EFFECTS OF A 12-WEEK ENDURANCE EXERCISE PROGRAMME ON SELECTED CLINICAL ATTRIBUTES AND QUALITY OF LIFE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER

A THESIS IN THE DEPARTMENT OF PHYSIOTHERAPY SUBMITTED TO THE FACULTY OF CLINICAL SCIENCES COLLEGE OF MEDICINE

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF DOCTOR OF PHILOSOPHY IN PHYSIOTHERAPY

DEGREE OF THE UNIVERSITY OF IBADAN

BY

ROTIMI OLANREWAJU, KAREEM
B. Physiotherapy; M.Sc (Physiotherapy) Ibadan, MNSP

JANUARY 2013

CERTIFICATION

We certify that this study was carried out by Mr. Rotimi Olanrewaju KAREEM under our supervision and the approval of Department of Physiotherapy, Faculty of Clinical Sciences, College of Medicine, University of Ibadan, Ibadan, Nigeria.

SUPERVISOR

Prof. Arinola O. SANYA

B.Sc Physiotherapy, PhD (Ibadan) FNSP
Deputy Vice-Chancellor (Administration)
University of Ibadan, Nigeria.

CO-SUPERVISOR

Dr O. F. AINA

MBBS, FWACP Associate Professor Department of Psychiatry, College of Medicine University of Lagos, Nigeria.

DEDICATION

This study is dedicated to the memory of my late mother
Deaconess Dorcas Olatinuke KAREEM
who died suddenly in the course of this work but her emphasis on positive impact and knowledge lives on.

iv

ABSTRACT

The increasing number of people diagnosed with depression and the reliance on drugs to manage this condition exposes patients to potentially harmful adverse effects such as overweight, cardiovascular diseases and low cardio-respiratory fitness. Previous studies focused on the effects of exercise on the mood of patients; however, there is paucity of scientific evidence about the effects of exercise intervention on the body composition of patients with major depressive disorder receiving antidepressant drug treatment. This study was designed to evaluate the effects of a 12-week endurance exercise programme on selected body composition indices, cardio-respiratory indices, quality of life and severity of depression in patients with major depressive disorder.

Ninety patients with major depressive disorder receiving antidepressants participated in this quasi-experimental study. They were consecutively recruited from Federal Neuro-psychiatric Hospital, Yaba and Lagos University Teaching Hospital, and assigned into either Experimental Group (EG) or Control Group (CG) using a simple random assignment technique. The EG went through relaxation exercises and a progressive endurance exercise programme in a circuit training pattern consisting of bicycle ergometry, aerobic dance, mat exercises, stair climbing and walking, three times per week for 12 weeks. Those in the CG had only relaxation exercises twice per week for 12 weeks. Both groups were assessed for Body Weight (BW), Percent Body Fat (PBF), Waist-Hip-Ratio (WHR), Body Mass Index (BMI), resting Systolic Blood Pressure (RSBP), resting Diastolic Blood Pressure (RDBP), resting Heart Rate (rHR), Cardio-Respiratory Fitness Index (CRFI), Quality of Life (QoL) and Severity of Depression (SOD_1 andSOD_2). The assessment were carried out at baseline and at the end of 2^{nd}, 4^{th}, 6^{th}, 8^{th}, 10^{th}, and 12^{th} week

using body composition monitor, digital sphygmomanometer, one-mile walk test, WHO(Five) well-being index, 17-item-Hamilton

Rating Scale for Depression (HRSD-17) and Beck Depression Inventory (BDI-II). Descriptive statistics, independent t-test, repeated measure ANOVA analysis with Bonferroni correction were used to analyse the data at p= 0.05.

Participants comprised of 72 females and 18 males. The EG and CG were comparable in age (38.7±11.1 vs. 39.1±10.9 years), height (1.6±0.1 vs. 1.6±0.1m) and body weight (76.7±15.8 vs. 76.6±13.2kg). The end of 12th week endurance exercise comparison of the two groups showed statistically significant difference in the BW (70.8±14.4 vs. 84.8±12.9kg), PBF (29.4±8.2 vs. 41.4±8.1%), WHR (1.3±0.7 vs. 1.4±0.2), BMI (25.3±5.1 vs. 30.6±4.3kg/m^2), SBP (104.7±6.8 vs. 128.9±12.2mmHg), DBP (65.3±5.6 vs. 83.4±3.9mmHg), RHR (76.4±5.9 vs. 92.0±8.9bpm), CRFI (97.6±8.2 vs. 119.08±8.9bpm), QOL (74.5±7.1 vs. 55.1±3.2%), SOD_1(17.6±1.2 vs. 20.3±2.1) and SOD_2 (18.1±1.6 vs. 20.6±2.0). However, the within-group analysis showed that there were statistically significant reduction in all the outcomes in the EG except QoL where participants recorded significant increase, while there were significant increase in all the outcomes of CG except SOD_1 and SOD_2 where significant reduction were recorded.

The 12-week endurance exercise controlled body adiposity, improved cardio-respiratory fitness and quality of life and reduced severity of depression in patients with major depressive disorder receiving antidepressants. Endurance exercise intervention is recommended to prevent antidepressant drug-induced weight gain in patients with major depressive disorder.

Key words: Body composition, Major depressive disorder, Antidepressants, Quality of life, Exercise programme

Word Count: 491

vi

ACKNOWLEDGEMENT

My gratitude goes to the Almighty God who is always my source, only You I will serve in my lifetime.

I am always indebted to Professor Arinola Olasumbo Sanya as my supervisor, a mother, a mentor and my teacher. Words cannot express my appreciation for your positive impact on my postgraduate education, my physical, spiritual and emotional life. Ma, your good works shall be bountifully rewarded and I pray that you will enjoy the sweet fruits of your labour.

Furthermore, special thanks to my co-supervisor, Dr. O.F Aina for your constant encouragement and insights during the study. Also, to Dr. A.T Olagunju (Consultant Psychiatrist) for your relentless effort and input to make this study a success, it is worthwhile knowing you. Similarly, big thank you to all the Consultant Psychiatrists in Federal Neuro-psychiatric Hospital (FNPH) Yaba, Lagos. Especially, Dr. R.A Adebayo and Dr. Oluwaniyi for their contribution to this study. Many thanks to Mrs. Tayo Adeife the Head, Department of Physiotherapy, FNPH and the entire staff of the department for their support and accommodation.

This acknowledgement will be incomplete without my lecturers, Dr. O. Ayanniyi, Prof. T.K Hamzat, Dr. B.O.A Adegoke and my HOD, Dr. Aderonke O. Akinpelu for your critical insights during the study, thank-you cannot thank you enough. My special appreciation goes to Dr. A.F Adeniyi and Dr. Omoyemi Ogwumike for their immense contribution to the success of this study

Finally, to my wife, Mrs Racheal O. Kareem for her total support and endurance during this work, you are a priceless Jewel. To my children, Ewaoluwa and Ololade, you are both wonderful! To my research assistants, Tobi, Ayo, Funsho and Lekan; thank you so very much for a job well done. Most importantly, my participants for making this dream a reality, God will restore you all.

TABLE OF CONTENTS

CHAPTER TWO: LITERATURE REVIEW

CHAPTER THREE:MATERIALS AND METHODS

LIST OF TABLES

TABLES

XV

LIST OF FIGURES

LISTS OF PLATES

PLATES:

APPENDICES

CHAPTER ONE

INTRODUCTION

1.1 Introduction

Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, low energy, and poor concentration (World Health Organization, 2011). Depressed people may lose interest in activities that once were pleasurable, experience difficulty concentrating, remembering details, or making decisions, and may contemplate or attempt suicide (National Institute of Mental Health, 2009). The presence of five or more of these symptoms everyday for at least two weeks is an indication for an evaluation for depression (Geddes and Butler, 2002).

Treatment with antidepressant drugs is the preferred choice in cases of moderate to severe depression. The rate of response to an antidepressant trial is about 60%, and is close to 80% if treatment with a second drug is tried after an initial antidepressant drug failure (Remick, 2002). Antidepressant drugs include the tricyclic antidepressants (TCAs) drugs, the selective serotonin reuptake inhibitors (SSRIs) and the monoamine oxidase inhibitors (Potter and Hollister, 2001).

Weight gain is a common and well-known adverse effect of short and long term antidepressant drug treatment (Deshmukh and Franco, 2003; Schwartz et al, 2007). It is also a serious concern for patients starting or already taking an antidepressant, and contributes to their reluctance to continue antidepressant drug treatment (Deshmukh and Franco, 2003). On the other hand, reducing weight gain once it has occurred and the associated risks can be very difficult (Deshmukh and Franco, 2003). Overweight is defined as a body weight that exceeds the acceptable weight for a particular person based on the individual's age, height and body frame (Kucmarski, 2000). It is also defined as body mass index (BMI) of 25 – 29.9kg/m^2; whereas obesity is defined as a BMI greater than or equal to 30kg/m^2 (WHO 1998; Uwaifo and Arioglu, 2004). Antidepressant drug treatment was found to be associated with a significant increase in body weight and body fat mass (Laimer et al, 2006; Helmich et al, 2010). Increased body fatness

constitutes a significant public health problem in the developed world and increasing rapidly in several developing nations associated with high morbidity, mortality and reduced quality of life (Sorenson, 2000; Uwaifo and Arioglu, 2004). Controlling weight gain in patients on antidepressant drug treatment is the ideal strategy, which involves increased caloric expenditure through endurance exercise programme.

Participation in physical exercise has been reported to be necessary for successful weight control and maintenance in all people (Powers and Howley, 2007) and also, shown to improve mood in depressed people (Blumenthal et al, 1999; Babyak et al 2000; Dimeo et al, 2001; Blumenthal et al, 2007).It has however been suggested that, caution needs to be exercised when applying these findings to patients with affective disorders (Knubben et al, 2007). Fitness levels have also been found to be lower in depressed individuals therefore, it has been argued that increased aerobic fitness may directly improve mood (Blumenthal et al, 1999; Jorm et al, 2002; Knubben et al, 2007). Two randomized controlled trials showed an association between exercise and reduction of symptoms in patients with major depression (Blumenthal et al, 1999; Dun, 2005). Likewise a recent cross-sectional study reported an inverse relationship between depression and physical activity in a sample of Nigerian adolescents (Adeniyi et al, 2011).

1.2 Statement of the Problem

The increasing number of people diagnosed with depression and the reliance on drugs to manage this condition exposes patients to potentially harmful side effects, such as overweight, cardiovascular diseases, low self esteem, and more depression (Carta et al, 2008; Helmich et al, 2010). Weight gain is a common and well known adverse effect of antidepressant drug treatment (Desmukh and Franco, 2003; Schwartz et al,2007). This is because major depressive disorder carries significant risks of death and disability, and the first line of management is drug treatment

targeted at remission of major depressive disorder, at this stage weight gain is overlooked. But, before remission is achieved, medically significant weight gain would have occurred.

However, growing evidence shows that participation in physical exercise programme improves the mood of patient with major depressive disorder, and those with poor response to anti-depressant drugs (Knubben et al, 2007; Carta et al, 2008; Helmich et al, 2010; George et al, 2012). Physical exercise has also been reported to be necessary for successful weight control and maintenance (Powers and Howley, 2007) but, there is paucity of scientific evidence about the effect of exercise intervention on the body composition of patients with depression receiving antidepressant drug therapy, hence, the need for this study. The question then was: what would be the effects of a twelve week endurance exercise programme on selected clinical attributes and quality of life in patients with major depressive disorder?

1.3 Aims of Study

The aims of this study were to:

(i) Evaluate the effects of a twelve week endurance exercise programme on the body composition of patients with major depressive disorder.

(ii) Evaluate the effects of a twelve week endurance exercise programme on the cardio-respiratory fitness of patients with major depressive disorder.

(iii) Evaluate the effect of a twelve week endurance exercise programme on the quality of life of patients with major depressive disorder.

(iv) Evaluate the effect of a twelve week endurance exercise programme on the severity of depression in patients with major depressive disorder.

1.4 Hypotheses

1.4.1 Major Hypothesis

An endurance exercise programme would have no significant effect on the body composition, cardio-respiratory fitness, quality of life and severity of depression in patients with major depressive disorder.

1.4.2 Sub Hypotheses

(1) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body weight (BW) between the experimental and control group.

(2) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme percent body fat (PBF) between the experimental and control group.

(3) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme waist-hip-ratio (WHR) between the experimental and control group.

(4) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body mass index (BMI) between the experimental and control group.

(5) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme cardio-respiratory fitness index (CRFI) between the experimental and control group.

(6) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting heart rate (RHR) between the experimental and control group.

(7) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting systolic blood pressure (SBP) between the experimental and control group.

(8) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting diastolic blood pressure (DBP) between the experimental and control group.

(9) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme quality of life (QOL) between the experimental and control group.

(10) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by HRSD-17 (SOD1) between the experimental and control group.

(11) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by BDI-II (SOD2) between the experimental and control group.

(12) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body weight (BW) of the experimental group.

(13) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme percent body fat (PBF) of the experimental group.

(14) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme waist-hip-ratio (WHR) of the experimental group.

(15) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body mass index (BMI)l of the experimental group.

(16) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme cardio-respiratory fitness index (CRFI) of the experimental group.

(17) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting heart rate (RHR) of the experimental group.

(18) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting systolic blood pressure (SBP) of the experimental group.

(19) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting diastolic blood pressure (DBP) of the experimental group.

(20) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme quality of life (QOL) of the experimental group.

(21) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by HRSD-17 (SOD1) of the experimental group.

(22) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by BDI-II (SOD2) of the experimental group.

(23) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body weight (BW) of the control group.

(24) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme percent body fat (PBF) of the control group.

(25) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme waist-hip-ratio (WHR) of the control group.

(26) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme body mass index (BMI)l of the control group.

(27) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme cardio-respiratory fitness index (CRFI) of the control group.

(28) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting heart rate (RHR) of the control group.

(29) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting systolic blood pressure (SBP) of the control group.

(30) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme resting diastolic blood pressure (DBP) of the control group.

(31) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme quality of life (QOL) of the control group.

(32) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by HRSD-17 (SOD1) of the control group.

(33) There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise programme severity of depression assessed by BDI-II (SOD2) of the control group.

1.5 Delimitation

1.5.1 Participants

This study was delimited to participants diagnosed of major depressive disorder and certified fit for exrcise by a psychiatrist. To be eligible to take part in this study:

(1) Participants were 20 years and above; diagnosed to have major depressive disorder (Knubben et al, 2007).

(2) Participants without cognitive impairments and associated organic diseases (Mather et al, 2002; Knubben et al, 2007).

(3) Participants must have been receiving antidepressant drug treatment for at least six weeks (Blumenthal et al, 2007).

1.5.2 Outcomes

(1) Body composition indices measured were Body Weight (BW), Percent Body Fat (PBF), Waist- Hip- Ratio (WHR) and Body Mass Index (BMI),

(2) Cardio-respiratory indices measured were Resting Heart Rate (RHR), Resting Systolic Blood Pressure (SBP), Resting Diastolic Blood Pressure (DBP), and Cardio respiratory Fitness Index (CRFI).

(3) Quality of Life Scores (QOL) were measured with WHO-Five-Wellbeing-Index(WHO-5)

(4) Severity of depression was measured with Hamilton Rating Scale for Depression (HRSD-17) and Beck Depression Inventory (BDI-II).

1.6 Limitation

The following were experienced during the study:

1. Absence of a true no-treatment control group due to ethical reasons may have effect on the internal validity of the outcome of this study.
2. Medication adverse effects such as dizziness and sleep disturbance prevented some of the participants from completing the twelve-week study period and others from participating in the study.
3. Difficulties such as proximity and financial constraints prevented some participants from participating in the study.

1.7 Significance of Study

1. The outcome of this study has provided clinical and scientific evidence for the usefulness of endurance exercise programme as a mediative and adjunct modality, in the overall management of patients with major depressive disorders, especially in relation to body composition, cardiovascular risk factors and quality of life. This may be of importance to clinicians especially the Psychiatrists, Psychologists and

Physiotherapists involved in the management of patients with major depressive disorder.

2. The outcome of this study may stimulate more research into other benefits of endurance exercise in the overall management protocol of patients with major depressive disorder.

CHAPTER TWO

LITERATURE REVIEW

2.1.1 Introduction

Historical Background

The term depression was derived from Latin verb "deprimere" which means to press down (Etymology Dictionary, 2008). In the 14th century, to depress meant to subjugate or to bring down in spirits and referred to as a great depression of spirit by Richard Baker's chronicle in 1665 and by Samuel Johnson in a similar sense in 1753 (American Medical Network, 2012). An early usage of depression as a psychiatric symptom was by French psychiatrist, Louis Delasiauve in 1856, and by the 1860s it was appearing in medical dictionaries to refer to a physiological and metaphorical lowering of emotional function (Radden, 2003).

The experience of depression has plagued humans since the earliest documentation of human experience (Gruenberg et al, 2005). Ancient Greek description referred to a syndrome of melancholia, which translated from the Greek means black bile. This Greek tradition referred to melancholic temperament which is comparable to our understanding of early onset dysthymic conditions or depressive personality (Gruenberg et al, 2005). During the late 19th and early 20th centuries, phenomenologist increasingly used the term depression or mental depression to refer to the clinical syndrome of melancholia. In1921, Kraepelin, distinguished mood which was dejected, gloomy, and hopeless in the depressive phase of manic-depressive insanity from the mood which was withdrawn and irritable in paranoia. The term major depressive disorder was introduced by a group of United States of America clinicians in the mid - 1970s as part of proposals for diagnostic criteria based on patterns of symptoms and was Incorporated into the DSM -111 in 1980.

Depression has a range of meaning – from a description of normal unhappiness through persistent and pervasive ways of feeling and thinking to psychosis (NIMH, 2009). Depression has been defined as an emotional state manifested by sadness, discouragement, self-depreciation and at times, inability to act for self. It is regarded as the most prevalent mental disorders in the general population and it is a common and important cause of morbidity and mortality worldwide (Lawlor and Hopker, 2001).

Features and Forms of Depression

According to the ICD-10 (WHO, 1992), core features of depression include pervasive low mood, loss of interest and enjoyment (anhedonia), and reduced energy with diminished activity. Other features include poor concentration and attention, poor self esteem and self confidence, ideas of guilt and unworthiness, bleak or pessimistic views of the future, ideas or acts of self harm or suicide, disturbed sleep and diminished appetite. Most depressions have triggering life events, especially in a first episode. Many patients present initially with physical symptoms (somatisation). The presence of physical symptoms indicates a somatic syndrome (melancholic or endogenous depression) and some may show multiple symptoms of depression in the absence of low mood.

Depression is a heterogeneous disorder that has been characterized and classified in a variety of ways. According to the American Psychiatric Association's fourth edition (2005) of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), several diagnoses of affective disorders are possible. Major depression and dysthymia (minor depression) are pure depressive syndromes, whereas bipolar disorder and cyclothymic disorder signify depression in association with mania (National Institute of Mental Health (NIMH), 2011). A simplified classification based on presumed origin is as follows: (1) reactive or secondary depression (most common), occurring in response to real stimuli

such as grief, illness, (2) endogenous depression, a genetically determined biochemical disorder manifested by inability to experience ordinary pleasure or to cope with ordinary life events; and (3) depression associated with bipolar affective (manic-depressive) disorder (Potter and Hollister, 2001).

According to the National Institute of Mental Health (2011), There are several forms of depressive disorders, these are:

Major Depression (also known as major depressive disorder, recurrent depressive disorder, clinical depression and unipolar depression) is characterized by a combination of symptoms that interfere with a person's ability to work, sleep, study, eat and enjoy once pleasurable activities (NIMH, 2011). Major depression is disabling, has high suicide tendency, and prevents a person from functioning normally. Some people may experience only a single episode within their lifetime, but more often a person may have multiple episodes (NIMH, 2011).

Minor Depression: This is characterized by having depressive symptoms for two weeks or longer, that do not meet full criteria for major depression (NIMH,, 2011). People with minor depression without treatment are not at high risk of developing major depressive disorder.

Chronic Depression (Dysthymic depressive disorder): is characterized by long–term symptoms, at least two years or longer, that may not be severe enough to disable a person but can prevent normal functioning or feeling well (NIMH, 2011). People with dysthymic depression may also experience one or more episodes of major depression during their lifetimes (NIMH,2011).

Bipolar Depression (manic – depressive disorder): is characterized by cycling mood changes from extreme high to extreme low (NIMH, 2011). The elevated moods are clinically referred to as mania or if milder, hypomania. Individuals who experience manic episode also commonly experience depressive episodes or symptoms, or a mixed state in which features of both mania and depression are present at the same time (Basco, 2005).

2.1.2 Aetiology and Risk Factors of Depression

Depression is thought to result from disruption of normal brain neurobiochemistry (Remick 2002). Neurotransmitters travel between nerve cells through synapses and abnormally low levels of serotonin and norepinephrine in the synapse are linked to depression (Potter and Hollister, 2001). Risk factors for depression include childhood events and current psychosocial adversity, a history of depression, chronic medical illness, female sex, being single or divorced, general medical disorders, current or previous alcohol abuse, use of certain medications, and stressful life events. Others are lack of social support, prolonged or unresolved grief and postpartum fatigue or sadness (Geddes and Buttler, 2002). The risk of major depressive disorder is also increased with specific medical conditions related more to a poor outcome than to a better one (Richard, 2005; Alison, 2009).

2.1.3 Epidemiology of Depression

Depression is a major cause of morbidity worldwide (WHO, 2008). Lifetime prevalence (Table 1) varies widely, from 4.3% in Nigeria to 16.6% in the United States of America (Gureje, 2011). Population studies have consistently shown major depression to be about twice as common in women as in men (Murphy et al, 2000; Gureje, 2011). People are most likely to suffer their first depression episode between the ages of 30 and 40 years,

and there is a second smaller peak of incidence between ages 50 and 60 years (Eaton et al, 1997).

However, there was decreased age of onset since World War II (Gureje, 2011). Also, there is conflict in the literature on the prevalence in elderly, and most data suggest reduction in this age group (Jorm, 2000), but a survey in Nigeria revealed that depression was higher in the elderly with the lifetime prevalence of 32.9% in female, 21.2% in male and26.1% in the entire group (Gureje, 2011). While the 12-month prevalence in the female is 9.3%, in male 6.6% and7.8% in the entire group respectively.

