A CROSS SECTIONAL STUDY OF THE ASSOCIATION BETWEEN ANTIRETROVIRAL THERAPY WITH DEPRESSION AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS INFECTED WITH HIV IN KASEMPA, ZAMBIA.

By

Edgar Mutimushi

A dissertation submitted to the University of Zambia in partial fulfillment of the requirements for the degree of Master of Science in HIV Medicine

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DECLARATION

I, **Edgar Mutimushi**, declare that this dissertation represents my own work, and that the work of others that has been used in this dissertation has been acknowledged and referenced. The work presented here has not been submitted for a degree, diploma or other qualification at this or any other university.

Candidate's Signature…… Date…….

Supervisor's Signature…….. Date…….

Co-Supervisor's Signature……Date……

CERTIFICATE OF APPROVAL

This dissertation of Edgar Mutimushi has been approved as fulfilling the requirements or partial fulfillment for the requirements for the award of Master of Science in HIV Medicine by the University of Zambia

Examiner 1…….Date……

Examiner 2……Date……..

Examiner 3……..……Date…….

ABSTRACT

A CROSS SECTIONAL STUDY OF THE ASSOCIATION BETWEEN ANTIRETROVIRAL THERAPY WITH DEPRESSION AND HEALTH RELATED QUALITY OF LIFE IN PATIENTS INFECTED WITH HIV IN KASEMPA, ZAMBIA.

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Background

Many HIV-infected patients are accessing antiretroviral therapy (ART) in Zambia. This has enabled them to live longer. However, it is necessary to determine whether such improvements are accompanied with parallel improvements in quality of life. The purpose of this research was to determine whether ART was associated with lower levels of depression and higher levels of health-related quality of life (HRQOL). The primary objective was to compare the association of ART with depression and Health Related Quality of Life (HRQOL) in treatment naïve and treatment experienced patients. The specific objectives were to screen for levels of depression and HRQOL in HIV infected patients, and to compare these levels between ART-experienced and ART-naïve patients

Methodology

This was a cross sectional study in which 140 HIV-infected adults (70 ART-experienced and 70 ART-naïve) in Kasempa district were enrolled by convenient sampling. Independent variables of sex, age, marital status, education and employment status were matched across the two groups to avoid their confounding effect and bias. Depression and HRQOL were screened using the CES-D and MOS-HIV tools respectively in both groups. The average scores for depression in both groups were compared using the t-test. Mental Health Summary scores (MHS) and Physical Health Summary scores (PHS) derived from the MOS-HIV tool were obtained by factor analysis and linearly transformed into a 0-100 scale. These scores were also compared between the two groups using the t-test. Multiple linear regression was used to determine the factors that were significantly associated with depression and HRQOL in both groups.

Results

The mean depression scores were found to be lower among ART-experienced clients compared with their ART-naïve counterparts with a mean difference of 7.40 (95% C.I 3.77-11.03; P < 0.0001). Overall, ART-experienced participants had higher HRQOL scores compared with their ART- naïve counterparts with differences of 23.0 (95% C.I 16.0-30.1; P < 0.0001) and 11.2 (95% C.I 6.0-16.4; P < 0.0001) in MHS and PHS scores respectively.

Discussion and Conclusion

Being ART-experienced was associated with lower depression scores and higher HRQOL scores when compared with being ART-naïve. Lower depression scores and higher HRQOL scores were associated with being male, married, single, asymptomatic and having higher CD4 counts.

Recommendations

It is recommended that clinicians caring for HIV-infected persons should be screening routinely for depression and HRQOL in these patients in order to identify clients who may need psychosocial care. This will ensure that complete and holistic treatment is offered to such clients.

Keywords: HIV/AIDS, Antiretroviral therapy, HRQOL, Depression

DEDICATION

This project is dedicated to my late father, Mr John Kabwe Mutimushi and to my mother Mrs Veronica Kombe Mutimushi for their tireless effort in ensuring that I got educated. It is also dedicated to my wife Veronica Kaliye Mutimushi for being patient and understanding.

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LIST OF ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral therapy
ARV	Antiretroviral
AUDIT	Alcohol Use Disorder Identification Test
BDI	Beck's Depression Inventory
CES-D	Centre for Epidemiologic Studies Depression
CSO	Central Statistics Office
DSM-IV	Diagnostic and Statistic manual of Mental disorders , fourth edition
EFV	Efavirenz
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HIV-1	Human Immunodeficiency Virus type - 1
HRQOL	Health Related Quality Of Life
MOS-HIV	Medical Outcome Survey – Human Immunodeficiency Virus
MDD	Major Depressive Disorder
OIs	Opportunistic Infections
PIs	Protease Inhibitors
PLWH	People Living With HIV
QOL	Quality Of Life
UNAIDS	Joint United Nations programmes on Acquired Immunodeficiency Syndrome
VL	Viral Load
WHO	World Health Organisation
WHOQOL	World Health Organisation Quality Of Life
WHOQOL-HIV	World Health Organisation Quality Of Life - Human

	Immunodeficiency Virus
WHOQOL-HIV-BRIEF	World Health Organisation Quality Of Life - Human Immunodeficiency Virus- BRIEF

OPERATIONAL DEFINITIONS

Antiretroviral (ARV): A drug given to suppress HIV viral replication resulting in a marked drop in viral load.

ART Experienced: For purposes of this study, these are adults who are infected with the HIV virus and have been on ART medication for at least three months.

ART Naïve: These are adults who are infected with the HIV virus but are not yet on ART medication.

Health Related Quality of Life: This refers to an individual's perception of their position in life and how this perception affects their health.

Depression: This is a mental disorder that affects emotions, behaviour and physical functioning. It is characterised by feelings of sadness, worthlessness, low self-esteem, hopelessness, apathy and loss of pleasure in daily activities.

Latest CD4 count: In this study, this refers to the latest CD4 count obtained in the last 180 days.

General Health Perception (GHP): The current health status of the participant based on the individual's judgement. Items in this dimension report the patient's general health, ability to resist illness and health outlook.

Physical Function (PF): The extent to which health interferes with a variety of physical activities like running, climbing up stairs etc.

Role Function (RF): The extent to which health interferes with the usual daily activities like house work, bathing etc.

Cognitive Function (CF): An intellectual process by which one becomes aware of, perceives or comprehends ideas. It involves all aspects of perception, thinking, reasoning and memory.

Body pain (BP): The intensity of body tenderness in the specified period.

Mental health (MH): The general state of mood and psychological wellbeing.

Energy/Vitality (EV): The measure of a patient's ability, energy and power.

Health Distress (HD): Mental or physical anguish or suffering.

Social Function (SF): The extent to which health interferes with the normal social activities like attending parties or visiting friends.

Quality of Life (QL): A single item dimension which measures the individual's

quality of life in the previous four weeks

Health Transition (HT): A measure of the amount of change in a patient's physical and emotional health in the previous four weeks.

Asymptomatic: WHO clinical stage I

Symptomatic: WHO clinical stages II, III and IV

1.0 INTRODUCTION

1.1 BACKGROUND

The 2011 Joint United Nations Programme on HIV/AIDS (UNAIDS) report showed that the estimated number of people living with HIV infection globally had increased from 28.6 million in 2001 to 34.0 million in 2010 while the number of new cases of HIV infections had decreased from 3.1 million to 2.7 million over the same period (UNAIDS World AIDS Day Report 2011). The report also showed that there was a reduction in the number of AIDS-related deaths globally, from 1.9 million in 2001 to 1.8 million deaths in 2010. The report further stated that although the percentage of people living with HIV (PLWH) appeared to have stabilized, the overall number of PLWH infection had steadily increased. This reflects that new HIV infections have continued to occur on a yearly basis and also shows that many HIV-infected persons are now accessing antiretroviral therapy (ART) which has helped to reduce HIV-related deaths in the recent years. According to the World Health Organisation (WHO) Global Health Observatory Data, the number of HIV-infected persons accessing ART has increased from 690,000 in 2000 to 14.9 million people in 2014 globally (WHO, 2015). And in Zambia, the number of HIV infected persons taking ART has increased from 344,407 in 2010 to 671,066 in 2014 while annual HIV-related deaths have reduced from 58,000 in 2010 to 19,000 in 2014 according to the UNAIDS Global AIDS Response Progress Report (GARPR) on Zambia (UNAIDS, 2015).

The primary objective of ART is to reduce HIV viral replication and thereby reduce the morbidity and mortality of HIV-infected patients. And since its advent in 1996, ART has led to a drastic reduction in HIV-associated mortality (Wong et al 2004, Sterne et al 2005, Hogg et al 2008, UNAIDS Report on Global AIDS Epidemic 2010).Therefore, HIV-infected persons are now living longer. This implies that HIV infection has now become a chronic disease. However, despite the reduction in mortality and morbidity caused by ART, HIV-infected persons continue to experience depression (Adewuya et al, 2007; Ciesla and Roberts, 2001) and poor health related quality of life (HRQOL) (Agrawal et al 2012).

It has therefore become important to determine the association between ART and levels of depression and HRQOL in these patients. There is need to determine whether the improvements in morbidity and mortality brought about by ART are associated with lower depression and higher HRQOL scores in these persons.

1.2 RATIONALE FOR STUDY

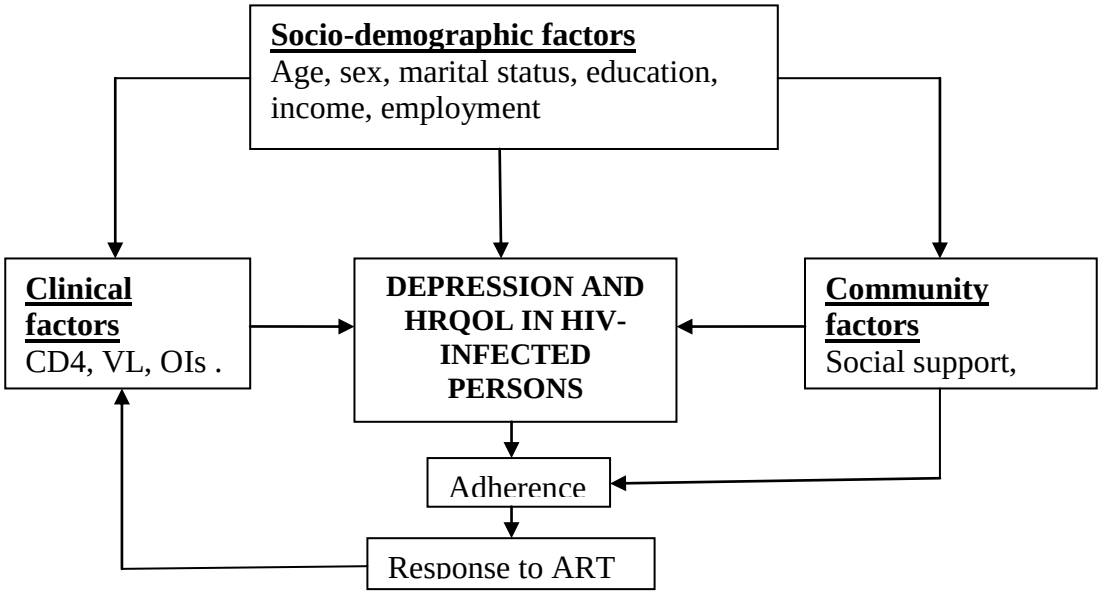
The Zambian government considers the management of HIV infection as a priority because of its devastating effect on the population. Therefore, the ministry of health (MOH) has scaled-up the provision of ART to HIV infected persons. The benefit of ART at reducing mortality and morbidity has been appreciated. It is important to understand the impact of ART not just its effect on physical health but also on the mental, psychological and social well-being. This study sought to show the association between ART with depression and HRQOL in HIV-infected persons in rural setting in Zambian. Clinicians, policy makers and the HIV-infected patients at large are expected to benefit from this study once the findings are published and disseminated.

The study will encourage clinicians practicing in Zambia to be screening for depression and HRQOL routinely in these persons. This will enable them to objectively quantify the patients' health and to track any changes in health with time in the course of treatment. The policy-makers in Zambia shall be equipped with the knowledge which will allow them make policies that will address socio-economic challenges that cause depression and poor HRQOL among HIV-infected patients. And the HIV-infected patients will benefit ultimately because the knowledge obtained from this study will be used by both the clinicians and policy-makers to address their challenges.

Finally, the study will provide additional information to the data that other researchers have already gathered on depression and HRQOL in sub-Saharan Africa and Zambia in particular.

1.3 CONCEPTUAL FRAMEWORK

Figure 1: Conceptual framework



1.3.1 Narrative for conceptual framework

Depression and HRQOL among HIV-infected persons are influenced by many factors. These include clinical, socio-demographic and community factors. These factors can either improve or make depression and HRQOL worse. There are interconnections and linkages within and across these factors. For instance, among clinical factors, a higher CD4 count can lead to a low Viral load (VL).

Linkages across these factors are many, for example, a supportive family can be linked to good adherence to antiretroviral (ARV) medication because a supportive family will encourage the patient to take the ARVs as prescribed by clinicians. Marital status is linked to social support because married persons get connected to other families through their spouses. Attainment of education can be linked to prevention of OIs because with education, HIV-infected persons will get equipped with the knowledge on the value of prophylaxis against these infections.

Depression and poor HRQOL can led to poor adherence to medication which can result in higher viral loads (VL), low CD4 counts and opportunistic infections.

1.4 STATEMENT OF THE PROBLEM

With the advent of ART, HIV-infected persons are now living longer. However, these patients continue to experience depression (Adewuya et al, 2007; Ciesla and Roberts, 2001) and poor HRQOL (Agrawal et al 2012). It is therefore necessary to find out if ART is associated with lower levels of depression and higher HRQOL scores apart from reducing deaths and morbidity among these patients.

1.5 RESEARCH QUESTION

How do the levels of depression and HRQOL differ in ART-experienced compared with ART-naïve HIV-infected patients?

1.6 HYPOTHESIS

1.6.1 Null hypothesis: Treatment with ART is not associated with better depression and HRQOL scores in patients infected with HIV.

1.7 OBJECTIVES

1.7.1 General objective

To determine the association of ART with depression and Health Related Quality of Life in HIV infected adults at Mukinge Mission Hospital and Kasempa Urban Clinic (KUC) in Kasempa district of Zambia.

