)	5.09	0.000	1.33
Depppre	2.113	0.665	(0.794, 3.432)	3.18	0.002	1.37
intervention						
1	-5.54	6.82	(-19.06, 7.99)	-0.81	0.419	1.45
Education_pt						
2	-17.0	17.0	(-50.8, 16.8)	-1.00	0.321	1.23
3	-5.48	9.81	(-24.93, 13.98)	-0.56	0.578	1.93
4	-6.39	9.31	(-24.85, 12.07)	-0.69	0.494	2.58
5	-20.9	12.4	(-45.6, 3.8)	-1.68	0.096	1.82
6	-5.6	11.9	(-29.2, 18.0)	-0.47	0.638	1.66
quantile						
2	0.1	12.3	(-24.2, 24.4)	0.01	0.992	1.22
3	-10.14	8.31	(-26.64, 6.35)	-1.22	0.225	1.30
4	-15.59	8.18	(-31.83, 0.64)	-1.91	0.060	1.78
5	-23.3	11.8	(-46.7, 0.0)	-1.98	0.050	1.39

Regression Equation

FDpo = 19.1 + 0.4277 FDpr + 2.113 Deppre + 0.0 intervention_0 - 5.54 intervention_1
+ 0.0 Education_pt_1 - 17.0 Education_pt_2 - 5.48 Education_pt_3 - 6.39 Education_pt_4
- 20.9 Education_pt_5 - 5.6 Education_pt_6 + 0.0 quantie_1 + 0.1 quantie_2
- 10.14 quantie_3 - 15.59 quantie_4 - 23.3 quantie_5

General Linear Model: Health Related Quality Of Life post versus HRQOLpr ... t_kind, quantile

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Tumor_size	Fixed	3	1, 2, 3
Cancer_stage	Fixed	4	1, 2, 3, 4
Metastasis	Fixed	2	1, 2
Treatment_kind	Fixed	7	1, 2, 3, 4, 5, 6, 7
quantie	Fixed	5	1, 2, 3, 4, 5

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
HRQOLpr	1	993.4	2.14%	809.8	809.8	3.02	0.086
intervention	1	14062.7	30.35%	8418.4	8418.4	31.35	0.000
Tumor_size	2	1452.4	3.13%	525.5	262.8	0.98	0.380
Cancer_stage	3	615.4	1.33%	628.3	209.4	0.78	0.508
Metastasis	1	146.2	0.32%	161.7	161.7	0.60	0.440
Treatment_kind	6	1856.2	4.01%	1873.9	312.3	1.16	0.333
quantie	4	1702.6	3.67%	1702.6	425.6	1.59	0.185
Error	95	25507.0	55.05%	25507.0	268.5		
Lack-of-Fit	83	20946.8	45.21%	20946.8	252.4	0.66	0.861
Pure Error	12	4560.2	9.84%	4560.2	380.0		
Total	113	46335.9	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
16.3858	44.95%	34.52%	*	*

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	36.9	12.0	(13.0, 60.8)	3.07	0.003	
HRQOLpr	0.181	0.104	(-0.026, 0.388)	1.74	0.086	1.24
intervention						
1	21.85	3.90	(14.10, 29.59)	5.60	0.000	1.62
Tumor_size						
2	4.50	5.74	(-6.89, 15.89)	0.78	0.434	3.28
3	-2.58	7.77	(-18.00, 12.83)	-0.33	0.740	4.74
Cancer_stage						
2	-11.87	8.61	(-28.96, 5.21)	-1.38	0.171	7.08
3	-9.63	9.01	(-27.52, 8.26)	-1.07	0.288	7.94
4	-6.6	10.7	(-27.8, 14.6)	-0.62	0.539	9.00
Metastasis						
2	5.28	6.80	(-8.22, 18.77)	0.78	0.440	2.37
Treatment_kind						
2	-48.2	19.1	(-86.2, -10.3)	-2.53	0.013	1.35
3	-1.9	17.4	(-36.5, 32.6)	-0.11	0.911	1.12
4	-2.92	6.81	(-16.44, 10.60)	-0.43	0.669	4.32
5	-4.94	8.63	(-22.07, 12.20)	-0.57	0.569	2.98
6	5.3	18.9	(-32.1, 42.7)	0.28	0.779	1.31
7	-7.21	8.08	(-23.26, 8.83)	-0.89	0.374	2.61
quantie						
2	0.79	6.81	(-12.72, 14.31)	0.12	0.907	1.28
3	6.46	4.65	(-2.78, 15.70)	1.39	0.168	1.38
4	7.06	4.09	(-1.06, 15.17)	1.73	0.088	1.51
5	12.31	6.19	(0.02, 24.59)	1.99	0.050	1.30

Regression Equation

HRQOLpost = 36.9 + 0.181 HRQOLpr + 0.0 intervention_0 + 21.85 intervention_1
+ 0.0 Tumor_size_1 + 4.50 Tumor_size_2 - 2.58 Tumor_size_3 + 0.0 Cancer_stage_1
- 11.87 Cancer_stage_2 - 9.63 Cancer_stage_3 - 6.6 Cancer_stage_4
+ 0.0 Metastasis_1 + 5.28 Metastasis_2 + 0.0 Treatment_kind_1
- 48.2 Treatment_kind_2 - 1.9 Treatment_kind_3 - 2.92 Treatment_kind_4
- 4.94 Treatment_kind_5 + 5.3 Treatment_kind_6 - 7.21 Treatment_kind_7
+ 0.0 quantie_1 + 0.79 quantie_2 + 6.46 quantie_3 + 7.06 quantie_4
+ 12.31 quantie_5

General Linear Model: QOL Post versus QOL Pre, ...ew, CommFa_new

Method

Factor coding (1, 0)

Factor Information

Factor	Type	Levels	Values
intervention	Fixed	2	0, 1
Marital_status	Fixed	2	1, 2
Any_other_disease	Fixed	2	1, 2
quantie	Fixed	5	1, 2, 3, 4, 5
CommP_new	Fixed	2	1, 2
CommFa_new	Fixed	2	1, 2

Analysis of Variance

Source	DF	Seq SS	Contribution	Adj SS	Adj MS	F-Value	P-Value
QOL Pre	1	23.145	20.48%	7.7631	7.76314	10.26	0.002
Agerespondent	1	5.348	4.73%	6.8615	6.86150	9.06	0.003
Deppre	1	2.858	2.53%	1.8328	1.83282	2.42	0.123
Anxpre	1	0.090	0.08%	0.7010	0.70096	0.93	0.338
intervention	1	0.241	0.21%	0.5304	0.53037	0.70	0.405
Marital_status	1	0.742	0.66%	0.9051	0.90507	1.20	0.277
Any_other_disease	1	0.061	0.05%	0.1797	0.17975	0.24	0.627
quantie	4	3.252	2.88%	3.2237	0.80592	1.06	0.378
CommP_new	1	0.122	0.11%	0.0495	0.04946	0.07	0.799
CommFa_new	1	1.444	1.28%	1.4436	1.44358	1.91	0.170
Error	100	75.697	66.99%	75.6972	0.75697		
Total	113	113.000	100.00%				

Model Summary

S	R-sq	R-sq(adj)	PRESS	R-sq(pred)
0.870041	33.01%	24.30%	102.035	9.70%

Coefficients

Term	Coef	SE Coef	95% CI	T-Value	P-Value	VIF
Constant	-1.948	0.698	(-3.333, -0.562)	-2.79	0.006	
QOL Pre	0.3096	0.0967	(0.1178, 0.5013)	3.20	0.002	1.39
Agerespondent	0.02751	0.00914	(0.00938, 0.04565)	3.01	0.003	1.20
Deppre	0.0429	0.0276	(-0.0118, 0.0976)	1.56	0.123	1.48
Anxpre	0.0279	0.0290	(-0.0296, 0.0854)	0.96	0.338	1.31
intervention						
1	-0.162	0.194	(-0.546, 0.222)	-0.84	0.405	1.41
Marital_status						
2	-0.195	0.179	(-0.550, 0.159)	-1.09	0.277	1.18
Any_other_disease						
2	0.119	0.244	(-0.365, 0.602)	0.49	0.627	1.19
quantie						
2	-0.157	0.353	(-0.856, 0.543)	-0.44	0.658	1.22
3	0.200	0.247	(-0.291, 0.690)	0.81	0.421	1.38
4	0.350	0.211	(-0.068, 0.768)	1.66	0.100	1.42
5	-0.026	0.328	(-0.676, 0.625)	-0.08	0.938	1.30
CommP_new						
2	-0.050	0.195	(-0.436, 0.336)	-0.26	0.799	1.23
CommFa_new						
2	-0.266	0.192	(-0.647, 0.116)	-1.38	0.170	1.10

Regression Equation

QOL Post = -1.948 + 0.3096 QOL Pre + 0.02751 Agerespondent + 0.0429 Deppre + 0.0279 Anxpre
+ 0.0 intervention_0 - 0.162 intervention_1 + 0.0 Marital_status_1
- 0.195 Marital_status_2 + 0.0 Any_other_disease_1 + 0.119 Any_other_disease_2
+ 0.0 quantie_1 - 0.157 quantie_2 + 0.200 quantie_3 + 0.350 quantie_4
- 0.026 quantie_5 + 0.0 CommP_new_1 - 0.050 CommP_new_2 + 0.0 CommFa_new_1
- 0.266 CommFa_new_2

Annex 15: Standard operating Procedure of the study

"The effect of inter-personal Psychotherapy on treatment outcome among breast cancer patients with common mental disorder."

