EFFECT OF COGNITIVE BEHAVIOURAL THERAPY ON CLINICAL DEPRESSION, ART ADHERENCE AND HIV STIGMA AMONG HIV-INFECTED OUTPATIENTS IN UASIN-GISHU COUNTY, KENYA

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DECLARATION AND RECOMMENDATION

Declaration

This thesis is my original work and has not been presented for an award of a degree in this or any other university.

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Recommendation

This thesis has been presented for examination with our approval as University Supervisors.

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DEDICATION

Primarily, I dedicate this work to the God Almighty by whose guidance and wisdom this onerous academic task has been accomplished, and to all HIV-infected patients who provided a perfect base upon which this work was built.

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ABSTRACT

Recent statistics indicate that HIV infection prevalence in Kenya is at 5.6 percent. Of note, HIV infection is commonly known for its tendency to present with comorbid conditions including neuropsychiatric disorders. Within this spectrum, depression, which is a mood disorder, is the most common neuropsychiatric disorder among persons living with HIV (PLHIV) occurring at rates 2 to 3 times higher than in HIV-negative persons. Depression contributes significantly to poor health outcomes among HIV-infected individuals by accelerating HIV progression. Evidently, depression has been associated with HIV-related stigma and non-adherence to Antiretroviral Therapy (ART) among PLHIV. However, proper recognition, timely diagnosis and treatment of depression among HIV-infected outpatients in Kenya remain low key. Most importantly, there is substantial evidence to support the use of psychotherapy and in particular Cognitive Behavioural Therapy (CBT) in the management of depression among PLHIV across diverse settings. The purpose of this study was to investigate the effect of CBT on depression, ART adherence and HIV stigma among HIV-infected outpatients in Turbo-Uasin Gishu County, Kenya. An experimental pretest/posttest control group design was adopted in this study, with CBT as the intervention in the experimental condition. The population of this study was 3000 HIV-infected adults attending Turbo Sub-County Hospital. A systematic random sampling was used to obtain an original sample size of 393 which was further subjected to eligibility criteria yielding 53 participants among whom 45 successfully completed the study against the desired powered sample size of 44. All participants were randomly assigned to either treatment or control conditions of the study in the ratio of 1:1. Patients randomised into the control group did not receive any form of psychotherapy during the active phase of the study period. Study variable measures were administered to participants both at baseline (one week before the intervention) and at month-2 post intervention assessment points. Data were collected using a set of instruments (PHQ-9 scale for depression; Patient Adherence

Record for ART adherence; and HIV/AIDS-Related Stigma Scale for HIV stigma) and keyed into R version 3.2.5 software for statistical computation. Study instruments had good validity and reliability properties, PHQ-9, $r = .74$, $p = .015$; AIDS-related Stigma, $r = .85$, $p = .002$ and Patient Adherence Record, $\kappa = .7$, $p = .010$. Data analysis was done using descriptive statistics and inferential statistics including: Mann-Whitney *U* test, Generalised estimating equations/GEE, Ordinal regression, Shapiro-Wilk *W* test for normality and Pearson's χ^2. The study established that CBT had a significant clinical effect and remission on depression (a *mean* drop of 5.8 points in PHQ-9 score from pre-to-posttest, $p = .001$); increasing ART adherence; $OR = 2.14$, 95% CI [1.31, 3.46]; and containing the escalation of HIV stigma as well as marginally lowering HIV internalised stigma ($p = .051$) among participants. The study also found a relatively large treatment effect size, $r = .5$ for CBT on depression and medium treatment effect size, $r = .4$ for CBT on ART adherence at month-2 posttest assessment. From the study results, it was concluded that CBT intervention was more effective for depression than the untreated control group, and that CBT participants had relatively better clinical outcomes for depression and medication adherence in the short term assessment. The study findings were important in providing empirical evidence in support for adaptation and application of group CBT as an effective psychological treatment for depression; and as an enhancer for medication adherence among PLHIV attending outpatient clinics in western Kenya. The study recommends that the Ministry of Health and agencies implementing HIV programmes should consider making necessary policies which may facilitate the integration of psychotherapy services into the routine HIV care to help patients deal with mental disorders that usually present along with HIV infection.

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LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
AMPATH	Academic Model Providing Access to Healthcare
APA	America Psychiatric Association
ART	Antiretroviral Therapy
ARV	Antiretroviral
CBT	Cognitive Behavioural Therapy
CD4	CD4 T-lymphocyte Cell
CI	Confidence Interval
DSM-5	Diagnostic and Statistical Manual of Mental disorders, Version 5
ES	Effect Size
f	Fisher's exact test Statistic
GEE	Generalized Estimating Equations
GSP	Group Support Psychotherapy
HIV	Human Immunodeficiency Virus
IPT	Interpersonal Therapy
IQR	Inter Quartile Range Score
KAIS	Kenya AIDS Indicator Survey
LMC	Low-and –Middle-income Countries
LTFU	Lost to Follow Up
MBCT	Mindfulness Based Cognitive Therapy
M	Mean
Md	Median Score
MoH	Ministry of Health
n	Sample Size
NACC	National AIDS Control Council

NASCOP National AIDS/STI Control Programme

OR Odds Ratio

P p-value (.05)

PHQ-2 Patient Health Questionnaire for Depression Screening

PHQ-9 Patient Health Questionnaire for Depression Assessment

PLHIV Persons Living with HIV/AIDS

R Statistical Software for Data Analysis.

r Strength of Effect Size

SD Standard Deviation

SE Standard Error

SSA Sub-Saharan Africa

UNAIDS The Joint United Nations Programme on HIV/AIDS

US United States of America

VAS Visual Analogue Scale

W Shapiro-Wilk test Statistic

WHO World Health Organisation

χ^2 Chi Square Test

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

HIV/AIDS pandemic still remains one of the leading health crises the world faces today. The global prevalence of HIV infection is estimated to be as high as 36.9 million with an incidence rate of 2 million new infections per year (UNAIDS, 2015). In 2014, there were 25.8 million people living with HIV in sub-Saharan Africa with 1.4 million new infections. Trends in new adult infections differ among regions. The epidemic continues to disproportionately affect sub-Saharan Africa which is home to 66% of all new HIV infections in 2014 (UNAIDS, 2015). The 2012 Kenya AIDS Indicator Survey (KAIS) by the Ministry of Health estimated that 5.6% of adults between ages 15 and 64 were living with HIV as of 2012 (NASCOP/KAIS, 2014). The survey further indicates that 7.7% of households in Kenya were affected by HIV in 2012. The percentage of Kenyans living with HIV has fallen by roughly 40% since 1996, although the number of people living with HIV is increasing due to population increases (NACC & NASCOP, 2012). An estimated 1.6 million Kenyans were living with HIV in 2013, with women representing 61% of all people living with HIV (NACC & NASCOP, 2014).

Findings from the recently released report by Global Burden of Disease/GBD Study 2015 (Wang *et al.*, 2016) on global trends of HIV prevalence and incidence revealed that more than 1.8 million Kenyans were living with HIV in 2015. Shocking but not surprising, this unfavourable finding revealed that there could be a dramatic increase in HIV-infections in Kenya with as many as 100,000 people getting newly infected with the virus annually. With an increase from 1.6 million infections in 2013 (NACC & NASCOP, 2014) to 1.8 million infections in 2015 (Wang *et al.*, 2016), the possibility to eliminate the AIDS epidemic by the year 2030 as was earlier anticipated by Kenyan Ministry of Health (NACC & NASCOP, 2012) remains uncertain. From the GBD study, the number of new HIV infections in Kenya is rising faster than any other country in sub-Saharan Africa and possibly the world over. Specifically, the number of new HIV cases grew by an average of 7 per cent per year, one of the highest increases in the world. The current upsurge in cases of new infections could be an indicator that efforts mounted by the Kenyan government and non-governmental agencies to stem the spread of HIV have grossly been undermined. Of great

concern is the fact that in the overall new adult HIV infections recorded in 2015, more than 46% were among adolescents and young people aged between 15 to 24 years. This is an indication that HIV has deep penetrative effect within the local population and thus remains a serious health crisis in Kenya. The high HIV incidence among the young adults in Kenya portends a negative outlook for the future generation in terms of possible disease escalation and poor health outcomes with serious economic repercussions. As depicted in recent statistics, approximately 35,822 Kenyans died of AIDS related causes in 2015(NACC & NASCOP, 2016).

Admittedly, the burden of HIV pandemic to the Kenyan population especially persons living with HIV remains a complex reality. First, there is not yet a tangible breakthrough in the world of medical research culminating into a successful discovery of HIV cure. Second, HIV infection is commonly known for its tendency to present with comorbid conditions including neuropsychiatric disorders. Within this spectrum, depression which is a mood disorder is the most common neuropsychiatric disorder affecting PLHIV, occurring at the rate of two to three times higher compared to the HIV-negative persons in diverse settings (Mogga *et al*., 2006; Olatunji, Mimiaga, O'Cleirigh, & Safren, 2006; Nakimuli *et al*., 2011). Regionally, it is estimated that the prevalence of depressive disorders and that of major depression is at 31% and 18% respectively across HIV clinics in sub-Saharan Africa (Nakimuli *et al*., 2011). In comparison, the prevalence of depressive disorders among PLHIV in Kenya has been reported to be as high as 42% (Ndetei *et al*., 2009). Studies conducted in western Kenya region have reported similar trends with results showing that as high as 42% of PLHIV attending outpatient clinics are presenting with depressive disorders (Monahan *et al*., 2008; Adina, 2016).

Depression in PLHIV has often been associated with adverse effects including poor adherence to antiretroviral treatment (ART). In a meta-analysis by Gonzalez *et al*. (2011), the presence of depression in PLHIV is a significant predictor of poor adherence. Earlier studies had also documented significant association between depression in PLHIV and poor adherence to ART (Ammassari *et al*., 2004; Treisman, & Angelino, 2007). Inconsistent compliance with ART could lead to inadequate viral suppression, and much worse treatment outcomes. Other researchers have reported that PLHIV suffering from depression progress faster from HIV to AIDS compared to non-depressed PLHIV (Leserman *et al*., 2000; Cruess *et al*., 2005), and generally have a poor quality of life (Sherbourne *et al*., 2000). In 2012, people in low- and middle-income countries

numbering 9.7 million received antiretroviral therapy, representing 61% of all who were eligible under the 2010 World Health Organization (WHO) HIV treatment guidelines (UNAIDS, 2013).

Kenya has an extremely high and disproportionate representation of persons living with HIV who are in need of urgent treatment. The total number of HIV-infected adults in need of ART as of 2013 was 760,000 out of which only 41.9% had access to antiretroviral medication (NACC & NASCOP, 2014). A recent study done by Global Burden of Disease network (2016) revealed that only 39 per cent of HIV-infected Kenyans were on antiretroviral therapy (ART) drugs. This is 4% below the regional average which stands at 43 per cent, and a pointer that 61% of persons living with HIV in Kenya are not on the life-saving ARV drugs. Apparently, any person infected with HIV who is not on ARV drugs is at risk of faster disease progression and being highly infectious to others in the population (Whelan, 2002). Arguably, there is a glaring need to expand access to care and increase ARVs uptake among PLHIV in Kenya as a way of combating the damaging socio-economic and physiological effects of HIV infection. Nevertheless, access to medication alone may not necessarily guarantee treatment adherence to antiretroviral therapy (ART). Therefore, ART treatment adherence is one of the primary strategies that ART implementing agencies require to help delay the emergence of resistant strains of HIV virus and ensure viral load suppression as well as the durability of the present regimens among PLHIV (Steel, Nwokike, & Joshi, 2007).

Non-adherence to ART is a common phenomenon among PLHIV. Non-adherence includes not taking medications at prescribed time intervals and non-compliance to dosing instructions regarding dietary or fluid intake (Paterson, Swindells, & Mohr, 2000). In developing countries, adherence rates are thought to be lower than that of developed countries which averages 50% for chronic illnesses (WHO, 2003). It is recognisable therefore that many patients could be experiencing difficulties in following their treatment regimen. Literature on antiretroviral therapy shows that adherence difficulties among PLHIV is highly prevalent with the rates varying between 37 and 83 percent, depending on the drug under study (Stein, Rich, & Maksad, 2000). With this generic trend in mind, it can be deduced that many patients in the sub-Saharan Africa including Kenya which is a HIV high burden country could be victims of non-adherence to medication, and thus warrants a study to innovate interventions that may bolster clinical care strategies for optimal adherence to ART.

Persons living with HIV are also faced with the burden of having to endure the emotional pain of stigma and discrimination. Boon *et al*. (2006) emphasised that HIV/AIDS is known to be associated with stigma. It has also been observed that HIV-related stigma is more highly damaging than any other disease-related stigma (Oyediran, Oladipo, & Anyanti, 2005). Research has shown that PLHIV who feel stigmatised are less likely to access HIV care services (Chesney & Smith, 1999; Bond, Chase, & Aggleton, 2002), which may in turn lead to poor access to available medications including antiretroviral therapy (ART), and eventually irregular use of medications. Other studies have also shown that PLHIV who have AIDS related stigma are more likely than those without stigma to present with poor psychological wellbeing, which may include high levels of stress and poor adaptation to daily challenges in life (Lichenstein, Laska, & Clair, 2002). Indeed, poor psychological wellbeing may be a precursor to the development of psychiatric disorders including depression. HIV-related stigma and discrimination persist as major obstacles to an effective HIV response in all parts of the world, with national surveys indicating that discriminatory treatment of PLHIV is still common in multiple facets of life, including access to health care. In 2012, as many as 61% of countries in the world reported the existence of anti-discrimination laws that protect people living with HIV (UNAIDS, 2013). A study conducted in Eldoret and Mosoriot in western Kenya on felt stigma among persons living with HIV in rural and urban centres revealed that HIV-related stigma was a prevalent phenomenon that affected PLHIV in both rural and urban settings in varying degrees (Yebei, Fortenberry & Ayuku, 2008).

Examining the association between depression and biopsychosocial variables is important because some of the variables including AIDS stigma, low CD4 counts and opportunistic infections have been shown to negatively influence health outcomes in PLHIV (Olley Seedat, Nel, & Stein, 2004; Cruess *et al*., 2005). The burden of depression, and its association with HIV stigma as well as poor adherence to antiretroviral treatment and a number of other variables among PLHIV have been investigated and the results documented. However, in an attempt to mitigate for the effects of clinical depression on PLHIV in the local setting, the study aimed to establish the effect of cognitive behavioural therapy (CBT) in the treatment of depression and its psychosocial correlates among PLHIV attending primary healthcare outpatient clinics in Uasin Gishu County, Kenya.

CBT is considered the gold standard in the psychotherapeutic treatment of disorders such as anxiety, depression, and eating disorders. For instance, meta-analytic studies have been published

reporting medium to large treatment effect sizes regarding the efficacy and effectiveness of CBT for anxiety and depression (Norton & Price, 2007; Hoffman & Smits, 2008; Stewart & Chambless, 2009). Similarly, a number of studies conducted over the last few decades have consistently demonstrated solid outcomes for CBT in the treatment of depression with different groups in manifold settings. These studies have demonstrated that CBT is more effective for depression in comparison to other treatment modalities, including medication. In a meta-analytic study conducted by Butler *et al.* (2006) on CBT treatment outcomes, the findings showed that CBT was consistently effective, and that, on the overall the intervention yielded large treatment effect sizes for depression.

Previous studies have found that CBT is significantly more effective in reducing depression among clients as compared to; the untreated clients, those treated as usual for their given medical conditions, and the wait-listed clients (Dobson, 1989; Gloaguen, Cottraux, Cucherat, & Blackburn, 1998; Wilson, Mottram, & Vassilas, 2008). A meta-study by Beltman *et al*. (2010) which examined 29 studies in the developed and developing nations conducted between 1984 and 2008 demonstrated that CBT was significantly more effective at reducing depressive disorder than the untreated control group. The meta-study also revealed that CBT group therapy was effective in reducing depressive symptoms among persons suffering from a variety of somatic diseases such as cancer, HIV infection, or renal failure. Group CBT compares favourably with individual CBT at three months post-treatment assessment, and significantly helps depressed patients more than the usual care (Huntley, Araya, & Salisbury, 2012). In sum, the use of CBT to treat depression has been proven to be more efficacious and superior to wait list, support groups, usual care groups, controls, and at least as effective as antidepressant medication (Amick *et al*., 2015), with more enduring effects than medication (Hollon *et al*., 2005; McHugh, Whitton, Peckham, Welge, & Otto, 2013).

There is robust evidence demonstrating that psychotherapy (particularly CBT) can be an effective healthcare service for a wide range of commonly experienced mental health and health conditions among PLHIV. Research shows that psychotherapy is as effective as medication in treating depression and is more effective than medication in preventing relapse ((De Maat, Dekker, Schoevers, & De Jonghe, 2006; Cuijpers *et al*., 2011a; Spielmans, Berman, & Usitalo, 2011). In spite of the aforementioned, it is interesting to note that there is paucity of information regarding

the application of CBT in the treatment of depression among HIV-infected population in Kenya, especially within the primary health care setting. The only related studies found in Kenya on CBT were on the systematic cultural adaptation of CBT to reduce alcohol use among PLHIV (Papas *et al*., 2010; 2011).