Table 1: Lifetime and 12-month Prevalence rates of depression in Selected Countries

Countries	Lifetime Prevalence	12-Month Prevalence
NIGERIA	4.3	1.2
U.S.A	16.6	6.2
EUROPE	12.8	3.9
NEW ZEALAND	16.0	5.7
MEXICO	7.2	3.7

(Gureje, 2011).

Major depressive disorder carries significant risk of death and disability, and it is the commonest psychiatry illness that is responsible for suicidal acts (Renick, 2002; Gureje, 2011). About 15 % of patients with major depressive disorder eventually kill themselves, and at least 66% of all suicides are preceded by major depression (Dinan, 1999; Bostwick and Pankratz, 2000; Remick, 2002: Gureje, 2011). Generally, depressed patients have five folds increased risk of death, but in Nigeria depressed patients have 18 folds increased risk of death (Gureje, 2011).

Depression is more disabling than many common chronic physical conditions (Gureje, 2011); this is presented on table 2. It is the leading cause of disability and premature death among people aged 18 to 44 years, and it is expected to be the second leading cause of disability for people of all ages by 2020 (WHO, 2008). It also can result in increased work absenteeism, short–term disability and decreased productivity (Gonzalez et al, 2010.) In 2004, depression was the third leading cause of disease burden worldwide and a leading cause of disability in high–income countries (WHO, 2008). According to WHO (2008), by 2020, depression is expected to be second only to cardiovascular disease in disease burden. It ranks 7th among the 20 leading cause of disability, with a severity weight of 0.70 -1.00, and caused the largest amount of non – fatal burden, accounting for almost 12% of all total years lived with disability worldwide (WHO, 2008). The economic consequences were estimated at $ 83 billion in the United States of America in 2000 and E118 billion in Europe in 2004 (WHO, 2008).

Table 2: Proportions of Subjects in each Disorder group with a Global rating of Severity of Disability in the Ibadan Study of Ageing.

Disorder	Male (%)	Female (%)	Total (%)
Depression	58	39.7	47.2
Arthritis	18.5	22.6	20.6
Back/Neck Pain	23.1	25.0	24.2
HBP*	31.2	16.7	25.0
Asthma	0.00	17.6	13.6
Diabetics	0.00	14.3	10.0

*High Blood Pressure (Gureje, 2011).

2.1.4 Measurement of Depression

There are many scales for measurement of depression, this reflects the divergence of conceptual approaches to depression and also the fact that depression is a syndrome rather than a single entity (Bech, 2002). No one symptom is diagnostic of depression, and different people exhibit widely different symptoms. Hence, a measurement scale has to cover several dimensions, and it is the choice of coverage that distinguishes most scales (Bech, 2002).

Depression scales are divided into self-rating methods and clinician-rating scales, which correspond roughly to their use in epidemiological versus clinical studies (Bech, 2002). Self-rating outcome measures in psychiatry include Beck Depression Inventory, Zung Self-Rating Depression Scale, Geriatric Depression Scale, Depression Adjective Check Lists, Carroll Rating Scale for Depression and Center for Epidemiologic Studies Depression Scale. While clinician-rating scale include Hamilton Rating Scale for Depression. Montgomery–Asberb Depression Rating Scale and Bech-Rafaelsen Melancholia Scale (Bech, 2002).

Hamilton Rating Scale for Depression: The Hamilton Rating Scale for Depression (HRSD) is a clinician-rating scale for indicating the severity of depression in patient already diagnosed with a depressive disorder (Blumenthal et al, 1999). It is the most widely used clinical rating scale for depression (Blumenthal et al, 1999; Gedder and Buttler, 2002). It is also useful for monitoring changes in depressive symptoms during treatment and in comparing the efficacy of various interventions. The HRSD contains 21 ratings, 17 of which are measure on three (0 to 2) or five (0 to 4) point scale and are used

in scoring the instrument. Different versions of HRSD include the 17-items and the 24-item version; however, the 17-item is regarded as the definite and the most used version . Blumenthal et al, (1999), evaluated the interrater reliability of the 17-item HRSD and found the interclass correlation to be 0.96. There is a consensus for interpretation of the total scores: very severe >23; severe-19-22; moderate- 14–18; mild, 8–13; and no depression(normal)- 0-7.

The Beck Depression Inventory: The Beck depression Inventory (BDI-I) is a 21-item self-report questionnaire consisting of symptoms and attitudes relating to depression, 15 of which covers emotions, four cover behavioural changes and six cover somatic symptoms (Beck et al, 1996). It is the most widely used self-report outcome measure in assessing severity of depression (Blumenthal et al., 1999 and Gedder and Buttler, 2002). The Beck Depression Inventory Second Edition (BDI-II; Beck et al, 1996) is a 21-item self-report instrument intended to assess the existence and severity of symptoms of depression as listed in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV, 2005). This new revised edition replaces the BDI and the BDI-1A, and includes items intending to index symptoms of severe depression, which would require hospitalization.

Items have been changed to indicate increases or decreases in sleep and appetite, items labeled body image, work difficulty, weight loss, and somatic preoccupation were replaced with items labeled agitation, concentration difficulty and loss of energy, and many statements were reworded resulting in a substantial revision of the original BDI and BDI-1A (Beck et al, 1996). When presented with the BDI-II, a patient is asked to consider each statement as it relates to the way they have felt for the past two weeks, to more accurately correspond to the DSM-IV criteria. Each of the 21 items corresponding to a

symptom of depression is summed to give a single score for the BDI-II. There is a four-point scale for each item ranging from 0 to 3. On two items (16 and 18) there are seven options to indicate either an increase or decrease of appetite and sleep. Total score of 0-13 is considered normal range, 14-19 is mild, 20-28 is moderate, and 29-63 is severe.

Beck Depression Inventory has been used for 35 years to identify and assess depressive symptoms, and has been reported to be highly reliable regardless of the population (Beck et al, 1996). It has a high coefficient alpha, (.80) its construct validity has been established, and it is able to differentiate depressed from non-depressed patients. For the BDI-II the coefficient alphas (.92 for outpatients and .93 for the college students) were higher than those for the BDI- 1A (.8 6). The correlations for the corrected item-total were significant at .05 level (with a Bonferroni adjustment), for both the outpatient and the college student samples. Test-retest reliability was studied using the responses of 26 outpatients who were tested at first and second therapy sessions one week apart. There was a correlation of .93, which was significant at $p < .001$.

One of the main objectives of this new version of the BDI was to have it conform more closely to the diagnostic criteria for depression, and items were added, eliminated and reworded to specifically assess the symptoms of depression listed in the DSM-IV (American Psychiatric Association, 1994), and thus increase the content validity of the measure (Beck et al, 1996). With regard to construct validity, the convergent validity of the BDI-II was assessed by administration of the BDI-1A and the BDI-II to two sub-samples of outpatients (N=191). The order of presentation was counterbalanced and at least one other measure was administered between these two versions of the BDI, yielding a correlation of .93 ($p<.001$) and means of 18.92 (SD = 11.32) and 21.888 (SD = 12.69) the mean BDI-II score being 2.96 points higher than the BDI-1A. Consistent with the

comparison of mean differences, the BDI-II scores are 3 points higher than the BDI-1A scores in the middle of the scale. Factorial validity has been established by the inter-correlations of the 21 items calculated from the sample responses. The BDI-II is intended to assess the severity of depression in psychiatrically diagnosed adults and adolescents 13 years of age and older. It is not meant to serve as an instrument of diagnosis, but rather to identify the presence and severity of symptoms consistent with the criteria of the DSM-IV (American Psychiatric Association, 1994).

2.2.1 Management of Depression

Treatment of depression requires a compassionate, nonjudgmental attitude on the part of the physician. Initially, physicians need to educate patients about the illness concept of depression and to specifically tell them of their expectations for significant or full recovery (instillation of hope) (Remick, 2002). Treatment is aimed and generally results in improved mood, social and occupational functioning, reduced morbidity and mortality; to prevent recurrence of depressive disorder; and to minimize adverse effects of treatment, improve quality of life, enhance functional capacity, improvement in medical health status, increased longevity, minimal adverse effects of treatment and lower health care cost. (Gedder and Buttler, 2002; Birrer and Vemuri, 2004). Improvement should be evident as early as two weeks after the start of therapy, but full therapeutic effects may require several months of treatment. (Birrer and Vemuri, 2004).

The appropriate treatment of depression is of special interest to primary care physicians, who treat the majority of this illness. Although it is reassuring that both antidepressant medication and psychological treatments are effective for patients with mild to moderate disease, physicians are left with the practical consideration of choosing which therapy to use, knowing that neither has yet been shown to be superior (Spencer and Nashelsky, 2005). Individualizing the treatment decision requires consideration of local

psychotherapy resources, relative expense of treatments, insurance coverage, and response to past therapies (Spencer and Nashelsky, 2005). Gedder and Buttler (2002), in their review of randomized controlled trials found out that the addition of drug treatment to interpersonal or cognitive therapy is more effective than non-pharmacologic therapy alone or drug treatment alone in severe depression.

Antidepressant Drug Therapy: Therapy with an antidepressant agent is the preferred treatment in cases of moderate to severe depression. The rate of response to an antidepressant trial is about 60% and is close to 80% of therapy if a second drug is tried after an initial antidepressant drug failure (Remick, 2002).

Selective Serotonin Reuptake Inhibitors: The safety and side effect profiles of selective serotonin reuptake inhibitors (SSRIs) make them the drugs of choice for treating most types of depression (with or without psychotic features). Because dosage adjustments are not required as frequently with these agents as with tricyclic antidepressants or monoamine oxidase inhibitors (MAOIs), fewer office visits are necessary (Birrer and Vemuri, 2004). Examples include Sertraline (Zoloft), Sertraline (Zoloft), Paroxetine (Paxil), Fluvoxamine (Luvox) and Citalopram (Celexa).

Tricyclic Antidepressants: Most tricyclic antidepressants are thought to be equally effective in elderly and younger patients. Tricyclic antidepressants have a long and successful history in the treatment of depression. Some of the most commonly used agents in this class are desipramine (Norpramin) and nortriptyline (Pamelor). These agents have fewer anticholinergic side effects than amitriptyline (Elavil), doxepin (Sinequan), and imipramine (Tofranil), which generally should be avoided in elderly patients (Birrer and Vemuri, 2004).

Monoamine Oxidase Inhibitors: Although MAOIs are thought to be dangerous and difficult to use, drugs such as phenelzine (Nardil) are relatively safe and effective in older patients. A full therapeutic response can be achieved after five to seven weeks of treatment. Hypotension, hypertension, and food-drug interactions are the most likely problems with MAOI use (Birrer and Vemuri, 2004).

Electroconvulsive Therapy: Electroconvulsive Therapy (ECT) is a very effective treatment for major depression (Jorm et al 2002). A typical course of ECT is 6 to 12 treatments, with 2 to 3 treatments given per week. Improvement is typically noted after the fourth treatment. ECT should be considered a first-line treatment in depressed patients with psychotic features, actively suicidal patients and patients who have not responded to or cannot tolerate antidepressant chemotherapy (Jorm et al, 2002).

Cognitive Behavioural Therapy: Cognitive Behaviour Therapy is a treatment intervention with documented efficacy. Cognitive behaviour therapy requires specialized training, can be administered individually or in a group setting, and typically require about 8 weekly sessions for efficacy (Remic, 2002). Rupke et al (2006), also showed that cognitive therapy is as effective and possibly more effective than pharmacotherapy in managing mild to moderate unipolar depression.

Exercise Therapy: There is evidence that exercise is beneficial for mental health; it reduces anxiety, depression, and negative mood, and improves self-esteem and cognitive functioning (Callaghan, 2004). Exercise is also associated with improvements in the quality of life of those living with psychiatric illnesses (Callaghan, 2004). Several randomized controlled trials have shown that physical activity improves the mood of patients with mild to moderate depression after several weeks and both aerobic and

anaerobic exercises have antidepressants effects (Singh et a,l 1997; Blumenthal et al, 1999; Mather et al, 2002)

2.3.1 Overview of Body Composition

Body composition is the term used to describe the different components that, when taken together make up the human body weight (Quinn, 2011). These are the lean tissues made up of muscles, bones and organs; the fat adipose tissues made up of essential fat, storage fat and non essential fat; and the elemental component made up of water, macro-elements and micro – elements (Quinn, 2011). Standard body weight scales provide a measure of total body weight, but do not determine the lean – to - fat ratio of the weight. There are many methods of assessing human body composition based on various models (Pietrobelli et al, 2001; Powers and Howley, 2007).

2.3.2 Models of Body Composition Assessment

Four–component Model: This model uses information on mineral, water, protein and fat to assess body composition. The measurements of each of these components allow one to account for variations in bone density and total body water (Powers and Howley, 2007).

Three–component Model: This model divides the body into body water, protein and mineral, and fat or body water and protein, mineral, and fat. The three – component model also allows one to account for variations in either bone density or body water and improve estimates of body fatness (Powers and Howley, 2007).

Two–component Model: This is the oldest model, which divides the body into two components: the fat mass and the fat – free mass. Although it is still the most commonly used approach to estimate percent fat, the assumptions underlying this model have been questioned, but the limitations of the two – component model have been addressed by the three and four component models (Powers and Howley, 2007).

2.3.3 Methods of Assessing Body Composition

The following is a summary of techniques providing information about the composition of the whole body and change in specific tissues of the body:

Isotope Dilution: In this method, total body water is determined by isotope dilution. A subject drinks an isotope of water that is distributed throughout the body water. After three to four hours of distribution of the isotope, a sample of body fluid (serum or saliva) is obtained and concentration of the isotope is determined. The volume of total body water is obtained by calculating how much body water would be needed to achieve that concentration. A person with a high volume of body water will dilute the isotope to a greater extent. In essence, people with high total body water volumes posse more lean tissue and less fat tissue, so that total body water can be used to determine body fatness (Powers and Howley, 2007).

Photo Absorptiometry: This method is used to determine the mineral content and density of bones. A beam of photons from iodine – 125 is passed over a bone, and the transmission of the photon beam through bone and soft tissue is obtained, the higher the absorption of the photons, the higher the mineral density and the lean tissue (Powers and Howely, 2007).

Potassium – 40: Potassium is located primarily within the cells, along with a naturally occurring radioactive isotope of potassium (^{40}K). The ^{40}K can be measured in a whole-body counter and is proportional to the mass of lean tissue (Power and Howley, 2007).

Hydrostatic (underwater) Weighing: Water has a density of about 1g/ml, and body fat with a density of about 0.900g/ml, will float in water. Lean tissue has a density of about 1.100 in adults and will sink in water. Whole body density provides information about the portion of the body that is lean and fat. Underwater weighing methods are commonly used to determine body density and the subsequent volume (Powers and Howley, 2007).

Dual Energy X-ray Absorptiometry (DEXA): In this new technology, a single x – ray source is used to determine whole – body and regional estimates of lean tissue, bone, mineral, and fat with a high degree of accuracy. The software required for this process continues to be refined, and DEXA is expected to play a major role in the future of body composition analysis (Van Loan, 1995; Powers and Howley, 2007).

Near Infrared Interactance (NIR): This method is based on the absorption of light, reflectance, and near infrared spectroscopy (Powers and Howley, 2007). A fibre-optic probe is placed over the biceps and an infrared light beam is emitted. The light passes through subcutaneous fat, muscle and is reflected by bone back to the probe. Generally, there has been little interaction between scientist and the manufacturers on the development and validation of this type of device. Recent studies suggest that this technology has a way to go (Bray and Atkinson, 1992; Mclean and Skinner, 1992, Powers and Howley, 2007).

Radiography: This method is based on the use of X-ray to measure the width of fat, muscle and bone. The measured fat width can be used to estimate total body fat (Power and Howley, 2007).

Ultrasound: In this method, sound waves are transmitted through tissues and the echoes are received and analysed. This technique is used to measure the thickness of subcutaneous fat (Brodie, 1998; Powers and Howley, 2007).

Nuclear Magnetic Resonance (NMR): This method is based on the use of electromagnetic waves transmitted through tissues. The waves are absorbed and then release energy at a particular frequency which is analyzed by computer to provide detailed images, then volumes of specific tissues can be calculated (Powers and Howley, 2007).

Total Body Electrical Conductivity (TOBEC): This method is based on the fact that lean tissues and water conduct electricity better than fat tissue. In using this method, the subject lies in a large cylindrical coil which develops electromagnetic field in the space enclosed by the cylindrical coil and this is affected by the subject's body composition (Power and Howley, 2007).

Air Displacement Plethysmography: This method uses body volume measurement obtained via air displacement plesthysmography, in contrast to water displacement that is used in hydrostatic weighing. The volume obtained can be used to calculate fat mass (Millard et al, 2001).

Skinfold Thickness: In this method, an estimate of total body fatness is made from a measure of subcutaneous fat. A number of skin fold measurements will be made to calculate body density (Power and Howley, 2007).

Bioelectrical Impedance Analysis (BIA): In this method, electrical current of about 50uA usually set at a frequency of 50kHz is applied to the extremities. The resistance to that current due to the specific resistivity and volume of the conductor (fat free mass) is measured Then, total body water is calculated, and the value can be used to estimate percent body fatness (Powers and Howley, 2007).

Some of these procedures are expensive in terms of personnel and equipment (e.g, potassium 40, TOBEC , Radiography, Ultrasound, NMR, DEXA, TBW) and are not used on a routine basis for body compassion analysis. Bioelectrical impedance analysis (BIA) has gained greater acceptance in the past few years, due to collaborative multi university research projects that showed it to be comparable to skinfold estimates of body fatness in men and women (Wagner and Heyward, 1999; Powers and Howley, 2007). The data from these techniques can be used alone or in combination to provide an assessment of body composition (Powers and Howley, 2007).

2.4.1 Effects of Antidepressant Drugs on Body Composition

Weight gain is a common and well–known adverse effect of short and long term antidepressant drug treatment (Deshmukh and Franco, 2003; Schwartz et al, 2007; Helmich et al, 2010). The weight gain is frequently overlooked because focus is on remission of depression (Shwartz et al, 2007). Two–third of patients with major depression present with weight loss, gaining weight can be associated with successful

treatment (Schwartz et, al 2007). Weight gain during antidepressant drug treatment is of serious concern and is drug-induced (Deshmukh and Franco, 2003; Schwartz et al, 2007). Weight gain during antidepressant treatment may be as early as the first week, predicting future weight gain (Schwartz et al, 2007). According to Laimer et al, (2006) antidepressant drug treatment was found to be associated with significant increase in body weight and body fat mass in six week.

2.4.2 Mechanism of Weight Gain as an Adverse Effect of Antidepressant Drug Treatment

Appetite is controlled by cultural, psychological neurochemical and metabolic factors. Among neurochemical factors, serotonin helps to regulate appetite and is the neurotransmitter most often manipulated in depression treatment (Schwartz et al, 2007). Serotonin receptor agonists have acute anorexigenic effect. For instance in rats, 5–HT2c receptors agonism decreases eating behaviour and mice lacking 5–HT2c receptors are obese (Curzon et al, 1998).

Also antidepressant drug treatment might increase serotonin in the synaptic cleft, allowing 5-HT2c receptor down–regulation that is slower than, but, similar in effect to the acute 5-HT2c pathway blockade (Schwartz et al, 2007). Antidepressant drugs have high affinity for blocking histaminergic (H2, 5HT2A, 5HT2c, 5HT3) receptors which have been associated with carbohydrate craving, low satiety rates and increased calorie intake (Schwartz et al, 2007). This may explain why antidepressant drugs pose the risk of weight gain.

2.5.1 Physical Fitness

Physical fitness is the ability of an individual to carry out and last on his activities of daily living without undue fatigue but with adequate vigour to carry out his leisure time pursuits and be able to take on unforeseen emergencies (Sanya, 2010). Both men and

women who reported increased levels of physical activity and fitness were found to have reductions in relative risk of mortality and morbidity of many diseases including but not limited to coronary heart disease, hypertension, type-2 diabetes, obesity, osteoporosis and depression (Pollock and Wilmore, 1990; Warbutton et al, 2006).

Physical fitness can be classified in terms of health-related and performance related components. Health related physical fitness is defined by those components related to health such as cardiovascular endurance, muscular strength, muscular endurance, flexibility and body composition (Anspaugh, 1997). Performance related physical fitness also referred to as sports fitness is described by those components related to performance such as speed, agility, power, coordination, balance and reaction time (Anspaugh, 1997). The health related components are of utmost importance because they make a person fit for life (Anspaugh, 1997).

2.5.2 Assessment of Physical Fitness

The exercise tests used to evaluate cardio-respiratory fitness may require a sub-smaximal or maximal effort by the subject. They may be conducted in a laboratory containing sophisticated equipment or on a running track with nothing more than a stopwatch (Powers and Howley, 2007). In sub-maximal graded exercise testing heart rate is measured at each stage of the test that progresses from light work to predetermined end point, such as 70-85% of predicted maximal heart rate. A treadmill, the bicycle ergometer, or a step bench can be used to impose the work rates (Powers and Howley, 2007). Another walk test used to evaluate cardio-respiratory fitness is the one-mile walk test. This test appears to fill a void in the field tests available to estimate cardio-respiratory fitness, since it uses a common activity and requires the simple measurement

of heart rate (Kline, 1987). The participant walks as fast as possible for one mile on a flat, measured track, and heart rate is measured in beats per minute at the end of the last lap. As a participant's fitness improves, the time required for the one mile and/or the heart rate response decreases (Powers and Howley, 2007).

2.6.1 Endurance Training

Endurance, as a measure of fitness is the ability to resist fatigue. It includes muscular endurance and cardiovascular endurance (Kisner and Colby, 2002). Muscular endurance refers to the ability of an isolated muscle group to perform repeated contractions over a period of time, whereas cardiovascular endurance refers to the ability to perform large muscle dynamic exercise for long periods of time (Kisner and Colby, 2002). Endurance training is dependent on exercise of sufficient intensity, duration and frequency. It produce a cardiovascular and/or muscular adaptation and is reflected in an individual's endurance. Walking, bicycling, and jogging are common modes of endurance training.

2.6.2 Considerations in Prescribing Exercises

Exercise prescription consists of the amount (dosage) of exercise and comprises of four factors which are intensity, frequency, duration and mode. The purpose of exercise prescription is to provide a level of exercise that is safe and that will enhance physical fitness, particularly cardiovascular function (Kisner and Colby, 2002). The prescription takes into account the individual's present physical function and adjusts the intensity, duration and frequency of exercise accordingly. The mode of exercise is important to ensure that activities are enjoyable as well as beneficial, which helps to ensure long term adherence (Kisner and Colby, 2002).