1.7.2 Specific objectives

1. To screen and estimate the levels of depression in ART-experienced and ART-naïve HIV-infected patients using the Centre for Epidemiologic Studies Depression (CES-D) scale [Appendix 8.5a, b].
2. To screen and assess the levels HRQOL scores in ART-experienced and ART-naïve HIV-infected patients using the Medical Outcomes Survey–HIV (MOS-HIV) questionnaire [Appendix 8.6a, b].
3. To determine other factors that are associated with depression and HRQOL in ART-experienced and ART-naïve HIV-infected persons.

2.0 LITERATURE REVIEW

a. Definition of depression and HRQOL in HIV- infected persons

Depression is a mental disorder that affects emotions, behaviour and physical functioning. It is characterised by feelings of sadness, worthlessness, low self-esteem, hopelessness, apathy and loss of pleasure in daily activities. Sometimes depressed persons have suicidal ideations and vegetative symptoms such as loss of appetite, fatigue and insomnia (American Psychiatric Association 2000). HIV-infected patients sometimes present with depression.

Quality of life (QOL) has been defined by the World Health Organisation Quality of life (WHOQOL) group as an "*Individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"* (WHOQOL group 1995). Since HIV-infected persons experience physical challenges of ill-health coupled with social and psychological stresses, they are prone to poor Health Related Quality of life (HRQOL).

Because of depression and poor HRQOL, HIV-infected persons, experience compromised health (Preamble to the constitution of the WHO 1946).

b. HIV-infected patients suffer from depression and poor HRQOL

Several studies have shown that HIV-infected patients suffer from higher levels of depression and compromised HRQOL compared with the general population.

In a cross sectional study by Adewuya et al (2007) it was shown that major depressive disorder (MDD) was three times common among HIV-infected persons compared with their uninfected counterparts in Nigeria. Ciesla and Roberts (2001) showed in a meta-analysis of ten studies that depression was twice as common among HIV-infected persons compared with the general population. In addition, several other studies have shown that HIV-infected persons experience poorer HRQOL compared with their uninfected counterparts (Lars et al 2000; Agrawal et al 2012).

c. How HIV infection leads to depression and poor HRQOL

Depression in HIV-infected patients can be classified as primary or secondary. It is primary when it is pre-existing with no known physical or psychological cause. And it can be referred to as secondary depression when it occurs as a consequence of the effects of the virus itself on the nervous system, or when it is caused by the effect of opportunistic infections, malignancies or medications. The HIV virus affects the sub cortical and fronto-striato areas of the brain causing inflammation resulting in depressive symptoms (Dube et al 2005; Ghafouri et al 2006; Robertson et al 2010). Opportunistic infections, malignancies of the central nervous system and endocrinopathies have been known to cause depression in these patients. Some ARVs, nutritional deficiencies of Vitamin 12, Vitamin 6 and folate can also cause depression in HIV-infected patients (Kerry no date; Cespedes and Aberg 2006).

HIV-infected patients experience physical, mental and social problems which arise as a result of stigma, discrimination, poverty and depression (Oluwafemi 2012). All these lead to poor HRQOL.

d. Factors associated with depression and HRQOL in HIV-infected persons

Several studies have shown that both depression and poor HRQOL in HIV-infected patients are associated with a number of factors. Advanced age, female gender, low education, unemployment and inadequate or lack of income are associated with depression and poor HRQOL in HIV-infected persons (Blalock et al 2002; Campsmith et al 2003; Vigneshwaran et al 2003; Bolton et al 2004; Ruiz et al 2005; Kaharuza et al 2006; Bongongo et al 2013). HIV-infected persons who are unmarried, separated or divorced together with those lacking social support and the ones experiencing stigma have been found to suffer from depression and poor HRQOL in a number of studies (Jia et al 2004; Nojomi et al 2008; Li et al 2009; Akena et al 2010; Oppong 2012; Herrmann et al 2013). Worsening clinical symptoms, poor adherence, suicidal ideation, declining CD4 cell counts and increased HIV viral loads have also been associated with depression and poor HRQOL (Leserman et al 1999; Call et al 2000; Evans et al 2002; Campsmith 2003; Ammassari et al 2004; Mannheimer et al 2005; Kaharuza et al 2006; Nojomi et al 2008).

e. Depression and poor HRQOL in HIV-infection in sub-Saharan Africa

In sub-Saharan Africa, the prevalence of depression among HIV-infected patients ranges from 1% to over 30% as reported by various researchers (Sebit et al 2003; Petrushkin et al 2005; Shisana et al 2005; Adewuya et al 2007). Some studies have shown that poor HRQOL in sub-Saharan Africa is also quite prevalent among these patients (Mweemba et al 2009; Mgaywa et al 2009; Selman et al 2011; Shakirat and Ibrahim 2013).

f. Effect of ART on depression and HRQOL in HIV-infected patients

Before the advent of ART, most studies showed a general trend towards worsening levels of depression and decline in HRQOL of HIV-infected patients (Wu et al 1993; Cochran and Mays 1994; Thompson et al 1994; Lenderking et al 1994).

However, after the advent of ART in 1996, a number of studies have shown stabilization and improvements in depression and HRQOL among these patients (Judd et al 2000; Patrizia et al 2003; Chan et al 2003; Burgoyne and Tan 2008). In developed countries, several studies have shown that treatment with ART has an overall effect of reducing depression and improving scores of HRQOL in HIV-infected patients. This has been observed in randomised controlled studies (Cohen et al 1998; Ravicki et al1999; Nieuwkert et al 2000; Carr et al 2000), retrospective cohort studies (Chan et al 2003; Low-Beer et al 2003) and prospective studies (Judd et al 2000; Rubkin et al 2000; Brechtl et al 2001; Saunders and Burgoyne 2002). These studies were however conducted in countries that are not resource-limited and sometimes were restricted to patients on specific combinations of particular ARVs unlike this study. In sub-Saharan Africa similar studies have been conducted with similar outcomes. These were cross sectional studies conducted in Zimbabwe and South Africa (Louwagie et al 2007; Patel et al 2009). Others were prospective cohort studies conducted in Uganda and South Africa (Jelsma et al 2005; Stangl et al 2007; Wagner et al 2012) all showed that treatment of HIV-infected persons with ART was associated with improvements in depression and HRQOL.

g. Depression and poor HRQOL studies in HIV-infected persons in Zambia

There are very few studies conducted in Zambia linking HIV infection to depression or to HRQOL and ART. Kwalombota M (2000) revealed that the prevalence of major depression among HIV-infected, pregnant women in Lusaka, Zambia was 85% though researchers in other countries have shown lower figures (Kapetanovic et al 2009; Rubin et al 2011). Chipimo JP and Fylkesnes K (2003) showed that the prevalence of depressive symptoms among HIV-infected patients in Lusaka was 21.2% and 12.2% among their uninfected counterparts. And concerning HRQOL, Mweemba et al in a cross-sectional descriptive study using the World Health Organisation Quality of Life-HIV (WHOQOL-HIV) tool showed that 17.8% of HIV-infected participants in that study had poor HRQOL (Mweemba et al 2009).

3.0METHODOLOGY

3.1 Study Setting

a. **Location:** The research was conducted in a rural setting in Kasempa, one of the districts in North-western province of Zambia. The district in 2014 had a projected population of 79,794 persons according to the Central Statistics Office (CSO) based on the population census of 2010. The prevalence rate of HIV in Kasempa then was 9% according to the National AIDS Council.

b. **Site:** The ART Clinics at both Mukinge Mission Hospital and Kasempa Urban Clinic (KUC) were the sites at which the research was conducted. These clinics are out-patient clinics at their respective health facilities. Both clinics cater for adults as well as children who are infected with HIV. According to data bases at both facilities, Mukinge Mission hospital had over 2000 clients enrolled onto ART and care while KUC had over 1200 clients on ART and care. The facilities are only 7 kilometres apart and are both accredited to offer ART services.

3.2 Study Population

Participants were HIV-infected adults receiving care at Mukinge Mission hospital and KUC. HIV-infected clients receiving ART and those that had not yet been started on ART were both enrolled into the study.

3.3 Eligibility criteria

The inclusion and exclusion criteria into both categories are outlined in the table below:

Table 1: ELIGIBILITY CRITERIA

CATEGORY	INCLUSION CRITERIA	EXCLUSION CRITERIA
ART-EXPERIENCED	Confirmed as HIV-infected. Must be 18 years old or above. Able and willing to give consent. On ART for three months or above.	History of psychiatric illness. Too ill and requires admission
ART-NAÏVE	Confirmed as HIV-infected Must be 18 years old or above. Able and willing to give consent.	Less than three months since HIV was diagnosed. History of psychiatric illness. Too ill and requires admission

3.4 Study Design

This was a quantitative cross sectional study. In this study, two groups of HIV-infected patients were compared. One group consisted of HIV-infected patients who had been on ART for three months and above (ART-experienced) while the other group consisted of HIV-infected patients who had never been on ART (ART-naïve). The study compared levels of depression and health-related quality of life (HRQOL) between these two groups.

3.5 Sampling

3.5.1 Sample size determination: Because this was a cross sectional study using two independent samples with depression and HRQOL as continuous dependent variables of interest, the following formula derived from Rosner Bernad's Fundamentals of biostatistics (Rosner 2000; Eng 2003) was used for sample size estimation: $2N = [4\sigma^2 (Z_{\alpha/2} + Z_{1-\beta})^2] / \delta^2$ Where:

N = Sample size for each group.

σ = Standard deviation of the outcome of interest.

δ = Maximum difference that we are willing to allow between two means.

$Z_{\alpha/2}$ = 1.96(Z statistic at 95% CI for two tailed t-test)

$Z_{1-\beta}$ = 0.842 (Z statistic at power [1-β] = 0.8)

δ/σ = Effect size

From the study by Patel R et al (2009) on the impact of ART on depression and HRQOL in Zimbabwe, it was observed that depression improved with an average δ of 2.965 and σ of 5.61. The resultant effect size (δ/σ) was thus equal to 0.53. A total sample size of 112 participants is estimated based on this improvement in depression. And from this same study, improvement in HRQOL was also noted with an average δ of 4.69 and σ of 9.28 yielding the effect size (δ/σ) of 0.50 which gives a sample size of 123 participants. Since the sample size 123 is larger than 112, the larger sample size of 123 was instead used in this study. Alternatively, by using the effect size ($\delta/\sigma = 4.69/9.28 = 0.5$), at the power of 80%, a sample size of 126 can be derived from standard tables as shown below:

Table 2: SAMPLE SIZE DETERMINATION

Effect size δ/σ	**Power of 80%, $Z_{1-\beta} = 0.842$**		**Power of 90%, $Z_{1-\beta} = 1.282$**	
	N_1	**$2N_1$**	**N_2**	**$2N_2$**
0.20	392	784	525	1050
0.31	162	324	217	434
0.50	63	**126**	84	168
0.80	25	50	33	66

The sample size of 126 was chosen instead of 123 derived from the formula because the 126 could easily be divided equally between the two arms (ART-naive and ART-experienced) in this study. The following assumptions were made in arriving at the final sample size:

I. It was assumed that there was going to be 10% fallout from this sample. Thus the sample size 126 was adjusted upwards to 138.9 (Rouded off to 140) participants. This sample was divided into two equal groups of 70 participants each. One group consisted of ART-naïve clients and the other group consisted of ART-experienced clients. And each group comprised of 35 males and 35 females.
II. The power (1-β) of 80% chosen for this study was assumed to be big enough to reduce the probability of a Type II error or false negative (β) from being committed. This gave the $Z_{1-\beta}$ value of 0.842.
III. Factors affecting depression and HRQOL in HIV-infected adults in Zimbabwe, in the study (Patel et al 2009) on which the sample estimation was based were assumed to be similar to the factors affecting depression and HRQOL in HIV-infected persons in Zambia being neighbouring countries in sub-Saharan Africa
IV. The tools used in the Zimbabwean study (Patel et al 2009) on which the sample estimation was based were assumed to have the same reliability and validity when used in this study in Zambia.

3.5.2 Controlling for confounding variables: In this study, some independent variables can act as confounding variables that can interfere with the association of ART with depression and HRQOL. Various studies have consistently shown that the major socio-demographic factors that have a significant influence on depression and HRQOL are gender, age, education, marital status, and employment status (Blalock et al 2002; Campsmith et al 2003; Vigneshwaran et al 2003; Bolton et al 2004; Ruiz et al 2005; Kaharuza et al 2006; Bongongo et al 2013). These factors are independent variables and were considered as confounding variables in this study.

Therefore they were controlled in order to minimise their interference on the association of ART with depression and HRQOL. Controlling for these variables was done by matching the two comparison groups on the basis of these confounding variables. For every ART-naïve participant enrolled with a specific confounding variable, there was an ART-experienced participant enrolled with a similar confounding variable. In this way, the comparison groups were made as identical as possible with respect to these confounding variables of concern. The matching proceeded as follows:

a) Gender

Depression and poor HRQOL are most common among females compared with their male counterparts (Vigneshwaran et al 2003; Kaharuza et al 2006).

In order to control for confounding caused by this gender difference, the number of male and female participants enrolled in the ART-experienced group were equal to the number of their respective male and female counterparts enrolled in the ART-naïve group.

b) Age

Older age has been associated with depression and poor HRQOL (Bolton et al 2004; Campsmith et al 2003). Studies have not always been consistent on the timing and distribution of depression and HRQOL over life time.

However, some studies have shown that the age of onset for depression occurs in the early teenage years before 20 when it rises sharply. After that it remains high with a peak around 35 to 49 years of age and later begins to decline reaching its lowest levels after around 65 years (Wittchen and Uhmman 2010; Hasin et al 2005; Kessler et al 2003). In keeping with these timings, age was categorised in the following groups: 18-34, 35-49 and $\geq$ 50 years. And the number of participants in each age group in the ART-experienced arm was equal to the corresponding number of counterparts in the ART-naïve arm.

c) Education

Depression and poor HRQOL are associated with lower education (Bolton et al 2004; Vigneshwaran et al 2003). To control for differences in the level of education attained, educational status was stratified into three categories as follows: pre-secondary, secondary and post secondary education. The number of participants in each level of education in the ART-experienced arm was matched with the number of corresponding counterparts in the ART-naïve arm.

d) Marital status

Depression and HRQOL are less common among married and single persons compared with their separated or divorced counterparts (Nojomi et al 2008; Andrade et al 2003). Marital status was controlled by being stratified into three categories as follows: married, single and separated/divorce/widowed.