Standard Operating Procedure for conducting a study on "The Effect of Interpersonal Psychotherapy on treatment outcome among Breast Cancer patients with Common mental disorder

Consent Procedure:

- ✓ Direct the participant to a quiet room designated for counseling/consenting.
- ✓ Ascertain participant's level of literacy. If illiterate, s/he should have a literate witness present and reasons for this should be explained. The participant may bring their own witness but when none is available, the data collectors may provide an impartial witness, who may be a member of the hospital staff that has no involvement with the study or a friend or family member of the participant. However, the designated person responsible for taking informed consent should ensure that there is no coercion from any witness chosen.
- ✓ Assure the participant that all communication between you, the subject and a witness, if applicable, is in complete confidence.
- ✓ Ask the participant the language in which they prefer to communicate
- ✓ Explain to the participant that s/he has come to the hospital because s/he is volunteer to participate if s/he would be prepared to undergo for further screening to establish her/his eligibility for a study.
- ✓ The purpose of the study, procedures involved in participation, number of days required for participation, schedule of visits, confidentiality, risks and discomforts, benefits and known side-effects and the right to refuse and withdraw at any stage of the study will be explained at length.
- ✓ Answer any questions the participant may have about study participation to their satisfaction.

- ✓ If the subject agrees, the relevant consent form will be signed and dated by the subject. This should also be signed and dated by the study staffs who have given the information and obtained the consent. The time for consenting should be recorded by both the staff and the patient.
- ✓ In case of illiterate subjects, thumb print of the subject will be accepted with the signature of a literate impartial witness as confirmation for consent. However, the impartial witness will write the name of the participant, the date and time as well as the initials of the subject in agreed boxes on behalf of the participant.
- ✓ If the potential subject cannot make decision during first interaction with the study staff, s/he should be given some time to think, discuss with the near and dear ones and decide.
- ✓ If the subject returns to the study centre and decides to participate at a later date, the informed consent procedure will need to be repeated.
- ✓ The study staff who is in charge of providing information and obtaining consent should finally document the consenting process (including how & when the information was given, how the subject reach at decision, concerns raised by the subject if any,...) on the source note.
- ✓ No study procedure shall be undertaken before informed consent is being obtained. Once consent is obtained, move to the next step of subject identification, screening, enrolment and/or counselling.
- ✓ Once consent is obtained, move to the next step of subject identification, screening and the psychotherapy.
- ✓ Re-consenting of a consented subject may be considered as necessary. Such conditions may include but not limited to: when wrong, edited, or amended version of the currently approved Informed Consent Form was used; when new version of Informed Consent Form becomes available in the course of subject's follow-up to accommodate changes in study procedures and/or new information. Re-consenting shall be given with provision of full information and explanation of the reason for re-consenting to ensure subject's full understanding.

Selection and recruitment Procedure:

By considering the standard recommendations; this clinical trial has the following initiatives to protect and respect the right, safety and wellbeing of potential subjects and to have fair selection of volunteers that are involved in the studies.

Study population

All women with Breast Cancer at Tikur Anbessa Specialized Teaching Hospital.

Source population

All stage Breast Cancer patients who are 18 years old and above and those that are diagnosed with common mental disorder at Tikur Anbessa Specialized Teaching Hospital, Addis Ababa, Ethiopia.

Recruitment plan

Potential study participants could be recruited using either of the following recruitment methods. It is always important to consider availability of ethical approval and resources for the chosen option(s) for recruitment.

1. Potential subjects will be communicated at the oncology Centre.
2. The Aim of the study will be clarified.
3. Will be appointed for or get formed consent in the trial room.

Initial evaluation to a potential volunteer

- On arrival in the trial room, a potential subject will be received by the study facilitator.
- After brief introduction, the study facilitator will provide information about the purpose of the study.
- If the potential participant is willing to have more information, please forward the subject to the study nurse/psychiatry nurse who is in charge of providing information and consent.

Information provision & obtaining informed consent for screening

- Pre-screening will be completed by the facilitator or study nurse/Psychiatry nurse on provision of information to the subject about the study.
- If the subject is volunteer and fit to the pre-screening evaluation then will be forwarded for detailed information provision and informed consent process.
- Once the subject has given informed consent and decided to undergo screening a unique study ID will be assigned and s/he will be registered on the screening form.
- Document subjects who have declined to provide consent in the pre-screening form.

Screening and enrolment

- Schedule for screening or proceed to screening examinations
- Review the baseline screening results as applicable and when necessary discuss with the PI, who is ultimately responsible for the final decision on participant eligibility for the study.
- Document the reasons for pre-screening or screening failures, if any, on the respective log.
- Determine eligibility based on the protocol-specified procedures.
- Schedule for eligible subjects to be enrolled into the study using the protocol-specified procedures (i.e. randomization) and register the subject on the enrolment log.

Screening and enrolment Procedure:

General procedures for screening and enrolment of a subject

- ✓ Make sure that the participant agreed to participate, signed and dated the Informed Consent Form.
- ✓ Assign or make sure a unique study number is assigned to the subject.
- ✓ Describe about the screening, reconfirm willingness and ensure privacy.
- ✓ Confirm eligibility of the participant based on history and screening or based on inclusion and exclusion criteria.
- ✓ Fill all relevant laboratory request forms.
- ✓ Send the participant to blood drawing room.
- ✓ Obtain lab results and record on source document.
- ✓ Explain the results to the participant and advise the participant to come on the next appointment if eligible.

- ✓ Eligible participants will be appointed for enrolment in to the study therefore explain the next procedure in the study and ensure an appointment card is given for the next scheduled visit to the site.
- ✓ Then s/he will be randomized (enrolled) and forwarded to the study room for taking the Psychotherapy on pre-scheduled appointment.

General criteria for screening a subject to BE study

The eligibility of a potential subject consenting to participate in this study will be screened on the basis of the following criteria. However, the responsible professional has to always check these general criteria against specific criteria that could be mentioned in a protocol for screening subjects to the study. These may include:

Inclusion Criteria

- ✓ All women who are aged 18 and above.
- ✓ All stage Breast cancer.
- ✓ Those that are diagnosed for common mental disorder with HADS measurements which is HADS>8 at Tikur Anbessa specialized teaching Hospital and those who are willing to be enrolled in the study.

Exclusion Criteria

- ✓ Those with severe physical illness.
- ✓ Severe mental illness (psychosis & mania).
- ✓ Functionally impairing substance abuse.
- ✓ Patients who are acutely suicidal will be excluded from the study.

Randomization Procedure

Data manager (for determination of treatment sequence on randomization):

- Generate a list of sequential number (e.g. from 001…) for the protocol specified sample size and randomize for assignment of treatment sequence using a computerized system or manually per the protocol recommended method.

  Generate the randomization list, seal in an envelope and deliver to the subjects.

- Always assign the reference as IPT group and TAU.

Sub-investigator (for generation of eligible participants list):

- Once screening is completed and eligible participants are identified, assign a sequential enrollment number to each eligible participant with the same fashion as that of the randomization list (i.e. from 001…..).

-Generate a list and send to the therapy room with a request for assignment of treatment sequence.

Investigator (for assignment of the specific group):

-Upon receipt of request from the sub-investigator, investigator assign IPT group and TAU group to each eligible participant according to the randomization list.

-Both of the groups will be linked to the psychiatry ward to get the usual treatment.

-Adjuvant psychotherapy will be delivered to the IPT group once a week for four consecutive weeks. The Psychotherapy will incorporate the following components in each predetermine session:

Interpersonal Psychotherapy Adapted for Ethiopian use:

Beginning Phase
Session -1

- **Establish the therapy relationship.**
- Screen for mental distress and symptoms, safety (suicidality & domestic violence & alcohol misuse) and functioning. (IPT-E case selection criteria: +CMD and able to attend sessions, without exclusion criteria of: psychosis, mania, cognitive impairment, acutely suicidality, or severe alcohol abuse.)
- Learn about problems associated with the onset of the symptoms and the people that help or hinder - with **the interpersonal inventory.**
- Formulate the IPT focus: loss, life changes (role transitions), or disagreements. When choosing the focus, ensure there is a temporal link to the onset or worsening of symptoms and associated distress.
- **Discuss goals** – to improve symptoms, improve functioning, improve relationships, and work through agreed-upon problem area/focus.
- **Provide feedback (or Psychoeducational)** to reassure the patient you understand they are suffering in connection to some triggers in their life. That the suffering is not necessarily his or her fault, that talking can help and he or she needs social support during this time of need. The point of this feedback is to promote a therapy relationship with your patient and engage them in treatment.

Middle Phase:

Session 2

- When patients discuss their problems and begin to make changes in their lives.

Link the focal area to onset or the continuing of symptoms and explore problems, relationships, and interactions associated with worsening, or improvement of their distress.

- Focus on communication and ways to handle interpersonal problems.

- Track symptoms, safety, functioning, and progress weekly by using the Treatment Tracking Form. (If on medication, monitor adherence & side effects.)
- Refer the patient to a mental health specialist or hospital emergency department if there are urgent safety concerns.
- For all focal areas, explore ways to recruit or use supports and use therapeutic communication, brainstorming, role plays and communication analysis to reveal opportunities to make changes and solve problems.

1. **LOSS/BEREAVEMENT as an IPT-E focus**
    - Grief is likely to be a helpful IPT-E focus for treatment when (i) you discover that the onset of the patient's current symptoms coincides with the death of a significant other, and often (ii) the patient displays emotion (verbally or non-verbally) during the process of discussing a lost significant other in Interpersonal Inventory.

Loss/Bereavement

- Explore in detail the circumstances of the significant other's death.
- Encourage the patient to speak about his or her relationship with the deceased (how they met, how their relationship evolved, the positive aspects and the disappointments).
- Throughout, encourage the patient to interact with caring friends and family and to find meaningful ways to use his or her time.

2. **SOCIAL ROLES AND ROLE TRANSITIONS as an IPT-E focus**

- Social roles are linked to our sense of self and help us define expectations that we have of one another. We all hold multiple social roles and these inevitably change over time. Examples of social roles include being a parent, child, sibling, spouse, employee, employer, friend, and neighbor. In IPT-E changes in these roles are called role transitions. Role transitions can be developmental, occupational, social, or biological; and can be planned and wanted, or unplanned and unwanted and are often associated with a loss of psychosocial support.

Life Changes—Social Role Transitions

- Encourage the patient to describe in detail the change/s with its associated disruptions.
- Explore positive aspects of the old role (mourning losses), and challenges and opportunities of the new role/life changes.
- Identify options to improve the situation and people who can help to make the new role easier.
- If the transition has no clear benefit to the patient – let him or her talk with you about their difficulties adapting to this new reality.