2.6.3 Efficacy of Endurance Exercises in Management of Depression

The potential use of aerobic exercise as an alternative or complementary treatment for depression has received considerable attention. Exercise may provide a feeling of body control, help to release anger and hostility, and distract patients from depressive thoughts (Knubben et al, 2007). Studies of young, middle-aged adults and elderly people suggest that aerobic exercise is superior to placebo or to no treatment and is better than or equal to other treatments, including psychotherapy or occupational therapy, in reducing depressive symptoms (Blumenthal et al, 1999; Mather et al 2002, Brosse et al, 2002; Knubben et al, 2007). Psychologically based explanations suggest that, exercise might interrupt dysfunctional thoughts, serve to distract negative thoughts, or, if the exercise programs are supervised or conducted in groups, increase social interaction (Jorm et al, 2002). Exercise may increase levels of the monoamine neurotransmitters that mediate stress and depressive reactions (Jorm et al, 2002).

In a study by McCann and Holmes (1984), forty-three depressed women were randomly assigned to either an aerobic exercise treatment condition and a placebo treatment condition, in which they practiced relaxation exercises, or a no-treatment condition. Aerobic capacity was assessed before and after the 10-week treatment period. Self-reported depression was assessed before, during and after the treatment period. The results indicated that subjects in the aerobic exercise condition evidenced reliably greater improvements in aerobic capacity than the subjects in either of the others, and that the subjects in the aerobic exercise condition evidenced reliably greater decreases in severity of depression than the subjects in the placebo condition or subjects in the no-treatment condition.

Blumenthal et al, (1999), in a study to assess the effectiveness of an endurance exercise program compared with standard antidepressant medication for treatment of depression, conducted a 16-week randomized controlled trial. One hundred and fifty-six men and women with major depressive disorder were assigned randomly to a program of aerobic exercise, antidepressants drug treatment, or combined exercise and medication. After 16 weeks of treatment, the groups did not differ statistically on Hamilton Rating Scale for Depression (HSRD-17) and Beck Depression Inventory (BDI).

In another randomized controlled trial, to investigate the effect of physical exercise on depressive state by Nabkasorn et al, (2006), forty-nine female volunteers (aged 18-20 years; mean 18.8 $\pm$ 0.7 years) with mild-to-moderate depressive symptoms, as measured by the Centre for Epidemiologic Studies Depression (CES-D) scale, were randomly assigned to either an exercise regimen or usual daily activities for eight weeks. The subjects were then crossed over to the alternate regimen for an additional eight-week period. The exercise program consisted of 50-minutes sessions per week of a group jogging and training at a mild intensity scores. After the sessions of exercise the CES-D total depressive score showed a significant decrease, whereas no effect was observed after the period of usual daily activities.

Babyak et al, (2000), conducted a study to assess the status of 156 adult volunteers with major depressive disorder 6 months after completion of a study in which they were randomly assigned to a 4-month course of aerobic exercise, antidepressant drug therapy, or a combination of exercise and antidepressant drugs. The presence and severity of depression were assessed by clinical interview using the Diagnostic Interview Schedule and the Hamilton Rating Scale for Depression (HRSD) and by self-report using the Beck

Depression Inventory. Assessments were performed at baseline, after 4 months of treatment, and 6 months after treatment was concluded (i.e. after 10 months). After 4 months patients in all three groups exhibited significant improvement; the proportion of remitted participants (i.e. those who no longer meet diagnostic criteria for MDD and had an HRSD score >8) was comparable across the three treatment conditions. After 10 months, however remitted subjects in the exercise group had significantly lower relapse rates (p = .01) than subjects in the medication group.

A study by Blumenthal et al, (2007), was aimed at assessing whether patients receiving aerobic exercise training performed either at home or in a supervised group setting achieve reductions in depression comparable to standard antidepressant medication and greater reductions in depression compared to placebo controls. After four months of treatment, 41% of the participants achieved remission, defined as no longer meeting the criteria for Major Depressive Disorder (MDD) and a HRSD score of <8. Patients receiving active treatments tended to have higher remission rates than the placebo controls: supervised exercise = 45%; home based exercise = 40%, medication = 47%, placebo = 31% (p = .057). All treatments groups had lower HRSD scores after treatment; scores for the active treatment groups were not significantly different from the placebo group. They concluded that, the efficacies of exercise in patients seem generally comparable with patients receiving antidepressant medication and both tend to be better than the placebo in patients with major depressive disorder.

2.7.1 Quality of Life in Patients with Major Depressive Disorder

Quality of life has been defined as a patient's general well –being, including mental status, stress level, sexual function and self –perceived health status. (Stedman, 2006). While health – related quality of life is a broad multidimensional concept that usually includes self reported measures of physical and mental health (Center for Disease Control, 2012). Most definitions explicitly state that the assessment of quality of life should take into account patient's subjective views of their life circumstances (Mendlowicz and Stein, 2000). These include perceptions of social relationship, physical health, functioning in daily activities and work, economic status and over-all sense of well being.

Moreover, measures of functioning focus on objective, quantifiable impairment that exist, while measures of quality of life assess enjoyment and life satisfaction associated with various activities. Evidence is accumulating that major depressive disorder is associated with poorer quality of life than community comparison cohort (Pyne et al, 1997; Rapaport et al, 2005). Also studies reported greater impairment in quality of life for major depressive disorder than other affective disorders (Schonfeld et al, 1997; Olfson et al, 1997; Rapaport et al, 2005).

CHAPTER THREE

MATERIALS AND METHODS

3.1.0 Materials

3.1.1. Participants

Participants for this study were 90 patients with major depressive disorder (MDD). They were diagnosed by psychiatrists and recruited from the Federal Neuro-psychiatric Hospital Yaba, (FNPH) and Lagos University Teaching Hospital (LUTH), Idi-Araba, Lagos State. The participants comprised of 72 females and eighteen (18) males, randomly assigned into experimental group (EG) and control group (CG) respectively. Their ages ranged between 20 and 70 years.

3.1.2 Inclusion Criteria for this study were:

1. The participants were patients with major depressive disorder (MDD)

2. The ages of participants were between 20 and 70

3. Participants were certified fit for exercise programme by a psychiatrist

4. Participants have received antidepressant drug therapy for at least six weeks

5. Participants were able to walk independently.

Those who met these criteria and willing to participate were recruited for this study.

3.1.3 Exclusion Criteria for this study were:

1. The patients who refused to volunteer and give consent to participate.

2. Patients with associated organic diseases, (Schizophrenic symptoms and epilepsy) and cardiovascular diseases (Hypertension and Heart failure) were excluded from this study.

3.1.4 Instruments

1. **Weighing Scale:** A portable digital weighing scale of the Omron BF511 brand calibrated in kilograms (0-150), was used to measure weights of the participants to the nearest 0.1 kilogramme.
2. **Height Meter:** A height metre (SECA-model 220, made in Germany) was used to measure height of participants in centimeters, was converted and recorded in the nearest 0.1 meter. It has a range of 0-200 centimetres.
3. **Tape Measure:** A non-elastic measuring tape (Butterfly brand, China) was used to measure the waist girth and the hip girth of the participants; it is calibrated from 1 to 150 centimetres. Obtained values were recorded to the nearest 0.1cm.
4. **Hamilton Rating Scale for Depression:** (Appendix 1) The HRSD is a 17-item clinical rating scale used to evaluate severity of depression. Each item has possible multiple responses with scores for each response. A score of 7 indicates none/minimal depression, 8-17 indicates mild depression, 18-25 indicates moderate depression and a score of over 26 indicates severe depression. HRSD-17 was administered at baseline and every two weeks for twelve weeks of the study.
5. **Beck Depression Inventory:** (Appendix 2) The BDI-II is a 21-item self-report questionnaire used to screen for depression. The items are usually summed in a total score; higher numbers indicate greater depression with a range of 0 to 63. Total score of 0 to 10 are regarded as normal, 11 to 16 as mild depression, 17 to 20 indicate borderline depression, 21 to 30 indicate moderate depression, 31 to 40 indicate severe depression and a score of over 40 indicate extreme depression (Beck, 1961). It was administered at baseline and every two weeks for twelve weeks of the study.

6. **Quality of Life Outcome Measure:** The WHO-five well being index was used to assess quality of life of participants prior to the beginning of the exercise training programme and every two weeks for twelve weeks of the study. (Bech, 2001).
7. **Bicycle Ergometre:** A stationary bicycle ergometer (Dynamix E-100 exerbike, made in England) was used for bicycle exercise programme.
8. **Stopwatch:** A stopwatch (Professional Quartz Timer) was used for timing during the assessment of cardio-respiratory indices and circuit exercise duration.
9. **Digital Automatic Blood Pressure Monitor:** A digital automatic blood pressure monitor (Motech True scan, Germany) was used to measure blood pressure and heart rate of the participants.
10. **Body Composition Monitor:** A body composition monitor (Omron BF 511) by Omron Healthcare Europe was used to estimate the percentage body fat of participants.
11. **Stairway:** A stationary wooden stairway, with rungs of variable heights was used for stair climbing exercises.
12. **Exercise Mat:** Participants used mats for exercises in lying position.
13. **Digital Music Box:** A music box player (Sony) with 4GB memory capacity was used to provide background music for the participants during exercise sessions.

3.1.5 Venue

The research was conducted in the Physiotherapy gymnasium of Federal Neuro-psychiatric Hospital Yaba, Lagos State.

3.2 Methods

3.2.1 Sample Size and Sampling Technique

Sample size calculation:

The minimum sample size was determined using the formula according to Cohen (1988):

$$N = \frac{n(Z_1 + Z_2)^2}{(ES)^2}$$

Wher N= sample size, n= number of group

$Z_{1=}$ standard normal distribution for statistical significance level usually set at 1.96 which corresponds to 95% confidence level.

Z_2= power level. The power of this study will be 0.8416 which corresponds to 80%.

ES = effect size, where medium ES = 0.5

$$N = \frac{2\,(1.96 + 0.84)^2}{(0.5)^2} = \frac{2\,(7.84)}{0.25} = 62.72$$ (Cohen, 1988).

Therefore, the minimum sample size estimated for this study in each group was 32 and total was approximately 64 participants. However, ninety (90) participants were recruited for this study.

Sampling Technique: Consecutive sampling technique was employed for this study.

3.2.2 Research Design

This study applied a quasi- experimental design with pre and post test control group.

3.3.3 Procedure for Data Collection

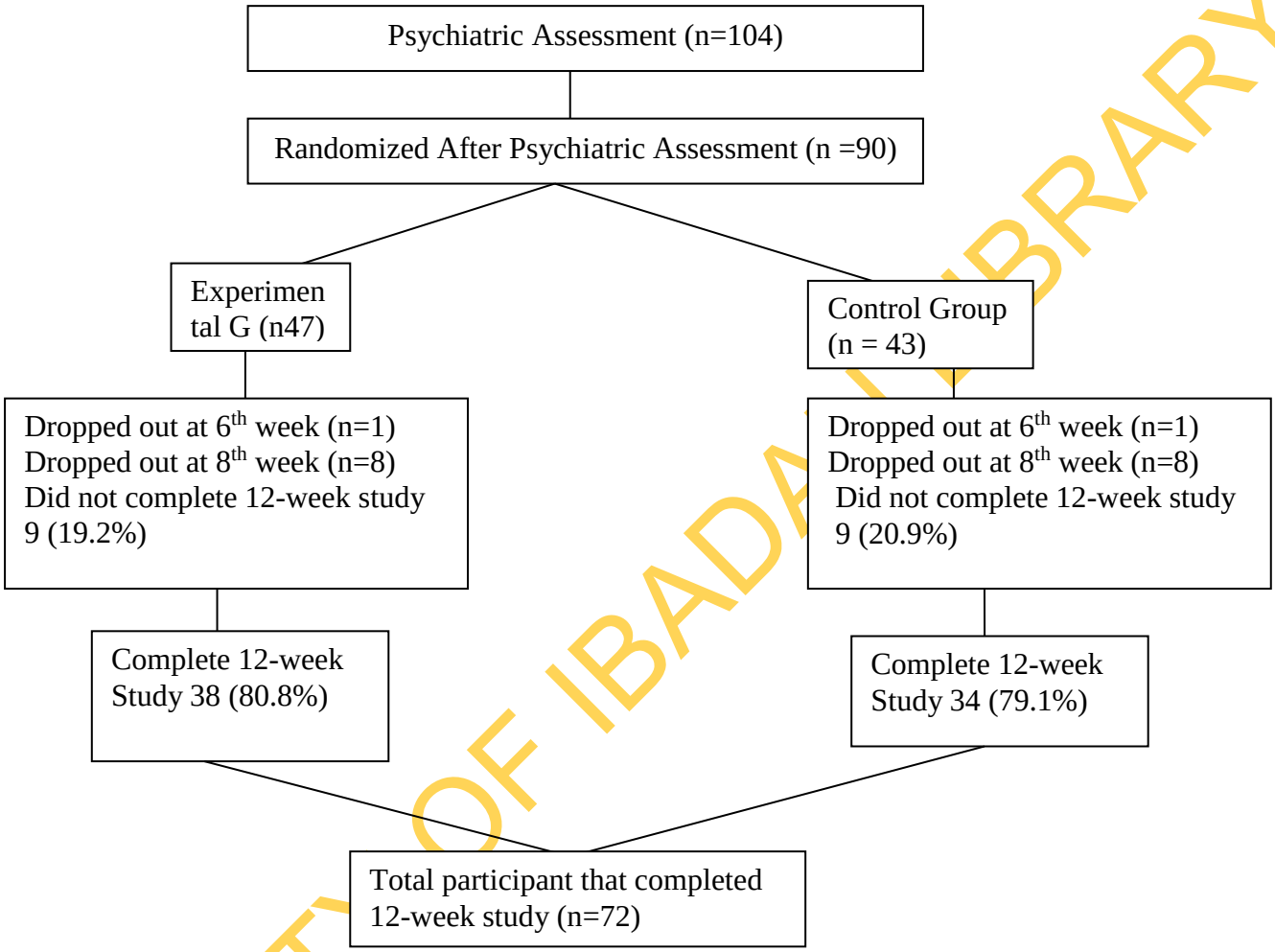

Figure 1. Flow Chart of Study Participation

Ethical approval was sought and obtained from the Federal Neuro-psychiatric Hospital Research Ethics Committee, Lagos University Teaching Hospital Research Ethics Committee, and University of Ibadan/ University College Hospital (UI/UCH) Health Research Ethics Committee. Also, Informed consent was sought and obtained from each participant and two cases of proxy informed consent by the relatives of participants were recorded, after the objectives and procedure of the study were clearly explained to each of them. Furthermore, their confidentiality was assured and safety ensured. They were also assured of their withdrawal from the study at anytime during the study.

There were two groups namely: the Control Group (CG) and the Experimental Group (EG). Each participant was randomly allocated to either of the two parallel groups after psychiatric assessment, using a simple random technique, where only the first participant picked from the randomization box to determine the group of the next participant in the order of patients' referral. For instance, if the first participant picks CG from the randomization box then the next participant is automatically assigned to EG or vice-versa. History and initial assessment of major depressive disorder and antidepressant drug usage was done for every participant. They were instructed to continue with their antidepressant drug. Also, participants were monitored for regular usage and dosage of antidepressant drug.

Control Group: Demographic and baseline data of participants were recorded as participants were being registered for the study, during their first visit. Each participant in this group carried out relaxation exercises twice in a week for twelve (12) weeks. The relaxation exercise included deep breathing, while at the same time tensing and relaxing different muscle groups of the upper limbs, abdomen and lower limbs in supine lying.

Body composition indices, cardio-respiratory indices, severity of depression, and quality of life were assessed at the baseline, and end of every two weeks for twelve weeks of the study.

Experimental Group: Demographic and baseline data of participants were recorded as participants were being registered for the study for the first time. This group participated in an endurance exercise programme in addition to relaxation exercises for twelve weeks. Measurement of body composition, cardio-respiratory fitness, severity of depression, and quality of life were taken at the baseline, and end of every two weeks for twelve weeks of the study. The severity of depression and quality of life of all the participants were rated by two psychiatrists, using concealment of allocation.

Precautions/Safety Measures

(a) Objects capable of self injury were kept away from the participants

(b) The accident and emergency centre of Federal Neuro-psychiatric Hospital Yaba Lagos was adequately informed about study days so as to prepare and rapidly respond to any emergency during the study.

(c) The body composition monitor was not used when the body and/or feet of participants were wet to avoid underestimation of percent body fat.

(d) Mobile phones and other electromagnetic devices were kept away to at least a distance of 7m from the monitor to prevent incorrect operation of the unit (Omron Healthcare, 2011).

(e) Participants were instructed to stand bare-footed on the main unit of the body composition monitor to ensure adequate sensitivity of the foot electrodes (Plate 1).

(f) Participants were constantly reminded not to eat when ready to engage in endurance exercise to prevent fainting attack.

Measurement of the Parameters

At the commencement of the study the following measurements were taken:

(a) Height: Each participant stood bare-footed, head straight and with his/her back and heel against the graduated height meter. The horizontal projection from the scale was brought into light contact with the vertex of the head of the subject and the height measurement was taken and recorded in centimeters and later converted to meters (NHANES-III Anthropometry Manual, 1998).

(b) Body Weight: Each subject was in light clothing without foot wear. Each subject stood on the weighing scale bare-footed and arms by his sides while looking straight ahead. The researcher then read off the weight of the participant in kilogramme (Omron Healthcare, 2011).

(c) Percent Body Fat: This was assessed with the aid of the Omron BF511 body composition monitor which measure the percentage of fat contained in the human body, through the bioelectrical impedance analysis (BIA) method. Personal data of the participants including height, weight, age and sex were input through appropriate keys into the monitor. The participant stood with bare feet slightly apart on the foot electrodes. The grip electrodes were held by wrapping the middle finger around the groove of the handle of the fat-o-meter. The shoulders were flexed to 90 degrees with the elbow straight while the participant stood still. The start button was then pushed in, after a few seconds, the fat percent was indicated on the display screen of the monitor (Plate 1).

(d) Blood Pressure: After the participant sat comfortably on a chair at a table, the cuff was wrapped to the upper arm and the start button was pushed then the cuff automatically inflated. Resting blood pressure and resting heart rate were automatically measured by oscillometric method and completed measurements displayed on the LCD display where the values of the blood pressure and resting heart rate were read and recorded (Motech True scan, 2010).

(e) Hip Circumference: The participant stood with the feet together. The maximum girth around the buttock, at the trochanteric level was measured using a tape measure (McArdle, 2002).

(f) Waist Circumference: The participant stood with the feet together. The minimum girth around the waist, which in some subjects could correspond to the abdominal girth, was measured with the aid of a tape measure (McArdle, 2002).

(g) Waist Hip Ratio: This was calculated using the formula; waist circumference divided by hip circumference (Wilmore and Costill, 2004).

PLATE 1: Assessment of Body composition indices using body composition monitor (Omron BF511).

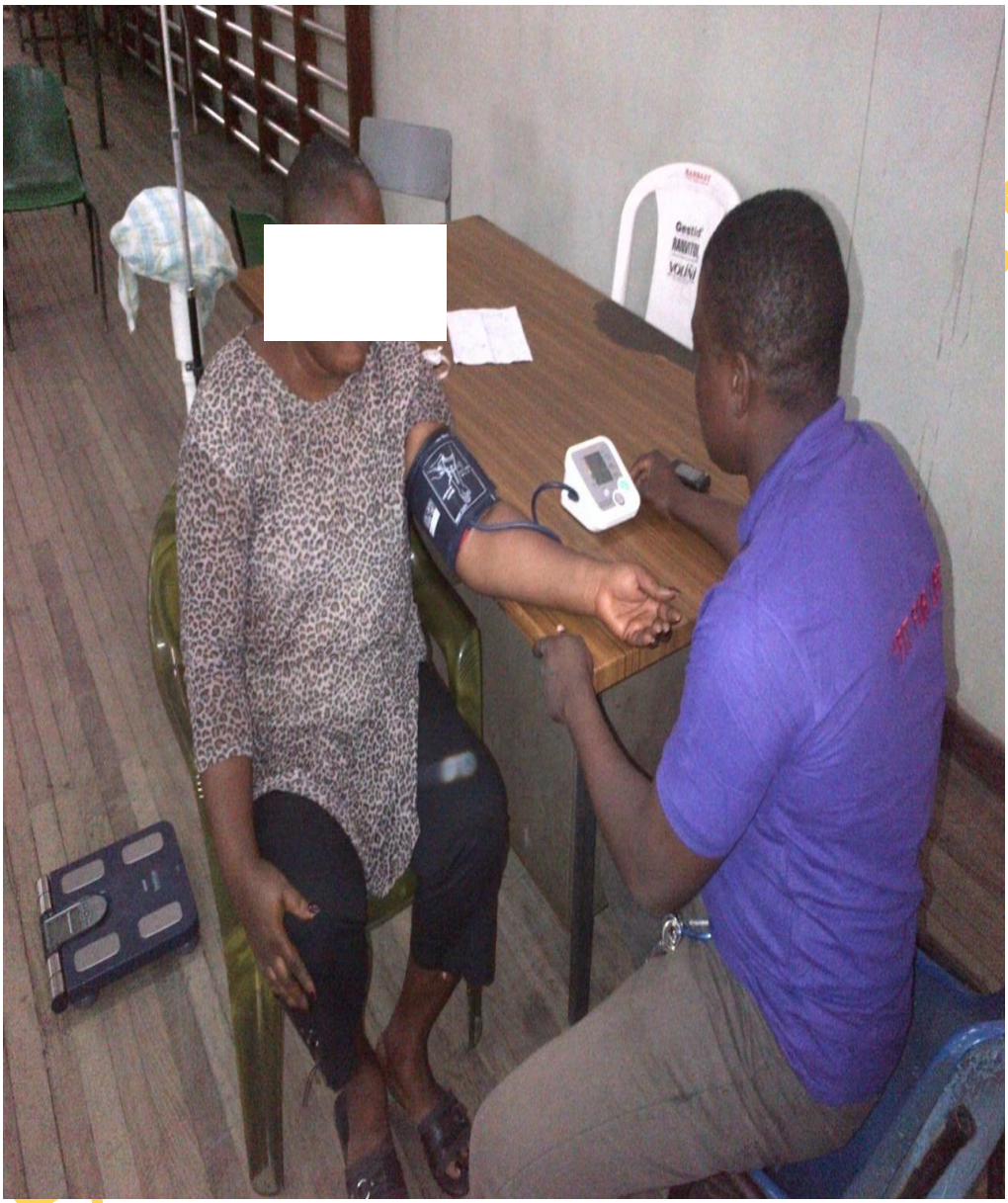

PLATE 2: Assessment of resting of blood pressure using automatic digital blood pressure monitor

(h) Cardio-respiratory Fitness Index (CFRI): This was measured using the one-mile walk test in which the heart rate is measured during the test (Kline, 1987; Powers and Howley, 2007). The participant walked as fast as possible for one mile on a flat, measured track, and the heart rate was measured at the end of the last lap. As a participant's fitness improves, the time required for the one mile and/ or the heart rate response decreases (Kline, 1987; Powers and Howley, 2007).