In this study, the researcher examines how CBT as a behaviour-change intervention may be applied in a primary healthcare setting to treat depression. In addition, the study investigates CBT's effect on poor medication adherence and HIV stigma as psychosocial sequelae of clinical depression among HIV-infected patients. This is significant because Kenya is one of the countries in sub-Saharan Africa with high HIV prevalence and escalating new HIV infections which can only be reversed through strict adherence to antiretroviral therapy. The observed gap with regard to the use of CBT for depression, ART adherence, and HIV stigma and the dearth of evidence supporting the use of CBT in primary healthcare settings in Kenya formed the basis and motivation for this study. Conceptually, a reduction in depression would lead to better medication adherence, elimination of stigma, improved health seeking behaviour and consequently better treatment outcomes for persons living with HIV.

1.2 Statement of the Problem

Clinical depression has been associated with sub-optimal benefit from Antiretroviral (ARV) medication-due to poor adherence and high levels of stigma among HIV-infected patients. Poor adherence to antiretroviral therapy poses the danger of precipitating the emergence of resistant strains of the virus and instability of treatment regimen among PLHIV. On the other hand, HIV stigma has been known to hinder HIV prevention and is associated with limited access to treatment due to low self-esteem, and lack of disclosure. Although depression can be treated only fewer patients with depression usually receive adequate treatment due to inaccessibility and high cost of pharmacological intervention in the local setting. This presents a predicament to the patients presenting with depressive disorders who cannot access psychiatric care and who may be at risk of severe depression which just like HIV infection is linked to immunosuppressive effect in the human body system. In this regard, the study sought to establish the effect of CBT (using group psychotherapy approach) intervention on depression and its correlates specifically, HIV stigma and poor ART adherence. CBT as an intervention and theory that guided the study holds the view that PLHIV may get depressed due to feelings of self-pity, others-pity, shame of being HIV-

infected, and the inclination to experience negative view of self, the world and the future as an outcome of psychological reaction to HIV diagnosis. Thus, this study was premised on the assumption that a reduction in levels of depression would result into increased ART adherence and reduced HIV stigma among the cohort of patients studied. Further, the researcher opined that if found effective, CBT would provide an alternatively cheaper and more accessible treatment option in the management of depression among PLHIV in primary healthcare settings. This may also offer a shift from overreliance on the use of antidepressants for depression. Interestingly, most of the research on this topic has been carried out in developed countries and other settings which may not be conclusive and applicable to the Kenyan situation. An objective and empirical study on the same topic in the Kenyan context was therefore essential to bridge the knowledge gap.

1.3 Purpose of the Study

The purpose of the study was to investigate the effect of Cognitive Behavioural Therapy (CBT) on clinical depression, ART adherence and HIV stigma among HIV positive adults attending HIV-outpatient clinic in Turbo Sub-County Hospital in Uasin Gishu County, Kenya.

1.4 Objectives of the Study

The specific objectives of the study were;

i. To establish the effect of Cognitive Behavioural Therapy on clinical depression among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya.

ii. To determine the effect of Cognitive Behavioural Therapy on antiretroviral therapy adherence among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya.

iii. To establish the effect of Cognitive Behavioural Therapy on HIV stigma among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya.

1.5 Research Hypotheses

The study sought to test the hypothesis that;

$H_0$1: There is no statistically significant difference in the levels of depression between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

$H_0$2: There is no statistically significant difference in the degree of adherence to antiretroviral therapy between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

$H_0$3: There is no statistically significant difference in the level of HIV stigma between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

1.6 Significance of the Study

Depression is a critical barrier that must be looked into when addressing HIV clinical care since the two illnesses are inherently intertwined and aggravate each other (Gupta, Dandu, Packel, Rutherford, Leiter, 2010). Previous studies have linked depression to poor antiretroviral medication adherence, which in turn leads to more rapid HIV progression to AIDS and death among HIV infected individuals (Holzemer, Corless, Nokes, Turner, & Brown, 1999; Evans *et al*., 2002). Persons living with HIV often present with depression as a comorbid condition which needs to be treated independently. Nevertheless, considering that a majority of PLHIV are already on antiretroviral medications which sometimes may have serious side effects, putting them on antidepressants may have further negative impact on their body systems physiologically, cognitively and emotionally. In view of the aforementioned, there is need to develop an intervention that may successfully manage depression and its correlates without adding more side effects as seen in the use of antidepressants (Gibson, Cartwright, & Read, 2014).

This study is significant in that it yields useful information for policy makers, healthcare providers, HIV programme administrators, psychotherapists and other stakeholders on the effectiveness of cognitive behavioural therapy for clinical depression among PLHIV in primary care settings in Kenya. The results of the study provide important information about the effectiveness of CBT intervention which may guide mental health practitioners, policy makers, clinicians and other stakeholders in making decisions relevant to HIV and depression comorbidity management. The study provides the clinicians, Ministry of Health (MoH) and other stakeholders with information

on the usefulness of CBT programme in enhancing antiretroviral treatment adherence among PLHIV and guide future decision making regarding HIV treatment. The study also provides evidence for use by HIV treatment programmes on how CBT intervention can be useful in improving access to care by eliminating stigma concerns among PLHIV in Kenya.

The study aimed at bridging the knowledge gap in the area of evidence-based psychological treatment for depression as a response to mental health needs of HIV-infected outpatients in a low income setting. The study also forms a basic source of reference for learners, psychotherapists, policy makers and other interested parties on how CBT intervention may be adapted in primary healthcare settings to treat depression among the terminally ill using a brief CBT group therapy approach. Ultimately, the study also provides a practical guide for mental health practitioners in formulating treatment plan for depressive disorders and other mood disorders prevalent in the local primary health care settings.

1.7 Scope of the Study

The study generated data from HIV-infected patients seeking care at HIV-outpatient clinic in Turbo Sub-County Hospital, Kenya. It was confined to an examination of the effect of cognitive behavioural therapy on depression, ART adherence and HIV stigma. The researcher applied the principles of cognitive and behavioural techniques in helping participants mediate change in the outcome of dependent variables of the study. The resultant change was assessed using pretest/posttest control group design, and the treatment effect size of CBT was determined using non-parametric statistics. The study covered the administrative area of Uasin Gishu county region.

1.8 Limitations of the Study

The study had the following limitations;

i. Only persons with ability to speak and/or write in English or Kiswahili language were recruited into the study. Thus, conducting the study in a peri-urban setting was an appropriate measure for overcoming the language barrier.

ii. Study participants in the intervention arm might have occasionally interacted with their counterparts in the control group during clinic visits or in their areas of residence. Thus, random replications design was adopted for this study to minimize threats of diffusion effect.

1.9 Assumptions of the Study

The study made three assumptions;

i. That study participants were of average to high levels of intelligence/education that allowed for optimal rational thinking and cognitive evaluation in CBT sessions.

ii. That participants' self-reports in response to questions in the data collection instruments were not compromised by recall bias and that data obtained was accurate and reliable, thus supporting the use of pretest/posttest research design.

iii. That study participants' level of depression influenced their experience of both internalised and enacted stigma as psychosocial correlates of depression in HIV infection.

iv. That a reduction in levels of depression would result into increased ART adherence and reduced HIV stigma among the cohort of patients studied. Further, the researcher opined that if found effective, CBT would provide an alternatively cheaper and more accessible treatment option in the management of depression among PLHIV in primary healthcare settings.

1.10 Operational Definition of Terms

For the purpose of this study, the following terms were defined as follows:

Antiretroviral Therapy: the administration of antiretroviral drugs to maximally suppress the HIV virus and stop the progress of HIV disease. Optimal adherence of >95% is usually desirable and patients who fail to attain such levels of adherence may be at risk of developing resistance to medication and thus, progress to symptomatic AIDS stage and die earlier than expected.

CD4 count: the number of T-lymphocyte cells contained in 1 millilitre quantity of human blood.

Clinical Depression/Major Depression/ Depression: is a state of low mood and aversion to activity that can affect a person's thoughts, behaviour, feelings and sense of well-being. People with depressed mood can feel sad, anxious, empty, hopeless, helpless, worthless, guilty, irritable, ashamed or restless. This mood disorder in extreme cases causes suicidal thoughts and inability to function optimally both cognitively and physically.

Cognitive Behavioural Therapy: a brief psychotherapeutic intervention used in the treatment of depression which holds that a person's way of thinking and acting affects the way they feel; and it helps individuals to identify irrational thoughts, maladaptive behaviours and replace them with more adaptive ones by learning healthier skills and habits. It is usually administered using either one-on-one or group approach. It is considered a brief therapy with sessions running from between 4 and 24. In this kind of therapy, participants learn through homework assignments, practice exercises and role-plays. The therapist facilitate change by use of techniques like psycho-education, coaching, modelling and teaching.

Cognitive Triad: this is a psychological concept advanced by Aaron T. Beck the founder of Cognitive Therapy, which holds the view that people usually get depressed due to the negative views they hold about the self, the world and the future consequent to traumatic life experience.

Counselling: is a type of talking therapy delivered by a professional therapist to allow a person to talk about their problem situations and feelings in a confidential and dependable environment.

Effect: the ability of a treatment intervention to yield a desired change or impact on the recipient.

Psychiatric Disorders: these are mental disorders or illnesses or brain diseases which cause an individual to experience distress, dysfunction, deviance and dangerousness in behaviour.

Psychosocial Correlates: these are psychological and/or socio-cultural variables linked to depression as a comorbid condition in HIV infection. Psychosocial and clinical variables sequelae of HIV-depression comorbidity include; low CD4 cells, HIV stigma, poor ART adherence, and opportunistic infections. For purposes of this study, the researcher only considered two psychosocial variables, that is, ART adherence and HIV stigma since the two usually occur as psychological reactions to HIV diagnosis and can only be managed through a psychological intervention like CBT.

Stigma: a mark of disgrace that sets a person a part and brings the experiences and feelings of shame, blame, hopelessness, distress and reluctance in seeking or accepting necessary help e.g. a patient refusing to visit HIV clinic for fear of being seen by neighbours or friends since this may disclose their HIV status and in turn cause isolation or discrimination.

Symptomatology: a set of symptoms characteristic of depression as a mental illness or symptoms exhibited by a depressed patient e.g. depressed mood is a feature of some psychiatric syndromes such as major depressive disorder.

Viral Load: the amount of HIV copies present in one millilitre quantity of human blood.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter presents a critical synthesis of literature reviewed relating to HIV-infection, clinical depression, antiretroviral therapy (ART) and HIV stigma among HIV-infected adults. In particular, the review focused on Cognitive Behavioural Therapy (CBT) as the intervention adopted in the study and how it relates to variables such as depression, ART adherence; and HIV stigma. It also presents the theories on which the study was embedded, the conceptual framework, and further highlights gaps that the study sought to fill.

2.2 Human Immunodeficiency Virus (HIV) Impact and Progression in the Human Body

Human Immunodeficiency Virus (HIV) enters the human body and targets leucocytes (white blood cells) that function as part of the natural immune system and are known as CD4 (component of differentiation) cells. CD4 are cells that regulate and control aspects of the immune system and fight off diseases in the body. Anytime there is an infection, CD4 cells front the infection-fighting army of the body to protect it from becoming ill. Any damage to the CD4 cells can greatly impair a person's disease-fighting capability thereby leading to poor health in general (United Nations Development Programme/UNDP, 2005). Once the HIV virus attaches itself to the CD4 cell, it injects its RNA into the cell. The RNA then fuses itself into the DNA of the host cell and becomes part of the cell's genetic makeup. Through the cell's division mechanism, the virus begins to replicate and produce itself in massive numbers of thousands of its copies. The mature copies get absorbed into the blood stream and attach themselves to other CD4 cells and continue replicating. As a result, the viral load in the blood increases and the number of CD4 cells declines.

Individuals infected with HIV usually go through various clinical stages that occur over a time span of five to 12 years (Evian, 2003). The stages include, the asymptomatic phase, when the person has the virus but displays no symptoms of the disease; the symptomatic phase, the person experiences episodes of mild sickness to severe illness; and finally the AIDS phase where a person suffers from high viral load and severe immunodeficiency that culminate into death. Persons infected with HIV may be categorized as either rapid or slow progressors (Evian, 2003). However,

it is not clear whether every person with the virus would progress to develop AIDS and HIV illnesses.

People experiencing rapid progression may develop immunodeficiency within five to seven years after infection. In some cases, it might take about three to four years. For slow progressors, they may remain well for up to more than 10 years with minimal or absent immunodeficiency. The existing health condition of a person living with HIV may dictate their pace of progression to symptomatic and AIDS phases. Diseases like malaria, TB, malnutrition may have an immune-suppressive effect and thus alter the natural course of HIV disease (Evian, 2003). Conditions like depression can also contribute to steeper decline of CD4 cells (Farinpour *et al*., 2003), and lack of adherence to medication thus leading to more rapid HIV progression to AIDS and death (Evans *et al*., 2002).

Since HIV progression is heavily dependent upon the strength of one's immunity as highlighted above, it is imperative to examine various conditions that may have a direct impact on a person's natural immune system. One of such conditions is clinical depression. However, the extent to which depression affects a person's immune system and its contribution to HIV progression among PLHIV is yet to be established within the western Kenya setting. Nevertheless, research studies conducted in this region have consistently revealed high prevalence rates of depression among this special population (Monahan *et al*., 2008; Adina, 2016) hence ventilating on HIV infection and depression comorbidity. Unfortunately, few studies have been done in an attempt to formulate a suitable psychotherapeutic intervention focused on helping PLHIV deal with depression which is a psychological disorder. The only treatment currently available is pharmacological treatment which is both expensive and not easily accessible in a primary healthcare setting due to few numbers of psychiatrists and mental health practitioners in the country. Currently, there are only 54 psychiatrists against a population of 43 million people in Kenya (Marangu, Sands, Rolley, Ndetei, & Mansouri, 2014). WHO (2011) reported a median mental health workforce to population ratio as 10.7 staff per 100 000 individuals globally. This is a sharp contrast to current resourcing to mental health in Kenya, which stands at 0.13 mental health staff per 100 000 people (Marangu, *et al*., 2014). This means that a lot of depression cases in Kenya, especially within primary care settings still go unrecognised and/or undiagnosed and therefore remain untreated.

2.3 Depression among Persons Living with HIV (PLHIV)

Depression or major depressive disorder is often defined in terms of symptomatology. According to the diagnostic statistical manual of mental disorders fifth version (DSM-5), depression is "characterised by discrete episodes of at least 2 weeks' duration (although most episodes last considerably longer) involving clear-cut changes in affect, cognition, and neurovegetative functions and inter-episode remissions" (APA, 2013, p. 155).

The development of depression among PLHIV is likely the result of a combination of biological and psychological factors. Some of the biological factors might include poor immunity, and the occurrence of multiple opportunistic infections. Psychological variables such as fear of death and dying from a terminal illness (Lichenstein *et al*., 2002), stigma (Simbayi, 2007), as well as the distress due to HIV diagnosis (Hand, Phillips & Dudgeon, 2006) may alone or in combination play a precipitating role in the development of clinical depression among PLHIV. Depression among PLHIV has been associated with numerous adverse events including poor immunity. A systematic review of 21 studies by Leserman (2008) revealed that, depressed patients who were HIV positive had higher viral loads and lower CD4 counts compared to the non-depressed HIV positive controls. Poor immunological status including low CD4 and high viral load counts are often considered markers of declining health among HIV-infected individuals. Cruess *et al*. (2005) observed that the presence of depression in HIV positive individuals was associated with impaired innate cells, which are responsible for mediating the development of HIV to AIDS. This implies that depression may be a catalyst in the progression of HIV infection from the less severe asymptomatic stage to the much dreaded symptomatic AIDS stage.

The presence of depression in PLHIV has also been associated with faster patient progression from HIV to AIDS and early death (Leserman, Petitto, Golden, Gaynes & Gu, 2000; Cruess *et al*., 2005). In a longitudinal study of 400 asymptomatic HIV positive men, those with depression progressed faster from an asymptomatic state to full blown AIDS at an average of 1.5 years, quicker than the non-depressed controls (Page-Shafer, Delorenze, Satariano, & Winkelstein, 1996). Similarly, Ickovics *et al*. (2001) studied 765 women, and found that those with depression were almost two times more likely to die from AIDS compared to the non-depressed controls over a seven-year study period.

One mechanism that may contribute to the association between depression and faster progression from HIV to AIDS is poor adherence to antiretroviral therapy (ART). A number of researchers have reported that depression is an important predictor of poor adherence to medications including antiretroviral treatment in PLHIV (Ammassari *et al*., 2004; Gonzalez, Batchelder, Psaros, & Safren, 2011). It is important for HIV positive patients to adhere to ART, since successful viral suppression requires close to 95% adherence to ART (Chesney, 2003). Poor adherence among patients is associated with inadequate viral suppression. Similarly, non-adherent patient may become vulnerable to drug resistance, and perhaps spread such resistant strains through sexual contact even to HIV negative individuals (Akena, Joska, Obuku, & Stein, 2013).

Studies conducted in diverse settings globally have consistently demonstrated that depression is a commonly-occurring disorder among PLHIV. A recent systematic review by Nakimuli *et al.* (2011) put the prevalence of depressive disorders at 31% and that of major depression at 18% across HIV clinics in sub-Saharan Africa. The prevalence of depressive disorders among PLHIV in Kenya has been reported to be as high as 42% (Ndetei *et al*., 2009). Studies conducted in western Kenya setting have reported similar trends with results showing that as high as between 13% and 25% of PLHIV in this region are presenting with clinical depression (Monahan *et al*., 2008; Adina, 2016).