3. INTERPERSONAL DISPUTES as a focus for IPT-E

- The third IPT-E focal area is interpersonal disputes or disagreements within significant current relationships. These disputes usually involve non-shared expectations or values, communication problems and difficulties understanding one another. It is important to realize that these differences may or may not be reconcilable. In the case of disputes, we need to ask several questions to determine when it is a clinical problem: How grave is the situation? How symptomatic is the patient? If the answer to both questions is "high," then treatment should be offered**.**

Disagreements

- Explore in detail the disagreement, and **the relationship** with the person whom they are in conflict with, the patient's view of **the issues** in dispute, other important people's views of the dispute, what he or she has tried, and would like to change
- Explore the patient's sense of the problem from the other person's point of view, how the two people that are in dispute impact upon one another, and his or her understanding of the other person's reactions and feelings.
- Explore specific examples of recent verbal exchanges (**communication analysis**) to clarify each party's position; explore their differing values and expectations; and foster an

understanding of one another's perspectives and limitations, to try and find more effective choices and ways of communicating.

Session 3

PSYCHOSOCIAL SUPPORTS:

- ✓ When we are unwell whether it is from an infectious disease or a Common Mental Disorder, we can benefit from support from others and from engaging or reengaging in social activities with others. Family members, friends or other people from the community can be critically helpful in many different ways. Helping others or receiving help from others can reduce feelings of loneliness, sadness and shame and can be energizing. Let's consider a range of experiences or types of support – from practical (those who help with specific tasks), to social or community-based with those who have shared interests or values, to trusted confidantes with whom feelings and more personal experiences can be shared.
- ✓ When using the interpersonal, closeness circle and/or conducting the interpersonal inventory, counsellors can help patients identify family or other people that may be helpful in this current stressful time of need. Consider with the patient, what kinds of responses or help from others, or engagement in activities with others that may alleviate their experience of suffering. And what activities if reinitiated could provide psychosocial support (e.g. family gatherings, outings with friends, visiting neighbors, social activities at worksites, sports, community activities).

BRAINSTORMING: In the latter middle phase of IPT-E, you will want your patients to begin to make changes in their relationships and communication, and find solutions to their problems - such as finding alternative, more strategic ways to have conversations about troublesome issues or recruiting people to support them. This is the time **to brainstorm** and think together with your patients, anticipating which of the potential solutions will most likely improve their relationships and reduce their symptoms. When brainstorming to solve interpersonal problems, you can ask: "what (solutions) have you thought about?" and "how do you think that/they will

work?" As a more objective observer, you can provide them with feedback and advice if your patient has limited insight into the potential negative consequences of their proposed solutions. They can try out the solutions generated in sessions; these can be used as opportunities for further learning, leading to modified ideas for alternative solutions.

ROLE PLAYS: can be used during an IPT-E session to develop and practice ways in which your patient learns to communicate better. To clarify what they wish to express and how they wish to interact, to foster a more satisfying sense of mutual understanding. As already mentioned, in planning future interactions we try to think forward about all the different options which might result in more satisfying outcomes in their relationship *and* in feeling better. It is important to consider the potential interpersonal consequences, looking at both 'give and get' in relationships (reciprocity), and the feelings and needs of both individuals in a relationship.

COMMUNICATION ANALYSIS: is a therapeutic strategy with the following steps:

(i) explore the details of a recent specific conversation that was emotionally upsetting;

(ii) make links between this interaction and the patient's distress;

(iii) explore emotions, intentions, needs, expectations and interpersonal impacts with consideration of the perspective of the other and

(iv) Brainstorm +/- role play to generate ideas for a future conversation with revised expectations, empathy and clearer expression.

Communication analysis provides a way of improving relationships and communication in order to understand the patient's relational problems. This can be achieved by simply asking questions such as, "what did you say," and "how did they respond," and "what was going on with your feelings," and "what did you want them to understand?" By linking the problematic communication and the symptoms or distress, your patient can consider alternative empathic approaches to interacting with realistic expectations.

CONCLUDING PHASE TASKS

Session 4

- All these techniques can be used to help patients resolve and manage their interpersonal problems, improve their relationships and in so doing alleviate symptoms and suffering. In the final session, counsellors will spend the first 15-20 minutes unpacking the events of the week using the middle phase therapeutic techniques. Then the final 2/3rd of the concluding session should be used to:

1. Review the patient's experience of treatment. Ask, in what way they may feel different, what has changed (symptoms, functioning, relationships, problems), and what they are taking away from the process of engaging in IPT-E. Acknowledge their efforts and therapeutic gains.

2. Contingency plan in the event of return of symptoms and discuss how to tell the difference between a "bad day" and the return of CMD. They should be aware to return to the clinic if they experience a relapse.

3. Ask if they have any worries or feelings about concluding treatment. In the ending phase old losses may be processed and `symptoms` from these may be mistaken for a reoccurrence of the original symptoms that brought the patient to treatment. Also therapists can get anxious about terminating a patient. It is important to disentangle this from the patient`s actual need for more treatment.

4. If they have recovered, provide reassurance that they should continue to remain well as a result of their efforts and psychosocial supports. If they are still symptomatic and functioning poorly, the IPT should be continued if possible, and medications considered. Consultation with peers on patients who are not responding to treatment can be helpful.

SESSION PLAN AND REPORT FORMAT

Session Plan and report for client ----------

By:

Submitted to

Addis Ababa University

Day……

Executive summary

This is a patient session report compiled for the last four sessions with client -----. The client was. In addition,

Session record 1

Date _ Month __Year ___Time (from _ to)
Name of the client Code

Session number 1

Goal of the session:

- ❖ Rapport development by:
  - ☛ Providing general information about our contact including the purpose of our session, its duration, confidentiality of client privacy and the consent to continue with the counseling sessions were discussed briefly.
  - ☛ Acquire background information about the life of the client.

Findings:

Conclusion

Recommendations

Therapist Name:- _____

Supervisor Name _____

Session record 2

Date ___ Month ___Year ___Time (from ___ to_____)
Name of the client :----------

Session number 2
Goal of the session:

Findings:
Conclusion
Recommendations
Therapist Name _____ Supervisor Name _____

Session record 3

Date _____ Month _____Year _____Time (from____ to _____) Name of the client----------
Session number 3 **Goal of the session:** ➢ ➢ ➢ ➢ ➢ ➢ ➢ .
Findings:
Conclusion

Recommendations
Therapist Name _____ Supervisor Name _____

Session record 4

Date ___ Month _____Year _____Time (from ____ to _____) Name of the client ----------
Session number 4 **Goal of the session:**

Findings:
Conclusion
Recommendations
Therapist Name _____ On site supervisor Name _____

Annex 16 : Training manual of the study

አዲስአባበዩኒቨርስቲ

የጤናሳይንስኮሌጅ

የህብረተሰብጤናአጠባበቅትምህርትቤት

የመረጃ ሰብሳቢዎች እና ተቆጣጣሪዎች የስልጠና ማኑዋል

የጥናቱአስተባባሪ- እጅጋየሁ በላይ(BSc)

አማካሪዎች ፡-አባቢ ዘርጋው (PhD)

ወሬሳው ኃይለስላሴ(MPH, PhDcan)

ዶ/ር ዋጀና(MD,Pathologist)

ዶ/ር ወንድማገኝ ጥግነህ(MD,Oncologist)

ዶ/ር ዮናስ ባህረጥበብ (MD,Psychiatrist)

ጥር፣ 2011 ዓ.ም

አዲስአበባ፤ኢትዮጵያ

ምስጋና

ከልብ የመነጨ መስጋናዬን ለዚህ ጥናት አማካሪዎቼ ለጥናቱ ተገቢውን አሰተያየት ብሎም ማስተካከያ ምላሽ ሲሰጡኝ ለነበሩት ለአቶ ወሬሳው ኃይለስላሴ እና ለ ዶ/ር አባቢ ዘርጋው አቀርባለው፡፡ ብሎም የተለያዩ ጥያቄዎችን እና ድጋፍ ደከመኝ ሰለቸኝ ሳይሉ ሲመልሱልኝ ለነበሩት ለ ዶ/ር ዋጀና፤ለዶ/ር ወንድማገኘው ጥግነህ፤ለዶ/ር ሚርጌሳ እና ለዶ/ር ዮናስ ባህረጥበብ ከፍ ያለ ምስጋናይን ማቅረብ እፈልጋለው፡፡በመጨረሻም የአዲስ አበባ ዩኒቨርሲቲ ህብረተሰብ ጤና ትምህር ክፍል ይሄን እድል ስለሰጠኝ እጅግ ማመስገን እፈልጋለው፡፡

Contents

1. መግቢያ

ካንሰር በጣም አደገኛ የሆነ የሰው ልጆች ላይ ከፍተኛ የአካል እና የስነልቦና ጫና የሚያድስ በሽታ ነው፡፡በተጨማሪከም ድብርት እና ጭንቀት በካንሰር ህሙማን ላይ በተደጋጋሚ የሚታዩ የስነ ልቦና ችግሮች እንደሆኑ ጥናቶች ያሳያሉ፡፡እንዲሁም ድብርት በአብዛኛው የሚስተዋል እና የሰዎችን ስሜት፤አስተሳሰባቸውን እንዲሁም ተግባራቸውን በአሉታዊ መንገድየሚለውጥ የስነልቦና ችግር ነው፡፡ዕነዚህም የስነልቦና እክሎች የካንሰር ህሙማን የህክምና ውጤት ላይ ከፍተኛ የሆነ አሉታዊ አስተዋፅኦ እንዳላቸው ጥናቶ ያሳያሉ፡፡