(i) Severity of Depression: Severity of depression was assessed by a consultant Psychiatrist with the Hamilton Rating Scale for Depression (HRSD-17) and Beck Depression Inventory (BDI-II). The HRSD is a 17-item clinical rating scale used to evaluate severity of depression. A score of 0-7 indicates none depression, 8-17 indicates mild depression, 18-25 indicates moderate depression and a score of over 26 indicates severe depression. HRSD-17 was administered at baseline and after every two weeks for twelve weeks study period. The BDI is a 21-item self-report questionnaire used to evaluate severity of depression, the items are summed in a total score; higher numbers indicate greater depression with a range of 0 to 63. It was also administered at baseline and after every two weeks for twelve weeks of the study.

(j) Quality of Life: The WHO-Five Well-being Index was used to assess quality of life of participants at baseline and after every two weeks for twelve weeks of the endurance exercise programme. The WHO-Five Well-being Index was derived from a larger rating scale developed for a WHO project on quality of life (Bech, 1996). Because positive psychological well-being has to include positively worded items only, the original 10 items were then reduced to five items (WHO-Five) which still covered positive mood (good spirits, relaxation), vitality (being active and waking up fresh and rested), and general interests (being interested in things) (Bech , 1996). Each of the five items is rated on a 6-point Likert scale from 0 (= not present) to 5 (=

constantly present). The theoretical raw score ranges from 0 to 25 and is transformed into a scale from 0 (worst thinkable well-being) to 100 (best thinkable well-being). Thus, higher scores mean better well-being. A score below 13 indicates poor well-being and is an indication for testing for depression under ICD-10.(WHO, 1992). In order to monitor possible changes in quality of life, the percentage score is used. The percentage value is obtained by multiplying the score by 4. A 10% difference indicates a significant change (WHO, 1998).

Pilot Study

A pilot study was conducted before the main study was commenced. The pilot study was to reveal the workability of methodology and the ability of the participants to cope with the exercise. It was discovered that participants were complaining about the tasking nature of the stepping exercise. However, the participants were more interested in the walking exercise, hence, a modification was introduced. The stepping station was replaced with walking exercise station.

3.2.4 Intervention

Endurance Exercise Programme

A familiarization session was held with participants randomly assigned to the EG before the commencement of the endurance exercise programme, to demonstrate the entire endurance exercise protocol to the participants by the researcher. Also, there was discussion and question about the general health status of participants. At the beginning of each exercise training session, participants were allowed to rest for at least 10 minutes after which their resting heart rate and blood pressure were

measured in sitting position. The exercise commenced with a warm up session, that lasted for five minutes.

Warm-up: Exercises were basically stretch exercises which included head turns, shoulder lifts, jumping jacks, leg swings, alternate high knee raises and forward bend of the trunk. Each of this was repeated 3-5 times. All these movements were done to the rhythm of aerobic music played in the background.

Main Exercise: The endurance exercise programme consisted of a circuit training pattern which enabled a number of participants to work out at one time (Honeybourne et al, 1996). The circuit consisted of 5 stations and each of the exercise was done for six minutes in each station, with one minute breathing exercise/rest before the participant moved on to the next station in a clockwise direction. The circuit exercise stations were:

Circuit Station 1: This is the station of bicycle ergometry and the intensity was determined by calculating 60% of the maximal heart rate (220-age years). The participants sat on the stationary bicycle, seat adjusted with participant's knee slightly flexed (5^0 – 10^0 degrees) from full extension and pedaled the bicycle freely for six minutes, while the target heart rate was monitored (Plate 3).

Circuit Station 2: In this station, the participants carried-out aerobic dance including trunk movement exercises. They stood with both feet slightly apart with their hands on their hips, leaned forward, backward, sideways and rotated the trunk and waist in rhythm with background music. Each of this movement was repeated 10 times for six minutes (Plate 4).

Circuit Station 3: Mat exercises such as alternate straight leg raising, head and shoulder lifts and bilateral leg raise were carried-out in this station (Plate 5). Participants carried-out these movements in supine lying in rhythm with background music provided by the music box. Each of this movement was done 10 repetitions.

Circuit Station 4: In standing position, participants climbed up and down 10 times on a stationary wooden stairway with rungs of heights, the movement up and down the stairs was guided by the tempo of the background music (Plate 6).

PLATE 3: Circuit station 1; shows participants using bicycle ergometer

PLATE 4: Circuit station 2; shows aerobic-dance of participants

PLATE 5: Circuit station 3; shows mat exercises of participants

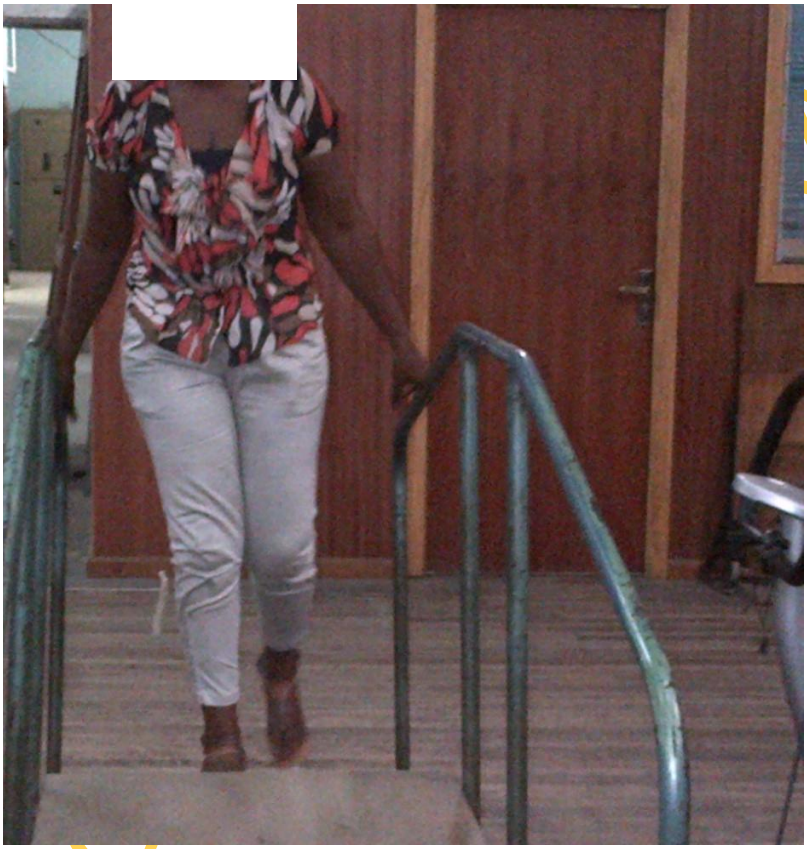

PLATE6: Circuit station 4; shows stair climbing exercise of participant

Circuit Station 5: In this station (Plate 7), participants carried-out a self paced walking exercise guided by the tempo of the background music. Participants walked the full length of the gymnasium (9.3m) to and fro for 25 times (232.5m). The entire duration of the endurance exercise per session lasted 50-75 minutes.

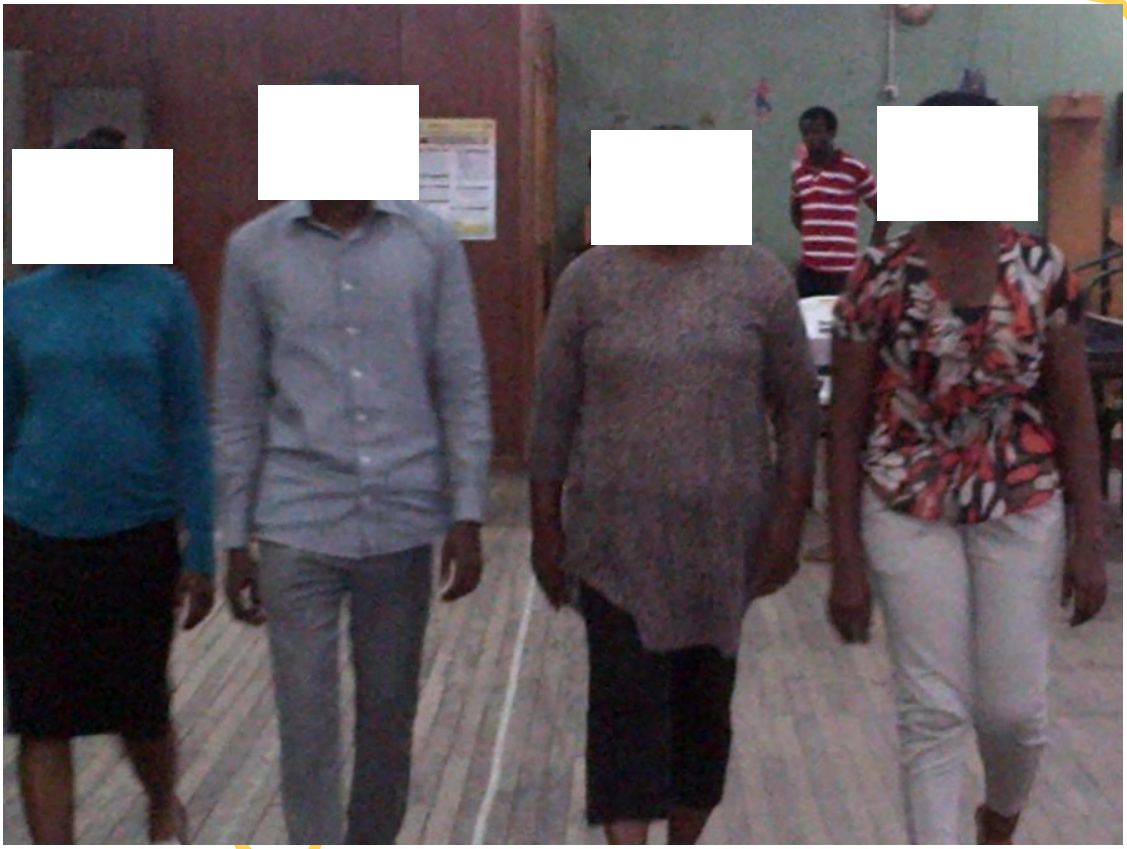

PLATE 7: Circuit station 5; shows walking exercise of participants

Cool Down: The cool down took place for five minutes at the end of the main exercise, which included stretch exercises and brisk walking.

Exercise Intensity: The exercise heart rate (training intensity) was 60-70 percent of the maximal heart rate which is the difference of 220 and age in years (220- age years), depending on individual participant and the initial level of fitness (Kisner and Colby, 2002).

Frequency: Endurance exercise was done three times a week on alternate days.

Progression of Exercise: There was an upward review of the initial 60% of HR_{max} to 65% and 70% at 5^{th} and 9^{th} week, while one minute was added to the duration of exercise in each circuit station at the beginning of 4^{th}, 7^{th} and 10^{th} week respectively, except in circuit station 5. In circuit station 5, there was an upward review of initial 25 times (232.5m) of to and fro covered distance of the gymnasium to 30(279m), 35(323.5m), 40(372m), 45(418.5m) and 50(465m) times at 3^{rd}, 5^{th}, 7^{th}, 9^{th} and 11^{th} week respectively. All the participants tolerated the intervention without complications.

3.3 Data Analysis

Data analysis of this study was based on intention-to-treat analysis which includes all participants in the groups to which they were randomly assigned regardless of the intervention they received and withdrawal from intervention during the study:

1. Descriptive statistics of mean, standard deviation and range were computed for all the parameters measured.

2. Tables and graphs were used to present data on body composition indices, cardio-respiratory indices, quality of life and severity of depression.
3. Independent t-test was used to compare the baseline biodata, baseline and immediate post 12 week data on body composition indices, cardio-respiratory indices, quality of life and severity of depression between the experimental and control group.
4. Repeated measure ANOVA was used to compare the baseline and the two weekly assessed data on body composition indices, cardio-respiratory indices, quality of life and severity of depression of the experimental and control group across the 12- week study period.
5. Post-hoc analysis was carried out for the analysis of variance where significant f-ratio was obtained with Bonferroni correction (adjustment of alpha; 0.05/4= 0.013) to see where significant difference lay.

   The alpha level was set at 0.05.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 RESULTS

4.1.1 Biodata of Participants

A total of ninety participants were involved in this study, comprising of seventy-two (72) females which represented eighty percent (80%) of the participants and eighteen (18) males which represented twenty percent (20%) of the participants respectively. The mean age of the participants was 38.9 ± 10.97 years, while the mean height was 1.66 ± 0.71meters as shown on table 3.

4.1.2 Distribution of Participants Across the 12-week Assessment Period.

Table 4 shows the distribution of participants across the twelve-week assessment period. It revealed that a total of forty seven participants (52%) started the study in the experimental group (EG) and thirty eight participants (42%) completed the study. While in the control group (CG) forty three participants (48%) started the study and thirty-four participants (38%) completed the study. Furthermore, table 2 revealed that the forty seven participants who started the study in the EG comprised of eight males and thirty nine females and the thirty eight that completed the study comprised of five males and thirty three females. In the same vein, the forty three that started the study in the CG comprised of ten males and thirty three females. While the thirty four that completed the study comprised of three males and thirty one females respectively.

Table 3: Biodata of Participants

Variables	X ± SD	N(%)	EG	CG
	n=90	n=90	X ± SD	X ± SD
Age (yrs)	38.9 ±10.97		38.73±11.12	39.09±10.94
Height (m)	1.66 ± 0.71		1.67±0.06	1.66±0.08
Weight (kg)	76.68±14.56		76.75±15.89	76.62±13.27
Male		18(20)		
Female		72(80)		

KEYS

X= Mean

SD= Standard Deviation

Yrs= Years

Kg= Kilogramme

m= Meters

EG= Experimental Group

CG= Control Group

Table 4: Distribution of Participants Across the 12-week Assessment Period

	Experimental Group			Control Group			
Period	Male	Female	Total	Male	Female	Total	Grand Total
Baseline	8	39	47	10	33	43	90
Week 2	8	39	47	10	33	43	90
Week 4	8	39	47	10	33	43	90
Week 6	8	38	46	9	33	42	88
Week 8	5	33	38	3	31	34	72
Week 10	5	33	38	3	31	34	72
Week 12	5	33	38	3	31	34	72

4.1.3 Comparison of Baseline Body Composition Indices, Cardio-respiratory Indices, Severity of Depression and Quality of Life Between the EG and CG using Independent t-test.

Table 5 shows the comparison of the mean values of the baseline body composition indices (BCI), cardio-respiratory indices (CRI), severity of depression (SOD1 and SOD2) and quality of life (QOL) between the experimental group (EG) and control group (CG). The table further revealed that there were no significant differences in the baseline mean values of the ages in years, height (HT), body weight(BWT), percent body fat(PBF), waist-hip-ratio(WHR), body mass index(BMI), resting systolic blood pressure(SBP), resting diastolic blood pressure(DBP), resting heart rate(RHR), cardio-respiratory fitness index(CRFI), severity of depression (SOD1 and SOD2) and quality of life (QoL) between the EG and CG respectively.

Table 5: Comparison of Baseline Body Composition Indices, Cardio-respiratory Indices, Quality of Life and Severity of Depression Between the EG and CG using Independent t-test.

Variables	BASELINE EG n=47 X ± SD	BASELINE CG n=43 X ± SD	t-value	p-value
AGE (Yrs)	38.73 ± 11.12	39.09 ± 10.94	0.15	0.88
HT (m)	1.67 ± 0.06	1.66 ± 0.08	0.25	0.80
BWT (kg)	76.75 ± 15.89	76.62 ± 13.27	0.04	0.97
PBF (%)	36.68 ± 9.88	34.09 ± 10.45	1.21	0.23
WHR	1.37 ± 0.14	1.39 ± 0.21	0.41	0.68
BMI(kg/m^2)	28.49 ± 5.91	27.78 ± 4.59	0.64	0.52
SBP (mmHg)	120.00 ± 12.80	118.07 ± 18.01	0.59	0.56
DBP (mmHg)	73.91 ± 14.99	72.56 ± 15.28	0.43	0.67
RHR (bpm)	89.76 ± 12.44	91.51 ± 15.13	0.60	0.55
CRFI (bpm)	114.38 ± 14.99	114.87 ± 14.06	0.16	0.87
SOD1	28.36 ± 2.44	27.71 ± 2.35	1.28	0.21
SOD2	29.36 ± 2.67	28.80 ± 2.76	0.97	0.34
QoL	43.38 ± 7.48	42.40 ± 6.17	0.68	0.50

Alpha Level = 0.05

KEYS

X= Mean
SD= Standard Deviation
Yrs= Years
Kg= Kilogramme
m= Meters
CG= Control Group
EG= Experimental Group
HT= Height
BWT= Body Weight
PBF= Percent Body Fat
BMI= Body Mass Index
WHR= Waist –Hip-Ratio
SBP=Resting Systolic Blood Pressure
DBP= Resting Diastolic Blood Pressure
RHR= Resting Heart Rate
CRFI= Cardio-respiratory Fitness Index
QOL= Quality of Life
bpm= Beat per minute
SOD1=Severity of Depression assessed by Hamilton Rating Scale of Depression
SOD2=Severity of Depression assessed by Beck Depression Inventory-II

4.1.4 Body Composition Indices (BCI), Cardio-respiratory Indices (CRI), Severity of Depression (SOD1 and SOD2) and Quality of life (QOL) in the Experimental Group (EG) Across the 12-week Assessment Period Using Repeated Measure ANOVA.

The mean values of the BCI, CRI, SOD1 and SOD2 and QOL in the EG across the 12-week study period were presented on table 6. The table revealed that there were statistically significant reductions in the body composition indices, cardio-respiratory indices, SOD1 and SOD2 except in the quality of life which recorded a statistically significant increase across the study period. Moreover, the pattern of reduction in the body composition indices, cardio-respiratory indices, SOD1 and SOD2 and increase in the quality of life were illustrated by graph on figure 2, 3, 4, and 5 respectively.

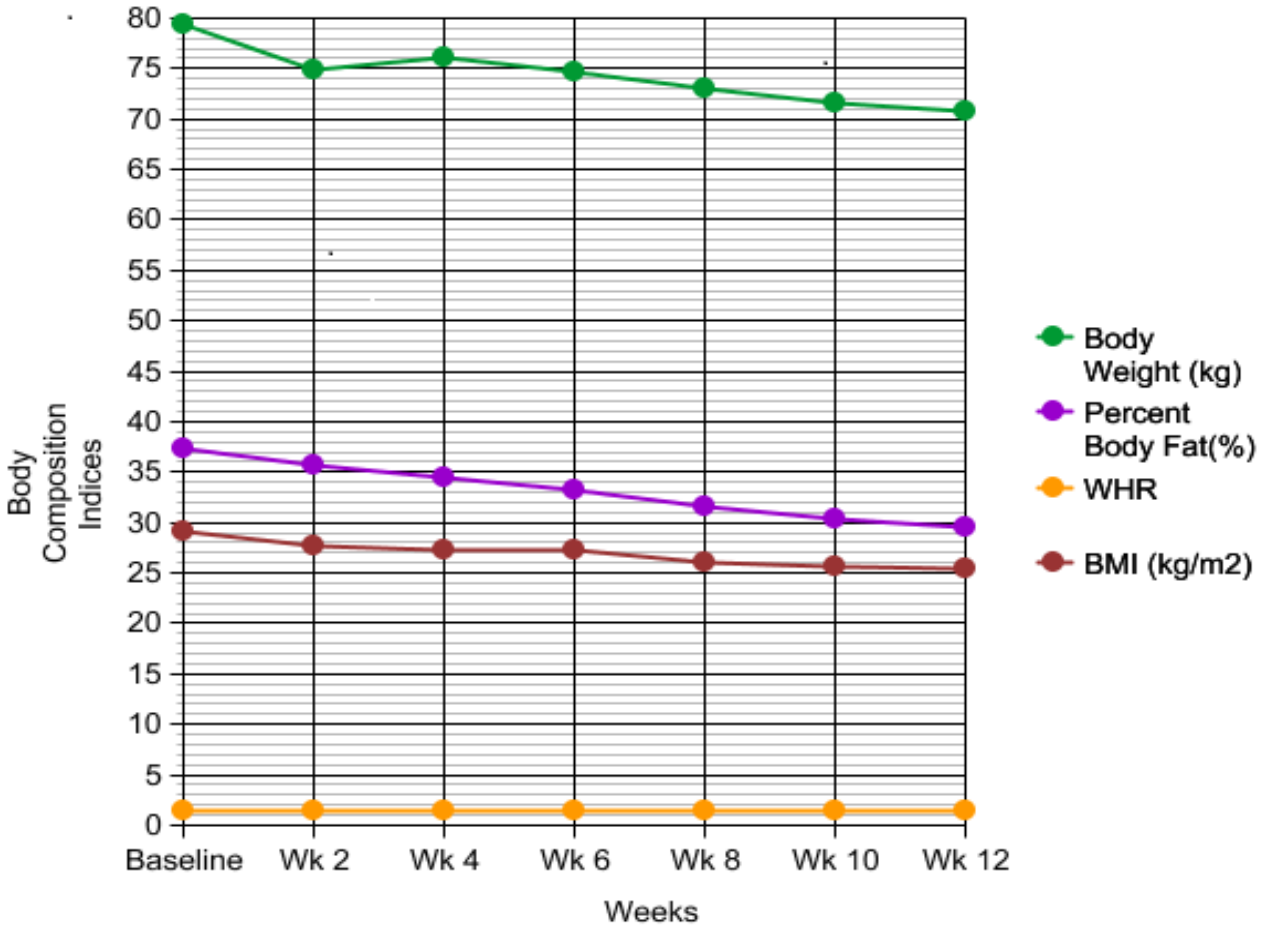

Figure 2. Mean Body Composition Indices of Exercise Group across the 12-week study period.