These findings highlight the fact that clinical depression could be a burden to PLHIV both within and beyond the local settings. Essentially, depression could be a burden due to its tendency to cause both cognitive and functional impairments among its victims. However, critical review of literature reveals that previous research has largely been confined to the epidemiological trends (prevalence and severity) of depression and with very little focus on possible intervention mechanisms. Manifestly, there has been glaring proclivity for overreliance on antidepressants as the singular treatment for depression in the general Kenyan population in spite of its prohibitive cost and the associated side effects. Broadly speaking, use of antidepressant medication and psychotherapy for depression are widespread and have the most clinical evidence. Conversely, the use of psychotherapy in the treatment of depression among PLHIV in Kenya has not been adequately researched. Therefore, the study aims to investigate the feasibility and effectiveness of CBT intervention for depression among adults with HIV infection. The essence of the study is it to provide working data on the effect of a 6-session group CBT for depression and present

quantitative evidence in support for adaptation of brief CBT as an alternative and cheaper treatment for depression among PLHIV in resource constrained primary healthcare settings. Currently, there is no visible empirical evidence on psychological treatment for depression in Kenya.

2.4 Antiretroviral Treatment (ART) Adherence among PLHIV

HIV/AIDS pandemic persistently remains a major global public health issue, with about 39 million lives lost so far. In 2014, about 1.2 million people died from HIV-related illnesses globally (UNAIDS, 2015). Additionally, the virus continues to infect individuals indiscriminately. The recent statistics indicate that between 1.9 and 2.4 million people got infected with the virus in the year 2013 globally, with sub-Saharan Africa accounting for almost 70% of the global total new HIV infections (UNAIDS, 2014). Evidently, this sad trend may continue being witnessed since there is not yet a cure for HIV infection. Nevertheless, with effective antiretroviral treatment, the spread and the deleterious effects of the virus can be controlled and persons infected with HIV can enjoy good health and productive lives.

Literature is scarce on the burden of non-adherence to ARV treatment such as the increased health care costs, effects on human resource productivity, disruption of families and communities, and morbidity and mortality in developing countries (WHO, 2006). However, it is well understood and documented that HIV/AIDS requires near perfect adherence to obtain successful treatment outcomes. Recent studies have estimated the required level of adherence for sustained virological suppression to be about 95%. Evidence-based data from developing countries regarding ART adherence rates, predictors, and the effectiveness of support interventions are limited. The implication is that there is urgent need for systematic data collection and analysis to estimate the prevalence of non-adherence and to make strong evidence-based recommendations on the best ways to improve medication adherence (Steel, Nwokike, & Joshi, 2007).

The use of antiretroviral drugs is increasingly becoming common around the world. In 2013, there were approximately 12.9 million PLHIV on antiretroviral therapy (ART) globally, with uptake in low-and –middle-income countries (LMC) standing at 11.7 million people receiving ART, which represents 36% of the 32.6 million people who were living with HIV in LMC. This translates to 1 in 3 adults receiving antiretroviral drugs (UNAIDS, 2014). World Health Organization (WHO, 2011), reported that if an HIV-positive person adheres to an effective ART regimen, the risk of transmitting the virus to their uninfected sexual partner can be reduced by 96%. Thus, the use of

ART is not only important in suppressing the replication of the virus in the human body but it also reduces significantly the transmission risk of HIV between sexual partners.

Antiretroviral therapy (ART) treatment adherence is one of the key mechanisms that help delay the emergence of resistant strains of the virus and enhances durability of the current regimens (Steel, *et al*., 2007). However, many Health care workers often find it difficult to identify patients who may or may not adhere to treatment. Non-adherence to drugs is a common phenomenon globally and has been seen in many cases of chronic diseases. In developing countries, adherence rates are thought to be lower than that of developed countries which averages 50% for chronic illnesses (WHO, 2003). It is obvious that many patients do experience difficulty in following their treatment regimen. Literature on antiretroviral therapy reports similar findings on adherence difficulties with the rates varying between 37 and 83 percent, depending on the drug under study (Stein, Rich, & Maksad, 2000). Some studies on levels of adherence have indicated that more than 10% of patients report missing one or more medication doses on any given day, and more than 33% report missing doses in the past two to four weeks (Chesney, 2000). It is estimated that 50% of prescriptions filled are not taken correctly. It is important to note that non-adherence includes not taking medications at prescribed time intervals and non-compliance to dosing instructions regarding dietary or fluid intake (Paterson, Swindells, & Mohr, 2000). In the current study, full adherence was defined as taking medication doses for no less than 95% of the monthly prescribed dosage for the last 30 days. This translates to a patient taking medication for at least 29 out of 30 days notwithstanding variations in the timing, and missing medication doses for more than one day or less than 95% of the monthly dosage constituted non-adherence.

The wellbeing of persons living with HIV is correlated with high levels of ART adherence of more than 90-95%. High adherence to antiretroviral treatment lengthens lives and revitalizes persons affected by the epidemic (Thames *et al*., 2012; Babson, Heinz, & Bonn-miller, 2013). ART works by reducing HIV viral load and increasing CD4 cells count as well as delaying the HIV clinical staging to AIDS stage thus reducing mortality (Egger *et al*. 2002; Wood *et al*., 2004a). Similarly, a reduction in HIV viral load is associated with a significant reduction of HIV transmission (Wood *et al*., 2008). Notwithstanding the importance of ART on HIV prevention, glaring disparities in health outcomes among PLHIV populations indicate the need to illuminate factors impeding effective ART adherence among marginalized populations in primary healthcare settings (Wood

et al., 2003a; Mills *et al*., 2006). It has also been observed that optimal adherence to ART often wane with time. This can be attributed to the fact that learned behaviours do change over time hence leading to non-adherence. So non-adherence remains a major concern as more patients get enrolled in ART programmes. And as more patients are expected to remain on ARVs for life, the need to develop additional interventions to maintain optimal adherence is imperative.

Kenya AIDS Indicator Survey(KAIS) 2014 report released by the Ministry of Health on the ART uptake trends in Kenya reveals that on the overall, 60.5% of all HIV-infected adults and adolescents eligible for ART were taking ART as of 2012 (NACC & NASCOP, 2014). The report revealed that among the infected individuals who had been initiated on ART 30 days prior to the survey, 83.7% reported they did not miss taking their ARVs and 75.4% of them were virally suppressed (defined as ≤1,000 copies/ml). Viral load suppression was higher among those adhering to ART (78.5%) compared with those who reported that they missed taking their ARVs 30 days prior to the survey (57.9%). These findings show that adherence to ART is the only way to ensure that PLHIV attain favourable treatment outcomes such as suppressed viral load and boosted immunity which protects the body against opportunistic infections. Presently, the number of PLHIV aged 15 years and above in need for ART is about 1,240,000 (NACC & NASCOP, 2016).

Review of quantitative studies on factors associated with poor adherence to ART treatment reveals that clinical depression and HIV stigma are the key contributors to poor ART adherence across diverse settings including Kenya (Odindo & Mwanthi, 2008; Mayston, Kinyanda, Chishinga, Prince, & Patel, 2012). And one of the serious problems facing the antiretroviral treatment programmes is the high rate of persons enrolled on treatment abandoning active care. Research has been established that about 40% of patients go unaccounted for three years after starting ARVs (Odindo & Mwanthi, 2008; Mayston *et al*., 2012). This unfortunate trend could perhaps be linked to the burden of having to take medication on a daily basis, and visiting HIV outpatient clinic every so often in the midst of contending with an array of mental reactions and stigmatising beliefs following HIV diagnosis. The interaction between mental health and treatment adherence is well documented across a range of chronic health conditions. In particular, depression has been established to have a significant impact on adherence to antiretroviral treatment according to a recent meta-analytic study by Gonzalez, Batchelder, Psaros, and Safren (2011).

Contrary to what is known by many clinicians working in HIV treatment programmes, ART adherence is a behaviour which a person is expected to learn after HIV diagnosis and initiation into treatment. A newly learnt behaviour may or may not persist for long unless there is sufficient motivation to reinforce the behaviour. And as expected the behaviour to adhere to HIV medication must be a lifelong commitment routinized into a person's daily activities and programmes. Given that ART adherence is a learnt behaviour which may wane with time, it is critical therefore that intervention strategies that will help PLHIV remain active in clinical care be devised. Such interventions may include counselling and psychotherapy founded on theoretical orientations which are accredited for behaviour change and reinforcement. Cognitive behavioural therapy (CBT) is among such interventions which are globally recognised for helping individuals learn healthier skills and habits that give yield to more adaptive behaviours like adherence to antiretroviral treatment.

Cases of non-adherence to treatment, high rates of depression among the HIV infected population in Kenya and patients getting lost from care are some of the key areas that have been investigated locally. Nonetheless, non-adherence to antiretroviral therapy remains disproportionately high in HIV care programmes especially at this point when the ministry of health has unveiled a new ART guideline which requires every person diagnosed HIV positive to be initiated on ARVs immediately (Ministry of Health/NASCOP, 2016). Locally, HIV care programmes have overtime relied upon medication counselling offered by clinicians to help optimise treatment benefits. So far, the outcome of such efforts has not generated any considerable difference in improving ART adherence. This gives a compelling cause to devise a strategy that may help intervene for poor medication adherence as a means to ensuring that patients are virally suppressed and thus prevent new infections. In the current study, the researcher would test the feasibility and use of CBT in enhancing ART adherence in a primary care setting. This would be useful in ventilating the potential of CBT as a medication adherence-enhancer especially among outpatients attending HIV clinics.

2.5 HIV Stigma among PLHIV

Stigma is an invisible mark signifying that a person is in possession of a discrediting social variance that produces devaluation (Bos, Pryor, Reeder, & Stutterheim, 2013; Pryor & Bos, 2015). Goffman (1963, p.3) defined stigma as "an attribute that is deeply discrediting" which leads an

individual to occupy a tarnished and discredited identity and place in society. Stigma has been associated with incurable and severe illnesses resulting from behavioural routes which are not in conformity with social norms (Crandall & Moriarty, 1995). The negative effects of stigma can lead to; disease transmission, failure to disclose one's status; delay in seeking care due to fear of being isolated (Genberg *et al*., 2007). HIV stigma has been cited as a barrier to HIV prevention, treatment and care in manifold settings (Fortenberry *et al*., 2002; Kalichman *et al*., 2005; Lieber, Li, Wu, Rotheram-Borus & Guan, 2006).

A substantial corpus of research literature has confirmed that HIV stigma is highly prevalent in the lives of PLHIV in diverse settings (Brickley *et al*., 2008; Bogart *et al*., 2008; Odindo & Mwanthi 2008; Li *et al*., 2009). Overtime, HIV stigma has been linked to poor ART adherence. A study conducted in US reported that patients with high stigma concerns were 3.3 times more at risk of not adhering to their treatment regimen (Dlamini *et al*., 2009). A related study done in Peru found that ART adherence improved with decreased stigma (Franke at al. 2008). Adherence to ART regimens is of utmost importance for treatment to be effective (Bansberg, 2006), and it is estimated that adherence to antiretroviral drugs must approach 95% for maximum treatment benefit (Paterson *et al*., 2000).

The stigma around HIV/AIDS is often more intense because it is associated with deviant groups, homosexuality, promiscuity, irresponsible behaviours and HIV is perceived to be contagious and deadly (Genberg *et al*., 2009; Quam 1990; Fife & Wright 2000; Visser & Lehobye 2006). Stigma among PLHIV can present either as enacted/perceived stigma or internalised/self-stigma. Enacted stigma concerns others psychological and social reactions towards someone with a stigmatized condition (Vogel, Nathaniel, & Hackler, 2007). Persons experiencing perceived stigma are vulnerable to certain tendencies like avoidance, rejection, isolation, physical withdrawal, poor social interaction and even blaming (Lyimo *et al*., 2014), and this has detrimental ramifications on patient's mental, social and physical wellbeing. Internalised stigma on the other hand occurs when the person suffering from a stigmatized disease condition turns public stigma to themselves (Mak, Poon, Pun, & Cheung, 2007; Stutterheim *et al*., 2009). Internalised stigma may lead to feelings of anger, helplessness, worthlessness, low self-esteem, depression among others (Corrigan & Watson 2002).

HIV/AIDS stigma has been found to have a direct link with both disclosure of status and coping (Qiao *et al*., 2012). Stigma, disclosure and coping independently affect each other and collectively impact self-care behaviours like treatment adherence. High levels of enacted and perceived stigma have been associated with suboptimal treatment adherence (Nam *et al*. 2008), and concealment of HIV sero-positive status (Birbeck *et al*., 2009). Apparently, past studies have revealed that, stigma, coping, disclosure and treatment adherence are directly interlinked (Smith *et al*., 2008; Kingori *et al*., 2013). A systematic review conducted among 26,715 HIV-positive persons living in 32 countries around the world found that HIV stigma does compromise adherence to ART treatment by undermining social support and adaptive coping strategies (Katz *et al*., 2013).

Notably, one of the challenges faced by PLHIV is accepting one's HIV status and employing appropriate coping mechanisms in response to this highly stigmatised medical condition. Coping strategies may either be positive or dysfunctional in terms of outcome. Dysfunctional coping outcomes may include poor adherence and depression (Lyimo *et al*., 2014). In addition, HIV stigma has been associated with depression, and adverse effects like poor adherence to medications, isolating self and poor access to HIV care (Kalichman & Simbayi 2003; Simbayi *et al*., 2007; Lia, Leea, Thammawijay, Jiraphongs, & Rotheram-Borusa, 2009). Heckman and others (2002) examined psychological symptoms among PLHIV aged over 50 and reported a 25% level of depression and linked these symptoms to HIV-related stigma. The experience of HIV-related stigma varies from one individual to another (Ownby *et al*., 2010). The negative consequences associated with AIDS related stigma in PLHIV are likely to exacerbate the adverse health outcomes of HIV positive individuals. Interestingly, a correlational trend between HIV stigma, poor ART adherence and clinical depression in PLHIV has not been fully established in resource-constrained settings, particularly sub-Saharan Africa. Similarly, intervention strategies that may help persons living with HIV overcome stigmatising beliefs consequent to a positive HIV diagnosis are in dearth.

2.6 Interventions for Depression and its Psychosocial Correlates among PLHIV

Knowledge about the burden of clinical depression and the factors that are associated with it forms the basis of holistic care for PLHIV who present themselves at primary healthcare settings. Depression which is a mood disorder is known to cause serious cognitive and socio-economic impairments if left untreated. Similarly, depression as a mental illness if not intervened for may

adversely and chronically affect its victims and render them less productive with time. The global pattern with regard to treatment of depression offers a two-pronged approach. The first approach is the use of pharmacotherapy which involves prescribing medication for instance antidepressants to the depressed patients. This approach is the most widespread especially in the local setting notwithstanding the high cost of the treatment and shortage of psychiatric professionals in primary care outpatient clinics. In addition, use of antidepressants in the treatment of depression has been linked to very serious adverse outcomes like a reduction of positive emotions, emotional detachment, personality changes, harmful effects on relationships, fear of addiction, and suicidality (Gibson *et al.*, 2014).

The second approach in the treatment of depression is the use of psychotherapy. This approach entails the application of skills and techniques aligned to different theoretical orientations found in the school of psychology. Every psychotherapist has their theoretical orientation which informs their methods of practice to treat depression among depressed clients in diverse settings. Psychological treatments for depression work by talking to patients, and helping them change negative patterns of thinking and acquire better coping skills so that they can be better equipped to deal with situational stresses and conflicts in life. Psychological therapies are accredited for the benefit of helping a person to recover and also helping prevent relapse into depression (Jorm, Morgan, & Hetrick, 2008). There are several types of psychological interventions which have proven to be effective in the treatment of depression:

i. **Cognitive Behavioural Therapy (CBT):** CBT is a structured psychological treatment which recognises that a person's way of thinking and behaviour directly influence the way they feel. CBT is one of the most effective treatments for clinical depression, and has been found to be useful for persons of different age brackets, including children, adolescents, and adults (Jorm *et al.*, 2008). In CBT, a client works with a psychotherapist to identify the patterns of thought and behaviour that are either contributing to their depression or hampering their recovery once they become depressed. CBT has an emphasis on changing thoughts and behaviour by teaching people to replace irrational thoughts with more rational ones, helping them to shift their self-defeating or unhealthy thought patterns and reactions to a more positive, realistic and solution-focused approach.

ii. **Interpersonal Therapy (IPT):** Interpersonal therapy is a structured psychological therapy which holds that depression could be a consequence of problems in personal relationships. Interpersonal therapy is based on the idea that relationship problems can aggravate the impact and severity of depression in a depressed person and may as well contribute to the cause. This therapy works by helping clients to identify dysfunctional patterns in their relationships that make them more susceptible to depression. In identifying these patterns, clients can focus more on improving relationships, coping with grief and devising new ways to get along with others (Jorm *et al*., 2008).

iii. **Group Support Psychotherapy (GSP):** Group Support Psychotherapy though not widespread, has been piloted and found to be effective for depression among PLHIV. A randomised controlled trial on Group support psychotherapy for depression treatment in people with HIV/AIDS in northern Uganda found that GSP significantly reduced the mean depression scores at 6 months post-treatment assessment. The study concluded that Group support psychotherapy (GSP) is a culturally sensitive intervention for depression and works by enhancing social support, teaching coping skills, and income-generating skills, to the depressed persons (Nakimuli-Mpungu *et al*., 2015).

iv. **Mindfulness Based Cognitive Therapy (MBCT):** Mindfulness based cognitive therapy is generally a group therapy and involves learning a type of meditation called 'mindfulness meditation'. The purpose of meditation is to teach people to focus on the here and now moment, taking note of whatever experiences coming to their mind, whether pleasant or unpleasant, without trying to change it. In the initial stages, the meditation is focused on physical sensations such as breathing, but later the focus is shifted to feelings and thoughts (Jorm *et al*., 2008).