እንደአለም አቀፍ የካንሰር እስታቲስቲክ ዘገባ በአለም ላይ የካንሰር 18.1 ሚሊየን አዲስ ታማሚ እና 9.1 ሚለየን ሞት በ 2018 ይኖራል ተብሎ ተገምቶ ነበር፡፡እናም ከዚህ ውስጥም የጡት ካንሰር ቀዳሚው ሴቶች ላይ የሚስተዋል የካን ሰር አይነት ሆኖ ተዘግቧል፡፡በአለም አቀፍ ደረጃ 2.1 ሚሊየን አዲስ የጡት ካንሰር ታማሚ ይኖራል ተብሎ ተገምቷል፡፡በአፍሪካም 7.3 ፐርሰንት ሞት በ 2018 እ.ኤ.አ ይኖራል ተብሎ ተገምቷል፡፡ ምንም እንኳን በኢትዮጵያ ከካንሰር ጋር በተያያዘ ውስን መረጃ ያለ ቢሆንም በ2015 እ.ኤ.አ አዲስ 21,563 ወንድ እና 42,722 ሴት አዲስ የካንሰር ህሙማን ይኖራሉ ተብሎ ተገምቷል፡፡በኢህም መሰረት በጣም በከፍተኛ ደረጃ ይስተዋላሉ የተባሉት የካንሰር አይነቶች የጡት ካንሰር እና የማህጸን ጫፍ ካንሰሮች ናቸው፡፡እንዲሁም በኢትዮጲያ በጥቁር አንበሳ የተሰራ ጥናት እንደሚያመለክተው የጡት ካንሰር 29.5% ብሎም የማህጸን ጫፍ ካንሰር 22.7% አካባቢ እንደሚደርስ ጥናቶች ያሳያሉ፡፡

የተለያዩ ነገሮች ለካንሰር ኢጋላጭ ያደርጋሉ ተብሎ ይጠበቃል፡፡ከነዚህም ውስጥ በዋናነት አጓጉል ልማዶች(ሲጃራ ማጨስ)፤የስራ ሁኔታ፤የትምህርት ደረጃ፤የአየር ሁኔታ፤በስነተዋልዶ ጉዳይ ተጋላጭ የሚያደርጉ ነገሮች(ጡት አለማጥባት)፤እንዲሁም የኢኮኖሚ ሁኔታ ተጋላጭ ያደርጋሉ ተብሎ ይታሰባል፡፡

በተጨማሪም የካንሰር ህሙማንን የህክምና ውጤት ላይ አሉታዊ ተጽእኖ ይኖራቸዋል ተብለው የሚጠቀሱ የተለያዩ ነገሮች አሉ፡፡ ከነዚህም ውስጥ የታማሚው የኢኮኖሚ ሁኔታ፤ታማሚው ከ ሃኪሙ/ሚ ጋር እንዲሁም ከቤተሰብ ጋር ያላት/ው ግንኙነት ወይም የመነጋገር ደረጃ፤አጠቃላይ የታማሚው የጤና ሁኔታ ብሎም ድብርት እና ጭንቀት የታካሚው የህክምና ውጤት ላይ አሉታዊ ተጽእኖ ይኖራቸዋል ተብለው ከሚጠቀሱ ችግሮች ውስጥ ዋና ዋናዎቹ ናቸው፡፡

ኢትዮጵያ ውስጥ ብዙ ጥናቶች ካንሰር ህሙማን ላይ የተሰሩ ቢሆንም የድብርት እና የጭንቀት ችግር በህሙማኑ ላይ የሚያስከትለው ችግር ብሎም በህክምና ውጤታቸው ላይ የሚያስከትለው ችግር እንዲሁም የጭንቀት እና የድብርት የስነልቦና ችግር ያለባቸው የካንሰር ህሙማን ለዚህ የስነልቦና ችግራቸው ህክምና (የስነልቦና ህክምና) ቢያገኙ የህክምና ውጤታቸው ላይ ምን ያህል መልካም አስተዋጽኦ ሊኖረው እነደሚችል የሚያሳይ ጥናት የለም፡፡ስለዚህ የዚህ ጥናት ዋና ዐላማም የሚሆነውም የጭንቀት እና የድብርት የስነልቦና ችግር ያለባቸው የካንሰር ህሙማን ለዚህ የስነልቦና ችግራቸው ህክምና (የስነልቦና ህክምና) ቢያገኙ የህክምና ውጤታቸው ላይ ምን ያህል መልካም አስተዋጽኦ ሊኖረው እንደሚችል ማጥናት ነው፡፡

2. የስልጠናውዓላማ

የዚህስልጠና ዋንኛ ዓላማዎች የሚከተሉት ናቸው፤

3. የስልጠናውዘዴ

- አሳታፊአቀራረብ
- የቡድንውይይት
- የተግባርልምምድ

4. መረጃውንለመሰብሰብ የሚያስፈል ጉዶክመንቶች እና መሳሪያዎች

የዚህን ጥናት መረጃ ለመሰብሰብ የሚያስፈልጉ ዶክመንቶች እና መሳሪያዎች የሚከተሉት ናቸው

- መረጃመግለጫ
- የፍቃደኝነትመሙያቅጽ
- የመጠይቅቅፅ
- የታካሚውካርድ
- እክሲቢርቶዎች
- እርሳሶች

5. ክፍያ

በዚህጥናትውስጥለሚሳተፉመረጃሰብሳቢዎችእናተቆጣጣሪዎችበአንድመጠይቅ 50 ብር የሚከፈላቸው ሲሆን ግማሹ ክፍያ መረጃው 50 በመቶ ሲሰበሰብ ይፈጸማል::ቀሪው ግማሽ ክፍያ ቀሪው መረጃተሰብስቦሲያልቅይከፈላል::

ክፍያውንየመፈጸምሀላፊነትየጥናቱዋናአስተባባሪይሆናል::

6. መረጃ በመሰብሰብ ሂደት ውስጥ የሚሳተፉ ሰዎች ሀላፊነት

a. የመረጃ ሰብሳቢዎች ሀላፊነት

- መረጃመሰብሰብከመጀመሩበፊትአስፈላጊውንስልጠናመውሰድ
- በጥናቱመስፈርትመሰረትበጥናቱውስጥየሚሳተፉሰዎችንመለየት

- ከጥናቱተሳታፊዎችፈቃደኝነታቸውንመቀበል
- ለጥናቱተሳታፊዎችበመጠይቅቅጽመሰረትቃለምልልስማቅረብ
- የጥናቱተሳታፊዎችንመሰረታዊመረጃዎችከታካሚውካርድላይመመዝገብ

b. የተቆጣጣሪሀላፊነት

- መረጃመሰብሰብከመጀመሩበፊትአስፈላጊውንስልጠናመውሰድ
- መረጃሰብሳቢዎችንማገዝ
- የመረጃመሰብሰብሒደቱንመከታተል
- የመጠይቆቹንሙሉነትማረጋገጥእናሙሉያልሆኑትንመጠይቆችመረጃሰብሳቢዎቹእንዲያሟሏቸውማድረግ
- በጥናቱውስጥጥቅምላይየሚውሉመጠይቆችንእናመሳሪያዎችንመረከብ

c. የጥናቱዋናአስተባባሪሀላፊነት

- የመረጃመሰብሰብሂደቱንማስተባበር
- አስፈላጊየሆኑስልጠናዎችንለመረጃሰብሳቢዎችመስጠት
- ለጥናቱአስፈላጊየሆኑእቃዎችንማቅረብ
- የመረጃመሰብሰብሂደቱንበየቀኑመቆጣጠር
- ለመረጃሰብሳቢዎችአስፈላጊውንድጋፍመስጠት
- ከመረጃሰብሳቢዎችጋርባለውስምምነትመሰረትክፍያመፈፀም
- የጥናቱንውጤትማሰተላለፍ

7. የጥናቱተሳታፊዎችሊያሟሏቸውየሚገቡመስፈርቶች

ቅጽ 1

ከላይበተጠቀሰውየጊዜገደብውስጥወደሆስፒታሉለክትትልየሚመጡትሁሉየዚህጥናትእጩተሳታፊዎችቢሆኑምበጥናቱውስጥለመሳተ ፍየሚችሉትግንየሚከተለውንመስፈርትያሟሉታካሚዎችብቻናቸው፤

1.ብረስትካንሰር; ,ሰርቫይካልካንሰር; ጋስትሮኢንተስታይናል ; ፕሮስቴትካንሰር; ነንሆድኪንሊምፎማበምርመራየተረጋገጠ

2.ለካንሰሩህክምናላይያሉ

3.እድሜአቸው 18 እና ከዛ በላይ

ቅጽ 2፡ መለያ

ይህ ክፍል የካንሰር ህሙማን መለያ ቁጥር፤ የህሙማኑን የጥናት ቡድን መለያ ቁጥር፣ የመረጃ ሰብሳቢዎችን እና የተቆጣጣሪዎችን ስም ለመመዝገብ ያገለግላል፡፡ ይህ ክፍል በጥናቱ ውስጥ የሚሰበሰቡትን መረጃዎች በአግባቡ ለማደራጀት እንዲሁም ለመረጃ ሰብሳቢዎች እና ተቆጣጣሪዎች ተገቢውን ክፍያ ለመፈፀም ያገለግላል፡፡ ቀጣዩ ስራ ይህንን ቅጽ መሙላት ነው፡፡ የጥናቱ ተሳታፊዎች የጥናቱን መስፈርት እንዳሟሉ ከተረጋገጠ እና በጥናቱ ውስጥ ለመሳተፍ ፍቃደኝነታቸው ከተጠየቀ በኋላ በመሆኑም በዚህ ቅጽ ውስጥ የሚገኙ መረጃዎች በሙሉ መሞላት ይኖርበታል፡፡

በጥናቱ ውስጥ የሚሳተፉ ጨቅላ ህፃናት መለያ ቁጥር- በዚህ ጥናት ውስጥ የሚሳተፉ ሁሉም የካንሰር ህሙማን ልዩ የሆነ የራሳቸው የመለያ ቁጥር ይኖራቸዋል፡፡ ይህ ማለት ሁለት ህሙማን ተመሳሳይ የሆነ የመለያ ቁጥር ሊኖራቸው አይችልም ማለት ነው፡፡ የተሳታፊዎቹም የመለያ ቁጥር የታሸጉት ፖስታዎች ውስጥ በሚገኙት ትንንሽ ወረቀቶች ላይ ተጽፈው የሚገኙ ሲሆን እነዚህ ቁጥሮች በፖስታዎቹ ላይ ተጽፈው ከሚገኙት ቁጥሮች የተለዩ ናቸው፡፡ የተሳታፊዎቹ የመለያ ቁጥሮች ተብለው የሚፃፉት ቁጥሮች በወረቀቶቹ ላይ የሚገኙት ቁጥሮች ብቻ ናቸው፡፡