And the number of clients in each category in the ART-experienced group was matched with their respective counterparts enrolled in the ART-naïve group.

e) Employment status

Persons who are employed have less depression and less poor HRQOL compared with their unemployed counterparts (Bongongo et al 2013; Blalock et al 2002). Employment status was stratified into two categories as follows: employed and unemployed. And the number of clients in each category in the ART-experienced group was matched with the number of their respective counterparts enrolled in the ART-naïve group.

Unmatched variables

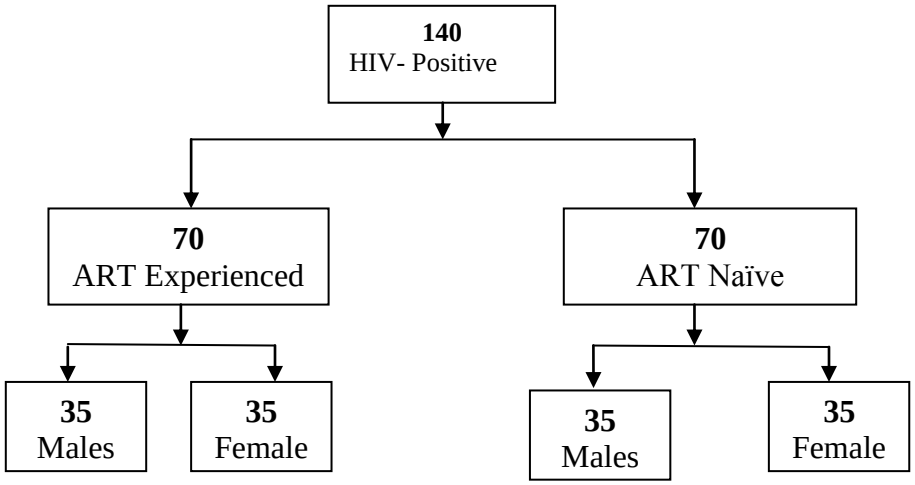
Matching on the basis of latest CD4 count and presence of symptoms was not considered because the ART-experienced group was expected to have better CD4 counts and less or no HIV-related symptoms as a result of ART compared with the ART-naïve group whose clients were not on treatment. The time since HIV was diagnosed was also not matched as this factor had not been extensively shown to affect depression.

3.5.3 Sampling method: In order to facilitate matching on the basis of age, sex, marital status, education, and employment status between the two arms, convenient sampling was conducted. The list of all clients booked for review on a particular day was obtained from the Sister in-charge of the ART clinic and their files pulled from the records room. The socio-demographic and clinical information from these files was extracted. And any information that was not available in the files was obtained during the interview. About 5-6 clients were picked from the list per day as long as they met the conditions for matching.
Enrolment into the ART-naïve and ART-experienced arms was conducted weekly on a rotational basis. In the first week, ART-naïve clients meeting the inclusion criteria were enrolled. And in the following week, ART-experienced participants were enrolled by matching them with their ART-naïve counterparts enrolled in the previous week.

The two weekly cycles were repeated until the sample size of 140 comprised of 70 ART-naïve and 70 ART-experienced HIV-infected clients was reached. With each cycle, sampling began with the ART-naïve clients because it was easier to find their matching counterparts among the ART-experienced clients since out of all the clients reviewed daily at the clinics, about 90% are ART-experienced and only 10% are ART-naïve. Each arm comprised of 35 males and 35 females. The sampling outline is as shown in figure 2.

3.5.4 Sampling outline

Figure 2: Sampling outline



3.6 Variables

3.6.1 Dependent variables:

a. **Depression scores** derived from the CES-D questionnaire

b. **HRQOL scores:** The two **summary scores** derived from the eleven dimensional scores by factor analysis namely:

1. Mental Health Summary score (MHS)
2. Physical Health Summary score (PHS)

3.6.2 Independent Variables:

a. **Service delivery factors**

i. Duration on ART treatment (only applicable to ART-experienced group)

ii. ART regimen (only applicable to ART-experienced group)

iii. ART status: This was the input variable of interest because this study sought to show the association of ART with depression and HRQOL in HIV-infected patients

b. **Socio-demographic characteristics:**

i. Age

ii. Sex

iii. Marital status
iv. Education background
v. Employment status

c. **Clinical factors:**
i. Latest CD4 count
ii. Presence of symptoms/signs (Based on WHO clinical Stages)
iii. Time since HIV diagnosis

3.7 Data Collection

3.7.1 Data collection tools

1. **Socio-demographic and background factors tool** [Appendix 10.3]: This tool elicited the following factors: Age, Sex, Marital status, Education background, Employment status, Time since HIV was diagnosed, ART status, Duration on ART (if on ART), Regime of ART (if on ART), Symptoms and latest CD4 count.

2. **Depression tool:** [Appendices: 8.5a, b]**:** The Centre for Epidemiologic Studies Depression scale (CES-D scale) was used. This is a screening tool for depression which is in form of a questionnaire and has been validated for use in Zambia (Chishinga et al 2011). It is a self-reporting tool. The CES-D measures a patient's depressive feelings and behaviour in the previous one week. The tool is comprised of twenty items in form of questions. There are four graded responses which are scored from 0 to 3 as follows: 0-Rarely or none of the time (<1 DAY), 1-Some or a little of the time (1-2 DAYS), 2-Occasionally or a moderate amount of the time (3-4 DAYS), 3-Most or all of the time (5-7 DAYS). The scores are then added together and their sum graded on a scale as follows: ≥ 22-Major depression, 15-21-Mild to moderate depression, < 15-No depression. This study, however focused on showing that scores in depression do increase on ART without necessarily paying attention to the grades.

3. **Health related quality of life tool** [Appendices:8.6a, b,]**:** The Medical Outcomes Survey–HIV (MOS-HIV) questionnaire was used. The tool is specific for HIV-infected patients and has been validated for use in a number of sub-Saharan African countries (Stangl et al 2012; Tonya et al 2009). It was administered via face to face interview. The MOS-HIV contains 35-items or questions which are grouped into eleven dimensions of HRQOL.

   These dimensions are: General health perception (GHP), Physical function (PF), Role function (RF), Cognitive function (CF), Body Pain (BP), Mental health (MH), Energy/Vitality (EV), Health distress (HD), Social function (SF), Quality of Life (QL) and Health Transition (HT). The 35 questions are aggregated into the 11 specific dimensions according to their numbers as shown in the table below:

   Table 3: AGGREGATION OF QUESTIONS INTO DIMENSIONS

DIMENSION	**QUESTION NO**
General health perception (GHP)	1 & 11a-11d
Physical function (PF)	4a-4f
Role function (RF)	5 & 6
Cognitive function (CF)	10a-10d
Body pain (BP)	2 & 3
Mental health (MH)	8a-8e
Energy /Vitality (EV)	9a-9d
Health distress (HD)	9e-9h
Social function (SF)	7
Quality of Life (QL)	12
Health Transition (HT)	13

   The responses to the questions are graded on a Likert scale. The average for each dimension is then calculated during analysis.

3.7.2 Data collection procedure

Data collection was conducted in a quiet secluded screening room within the clinics. It was conducted as a face to face interview after the interviewer had introduced himself to the participant.

The participant was told the purpose of the interview after which consent from the participant was then obtained. The interviewer read the questions and responses to the participant. And the response chosen by the participant was then marked. The medium of communication was English or the local language of Kaonde which is the commonly spoken language in Kasempa. The interview included a short physical examination [Appendix 10.4] to screen for any signs and symptoms of HIV infection. No blood samples were drawn for latest CD4 count determination during the interview as patients with pending CD4 count were easily referred to the laboratory for this investigation.

3.8 Ethical Considerations

a. **Ethical review**: This research proposal, the information form, the informed consent form, and the tools had ethical approval by the ERES Converge IRB. This had been done in keeping with ethical requirements when dealing with human subjects.

b. **Informed consent**: Prior to enrolment into this study, informed consent was obtained from participants that were willing to take part. A specific consent form designed for the purpose was administered. This form explained the purpose of the study and the researcher provided any further clarifications that the participants requested [Appendices 8.2a, b].

c. **Risks**: Participants were not expected to suffer any risks in this study because only responses to questions were required.

d. **Benefits:** There was no direct or immediate benefit to the participants in this research. However, it is hoped that when findings of this study are published, many clinicians will see the need to be screening for depression and HRQOL routinely in HIV-infected persons for management of their psycho-social problems.

e. **Confidentiality**: Privacy and confidentiality were ensured during this study. Questionnaires were administered in a private room. Names of participants were not recorded on the tools. Serial numbers were used to identify the documents without linking them to any names of participants. Only the researcher had access to the documents which were kept under lock and key. And only the researcher's computer stored the data.

3.9 Data Analysis

3.9.1 Data management

The data was entered in Statistical Package for the Social Science version 21 (SPSS-21) and Excel for analysis.

3.9.2 Variable categorization

Some studies have shown that the age of onset for depression occurs in the early teenage years before 20 when it rises sharply. After that it remains high with a peak around 35 to 49 years of age and later begins to decline reaching its lowest levels after around 65 years (Wittchen and Uhmman 2010; Hasin et al 2005; Kessler et al 2003). In keeping with these timings, age was categorised in the following groups: 18-34, 35-49 and ≥ 50 years. Under education, the category "Pre-secondary" included persons who had never been to school or had only attended nursery, pre-school or primary school.

Under employment status, persons who were "Unemployed" included students, house-wives and persons with no income. CD4 counts was dichotomized into ≤ 350 cells /µl and >350cells /µl because 350cells /µl was the cut off for commencing ART in adults at the time of the research. The rest of the variables were categorized as shown in Table 4 above.

Table 4: CATEGORIZATION OF VARIABLES AND VARIABLE TYPE

Variable	Variable categories	Variable type
1.Sex	Female	Categorical
	Male	
2.Age	18-34	Categorical
	35-49	
	≥50	
3.Marital Status	Separated/Divorced/Widowed	Categorical
	Single	
	Married	
4.Education	Pre-secondary	Categorical
	Secondary	
	Post-secondary	
5.Employment status	Unemployed	Categorical
	Employed	
6.ART status	Naïve	Categorical
	Experienced	
7. ART Regimen*	1st line	Categorical
	2nd line	
8.Presence of Symptoms	Symptomatic	Categorical
	Asymptomatic	
9. Length on ART*	≤ 1 Year	Categorical
	> 1 Year	
10.Latest CD4 count	≤350 cells /µl	Categorical
	>350 cells /µl	
11.Time since HIV diagnosis	≤ 1 Year	Categorical
	> 1 Year	

*Only applicable to ART-experienced participants.

3.9.3 Statistical Analysis

a) Descriptive statistics

Comparison of baseline socio-demographic and clinical characteristics between ART-naïve and ART- experienced HIV-infected patients was done. There was no need to check the difference in the categorical variables of age, sex, marital status, education and employment status between the two arms because these variables were matched. The unmatched categorical variables were compared using Chi-square test (X^2). The p-value was set at <0.05 and confidence interval (CI) at 95%.

b) Multivariate analysis

Regression analysis was used to show the variables that significantly influence depression and HRQOL in HIV-infected persons. The baseline socio-demographic and clinical characteristics, namely age, sex, marital status, education, employment status, symptoms, CD4 count and time since HIV diagnosis were treated as independent variables. And by employing multiple linear regression analysis, the study showed how these factors influenced depression and HRQOL in these clients. Categorical variables were coded in order to fit into the regression model.

c) Comparison of Depression and HRQOL scores between ART-experienced and ART-naive clients

I. **Depression:** The means or averages of the Depression scores from the CES-D tool for each of the two groups of participants were calculated. Then the student t-test for independent samples was employed to compare these means in order to reject or accept the null hypothesis. The p-value was set at <0.05 and confidence interval (CI) at 95%.

II. **HRQOL:** From the MOS-HIV tool, the scores of each of the 11 dimensions were added for each of the two categories of participants. Some items of the tool are graded such that a higher score indicates a health status (eg Poor = 1, Fair = 2, Good = 3, Very good = 4, Excellent = 5) while for others, a higher score indicates low heath perception (eg Excellent = 1, Very good = 2, Good = 3, Fair = 4, Poor = 5). At analysis the later had their scores reversed so that a higher score corresponded to a higher health perception. The items/questions whose scores were reverse coded are 1, 2, 3, 8b, 8d, 9a, 9d, 11b, 11c, 12 and 13. Raw scores for each dimension were then calculated by computing the mean of the items/questions scores for that dimension. The raw dimensional scores were then linearly transformed into 0-100 scale to enable comparison across different dimensions using the formula below:

$$Y = \{100 \times [(RS - MIN)] / (MAX - MIN)\}$$

Where:

Y	=	Transformed score for a given HRQOL dimension
RS	=	Raw score for a given HRQOL dimension
MIN	=	Minimum possible raw score
MAX	=	Maximum possible raw score

The transformed scale scores were then subjected to Principal Components Analysis (PCA) with oblique rotation using SPSS coupled with parallel analysis. This yielded two components which were called Mental health component and Physical health component. The scoring coefficients for these components were then used to construct two summary scores. These were Physical Health Summary (PHS) score and the Mental Health Summary (MHS) score. The PHS score was constructed by multiplying each of the eleven transformed dimensional scores by its respective physical factor scoring coefficient and summing their products. Similarly, the MHS score was constructed by multiplying each of the eleven transformed dimensional scores by its respective mental factor scoring coefficient and summing the products.

The MHS and PHS scores produced were then linearly transformed into 0-100% scale for both ART-naïve and ART-experienced participants. Then the transformed scores were compared between the two group using the student t-test for independent samples to determine the significance of the differences in MHS and PHS between the two groups of participants. The p-value was set at <0.05 and confidence interval (CI) at 95%.

4.0 RESULTS

4.1 Demographic and clinical characteristics of participants

A total of 140 participants were enrolled into the study in two groups or arms. Half 70 (50%) of the participants were ART-naïve and the other half 70 (50%) were ART-experienced. Between the two arms, the number of participants enrolled were matched (Table 6) on the basis of age, sex, marital status, education and employment status. This was done in order to facilitate comparison of the two arms by reducing confounding and bias that could arise from these variables.