In the context of sub-Saharan Africa, the use of psychological treatments for depression and its psychosocial correlates is not quite visible with only a few studies reporting the use of psychotherapy to treat HIV stigma and depression. For instance, the use of CBT is reported in a study done in South Africa on stigma and discrimination among HIV-infected women (Tshabalala & Visser, 2011), and the use of Group Support Psychotherapy for depression treatment in people

with HIV/AIDS in northern Uganda (Nakimuli-Mpungu *et al*., 2015). The findings from these studies showed that psychological intervention can be effective for HIV stigma and depression among PLHIV.

In the present study, the researcher adopted CBT approach as the preferred intervention in the context of psychological treatment of depression among individuals with HIV. CBT is among interventions which are globally recognised for helping individuals learn healthier skills and habits that yield more adaptive behaviours, like adherence to antiretroviral treatment (Safren *et al*., 2012) and challenging negative thoughts that lead to depression and stigma. CBT is known to be brief, structured and superior to other interventions like medication (Amick *et al*., 2015). The researcher further postulated that the success of the study on the effect of CBT for clinical depression, HIV stigma and poor ART adherence would translate into improved quality of treatment outcomes for PLHIV in the local primary care settings.

2.7 Cognitive Behavioural Therapy- Study Intervention

Cognitive Behavioural Therapy (CBT) refers to a class of interventions that share the basic premise that mental disorders and psychological distress are maintained by cognitive factors. The core premise of this treatment approach, as pioneered by Aaron Beck (1970) and Albert Ellis (1962) who hold the view that maladaptive cognitions contribute to the maintenance of emotional distress and behavioural problems. According to Beck's model (Cognitive Therapy), these maladaptive cognitions include general beliefs or schemas, about the world, the self, and the future, giving rise to specific and automatic thoughts in particular situations. The basic model posits that therapeutic strategies to change these maladaptive cognitions lead to changes in emotional distress and problematic behaviours (Beck, 1970). Since these early formulations, a number of disorder-specific CBT protocols have been developed that specifically address various cognitive and behavioural maintenance factors of the various disorders. Although these disorder-specific treatment protocols show considerable differences in some of the specific treatment techniques, they all share the same core model and the general approach to treatment.

Consistent with the medical model of psychiatry, the overall goal of treatment is symptom reduction, improvement in functioning, and remission of the disorder. In order to achieve this goal, the patient becomes an active participant in a collaborative problem-solving process to test and challenge the validity of maladaptive cognitions and to modify maladaptive behavioural patterns.

Thus, modern CBT refers to a family of interventions that combine a variety of cognitive, behavioural, and emotion-focused techniques (Hofmann, 2011). Although these strategies greatly emphasize cognitive factors, physiological, emotional, and behavioural components are also recognized for the role that they play in the maintenance of the disorder.

A meta-analysis by Hofmann *et al*. (2012) indicated that CBT for depression was more effective than control conditions such as waiting list or no treatment, with a medium effect size. However, studies that compared CBT to other active treatments, such as psychodynamic treatment, problem-solving therapy, and interpersonal psychotherapy, found mixed results. Specifically, meta-analyses found CBT to be equally effective in comparison to other psychological treatments (Beltman, Oude Voshaar, & Speckens, 2010; Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010; Pfeiffer, Heisler, Piette, Rogers, & Valenstein, 2011). Other studies, however, found favourable results for CBT (Jorm, Morgan, & Hetrick, 2008; Di Giulio, 2010; Tolin, 2010). For instance, Jorm *et al.* (2008) found CBT to be superior to relaxation techniques at post-treatment. Additionally, Tolin (2010) showed CBT to be superior to psychodynamic therapy at both post-treatment and at six months follow-up, although this occurred when depression and anxiety symptoms were examined together. Compared to pharmacological approaches, CBT and medication treatments had similar effects on chronic depressive symptoms, with effect sizes in the medium to large range (Vos, Haby, Barendregt, Kruijshaar, Corry, & Andrews, 2004). Other studies indicated that pharmacotherapy could be a useful addition to CBT; specifically, combination therapy of CBT with pharmacotherapy was more effective in comparison to CBT alone (Chan, 2006).

The primary aim of CBT intervention is to rapidly help clients improve on their feelings, moods and change their self-defeating behaviours and it is more present and/or future-focused compared to the traditional therapies (Bush, 2003). CBT works by way of altering a person's thought patterns, feelings, ideas, attitudes, and mental imagery for better. This informs the cognitive aspect of CBT. Similarly, CBT helps clients evaluate challenges and opportunities with a clear and sober mind and in taking actions that yield desirable outcomes. This is the behavioural aspect of CBT.

2.7.1 Cognitive and Behavioural Techniques

CBT is based on the idea that organisms survive through processing of information, however in various psychopathological conditions like depressive disorders, generalized anxiety disorders,

mania, and paranoid states, there is a systematic bias in the client's information-processing system, thereby causing interpersonal problems and creates a threat to survival indirectly (MHA, 2014). In the case of depressed clients, the selective bias leads them into themes of hopelessness, helplessness, loss and defeat. The CBT overall strategy is the collaborative work between therapist and client in exploring dysfunctional interpretations and attempt to modify them. Further, guided discovery of identifying the client's misperceptions and beliefs is made. These are then linked to related past experiences thereby creating a rich tapestry in telling the story of the client's presenting problem.

The commonest technique in CBT is the use of verbal techniques in bringing forth the client's automatic thoughts, analyse the logic behind such thoughts, identify unsupportive assumptions, and examine the extent of validity of such assumptions. Once the assumptions are identified, then modification process may commence by asking the client if the assumption is reasonable, by having the client generate pros and cons of the assumption, and by presenting evidence that contradict the identified assumptions (Corey, 2005). Specific cognitive and behavioural techniques include the following:

i. **De-catastrophizing**: this method refers to re-evaluating and modifying thoughts considered catastrophic (Beck, Wright, Newman, & Liese, 1993). This is the "what-if" technique which helps clients prepare for the worst case scenario. The key task is to confront the feared consequences. This is helpful in decreasing avoidance. For instance, a person diagnosed HIV-positive may be hesitant to carry treatment medication home for fear of being asked intrusive questions concerning their status. The therapist may help such a client confront his fears by asking; would it be more beneficial to adhere to treatment regimen and live longer than to decline carrying the medication home and cut short your life? What is the worst that can happen if people discovered that you are HIV positive?

ii. **Reality testing**: this is a cognitive restructuring technique which involves teaching a client to question the evidence for every automatic thought that comes to mind. For instance, a client may ask themselves "what is the evidence that people with HIV infection are cursed"?

iii. **Homework assignments**: this is a technique and a way of enhancing successful treatment outcome of therapy whereby clients are assigned either formal or informal take home assignments. Formal homework tasks involve the practice of behavioural and cognitive techniques in between sessions' schedules (Beck *et al*., 1993). Assignments typically focus on self-monitoring, structuring time effectively, and implementing procedures for dealing with actual situations.

iv. **Behavioural rehearsal and role-playing**: this technique is used to practice skills or techniques learnt during therapy sessions which are later applied in real life situations. Role-playing is first modelled by the therapist before the clients, in the case of group therapy, clients are paired to practise the same set of skills and techniques.

v. **Socratic questioning**: this is a philosophical questioning technique which helps clients to identify and modify maladaptive thought patterns. The therapist and client collaboratively work to uncover the interpretations and evaluations that may contribute to the client's problems. The therapist asks questions to solicit for underlying meanings to the client's distress and looks out for evidence for-and-against client's belief (Moorey, 2000). This technique of questioning aims at promoting insight and well-reasoned decisions by making the client conscious of important information. The process involves rationalization through questioning and reflection and the goal is to make the client think independently, rationally and soberly (Beck *et al*., 1993).

vi. **Modifying negative automatic thoughts:** The initial step is to help the client learn how to recognise maladaptive thoughts and then learn how to challenge such negative thoughts (Moorey, 2000; Plotnik, 2002). Modifying negative thinking is done through cognitive restructuring and Socratic questioning by the therapist who models the same for the client. While the therapist models this technique in session, the client is expected to practise the same skills outside therapy. This process takes time and practice before the client internalises the ability to identify and modify negative automatic thoughts (Moorey, 2000).

vii. **Reattribution:** a technique which tests client's automatic thoughts, beliefs and assumptions by considering alternative causes of events. This particularly helps when clients think that they are the cause of problem events. For instance, a client may say; "*if only I never got married, I'd be living without HIV today*". The therapist may challenge this line of thought by asking, "*what would you do differently if you discovered that it is not your spouse who infected you with HIV, but the contaminated blood you were transfused with when you got involved in a road accident*."

2.7.2 Shortcomings of CBT Intervention

CBT intervention is famed for its effectiveness in treating depression, anxiety and other similar disorders. Its effectiveness in treating depression favourably compares to that of antidepressant medication (Vos *et al*., 2004). Above all, CBT has been proven to be better than pharmacological intervention in avoiding treatment failures and post-treatment relapse. CBT has been the preferred treatment for loneliness, procrastination, panic attacks, phobias and posttraumatic stress disorder (Bush, 2003).

The demerit of CBT is that sometimes the client may have difficulty identifying emotions and thoughts. It is a common occurrence for clients to experience emotions before recognising thoughts that precede such emotions. This can make it difficult to ascertain the real thoughts that elicited the emotional response. To assist clients in identifying their thoughts, therapists may need to use objective questioning techniques to isolate such thoughts. For instance, "What was going through your mind at that time?" "And how did that make you feel?" CBT requires that clients participate in monitoring their thoughts, emotions, behaviours as well as doing homework. This might not work maximally for clients who are unmotivated and/or resistant to change.

Another criticism levelled against CBT is that, clients may agree with treatment principles but cannot seem to change their way of thinking. Most often, clients may report a good understanding of the principles of CBT on an intellectual level, but cannot seem to apply them in real life situation in a way that promotes practical change (Sanders & Wills, 2005). Overtime, it has been observed that CBT may only work well with people of average intellectual capacity. Therefore, difficulty in thinking abstractly may be an impediment to this important process and limit the efficacy of CBT

techniques, particularly for clients with low intellectual capacity and/or with rigid thought processes (Epstein *et al*., 1988).

2.7.3 Guideline for the CBT Intervention Model

The guideline model adopted for the study is the Beck's cognitive model of depression and mania. This model holds that feelings of depression are aggravated by thought patterns that amplify mood swings. For instance, persons who are depressed have the tendency to become more negative in how they see themselves, their world and their future. This phenomenon is what Beck calls the "negative cognitive triad". This negativity attributed to depression often results into, negative conclusions, over-generalisation, self-blame, and seeing things from a singular perspective of all-or-nothing. Mood shifts and negative thinking may also result into behaviour change like avoiding social interactions. Dysfunctional underlying beliefs may equally contribute to cognitive vulnerability which develop through experiential learning and drive thinking and behaviour. These beliefs may be activated by certain life events with specific meaning to an individual person like feelings of rejection and not being loved by members of immediate family (Beck *et al*., 1993; Wiser, Goldfried, Raue, & Vakoch, 1996; Scott, 2001).

Cognitive therapy is influenced by the cognitive model which presumes that people's emotions and behaviours are dictated by their perception of events around their lives (Beck, 1995). Cognitive therapy is aimed at minimizing the specific cognitive distortions, reduce environmental stressors, create support, develop behavioural skills and help clients communicate their concerns adaptively, clearly and soberly (Reinecke, 1994). A treatment intervention model suggested to be used with the HIV-infected adults in dealing with depression and HIV stigma is based on this theoretical framework. The outcome goals of the suggested treatment are to help the participants overcome symptoms of depression and cope with stigma by creating rapport with them to elicit necessary information and to generate symptom relief and to inspire hope (Bea & Tesar, 2002). Relief from symptoms makes the client feel better and builds confidence in client that CBT model works well hence fostering treatment alliance (Allison & Denman, 2001).

A good therapeutic relationship with clients begins with introduction that includes capturing expectations and asking questions about thoughts and feelings about participating in therapy. This process helps to put clients at ease, provide necessary information to the therapist/researcher about

clients' expectations and above all, offers a space to establish the relationship between thoughts and emotions. At the commencement of the sessions the researcher/therapist introduces the concept of CBT to help participants familiarise with the intervention and possibly derive symptom relief. Cognitive misconceptions, distortions and biases are dealt with one by one and progressively as the sessions continue. The conduct and procedure of the therapeutic process is discussed under chapter three.

2.7.4 Conducting Group CBT

Muñoz, Ghosh-Ippen, Rao, Le, and Dwyer (2000) cited four key elements considered to be the most important in providing group CBT. They include; (a) a convincing rationale for the intervention, (b) training in practical skills to change mood-related thoughts or behaviours, (c) encouraging practice of the skills outside of the therapy sessions, and (d) attribution of improvement to the use of the skills and not to therapist contact. In addition, they strongly recommended that therapists should make sure that all the four elements are adequately covered during each session of therapy. Every session ought to begin by outlining the purpose of the group and the justification for learning what will be shared during that particular session. In each session there should be specific set of skills that participants will be taught and that group facilitators must find strategies to increase the chances that the participants will actually try out the skills learnt in their everyday lives. In practicing these skills, the client will evaluate which skills work best and identify which skills can be modelled to adapt best for their unique phenomenological world. More importantly, the therapist should always remember to emphasize during each session that the group therapy sessions will come to an end, nevertheless, if they continue to practice the skills they are acquiring during therapy, they will become more proficient at using them, and as a result can expect to continue to improve even after treatment terminates (Munoz *et al*., 2000).

To successfully implement CBT, the therapist must be someone who is very conversant with basic CBT methods, and basic therapeutic interviewing methods for rapport building. CBT methods require a great deal of work from the client. In other therapeutic approaches like person-centred (more open-ended talk therapies), the client may come without any preparations and is allowed to explore whatever issues or topics which happen to be foremost in his mind at the time. On the contrary, CBT methods encourage the participant to concentrate on learning specific techniques during each session, and the participant is expected to practice these skills and bring back written

homework assignments bearing the records of the outcomes. This may be too demanding, especially for someone who is depressed. It is therefore crucial that the CBT therapist plays an important role of reinforcing this in the client's mind. This can be best done if the therapist convincingly makes the client see that he understands his/her problem situation, empathises with the client's feelings, and is able to give directions out of the client's present situation (Munoz *et al*., 2000).

Carl Rogers in 1951 came up with three cardinal interviewing techniques which are very helpful in establishing rapport in CBT therapy; these include paraphrasing, reflection of feelings, and summarizing (Rogers, 1951). Paraphrasing entails stating back what the patient said in the facilitator's own words so as to ensure that the therapist perceived correctly, and at the same time to ensure that the client knows that the therapist was actively listening and got the content of the message. If the therapist never understood rightly or fully, the client can then correct him. Reflection of feelings involves digging deeper and going beyond the statements of what the client actually said, and describing what the feelings of the client are. This method is an effective way to check whether the therapist accurately understood the client's emotional state, and letting the patient recognize that the therapist empathizes with his emotional reactions. Summarizing is done from time to time throughout the session. It involves putting together the most recent moments of conversation to make the client easily digest the content, and reframing the matter at hand in a manner that allows the client to see the situation from a more panoramic, objective and hopefully healthier perspective (Munoz *et al*., 2000).

2.7.5 Basics of Group Therapy

Group therapies often aim to fulfil two purposes, that is, psycho-education, in which members can learn about clinical depression and/or its correlates and strategies to decrease the odds of becoming depressed in the near or distant future, and psychotherapy, where members who are presently depressed can gain understanding about factors that precipitate their depression and learn ways to treat their disabling disorder. Usually group membership consists of 6-10 participants per group (Munoz *et al*., 2000). Other basic considerations include;

i. **Therapist's Qualifications:** A good understanding and training in the assessment and treatment of mental disorders, is a fundamental requisite for a CBT group therapist.

It is highly recommended that a CBT therapist must have a previous coursework and training in mental health profession, for instance psychology, counselling, psychiatry, or psychiatric social work. Additionally, the group leader must have trainings in the general principles of cognitive behavioural therapy and their practical application. Group leaders who are leading a psychotherapy group should have advanced trainings in mental health (at least at the Master's degree level) in assessment and psychotherapy (Munoz *et al*., 2000).

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ii. **Group members - initial considerations:** In constituting a group for therapy, it is essential to take into account the general characteristics of the group. Some of the socio-demographic characteristics to consider include gender, age, education, socioeconomic status, and reading level. It is imperative to recognize how these factors may relate to session attendance, motivation for participation, and ability to understand the rationale of the group and follow the group structure and content. In addition, it is important to recognize limitations such as transportation, childcare, distance that are associated with the realities of the participants' lives.

iii. **Exclusion and inclusion criteria:** It is important to consider at the onset the exclusion and inclusion criteria for group participants. This decision may be pegged in part on the membership of the group (for instance severity of symptoms, population targeted) and/or qualifications of the group leader and supervisors to competently handle the frequency and severity of presenting symptom level. The exclusion criteria include: (a) individuals who are presenting with psychosis; (b) individuals presenting with primary disorder other than a mood disorder like, post-traumatic stress disorder; (c) individuals who are on alcohol or other depressive substances; and (d) individuals with antisocial, aggressive and monopolizing behaviours which may affect the group process negatively. Inclusion criteria include individuals who meet criteria for major depression, other clinical depressive disorders, and those who have significant depressed mood along with another diagnosis.