ቅጽ 3፡ የጥናቱን ተሳታፊዎች የተመለከቱ መሰረታዊ መረጃዎች

ይህ ቅጽ ስድስት ክፍሎች ያሉት ሲሆን የመጀመሪያው ስለ ህሙማኑ የድብርት(የድባቴ) እና የጭንቀት ሁኔታ፤ሁለተኛው የህሙማኑ መሰረታዊ መረጃዎች የሚፃፉበት፤ሶስተኛው የካንሰር ሁኔታቸውን የተመለከተ ሲሆን ፤ሌላኛው ደግሞ የእገዛ ሁኔታቸውን የተመለከተ ሌላው ደግሞ ሌላ ህመማቸውን የተመለከተ ይሆናል ማለት ነው፡፡

8. የመረጃ አሰባሰብ ቅደም ተከተል

- ለተሳታፊዎችሰላምታካቀረቡበኋላእራስንማስተዋወቅ
- ተሳታፊዎች ተረጋግተው የጥናቱን መረጃ ለመስጠት አመቺ ሁኔታ እስኪፈጠር መጠበቅ
- በጥናት መረጃ ቅጽ ላይ የሰፈረውን ሁሉንም መረጃ ለተሳታፊዎች ማንበብ
- የጥናቱ ተሳታፊዎች ስለጥናቱ እና ስለመረጃ አሰባሰቡ ሒደት በሚገባ መረዳታቸውን ማረጋገጥ
- የጥናቱተሳታፊዎችጥናቱንአስመልክቶለሚያነሱዋቸውጥያቄዎችበትህትናእናበአግባቡመልስመስጠት

- የጥናቱ ተሳታፊዎች በጥናቱ ውስጥ እንዲሳተፉ ያለማስገደድ
- የጥናቱተሳታፊዎችበጥናቱውስጥለመሳተፍከተስማሙፊርማቸውንወይንምየጣትአሻራቸውንበተገቢውቦታላይእንዲያሳርፉ ማድረግ
- የጥናቱተሳታፊዎችበጥናቱውስጥለመሳተፍካልተስማሙተገቢውንየህክምናአገልገሎትእነዲያገኙማድረግ

የጥናቱንመስፈርትያሚሉተሳታፊዎችሁሉበጥናቱውስጥለመሳተፍይስማማሉተብሎአይጠበቅም፡፡

በዚህጊዜማድረግየሚገባውየመጀመሪያውነገርእነዚህተሳታፊዎችበጥናቱውስጥለመሳተፍያልፈለጉበትንምክንያትለመረዳትመሞከርነ ው፡፡ተሳታፊዎቹበጥናቱውስጥለመሳተፍፍቃደኛያልሆኑትበመረጃእጥረትከሆነተገቢውንመረጃመስጠትያስፈልጋል፡፡

ነገርግንተሳታፊቹበግድእነዲሳተፉማድረግተገቢአይደለም፡፡

ተሳታፊዎቹበጥናቱውስጥላለመሳተፍከወሰኑየተሳታፊውንየመለያቁጥርበመፃፍታካሚውንበተመለከተበህክምናካርዱላይየሚገኙትመ ረጃዎችበክፍል 4ቅጽላይመመዝገብይኖርባቸዋል፡፡

የመረጃመሰብሰቢያቅጾች

1. መረጃ መግለጫ

Informed Consent and/or Ascent form (Amharic version)

አዱስአበባዩኒቨርስቲጤናሣይንስፊኩሌቲየህብረተሰብጤናአጠባበቅትምህርትክፌሌየተጠያቂው / መሊሾችየመረጃቅፅ

ጤናይስጥሌንእንደምንነዎት

ስሜ———————— ይባላል፡፡እርስዎበዚህጥናትውስጥእንዲሳተፉተጋብዘዋል፡፡

ጥናቱምየድባቴናየጭንቀትችግርያለባቸውየካንሰርበሽታህሙማን፤

የድባቴእናየጭንቀትህክምናማግኘትበካንሰርህክምናውጤትላይየሚኖረውንአስተዋጽኦየሚመለከትነው፡፡

ከዚህጥናትከሚገኝመረጃእናውጤትለድባቴናለጭንቀትየተጋለጡየካንሰርህሙማንየስነልቦናህክምናማግኘታቸውየሚኖረውንጠቃሜ ታብሎምየካንሰርህሙማንንየህክምናውጤትላይተፅእኖየሚያመጡነገሮችንለይተንእናውቃለንየሚልተስፋአለን፡፡

ተግባራት፡በፍቃድዎ፤የእርስዎንመረጃዎችማለትም (እድሜዎን፣የትምህርትደረጃዎን፤የወርገቢዎን፤የጋብቻሁኔታዎን) እናምየአሁንየህክምናሁኔታዎንየሚመለከትመጠይቅማለትም (የእባጩመጠን፤የካንሰሩደረጃ፤ የመጀመሪያየካንሰርምርመራዎጊዜእድሜዎስንትእንደነበር፤የመጀመሪያየካንሰርምርመራዎወቅትየካንሰሩየስርጭትሁኔታ) በተመለከተከህክምናማህደርዎላይመረጃየሚወሰድሲሆንሌሎችጠቃሚመረጃዎችማለትምሃይማኖት፤የድጋፍሁኔታ፤

ከሃኪምዎብሎምከቤተሰብዎጋርየህክምናሁኔታዎንበተመለከተያሎትግንኙነትእርሶንበመጠየቅእናገኛለን፡፡

የስነልቦናሁኔታዎንየሚመለከትምመረጃ(ስለድባቴእናየጭንቀትሁኔታዎ)ለዛበተዘጋጀ የሆስፒታል የድባቴናየጭንቀትመለኪያመጠይቅእርስዎንበመጠየቅመረጃእንወስዳለን፡፡እርስዎንናየጤንነትሁኔታዎንምበተመለከተበእርሶየሚሞላለዛየተዘጋጀ መጠይቅአለ፡፡

በተጨማሪምጥናቱሁለትቡድንይኖረዋል፡፡ይህምቡድን-1.ተጨማሪየስነልቦናህክምናየሚያገኝቡድንሲሆንሌላኛውቡድን -2.ደግሞተጨማሪ የስነልቦናህክምና(የተለመደውንህክምናየሚያገኝ)ቡድን ይሆናልማለትነው፡፡እርስዎበዚህጥናትላይእንዱሳተፉ የተመረጡትበተደጋጋሚበተደረገየኢጋጣሚየናሙናአወሳሰድስሌትመሰረትነው፡፡ከጥናቱበፊትበጥናቱጊዜም ሆነከጥናቱበኋላመጀመሪያሲከታተሉየነበረውንህክምናያገኛሉ፡፡

በመጨረሻምስነልቦናዎሁኔታ(የድባቴናየጭንቀትመጠንዎ)ብሎምየእርስዎየጤናዎሁኔታበጥናቱመጀመሪያበመጠይቅ በተለካበት ሁኔታ ይለካል ማለትነው፡፡

ጥቅምናጉዳትንበተመለከተ

ይህጥናትያንያህልጉዳትኢይኖረውም፡፡

ይህምየሆነውየስነልቦናህክምናየድባቴእናየጭንቀትችግርወይምየስነልቦናችግርላለባቸውየሚሰጥተጨማሪህክምናስለሆነነው፡፡

ይህየስነልቦናህክምናበቀዳሚነትሲሰጣቹየነበረውህክምናላይተፅእኖየሚያደርግኢይደለም፡፡

ምናልባትህክምናውንበባለሙያሲያገኙከባለሙያውጋርስለግልጉዳይዎከማውራትዎአንጻርትንሽየመረበሽስሜትሊሰማዎይችላል፡፡

በተጨማሪምይህየስነልቦናህክምናየተወሰነጊዜዎንወስድይችላል፡፡በዚህጥናትተሳታፊበመሆንዎ፤ስለካንሰር፤ስለጭንቀትእናድባቴ፤ ብሎምየስነልቦናችግሮችበካንሰርህክምናውጤትዎላይስለሚኖረውተፅእኖግንዛቤይኖርዎታል፡፡

ምናልባትቀጥተኛተጠቃሚላይሆኑይችሉይሆናል፤

ነገርግንተሳትፎዎየአሁንየህክምናሁኔታዎንብሎምየወደፊትየካንሰርህሙማንንየህክምናውጤትበከፍተኛሁኔታየሚቀይርእናየሚጠቅም ሊሆንይችላል፡፡

መብትንናሚስጥርንመጠበቅንበተመለከተ

ሁሉምተግባርወይንምህክምናብቃቱናስልጠናውባላቸውየጤናባለሙያዎችማለትምበስነልቦናህክምናሙያነርሶች፣ በነርሶችእናእንደርሶአይነትየስነልቦናችግርላለባቸውሰዎችህክምናለመስጠትስልጠናውንበወሰዱባለሙያዎችይካሄዳል፡፡

በህክምናመስጫቦታውአስፈላጊመረጃዎችእስኪሰበሰብድረስመቆየትይችላሉ፡፡

የህክምናምሆነየስነልቦናሁኔታዎንለማወቅለሚጠየቁትጥያቄየሚሰጡትመረጃበሚስጥርነትየሚያዝይሆናል፡፡

አስፈላጊውመረጃከተወሰደበኋላየእርሰዎመረጃበተሰጠውየሚስጥርቁጥር

መሰረትተመዝግቦየሚቀመጥይሆናል፡፡በዚህጥናትውስጥየመካተትምሆነጥናቱውስጥያለመካተትሙሉመብትዎየተጠበቀነው፡፡

በማንኛውምምክነያትበጥናቱውስጥመቆየትካልፈለጉወይምምቾትካልተሰማዎየማቋረጥመብትዎሙሉበሙሉየተጠበቀነው፡፡

አለመሳተፍወይምተሳትፎንማቋረጥየሚያገኙየነበረውንህክምናአይከለክልም(ተፅእኖ) አያረግም፡፡

የሰጠዎትንመረጃበሚመለከትጥያቄክልዎእባክዎነፃሆነውይጠይቁ፡፡

ለተጨማሪማብራርያየጥናቱንዋናአስተባባሪየሚከተለውንአድራሻበመጠቀምማነጋገርይችላሉ፡፡

የጥናቱአስተባባሪ፡እጅጋየሁበላይ

ስልክ፡ 0921388192

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አማካሪዎች፡ዶ/ርአባቢዘርጋው

አ/ቶወሪሳውኃይለስላሴ

የተሰጠውንመረጃመሰረትበማድረግ፤ጥናቱውስጥለመሳተፍፍቃደኛነዎት?