In terms of age categories of 18-34, 35-49 and ≥ 50 years, the numbers of participants who were enrolled in each category by matching across the two arms were 32 (46%), 32 (46%) and 6 (8%) respectively. There were no participants older than 64 years. Most of the participants (46%) were in the age categories of 18-34, 35-49 years in both arms respectively

Marital status was also divided into three categories; namely Married, Single or Widowed/Divorced/Separated (W/D/S). Most (66%) of the participants were married in both arms. Participants who were single were in the minority (9%) in both arms.
Twenty one percent (21%) of the respondents in both arms were separated, divorced or widowed.

The level of education attained was categorized into Pre-secondary, Secondary and Post-secondary education. Most of the participants (61%) had attained secondary school education. However, only 12% had attained Post-secondary education in both arms.
In terms of employment status, most of the participants (61%) were in some form of gainful employment in both arms. This was either formal or informal employment. Only 39(%) said they were not employed.

Ninety-four (94%) of ART-experienced participants were on the first-line of ART drugs and only 6% had moved to 2nd line

Table 5: **BASELINE SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS**

Variable	**Variable category**	**ART- Naïve N = 70(%)**	**ART-Experienced N = 70(%)**
1.Age(Years)	18-34 35-49 ≥50	32(46) 32(46) *6(8)*	32(46) 32(46) *6(8)*
2.Sex	Male Female	35(50) 35(50)	35(50) 35(50)
3.Marital Status	Single Married S/D/W*	9(13) 46(66) 15(21)	9(13) 46(66) 15(21)
4.Education	Pre-secondary Secondary Post-secondary	19(27) 43(61) 8(12)	19(27) 43(61) 8(12)
5.Employment status	Unemployed Employed	27(39) 43(61)	27(39) 43(61)
6. ART Regimen	1st line 2nd line	N/A N/A	66(94) 4(6)
7.Presence of Symptoms	Asymptomatic Symptomatic	42(60) 28(40)	56(80) 14(20)
8. Length on ART	≤ 1 Year >1 Year	N/A N/A	10(14) 60(86)
9.Latest CD4 count	≤350 cells /µl >350 cells /µl	43(61) 27(39)	18(26)** 52(74)**
10.Time since HIV diagnosis	≤ 1 Year >1 Year	52(74) 18(26)	13(19)** 57(81)**

*S/D/W : Separated/Divorced/Widowed.
** The differences in these categories of variables were statistically significant $P < 0.05$) different between the two groups of participants.

Most of the participants were asymptomatic in both arms. However, there were more asymptomatic clients among ART-Experienced clients (80%) compared with their ART-naïve counterparts (60%). Conversely, there were more symptomatic participants among the ART-naïve participants (40%) compared with the ART-experienced participants (20%). Most of the participants (61%) among the ART-naïve clients had latest CD4 counts which were less than 350 cells/µL whereas among the ART-experienced participants, the majority (74%) had CD4 counts of more than 350 cells/µL.

The cut-off of 350 cells/μL was used because this was the threshold for initiating ART at the time of this research. In the ART-naïve group, most of the participants (74%) had their diagnosis of HIV infection made less than a year prior to this interview. But in the ART-experienced arm, most of the participants (81%) had this diagnosis made over a year prior to the interview.

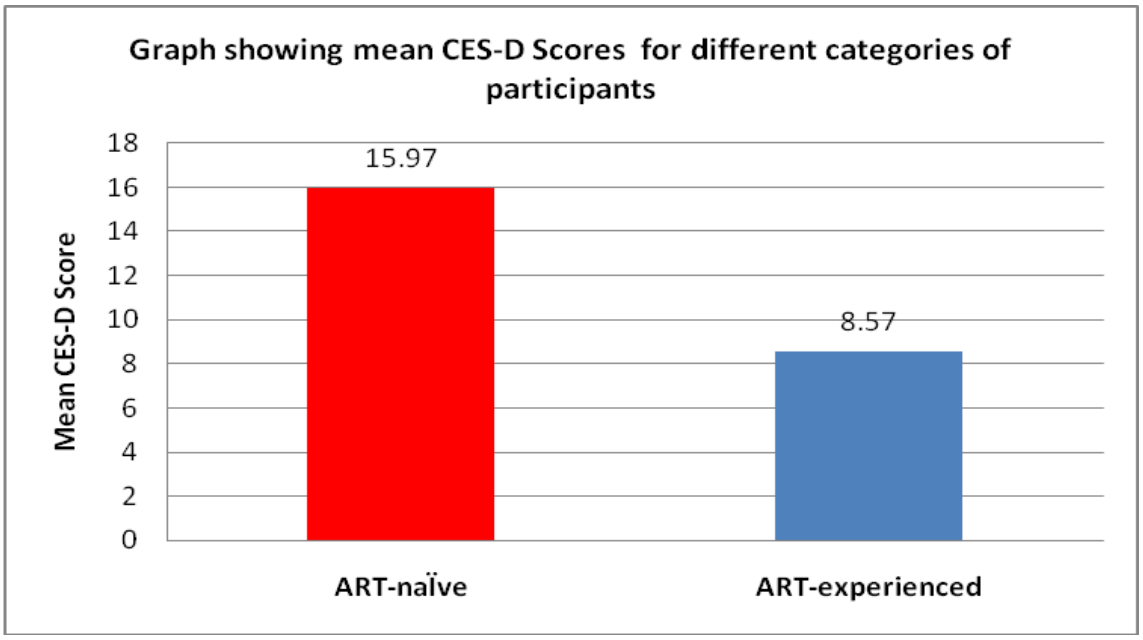
4.2 Comparison of Depression in ART-naïve and ART-experienced clients

Depression scores as assessed by the Centre for Epidemiologic Studies Depression (CES-D) scale for the seventy pairs of participants are displayed on the graph in Figure 3. The graph shows that in general, ART-naïve participants had higher depression scores with a mean score of 15.97, while their ART-experienced counterparts had lower depression scores with a mean of 8.57.

There was thus an average reduction in depression scores of 7.40 (SD = 15.4; CI 95%: 3.77–11.03) as shown in Table 6.

By employing the Student t-test for independent samples, a t-statistic of 4.4 was calculated which yielded a *P* value of < 0.0001 at 69 degrees of freedom. This value of *P* was statistically significant confirming that ART-experienced clients had lower levels of depression compared with their ART-naïve counterparts.

Figure 3



ART-naïve clients had higher levels of depression scores compared with their ART-experienced counterparts.

Table 6: **MEAN DEPRESSION SCORE DIFFERENCE AND ITS STATISTICAL SIGNIFICANCE**

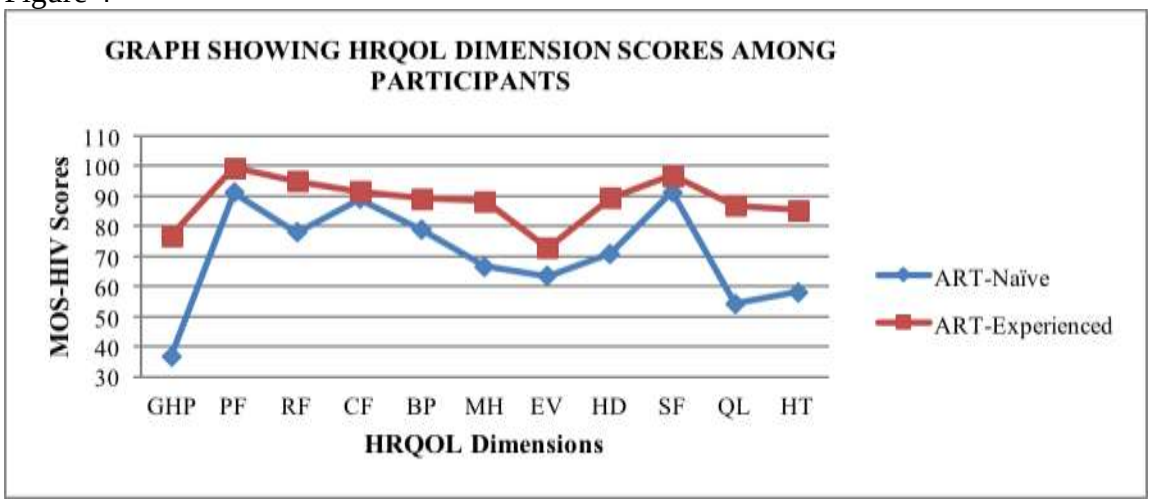
Mean Depression Scores			S.D	95% Confidence Interval		*P*
ART naive	**ART experience**	**Score Difference**		**Lower**	**Upper**	
15.97	8.57	7.40	15.43	3.77	11.03	< 0.0001

The mean difference between the two arms was 7.40. And by using the t-test for independent samples, the value of *P* for this difference was $P < 0.0001$. This difference was statistically significant.

4.3 Comparison of HRQOL in ART-naïve and ART-experienced clients

Figure 4 shows that on average, ART-experienced participants had higher scores of HRQOL in almost all dimension except for cognitive function (CF) and social function (SF) where the difference was not significant. Table 7 shows the same information. The table also shows that MHS and PHS components were higher among ART-experienced participants compared with their ART-naive counterparts.

Figure 4



The graphs show that the HRQOL Dimensional scores for ART-experienced participants were higher compared with the ART-naïve participants

Table 7: **MEAN HRQOL DIMENSIONAL SCORES AND SUMMARY SCORE COMPONENTS OF THE ART-NAÏVE AND ART-EXPERIENCED PARTICIPANTS**

Dimensions/ Components	Experienced	Naive	Paired Differences				P
			Mean Difference	Std. Deviation	95% C. I.		
					Lower	Upper	
GHP	76.9	36.8	40.1	43.0	30.0	50.2	.000*
PF	99.4	90.9	8.5	17.6	4.3	12.6	.000*
RF	95.0	77.9	17.1	44.2	6.7	27.6	.000*
CF	91.4	89.1	2.3	23.1	-3.1	7.7	**.203**
BP	89.1	78.6	10.5	32.5	2.9	18.2	.004
MH	88.2	66.6	21.6	36.9	12.9	30.3	.000*
EV	72.7	63.5	9.2	22.9	3.8	14.6	.000*
HD	89.5	71.1	18.4	39.8	9.1	27.8	.000*
SF	96.8	91.4	5.4	29.6	-1.6	12.4	**.063**
QL	86.8	55.4	31.4	43.5	21.2	41.7	.000*
HT	85.3	58.2	27.1	48.9	15.6	38.7	.000*
MHS	**84.1**	**61.1**	23.0	29.8	16.0	30.1	.000*
PHS	**93.3**	**82.1**	11.2	22.1	6.0	16.4	.000*

*P < 0.00001. ART-experienced participants had higher HRQOL dimensions and components compared with those of their ART-naïve counterparts. Using the t-test for independent samples, the values of P were less than 0.05 (significant) except for the CF and SE dimensions.

4.4 Factors associated with Depression and HRQOL in HIV-infected persons

Multiple linear regression using SPSS was employed to identify the independent variables that were significantly associated with depression and HRQOL in HIV-infected persons. The independent variables entered in the regression were those identified from literature as contributing significantly to depression and HRQOL in these patients. These variables were age, sex, education, marital status, employment status, symptoms, CD4 count and duration since HIV was diagnosed (Wittchen and Uhmman 2010; Hasin et al 2005; Kessler et al 2003; Vigneshwaran et al 2003; Kaharuza et al 2006; Bolton et al 2004; Nojomi et al 2008; Andrade et al 2003; Bongongo et al 2013; Blalock et al 2002; Sekabira R et al 2012). The dependent variables against which these independent variables were regressed were depression scores and HRQOL summary scores of MHS and PHS which were continuous variables. For each of the dependent variables, the model was stratified into ART-naïve and ART-experienced arms.

Table 8 below shows regression coefficients for depression, MHS and PHS scores for each independent variable separated into ART-naïve and ART-experienced arms. Statistically significant coefficients (with P <0.05) are highlighted in bold. The adjusted R^2 for all independent variables regressed against depression, MHS and PHS scores for both ART-naïve and ART-experienced groups ranged between 0.17 and 0.77. This meant that 17% to 77% of the variability in dependent variables among ART-naïve and ART-experienced participants combined could be accounted for by those independent variables in the models.

A male participant was expected to be 0.49 scores less depressed and to have 0.56 MHS scores higher than the female counterpart among ART-naïve clients when all other independent variables are controlled.

Depression scores among single ART-naïve clients were expected to be 0.14 lower compared with the widowed, divorced or separated (W/D/S) participants assuming that all other variables were held constant. And among these same ART- naïve participants, those that were married had 0.26 PHS scores higher than their W/D/S counterparts. However, married ART-experienced participants were expected to have 0.17 MHS scores below their W/D/S colleagues when all other independent variables are held constant. Asymptomatic ART-experienced participants were expected to have 0.16 MHS scores less than their symptomatic colleagues. But they were also expected to have 0.25 PHS scores higher than their symptomatic counterparts when all other independent variables are held constant. And the same ART-experienced participant with CD4 count greater than 350 Cells/μL was expected to have 0. 90 MHS scores and 0.33 PHS scores higher than the counterpart with CD4 count less than 350 Cells/μL when other independent variables are held constant.