2.8 Research Gaps

For a nation with increasingly high numbers of persons living with HIV like Kenya, it would be critical to devise a feasible intervention which may help address both clinical and psychosocial challenges of HIV infection. Ideally, depression which often leads to poor treatment adherence and stigmatising beliefs (which usually hinder access to health care) among PLHIV should be promptly diagnosed, recognised and possibly treated. As it is evident from quantitative studies conducted in manifold settings in sub-Saharan Africa (SSA), a part from psychiatric care, the option of using psychotherapy and counselling have been explored and found effective for depression and its correlates among PLHIV (Andersen, 2009; Andersen *et al*., 2016; Chibanda *et al*., 2015; Tshabalala & Visser, 2011; Nakimuli-Mpungu *et al*., 2015). Kenya being a HIV high burden country just like South Africa, Uganda, and Malawi provides a potential ground to test the feasibility of psychotherapy for psychosocial correlates of HIV infection.

Ostensibly, the current study provides the first discourse on the feasibility of a brief group-CBT psychotherapy among PLHIV in a primary healthcare setting in the region. CBT was originally designed as a treatment for individuals, however, it has been adapted for use with groups (Rose, 1999). Group therapy is a popular mode of therapy for both therapists and clients. Group therapy is a highly effective form of psychotherapy that is based on interdependence and interaction among the group members who mutually disclose personal material (Lasky & Riva, 2006). Groups composed of participants from a diversity of backgrounds can enrich the psychotherapeutic experience and interpersonal interaction for each member (Gladding, 2003). In the current context, one of the benefits of group-CBT would be cost-sharing. Group psychotherapy offers affordable treatment option especially for those who cannot afford the cost of either individual therapy or pharmacological intervention. For the case of PLHIV in primary healthcare settings, group-CBT would be more appealing particularly for those whose economic power has grossly been impacted and/or eroded by HIV infection.

The use of CBT intervention for various psychological conditions and the treatment effect thereof in HIV-infected population in SSA have invariably demonstrated solid outcomes for CBT. However, in delivering CBT intervention, researchers and practitioners usually customise their treatment formulation in terms of, approach to therapy (individual therapy or group therapy); number of sessions (between 4 and 24); frequency of sessions (weekly or biweekly); qualifications

and the training orientation of the interventionists (psychotherapists or paraprofessionals). For instance, Andersen *et al*. (2016) adopted individual therapy approach that was delivered by nurses in 45-60 minutes for 8 sessions with a sample of 14; Chibanda *et al*. (2015) adopted individual therapy approach delivered by nurses in 45-60 minutes for 6 sessions with a sample of 42; Tshabalala and Visser (2011) adopted individual therapy approach which was delivered by psychologists in 45 minutes for 8 sessions with a sample of 20. Apparently, all the aforementioned studies were conducted outside of a primary healthcare setting. Of note, most of the previous studies used different cadres of interventionists to deliver CBT which in turn makes it hard to benchmark on the effectiveness of the intervention. Munoz *et al*. (2000) recommend that CBT facilitators should possess advanced training in assessment and psychotherapy of at least Master's degree level.

In comparison to previous studies conducted among PLHIV in sub-Saharan Africa, the present study fills the methodological gaps in literature on CBT which is currently limited to individual therapy approach (Tshabalala & Visser, 2011; Andersen *et al*., 2016; Chabanda *et al*., 2015). First, the study examines three outcome variables that is, depression, adherence and stigma as co-occurring psychosocial conditions in HIV infection. Secondly, the study uses a pre/post-test design with an untreated control group to warrant within/between groups comparisons for purposes of determining true treatment effect size and assessing the direction of change as required in a study of this nature which tests elements of effectiveness and efficacy of an intervention. Thirdly, the study caps the number of therapy sessions to 6 with each session lasting 2 hours to control for dropouts since HIV outpatients are prone to falling sick unpredictably. Fourthly, the intervention is delivered by a professional therapist using group therapy approach that fosters vicarious learning which is critical in reinforcing participants' efficacy to mediate change in line with the goals and objectives of therapy. Fifthly, the study follow up period is set at two months post-treatment to allow for critical outcome assessment of treatment gains in the short term period. Finally, the study employs a replications design using three cohorts of participants to control for any inherent differences in the socio-behavioural and clinical characteristics of the patients which could threaten the validity of the study findings.

2.9 Theoretical Framework

Different psychological theorists from the three foundational schools of psychology, that is; psychoanalytic, behavioural and humanistic hold certain views on how to apply psychotherapy. Every psychotherapist has their theoretical orientation which informs their methods of practice to inspire or produce change and growth in clients. Clients that opt for psychotherapy oftentimes do present with an array of problem situations. The solution of a problem that originates from a physiological condition like HIV infection will be different from that which arises from work or family setting (Weiten, 2002).

In the current research, the investigator adopted Cognitive Behavioural Therapy (CBT) to guide this study. The work of Albert Ellis (1962) gave great momentum to the development of cognitive behaviour therapy through his Rational Emotive Behaviour Therapy (REBT). Both Ellis and Aaron Beck (the founder of Cognitive Therapy) believed that people can wilfully espouse reason. Both viewed the client's underlying irrational beliefs and assumptions as targets of intervention. Both rejected their psychoanalytic training and resorted to active, direct dialogues with clients rather than passive listening. REBT is a comprehensive cognitive-affective behavioural theory which holds the view that thoughts, feelings, desires, and actions are integrative and interact with each other (Ellis, 1995). Whereas Ellis confronted and persuaded clients to change their unrealistic life philosophies, Beck on the other hand regarded his clients as colleagues with ability to research verifiable reality (Beck & Weishaar, 1995).

Beck's Cognitive Therapy embraces both behavioural experiments and verbal procedures in examining alternatives to client's maladaptive interpretations and generating contradictory evidence that supports better adaptive beliefs which in turn yields the desired change (Beck & Weishaar, 1995). In this study, CBT was the therapy used to help HIV-positive adults to deal with clinical depression, poor ART adherence and HIV stigma. CBT is premised on the assumption that irrational thoughts and maladaptive behaviours are learnt from life experiences and these can be corrected by way of modifying such experiences (Bea & Tesar, 2002). The basic premise of CBT is that difficult emotions can only be changed by targeting the thoughts and behaviours that are contributing to the distressing emotions. That is, change in thoughts and behaviours consequently leads to change in emotions. Hence, the choice of traditional CBT approach as a theoretical framework for this study.

CBT as a psychotherapy is a combination of cognitive and behaviour therapies (Bush, 2003; Wiser *et al*., 1996). CBT is used to help patients or clients modify their maladaptive thoughts patterns and behaviours that are inconsistent with the existing reality (Beck *et al*., 1979). CBT is considered one of the most effective psychotherapeutic interventions worldwide. CBT is highly structured and is a skills-based approach informed by social learning theory (Bandura, 1969). It teaches coping skills that boost self-efficacy which is an active ingredient of the intervention. CBT has been employed in various parts of sub-Saharan Africa to help HIV infected women deal with stigma and discrimination in South Africa (Tshabalala & Visser, 2011), to reduce risky sexual behaviours among HIV infected Zambian couples (Jones, Ross,Weiss, Bhat, & Chitalu, 2005), to improve mood among Nigerian surgical patients (Osinowo, Olley, & Adejumo, 2003), and to help HIV infected outpatients to reduce alcohol in western Kenya (Papas *et al*., 2010). Overtime, CBT has been proven to be consistent and compatible with other treatment approaches including traditional counselling (Morgenstern *et al*., 2001) and has been used in dealing with a number of other psychiatric disorders including depression, among other disorders (DeRubeis & Crits-Christoph, 1998).

In CBT, the therapist plays an active role of taking clients through a rigorous diagnostic process at initial sessions to ensure that client's needs and problem situations are pointed out accordingly. The therapist is an active participant in solving the client's problems. CBT presents an explicit, understandable and flexible treatment strategy that reflects client's individual needs (Tshabalala & Visser, 2011). This is what makes CBT unique in comparison to other psychotherapies. CBT as a psychotherapy incorporates the elements resembling education, coaching or tutoring. Here, the client is guided by the expert hand of a therapist in sharing their stories, setting treatment goals and in deciding which techniques work well for them (Bush, 2003).

CBT was originally a treatment design tailored for individuals but with time it has been adopted for use with groups (Rose, 1999). CBT as one of the therapeutic approaches that focuses on insight can be used on either individual or group therapy (Kaplan & Sadock, 1993). CBT is generally considered a short-term therapy in which client(s) and therapist work collaboratively to identify thoughts and behaviours contributing the presenting problem (Mental Health Academy/MHA, 2014). CBT is an intensive, short-term (four to 24 weekly sessions), problem-oriented approach. It was designed to be quick, practical and goal-oriented. In CBT session, a client identifies the

maladaptive patterns and replaces them with rational thoughts and behaviours which are more adaptive, practical, and helpful (Jorm *et al*., 2009).

In CBT, the psychotherapist uses the trouble-causing thoughts and behaviours to equip the client with necessary skills and techniques to change their way of thinking, feeling, and behaviour in a given situation. The CBT-generated skills enable the individual to be cognizant of thoughts and emotions; to establish how situations, thoughts, and behaviours influence emotions; and to improve how they feel by changing dysfunctional thoughts and behaviours (MHA, 2014). The underlying principle of CBT practice is the collaborative skill acquisition and take home assignments in between sessions. This is what makes CBT unique from typical "talk" therapies (Schmied & Tully, 2009; Grazebrook *et al*., 2005).

2.9.1 Conceptual Framework

The researcher acknowledges the fact that Cognitive Behavioural Therapy as discussed above has been developed, implemented and evaluated in different parts of the world. From the review of literature, CBT for depression in a group setting within primary healthcare has not been systematically implemented in Kenya and there is no framework that has been developed to guide its implementation. From the theoretical framework, it emerges that CBT theory has concepts that are relevant in addressing the problem of depression and its correlates among PLHIV. Thus, for CBT to be effectively implemented, the therapist should appreciate the underlying situations, thoughts, emotions and behaviours which might be the triggers of clinical depression, poor adherence and stigma among PLHIV. The researcher is also aware that it is in challenging the aforementioned elements by way of applying the principles of CBT that clients may achieve the desired outcomes. The operational form of the independent variable in the study is Cognitive Behavioural Therapy (CBT) which is the treatment intervention adopted for the experimental group of the study. The operational forms of the dependent variables in the study were; clinical depression, HIV/AIDS stigma and antiretroviral therapy adherence. Intervening variables include; alcohol use, residual effects of antidepressants and/or counselling. The intervening variables as confounders of the validity of study results were controlled for through participants' enrolment eligibility criteria which excluded patients on antidepressants and active professional counselling as well as those who regularly use alcohol. The conceptual framework indicating the relationship between the independent and dependent variables of the study is as demonstrated in Figure 1.

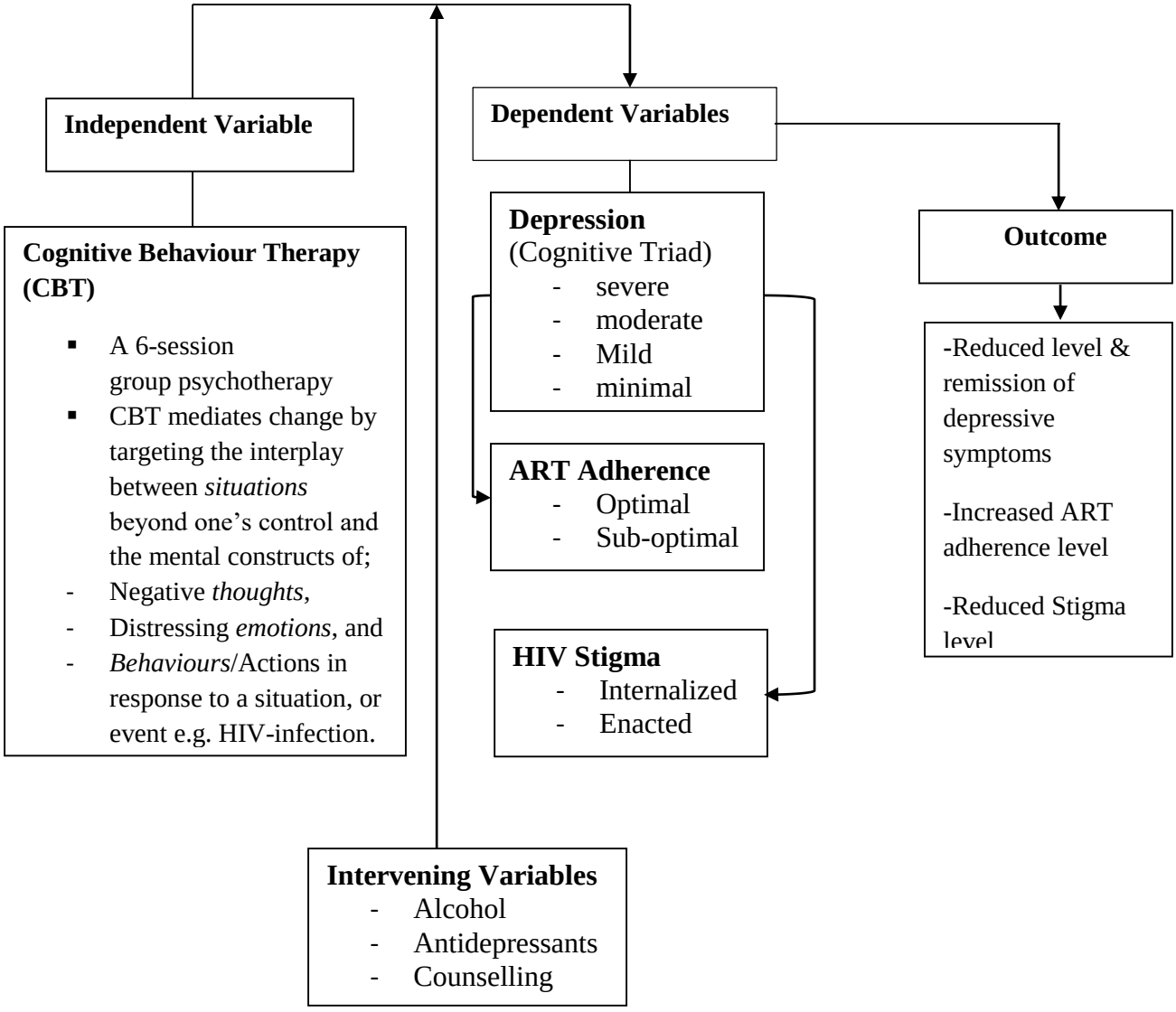


Figure 1. Clinical Effect of CBT on Clinical Depression, ART Adherence and HIV Stigma
Source: Researcher

Independent variable: The independent variable in the study is Cognitive Behavioural Therapy (CBT). CBT is the treatment intervention that was manipulated to assess for outcome change difference on the dependent variables. In delivering CBT, the Therapist focused on the fundamental components that are comprised of the following in each session presented during a standard 2-hour session:

- Rapport-building for collaborative therapeutic work.
- Determination of the participants' schema with reference to depression, treatment adherence and stigma.
- Psychoeducation on Depression, ART adherence and HIV Stigma.
- Discussion on various steps of CBT, and adaptive thoughts about presenting issues.
- Motivational dialogue to reinforce change.
- Behavioural activation techniques.
- Cognitive restructuring and problem-solving techniques, among others.

The above mentioned components operationalise the independent variable in terms of describing the content of therapy sessions that study participants were taken through for a period of six weeks. CBT intervention was only delivered to participants in the experimental group and its effect was assessed at two months post treatment.

Dependent Variables: The dependent variables in this study included; Clinical depression, ART Adherence and HIV Stigma.

i. **Clinical Depression**: This was measured using patient health questionnaire for depression (PHQ-9 Scale) to assess for variance in levels of depression at pre- and post-treatment stages of the study. The scores derived from the scale indicated depression severity levels (minimal, mild, moderate, or severe) for each and every participant. The scores were assessed to indicate any change attributable to CBT intervention and the magnitude of treatment effect size thereof.

ii. **ART Adherence**: This was measured using Patient Adherence Record to assess for variance in the degree of adherence at pre- and post-treatment phases of the study. Adherence level was defined as either optimal or sub-optimal. Optimal adherence means taking at least 95% of the monthly prescribed medication. Sub-optimal adherence means taking not taking the prescribed medication or taking less than 95% of the monthly dosage.

iii. **HIV Stigma**: This was measured using HIV stigma scale to assess for variance in levels of stigma at pre- and post-treatment phases of the study. Two aspects of HIV related stigma were assessed, that is internalised and externalised stigmas. Enacted stigma concerns others psychological and social reactions towards someone with HIV condition, whereas internalised stigma occurs when the person suffering from a stigmatized disease condition (HIV) turns public stigma to themselves.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the procedures and the methods the researcher employed to carry out the study. It systematically presents various aspects of the study including; research design, location of the study, population, sampling procedure and sample size, instrumentation, data collection and analyses that were employed in the study.