ፍቃደኛነኝፍቃደኛአይደለሁም

የፍቃደኝነትመጠየቂያቅፅ

የጥናቱንተግባራትሙሉበሙሉከተረዳውበኋላበጥናቱውስጥበፍቃዴለመሳተፍተስማምቻለው፡፡

የተሳታፊ

ፊርማ ----------ቀን----------

2. በተሰጠመረጀላይ የተመሰረተፍቃደኛነትቅጽለህመምተኛው

የዚህጥናትአላማ፣ጥቅም፣ጉዳት፣ቅደምተከተል፣ሚስጥራዊነትበሚገባኝቋንቋተነቦልኝተገልፆልኛል፤
እንዲሁምበዚህጥናትውስጥመቀጠልምሆነበማንኛውምሰዓትማቋረጥእንደምችልተነግሮኛል።።
በዚህጥናትለመሳተፍፈቃደኛነኝ።:

በዚህጥናትላይየእርስዎፊርማምንማለትነው ?

የእርስዎ ፊርማ ማለት

- የዚህጥናትአላማ፣ጥቅም፣ቅደምተከተልበተገቢውሁኔታአውቀዋል
- ከመፈረምዎ በፊት ማንኛውንም ጥያቄ ለመጠየቅ እድል ተሰትዎታል
- በዚህ ጥናት ለመሳተፍ ፈቃደኛ ነዎት

የተሳታፊው:

ፊርማ (የግራእጅአውራጣትአሻራ) _____ቀን_____

የጠያቂውሙሉስምየጠያቂውፊርማ_____

የመጠይቁዉጤትማረጋገጫ (በጥናቱተቆጣጣሪባለሙያመረጋገጥአለበት)

ሙሉበሙሉየተሞላ ☐

በከፊልየተሞላ ☐

የተቆጣጣሪስም_____ ፊርማ_____ቀን_____

ክፍልአንድ: ክፍል 1.የሆፒታል ውስጥ የጭንቀትና የድባቴ መለኪያ መጠይቆች

ጥያቄ ቁጥር፡- 101፤103፤105፤107፤109፤110፤113 (የድባቴ ወይም ድብርትን) ለመለካት የሚጠቅሙ መጠይቆች ሲሆኑ

ጥያቄ ቁጥር፡- 102፣104፣106፣108፤111፤112፤114(በቢጫ ቀለም የተመለከቱት መጠይቆች)

እነዚህም ጥያቄዎች እያንዳነዱ አራት አማራጭ መልሶች ያላቸው ሲሆን፤ተሳታፊው በመጀመሪያ አዎ ወይም አይደለም ብሎ ከመለሰል(ችል)ን በኋላ፤ ከዛ መልሳቸው በመነሳት ለቀጠይ ምላሻቸው ምርጫዎችን በመንገር የነገሩን ምላሽ ላይ እናከባለን ማለት ነው፡፡

ከተሳታፊው ጋር መጠይቃችንን ከጨረስን በኋላ ተሳታፊውን ከመሰናበታችን በፊት ያከበብነውን ምላሽ(ያከበብነውን ቁጥር)መደመር ይጠበቅብናል፡፡ስለዚህ የድምሩ ውጤት ለድብርት ጥያቄ ለብቻ እንዲሁም ለ ጭንቀት ጥያቄ ለብቻ

1*ከ 0-7 ከሆነ ይህ(ይህች) ታካሚ የስነልቦና ችግር የለባትም ማለት ነው ስለዚህ በጥናቱ ውስጥ አይካተትም/አትካተትም፡፡

2*ከ 8-10 ከሆነ መጠነኛ የድብርትና የጭንቀት ችግር አለበት ስለዚህ ጥኛታችን ውስጥ ይካተታሉ ማለት ነው፡፡ስለዚህ ወደ ቀጣዩ ጥያቄ እናመራለን ማለት ነው፡፡

3*ከ 11-14 ከሆነ መካከለኛ የጭንቀት እና የድባጤ ችግር አለበት/ባት ስለዚህ ይህም ታካሚ ጥናት ውስጥ ተካቶ ተገቢው የስነልቦና ህክምና ይደረግለታል ማለት ነው፡፤

4*ከ 14-21 ከሆነ ከፍተኛ የድብርትበና የጭንቀት ችግር አለበት ወይም አለባት ማለት ነው ስለዚህ ይህ ከፍተኛ የድብርት እና የጭንቀት ችግር በስነልቦና ህክምነቃ ለብቻው የሚድን ስላልሆነ ይህን ታማሚ ወደ ሣይካትሪ ዲፓርትመንት ሊንክ ማድረግ ሊጠበቅብን ይችላል፡፡ስለዚህ ወዲያውኑ የዚህን ጥናት ዋና አስተባባሪ ማግኘት እና ማነጋገር ይጠበቅባቹሃል ማለት ነው፡፡

ስለዚህ ከተራ ቁጥር 1 እና 4 ውጪ ሌላውን መስፈርት ያሟሉ ህሙማን በጥናቱ ተካታች ስለሚሆኑ የሚቀጥለውን መጠይቅ ዕንሞላለን ማለት ነው፡፡

ክፍል 2 ማህበረሰባዊመረጃዎችንየተመለከተመጠይቅመሠረታዊመረጃ እባኮዎትክክለኛመልስዎንያክብቡ

ጥያቄቁጥር 201፡እድሜ

በሙሉ አመት ይቀመጥ አንዲሁም አመተ ምህረት ይሞላ

ጥያቄቁጥር 202-208

የጥናቱ ተሳታፊ ምላሽ ሲሰጥ የምላሽ ሳጥን ውስጥ ያለትን ቁጥሮች ይከበብ

ክፍል 3 የቤትውስጥማህበራዊናኢኮኖሚያዊደረጃ (wealth index) የሚቀጥለው መጠየቅ የቤተሰብ ንብረት አገልግሎትና የቤት ሁኔታን የሚቃኝ ይሆናል፡፡እባእዎ መልስን በተሰጠው መልስ ሳጥን ውስጥ ያክብቡ፡፡

ጥያቄቁጥር 309-315

የጥናቱ ተሳታፊ ምላሽ ሲሰጥ የምላሽ ሳጥን ውስጥ ያለትን ቁጥሮች ይከበብ፡፡

ክፍል4. ከገንዘብድጋፍጋርበተያያዘየሚሰጥጥያቄዎች

ለምሳሌ በጥያቄ ቁጥር 401 ላይ ‘‘ተሳታፊው የገንዘብ ድጋፍ ያገኛሉ?’’ ብለው ሲጠይቁ ከታች

በምሳሌው እንደሚታየው የተሳታፊውን ምላሽ ማክበብ ይኖርበታል፡፡

ቁጥር	ጥያቄዎች	መልስ	ይዘላል
401	የገንዘብ ድጋፍ ያገኛሉ?	1.አዎ 2 የለም	

ክፍል 5 ግንኙነትንወይምንግግርንበተመለከተየሚሰጥመጠይቅ

ከጥያቄ ቁጥር 501-503 ያለውን ጥያቄ ከላይ ባለው አካሄድ መሰረት የተሳታፊውን ምላሽ በማከበብ ይኖርቦታል፡፡

	ሰነ-ኣይምሮ እርዳታ ፍላጎት	ፍላጎትያለመኖር		ፍላጎትመኖር		
		ይሄችግርየለ ኝም	**ፍላጎቴተሞ ልቶል**	**ትንሽፍ ላጎትአ ለኝ**	**መጠነኛፍላጎ ትአለኝ**	**ከፍተኛፍላጎ ትአለኝ**
309	በህይወትአልቆይምየሚልስሜትተሰምትዎትየስነ-ልቦናእርዳታፈልገውነበር?	1	2	3	4	5

ከህመምተኛው መረጃ ማህደር ላይ የሚወሰድ መረጃ

ክፍል 6 ፡.ከህመምተኛው የካንሰር ሁኔታ ጋር ተያያዘ የሚሰጥ መጠይቅ

የሚከተለውን መጠይቅ መረጃ ሰብሳቢው ወይም ሰብሳቢዋ ከካርዱ ላይ በሚከተለው መልኩ ከካርዱ ላይ በመውሰድ ማከበብ ይኖርበታል፡፡

ቁጥር	**ጥያቄ**	**መልስ**	**ይዘለል**
601	የእባጩመጠን	1.<2 2.2-5 3.>5	
602	የእባጩደረጃ	1.ደረጃ 1 2.ደረጃ 2 3.ደረጃ 3 4.ደረጃ 4	
603	መጀመሪያ ያወቁ ጊዜ የስርጭት ሁኔታ	1.ተሰራጭቶነበር 2.ስርጭትአልነበረም	

ክፍል-7 ሌሎች የህመም ሁኔታዎችን የተመለከተ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
701.	ለሌላየበሽታሁኔታበቅርብተመርምረውያውቃሉ?	1.አዎ 2.የለም (2)	
702.	መልስዎአዎከሆነየመጨረሻምርመራዎንመቼአረረጉ?	1.<6 ወር 2.6-12 ወር 3.>12 ወር	