Table 8: **MULTIPLE LINEAR REGRESSION COEFFICIENTS FOR DEPRESSION, MHS AND PHS SCORES**

Variable	REGRESSION COEFFICIENTS					
	ART - Naive			ART - Experienced		
	CES-D	MHS	PHS	CES-D	MHS	PHS
Age (years)						
18-34	Ref	Ref	Ref	Ref	Ref	Ref
35-49	-0.057	0.068	-0.005	0.020	-0.052	-0.013
50-64	-0.002	-0.063	0.090	0.099	-0.094	0.010
Sex						
Female	Ref	Ref	Ref	Ref	Ref	Ref
Male	**-0.49*** **	**0.565** **	0.140	-0.025	-0.188	0.126
Marital Status						
W/D/S	Ref	Ref	Ref	Ref	Ref	Ref
Single	**-0.136***	0.017	0.204	0.032	-0.051	0.108
Married	-0.121	-0.068	**0.264***	0.167	**-0.175***	-0.047
Education						
Pre-Secondary	Ref	Ref	Ref	Ref	Ref	Ref
Secondary	-0.048	-0.006	0.108	0.037	0.017	-0.175
Post-	-0.054	-0.069	0.162	0.002	-0.038	-0.013
Employment Status						
Unemployed	Ref	Ref	Ref	Ref	Ref	Ref
Employed	-0.349	0.335	0.085	-0.055	0.178	-0.016
Symptoms						
Symptomatic	Ref	Ref	Ref	Ref	Ref	Ref
Asymptomatic	-0.129	0.001	0.428	-0.015	**-0.160***	**0.250***
CD4 Count						
≤350 Cells/μL	Ref	Ref	Ref	Ref	Ref	Ref
>350 Cells/μL	0.013	0.047	-0.093	**-0.802*****	**0.895** **	**0.330** **
HIV Duration						
<1 Year	Ref	Ref	Ref	Ref	Ref	Ref
>1 Year	0.107	-0.107	-0.072	0.072	-0.112	0.040

NB: Only regression coefficients which are statistically significant (P < 0.05) are highlighted.
Ref: Means that particular category for the variable is a reference point.
W/D/S: Widowed / Divorced / Separated.
***P <0.001; ** P = 0.001-0.01; * P = 0.01-0.05
Ref: Reference category

5.0 DISCUSSION

The study demonstrated that ART-experienced adults had lower depression scores and higher HRQOL scores compared with their ART-naive HIV-infected counterparts at Mukinge Mission Hospital and Kasempa urban clinic in Kasempa District of Zambia. This is shown in Figures 3 and 4 and in tables 6 and 7. The study also showed that there were factors that were significantly associated with depression and HRQOL in these patients as shown in table 8. These findings are consistent with prior cross sectional studies (Louwagie et al 2007; Patel et al 2009) and some prospective cohort studies (Jelsma et al 2005; Stangl et al 2007; Wagner et al 2012) conducted in other sub-Saharan African countries.

Most (66%) ART-experienced participants were on the first line regimen. One explanation for this could have been lack of routine access to viral load testing by which virologic failure could have been detected early enough to warrant switching to second line where necessary. Secondly, there could have been shortage of medical officers with the expertise to switch clients to second line if any of them were failing first line. There were more asymptomatic ART-experienced participants (80%) compared with the ART-naïve counterparts (60%). This is because ART reduces the HIV-viral load and this in turn results in improved immune system which leads to a reduction in the number of opportunistic infections and hence less symptoms. This finding is in tandem with what Sekabira R et al (2012) found in Uganda.

Seventy-four percent (74%) of ART-experienced participants had CD4 counts greater than 350 cells/µl compared with their ART-naïve counterparts where only 39% had CD4 counts greater than 350 cells/µl. This is expected because ART reduces viral load which in turn results in a rise in CD4 count as there will be less viruses to infect the CD4 cells in ART-experienced participants. The finding is consistent with what Sekabira R et al (2012) found in Uganda. The results show that of all the ART-naive participants interviewed, 61% who had CD4 counts less than 350 cells/µl had not yet been put on treatment. This can be attributed to the fact that for the majority, the interview took place on the actual day when they were booked to be commenced on ART.

Figure 4 and Table 7 demonstrate that there were significant differences in all dimensions of HRQOL scores between ART-naïve and ART-experienced participant except for cognitive functions (CF) and social function (SF) dimensions. Generally, ART-naïve adults had lower scores in all dimensions of HRQOL. This could be attributed to self stigmatization, denial and self condemnation. This is coupled with poor physical health which manifests in form of various symptoms. However, all these manifestations are diminished in the ART-experienced clients.

Male gender as opposed to female gender was associated with improvements in depression and MHS score among HIV-naïve participants. This is what several other studies have shown (Vigneshwaran et al 2003; Kaharuza et al 2006). But among ART-experienced participants, gender difference did not cause any statistically significant changes in both depression and HRQOL.

Being single or married was generally associated with improvements in depression or in PHS component of HRQOL respectively among ART-naïve participants. A number of studies have shown similar findings (Nojomi et al 2008; Andrade et al 2003). Marriage facilitates increased social support leading to improvements in depression and in HRQOL and the opposite is true in case of death or loss of a spouse. However, among ART-experienced participants there was marginal decline in MHS score among married participants compared with their W/D/S counterparts. This was the same even in univariate analysis. The decline in MHS score among these married ART-experienced participants could be attributed to other specific, extrinsic factors affecting their HRQOL which this study may have not highlighted.

Being asymptomatic was associated with improvements in MHS and in PHS scores among ART-experienced participants as observed by other researchers (Leserman et al 1999; Sekabira R et al 2012; Nojomi et al 2008). This is what is expected because ART reduces the number of symptoms and this ultimately contributes to improved quality of life. And finally, CD4 cell count greater 350 cells/μL was associated significantly with improvements in depression, MHS and PHS. An explanation to this could be that with higher CD4 counts, the immune system is improved and clients are able to fight

opportunistic infections thereby improving their quality of life. Age, education, employment status and duration with HIV diagnosis showed no significant association with depression and HRQOL in this study.

The study had some limitations. Because the study did not involve focus group discussions, other factors contributing to depression and poor HRQOL in participants could have been missed. Secondly, both the CES-D for screening depression and the MOS-HIV tool for HRQOL are largely subjective. As such, responses could have been influenced by some transient circumstances prevailing in the life of the respondents at the time of the interview. For instance, nursing a sick relative can cause depression and lead to poor HRQOL which can result in reporting bias. Matching of participants between the two groups on the basis of specific independent variables helped to minimise these limitations. And strict adherence to inclusion and exclusion criteria to some degree also helped to reduce reporting bias. Finally, the sample size was adequate enough to further minimise bias.

6.0 RECOMMENDATIONS

Screening tools used when reviewing these patients need to be revised so that they can contain a component for highlighting depression and HRQL. And now that the benefit of ART has been highlighted, clinicians should endeavour to initiate ART in HIV-infected persons as early as possible. It is further recommended that a longitudinal, cohort study needs to be conducted in Zambia on the effect of ART on depression and on HRQOL so that a direct cause–effect relationship can be established. This will also act as a build-up on the findings of this study. Finally, the health delivery system should be organised in such a way that HIV infected persons are linked to support groups and to some income generating activities that can facilitate improvement of quality of life in these persons.

7.0 REFERENCES

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8.0 APPENDICES

APPENDIX 8.1a: **INFORMATION SHEET (English)**

Information sheet to participate in the research on the effect of anti-retroviral therapy on depression and quality of life in patients infected with HIV

Introduction

This research is being conducted by DR. MUTIMUSHI EDGAR, a postgraduate student at the University of Zambia, School of Medicine.

Background

The research is aimed at demonstrating that Antiretroviral Therapy (ART) leads to improvements in depression and quality of life in HIV-infected patients. This will be demonstrated by comparing levels of depression and quality of life in HIV-infected patients who are on ART and HIV-infected patients who are not yet on ART at Mukinge Mission Hospital and Kasempa Urban Clinic (KUC) in Kasempa district.

Procedure

If you agree to participate in this research, you will first be required to provide information concerning your age, level of education, occupation, income, latest CD4 count and information related with your HIV state. After this, you will be requested to provide answers to questions on depression and on your quality of life.

Confidentiality

All the information that you will provide will be considered confidential. Your name or any other identifying information will not appear on any documents or on any blood samples that you may be asked to submit. No persons other than the researcher and supervisors will have access to information gathered.

Risks and discomforts

You are not expected to suffer any risks in this study because only your responses to questions will be required. However, if you have never had your CD4 count checked in the last six months a fresh blood sample will have to be drawn from you to check your latest CD4 count. This procedure is not expected to pose any new risks.

The risks involved in this procedure are minimal. They include the discomfort associated with drawing blood, rarely bruising and infection at the site of needle stick.

Everything possible will be done to minimize or prevent the occurrence of these events. And should any of these occur, you will receive immediate attention.

Benefits

There are no immediate benefits in participating in this research. But the information that you will provide can help health care providers in managing depression and impaired quality of life in persons like you who are infected with the HIV virus.

Voluntary participation and right to withdraw

Your participation in the research is voluntary. You are not under obligation to take part in the research. You may choose not to participate in this study and you are at liberty to withdraw your participation at any time. You do not have to explain why you do not wish to participate.

Right to seek clarification

You may ask questions now, or at any time during the study. If you have any questions, or if any problems arise, you can contact DR. MUTIMUSHI EDGAR at the address shown below.

Provision for standard of care

Should you choose to participate or not to participate or to withdraw from the study, you shall not suffer any penalty or loss of care. You will still continue to receive the standard care that you are entitled to at this ART clinic.

Contact information

In case you seek any clarification or you have questions, comments or concerns, you can contact the researcher DR. MUTIMUSHI EDGAR at the University of Zambia, School of Medicine based at the University Teaching Hospital. The mobile phone number is 0976541887, and email: mutimushiedgar@yahoo.com. The full address is: The University of Zambia, School of Medicine, Department of Internal Medicine, P.O. Box 50110, LUSAKA, Phone/Fax: +260-211-2514424.

This research protocol has ethical approval by ERES Converge IRBat the following address:

The Secretary
ERES Converge IRB
33 Joseph Mwilwa Road
Rhodes Park
Lusaka, Zambia
Tel: +260-955-155633/4, Email: eresconverge@yahoo.co.uk

APPENDIX 8.1b: **INFORMATION SHEET (Kaonde)**

Kipepala kya biintu bya kwingijisha mu lupeso lwakumona bingila muchiwaanti-retroviral therapy mu kukimfya misongo ya bulaanda ne muchima kupelelwa kabiji nge uukanjizha buumi mu bwikalobwa balwaazhi baji na kikola kya HIV.

Ntatwiilo (Introduction)

Luno lupeso lwa ba DR. MUTIMUSHI EDGAR, baana basuukulu-kata ku sukuulu mukataampe wa mu University wa mu Zambia kukipamo koobafunjila bya michi.

Kishiina (Background)

Kuno kupesa-pesa kwaaimana pakumweesha amba muchi waAntiretroviral Therapy (ART) ukeepesha bulaanda ne muchima kupelelwakabiji ukanjizha buumi mubwikalo bwa mulwaazhi wa HIV. Kino ki koobiwa pa kwesekaanya bipimo bya bulaanda ne muchima kupelelwa kabiji ne buumi mubwikalo bwa balwaazhi ba kwaachiwa na HIV batambula muchi (wa ART) ne boba babula kutendeka kutoma muchi (not yet on ART) ku kipateela kya Mukinge Mission ne Kasempa Urban Clinic (KUC) munkambi ya Kasempa.

Ndoonda (Procedure)

Inge wa swa kuseenda lubaji muluno lupeso kyafwainwa patanshi ubulangane myaaka ya kuseemwa, kipimo kya luufundo (level of education), nkito yo mwiingila mu bwikaalo, kupimwa kwa katataaka kya CD4 count kabiji ne bikwabotu byatala ku HIV woobe. Pakupwisha kuuba bino musa kukumbula meepuzho pa bulaanda ne muchima kupelelwa kabiji ne pabuumi mubwikalo bweenu.

Bufyamfya (Confidentiality)

Byoonse byo musakubulang'ana bisakwikala ke bya bufyamfya. Jishina nangwa byoonse byomusakubwangána keechi bikaleembwapo pa mapeepala nangwatu sawaakya ufuma pakupwisha kupima mashiine. Kafwaako baantu nangwa bakwaabo bapesa-pesa nangwa bakapitawa bakapeewa byo mapaana leelo ne.

Bisulwamana ne byumfwisha bibi (Risks and discomforts)

Keechi mwafwaainwa kwaakamwa amba kampepo mwapita mubya lukatazho ne maambo anweeba musa kukumbula ngatu meepuzho. Bino inge ke mwapimishaapo CD4 count pa bang'ondo baatanu naumo (six months) baapita kuunyuma, kyawaama bemufumye mashi bee apime, pakuuba amba muyuke CD4 count yeenu yabukuumo. Kisakubiwa kechi kisakuleeta bisulwamalwa ne. Bisulwamalwa pakufumya mashi bichechetu. Pajitu ku taanta kucheche pakufumya mashi, kechi bilenga biloonda nangwa bikola ne.

Mashinda onse aleeta bino akepeshiwa nangwa afumishiwapo. Umvwe byatongolwa byamweeka, bukiji-bukijitu basakwingijilapo.

Byakumwenamo (Benefits)

Mukuibiimba mukupesa-pesa amwe kemuji byakumwenamo ponkapotu ne. Bino byo musakubuulangána byakonsha kupaana bukwasho ku bengila mu fipatela kukwasha balwazhi ba HIV nge anweeba mu misongo ya kumvwa bulaanda ne muchima kupelelwa kabiji ne buumi mu bwikalo nge bwatama.

Nsaambu yakuibiimbamo nangwe kukaana (Voluntary participation and right to withdraw)

Kwibiimba mukuno kupesa-pesa kyakuipaana. Keechi kyakukanjikizha ne. Mulina luusa lwakukaana. Mwakoonsha kusala kwiibimbamo nangwe kukaana pakimye kyonse. Kabiji muji nansaambu yakuzhindamatu kwakubula kwamba kyomwakaaina kutoola lubaaji.

Nsaambu yaakusakisha kumvwikisha (Right to seek clarification)

Mwaakoonsha kwipuusha meepuzho kyonka kino kimye, nangwa kimye kikwaabo satuubeena kufuunda. Inge muji nabyakwipuzha nangwa makatazho mwakoonsha kutumina baDR. MUTIMUSHI EDGAR kwingijisha keeyala waneembwa munshi.

Kupainwa bukwasho bwafikiilamo (Provision for standard of care)

Inge mwasaka nangwa mwa kaana nangwa mwasaka kulekela pakachi kwibiimbamo mukupesa-pesa akwe, kemusakuleka kukwashiwa ne. Mukatwajijila nakutambula bukwasho bwafikilamo ku clinic kya ART.