3.2 Research Design

An experimental study design was used by the researcher to evaluate the effect of CBT intervention on clinical depression, ART adherence and HIV-stigma. The independent variable was CBT group therapy. Specifically, Pretest/Posttest Control-Group design was used to test the hypotheses of the study. The design involved administering a pretest, followed by an intervention then a posttest measure to at least two equivalent groups. The advantage of the design is that it ensures that measures of dependent variable(s) is equivalent at the beginning of the study (Jackson, 2003). This design is favoured for a study that seeks to establish change as an outcome of an intervention especially in psychological researches (Creswell, 2003). In experimental studies such as this, the treatment can only be considered effective if there is a significant change from pretest (baseline) scores to posttest scores among participants in the experimental group relative to change reported in the control group (Jackson, 2003). The purpose of including a control group in the study is to control for external events which may influence the behaviour of participants and compromise the validity of the experimental outcome. Similarly, replication is important in reducing variability in experimental results thereby increasing the significance of findings and the confidence level with which the researcher can draw conclusions about the intervention. Replication was achieved in the current study by grouping participants into three distinct cohorts in both arms of the study. The design used in the current study is depicted in Figure 2.

Experimental Group **R**_____ **O** _____ **X** _____ **O**

Control Group **R** _____ **O** _____ **O**

Note. R=randomization, O= Pretest, X= treatment, O = Posttest; treatment (X) was only provided to the experimental (CBT) group.

Figure 2. Study Design (adopted from Creswell, J. 2003)

In this kind of design, the strongest comparisons come from randomly assigning participants to either conditions of the study at enrolment. The element of randomization was considered in this research and participants were assigned to either experimental or control groups. It is only through random assignment that the researcher can ensure that groups are actually comparable and that observed variance in outcome measure is not the result of extraneous factors (Gribbons & Herman, 1997). In the current study, cognitive behavioural therapy (CBT) was the intervention and the expected outcome measures were change in levels of depression, ART adherence and HIV stigma from pre-to-posttest. The pretest measures were administered to both groups one week before the commencement of treatment. Thereafter, the treatment was administered for six consecutive weeks and a posttest assessment was done two (2) months after treatment termination.

3.3 Location of the Study

The study was conducted at Turbo Sub-County Hospital, HIV-outpatient Clinic which is run by AMPATH (Comprehensive HIV care and research centre of Moi University/Moi Teaching and Referral Hospital and a consortium of North American Universities led by Indiana University in Indianapolis) and is located 30km from Eldoret Town, Kenya (Appendix L). Eldoret is the administrative headquarters of Uasin Gishu County which is situated in the North-Rift part of Kenya. Uasin Gishu County is divided into six administrative units known as sub-counties and among them is Turbo Sub-county. Uasin Gishu County is home to a population of approximately 1.1 million as of 2013, and 25000 HIV positive adults (and records 1921 new infections per year) with overall HIV prevalence of 4.3% (NACC & NASCOP, 2014). Turbo Sub-County Hospital has about 3,000 patients seeking care in the HIV-outpatient clinic section (www.hiskenya.org), making it one of the high volume HIV treatment centres in Uasin Gishu County. In addition, the patients seeking care at Turbo HIV-outpatient clinic have participated in previous studies which established

high prevalence of stigma and depression (Yebei *et al*., 2008; Adina, 2016), thereby making them an important population for the study.

3.4 Target Population

The study population consisted of HIV positive adults attending HIV-outpatient clinic that were medically stable and had been on antiretroviral therapy for at least 3 months. Psychological distress as a result of being recently diagnosed with HIV, and medical illnesses which could present depression-like symptoms were controlled for in the study by considering only stable patients, thus avoiding over-diagnosing depression. Patients were excluded if they presented with a mental illness requiring admission or if they were on alcohol or any other drug of abuse which could be a depressant by nature. There were about 3,000 HIV-infected adults enrolled and active in care at the Turbo Hospital HIV-outpatient clinic. The study confined itself to Turbo Sub-County Hospital HIV outpatient clinic in Uasin Gishu County. The clinic was considered ideal for this kind of study since it is a high volume HIV comprehensive care clinic and serves varied demographic of patients and is located in a cosmopolitan semi-urbanite region. In addition, the clinic offers partial psychiatric services for patients presenting with mental illnesses including mood disorders through psychiatric-nursing intervention on a weekly basis. Thus, it was convenient to refer participants enrolled in the study who had symptoms of severe depression illness and intense suicide ideations in line with the ethical requirements of good clinical practice in research involving patients.

3.5 Sampling Procedures and Sample Size

The nature of research is such that it cannot include in a single study all the elements or cases that might be related to the research objective or hypothesis hence the need for a sample derived from a population of study (Macnee, 2004). In this respect, sampling was applied in this study since the target population was large. Sampling is the process of selecting cases that are representative of an entire population with a view to making inferences about the population under study (Polit & Beck, 2012). Sampling helps the researcher to achieve statistical conclusions, validity and to generalise their study findings and results. In order to achieve these goals in this study, the researcher defined eligibility criteria (inclusion and exclusion criteria) before sampling the study participants. Likewise, a reconnaissance survey of the patients' clinic records was carried out in order to establish the population of PLHIV attending HIV-outpatient clinic in Turbo Sub-County Hospital. A systematic random sample was drawn from a list of 3000 outpatients seeking care at

Turbo HIV clinic. A table of random numbers was used to identify the initial sampling point. Every 4th person in the clinic attendance list was selected such that an initial group of 393 was obtained.

Sample size determination in experimental research like the current study takes into consideration the use of power analysis (Lipsey, 1990). This involves; level of statistical significance, amount of power desired in the study (high, medium and low), and the effect size (expected difference between the Means in control and experimental groups expressed in Standard Deviation units). Conventionally these units are set at: Alpha = .05 (CI, 95%), Power =.80, and Effect =.50. In this way, the sample assigned to treatment and control groups provides the greatest sensitivity necessary to conclude that the treatment effect on the outcome measure is actually due to the experimental manipulation (Cohen, 1977; Lipsey, 1990). The researcher assumed that the sample size that would detect a difference in depression scores between the two groups would also answer the question of whether the stigma scores or the ART adherence scores in the two groups was the same or different. Thus, depression alone was considered in the determination of the sample size. Under the assumption that the standard deviation is 10 units and the difference in the change in depression scores between the two groups assumed to be 6, 80% powered sample size would be equal to 22 subjects per group. There were two post randomization measurements.

Subsequently, the desired minimum powered sample size of the study was 44, that is, 22 in the intervention group and 22 in the comparison group before adjusting for attrition (filtering out non-completers at month-2 posttest assessment). To achieve the desired sample size of 44, the researcher factored in a retention rate of 85% thereby increasing the actual sample to 52. With a sample size of 52 or more, participants' attrition which is a common phenomenon in experimental studies was fairly controlled for. In total, 53 participants were recruited in the study, and only 45 of them successfully completed, that is, 21 for the experimental/CBT group and 24 for the control group. In spite of the attrition cases, a retention rate of 85% was achieved, and the resultant sample was deemed sufficient to provide a basis for statistical analysis of the effect of study intervention. The primary objective of the study was to compare the changes in the amount of depression scores, HIV stigma scores and ART adherence scores between the control and the experimental/CBT group.

A powered sample size to answer the above mentioned primary objective was determined using the formula given below (Morgan & Case, 2013).

$$n = 4 \times \sigma^2 \times \left[\frac{1 + (r-1) \times \bar{\rho}_{ij}}{r} - \bar{\rho}_{0i}^2 \right] \times \left(\frac{Z_{1-\alpha/2} + Z_{\beta}}{\nabla} \right)^2$$

$$= 4 \times 10^2 \times \left[\frac{1 + (2-1) \times 0.5}{2} - 0.5^2 \right] \times \left(\frac{1.96 + 0.84}{6} \right)^2$$

$$= 44$$

Where;

n is the sample size

σ is the standard deviation, ∇ is the difference in depression scores between the two groups.

r is the number of post randomization measurements,

$\bar{\rho}_{ij}$ is the correlation between the two repeated measures, $\bar{\rho}_{0i}$ is the average of the two correlations between the baseline(pretest) and the post intervention (posttest) measurements.

$Z_{1-\alpha/2}$ and Z_{β} are the $(1-\%_2)\times 100\%$ and the $(1-\beta)\times 100\%$ percentiles of the standard normal distribution under the type I and type II errors respectively. Type I error was taken to be 5%.

To adjust for attrition, the sample size obtained above (n = 44) was divided by the retention rate (equal to 85%) to give the final sample size of 52.

3.6 Instrumentation

Based on the objectives of the study, the researcher collected data using instruments which are recognised as having good psychometric properties to measure the study dependent variables, that is Patient Health Questionnaire-9 for depression severity, Patient Adherence Record for ART adherence, and HIV/AIDS-related Stigma Scale for HIV Stigma. All the three instruments were preferred since they have been tested and used among HIV-infected populations in sub-Saharan Africa. In addition, all the instruments were readily available and were obtained free of charge from the developers under the open-source internet access rules with a disclaimer that their usage is restricted to research and non-commercial practice only.

3.6.1 Study Measures

i. **a. Patient Health Questionnaire (PHQ-2) for Depression Screening:** Patient Health Questionnaire-2 (PHQ-2) mini-scale is a subset of PHQ-9 scale and is derived from the first two items in the PHQ-9 for the Primary Care Evaluation of Mental Disorders (*PRIME-MD*; Spitzer, Kroenke, & Williams, 1999). The mini-scale has been used in sub-Saharan Africa settings including Kenya and Uganda to screen for depression among PLHIV (Monahan *et al*., 2008; Akena *et al*., 2013). PHQ-2 is a brief instrument which is easy and quick to administer especially within a busy health facility. PHQ-2 score of ≥3 has been found to demonstrate high sensitivity (85%) and specificity (95%) for diagnosing any PHQ-9 depressive disorder (Monahan *et al*., 2008). In screening for depression, a patient may be deemed to be presenting with a depressive disorder if they endorse positive for at least one item in the PHQ-2 mini scale with a score of ≥3. In the current study, any patient who endorsed positive for either of the two items in the PHQ-2 mini-scale with a score at least 3 (Appendix C) was considered a potential participant for recruitment into the study. However, a participant was recruited after undergoing a further assessment for depression using PHQ-9 scale and attained at least 5 points from the summative score.

b. Patient Health Questionnaire (PHQ-9) for Depression Assessment: Patient Health Questionnaire-9 (PHQ-9) from the Primary Care Evaluation of Mental Disorders (Spitzer *et al*., 1999) was used as a brief structured interview for diagnosing depression (a mood disorder) as classified under section two of DSM-5 (American Psychiatric Association/APA, 2013). The PHQ-9 scale screens for nine major depression symptoms and yields a total depression severity score (Appendix D) and has been used in a number of studies as a diagnostic instrument among PLHIV including western Kenya setting (Monahan *et al*., 2008). A diagnosis of depression was arrived at for participants with a score of at least 5 out of the 27 from the PHQ-9 scale, and the participants were judged to have social and/or occupational impairments as a result of the symptoms. Persons diagnosed with major depression severe (a score of > 20) and/or a positive score for suicidality on PHQ-9 were referred for psychiatric intervention. Levels of depression

severity among study participants were categorised as minimal, mild, moderately-severe, and severe in relation to the PHQ-9 standard cut-off guidelines as follows;

5-9: Minimal depression -*Minor*

10-14: Major depression-*Mild*

15-20: Major depression-*Moderately severe*

>20: Major depression- *Severe*

ii. **Patient Adherence Record for ART:** ART adherence was assessed using Patient Adherence Record adapted from a *Multi-Method Tool to Measure ART Adherence* developed by Steel *et al*. (2007). Specifically, ART adherence was assessed using both Self-reporting questionnaire (4 items) and visual analogue scale. In assessing for adherence using self-reporting questionnaire, the number of **No** answers to the four questions are counted; if all 4 answers are **No,** then the client is classified as being highly adherent, if there is 1 **Yes** answer, then the client is classified as being moderately adherent, and where there are 2 or more **Yes** answers, the client is classified as having low adherence. For the visual analogue scale (VAS) a score of ≥95%, 75-94%, and <75%; would translate to high, moderate and low adherence (Appendix E). Self-report questionnaire and Visual Analogue Scale were used to help corroborate and validate the scores endorsed by study participants.

iii. **AIDS-Related Stigma Scale to Measure internalised and enacted HIV Stigma:** AIDS-related stigma scale is a 9 item scale that was assembled from the previous two AIDS stigma scales developed by Seth Kalichman and team for use in sub-Saharan Africa (Kalichman *et al*., 2005; Kalichman *et al*., 2009). The first of the two AIDS-related stigma scales was developed for use among the general population and the second one was specifically for internalised AIDS stigma. In assembling the AIDS-related stigma scale for the current study, the researcher adopted 5 items from the internalised stigma scale (Kalichman *et al*., 2009), and four items in the general AIDS-related stigma scale (Kalichman *et al*., 2005). The internalised stigma scale had been validated among people living with HIV/AIDS in Cape Town South Africa (*n* =1068), Swaziland (*n* = 1090), and

Atlanta US (n = 239) and showed that the internalised AIDS stigma scale was internally consistent (overall alpha coefficient, Cronbach's $\alpha = 0.75$) and time stable ($r = 0.53$). The AIDS-related stigma scale had been validated among 2306 South Africans and showed that the AIDS-related stigma scale was internally consistent (overall alpha coefficient, $\alpha = 0.75$) and time stable ($r = 0.67$). For the purpose of this study, the scale was adapted as a standardised version of the AIDS-related stigma scale (Appendix F). The 9 item AIDS-related stigma scale taps into abroad range of stigmatizing beliefs including negative beliefs towards self and others (internalised and enacted variables of stigma). The 9 items included in the modified scale were selected based on their relevance to the study context, and the items were selected with guidance of experts. The researcher modified the response into a 4-point Likert-type scale (strongly disagree, disagree, agree, and, strongly agree) to help measure the degree of agreement as opposed to the basic binary response type of Disagree/Agree. The 9-item modified scale was assessed for internal consistency which yielded Cronbach alpha coefficient of, $\alpha = .79$ (Appendix F). This was considered acceptable because ideally, Cronbach alpha coefficient of a scale should be .7 and above (DeVellis, 2003). The scale is interpreted in a way that a high score translates into experience of high levels of stigma.

3.7 Validity of Data Collection Instruments

The study instruments adapted for this study have been found to be valid for use within the sub-Saharan Africa context. For instance, Monahan *et al*. (2008) conducted an overall validity study of PHQ-2 and PHQ-9 in the western Kenya setting among the HIV infected population and concluded that the instruments are valid for assessing depressive disorders. Similarly, the AIDS related Stigma Scale has been found to have robust evidence for indicators of validity. The scale assesses a broad range of stigma beliefs including repulsion, avoidance, and persecution (Kalichman *et al*., 2005; Kalichman *et al*., 2009). Additionally, the multi-method adherence assessment tool has been validated and accepted for routine use in busy ART clinics in sub-Saharan Africa (Steel *et al*., 2007). However, because the tools were adapted versions for the study, the researcher ensured that all variables under study were covered in the study measures. The researcher also sought the guidance of expert clinicians and the supervisors to ascertain the validity of the study instruments and appropriate adjustments were made to address any validity weaknesses.

3.8 Reliability of Data Collection Instruments

The study used instruments which are recognised as having good psychometric properties to score for the dependent variables. PHQ-9 Scale (Spitzer, *et al*., 1999) have been used in a number of studies as a diagnostic instrument among PLHIV including western Kenya setting with a reliability coefficient of r = .78 at baseline (Monahan *et al*., 2008). The AIDS related stigma scale is also credited for it good reliability measures with an internal consistency coefficient of .75. However, the reliability of the patient adherence record (PAR) tool had to be ascertained because it previously reported low reliability (Self-reporting, r = .53; Visual Analogue Scale, r = .52). Most importantly, in the context of the current study there was need to determine the reliability of the adapted instruments. A test-retest reliability using a sample of 10 participants (20% of the study sample size) yielded the following Pearson Correlation coefficients r = .74(n =10), p = .015 and r = .85(n =10), p =.002 for PHQ-9 and AIDS related stigma respectively. An inter-rater reliability coefficient of Kappa Measure of Agreement value of, κ = .66, with a significance of p = .010 was obtained for PAR (appendix H). According to Peat (2001), a value of .5 for Kappa represents moderate agreement, above .7 represents good agreement, and above .8 represents very good agreement. So in this case the level of agreement between the self-report and visual analogue scale (VAS) was good. A reliability coefficient of .7 and above is considered sufficient for a research instrument (Kothari, 2008). All the three instruments were considered reliable and acceptable for administering study measures since they all reported good reliability index of $\geq$ .7.

3.9 Data Collection Procedure

After obtaining approval from the Board of Postgraduate Studies of Egerton University and subsequently the requisite ethical clearance (Appendix K) from Egerton University Research Ethics Committee (EUREC), and formal ethical approval (Appendix I) from the Institutional Research Ethics Committee (IREC) of Moi Teaching and Referral Hospital/Moi University College of Health Sciences on behalf of National Commission for Science, Technology and Innovation (NACOSTI) as required for studies involving patients in a healthcare setting, a written permission was sought from the AMPATH Research Office in Eldoret to allow the researcher collect data needed for this study (Appendix J).

The actual study process begun with researcher first obtaining the clinic attendance list which is usually populated on a daily basis from the records department. The list contained between 100-

200 names of patients scheduled for clinic visit for each day of the week. From the clinic data, the researcher further established that the HIV-outpatient clinic had about 3000 adult patients that were active in care and had their appointments to attend clinic booked on a monthly basis. From the patient list, potential clinic attendees were approached based on systematic random sampling and informed consent obtained (Appendix A).