ከላይ በሰንጠረዡ ላይ እንደተመለከተው ከካርዱ ላይ የተሳታፊውን መረጃ በመውሰድ መግለጽ(ማከበብ) ይኖርቦታል፡፡

3. የመጠይቅቅጽ

ክፍል 1.የሆፒታል ውስጥ የጭንቀትና የድባቴ መለኪያ መጠይቆች

የሆስፒታል የጭንቀትና የድባቴ መለኪያ

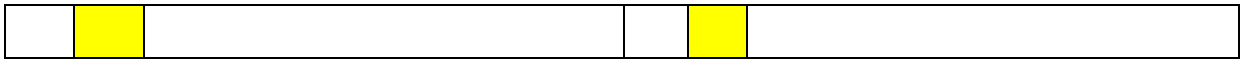
ክፍል-1 :የሆስፒታል ውስጥ የጭንቀትና የድብርት መለኪያ መጠይቆች

ስነልቦና ብ□ በሽ□ዎች ላ□ □ራሱ □ሆነ ሚና እንቁለዉ □□ወቃል እናም ሀኪምዎ □ሚሰማዎትን ስሜት ካወቁ በ□ንብ ሊረ□ዎት ይችላሉ፡፡ባለ□ዉ ሣምንት □ዙሰማዎን ትክክለኛ ስሜት መሠረት በማትረፅ □□ና ባለሙ□□ ቀ□ሎ ለሚ□□ቁዎት □□ቁ ተ዗ዉን መልስ □ስ□፡፡በተቻለ መ□ን ሲመልሱ ብ□ ቂ□ አይ□ ሰ□ ፣ ምናልባትም እን□ተ□□ቁ ወቂ□ዉነ □ሙ□ልዎት መልስ ትክክለኛ ስሜትዎን ሊ዗ልን □ችላል፡፡

ት	□		ት	□	
		□ሙ□ ነቅ ወ□ም □መወ□ር ስሜት ምን □ህል □ሰማዎ□ል?			□ስተኛ ነዎት?
	3	በ□ም ብ□ ቂ□	3		ምንም □ስተኛ አ□□ለሁም
	2	ብ□ ቂ□	2		ብ□ ቂ□ □ስተኛ አይ□ለሁም
	1	አል□ አል□	1		ብ□ም ባ□ሆን □ስተኛ ነኝ
	0	ምንም አ□ሰማኝም	0		አብ□ኛውን ቂ□ □ስተኛ ነኝ
		ቀ□ም ሲል □ስ□ሰቱዎ □ነበሩ ነ዗ሮች አሁን ምን □ህል □ሰ□ስቱዎ□ል?			ተረ□ፅተዉ መቀመ□ እና □ኽ ማለት □ችላሉ?

0		አሁንም እን□ትሮዉ □ሰ□ስቱኛ ል		0	ሁሌም እችላለሀ
1		ከድሮዉ ትንሽ ቀንሳ.ል		1	አብ□ሯውን ቂ□ እችላለሁ
2		በ□ቂቱ □ሰ□ስቱኛል		2	ብዙውን ጊዜ አልችልም
3		□ ራሽ አ□ሰ□ስቱኝም		3	ምንም አልችልም
		አንድ መ□□ ነዉር ሊ.□□□ምዎ □ተቃረበ □ሚመስል □አርሀት ስሜት □ሰማዎተል?			ስራዎን ሲ.ያከናዉኑ ወ□ተ አ□ነትዎ ምን □ህል □ቀነሰ □መስልዎ□ል?
	3	እ□ፅ በ□ም □ሠማኛል	3		እ□ፅ በ□ም ብ□ ጊ□
	2	በ□ም □ሠማኛል	2		በ□ም ብ□ ጊ□
	1	በ□ቂቱ □ሠማኛል	1		አል□ አል□
	0	ምንም አ□ሠማኝም	0		ምንም አልቀነሰም
		መሳቅና □ነዉሮችን አስቂኝ □ን ማየት □ችላሉ?			ሆት አካባቢ □ሚሰማ □መ□ንዉ□ ወ□ም □መሸበር ስሜት □ሰማዎ□ል?
0		አብ□ሯውን ቂ□ እችላለሁ		0	ምንም አ□ሰማኝም
1		እን□ትሮዉ ባ□ሆንም እችላለሁ		1	አል□ አል□
2		በ□ቂቱ እችላላሁ		2	ብ□ ጊ□
3		ምንም አልችልም		3	በ□ም ብ□ ጊ□
		ጭንቀትን □ሚ□□ ሩ ሀሳቦች በአምሮዎ ምን □ህል ቂ□ □መላለሳሉ?			ለአለባበስዎ ትኩረትን መስ□ት አቁመኝል?

	3	በ□ም ብ□ ቺ□	3		አዎን ምንም ትኩረት እ□ሠ□ሁ አይ□ለም
	2	ብ□ ቺ□	2		□ም□ልቶውን □ህል ትኩረት እ□ስ□ሁ አይ□ለም
	1	አብ□ኛውን ቺ□ ባ□ሆንም አል□ አል□	1		ትሮ ከምሰ□ዉ ትኩረት በ□ቂቱ □ነሰ ትኩረትን እሰ□ለሁ
	0	አንቴንዴ ብቻ	0		ሁሌም □ምሰ□ውን ትኩረት እሰ□ለሁ
		አንድ ቦ□ መሄት □ለብዎ □መስል ተረ□ግቶ መቀመ□ □ቸቱርዎ□ል ?			በትንገት □መ□ንገጥ ወ□ም □መሸበር ስሜት □ሰማዎ□ል?
	3	በ□ም ብ□ ቺ□ □ቸፅረኛል		3	በ□ም ብ□ ቺ□ □ሰማኛል
	2	ብ□ ቺ□ □ቸፅረኛል		2	ብ□ ቺ□ □ሰማኛል
	1	ብ□ም አ□ቸፅረኝም		1	አል□ አል□ □ሰማኛል
	0	ምንም አ□ቸፅረኝም		0	ምንም አ□ሰማኝም
		መቸ ነቶሮችን በ□ስ□ □□ብቃሉ?			በሬቲ□ ወ□ም □ቴሌቪ.ዴን ኘ ሮግራሞች ራስዎን □ሰ□ስ□ሉ?
0		አዎ ሁሌም በተለመ□ዉ ወ□ም በትሮዉ መ□ን □ብቃለሀ	0		አዎን ብ□ ቺ□
1		ከድሮዉ ወ□ም ከተለመ□ዉ በ□ቂቱ ባነሰ መ□ን □ብቃለሀ	1		ብ□ም ባ□ሆን አዎ
2		ከድሮዉ ወ□መ ከተለመ□□ ባነሰ መ□ን □ብቃለሀ	2		አል□ አል□
3		ምንም በ□ስ□ አል□ብቅም	3		በ□ም አል□ አል□



(5) 0-7 Normal (የድብርት እና የጭንቀት ምልክቶች የሉም)
(6) 8-10 Mild (በትንሹ የድብርትና የጭንቀት ምልክቶች አለ)
(7) 11-14 Moderate(በመጠኑ » » »)
(8) 14-21 Severe (በከፍተኛ ደረጃ » » »)

ይህንን የምናገኘው ለድብርት ለብቻ ብሎም ለጭንቀት ለብቻ ምላሻቸው ላይ በማከበብ እና በመደመር ይሆናል ማለት ነው::

ውጤቱን እንደሚከተለው ያስቀምጡ::

A=----------
D=----------

ክፍል 2 ማህበረሰባዊመረጃዎችንየተመለከተመጠይቅመሠረታዊመረጃ
እባኮትክክለኛመልስዎንያክብቡ

ቁጥር	ጥያቄ	መልስ	ይዘለል
201	እድሜ		
202	ሀይማኖት	1.ኦርቶዶክስ 2. ካቶሊክ 3.ፕሮቴስታንት 4. ሙስሊም 5. ሌላጥቅስ----------	
203	የቤተሰብቁጥርአንተን/አንቺንጨምሮ		
204	የወላጅአባት/ሽየትምህርትደረጃ	1.ያልተማረ (ማንበብናመፃፍየማይችል) 2.ማንበብናመፃፍየሚችል 3.የመጀመሪያደረጃያጠናቀቀ(ክፍል1-8) 4.ሁለተኛደረጃያጠናቀቀ (9-12) 5.ኮሌጅወይምየሙያት/ት 6.የኮሌጅምሩቅወይምከዛበላይ 8.አላውቅም 9.በህይወትየለም	
205	የወላጅእናትሽ/ህየትምህርትደረጃ	1.ማንበብናመፃፍየማትችል 2.ማንበብናመፃፍየምትችል 3.የመጀመሪያደረጃያጠናቀቀች (ክፍል1-8) 4. ሁለተኛደረጃያጠናቀቀች (9-12) 5. ኮሌጅወይምየሙያት/ት	

		6. የኮሌጅምሩቅወይምከዛበላይ 7. አላውቅም 8.በህይወትየለችም	
206	አሁንከማንጋርነውየሚኖሩት	1.ከሁለቱምወላጆቼጋር 2. ከእናቴጋርብቻ 3. ከአባቴጋርብቻ 4. ከእናቴወንድምጋር 5. ከአያቴጋር 6. ከአክስቴጋር 7.ከአሳዳጊዎቼጋርእናከእንጀራእናቴወይምአባቴጋር 8. ከጓደኞቼጋር 9. ሌላካለጥቀስ	
207	የት/ትደረጃ		
208	የተማሩበትየት/ትቤትአይነት	1.የግልሚስጥር 2.መንግስታዊ /የህዝብ	

ክፍል3-የቤትውስጥማህበራዊናኢኮኖሚያዊደረጃ(wealthindex)