Komwafwaikwa kutuma (Contact information)

Inge musaka miikuumbu kumeepuzho omuji naao byakubiikapo nangwa bikwaabotu, mwakonsha kubula baampesa ba DR. MUTIMUSHI EDGAR ku university waamu Zambia ku sukuulu koobafunjila bya michi uji ku kipateela kikataampe kya University Teaching Hospital (UTH). Nambala yakamatayi 0976541887, email: mutimushiedgar@yahoo.com. Keeyala: The University of Zambia, School of Medicine, Department of Internal Medicine, P.O. Box 50110, LUSAKA, Phone/Fax: +260-211-2514424. Ndoonda yaluno lupeso yaaswishiwa ku ERES Converge IRB pauno keeyala:

The Secretary

ERES Converge IRB

33 Joseph Mwilwa Road

Rhodes Park

Lusaka, Zambia

Tel: +260-955-155633/4, Email: eresconverge@yahoo.co.uk

APPENDIX 8.2a: **CONSENT FORM (English)**

Consent Form to participate in the research on the effect of anti-retroviral therapy on depression and quality of life in patients infected with HIV.

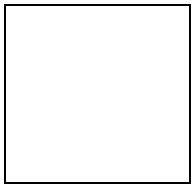
Participant's Statement

I have read the information from the information sheet, or it has been read to me. I have understood its contents. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my further medical care or employment.

Name of Participant

_____

Signature of Participant OR Thumb print of Participant



_____

Date: _____

Interviewer's Signature:

_____

Date: _____

APPENDIX 8.2b: **CONSENT FORM (Kaonde)**

Kipeepala pakutambwila luusa pakuuba amba muibimbemo mukupesa-pesa mukuyuuka bingiila muchi wa anti-retroviral therapy mukukwaasha balwazhi baakwatwa na HIV mumisongo ya buulanda ne muchima kupelelwa kabiji ne byo buumi bwaabo buji.

Byaambo bya wakuibimbamo (Participant's Statement)

Nataanga nangwa bantaangila byaneembwa nekumvwa byaneembwapo. Naitaba kuseendako lubaji mukupesa-pesa kuno sanayuuka kuubaamba njinaluusa lwakuleka kuibimbamo pakimye kili kyonse, kumfumya pabo batambula bukwaasho nangwa ku ntamfisha nkiito ne.

Jizhinaja wakuibimbamo (Name of Participant):

_____

Pakusayina NANGWA Pakufwaatika Kyaala

_____

Juuba (Date): _____

Pakusayina wakutaangyila misaambo (Interviewer's Signature):

_____

Juuba (Date): _____

APPENDIX 8.3: **SOCIO-DEMOGRAPHICS FORM (Socio-demographics and health characteristics of participants)**

Tick (✓) where appropriate

1. AGE

18-34 Years	
35-49 Years	
50-64 Years	
≥ 65Years	

2. SEX

Male	
Female	

3. MARITAL STATUS

Single	
Married	
Separated/Divorced/Widowed	

4. EDUCATION

Pre Secondary	
Secondary	
Post Secondary	

6. ART STATUS

Experienced	
Naive	

7. ART REGIMEN

First Line	
Second Line	
Third Line	

8. PRESENCE OF ANY SYMPTOMS

Asymptomatic	
Symptomatic	

9. ART DURATION

When did you start taking ART?

10. LATEST CD4 COUNT

≤ 350 cells/µl	
350 cells/µl	

5. EMPLOYMENT STATUS	**11. HIV DIAGNOSIS**
Unemployed ☐ Employed ☐	When were you diagnosed with HIV? ☐

APPENDIX 8.4: **PHYSICAL EXAMINATION**

PHYSICAL EXAMINATION (Tick ✓)			
	Normal	*Abnormal*	*Description of any abnormal findings*
Skin	☐	☐	
Eyes	☐	☐	
Ears/Nose	☐	☐	
Oral	☐	☐	
Lymph nodes	☐	☐	
Heart	☐	☐	
Lungs	☐	☐	
Abdomen	☐	☐	
Urogenital	☐	☐	
Musculoskeletal	☐	☐	
Neurological	☐	☐	

APPENDIX 8.5a: CES-D (English)

Centre for Epidemiologic Studies Depression Scale (CES-D)– English

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	Rarely or none of the time	Some or a little of the time	Occasionally or a moderate amount of	Most or all of the time
Number of days	(<1 day)	(1-2)days	(3-4 days)	(5-7days)
1. I was bothered by things that usually don't bother me				
2. I did not feel like eating; my appetite was poor.				
3. I felt that I could not shake off the **blues** even with help from my family or friends.				
4. I felt I was just as good as other people.				
5. I had trouble keeping my mind on what I was doing.				
6. I felt depressed.				
7. I felt that everything I did was an effort				
8. I felt hopeful about the future.				

9. I thought my life had been a failure.				
10. I felt fearful				
11. My sleep was restless				
12. I was happy.				
13. I talked less than usual.				
14. I felt lonely.				
15. People were unfriendly.				
16. I enjoyed life.				
17. I had crying spells.				
18. I felt sad				
19. I felt that people dislike me.				
20. I could not get "going."				

TO SCORE:

Step 1: For each answer, assign the following value:

0-Rarely or none of the time (<1 day)

1-Some or a little of the time (1-2 days)

2-Occasionally or a moderate amount of the time (3-4 days)

3-Most or all of the time (5-7 days)

Step 2: Add the total scores and refer to this scale:

- *If the score is 22 or higher, the patient may be suffering from a major depression.*
- *If the score is 15 to 21, the patient may be suffering from mild to moderate depression.*
- *If the score is below 15, this test does not indicate that the patient is depressed*

THANK

APPENDIX 8.5b: CES-D (Kaonde)

Centre for Epidemiologic Studies Depression Scale (CES-D) – Kaonde

Panshi apepajimisaango mwaumvwengene ne kuuba. Mwaane mbulaiko bimye mwaumvwengene bibye mu muluungu umo waapitapo.

	Jimo jimo nangwa ne	Kimye kimo nangwa	Bimye bimo nangwa bime	Javula nangwa bimye
Mooba (Days)	(<1)	(1-2)	(3-4)	(5-7)
1. Nakatazhiwe nabiintu bibula kunkatazha javula.				
2. Keechi nasakile kuja ne; maambo keechi najinga na kijiika ne.				
3. Naumvwinengatu bulaanda ne muchima kupelelwanangwa kisemi ne bakweetu bankwashishe nga.				
4. Naumvwinengatu noobe njiitu buloongo byonka biji baantu bakwaabo.				
5. Kyankateezhenga kutaya maana kubyo naubilenga.				
6. Naumvwinetu bulaanda ne muchima kupelelwa.				
7. Nalangulukilenga namba byoonse byo naubileenga byaji byakuikanjizha.				
8. Najiinga naluketekelo lwa lutwe lwaami.				

9. Nalangulukiile namba nakaankalwa mu bwiikalo bwaami.				
10. Najinga na mooyo.				
11. Nakankelwe ku laala				
12. Nasangaleele..				
13. Keechi na ambile javuula byoo na amba mooba aku nyuma..				
14. Naumvwinetu noobe nji buunke.				
15. Baantu ke bansanga leejile ne.				
16. Nasekejiile na bwikalo bwaami..				
17. Naendelengatu nakujila.				
18. Naumvwine bu laanda.				
19. Naumvwine noobe baantu bampaata.				
20. Keechi nakonseshe kutwajijila.				

TO SCORE: **Step 1:** For each answer, assign the following value: *0-Rarely or none of the time (<1 day)* *1-Some or a little of the time (1-2 days)* *2-Occasionally or a moderate amount of the time (3-4 days)* *3-Most or all of the time (5-7 days)*	**Step 2:** Add the total scores and refer to this scale: • *If the score is 22 or higher, the patient may be suffering from a major depression.* • *If the score is 15 to 21, the patient may be suffering from mild to moderate depression.* • *If the score is below 15, this test does not indicate that the patient*

	is depressed

TWASAANTA

APPENDIX 8.6a: **MOS-HIV TOOL (English)**

Medical Outcomes Study-HIV Health Survey - English

I would like to ask you a few questions about your health.

1. In general, would you say your health is: (Check One)		
Excellent	1	☐
Very Good	2	☐
Good	3	☐
Fair	4	☐
Poor	5	☐
2. How much **bodily** pain have you generally had during **the past 4 weeks?**(Check One)		
None	1	☐
Very Mild	2	☐
Mild	3	☐
Moderate	4	☐
Severe	5	☐
Very Severe	6	☐
3. During **the past 4 weeks**, how much did pain interfere with your normal work (or your normal activities, including work outside the home and housework)? (check one)		
Not at all	1	☐
A little bit	2	☐
Moderately	3	☐
Quite a bit	4	☐
Extremely	5	☐

4. The following questions are about activities you might do during a typical day. Does your **health now limit you** in these activities? If so, how much?				
(Check **one** box on **each** line.)		**1. YES, limited a lot**	**2. YES, limited a little**	**3. NO, not limited**
a	The kinds or amounts of **vigorous** activities you can do, like lifting heavy objects, running or participating in strenuous sports.	☐	☐	☐

b	The kinds or amounts of **moderate** activities you can do, like washing clothes, moving a jerrican of water or carrying groceries.	☐	☐	☐
c	Walking uphill or climbing stairs.	☐	☐	☐
d	Bending, lifting light objects or kneeling.	☐	☐	☐
e	Walking a distance, like the length of a football pitch, about 100 meters.	☐	☐	☐
f	Eating, dressing, bathing or using the toilet.	☐	☐	☐

5. Does **your health** keep you from working at a job, doing work around the house or going to school? (Check One)		
Yes	1	☐
No	2	☐
6. Have you been unable to do **certain kinds or amounts** of work, housework, or schoolwork because of your health? (Check One)		
Yes	1	☐
No	2	☐

For each of the following questions, please check the box for the one answer that comes closest to the way you have been **feeling during the past 4 weeks.**						
	All of the time	**Most of the time**	**A Good Bit of the time**	**Some of The time**	**A Little of the time**	**None of The time**

7. How much of the time, during the past 4 weeks, has your **health limited your social activities** (like visiting with friends or close relatives)?		1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
8. How much of the time, during the past 4 weeks:		**All of the time**	**Most of the time**	**A Good Bit of the time**	**Some of the time**	**A Little ofthe time**	**None of the time**
a	Have you been a **very nervous person?**	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
b	Have you felt **calm and peaceful**?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Have you felt downhearted and blue(**depressed**)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
d	Have you been a happy person?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
e	Have you felt sodown in the dumps(**depressed**)thatnothing could cheer you up?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
9. How often during the **past four weeks:**		**All of the time**	**Most of the time**	**A Good Bit of the time**	**Some of the time**	**A Little of the time**	**None of the time**

a	Did you feel full of pep (**Full of life and energy, joyful, glad**)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
b	Did you feel worn Out (**Totally without energy**)?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Did you feel tired?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
d	Did you have enough energy to do the things you wanted to do?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
e	Did you feel weighed down by your health problems?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
f	Were you discouraged by your health problems?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
g	Did you feel despair over your health problems?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
h	Were you afraid because of your	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
10. How much of the time, during the **past 4weeks:**		**All of the time**	**Most of the time**	**A Good bit of the time**	**Some of the time**	**A Little of the time**	**None of the time**
a	Did you have Difficulty reasoningand solvingproblems, for example,						

	makingplans, makingdecisions, learningnew things?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

(Check One)		**All of the time**	**Most of the time**	**A Good bit of the time**	**Some of the time**	**A Little of the time**	**None of the time**
b	Did you forget things that happened recently, for example where you put things and when you had appointments?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Did you have trouble keeping your attention o any activity for long?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

11. Please check the box that best describes whether each of the following statements is true or false for you.

(Check one box on each line)		**Definitely True**	**Mostly True**	**Not Sure**	**Mostly False**	**Definitely False**
a	I am somewhat ill	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b	I am as healthy as anybody I know	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c	My health is excellent	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
d	I have been feeling bad lately	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

12. How has the quality of your life been during the **past 4 weeks**? That is, how have things been going for you? (Check One)

Very well; could hardly be better	1	☐
Pretty Good	2	☐
Good and bad parts about equal	3	☐
Pretty bad	4	☐
Very bad; could hardly be worse	5	☐
13. How would you rate your physical health and emotional condition now compared to **4 weeks ago**? (Check One)		
Much better	1	☐
A little better	2	☐
About the same	3	☐
A little worse	4	☐
Much worse	5	☐
THANK YOU VERY MUCH		

APPENDIX 8.6b: **MOS-HIV TOOL (Kaonde)**

Medical Outcomes Study-HIV Health Survey - Kaonde

Naakoonzha kumipuzhako mepuzho acheche pa buumi bwenu.