Consented patients were screened for depression in one-on-one clinical interview using the PHQ-2 mini-scale (Appendix C) based on the following eligibility criteria: The inclusion criteria were; (1) a primary diagnosis of depressive disorder based on PHQ-9 score of 5 or higher to include people with less severe depression to severe depression who frequently visit HIV-outpatient clinic and who could respond to CBT; (2) sufficient command of English/Kiswahili language to enable study participants write and report homework assigned during therapy sessions; (3) HIV diagnosis at least 6 months prior to the study; (4) being on antiretroviral medication for the past 3 months to help assess for the degree of adherence; and (5) seemingly medically stable to attend CBT's six weekly sessions. The exclusion criteria were; (1) intense suicidal intent requiring inpatient admission; (2) a history suggestive of alcohol misuse or drug dependence; (3) a history of bipolar affective disorder; (4) the presence of hallucinations or delusions; (5) having received electroconvulsive therapy within the previous 6 months, because of possible residual effects on cognition.

A total of 53 participants were recruited and subsequently grouped into three cohorts. Grouping participants into cohorts was helpful in controlling for diffusion effect which could compromise the external validity of the study (Kothari, 2008). Similarly, putting study participants into cohorts was helpful in creating small manageable group sizes which was ideal for effective delivery of CBT therapy. Subsequently, the participants went through the process of random assignment where each participant was asked to pick at random numbers placed in opaque envelops before they were assigned to either arm of the study. The numbers were written on a folded piece of paper labelled as either 1 or 2. Participants who picked a piece of paper labelled 1 were assigned to the treatment group (CBT) and those who picked the piece labelled 2 were assigned to the comparison group (control). After randomization, the researcher administered the study dependent variable measures to collect baseline data which constituted pretest scores for both arms of the study. The measures administered were; Depression scale (PHQ-9); Patient Adherence Record; and the HIV

stigma scale as well as the socio-demographic questionnaire to all consented and enrolled participants in the study. The baseline measures of the study were administered one week before the commencement of the psychotherapy sessions.

Consequently, all participants in the experimental group (*n*=26) were taken through a six weekly session of CBT intervention programme with each session lasting for 2(two) hours. The sessions were delivered to participants in cohorts using CBT group therapy approach. Each cohort had a minimum of 6 participants. The CBT treatment groups were gender-stratified in order to avert any gender-based power differentials inherent in patriarchal societies like Kenya. The CBT intervention was delivered by the researcher who is an experienced CBT therapist and a Psychology doctoral candidate. Participants in the control group were however not offered any form of psychotherapeutic intervention except for the treatment as usual care involving all HIV patients for the entire period of the study. The summary of the procedure that was followed to implement CBT intervention is in as shown in Appendix G. After successful completion of CBT programme, post intervention assessment was conducted where posttest measures were obtained from participants in both arms of study. The posttest data were collected at the month-2 post-treatment session. This was helpful in controlling for variance due to time lapse and residual effect of treatment on cognition which could compromise the true treatment change effect attributable to CBT intervention. A summary outlining key milestones of the entire study procedure is presented in Figure 3. Specifically, the diagram presents flow of participants from enrolment (n=393) to posttest (n=45) stratified by study conditions and in conformity with the true experimental research design using pre-and-posttest control group strategy.

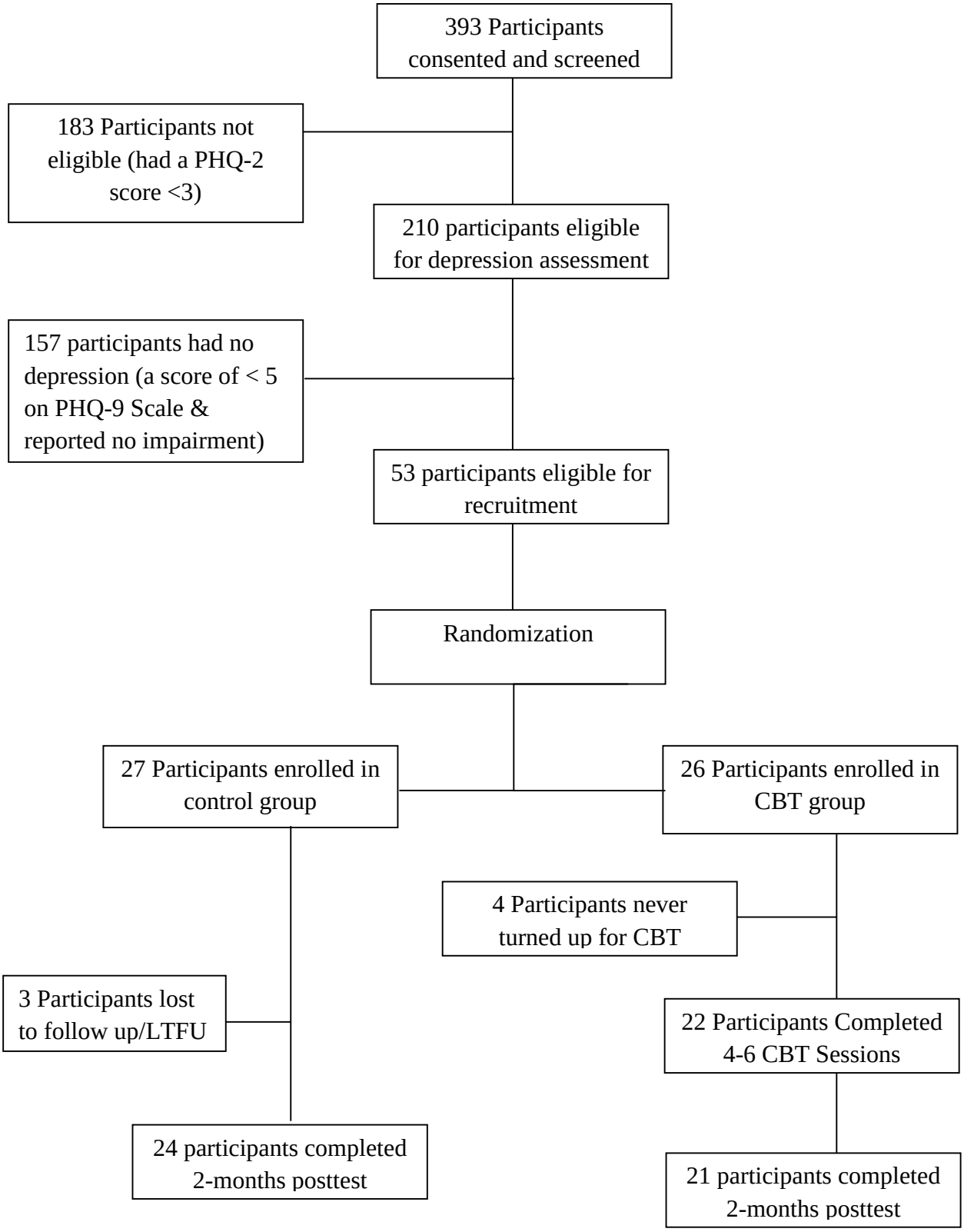


Figure 3. Participants Enrolment Schema

3.9.1 Cognitive Behavioural Therapy Session Outline

The researcher opted for a brief CBT therapy model which was administered using a group therapy approach. This model was preferred since HIV-infected patients often experience fluctuation in medical stability and therefore longer sessions could result into higher attrition rates. Similarly, given that the study site was a peri-urban setting, patients could easily change their residence through migration processes. The choice of six sessions was based on the recommendations of Jorm *et al*. (2013) which emphasised that CBT group therapy can be delivered in between four to 24 sessions. In addition, a previous application of CBT in a HIV population provided evidence that a 6-weekly session is effective in the low-resourced settings of western Kenya (Papas *et al*., 2011).

The participants enrolled to the CBT intervention were taken through a six-week psychotherapy programme which focused on different components of the CBT model. The components include; thoughts, emotions, and behaviour. The researcher applied an array of both cognitive and behavioural techniques to help participants grasp the concept of CBT intervention. At the centre of the intervention was the need to empower the participants to take charge of their thoughts, and feelings as well as the behaviour consequent to such. The participants were encouraged to learn pertinent skills that would help them cope with the negative experiences of depressive symptoms and stigmatising beliefs. The participants were actively engaged in homework assignments to help them build a solid toolbox of skills from which and where they would draw the requisite coping skills during the normal phase of their lives at post-treatment. A summary of the specific content of each session is presented in Appendix G. The treatment session outline was as follows;

Session one: The initial session was used to establish rapport with the participants, setting up ground rules and group norms; and to review their current understanding of depression, treatment adherence and HIV stigma; and to lay foundation for the treatment. Firstly, the participants were given an overview of the treatment, and then talked through what was expected of them during treatment. They were also taken through psycho-education which exposed them to a discussion on facts about HIV/AIDS, HIV and depression comorbidity, and the interplay between depression and related outcomes like stigma, poor adherence, and suicidality. Finally, participants were introduced to learning about CBT, the treatment. This first session was a little different from the other sessions in that the facilitator had to do a lot of talking to provide participants with a lot of

information providing the basis for CBT intervention**.** The participants were informed that during each session, the group and the therapist would define the problem, generate alternative solutions, make decisions about the solutions, and develop a role-play for implementing the agreed upon solutions. This information was reviewed during subsequent sessions to address strategies for overcoming depression and related outcomes. The session came to a close with a home-work assignment given to the participants to initiate a process of helping them practice coping skills for subsequent use after the termination of CBT treatment.

Session two: During the second session, the therapist continued to strengthen the working relationship and build upon the therapeutic alliance with the participants. A review of the homework practice assignment was conducted to create a link between session one and two to ensure that there was a complete understanding of previous session and to address any concerns as well as assist in reducing any anxiety or unidentified emotions that might have developed after the initial session. Afterward, the participants were introduced to CBT model with a specific focus on "thoughts patterns" including, automatic thoughts, negative thoughts and monitoring of automatic thoughts. Thought evaluation is important in helping individuals appreciate how negative thoughts may contribute to depression and vice versa. The session ended with assigning of take home practice exercise to participants.

Session three: During the third session, the therapist presented and discussed the CBT approach and conducted a brief motivational discussion regarding making changes about negative thoughts and beliefs about HIV/AIDS. The presentation of the CBT model happened interactively, thereby eliciting various thoughts, behaviours, and potential physical aspects of HIV treatment avoidance and addressing their effects on health outcomes. The motivational components involved eliciting the merits of treatment adherence and demerits of lack of adherence. This was the behavioural analysis component which helped participants tie together the various components of CBT model, that is, how thoughts and emotions contribute to behaviour and the consequences thereof.

Session four: During the fourth session, the therapist focused on cognitive restructuring by focusing on the maladaptive thinking of the client. With the help of participants, the therapist highlighted and addressed the negative thoughts and core beliefs related to HIV/AIDS, medication adherence, as well as avoidance of activities and individuals that increase the maladaptive thinking. Similarly, the therapist introduced and increased the participants' awareness of the cognitive

distortions. One such approach was to focus on the negative thoughts (e.g., "*because I got HIV I will die soon and so I don't need to invest into the future"; "if I only I'd never gotten married to this reckless man/woman, I'd not be having AIDS today"*). This was done in order to invite the participants to contribute in producing more positive viewpoints with reference to how HIV infection may lead to depression, lack of treatment adherence and stigmatizing beliefs if irrational thoughts are not dealt with and replaced with more rational ones. During this session, participants expressed thoughts like; "*ever since I tested positive for HIV, I've never felt beautiful anymore", "I no longer work hard because I'll soon be gone", "if my parents were rich I'd have contracted HIV……I went after men because I needed money for my personal use".* Session four was the crux of the intervention and presented with lots of emotional explosions.

Session five: During the fifth session, the therapist assisted the participants to question and evaluate their automatic thoughts and develop strategy to overcome depressive tendencies by generating more positive ways of viewing HIV infection. The fifth session primarily focused on thought evaluation and problem-solving techniques. This was achieved by exposing the participants to two primary skills that are targeted at reducing the emotional distress that leads to task avoidance. The first skill was to assist the participants in dissecting the problem situation into its perspective parts, which is, developing the skills necessary to break down overwhelming tasks into manageable steps. The second skill was learning how to make informed decisions.

Session six: The sixth session was focused on helping participants cope with stigma and triggers of stigma like situations, questions, and experiences. The participants were taken through a role-play exercise on how to respond to people's concerns and questions which could expose their HIV status. For instance, *how to respond to friends or relatives who may want to know why they were taking medication and yet not looking sick*. The participants were also trained on generating long term plans to help them stay on the recovery path. This involved identifying negative automatic thoughts and generating alternative thoughts as well as challenging irrational thoughts and beliefs using Socratic questioning technique. The session was terminated with a motivational talk aimed at encouraging participants to continue with practice exercises back at home in addition to applying skills and techniques learnt from the CBT treatment in real life situations as a way of sustaining the gains made from therapy on long term basis.

3.10 Data Analysis

The study measures yielded quantitative data which created a platform for comparing the results of experimental group with that of the control group. The quantitative data collected was subjected to computerised statistical procedures that provided ways of dealing with large data sets. The advantage of quantitative data is that it allows for the use of statistical techniques that permit research hypotheses to be rigorously tested (Louw & Edwards, 1998). To this end, the quantitative data collected in this study was used to test hypotheses and determine the extent of how variables under study interacted.

Statistical analysis was done using software for statistical computing known as R, version 3.2.5 (R Core, 2016). Categorical variables were summarized as frequencies and the corresponding percentages. Continuous variables were assessed for normality using Shapiro-Wilk test and graphical approach. The Gaussian assumptions were violated (The Shapiro–Wilk test statistic $W = 0.831$, $p<0.001$), so continuous variables were summarized as median and the corresponding inter-quartile range (IQR). Comparison between the two arms of the study and independent categorical variables was done using Pearson's Chi Square test. However, whenever the Chi Square assumptions were violated the researcher conducted Fisher's exact test. Association between the CBT and continuous independent variables was assessed using the non-parametric Mann-Whitney U test statistic (Wilcoxon two-sample test).

Regression analysis was used to model the effect of CBT on the depression scores, HIV/AIDs stigma scores and ART adherence. The researcher modelled the former two as continuous outcome variables using Generalised estimating equations (GEE), and the last using ordinal logistic regression model assuming proportional odds between the levels of the treatment (proportional odds logistic regression model). Variability between participants was accounted for using robust standard error. The researcher compared models using likelihood ratio test to determine whether there was sufficient evidence to warrant inclusion of the interaction terms. The analysis reported the estimates, mean change for the linear regression and odds ratios (*OR*) for the logistic regression model, alongside the corresponding 95% confidence intervals (95% CI). The results were presented using tables and graphs. Table 1 presents a summary of the statistical techniques used in data analysis.

Table 1

Summary of Data Analysis

	Research Hypotheses	**Independent variable**	**Dependent variable**	**Statistical Tests**
1	There is no statistically significant difference in the levels of depression between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest.	CBT Intervention	Level of Clinical Depression	Descriptive, Shapiro-Wilk *W* test, GEE, Mann-Whitney *U* test
2	There is no statistically significant difference in the degree of adherence to antiretroviral therapy between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest.	CBT Intervention	Degree of ART Treatment adherence	Descriptive, χ^2 , Ordinal Logistic Regression, Mann-Whitney *U* test
3	There is no statistically significant difference in the level of HIV stigma between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest.	CBT Intervention	Level of AIDS related Stigma	Descriptive, χ^2 , GEE

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

This chapter presents the results and discussions of this study whose main purpose was to establish the effect of cognitive behavioural therapy on clinical depression, and its psychosocial correlates among HIV-infected patients attending Turbo Sub-County Hospital HIV-outpatient clinic. The chapter also offers interpretations regarding the impact of CBT intervention on the direction of change on dependent variables as modelled using various statistical methods. This chapter is organised into sections which cover description of the study participants and results for the effect of cognitive behavioural therapy (CBT) on depression; the effect of CBT on antiretroviral treatment (ART) adherence; and the effect of CBT on HIV related stigma. Throughout the chapter, terms baseline, pretest and post randomisation carry the same meaning, that is, the period before intervention; and terms posttest and post treatment also bear the same meaning (2 months after therapy termination). The terms may be used interchangeably.

4.2 Description of Study Participants

In order to form the basis for the chapter, this section presents a descriptive account of the study participants in light of their socio-demographic and clinical characteristics at baseline. Table 2 presents the results of socio-demographic and clinical characteristics of study participants. A total of 53 participants were recruited and enrolled into the study. The overall median age was 35.0 (IQR: 32.0, 40.0) years with a minimum and maximum of 19.0 and 54.0 years. This resonates with KAIS report of 2012 which revealed that HIV prevalence increases with age and peaks at 35–39 years (NASCOP, 2014). People in this age bracket tend to be more sexually active and may be in multiple relationships. More than half of the participants (58.5%) were male. The median years of education was 10.0 (IQR: 8.0, 12.0) with a minimum and a maximum of 6.0 and 16.0 years indicating that more than half of the participants (58.4%) had attained a minimum of secondary school education. Up to 39.6% were married, and 39.6% were employed. All patients enlisted in the study had a sero-positive status for HIV. The median duration timeline since HIV diagnosis was 2.0 (IQR: 2.0, 3.0) years. There were those who were just one year since diagnosis and those who were six years since HIV diagnosis; about one fifth (22.6%) of the them underwent HIV posttest counselling. About a third (34.0%) of the participants had difficulty in remembering to

take medication although none of the participants took a break from medication. Approximately half (49.1%) of the participants reported having missed some dose of the medicines in the last 30 days, and 47.2% were fully adherent to antiretroviral treatment (ART). The study participants were grouped into three gender stratified cohorts with the second group being the largest (41.5%). Each cohort was randomised into two groups that is, treatment and control groups. The number of participants randomised into each treatment (CBT) cohort was between 7 and 9. This conformed to the recommended range of between 6 and 10 participants for group CBT (Munoz *et al*., 2000).