የሚቀጥለውመጠየቅየቤተሰብንብረትአገልግሎትናየቤትሁኔታንየሚቃኝይሆናል፡፡

እባእዎመልስንበተሰጠውመልስሳጥንውስጥያክብቡ፡፡

ቁጥር	ጥያቄ	መልስ	ይዘላል
301	ቴሌቪዥን	1.አዎ 2. የለም	
302	ሬድዮ /ቴፕሬኮርደር	1.አዎ 2.የለም	
303	ሞባይልስልክ	1.አዎ 2.የለም	
304	ሞባይልየለም/የገመድስልክ	1.አዎ 2.የለም	
305	የኤሌትሪክምድጃ	1 አዎ 2.የለም	
306	ፍሪጅ	1.አዎ 2. የለም	
307	ላውንደሪ (የልብስማጠቢያ	1.አዎ 2.የለም	
308	ሶፋ	1.አዎ 2.የለም	
309	ሳይክል/ሞተርሳይክል	1.አዎ 2. የለም	
310	መኪና	1 አዎ 2.የለም	
311	የቤትውስጥሰራተኛ	1.አዎ 2.የለም	

2.የቤትሁኔታ፣የሚከተለውመጠየቅየእርሶንየቤትሁኔታየሚቃኝይሆናልእባኮዎመልስበትክክለኛውመልስላይያክብቡ

312	የመኖሪያቤትባለቤትነት	1.የግል 2.የመንግስት 3.ኪራይ 4.ሌላጥቅስ
313	የክፍልቀጥር	
314	በአንድክፍልውስጥየሚተኛውየሰውብዛት	1.ተፈጥራዊቁስ (ሣር) 2.ቆርቆሮ 3.ሸክላ 4.ሌላጥቅስ
315	የጣሪውሁኔታ	1. ጭቃ 2. ጣውላ 3. የሲሚንቶወለል 4. ሴራሚክ 5. ምንጣፍ 6. ሌላ (ጥቅስ)

ክፍል4. ከገንዘብድጋፍጋርበተያያዘየሚሰጥጥያቄዎች

ቁጥር	ጥያቄዎች	መልስ	ይዘላል
402	የገንዘብድጋፍያገኛሉ?	1. አዎ 2. የለም	
402	መልሶአዎከሆነ ከማንነውድጋፍየሚገኙት	1. ከቤተሰብአባል 2. ከዘመድ 3. ከጎረቤት 4. ከጤናባልሙያ 5. ሌላ	
403	መልሱአዎከሆነየሚያገኙትድጋፍቋሚነው?	1. አዎ 2. የለም	

ክፍል 5 ግንኙነትንወይምንግግርንበተመለከተየሚሰጥመጠይቅ

ቁጥር	ጥያቄ	መልስ	ብዛት
501	ከህኪምጋርያሎትግንኙነትምንይመስላልምን ንበተመለከተንግግርያደርጋሉ?	1.ከህመሙጋርየተገናኙነገሮችንበሙሉ(የመድሃኒትአይነትየሚያስጨንቁኝንነገሮችየህክም ናወጪ፣ስለስሜቶቼ 2. ጥቂትነገሮች (ስለህክምናውአይነትእንዲሁምወጪ) 3. ጥቂትነገሮችንስለህክምናሁኔታ	
502	ከቤተሰቦትጋርያሎትግንኙነትምንይመስላል ምንንበተመለከተንግግርያደርጋሉ?	1.ከህመሙጋርየተገናኙነገሮችንበሙሉ(የመድሃኒትአይነትየሚያስጨንቁኝንነገሮችየህክም ናወጪ፣ስለስሜቶቼ 2. ጥቂትነገሮች (ስለህክምናውአይነትእንዲሁምወጪ) 3. ጥቂትነገሮችንስለህክምናሁኔታ	
503	ስሜቶንየሚካፈሎት ሰውአለ?	1. አዎየማካፍለውሰውአለ 2. የለምምንምአይነትድጋፍአላገኝም	

ክፍል 6.ከህመምተኛው የካንሰር ሁኔታ ጋር ተያያዘ የሚሰጥ መጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
601	የእባጩመጠን	1.<2 2.2-5 3.>5	
602	የእባጩደረጃ	1.ደረጃ 1 2. ደረጃ 2 3. ደረጃ 3 4. ደረጃ 4	
603	መጀመሪያያወቁጊዜየስርጭትሁኔታ	1.ተሰራጭቶነበር 2.ስርጭትአልነበረም	

ክፍል-7 ሌሎችየህመምሁኔታዎችንየተመለከተመጠይቅ

ቁጥር	ጥያቄ	መልስ	ይዘለል
701.	ለሌላየበሽታሁኔታበቅርብተመርምረውያውቃሉ?	1.አዎ 2.የለም	
702.	መልስዎአዎከሆነየመጨረሻምርመራዎንመቼአረረጉ?	1.<6 ወር 2.6-12 ወር 3.>12 ወር	

ክፍል 8 : EORTC QLQ-C30 (አትም3)

እርስዎንናጤንነትዎንበተመለከተየተወሰኑነገሮችንለማወቅእንፈልጋለን።

እባክዎትንየሚከተሉትንጥያቄዎችበሙሉእርስዎትክክለኛነውብለውያመኑበትንበማክበብይመልሱ። «ትክክለኛ» መልስወይም «የተሳሳተ» መልስየሚባልየለም።የሚሰጡትመረጃሁሉምስጢራዊነቱበደንብየተጠበቀይሆናል።

እባክዎንየእርስዎንየአባትዎንናየኢያትዎንየስምመጀመሪያፊደልይጻፉ፡- ----------

የተወለዱበትዕለት (ቀን፣ወር፣ዓም)፡-----------

የዛሬውዕለት (ቀን፣ወር፣ዓም)፡----------

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		በጭ ራሽ	በትን ሹ	በመ ጠኑ	በጣምበ ብዛት
801.	እንደከባድዘንቢልወይምሻንጣመሸከምየመሳሰሉጉልበትየሚጠይቁእንቅስቃሴዎች ንለማድረግችግርአለብዎት?	**1**	**2**	**3**	**4**
802.	ረዥምየእግርጉዞለማድረግችግርአለብዎ?	**1**	**2**	**3**	**4**
803.	ከቤትዎውጭአጭርየእግርጉዞለማድረግችግርአለብዎ?	**1**	**2**	**3**	**4**
804.	በህመምዎየተነሳበቀንአልጋላይወይምወንበርላይሆነውረዘምላለሰዓትያሳልፋሉ?	**1**	**2**	**3**	**4**
805.	ሲመገቡ፣ሲለብሱ፣ሲታጠቡወይምሽንትቤትሲጠቀሙእገዛያስፈልግዎታል?	**1**	**2**	**3**	**4**
ባለፈውሳምንትውስጥ፡-		በጭ ራሽ	በትን ሹ	በመ ጠኑ	በጣምበ ብዛት
806.	ስራዎትንወይንምየዕለትተለትእንቅስቃሴዎትንለማከናወንተገድበውነበር?	**1**	**2**	**3**	**4**
807.	በትርፍጊዜየሚከናወኑስራዎችንወይንምሌሎችየመዝናኛጊዜዎችንለማሳለፍገድቦዎ ትነበር?	**1**	**2**	**3**	**4**

808.	ሲተነፍሱየትንፋሽማጠርአጋጥሞትነበር?	**1**	**2**	**3**	**4**
809.	የህመምስሜትነበረብዎ?	**1**	**2**	**3**	**4**
810.	ከወትሮውየተለየዕረፍትአስፈልጎዎትነበር?	**1**	**2**	**3**	**4**
811.	የዕንቅልፍችግርነበረብዎ?	**1**	**2**	**3**	**4**
812.	አቅምያንስዎትነበር?	**1**	**2**	**3**	**4**
813.	የምግብፍላጎትዎቀንሷል?	**1**	**2**	**3**	**4**
814.	የማቅለሽለሽስሜትነበረብዎ?	**1**	**2**	**3**	**4**
815.	አስመልሶዎትነበር?	**1**	**2**	**3**	**4**
816.	የሰገራድርቀትነበረብዎ?	**1**	**2**	**3**	**4**
ባለፈውሳምንትውስጥ፡-					
817.	ተቅማጥነበረብዎ?	**1**	**2**	**3**	**4**
818.	የድካምስሜትነበረዎ?	**1**	**2**	**3**	**4**
819.	ህመሙየዕለትተዕለትእንቅስቃሴዎትንያውክብዎነበር?	**1**	**2**	**3**	**4**
820.	አንድአንድነገሮችንትኩረትሰጥተውለመስራትያውክዎትነበር (ለምሳሌ፤ ጋዜጣለማንበብ፣ራዲዮለማዳመጥ)?	**1**	**2**	**3**	**4**
821.	የውጥረትስሜትነበረብዎ?	**1**	**2**	**3**	**4**
822.	የመጨነቅስሜትነበረብዎ?	**1**	**2**	**3**	**4**
823.	የመጨነቅስሜትነበረብዎ?	**1**	**2**	**3**	**4**

824.	የመደበርስሜትነበረብዎ?	**1**	**2**	**3**	**4**
825.	ነገሮችንየማስታወስችግርነበረብዎ?	**1**	**2**	**3**	**4**
826.	አካላዊሁኔታዎወይምየሚከታተሉትህክምናበቤተሰባዊህይወትዎላይያሳደረውተጽዕኖነበር?	**1**	**2**	**3**	**4**
827.	የጤናዎሁኔታወይምየሚከታተሉትህክምናበማህበራዊሕይወትዎበሚደርጉትእንቅስቃሴዎላይያሳደረውተጽዕኖነበር?	**1**	**2**	**3**	**4**
828.	የጤናዎሁኔታወይምየሚከታተሉትህክምናገንዘብእንዲያጥርዎ /እንዲቸግርዎ/ አድርጓል?	**1**	**2**	**3**	**4**
ለሚከተሉትጥያቄዎችከ**1-7** ካሉትቁጥሮችውስጥእርስዎንበደንብየሚገልጽዎንአንዱንቁጥርያክብቡ					
829.	በአጠቃላይባለፈውሳምንትየነበረዎንየጤንነትሁኔታእንዴትይመዝኑታል? 1 2 3 4 5 6 7 በጣምመጥፎ እጅግበጣምጥሩ				
830.	በአጠቃላይባለፈውሳምንትየነበረዎንየኑሮሁኔታጥራትእንዴትይመዝኑታል? 1 2 3 4 5 6 7 በጣምመጥፎ እጅግበጣምጥሩ				