1. Mubwiipi, buumi bwenu buji: (Tongolayi kimo)		
Bwakijisha tu kuwama	1	☐
Bwawaamisha	2	☐
Bwawaama	3	☐
Bujitu pakachi	4	☐
Bwatama	5	☐
2. Nga'nyi **misongo ikola** mumubiji **milungu iina yaapitapo?**(Tongolayi kimo)		
Kafwaako	1	☐
Pachechetu	2	☐
Yaavula	3	☐
Yaavulako	4	☐
Yavujishatu	5	☐
Yavujisha kyakuuba	6	☐
3. Noobe **mumilungu iina yapitapo** misongo mumubiji yaaleta byeepi lukabisha mumingilo yoomwingila mooba onse (kubikapotu ya mu nzuubo nangwa yapangye)? (Tongolayi kimo)		
Kafwako ne	1	☐
Pacheche	2	☐
Pakachi-nakachi	3	☐
Byoobyaako	4	☐
Kyaakizhaamo	5	☐

4. Ano meepuzho aakwaata pa miingilo mwaafwainwa kwiingila pajuuba. **Buumi bweenu kino kimye bwiimulengela kukankalwa** kwiingila nyi? Ngebyo kiji, mukankalwa byepi?				
(Tongolayi cimo.)		**EE MWANE kupelelwa javula**	**EE MWANE kupelelwa pacheche**	**INE MWANE kupelelwa kafwako**
a	Musaango nangwa byaakwingila bilengela **kwivulumbya** pakwiibyuuba	☐	☐	☐

	noobe kushikula bya neema, kunyeema nangwa kwiibimba mubisela bikeba bulume.			
b	Musaango nangwa buvule bwa biintu byakuuba bijitu **pakachi nakachi** byoo mwakoonsha kuuba noobe kuchapa bivwalo, kutoola kipooma kyameema nangwa kuseenda milooba nebiintu bikwaabo byaapotwa.	☐	☐	☐
c	Kukanjila mutuumba nangwa pa maleela.	☐	☐	☐
d	Kubandama, kushikula bipe byapeela nangwa kufukamina mu manuungo.	☐	☐	☐
e	Kweenda museeke noobe mu buula bwa kibaanza kya mpila.	☐	☐	☐
f	Kuja, kuvwaala, koowa nangwa kwingijisha kyoolonyi.	☐	☐	☐

5. **Butuuntulu bwa mubiji** woobe bukukaanya kusebeeza nkito nangwa kuwaamisha palubaazha nangwa kuya kusukuulu nyi? (Tongolayi kimo)		
Ee mwane	1	☐
Ine mwane	2	☐
6. Keechi mwaajikukoonsha **kwiingilapo** mingiilo yaaku nzuubo nangwa ku sukuulu namaambo abutuuntulu bwamuubiji weenu? (Tongolayi kimo)		
Ee mwane	1	☐
Ine mwane	2	☐

Mu ano meepuzho, monayi mukabokooshi mukuumbu waafweenyesha kubwiipi nabyoo mwaumvwanga **milungu iina yaapitaapo**						
	Byoonse bimye	**Kimye kyavula bingi**	**Kimye kyavula pache che**	**Kimye jimo jimo**	**Kakimye kache che**	**Nangwa kimo kimye**

7. Bimye biinga mumilungu iina yaapitapo **buumi kumikaanya kupeempula bakweenu nyi**?		1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
8. Bimye biinga mumilungu iina yaapitapo:		**Byoonse bimye**	**Kimye kyavula bingi**	**Kimye kyavula pache che**	**Kimye jimo jimo**	**Kakimye kache che**	**Nangwa kimo kimye**
a	Mwaaji **kuyuulasa biingi na mooyo nyi?**	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
b	Mwakyumvwa kala **muteende** kukokola nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Mwaakyuumv wapo **bulaanda** nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
d	Mwaakisangala lapo nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
e	Mwaakyumvwa bulanda ne muchima kupelelwa kyakuuba keechi muuntu mukwabo kumisangalalika ne?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
9. Bimye biinga mumilungu iina yaapitaapo**:**		**Byoonse bimye**	**Kimye kyavula bingi**	**Kimye kyavula pache che**	**Kimye jimo jimo**	**Kakimye kache che**	**Nangwa kimo kimye**
a	Mwaaumvwine po kwiikala nabuumi bwa vuula ne bulume, lusekeelo nekusaangalala nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

b	Mwaaumvwine po kupwaamo kwakubula ngovu yoonse nyi.?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Mwaaumvwine po kukooka nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
d	Mwajingapo nabulume bwakuuba nkito yomwakebeele kuuba nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
e	Mwaakyumvwi neepo kineme nezhi nalukatazho lwa bumi bweenu nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
f	Lukatazho lwa buumi bwenu lwamibwezhez he panshi nyi.?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
g	Mwaaumvwine kupopomenwa nalukatazho lwa buumi bweenu nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
h	Mwaajinga na mooyo na maambo a buumi bwenu nyi?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
10 Bimye biinga **mumilungu iina** yaapitaapo**:**		**Byoonse bimye**	**Kimye kyavula bingi**	**Kimye kyavula pache**	**Kimye jimo jimo**	**Kakimye kache che**	**Nangwa kimo kimye**
a	Mwataine lukatazho pakulanguluka amba mupwiisha lukatazho	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

	noobe kutanchika bya kuuba ne kufuukula bya kuuba?						

(Tongolayi kimo)		**Byoonse bimye**	**Kimye kyavula bingi**	**Kimye kyavula pache che**	**Kimye jimo jimo**	**Kakimye kache che**	**Nangwa kimo kimye**
b	Mwaavulamineko biintu byamwekele kataataka, noobe kuluuba pomwabikile biintu ne kuluuba amba mwaaji kulayangana na muntu?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐
c	Mwaashupikilenga pakuuba amba mutekesheko muchima kimye kyabaaya mukulondela bibeena kuubiwa?	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	6 ☐

11. Tongolayi kabokooshi muji mukuumbu waalondolola bulongo pabyoonse byaaneembwa pakuuba amba muyuuke weepi mukuku waakine nangwa waabubela

(Tongolayi kabookoshi kamo)		**Kishinka kyakinekin**	**Kishinka**	**Kenayukane**	**Bubela**	**Bubela bwakinekin**
a	Mbena kumvwa kubela	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
b	Njitu buloongo byonka biji muuntu ense.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
c	Buumi bwanji bwachijisha kuwama.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

d	Katataka mbenakumvwa bibi.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

12. Butuuntulu bwa buumi bweenu mumiluugu iina yapiita bwajinga byeepi? Kookuuba amba biintu byaendanga byeepi? (Tongolayi kimo)		
Buloongo biingi	1	☐
Buloongo	2	☐
Buloongo na kutaama pamotu	3	☐
Bya taama	4	☐
Bya taamisha	5	☐
13. Kweesakanya miluungu iina yaapitaapo kana mwaakonsha buumi mu mubiji na mu maana ubeena kumvwa byeepi? (Tongolayi kimo)		
Buloongo biingi	1	☐
Buloongo pache che	2	☐
Kiimo tu	3	☐
Kutaama pache che	4	☐
Kutamisha	5	☐
NASAANTA BIINGI MWAANE		

APPENDIX 8.7: **TIME TABLE**

The table below shows the time lines during which various research activities were conducted.

	May 2013	April2014	May 2014	June 2014	July 2014	Augt 2014	Sept 2014	Oct 2014	Nov 2014	Dec 2014	Jan 2015	Feb 2015	Mar 2015	April 2015	May 2015	June 2015	July 2015	Aug 2015	Sept 2015
Present to department	■																		
Submit proposal to Asst Dean (PG) office		■																	
Present at GPPF(Graduates Forum)		■																	
Submit proposal to Ethics Committee			■																
Review /approval by Ethics Committee				■	■	■	■	■											
Enrol patients and collect data									■	■	■								
Analyze data												■	■	■	■				
Write dissertation																■	■	■	
Submit final dissertation																			■

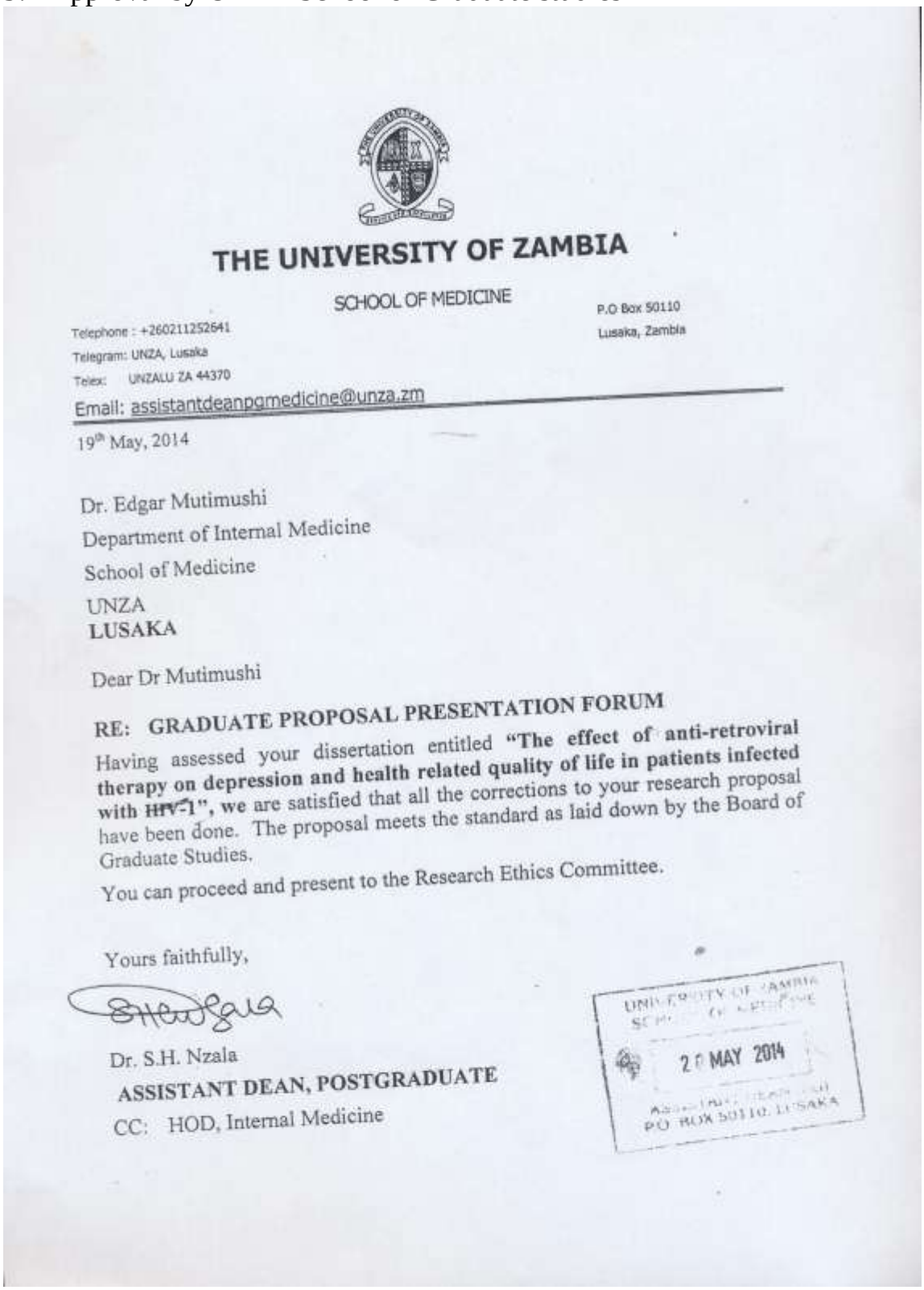
APPENDIX 8.8: **BUDGET**

The following table shows the budget and money spent on conducting this study:

Fixed Assets:	University Funding	ZMK	000.00
Recurrent Expenditure:	Ethics fees	ZMK	1,000.00
	Administrative fees	ZMK	000.00
Research Activities:	Transport	ZMK	2,000.00
	Stationary	ZMK	400.00
	Printing	ZMK	800.00
	Binding	ZMK	800.00
	Consultation fees	ZMK	1,000.00
	Client fees	ZMK	000.00
	Thesis Preparation fees	ZMK	500.00
TOTAL		**ZMK**	**6,500.00**

9.0 ATTACHMENTS

9.1 Approval by UNZA School of Graduate studies



THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

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Lusaka, Zambia

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Email: assistantdeanpgmedicine@unza.zm

19th May, 2014

Dr. Edgar Mutimushi
Department of Internal Medicine
School of Medicine
UNZA
LUSAKA

Dear Dr Mutimushi

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Having assessed your dissertation entitled **"The effect of anti-retroviral therapy on depression and health related quality of life in patients infected with HIV-1", we** are satisfied that all the corrections to your research proposal have been done. The proposal meets the standard as laid down by the Board of Graduate Studies.

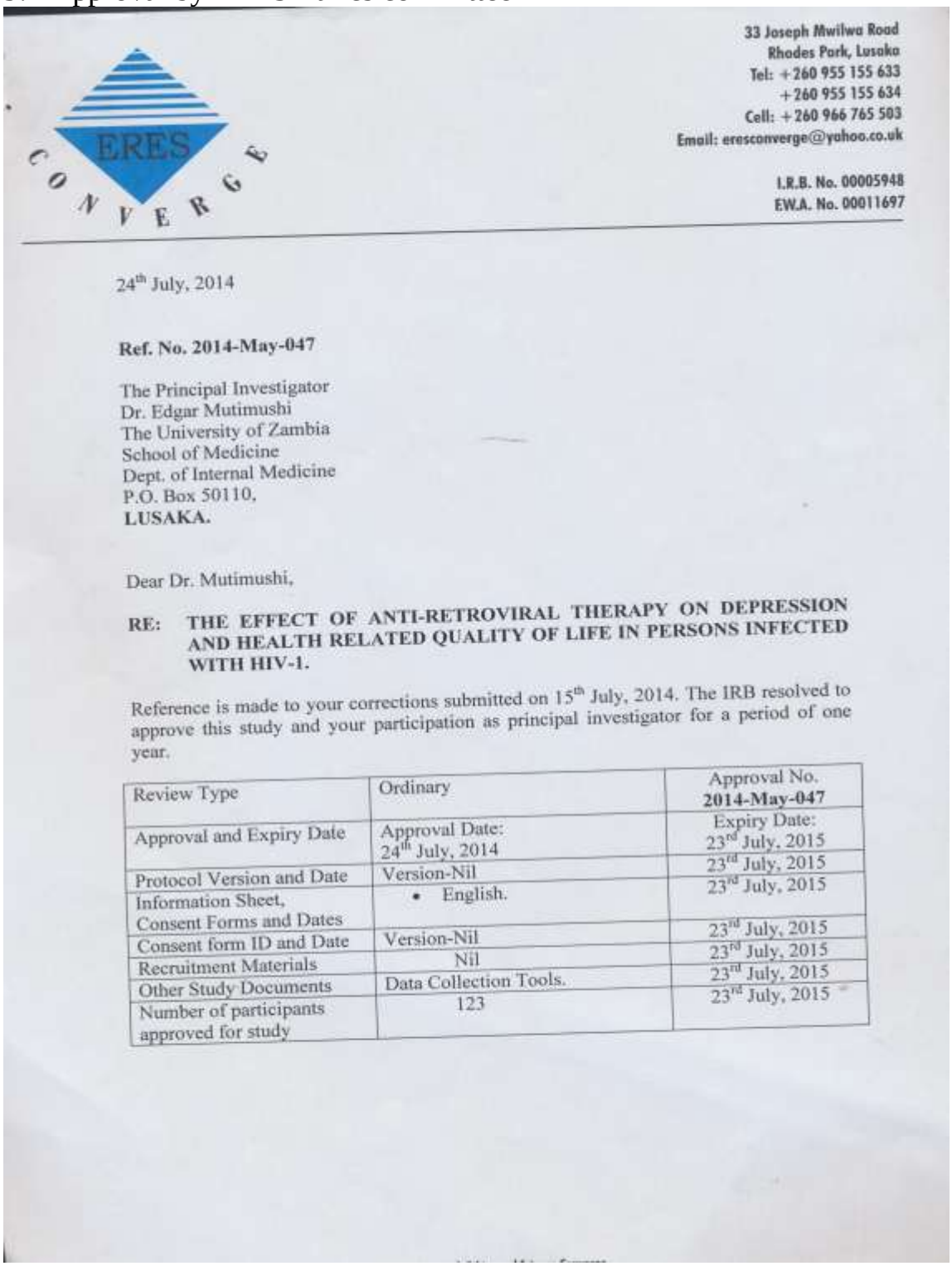
You can proceed and present to the Research Ethics Committee.