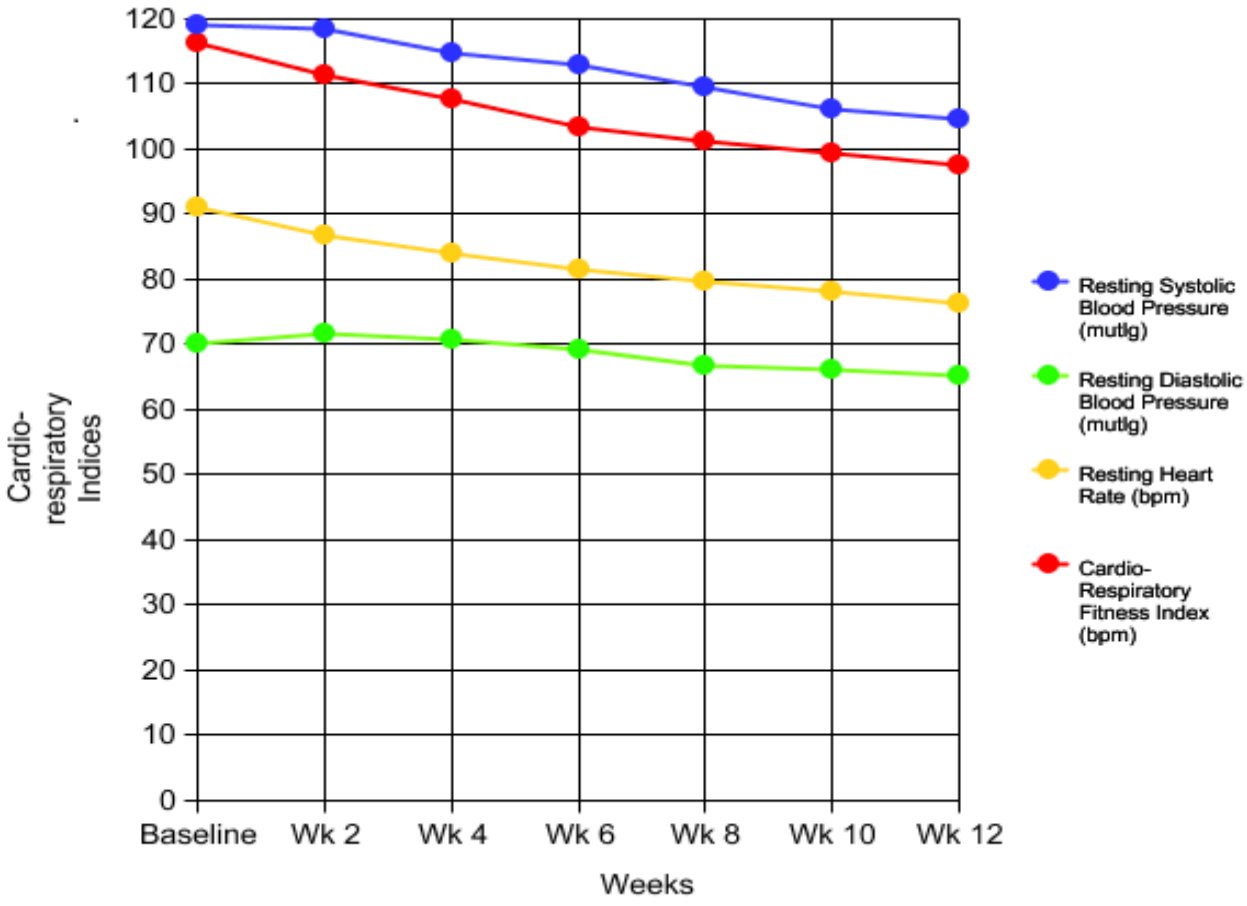

Figure 3. Mean Cardio-respiratory Indices of Exercise Group across the 12-week study period.

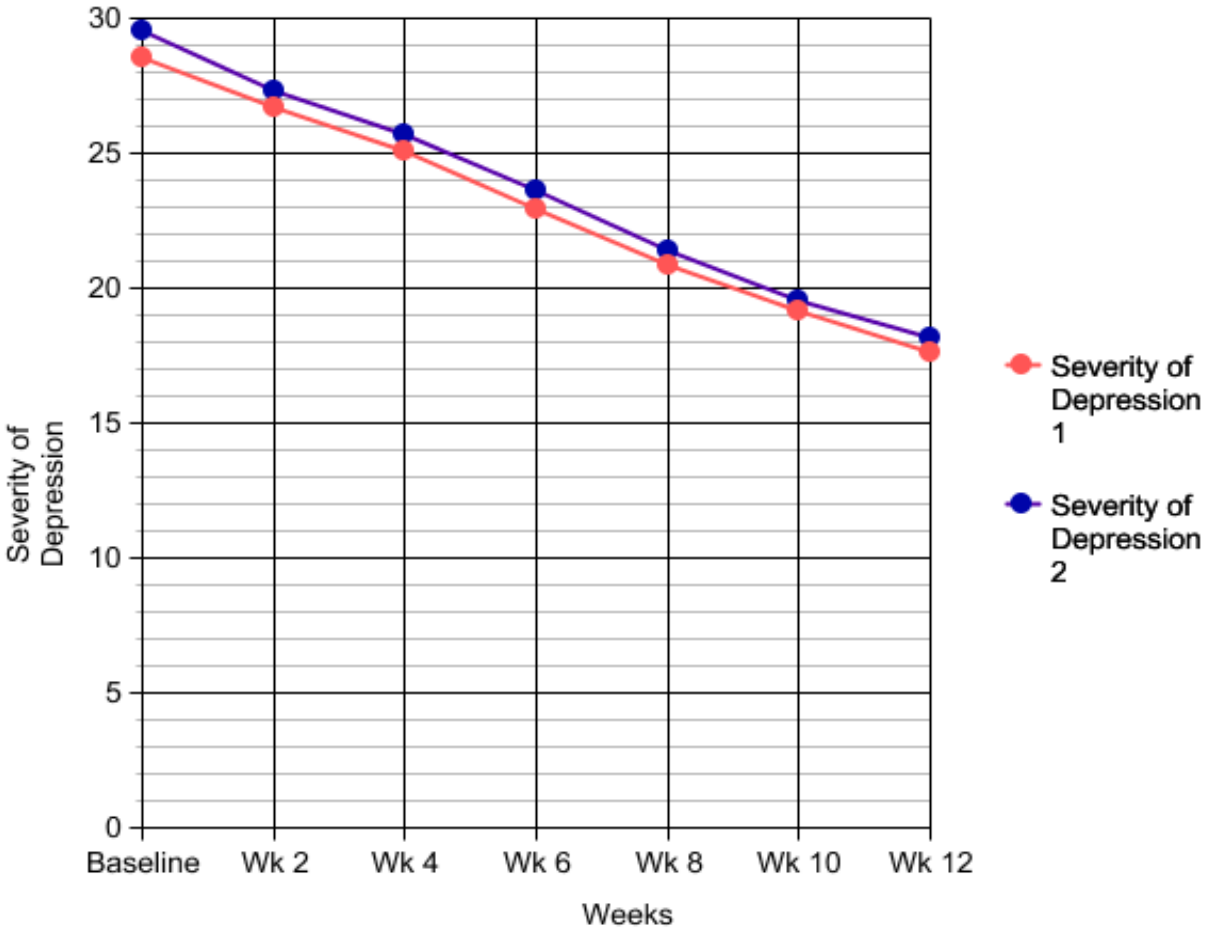

Figure 4. Mean Severity of Depression of Exercise Group across the 12-week study period.

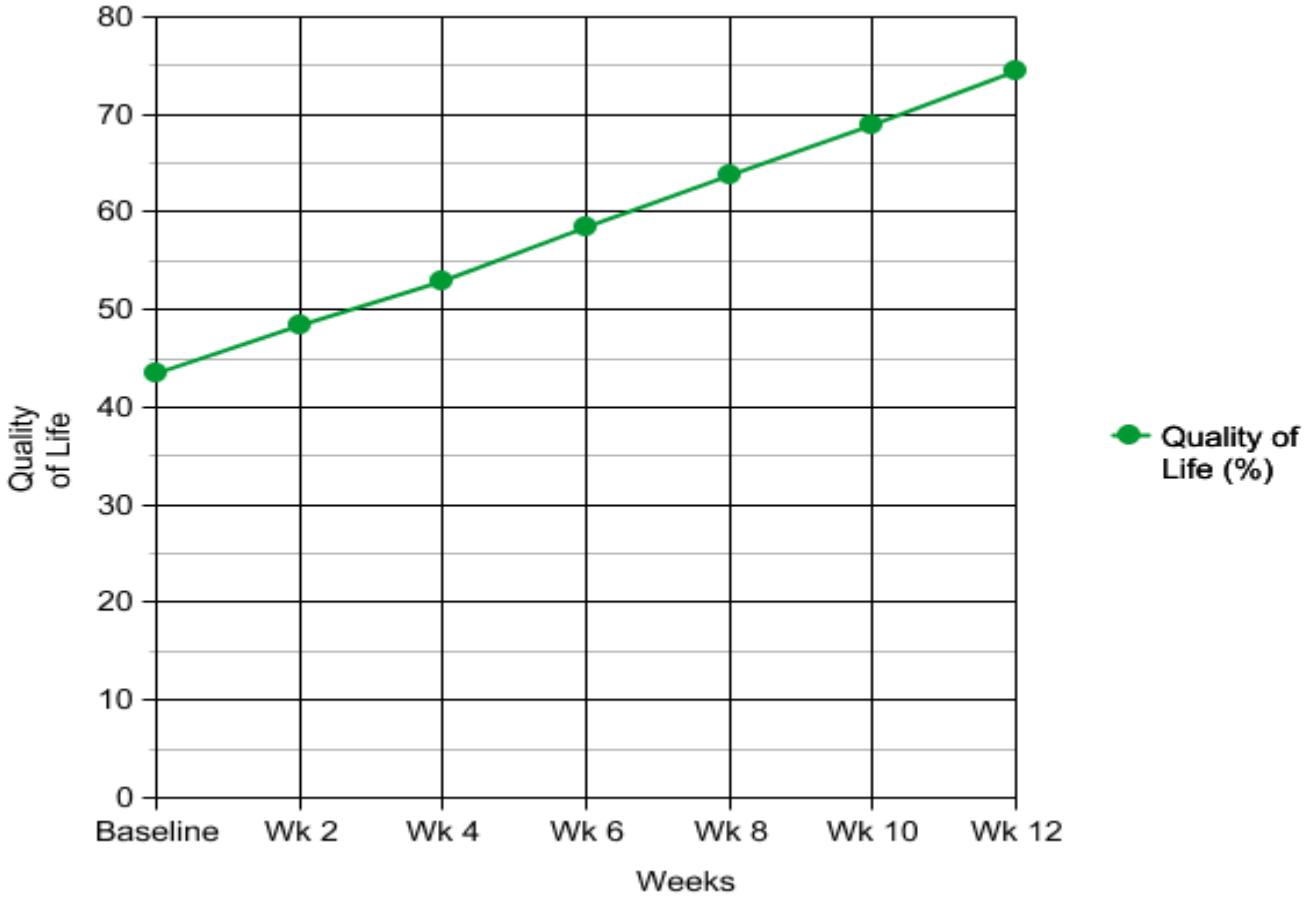

Figure 5. Mean Quality of Life of Exercise Group across the 12-week study period

4.1.5 Body Composition Indices (BCI), Cardio-respiratory Indices (CRI), Severity of Depression(SOD1&SOD2) and Quality of Life (QOL) in the Control Group(CG) Across the 12-week Assessment Period Using Repeated Measure ANOVA

The mean values of the BCI, CRI, SOD1 & SOD2 and QOL in the CG across the 12-week study period were presented on table 7. The table revealed that there were statistically significant increase in the body composition indices, cardio-respiratory indices and quality of life except in the SOD1 & SOD2 which recorded statistically significant reduction across the study period. Furthermore, the pattern of increase in body composition indices, cardio-respiratory indices, quality of life and reduction of SOD1 & SOD2 were illustrated by graph on figure 6, 7, 8 and 9 respectively.

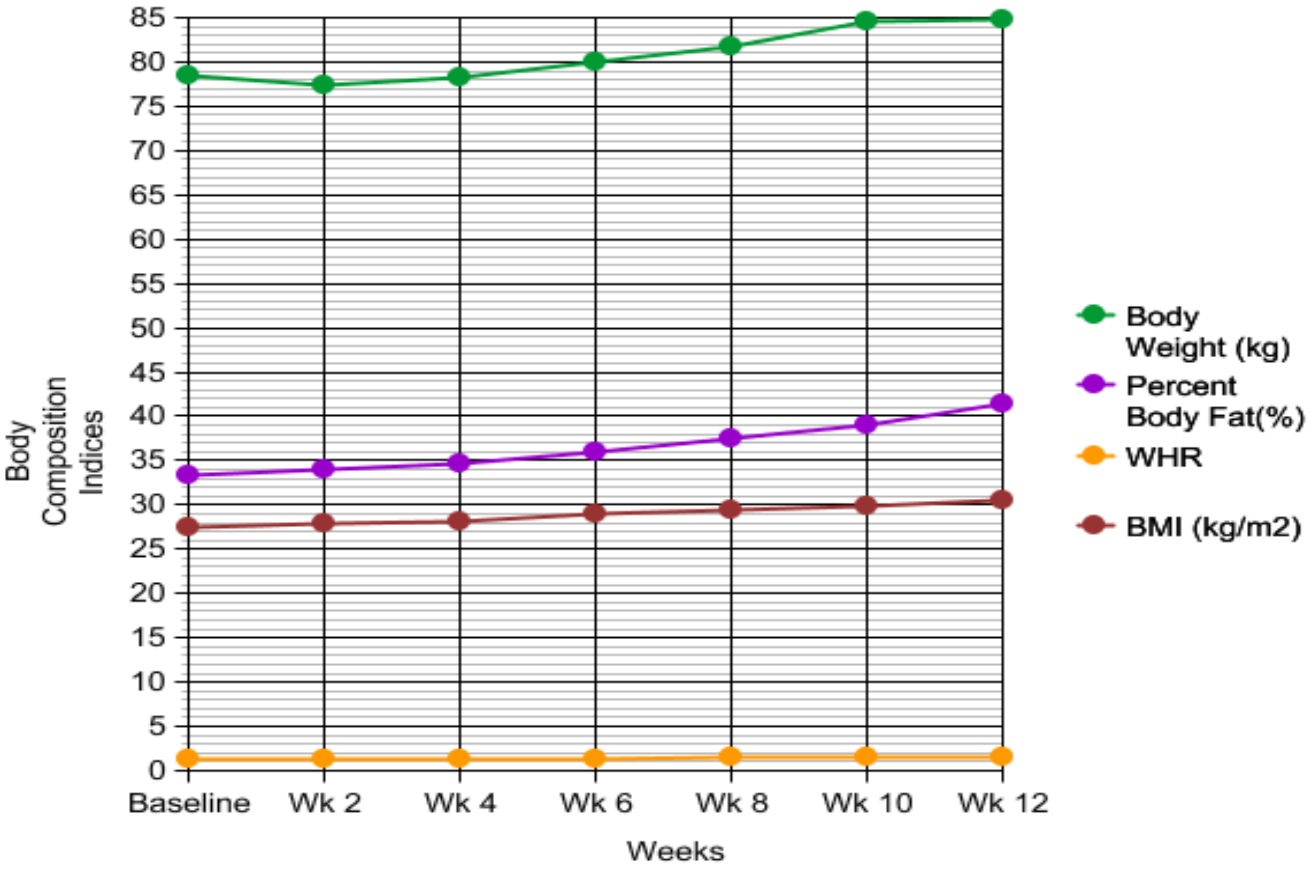

Figure 6. Mean Body Composition Indices of Control Group across the 12-week study period.

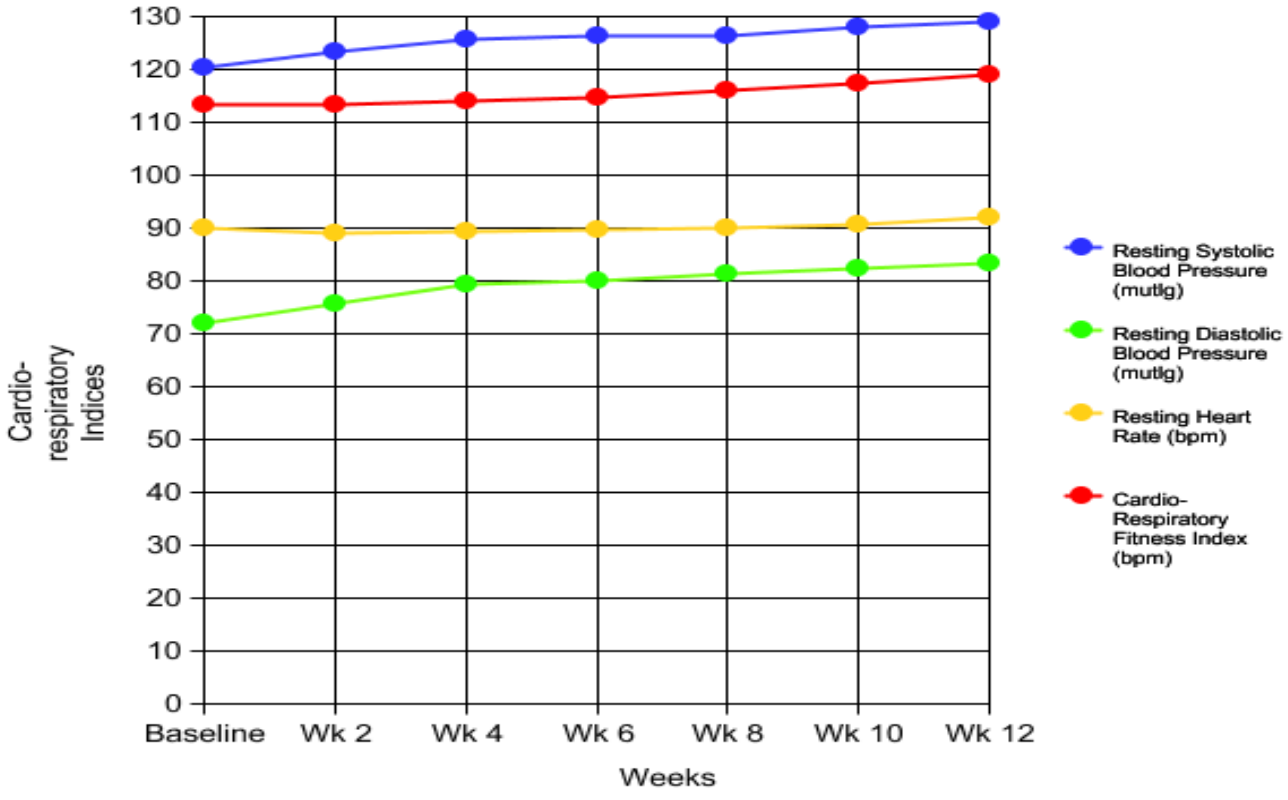

Figure 7. Mean Cardio-respiratory Indices of Control Group across the 12-week study period.

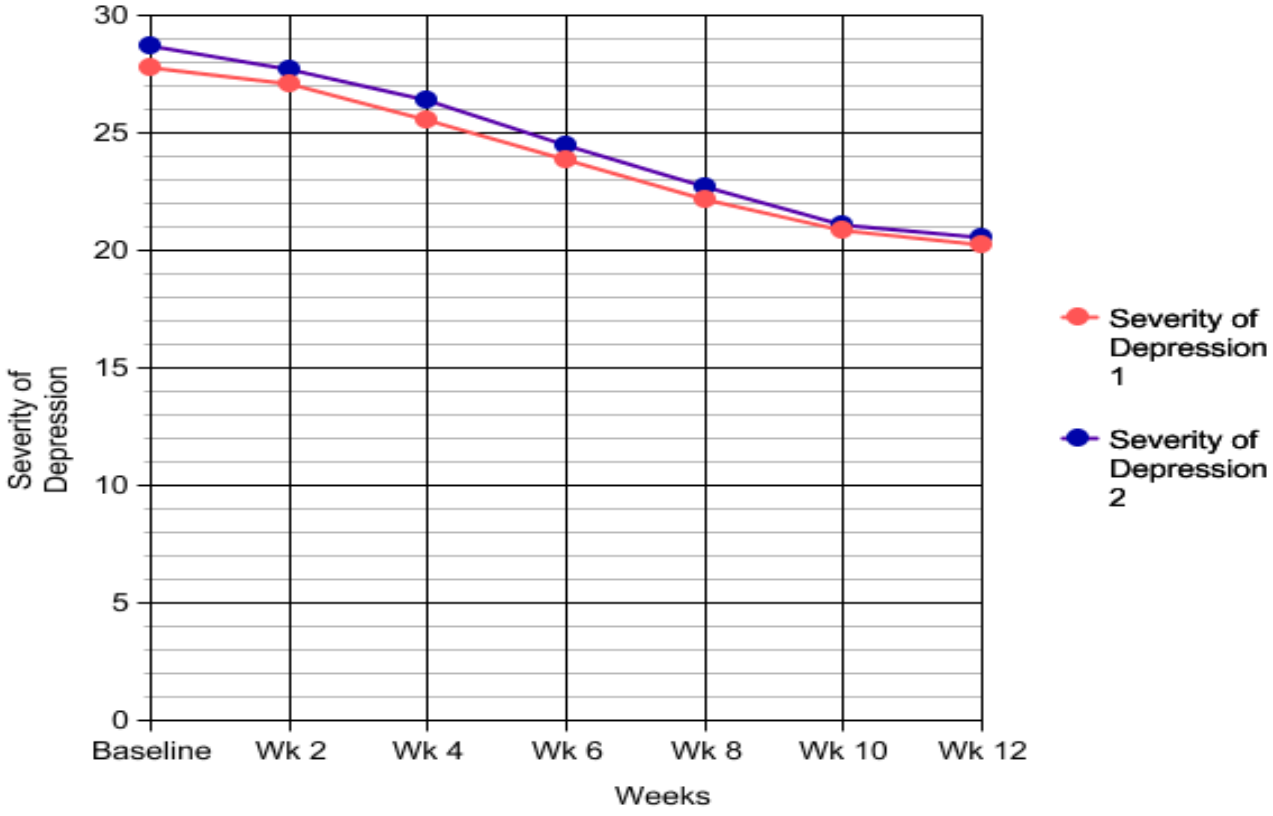

Figure 8. Mean Severity of Depression of Control Group across the 12-week study period.

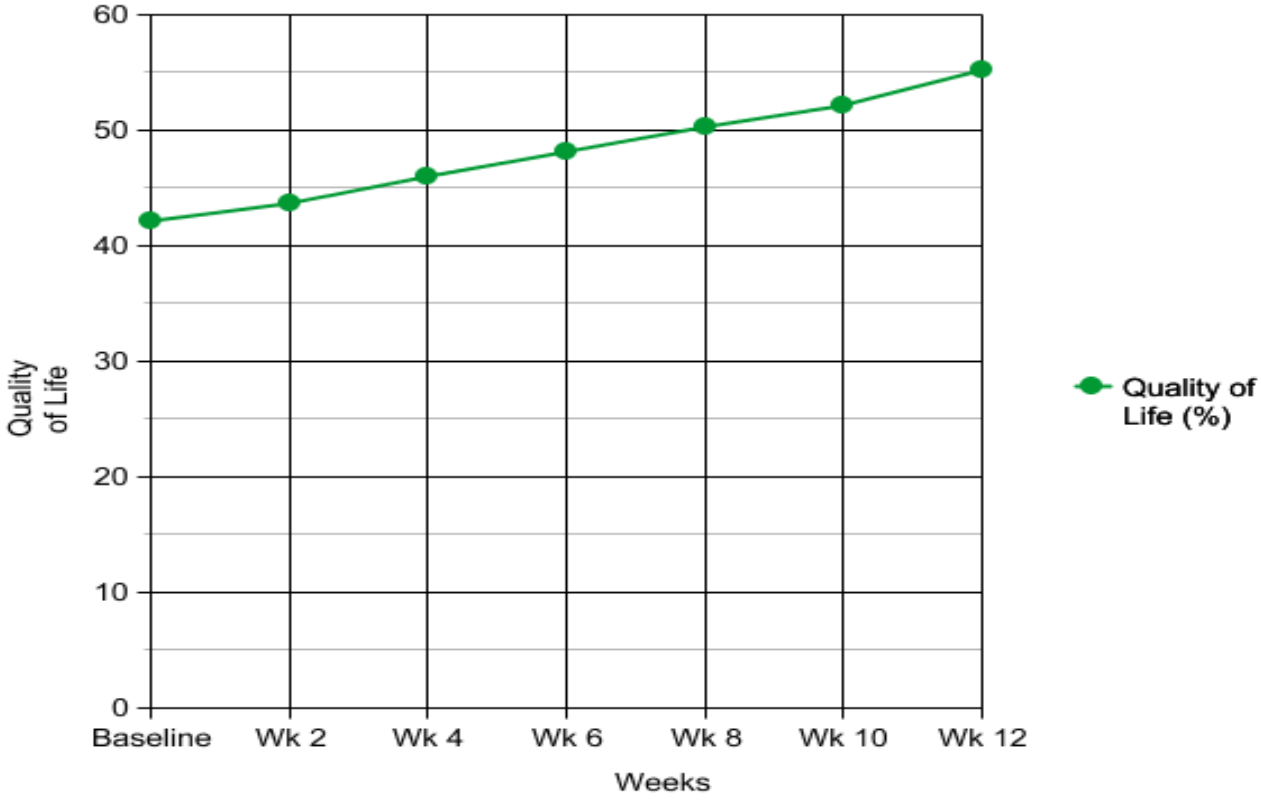

Figure 9. Mean Quality of Life of Control Group across the 12-week study period.

4.1.6 Comparison of Post 12-week Body Composition Indices, Cardio-respiratory Indices, Severity of Depression and Quality of Life Between the Experimental Group(EG) and Control Group(CG) Using independent t-test.

Table 8 presents the post 12 weeks mean body composition indices (BCI), cardio-respiratory indices (CRI), severity of depression (SOD1 and SOD2) and quality of life (QOL) comparison between the exercise and control group. The table revealed that there were statistically significant differences in the body composition indices, cardio-respiratory indices, severity of depression and quality of life between the experimental and control group.

Table 8: Comparison of Post 12-Week Body Composition Indices, Cardio-respiratory Indices, Severity of Depression and QoL Between the EG and CG using Independent t-test

Variables	WK 12 EG n=47 X ± SD	WK 12 CG n=43 X ± SD	t-value	p-value
BWT (kg)	70.85 ± 14.34	84.84 ± 12.90	4.35	0.00*
PBF (%)	29.45 ± 8.23	41.40 ± 8.196	6.17	0.00*
WHR	1.34 ± 0.72	1.44 ± 0.22	2.45	0.02*
BMI(kg/m^2)	25.35 ± 5.06	30.61 ± 4.36	4.72	0.00*
SBP (mmHg)	104.72 ± 6.84	128.97 ± 12.21	10.40	0.00*
DBP (mmHg)	65.31 ± 5.75	83.39 ± 3.96	15.55	0.00*
RHR (bpm)	76.42 ± 5.95	92.03 ± 8.96	8.71	0.00*
CRFI (bpm)	97.67 ± 8.29	119.08 ± 8.95	10.53	0.00*
SOD1	17.61 ± 1.29	20.25 ± 2.08	6.48	0.00*
SOD2	18.14 ± 1.57	20.56 ± 2.01	5.69	0.00*
QOL	74.56 ± 7.17	55.17 ± 3.22	14.81	0.00*

Alpha Level = 0.05 * Indicates significant difference at p< 0.05

KEYS

X= Mean
SD= Standard Deviation
Yrs= Years
Kg= Kilogramme
m= Meters
CG= Control Group
EG= Experimental Group
HT= Height
BWT= Body Weight
PBF= Percent Body Fat
BMI= Body Mass Index
WHR= Waist –Hip-Ratio
SBP=Resting Systolic Blood Pressure
DBP= Resting Diastolic Blood Pressure
RHR= Resting Heart Rate
CRFI= Cardio-respiratory Fitness Index
QOL= Quality of Life
bpm= Beat per minute
SOD1=Severity of Depression assessed by Hamilton Rating Scale of Depression
SOD2=Severity of Depression assessed by Beck Depression Inventory-II

KEY

BWT	=	Body Weight
PBF	=	Percent Body Fat
WHR	=	Waist-Hip-Ratio
BMI	=	Body Mass Index
SBP	=	Resting Systolic Blood Pressure
DBP	=	Resting Diastolic Blood Pressure
RHR	=	Resting Heart Rate
CRFI	=	Cardio-respiratory Fitness Index
SOD 1	=	Severity of Depression assessed using 17-item Hamilton Rating Scale of Depression -17
SOD 2	=	Severity of Depression assessed using Beck Depression Inventory-11
QOL	=	Quality of Life
kg	=	Kilogramme
M^2	=	Metres Square
%	=	Percentage
mmHg	=	Millimeter of Mercury
bpm	=	Beat Per Minute
X	=	Mean
SD	=	Standard Deviation
EG	=	Experimental Group
CG	=	Control Group
*	=	Significant difference at $p<0.05$

4.1.7 Post-hoc Analysis of Body Composition Indices (BCI), Cardio-respiratory Indices (CRI), Severity of Depression(SOD1&SOD2) and Quality of Life (QoL) in the Experimental (EG) and Control Group(CG) Across the 12-week Assessment Period with a Bonferroni adjustment of alpha

The post-hoc analysis for the comparison of each of the BCI, CRI, SOD1&SOD2 and QoL in the EG and CG across the seven periods with a Bonferroni adjustment of alpha is shown on Table 9 to 19. The analysis revealed twenty one pair wise comparisons for each index. These were 0 versus 2 (baseline vs. week 2), 0 versus 4 (baselin vs. week 4), 0 versus 6 (baseline vs. week 6), 0 versus 8 (baseline vs. week 8), 0 versus 10 (baseline vs. week 10), 0 versus 12 (baseline vs.week12), 2 versus 4 (week 2 vs. week 4), 2versus 6 (week 2 vs. week 6), 2 versus 8 (week 2 vs. week 8), 2 versus 10 (week 2 vs. week 10), 2 versus 12 (week 2 vs. week 12), 4 versus 6 (week 4 vs. week 6), 4 versus 8 (week 4 vs. week 8), 4 versus 10 (week 4 vs. week 10), 4 versus 12 (week 4 vs. week 12), 6 versus 8 (week 6 vs. week 8), 6 versus 10 (week 6 vs. week 10), 6 versus 12 (week 6 vs. week12), 8 versus 10 (week 8 vs. week 10), 8 versus 12 (week 8 vs. week 12), and 10 versus 12 (week 10 vs. week 12) respectively.

In the experimental group significant differences correspond to statistically significant reduction in all the outcomes except, quality of life where significant difference corresponds to statistically significant increase. On the contrary, significant differences correspond to statistically significant increase in all the outcomes of control group except, severity of depression where significant difference corresponds to statistically significant reduction.

4.1.8 Hypotheses Testing

Hypothesis 1

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body weight (BWT) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 4.35

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 2

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise percent body fat (PBF) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 6.17

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 3

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise waist-hip-ratio (WHR) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 2.45

p-value: 0.02

conclusion: Since p<0.005 the null hypothesis was hereby REJECTED

Hypothesis 4

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body mass index (BMI) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 4.72

p-value: 0.00

conclusion : Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 5

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting systolic blood pressure (SBP) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 10.40

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 6

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting diastolic blood pressure (DBP) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 15.55

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 7

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting heart rate (RHR) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 8.71

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 8

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise cardio-respiratory fitness index (CRFI) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 10.53

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 9

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by HRSD-17 (SOD 1) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 6.48

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 10

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by BDI-II (SOD 2) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 5.69

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 11

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise quality of life (QoL) between the experimental and control group.

Alpha: 0.05

Test Statistics: Independent t-test

t-value: 14.81

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 12

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body weight (BWT) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 7.77

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 13

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise percent body fat (PBF) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 159.95

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 14

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise waist-hip-ratio (WHR) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 9.81

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 15

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body mass index (BMI) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 45.38

p-value: 0.00

conclusion : Since $p<0.05$ the null hypothesis was hereby REJECTED

Hypothesis 16

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting systolic blood pressure (SBP) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 33.82

p-value: 0.00

conclusion: Since $p<0.05$ the null hypothesis was hereby REJECTED

Hypothesis 17

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting diastolic blood pressure (DBP) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 6.21

p-value: 0.00

conclusion: Since $p<0.05$ the null hypothesis was hereby REJECTED

Hypothesis18

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting heart rate (RHR) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 39.47

p-value: 0.00

conclusion: Since $p<0.05$ the null hypothesis was hereby REJECTED

Hypothesis 19

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise cardio-respiratory fitness index (CRFI) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 51.81

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 20

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by HRSD-17 (SOD 1) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 554.87

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 21

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by BDI-II (SOD 2) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 444.49

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 22

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise quality of life (QoL) of the experimental group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 386.11

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 23

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body weight (BWT) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 49.25

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 24

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise percent body fat (PBF) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 264.93

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 25

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise waist-hip-ratio (WHR) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 25.20

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 26

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise body mass index (BMI) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 110.88

p-value: 0.00

conclusion : Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 27

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting systolic blood pressure (SBP) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 15.13

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 28

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting diastolic blood pressure (DBP) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 33.11

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 29

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise resting heart rate (RHR) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 2.59

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 30

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise cardio-respiratory fitness index (CRFI) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 13.09

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 31

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by HRSD-17 (SOD 1) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 254.19

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 32

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise severity of depression assessed by BDI-II (SOD 2) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 220.98

p-value: 0.00

conclusion: Since p<0.05 the null hypothesis was hereby REJECTED

Hypothesis 33

Statement: There would be no significant difference in the baseline and immediate post twelve weeks endurance exercise quality of life (QoL) of the control group.

Alpha: 0.05

Test Statistics: Repeated measure ANOVA

f-ratio: 150.30

p-value: 0.00

conclusion: Since $p<0.05$ the null hypothesis was hereby REJECTED

4.2 DISCUSSION

4.2.1 Biodata and Distribution of Participants Across the 12-week Assessment Period

A total of ninety participants were involved in this study. Eighteen patients (20%) dropped out before the completion of the 12-week endurance exercise programme. Similar drop-out of 20.5% (32 out of 156) was recorded in a randomized controlled trial which compared the response of endurance exercise, drugs or a combination of both in older patients with major depressive disorder (Blumenthal et al, 1999). In contrast, a drop out of 7.7% (3 out of 39 participants) was recorded in another randomized controlled study which evaluated the effects of a short-term endurance training programme in patients with major depression receiving antidepressant drug treatment (Knubben et al, 2007). Primarily, in this study, the medication adverse effects (e,g dizziness and sleep disturbance) and difficulties attending the exercise classes were responsible for the majority of participants who dropped out.

4.2.2 Comparison of Baseline Body Composition Indices, Cardio-respiratory Indices, Severity of Depression and Quality of Life Between the Experimental and Control Group

At baseline there were no statistically significant differences in the mean ages and heights of the participants in experimental group (EG) and control group (CG). Also, similar trend was recorded in the body composition indices (BWT, PBF, WHR and BMI), cardio-respiratory indices (SBP, DBP, CRFI and RHR), Severity of depression (SOD1 and SOD2) and quality of life (QOL) between the EG and CG. The interpretation of this observation is that the two groups were independent and comparable in age, height, body composition indices, cardio-respiratory indices, severity of depression and quality of life.

Therefore, any difference recorded thereafter could be attributed to the endurance exercise intervention of the study.

4.2.3 Comparison of Post 12-week Endurance Exercise Body Composition Indices Between the Experimental and Control Group

The results of this study revealed that at the end of the twelve weeks endurance exercise programme, participants in the experimental group (EG) had statistically significant reduction in their body composition indices (BCI), cardio-respiratory indices (CRI) and severity of depression (SOD) but, had a statistically significant increase in quality of life (QOL). On the other hand, the participants in the control group (CG) had statistically significant increase in the BCI, CRI and QOL, but had significant reduction in severity of depression. The participants in EG went through a supervised, monitored and carefully progressed endurance exercise. The significant reduction of the body composition indices in the EG could be explained by the effects of endurance exercise on caloric expenditure, net loss of appetite and reduction of rate of gain in fat cell number. Weight gain occurs when there is a constant increase in caloric intake compared to energy expenditure (change in energy stores = energy intake – energy expenditure). Considering this equation of energy stores and results from this study, endurance exercise therapy can be an important modifying and mediative modality to prevent, control and reduce excessive body weight (BWT), percent body fat (PBF), waist-hip-ratio (WHR) and body mass index (BMI), in patients receiving antidepressant drug treatment. It had also been reported that subjects that have not been exposed to structured exercise programme or participated in exercise in the past show a net loss of appetite when they engage themselves in structured exercise programme (Powers and Howley, 2007). This report could also be used to explain the significant reduction of body composition indices in the experimental group.

Other mechanisms that could explain the significant reduction in BCI was; mobilization of fat from visceral adipose tissue resulting in an improved fat distribution as reported by Ross and Rissanen (1994). Similarly, free fatty acids at moderate intensities of endurance exercise could have been mobilized from the periphery to provide the majority of fuel used and help in the maintenance of fat balance. In the same vein, studies had reported that endurance exercise carried out for at least three times per week with intensities of about 55-70%HRmax and lasting for 30-40minutes expend 250-300kcal per session (Pollock and Wilmore, 1990; Powers and Howley, 2007).

Emphatically, there is dearth of literature on the effects of endurance exercise programme on antidepressant drugs induced changes in the body composition of patients receiving antidepressant drug treatment. Despite the fact that studies had reported the short and long term effects of antidepressant drug treatment on weight gain and fatness (Deshmukh and Franco, 2003; Laimer et al, 2006; Schwartz et al, 2007). This is because weight gain is frequently overlooked because focus is on remission of depression and weight gain may be substantially greater after remission of depression is achieved (Schwartz et al, 2007). Therefore, the findings of this study is suggesting a new model of treatment protocol in the overall management of patients with major depressive disorder; receiving antidepressant drug treatment, especially in relation to body composition. Meaning that, clinicians (Psychiatrists, Physiotherapists, Psychologists, and others) involved in the management of major depressive disorder could synchronise endurance exercise intervention with antidepressant drug treatment at the commencement of management.

However, the significantly higher body composition indices in the control group could be explained by the non-participation in the endurance exercise programme during the study

period. Also, considering the findings from studies that antidepressant drugs induced body composition changes is a common and well-known adverse effect of short and long term treatment (Deshmukh and Franco, 2003; Laimer et al, 2006; Schwartz et al, 2007). This could be a major contributor to the significantly higher body weight (BWT), percent body fat (PBF), waist-hip-ratio (WHR), and body mass index (BMI) recorded in the control group. Though, the mechanism is not clearly known, but previous studies (Deshmukh and Franco 2003; Laimer et al, 2006; Schwartz et al, 2007; Helmich et al, 2010), have explained that serotonin helps regulate appetite and carbohydrate intake, and is the most manipulated neurotransmitter in antidepressant drug treatment which is associated with carbohydrate craving, low satiety rates and increased calorie intake. Another plausible mechanism is the high affinity antidepressant drugs have for blocking histerminergic receptors which have also been associated with excessive appetite and increase food intake (Deshmukh and Franco 2003; Schwartz et al, 2007).

4.2.4 Comparison of Post 12-week Endurance Exercise Cardio-respiratory Between the Experimental and Control Group.

The participants in the experimental group (EG) had statistically significant reduction in the resting heart rate (RHR), resting systolic blood pressure (SBP), resting diastolic blood pressure (DBP) and cardio-respiratory fitness index (CRFI) which indicated improved aerobic capacity. Whereas, the participants in the control group (CG) had statistically significant increase in the resting heart rate (RHR), resting systolic blood pressure (SBP), resting diastolic blood pressure (DBP) and cardio-respiratory fitness index (CRFI) which indicated reduction in aerobic capacity. The results of this study is in agreement with the findings of Blumenthal et al, (1999) who reported reduction in resting cardiovascular parameters and improved aerobic capacity in participants combining antidepressant drug

and endurance exercise and exercise only as opposed to participants placed on antidepressant drug only who had reduction in aerobic capacity.

Kelley et al, (2001), also reported that endurance exercise was associated with reduction in resting systolic and diastolic blood pressure. The reduction in resting heart rate is one of the basic physiologic adaptations that occur as a result of endurance exercise. Such change maybe important in the reduction of resting systolic and diastolic blood pressure as observed in this study. In addition, all the participants in the experimental group (EG) recorded steady improvement in their physical fitness evidenced by their cardio-respiratory fitness index and their ability to tolerate the progression of the endurance exercise during the twelve week study period. On the other hand, the significant increase in resting systolic blood pressure (SBP), resting diastolic blood pressure (DBP), resting heart rate (RHR) and reduced aerobic capacity in the control group can be attributed to non-participation in the endurance exercise programme.

4.2.5 Comparison of Post 12-week Endurance Exercise Severity of Depression (SOD 1 and SOD 2) Between the Experimental and Control Group

The participants of experimental and control groups in this study yielded identical results in severity of depression. Both groups exhibited statistically significant reduction on the Hamilton Rating Scale of Depression HRSD-17 (SOD1) and Beck Depression Inventory (SOD2) across the 12-week study period. Furthermore, at the end of the study, the mean depression scores in the exercise group were significantly lower than in the control group. Therefore, the findings of this study suggest that a 12-week endurance exercises can be a useful adjunct modality to reduce the severity of depression in patients with major depressive disorder receiving antidepressant drug treatment.

Similar pattern were reported by Blumenthal et al, (1999), who assessed the effects of exercise training in older patients with major depressive disorder in a randomized control trial; Knubben et al, (2007), who evaluated the effects of a short term endurance training programme in patients with major depression and Gorge et al, (2012) who evaluated the comparative effects of a 12-week aerobic exercise versus antidepressant medication in young adult males with major depressive disorder. Several mechanisms could explain the reduction in severity of depression scores:

Primarily, both groups were receiving antidepressant drug treatment which was aimed at reducing depression symptoms. The mechanism of action of antidepressant drugs to achieve antidepressant effects, include blockade of histamine H1 and serotonin 2c preceptor, thereby modulating neurotransmitter systems at the hypothalamic level and subsequent recovery from clinical depression. So also, selective serotonin reuptake inhibitors treatment increase serotonin in the synaptic cleft, allowing 5-HT2C receptor down-regulation similar to acute 5-HT2C blockade which resulted in recovery from clinical depression. While monomaine oxidase inhibitors inhibit an enzyme involved in the metabolism of biogenic amines (norepinephrine, epinephrine, dopamine, serotonin) to regulate neurotransmission in the brain (Deshmukh and Franco, 2003; Schwartz et al, 2007; Helmich et al, 2010) with a resultant recovery from clinical depression.

Similarly, one of the mechanisms through which exercise produces the antidepressant effects might be similar to that of the antidepressant drug treatment, since exercise also affects the central serotonergic system (Helmich et al, 2010). The synthesis of brain 5-HT depends on two main variables, the neuronal concentration its precursor, tryptophan (Trp) and the activity of its rate limiting enzyme, tryptophan hydroxylase (Helmich et al, 2010).

Physical exercise increase blood free tryptophan and decreases albumin bound tryptophan both in animals and humans (Fischer et al, 1999; Helmich et al, 2010) by increasing the rate of lipolysis. It had been shown in humans that an increase in levels of the serotonin metabolite, 5-hydroxyindoleacetic acid follows physical exercise (Helmich et al, 2010). Since tryptophan is competing with other amino acids like valine, leucine and isoleucine to enter the brain, it has been demonstrated that exercise decreases the level of these amino acids leading to higher availability of the serotonin precursor, tryptophan in the brain (Pardridge, 2007). Therefore, the higher concentrations of tryptophan in the blood plasma and also in the cerebrospinal fluid following exercise enhance the serotonin neurotransmission in the brain and recovery from clinical depression (Helmich et al, 2010). Likewise, increased levels of norepinephrine and its metabolites as well as the activation of tyrosine hydroxylase, an enzyme that is involved in the production of norepinephrine is also observed after acute and chronic exercise in animals (Helmich et al, 2010). In the view of the above explanation, it can be presumed that exercise produces the same mood-elevating effects as antidepressants by altering the availability of norepinephrine (Helmich et al, 2010).

Psychological mechanism also explained that endurance exercise may provide a feeling of body control, help release anger and hostility and distract patients from depressive thoughts (Knubben et al, 2007). Motivation, expectations and human contact may influence the mood of participants in this study and this partially explains the improvement observed in the two groups. Summarily, in this study, the participants in exercise group had double antidepressant therapy from both the drug and endurance exercise, while the participants in control group had their antidepressant from the drug only. This further explained the significant lower mean depression scores observed in the exercise group compared to the control group. The findings of the literature (Blumenthal

et al, 1999; Knubben et al, 2007; Carta et al, 2008; Helmich et al, 2010; George et al, 2012), and this study is further confirming the adjunctive treatment role of endurance exercise.