Yours faithfully,

Dr. S.H. Nzala
ASSISTANT DEAN, POSTGRADUATE
CC: HOD, Internal Medicine

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
20 MAY 2014
ASSISTANT DEAN (PG)
P.O BOX 50110, LUSAKA

9.2 Approval by ERES Ethics committee



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I.R.B. No. 00005948
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24th July, 2014

Ref. No. 2014-May-047

The Principal Investigator
Dr. Edgar Mutimushi
The University of Zambia
School of Medicine
Dept. of Internal Medicine
P.O. Box 50110,
LUSAKA.

Dear Dr. Mutimushi,

RE: THE EFFECT OF ANTI-RETROVIRAL THERAPY ON DEPRESSION AND HEALTH RELATED QUALITY OF LIFE IN PERSONS INFECTED WITH HIV-1.

Reference is made to your corrections submitted on 15th July, 2014. The IRB resolved to approve this study and your participation as principal investigator for a period of one year.

Review Type	Ordinary	Approval No. **2014-May-047**
Approval and Expiry Date	Approval Date: 24th July, 2014	Expiry Date: 23rd July, 2015
Protocol Version and Date	Version-Nil	23rd July, 2015
Information Sheet, Consent Forms and Dates	• English.	23rd July, 2015
Consent form ID and Date	Version-Nil	23rd July, 2015
Recruitment Materials	Nil	23rd July, 2015
Other Study Documents	Data Collection Tools.	23rd July, 2015
Number of participants approved for study	123	23rd July, 2015

Specific conditions will apply to this approval. As Principal Investigator it is your responsibility to ensure that the contents of this letter are adhered to. If these are not adhered to, the approval may be suspended. Should the study be suspended, study sponsors and other regulatory authorities will be informed.

Conditions of Approval

- No participant may be involved in any study procedure prior to the study approval or after the expiration date.
- All unanticipated or Serious Adverse Events (SAEs) must be reported to the IRB within 5 days.
- All protocol modifications must be IRB approved prior to implementation unless they are intended to reduce risk (but must still be reported for approval). Modifications will include any change of investigator/s or site address.
- All protocol deviations must be reported to the IRB within 5 working days.
- All recruitment materials must be approved by the IRB prior to being used.
- Principal investigators are responsible for initiating Continuing Review proceedings. Documents must be received by the IRB at least 30 days before the expiry date. This is for the purpose of facilitating the review process. Any documents received less than 30 days before expiry will be labelled "late submissions" and will incur a penalty.
- Every 6 (six) months a progress report form supplied by ERES IRB must be filled in and submitted to us.
- ERES Converge IRB does not "stamp" approval letters, consent forms or study documents unless requested for in writing. This is because the approval letter clearly indicates the documents approved by the IRB as well as other elements and conditions of approval.

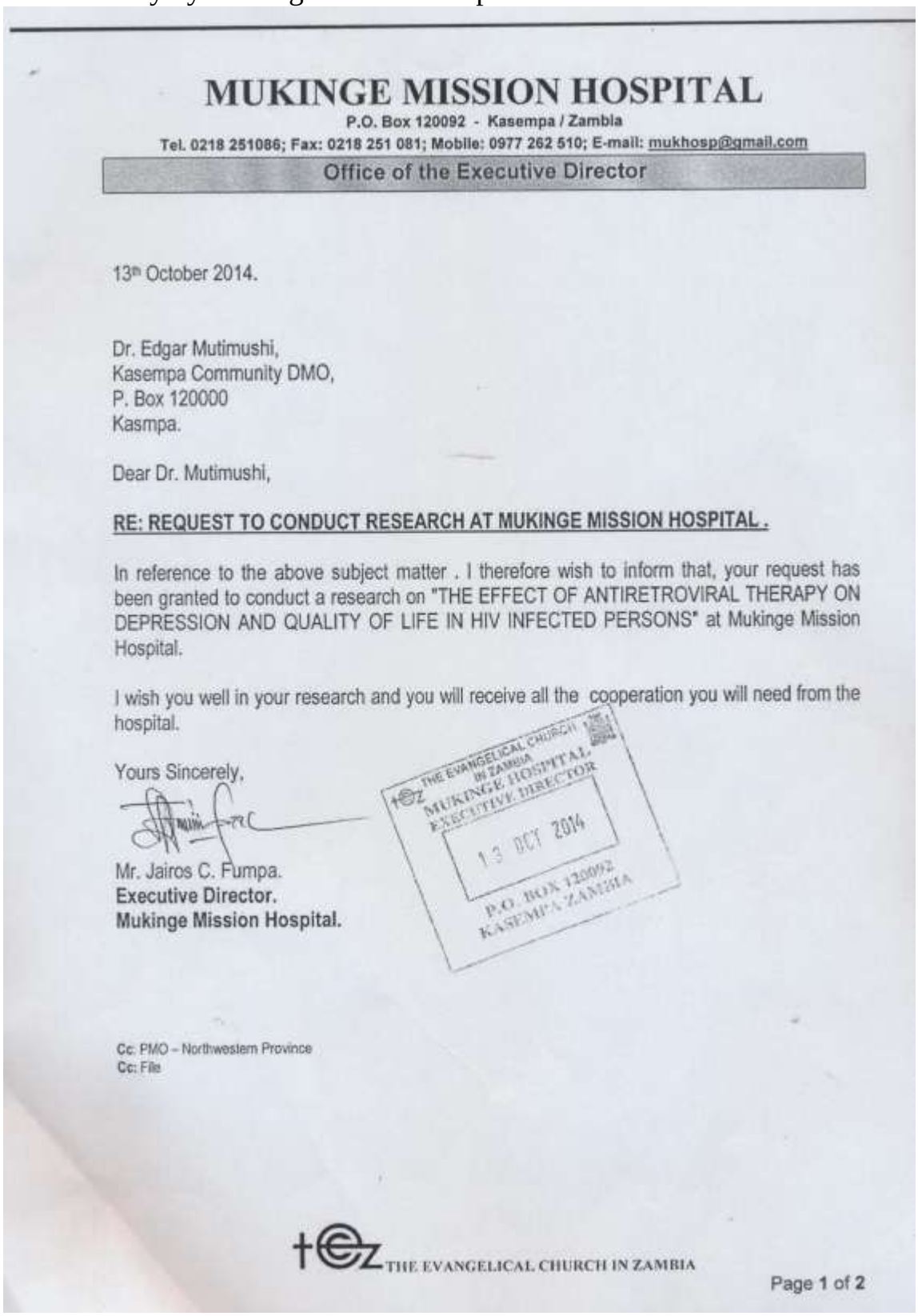
Should you have any questions regarding anything indicated in this letter, please do not hesitate to get in touch with us at the above indicated address.

On behalf of ERES Converge IRB, we would like to wish you all the success as you carry out your study.

Yours faithfully,
ERES CONVERGE IRB

Dr. E. Munalula-Nkandu
BSc (Hons), MSc, MA Bioethics, PgD R/Ethics, PhD
CHAIRPERSON

9.3 Authority by Mukinge Mission Hospital



MUKINGE MISSION HOSPITAL

P.O. Box 120092 - Kasempa / Zambia

Tel. 0218 251086; Fax: 0218 251 081; Mobile: 0977 262 510; E-mail: mukhosp@gmail.com

Office of the Executive Director

13th October 2014.

Dr. Edgar Mutimushi,
Kasempa Community DMO,
P. Box 120000
Kasmpa.

Dear Dr. Mutimushi,

RE: REQUEST TO CONDUCT RESEARCH AT MUKINGE MISSION HOSPITAL .

In reference to the above subject matter . I therefore wish to inform that, your request has been granted to conduct a research on "THE EFFECT OF ANTIRETROVIRAL THERAPY ON DEPRESSION AND QUALITY OF LIFE IN HIV INFECTED PERSONS" at Mukinge Mission Hospital.

I wish you well in your research and you will receive all the cooperation you will need from the hospital.

Yours Sincerely,

THE EVANGELICAL CHURCH IN ZAMBIA
MUKINGE HOSPITAL
EXECUTIVE DIRECTOR
13 OCT 2014
P.O. BOX 120092
KASEMPA ZAMBIA

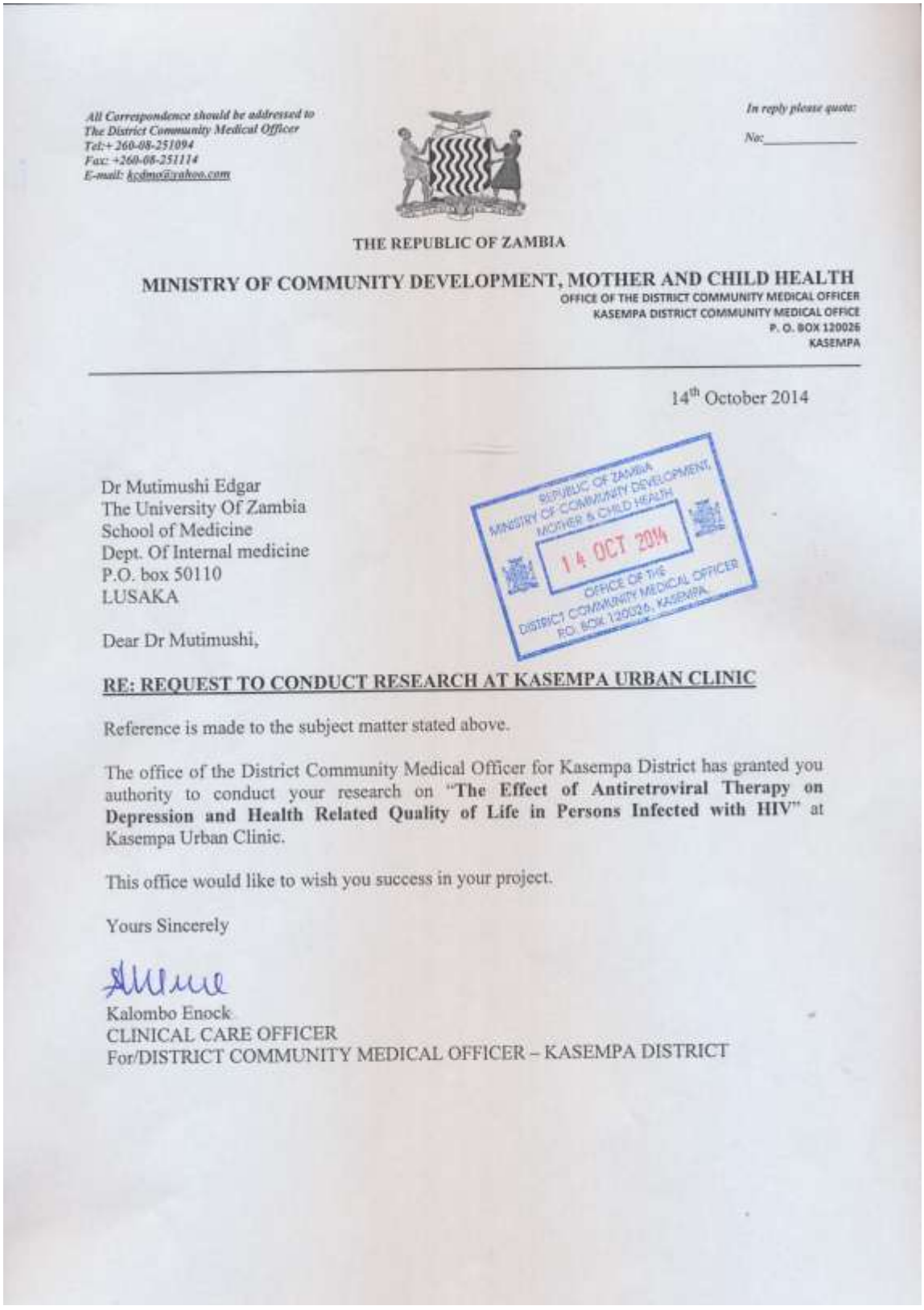
Mr. Jairos C. Fumpa.
Executive Director.
Mukinge Mission Hospital.

Cc: PMO – Northwestern Province
Cc: File

THE EVANGELICAL CHURCH IN ZAMBIA

Page 1 of 2

9.4 Authority by Kasempa Urban Clinic



All Correspondence should be addressed to
The District Community Medical Officer
Tel:+ 260-08-251094
Fax: +260-08-251114
E-mail: kcdmo@yahoo.com

In reply please quote:
No:_____

THE REPUBLIC OF ZAMBIA

MINISTRY OF COMMUNITY DEVELOPMENT, MOTHER AND CHILD HEALTH
OFFICE OF THE DISTRICT COMMUNITY MEDICAL OFFICER
KASEMPA DISTRICT COMMUNITY MEDICAL OFFICE
P. O. BOX 120026
KASEMPA

14th October 2014

REPUBLIC OF ZAMBIA
MINISTRY OF COMMUNITY DEVELOPMENT, MOTHER & CHILD HEALTH
14 OCT 2014
OFFICE OF THE DISTRICT COMMUNITY MEDICAL OFFICER P.O. BOX 120026, KASEMPA

Dr Mutimushi Edgar
The University Of Zambia
School of Medicine
Dept. Of Internal medicine
P.O. box 50110
LUSAKA

Dear Dr Mutimushi,

RE: REQUEST TO CONDUCT RESEARCH AT KASEMPA URBAN CLINIC

Reference is made to the subject matter stated above.

The office of the District Community Medical Officer for Kasempa District has granted you authority to conduct your research on "**The Effect of Antiretroviral Therapy on Depression and Health Related Quality of Life in Persons Infected with HIV**" at Kasempa Urban Clinic.

This office would like to wish you success in your project.

Yours Sincerely

Kalombo Enock
CLINICAL CARE OFFICER
For/DISTRICT COMMUNITY MEDICAL OFFICER – KASEMPA DISTRICT