4.2.6 Comparison of Post of 12-week Endurance Exercise Quality of Life Scores Between the Experimental and Control Group

In this study, all the participants were initially depressed (major depressive disorder) and all exhibited significant reduction in severity of depression, we can say that it is likely that the improvement in the underlying depression caused the improvement in mental health and positive impact on quality of life. The findings of this study that participants at baseline recorded reduced quality of life was in agreement with the findings of Rapport et al, (2005) and Carta et al, (2008) who reported lower quality of life in patients with major depressive disorder than other affective disorders. Furthermore, the participants in the exercise group had significant increase in the quality of life across the 12-week study period and significant difference compared to the participants in the control group at the end of the 12-week endurance exercise. While the participants in the control group also had significant increase in the quality of life across the 12-week study period but recorded lower mean scores compared to participants in the exercise group.

The results observed in the experimental group could be attributed to the participation in the endurance exercise programme. The findings of this study is in agreement with the findings of Carta et al, (2008), who compared the change in quality of life in two groups (Antidepressant drug and exercise-Experimental; Antidepressant drug only-Control) of thirty depressed women. This is because of the mediative and adjunctive treatment role of endurance exercise in the management of patients with major depressive disorder.

Participants in experimental group received both the antidepressant effects of drug and endurance exercise (adjunctive), while at the same time experienced the control effects (mediative role) of endurance exercise on body weight, percent body fat, waist-hip-ratio, body mass index and the effects on the cardio-respiratory fitness index, resting systolic blood pressure, resting diastolic blood pressure and resting heart rate. All these impacted positively on the overall well-being of participants in the exercise group and a resultant improvement in quality of life. These effects could be explained by biological mechanisms which observed that endurance exercise generate changes in the concentration of several biologically active molecules, such as adrenocortiocotropic hormone, cortisol, cathecolanines, opiod peptides cyctokins and beta endorphins (Knubben et al, 2007 and Carta et al, 2008). Also, psychological mechanism explained that group exercise enhances social communication and interaction among the participants (Carta et al, 2008). Other factors are motivation, expectation, human contact and group participation in exercise, which may enhance social communication and interaction among participants (Carta et al, 2008).

The limitations of this study were absence of a true no-treatment control group due to ethical reasons. Also, drug adverse effects such dizziness and sleep disturbance prevented some potential participants from participating and others from completing the twelve weeks endurance exercise programme. However, patients to be placed on antidepressant drugs should be assessed and planned for caloric expenditure through endurance exercise before medically significant antidepressant drugs induced body composition changes and its associated risks occur

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 SUMMARY

Major depressive disorder is an illness characterized by feelings of sadness, anxiety, emptiness, hopelessness, worthlessness, guilt, irritability or restless (National Institute of Mental Health, 2009). The increasing number of people diagnosed with major depression and the reliance on drugs to manage this condition exposes patients to potentially harmful adverse effects such as overweight, cardiovascular diseases and low cardio-respiratory fitness. Previous studies focused on the effects of exercise on the mood of patients; however, there is paucity of scientific evidence about the effects of exercise intervention on the body composition of patients with major depressive disorder receiving antidepressant drug treatment, hence, the need for this study. This study was designed to evaluate the effects of a twelve (12) week endurance exercise programme on selected body composition indices, cardio-respiratory indices, quality of life and severity of depression in patients with major depressive disorder.

The term major depressive disorder was introduced by a group of United States of America Clinicians in the mid-1970s as part of proposals for diagnostic criteria based on patterns of symptoms and was incorporated into the Diagnostic and Statistical Manual Disorders (DSM-III) – III in 1980 (Philipp et al, 1991). Other forms of depressive disorders are minor, chronic and bipolar depression. Treatment with an antidepressant agent is the preferred choice in cases of moderate to severe depression. Weight gain is a common and well-known adverse effect of short and long term antidepressant drug treatment (Deshmukh and Franco, 2003; Schwartz et al, 2007). Whereas, increased body

weight and fatness constitute significant public health problem in the developed world and increasing rapidly in several developing nations associated with high morbidity, mortality, (Sorenson, 2000; Uwaifo and Arioglu, 2004) and reduced quality of life. However, participation in physical exercise has been reported to be necessary for successful weight control and maintenance in all people (Klem et al, 1997; Powers and Howley, 2007) and also, shown to improve mood in depressed people (Blumenthal et al, 1999; Babyak et al, 2000; Dimeo et al, 2001; Blumenthal et al, 2007; Knubben et al, 2007).

Ninety patients with major depressive disorder receiving antidepressant drug treatment participated in this quasi-experimental study. They were consecutively recruited from Federal Neuro-psychiatric Hospital, Yaba and Lagos University Teaching Hospital, and assigned into either Exercise Group (EG) or Control Group (CG) using a simple random assignment technique. The EG went through relaxation exercises and a progressive endurance exercise programme in a circuit training pattern consisting of bicycle ergometry, aerobic dance, mat exercises, stair climbing and walking, three times per week for 12 weeks. Those in the CG had only relaxation exercises twice per week for 12 weeks. Both groups were assessed for Body Weight (BWT), Percent Body Fat (PBF), Waist-Hip-Ratio (WHR), Body Mass Index (BMI), resting Systolic Blood Pressure (SBP), resting Diastolic Blood Pressure (DBP), resting Heart Rate (RHR), Cardio-Respiratory Fitness Index (CRFI), Quality of Life (QOL) and Severity of Depression (SOD_1 andSOD_2). The assessment were carried out at baseline and at the end of 2^{nd}, 4^{th}, 6^{th}, 8^{th}, 10^{th}, and 12^{th} week using body composition monitor, digital sphygmomanometer, one-mile walk test, WHO(Five) well-being index, 17-item-Hamilton Rating Scale for Depression (HRSD-17) and Beck Depression Inventory (BDI-II). Descriptive statistics,

independent t-test, repeated measure ANOVA and Bonferroni post-hoc analysis were used to analyse the data at p= 0.05.

At baseline the EG and CG were comparable in age (38.7±11.1 vs. 39.1±10.9 years), height (1.6±0.1 vs. 1.6±0.1m) and body weight (76.7±15.8 vs. 76.6±13.2kg). The end of 12th week endurance exercise comparison of the two groups showed statistically significant difference in the BWT (70.8±14.4 vs. 84.8±12.9kg), PBF (29.4±8.2 vs. 41.4±8.1%), WHR (1.3±0.7 vs. 1.4±0.2), BMI (25.3±5.1 vs. 30.6±4.3kg/m^2), SBP (104.7±6.8 vs. 128.9±12.2mmHg), DBP (65.3±5.6 vs. 83.4±3.9mmHg), RHR (76.4±5.9 vs. 92.0±8.9bpm), CRFI (97.6±8.2 vs. 119.08±8.9bpm), QOL (74.5±7.1 vs. 55.1±3.2%), SOD_1(17.6±1.2 vs. 20.3±2.1) and SOD_2 (18.1±1.6 vs. 20.6±2.0). However, the within-group analysis showed that there were statistically significant reduction in all the outcomes in the EG except QOL where participants recorded significant increase, while there were significant increase in all the outcomes of CG except SOD_1 and SOD_2 where significant reduction were recorded. The statistically significant values recorded in the EG could be explained by the effects of the endurance exercise on caloric expenditure, net loss of appetite, reduction of rate of gain in fat cells and loss of more fat tissue. Likewise, the effect of endurance exercise resulted in improved aerobic capacity, mood and quality of life respectively.

5.2 CONCLUSIONS

According to the findings of this study, the following conclusions were drawn that:

1. Significant weight gain and body composition changes occurred with antidepressant drug treatment.
2. Significant reduction in cardio-respiratory fitness index occurred with antidepressant drug treatment.
3. Significant elevation of resting systolic blood pressure, resting diastolic blood pressure and resting heart rate occurred with antidepressant drug treatment.
4. A twelve week endurance exercise adequately controlled body adiposity, substantially improved cardio-respiratory fitness and quality of life, and also reduced severity of depression in patients with major depressive disorder; receiving antidepressant drug treatment.
5. Endurance exercise programme is a beneficial and effective clinical mediative and adjunctive intervention which should be included in the total management of patients with major depressive disorder.

5.3 RECOMMENDATIONS

Based on the findings of this study, the following recommendations were made to:

1. **Psychiatrists and Psychologists**

   Early endurance exercise intervention is key to preventing weight gain and its associated risks in patients with major depressive disorder, receiving antidepressant drug treatment. Therefore, it is recommended that psychiatrists should involve the physiotherapists at the early phase of management. Concurrent administration of endurance exercise intervention with antidepressant drug treatment is hereby recommended.

2. **Physiotherapists**

   Participation in endurance exercise by patients with major depressive disorder requires continuous motivation, encouragement and commitment on the part of the physiotherapist. It is recommended that physiotherapist should dedicate themselves to making their services available to patients with major depressive disorder, clinicians involved in the management of depressive disorder and psychiatry at large.

3. **Government and Health Planners**

   That from the results of this study, it is recommended that health planners and policy makers at all levels of government, should provide recreational facilities in the neighbourhood, communities, wards, such that all citizens have access to affordable recreational facilities.

4. **Researchers**

   Future researches can replicate this study to evaluate comparative effects of endurance and resistance exercises in patients with major depressive disorder and other psychiatric disorders across all age group.

REFERENCES

Adeniyi, A.F., Okafor, N.C., Adeniyi, C.Y (2011): Depression and physical activity in a sample of Nigerian adolescents:levels, relationships and predictors. Child and Adolescent Psychiatry and Menthal Health 5:16.

Alison, L., (2009): Treatment-resistant depression. American Academy of Family Physicians 80(2):167-172. www.aafp.org/afp.

American Medical Network (2011): Major depressive disorder. Retrieved May 20, 2012 at 12:13am. http://www.health.com/psy/major-depressive-disorder/

American Psychiatric Association, (2005): Diagnostic and statistical manual of mental disorders 4th ed, Washington DC.

Babyak, M.A., Blumenthal J.A., Herman S., Khatri P., Doraiswamy M., Moore, K. Craighead, E. Baldewiez, T.T., Krishnan, K.R., (2000): Exercise Treatment for Major Depression: Maintenance of Therapeutic Benefit at 10 Months Psychosomatic Medicine 62:633-638

Basco, M.R., (2005): The biopolar workbook tool for controlling your mood swings. Guliford press. ISBN 978-1-59385-162-0. Retrieved May 11, 2012. http://www.nimh.nih.gov

Bech, P., (2002): The bech-rafealsen melancholia scale in clinical trials of therapies in depressive disorders: A 20 year review of its use as outcome measure. Acta Psychiatrica Scandinavica, 106:252-264

Birrer, R.B. Vemuri, S.P., (2004): Depression in later life: a diagnostic and therapeutic challenge. American Family Physician, 69 (10)

Blumenthal, J.A., Babyak, M.A., Moore, K.A., Craighead, W.A., Herman, S., Khatri, P. Moore, K., (1999): Effects of exercise training on older patients with major depression. Archives of Internal Medicine 159:2349-56

Blumenthal, J.A., Babyak, M.A., Doraiswamy, P.M., Watkins, L., Hoffman, B.M., Barbour, K.A., Moore, K., (2007): Exercise and pharmacotherapy in the treatment of major depressive disorder. Psychosomatic Medicine 69:587-596

Bostwick, J.M., Pankratz, V.S., (2000): Affective Disorders and Suicide Risk: a re-examination. American Journal of Psychiatry; 157:1925-32

Brosse, A.L.Sheets, E.S. Lett, H.S. Blumenthal, J.A., (2002): Exercise and the treatment of clinical depression in adults: recent findings and future directions. Sports Medicine 32(12):741-760.

Carta, M.G., Hardoy, M.C., Pilu, A., Sorba, M., Floris, A.L., Mannu, F.A., Baum, A., Cappai, A., Claudio, V., Sal vi, M., (2008): Improving physical quality of life with group physical activity in the adjunctive treatment of major depressive disorder. Clinical Practice and Epidemiology in Mental Health:4(1)1-6.

Centre for Disease Control and Prevention (2012): Health related quality of life. Retrieved June 18, 2012 at 9:22pm. http://www.cdc.gov/hrgol.

Callaghan, P., (2004):Major depression a perspective on nursing care. Journal of Psychiatric and Mental Health Nursing 11, 476-483

Cohen, J.A., (1988): Statistical Power Analysis for the Behavioural Sciences. 2nd ed, Hillsdale, New Jersey. Lea, 56:102

Deshmukh, R., Franco, K., (2003): Managing weight gain as side effect of antidepressant therapy. Cleveland Clinic Journal of Medicine 70 (7): 614-623

Dimeo, F., Bauer, M., Varahram, I., (2001): Benefits from aerobic exercise in patients with major depression: a pilot study: British Journal of Sports Medicine; 35:114-17

Dun, A.L., Trivedi, M.H., Kampart, J.B., (2005): Exercise treatment for depression: efficacy and dose response. American Journal of Preventive Medicine 28:1-6

Etymology Dictionary (2012) Online etymology dictionary. Retrieved Feburary 20, 2012 at 11:12pm from http://dictionary.reference.com/browse/depress.

Franklin, D. J., (2003): Types of depression. Psychology Information Online. Retrieved April 12, at 6:20 p.m from http://www.psychologyinfo.com/depression/depression-types.html

Geddes, J.R. and Butler, R., (2002): Depressive disorders. American Family Physician 65:7

George, J., Chandran, M., Sandesh, T., (2012): Effect of 12 weeks aerobic exercises versus antidepressant medication in young adult males diagnosed with major depressive disorder. Journal of Biology, Agriculture and Healthcare.2(5)70-77.

Gonzalez, O., Berry, J.T., McKnight-Eily, L.R., Strine, T., Edwards, V.J., Lu, H., Croft, J.B (2010): Current depression among adults-United States, 2006 and 2008. Morbidity and Mortality Weekly Report 38 (59): 1229

Gruenberg, A.M., Goldstein, R.D., Pincus, H.A., (2005): Classification of depression: Rsearch and Diagnostic Criteria. DSM-IV and ICD-10. Retrieved April 26, 2012 at 3:30pm. http://media.wiley.com/product-data/excerpt/50/35273078/3527307850.pdf.

Gureje, O., (2011): Depression: a disability killer on the prawl. Yaba news; A publication of the Federal Neuro – Psychiatric Hospital, Yaba, Lagos. 6(1)4-8.

Helmich, I., Latini, A., Sigwalt, A., Carta, M.G., Machado, S., Velasques, B., Ribeiro, P., Budde, H., (2010): Neurobiological alterations induced by exercises and their impact on depressive disorders. Clinical Practice & Epidemiology in Mental Health. 6:115 - 125

Jorm, A.F., Christenses, H., Griffiths, K.M., Rodgers, B., (2002): Depression in the community: effectiveness of complementary and self-help treatments for depression .Medical Journal of Australia 176: S84-S95

Jorm, A.F., (2000): Does old age reduce the risk of anxiety and depression? A review of epidemiological studies across the adult life span. Psychological Medicine. 30(1):11-22 PMID10722172.

Kelley, G.A., Kelley,K.A., and Vu Tran, Z.(2001): Aerobic exercise and resting blood pressure: A Meta-Analytic Review of Randomised, Controlled Trials. Preventive Cardiology 4:73-80

Kisner, C. Colby L.A., (2002): Therapeutic Exercises: Foundation and Techniques 4th editon Philadelphia. F.A Davis Company 149-170

Knubben, K. Reischies F.M. Adli, M. Schlattmann, P. Bauer, M. Dimeo, F., (2007): A randomized, controlled study on the effects of a short-term endurance training programme in patients with major depression British Journal of Sports Medicine; 41:29-33

Kuczmarski, R. J. Flegal, K. M., (2000): Criteria for definition of overweight intransition: background and recommendations fo the United States. American Journal of Clinical Nutrition 72: 1074-81

Laimer, M., Kramer – Reinstadler, K., and Rauchenzauner, M., (2006): Effect of mirtazapine treatment on body composition and metabolism. Journal of Clinical Psychiatry. 67(3): 421 – 4.

Lawlor, D.A. Hopker, W., (2001): The effectiveness of exercise as an intervention in the management of depression: systematic review and meta-regression analysis of randomized controlled trial. British Medical Journal 322:763

McArdle, W.D., Katch, F.I. and Katch, V.L (2002): Essentials of Exercise Physiology 2nd ed, New York, Lippincott Williams and Wilkins, 221-236

Mather, A.S. Rodriguez, C. Guthrie, M.F., (2002): Effects of exercise on depressive symptoms in older adults with poorly responsive depressive disorder: randomized controlled trial. British Journal of Psychiatry; 180:411-15

Mendlowics, M.V., Stein, M.B., (2000): Quality of life in individuals with anxiety disorders. American Journal of Psychiatry 157:667-682.

Millard-Strafford, M.L., (2001) Use of air displacement plethysmography for estimating body fat in a four-component model. Medicine and Science in Sports and Exercise 33(8):1311-17

Murphy, J.M., Laird, N.M. Monson, R.R. Sobel, A.M. Leighton, A.H., (2000): A 40-year perspective on the prevalence of depression. The stirling county study. Archives of General Psychiatry 57:209-215

Nabkasorn, C. Miyai, N. Sootmongkol, A. Junprasert, S., Yamamoto, H. Arita, M. Miyashita, K., (2006): Effects of physical exercise on depression, neuroendrocrine stress hormones and physiological fitness in adolescent females with depressive symptoms. The European Journal of Public Health 16(2):179-184

National Institute of Mental Health (2009): Women and depression: Discovering hope. United States Department of Health and Human Services. Retrieved March 10,2011 at 1:34 a.m from http:// www.nimh.nih.gov/health/publications/women-and-depression-discovering hope/index.shtml.

Omron Healthcare (2011): Body Composition Monitor: BF511 Instruction manual. IM-HBF-511-E-02-12/085322544-OB.11-12.

Pardridge, W.M., (2007): Blood-brain barrier delivery of protein and non-viral gene therapentics with molecular Trojan horses. Journal of Control Release. 122(3):345-348.

Pietrobelli, A., Heymsfield, S.B., Wang, Z.M., Gallangher, D., (2001): Multicomponent body composition models: Recent advances and future directions. European Journal of Clinical Nutrition 55:69-75

Potter, W.Z. Hollister, L.E., (2001): Antidepressant agents. Basic and Clinical Pharmacology 8th ed, New York. McGraw- Hill Companies 498-511

Powers, S.K. Howley, E.T., (2007): Exercise physiology: Theory and application to fitness and performance.6th ed, New York. McGraw-Hill Companies 299-317

Quinn, E., (2011): Body composition and percent body fat. About.com Health's Disease and Condition Retrieved on January 14, 2012 at 10:36pm from http://sportsmedicine.about.com/od/fitnessevalandassessment/a/Bodycomp.htm.

Radden, J., (2003): Is this dame melancholy? Equating today's depression and past melancholia. Philosophy, Psychiatry & Psychology. 10(1):37-52. Retrieved June 30, 2012 at 5:20pm. http://muse.jhu.edu/journals/philosophy-psychiatry-and-psychology/v010/10.1radden01.html.

Rapaport, M.H., Clary, C., Fayyard, R., Endicott, J., (2005): Quality-of-life unpairment in depressive and anxiety disorders. American Journal of Psychiatry 162: (6) 1171-78

Remick, R.A., (2002): Diagnosis and management of depression in primary care: a clinical update and review. Canadian Medical Association Journal, 167 (11)

Richards, H., (2005): Depression in neurological disorders: Parkinson's, multiple sclerosis and stroke. Journal OF Neurology Neurosurgery and Psychiatry 76:148-152

Rupke S.J., Blecke D. and Renfrow M. (2006): Cognitive Therapy for Depression. American Family Physician 73:1

Sanya, A.O., (2010): Physiotherapy and wellness: Rungs of the ladder. An Inaugural lecture. Ibadan University Press Ibadan: 1-39

Schwartz, T., Meszaros, Z.S., Khan, R., Nihalani, N., (2007): How to control weight gain when prescribing antidepressants. Current Psychiatry 6(5)43-54.

Stedman's (2006): Stedman's Medical Dictioonary , 28th edn. Lippincott Williams and Wiilkins. Retrieved June 18, 2012 at 9.04pm. http://dictionary.web.md.com/terms/quality-of-life .

Sorenson, T. I.A., (2000): The changing lifestyle in the world; body weight and what else. Diabetic Care 23 (2): 1-4

Spencer, D.C. Nashelsky, J., (2005): Counseling or Antidepressants for Treating Depression? American Family Physician 72:11

Trivedi, M.H. Fava, M. Wisniewki, S. R., (2006): Medication augmentation after the failure of SSRIs for depression. New England Journal of Medicine 354(12):1243-1254

Uwaifo, G. Arioglu, E., (2006): Obesity. Retrieved March 15, 2011 at 12pm from http://www.emedcine.com/med/topics1653.htm

Wagner, D.R., Heyward, V.H., (1999): Technique of body composition assessment. A review of laboratory and field methods. Research Quarterly for Exercise and Sport 70:135-49

Warburton, D.E.R. Nicol, C.W. Bredin, S.S.D., (2006): Health benefits of physical activity: the evidence Canadian Medical Association Journal 174(6) 32

World Health Organization, (1992):The ICD-10 Classification of mental and behavioural disorders: Clinical Descriptions and Diagnostic Guidelines. Geneiva Switzerland.

World Health Organization (1998): Obesity: preventing and managing the globals epidemic. Report of WHO Consultation, Presented AT THE World Health Organization, June 3-5, 1997; Geneva, Switzerland. Publication WHO/NUT/NCD/98. 1:1998

World Health Organization, (2008): The global burden of disease: 2004 update. Geneiva Switzerland. WHO Press: 2008 Retrieved on February 15,2011 at 5:30pm from http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf.

World Health Organization (2011): Initiative on depression in public health. http://www.who.int/mental_health/management/depression/definition/en/index1.html Retrieved May 11, 2011 7:55am.

Federal Neuro-Psychiatric Hospital, Yaba
Management Board
FEDERAL NEURO-PSYCHIATRIC HOSPITAL, YABA - LAGOS

Ref: FNPHY/ERC/11/039

23 August 2011.

Mr. Kareem, Rotimi Olanrewaju
Department of Physiotherapy,
College of Medicine, University of Ibadan, Ibadan,
Oyo State.

Dear Mr. Kareem,

RE: EFFECTS OF A TWELVE-WEEK ENDURANCE EXERCISE PROGRAMME ON SELECTED CLINICAL ATTRIBUTES AND QUALITY OF LIFE IN PATIENTS WITH DEPRESSION.

I am directed to refer to your letter dated 07 June 2011 on the above subject matter and to convey approval for you to conduct your research as you requested.

A copy of your final project should be sent to the hospital library for record purpose.

Mr. I. G. Amoo
Secretary: Ethical Review Committee

8, Harvey Road,
P.M.B. 2008
Yaba, Lagos, Nigeria.
Tel: 01 - 774 3174
E-mail:
neuropsychiatrichospitalyaba@yahoo.com
Website:
www.neuropsychiatrichospitalyaba.org

Mental Health Service Provider since 1907

LAGOS UNIVERSITY TEACHING HOSPITAL
HEALTH RESEARCH AND ETHICS COMMITTEE

PRIVATE MAIL BAG 12003, LAGOS, NIGERIA
e-mail address: luthethics@yahoo.com

Chairman
ASSOC. PROF. N. U. OKUBADEJO
MB. ChB, FMCP

Administrative Secretary
MR. D. J. AKPAN
B.Sc. BUS. ADMIN, MIHSAN

Chief Medical Director:
PROF. AKIN. OSIBOGUN
MBBS (Lagos), MPH (Columbia), FMCPH FWACP

Chairman, Medical Advisory Committee
DR. M. O. OGUNLEWE
BDS, FWACS.

LUTH HREC REGISTRATION NUMBER: NHREC: 19/12/2008a
Office Address: Room 107, 1st floor, LUTH Administrative Block
Telephone: 234-1-5850737, 5852187, 5852209, 5852158, 5852111

20th October, 2011

NOTICE OF EXPEDITED REVIEW AND APPROVAL

PROJECT TITLE: "EFFECTS OF A TWELVE-WEEK ENDURANCE EXERCISE PROGRAMME ON SELECTED CLINCAL ATTRIBUTES AND QUALITY OF LIFE IN PATIENTS WITH DEPRESSION".
HEALTH RESEARCH COMMITTEE ASSIGNED NO.: ADM/DCST/HREC/250
NAME OF PRINCIPAL INVESTIGATOR: ROTIMI OLANREWAJU KAREEM
ADDRESS OF PRINCIPAL INVESTIGATOR: DEPT. OF PHYSIOTHERAPY, UNIVERSITY OF IBADAN.
DATE OF RECEIPT OF VALID APPLICATION: 17-08-11
DATE OF MEETING WHEN FINAL DETERMINATION OF RESEARCH WAS MADE: 05-10-11

This is to inform you that the research described in the submitted protocol, the consent forms, and all other related materials where relevant have been reviewed and given full approval by the Lagos University Teaching Hospital Health Research Ethics Committee (LUTHHREC).

This approval dates from 05-10-2011 to 05-10-2012. If there is delay in starting the research, please inform the HREC so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of this dates. All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study. In multiyear research, endeavor to submit your annual report to the HREC early in order to obtain renewal of your approval and avoid disruption of your research.

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

DR. N. U. OKUBADEJO
CHAIRMAN, LUTH HEALTH RESEARCH AND ETHICS COMMITTEE

INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT)
COLLEGE OF MEDICINE, UNIVERSITY OF IBADAN. IBADAN, NIGERIA.
Director: **Prof. A. Ogunniyi,** B.Sc(Hons), MBChB, FMCP, FWACP, FRCP (Edin), FRCP (Lond)
Tel: **08023038583, 08038094173**
E-mail: **aogunniyi@comui.edu.ng**

UI/UCH EC Registration Number: **NHREC/05/01/2008a**

NOTICE OF FULL APPROVAL AFTER FULL COMMITTEE REVIEW

Re: Effects of a Twelve-Week Endurance Exercise Programme on Selected Clinical Attributes and Quality of Life in Patients with Depression.

UI/UCH Ethics Committee assigned number: UI/EC/11/0130

Name of Principal Investigator: **Rotimi O. Kareem**

Address of Principal Investigator: Department of Physiotherapy,
College of Medicine,
University of Ibadan, Ibadan

Date of receipt of valid application: 27/05/2011

Date of meeting when final determination on ethical approval was made: **N/A**

This is to inform you that the research described in the submitted protocol, the consent forms, and other participant information materials have been reviewed and *given full approval by the UI/UCH Ethics Committee.*

This approval dates from 27/02/2012 to 26/02/2013. If there is delay in starting the research, please inform the UI/UCH Ethics Committee so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the* UI/UCH EC *assigned number and duration of* UI/UCH EC *approval of the study.* It is expected that you submit your annual report as well as an annual request for the project renewal to the UI/UCH EC early in order to obtain renewal of your approval and avoid disruption of your research.

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

UI/UCH EC
2 7 FEB 2012
APPROVED
COLLEGE OF MEDICINE, U.I

Prof. A. Ogunniyi
Director, IAMRAT
Chairman, UI/UCH Ethics Committee
E-mail: uiuchirc@yahoo.com

DEPARTMENT OF PHYSIOTHERAPY

COLLEGE OF MEDICINE
UNIVERSITY OF IBADAN, IBADAN, NIGERIA

FAX: 234 - 02 - 2411768
TELEX: Campus 31128 NG

HEAD OF DEPARTMENT

MAILING ADDRESS:
COLLEGE OF MEDICINE (UCH)
P.M.B. 5017, G.P.O.
IBADAN, NIGERIA.
TELEPHONE: 02-2410088, 2413503.
2410109, 2410212,
Exts: 3366,3367, 3357, 3207.

INFORMED CONSENT FORM

IRB Research approval number:_____

This approval will lapse on:_____

My names are KAREEM Rotimi Olanrewaju . I am a postgraduate student of the Department of Physiotherapy, College of Medicine, Universityof Ibadan. I am carrying out a research titled: EFFECTS OF A TWELVE-WEEK ENDURANCE EXERCISE PROGRAMME ON SELECTED CLINICAL ATTRIBUTES AND QUALITY OF LIFE IN PATIENTS WITH DEPRESSION. The purpose of the study is to find out the efficacy of a twelve-week endurance exercise programme on the body composition, selected cardio-respiratory indices, quality of life and severity of depression in patients with depression. A total of 70 participants will be involved in this study and be randomly allocated into two groups. Participants will be engaged in a period of twelve weeks throughout the study. Participants in exercise research group will go through endurance exercise intervention for twelve weeks, while the participants in the control research group will undergo only relaxation exercise.

You will be required to carry out endurance exercises, for three times per week with a day of rest in between. Exercise sessions will be carried out in the Physiotherapy Department of Federal Neuro-psychiatry Hospital Yaba, Lagos State with an estimate of 45minutes per session. It is expected that individuals increasing their level of physical activity may experience some side effects such as fatigue and muscle soreness. To prevent that, the exercise programme has been structured to start with a warm-up and end with a cool-down, to progress gradually and will be performed under supervision of the researcher. Some measurement will be carried out on you during the course of the study to assess your body composition, cardio-respiratory fitness, quality of life and severity of depression, at the beginning and every two weeks throughout the duration of the study.

Participation in this study is free. The goal of this research is to find ways of reducing/control weight gained during antidepressant drug treatment, while promoting your health, improving your quality of life and reducing the severity of depression through endurance exercise. All information collected in this study will be given coded numbers and will not be linked with you in anyway, and your name or any identifier will not be used in any publication or reports from this study. Participation in this study is entirely voluntary, and you can choose not top participate, or withdraw from this research at any time. Please, note that some of the information that has been obtained from you before you choose to withdraw may be modified and used in reports and publications. In case you suffer any injury as direct result of your participation in this study, you will be treated and the researcher will bear the cost.. During the course of this research, you will

be given any information that may affect your continued participation or your health. I will appreciate your cooperation.

I have fully explained this research to _____

And have given sufficient information, including risks and benefits to make an informed decision.

Date:_____ Signature: _____

Name: _____

I have read the description of this study, and I understand that my participation is voluntary. I know enough about the purpose, method, risks and benefit of this research study and have decided to be part of it. I also understand that I may freely stop being part of this study at any time.

Now that the study has been well explained to me and I fully understand the content of the study process, I hereby sign my consent to participate in this study.

Date: _____ Signature: _____

Name: _____

Witness Signature/Thumbprint:_____ Witness Name: _____

HAMILTON DEPRESSION RATING SCALE (HAM-D)

(HAM)

Patient Information								
Patient		Date	Day	Mth.	Year	Time	Hour	Min
Personal notes								

TICK APPROPRIATE BOX FOR EACH ITEM

1. Depressed mood This item covers both the verbal and the non-verbal communication of sadness, depression, despondency, helplessness and hopelessness.	
0 - Neutral mood.	☐
1 – When it is doubtful whether the patient is more despondent or sad than usual. E.g. the patient vaguely indicates to be more depressed than usual.	☐
2 – When the patient more clearly is concerned with unpleasant experiences, although he still is without helplessness or hopelessness.	☐
3 – The patient shows clear non-verbal signs of depression and/or is at times overpowered by helplessness or hopelessness.	☐
4 – The patient's remark on despondency and helplessness or the non-verbal ones dominate the interview in which the patient cannot be distracted.	☐

2. Self-depreciation and guilt feelings This item covers the lowered self-esteem with guilt feelings.	
0 – No self-depreciation or guilt feelings.	☐
1 – Doubtful whether guilt feelings are present, because the patient is only concerned with the fact that he during the actual illness has been a burden to the family or colleagues due to reduced work capacity.	☐
2 – Self-depreciation or guilt feelings are more clearly present because the patient is concerned with incidents in the past prior to the actual episode. E.g. the patient reproaches himself small omissions or failures, not to have done his duty or to have harmed others.	☐
3 – The patient suffers from more severe guilt feelings. He may express that he feels that the actual suffering is some sort of a punishment. Score 3 as long as the patient intellectually can see that his view is unfounded.	☐
4 – The guilt feelings are firmly maintained and resist any counterargument, so that they have become paranoid ideas.	☐

3. Suicidal impulses

0 – No suicidal impulses.	☐
1 – The patient feels that life is not worthwhile, but he expresses no wish to die.	☐
2 – The patient wishes to die, but has no plans of taking his own life.	☐
3 – It is probable that the patient contemplates to commit suicide.	☐
4 – If during the days prior to the interview the patient has tried to commit suicide or if the patient in the ward is under special observation due to suicidal risk.	☐

4-6: Note: Administration of drugs- sedative or others – shall be disregarded

4. Initial insomnia	
0 – Absent	☐
1 – When the patient 1 (-2) out of the last 3 nights has had to lie en bed for more than 30 minutes before falling asleep.	☐
2 – When the patient all 3 nights has been in bed for more than 30 minutes before falling asleep.	☐

5. Middle insomnia The patient wakes up one or more times between midnight and 5 a.m. (if for voiding purpose followed by immediate sleep rate 0).	
0 – Absent	☐
1 – Once or twice during the last 3 nights.	☐
2 – At least once every night.	☐

6. Delayed insomnia = Premature awakening The patient wakes up before planned by himself or his surroundings.	
0 – Absent	☐
1 – Less than 1 hour (and may fall asleep again).	☐
2 – Constantly – or more than 1 hour too early.	☐

7. Work and interests This item includes both work carried out and motivation. Note, however, that the assessment of tiredness and fatigue in their physical manifestations is included in item 13 (general somatic symptoms) and in item 23 (tiredness and pain). **A. At first rating of the patient**	
0 – Normal work activity.	☐
1 – When the patient expresses insufficiency due to lack of motivation, and/or trouble in carrying out the usual workload, which the patient, however, manages to do without reduction.	☐
2 – More pronounced insufficiency due to lack of motivation and/or trouble in carrying out the usual work. Here the patient has reduced work capacity, cannot keep normal speed, copes with less job or in the home; the patient may stay home some days or may try to leave early.	☐
3 – When the patient has been sick-listed, or if the patient has been hospitalized (as day-activities).	☐
4 – When the patient is fully hospitalized and generally unoccupied without participation in the ward activities.	☐
B. At weekly ratings	
0 – Normal work activity. a) The patient has resumed work at his/her normal activity level. b) When the patient will have no trouble to resume normal work.	☐
1 a) The patient is working, but at a reduced activity level, either due to lack of motivation or due to difficulties in the accomplishment of his normal work. b) The patient is not working and it is still doubtful that he can resume his normal work without difficulties.	
2 – The patient is working, but at a clearly reduced level, either due to episodes of non-attendance or due to reduced work time. The patient is still hospitalized or sick-listed, participates more than 3-4 hours per days in ward (or home) activities, but is only capable to resume normal work at a reduced level. If hospitalized the patient is able to change from full stay to day-patient status.	☐
3 – When the patient has been sick-listed, or if the patient has been hospitalized (as day-activities).	☐
4 – When the patient is fully hospitalized and generally unoccupied without participation in the ward activities.	☐

8. Retardation (general)	
0 – Normal verbal activity, normal motor activity with adequate facial expression.	☐
1 – Conversational speed doubtfully or slightly reduced and facial expression doubtfully or slightly stiffened (retarded).	☐
2 – Conversational speed clearly reduced with intermissions; reduced gestures and slow pace.	☐
3 – The interview is clearly prolonged due to long latencies and brief answers; all movements were slow.	☐
4 – The interview cannot be completed, retardation approaches (and includes) stupor.	☐

9. Agitation	
0 – Normal motor activity with adequate facial expression.	☐
1 – Doubtful or slight agitation. E.g. tendency to changing position in chair or at times scratching his head.	☐
2 – Fidgeting; wringing hands, changing position in chair again and again. Restless in ward, with some pacing.	☐
3 – Patient cannot stay in chair during interview and/or much pacing in ward.	☐
4 – Interview has to be conducted "on the run". Almost continuous pacing. Pulling off clothes, tearing his hair.	☐

10. Anxiety (psychic) This item includes tenseness, irritability, worry insecurity, fear and apprehension approaching overpowering dread. It may often be difficult to distinguish between the patient's experience of anxiety ("psychic" or "central" anxiety phenomena) and the physiological ("peripheral") anxiety manifestations, which can be observed, e.g., hand tremor and sweating. Most important is the patient's report on worry, insecurity, uncertainty, and experiences of dreadfulness i.e. the psychic ("central") anxiety.	
0 – The patient is neither more nor less insecure or irritable than usual.	☐
1 – It is doubtful whether the patient is more insecure or irritable than usual.	☐
2 – The patient expresses more clearly to be in a state of anxiety, apprehension or irritability, which he may find difficult to control. It is thus without influence on the patient's daily life, because the worrying is still about minor matters.	☐
3 – The anxiety or insecurity is at times more difficult to control, because the worrying is about major injuries or harms, which might occur in the future. E.g.: the anxiety may be experienced as panic, i.e. overpowering dread. Has occasionally interfered with the patient's daily life.	☐
4 – The feeling of dreadfulness is present so often that it markedly interferes with the patient's daily life.	☐

11. Anxiety (somatic) This item includes physiological concomitants of anxiety: All feeling states should be rated under item 10 and not here.	
0 – When the patient is neither more nor less prone than usual to experience somatic concomitants of anxiety feeling states.	☐
1 – When the patient occasionally experiences slight manifestations like abdominal symptoms, sweating or trembling. However, the description is vague and doubtful.	☐
2 – When the patient from time to time experiences abdominal symptoms, sweating trembling etc. Symptoms and signs are clearly described, but are not marked or incapacitating, i.e. still without influence on the patient's daily life.	☐
3 – Physiological concomitants of anxious feeling states are marked and sometimes very worrying. Interfere occasionally with the patient's daily life.	☐
4 – The feeling of dreadfulness is present so often that it markedly interferes with the patient's daily life.	☐

12. Gastro-Intestinal Symptoms may stem from the entire gastro-intestinal tract. Dry mouth, loss of appetite, and constipation are more common than abdominal cramps and pains. Must be distinguished from gastro-intestinal anxiety symptoms ("butterflies in the stomach ") or loose bowel movements) and also from nihilistic ideas (no bowel movements for weeks or months; the intestines have withered away) which should be rated under 15 (Hypochondriasis).	
0 – No gastro-intestinal complaints (or symptoms unchanged from before onset of depression).	☐
1 – Eats without encouragement by staff, and food intake is about normal, but without relish (all dishes taste alike and cigarettes are without flavour). Sometimes constipated.	☐
2 – Food intake reduced, patient has to be urged to eat. As a rule clearly constipated. Laxatives are often tried, but are of little help.	☐

13. General Somatic Central is feelings of fatigue and exhaustion, loss of energy. But also diffuse muscular achings and pains in neck, back or limbs, e.g. muscular headache.	
0 – The patient is neither more nor less tired or troubled by bodily discomfort than usual.	☐
1 – Doubtful or very vague feelings of muscular fatigue or other somatic discomfort.	☐
2 – Clearly or constantly tired and exhausted, and/or troubled by bodily discomforts, e.g. muscular headache.	☐

14. Sexual Interests This subject I often difficult to approach, especially with elderly patients. In males try to ask questions concerning sexual preoccupation and drive, in females responsiveness (both to engage in sexual activity and to obtain satisfaction in intercourse).	
0 – Not unusual.	☐
1 – Doubtful or mild reduction in sexual interest and enjoyment.	☐
2 – Clear loss of sexual appetite often functional impotence in men and lack of arousal or plain disgust in women.	☐

15. Hypochondriasis Preoccupation with bodily symptoms or functions (in the absence of somatic disease).	
0 – The patient pays no more interest than usual to the slight bodily sensations of every day life.	☐
1 – Slightly or doubtfully more occupied than usual with bodily symptoms and functions.	☐
2 – Quite worried about his physical health. The patient expresses thoughts of organic disease with a tendency to "somatise" the clinical presentation.	☐
3 – The patient is convinced to suffer from a physical illness, which can explain all his symptoms (brain tumour, abdominal cancer, etc.), but the patient can for a brief while be reassured that this is not the case.	☐
4 – The preoccupation with bodily dysfunction has clearly reached paranoid dimensions. The hypochondriacal delusions often have a nihilistic quality or guilt associations: to be rotting inside; insects eating the tissues; bowels blocked and withered away, other patients are being infected by the patient's bad odour or his syphilis. Counter-argumentation is without effect.	☐

16. Loss of insight This item has, of course, only meaning if the observer is convinced that the patient at the interview still is in a depressive state.	
0 – The patient agrees to have depressive symptoms or a "nervous" illness.	☐
1 – The patient still agrees to being depressed, but feels this to be secondary to non-illness related conditions like malnutrition, climate, overwork.	☐
2 – Denies being ill at all. Delusional patients are by definition without insight. Enquiries should therefore be directed to the patient's attitude to his symptoms of Guilt (item 2) or Hypochondriasis (item 15), but other delusional symptoms should also be considered.	☐

17. Weight loss Try to get objective information; if such is not available be conservative in estimation. **A. At first interview this item covers the whole actual period of illness**	
0 – No weight loss.	☐
1 – 1-2.5 kg weight loss.	☐
2 – Weight loss of 3 kg or more.	☐
B. At weekly interviews	
0 – No weight loss.	☐
1 – ½ kg pr week.	☐
2 – 1 kg or more per week.	☐

Roche

V 0477

Beck Depression Inventory

CRTN: _____ CRF number: _____ Page 14 patient inits: _____

Baseline

BDI-II

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness
- 0 I do not feel sad.
- 1 I feel sad much of the time.
- 2 I am sad all the time.
- 3 I am so sad or unhappy that I can't stand it.

2. Pessimism
- 0 I am not discouraged about my future.
- 1 I feel more discouraged about my future than I used to be.
- 2 I do not expect things to work out for me.
- 3 I feel my future is hopeless and will only get worse.

3. Past Failure
- 0 I do not feel like a failure.
- 1 I have failed more than I should have.
- 2 As I look back, I see a lot of failures.
- 3 I feel I am a total failure as a person.

4. Loss of Pleasure
- 0 I get as much pleasure as I ever did from the things I enjoy.
- 1 I don't enjoy things as much as I used to.
- 2 I get very little pleasure from the things I used to enjoy.
- 3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings
- 0 I don't feel particularly guilty.
- 1 I feel guilty over many things I have done or should have done.
- 2 I feel quite guilty most of the time.
- 3 I feel guilty all of the time.

6. Punishment Feelings
- 0 I don't feel I am being punished.
- 1 I feel I may be punished.
- 2 I expect to be punished.
- 3 I feel I am being punished.

7. Self-Dislike
- 0 I feel the same about myself as ever.
- 1 I have lost confidence in myself.
- 2 I am disappointed in myself.
- 3 I dislike myself.

8. Self-Criticalness
- 0 I don't criticize or blame myself more than usual.
- 1 I am more critical of myself than I used to be.
- 2 I criticize myself for all of my faults.
- 3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes
- 0 I don't have any thoughts of killing myself.
- 1 I have thoughts of killing myself, but I would not carry them out.
- 2 I would like to kill myself.
- 3 I would kill myself if I had the chance.

10. Crying
- 0 I don't cry anymore than I used to.
- 1 I cry more than I used to.
- 2 I cry over every little thing.
- 3 I feel like crying, but I can't.

THE PSYCHOLOGICAL CORPORATION®
Harcourt Brace & Company
SAN ANTONIO
Orlando • Boston • New York • Chicago • San Francisco • Atlanta • Dallas
San Diego • Philadelphia • Austin • Fort Worth • Toronto • London • Sydney

Subtotal Page 1

Continued on Back

0154018392
NR15645

Roche

V 0477

Beck Depression Inventory

CRTN: _____ CRF number: _____ Page 15 patient inits: _____

Baseline

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I don't consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.
1a I sleep somewhat more than usual.
1b I sleep somewhat less than usual.
2a I sleep a lot more than usual.
2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1–2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before.
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

3 4 5 6 7 8 9 10 11 12 A B C D E

_____ Subtotal Page 2
_____ Subtotal Page 1
_____ Total Score

NR15645

Psychiatric Research Unit
WHO Collaborating Centre in Mental Health

WHO (Five) Well-Being Index (1998 version)

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	Over the last two weeks	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1	I have felt cheerful and in good spirits	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
2	I have felt calm and relaxed	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
3	I have felt active and vigorous	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
4	I woke up feeling fresh and re-sted	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
5	My daily life has been filled with things that interest me	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

Scoring:

The raw score is calculated by totalling the figures of the five answers. The raw score ranges from 0 to 25, 0 represent-ing worst possible and 25 representing best possible quality of life.

To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.