Table 2

Overall Socio-demographic and Clinical characteristics of Study Participants

Variable	**Category**	***Mdn* (IQR) or *n* (%)**
Age (years)		35.0 (32.0, 40.0)
Education (years of schooling)		10.0 (8.0, 12.0)
HIV diagnosis time line		2.0 (2.0, 3.0)
Cohorts	1	14 (26.4%)
	2	22 (41.5%)
	3	17 (32.1%)
Gender	Male	31 (58.5%)
	Female	22 (41.5%)
Civil status	Cohabiting	4 (7.55%)
	Married	21 (39.6%)
	Separated/divorced	12 (22.6%)
	Single	16 (30.2%)
Current Employment status	Employed	21 (39.6%)
	Self-employed	9 (17.0%)
	Unemployed	23 (43.4%)
HIV Posttest Counselling		12 (22.6%)
Difficulty to take medication		18 (34.0%)
Missed any dose in the last 30 days		26 (49.1%)
ART adherence	≤ 74%	17 (32.1%)
	75 - 94%	11 (20.8%)
	≥95%	25 (47.2%)

4.2.1 Comparison of Baseline Socio-Demographic and Clinical Characteristics of Study Participants Stratified by Treatment Arms

Table 3 presents results on a comparison of the baseline demographic, socio-economic, and clinical characteristics of study participants based on treatment groups. From inferential statistical analysis, Chi square test results did not reveal any potential differences between CBT and control arms of the study, $p > .05$ at baseline. This finding shows that the two groups were equivalent at pretest thus resonating with the use of pretest/posttest control group design in the current study which sought to compare the two groups on the dependent variable measures across time points.

Table 3

Participants Socio-demographic and Clinical Characteristics across Treatment Arms

Variable	**Category**	**Control n=27 (50.9%)**	**CBT n=26 (49.1%)**	***P-value***
Age (years)		35.0 (27.5, 40.5)	36.5 (33.0, 40.0)	0.454
Education (years of schooling)		10.0 (8.0, 12.0)	9.5 (7.3, 12.0)	0.670
HIV diagnosis timeline		2.0(2.0, 3.0)	2.0 (1.3, 3.0)	0.519
Cohorts	1	6 (22.2%)	8 (30.85)	
	2	13 (48.1%)	9 (34.6%)	0.591
	3	8 (29.6%)	9 (34.6%)	
Gender	Male	14 (51.9%)	17 (65.4%)	0.318
	Female	13 (48.1%)	9 (34.6%)	
Civil status	Cohabiting	1 (3.7%)	3 (11.5%)	
	Married	13 (48.1%)	8 (30.8%)	
	Separated/divorce	3(11.15)	9 (34.6%)	0.111
	Single	10 (37.0%)	6 (23.1%)	
Education level	Upper primary	12 (44.4%)	10 (38.5%)	
	Secondary	12 (44.4%)	15 (57.7%)	0.495
	College/University	3 (11.1%)	1 (3.8%)	
Current Employment status	Employed	12 (44.4%)	9 (34.6%)	
	Self-employed	6 (22.2%)	3 (11.5%)	0.292
	Unemployed	9 (33.3%)	14 (53.8%)	
Ability to speak/write Swahili		27 (100.0%)	26 (100.0%)	-
HIV posttest counselling		5 (18.5%)	7 (26.9%)	0.526
Difficult to remember to take medication		8 (29.6%)	10 (38.5%)	0.497
Missed any dose in the last 30 days		13 (48.1%)	13 (50.0%)	0.893
ART adherence	< 75%	10 (37.0%)	7 (26.9%)	
	75-94%	5 (18.5%)	6 (23.1%)	0.714
	≥ 95%	12 (44.4%)	13 (50.0%)	

4.3 Effect of Cognitive Behavioural Therapy (CBT) on Clinical Depression

This section systematically details out the findings on the first objective of the study that tested the hypothesis which sought to establish if there was any significant difference in the level of depression between participants enrolled in CBT and their counterparts in the control group consequent to study intervention. The section presents results of descriptive statistics on levels of depression at pre-and posttest assessments; describes the trend of change in levels of depression from pre-to posttest phase of the study, and draws a comparison between the CBT group and control group at pre-and post-intervention using inferential statistics. In addition, a regression model showing the effect of CBT on the remission of depression symptomatology is presented. The analyses and results of the study take into account the recommended prototypic outcome measures in experimental studies, which include assessing direction of change, magnitude of this change, and the ease with which the participants changed (Rosenthal & Rosnow, 1991).

4.3.1 Comparison of Pretest Depression Scores across Treatment Arms

Table 4 shows results of participants' overall depression scores at pretest. To assess for depression, PHQ-9 scale was used to measure depressive symptomatology over a period of two weeks and descriptive statistics were used to summarize general findings about how participants responded to the scale items as it applied to them. More than half of the participants (52.8%) expressed lack of interest or pleasure in doing things for more than half the days or nearly every day. Another 56.6% had feelings of being depressed or hopeless for more than half the days or nearly every day. Close to 80% of the participants (77.4%) were feeling tired or having little energy, and 67.9% had poor appetite or a tendency to overeat. Half of the participants (49.1%) had trouble concentrating on things such as reading the newspaper or watching television. Over half (52.8%) were talking or moving so slowly or have been moving around a lot more than usual that other people could notice. One third (29.3%) had at one point in time had thoughts that they would be better off dead or hurting oneself in some way. Of interest to note is that serious symptoms which are usually associated with clinical depression were well observed among the study participants at pretest just like in previous studies on depression (Boschloo, van-Borkulo, Borsboom & Schoevers, 2016; Fried, Pskamp, Nesse, Tuerlinckx & Borsboom, 2015).

Table 4

Overall Pretest Measures of Depression Symptoms

Variable	**Response**	***n* (%)**
Little interest or pleasure in doing things	Several days	25 (47.2%)
	More than half the days	19 (35.8%)
	Nearly every day	9 (17.0%)
Feeling down, depressed, or hopeless	Several days	23 (43.4%)
	More than half the days	18 (34.0%)
	Nearly every day	12 (22.6%)
Trouble falling asleep or staying awake	Not at all	16 (30.2%)
	Several days	19 (35.8%)
	More than half the days	7 (13.2%)
	Nearly every day	11 (20.8%)
Feeling tired or having little energy	Not at all	12 (22.6%)
	Several days	25 (47.2%)
	More than half the days	2 (3.8%)
	Nearly every day	14 (26.4%)
Poor appetite or overeating	Not at all	17 (32.1%)
	Several days	25 (47.2%)
	More than half the days	4 (7.5%)
	Nearly every day	7 (13.2%)
Feeling bad about yourself – or that you are a failure or have let yourself/family down	Not at all	29 (54.7%)
	Several days	9 (17.0%)
	More than half the days	4 (7.5%)
	Nearly every day	11 (20.8%)
Problem concentrating	Not at all	27 (50.9%)
	Several days	10 (18.9%)
	More than half the days	7 (13.2%)
	Nearly every day	9 (17.0%)
Psychomotor problems	Not at all	25 (47.2%)
	Several days	7 (13.2%)
	More than half the days	9 (17.0%)
	Nearly every day	12 (22.6%)
Suicidal ideation	Not at all	38 (71.7%)
	Several days	8 (15.1%)
	More than half the days	2 (3.8%)
	Nearly every day	5 (9.4%)

Note. Not at all = 0, several days=1, More than half the days=2, nearly every day=3

Table 5 presents results of Fisher's test that was used to assess for potential inherent differences in depression scores between study conditions at pretest (N = 53). The results did not reveal any statistically significant differences, p >.05, thus it was safe to infer that the groups were equivalent.

Table 5

Pretest Depression Assessment by Treatment Arms of the Study

Variable	Response	Control(n=27)	CBT(n=26)	Fisher's *P*
Little interest or pleasure in doing things	Several days More than half the days Nearly every day	13 (48.1%) 9 (33.3%) 5 (18.5%)	12 (46.2%) 10 (38.5%) 4 (15.4%)	1.000
Feeling down, depressed, or hopeless	Several days More than half the days Nearly every day	14 (51.9%) 7 (25.9%) 6 (22.2%)	9 (34.6%) 11 (42.3%) 6 (23.1%)	0.386
Trouble falling asleep or staying awake	Not at all Several days More than half the days Nearly every day	8 (29.6%) 8 (29.6%) 2 (7.4%) 9 (33.3%)	8 (30.8%) 11 (42.3%) 5 (19.2%) 2 (7.7%)	0.104
Feeling tired or having little energy	Not at all Several days More than half the days Nearly every day	6 (22.2%) 14 (51.9%) 1 (3.7%) 6 (22.2%)	6 (23.1%) 11 (42.3%) 1 (3.8%) 8 (30.8%)	0.907
Poor appetite or overeating	Not at all Several days More than half the days Nearly every day	9 (33.3%) 13 (48.1%) 1 (3.7%) 4 (14.8%)	8 (30.8%) 12 (46.2%) 3 (11.5%) 3 (11.5%)	0.837
Feeling bad about yourself – or that you are a failure or have let yourself/family down	Not at all Several days More than half the days Nearly every day	11 (40.7%) 7 (25.9%) 2 (7.4%) 7 (25.9%)	18 (69.2%) 2 (7.7%) 2 (7.7%) 4 (15.4%)	0.151
Problem concentrating	Not at all Several days More than half the days Nearly every day	12 (44.4%) 6 (22.2%) 3 (11.1%) 6 (22.2%)	15 (57.7%) 4 (15.4%) 4 (15.4%) 3 (11.5%)	0.621
Psychomotor problems	Not at all Several days More than half the days Nearly every day	14 (51.9%) 2 (7.4%) 5 (18.5%) 6 (22.2%)	11 (42.3%) 5 (19.2%) 4 (15.4%) 6 (23.1%)	0.680
Suicidal ideation	Not at all Several days More than half the days Nearly every day	21 (77.8%) 3 (11.1%) 0 (0.0%) 3 (11.1%)	17 (65.4%) 5 (19.2%) 2 (7.7%) 2 (7.7%)	0.453

Table 6 presents results of Mann-Whitney *U* test that was used to compare and establish if there was any statistically significant difference in baseline depression scores between CBT and control groups for the data that made it into final analysis after filtering out participants who never completed the study (n = 46). Based on a p-value threshold of .05, the results revealed that there was no statistically significant difference between CBT group (Mdn = 9.00, n = 22) and control group (Mdn = 9.00, n = 24), U = 243, Z = .469, p = .639. Thus, it was statistically viable to compare the two study conditions on outcome variables with a great degree of certainty.

Table 6

Results of the Mann Whitney U Test to Compare the Groups' Pretest Depression Symptom Scores

Groups	**N**	**Mean Rank**	**Sum of Ranks**	**U**	**Z**	**p**
Experimental Group	22	20.53	585.00	243.00	0.469	.639*
Control Group	24	21.45	496.00			

Note. * The difference is insignificant since p>.05.

The results from both Fisher's exact test (N = 53) and Mann-Whitney *U* test (N = 46) reveal that participants assigned to either CBT or control arms of the study never had any significant differences at pretest. This was important in ascertaining that any change differences in levels of depression reported at posttest assessment may solely be attributed to the effect of CBT intervention on depression among study participants. Moreover, the baseline scores obtained provided a vital platform for conducting within-group and/or between-groups comparisons at posttest assessment, and thus helping the researcher to determine the change trajectories and treatment effect size of CBT for depression.

4.3.2 Posttest Depression Scores across the Treatment Arms

Table 7 presents participants score on depression variables at month-2 outcome assessment. Change in depression symptomatology at month-2 post-treatment follow up was measured using PHQ-9 scale for depression severity and the analysis was done using descriptive statistics and Fisher's exact test. The PHQ-9 scores were disaggregated by treatment arms to allow for comparison on how participants in CBT and control groups scored for depressive symptoms in the PHQ-9 scale.

Table 7

Results of Posttest Depression Assessment by the Treatment Arms

Variable	Category	Control 24 (53.3%)	CBT 21 (46.7%)	Fisher's exact *P*
Little interest or pleasure in doing things	Not at all	2 (8.3%)	14 (66.7%)	0.0001
	Several days	11 (45.8%)	6 (28.6%)	
	More than half the days	7 (29.2%)	1 (4.8%)	
	Nearly every day	4 (16.7%)	0 (0.0%)	
Feeling down, depressed, or hopeless	Not at all	10 (41.7%)	14 (66.7%)	0.032
	Several days	8 (33.3%)	5(23.8%)	
	More than half the days	3 (12.5%)	1 (4.8%)	
	Nearly every day	3 (12.5%)	1 (4.8%)	
Trouble falling or staying awake	Not at all	7 (29.2%)	8 (38.1%)	0.576
	Several days	11 (45.8%)	7 (33.3%)	
	More than half the days	2 (8.3%)	4 (19.0%)	
	Nearly every day	4 (16.7%)	2 (9.5%)	
Feeling tired or having little energy	Not at all	7 (29.2%)	7 (33.3%)	0.803
	Several days	9 (37.5%)	10 (47.6%)	
	More than half the days	3 (12.5%)	2 (9.5%)	
	Nearly every day	5 (20.8%)	2 (9.5%)	
Poor appetite or overeating	Not at all	12 (50.0%)	11 (52.4%)	0.424
	Several days	6 (25.0%)	8 (38.1%)	
	More than half the days	1 (4.2%)	1 (4.8%)	
	Nearly every day	5 (20.8%)	1 (4.8%)	
Feeling bad about yourself – or that you are a failure or have let yourself or your family down	Not at all	15 (62.5%)	18 (85.7%)	0.296
	Several days	3 (12.5%)	2 (9.5%)	
	More than half the days	3 (12.5%)	1 (4.8%)	
	Nearly every day	3 (12.5%)	0 (0.0%)	
Problem concentrating	Not at all	8 (33.3%)	16 (76.2%)	0.017
	Several days	9(37.5%)	2 (9.5%)	
	More than half the days	2 (8.3%)	2 (9.5%)	
	Nearly every day	5 (20.8%)	1 (4.8%)	
Psychomotor problems	Not at all	15 (62.5%)	17 (81.0%)	0.510
	Several days	4 (16.7%)	3 (14.3%)	
	More than half the days	3 (12.5%)	1 (4.8%)	
	Nearly every day	2 (8.3%)	0 (0.0%)	
Suicidal ideation	Not at all	21 (87.5%)	20 (95.2%)	1.000
	Several days	2 (8.3%)	1 (4.8%)	
	More than half the days	0 (0.0%)	0 (0.0%)	
	Nearly every day	1 (4.2%)	0 (0.0%)	

An examination of Table 7 shows that the results of both descriptive and inferential statistical analyses applied to the posttest depression scores of participants in the experimental and control groups revealed a statistically significant difference. The assessment of depression scores at month-2 posttest revealed that the participants in the CBT condition were less likely to have little interest or pleasure in doing things, less likely to feel down, depressed, or hopeless, and less likely to have trouble concentrating on things, such as reading the newspaper or television, p = 0.0001, 0.032 and 0.017 respectively. Further, the results revealed that there was a trend among those in the CBT arm not to experience trouble falling asleep or staying awake, not to feel tired or have little energy, to feel bad about oneself – or that one is a failure or have let down oneself or the family, and not to experience psychomotor problems. These findings reveal that CBT works by targeting major depressive symptoms and thus had a significant clinical impact on remission of depressive symptoms among participants at posttest assessment.

4.3.3 Clinical Significance of Posttest Depression Scores Stratified by Treatment Arms

Table 8 presents results of descriptive statistics used to establish the magnitude of change in PHQ-9 scores among PLHIV in the experimental and control groups of the study at the critical month-2 outcome assessment stratified by clinical significance.

Table 8

Clinical Effect of CBT on Depression Symptoms at Posttest among Study Participants

Variable	**Category**	**Control (n=24)**	**CBT(n=21)**
Drop in PHQ-9 score	< 5 points	20(83.3%)	6(28.6%)
	≥ 5 points	4(16.7%)*	15(71.4%)*
	Total	24(100%)	21(100%)

Note. *A drop of ≥5 points at posttest is clinically significant based on PHQ-9 standard cut-offs

An assessment of findings in Table 8 shows the results of change in depression scores as measured using PHQ-9 from baseline to posttest. The results show that 71.4% (CBT) and 16.7% (control) participants had a drop of at least five points at post treatment outcome assessment. With a drop of five points in depression scoring scale measured using PHQ-9, a participant is deemed to have moved from a more severe to a less severe depressive state, and the change in depression symptoms

is considered clinically significant (Spitzer *et al*., 1999). CBT participants had a better change outcome and this reveals that a majority of them did respond adequately to psychotherapy and achieved remission of symptoms.

4.3.4 Depression Score Trajectories for CBT and Control Groups

To assess for the direction of change in depression levels from pretest to posttest phase of the study, PHQ-9 scores for depression obtained were computed and a comparison made within and between participants across the study arms at a two-point timeframe. Figure 4 presents the results of change trajectories within each group and a comparison between CBT and control arms of the study. The trajectories basically depict a general trend on how participants presented with depression at baseline and follow up periods. As expected, participants in both groups had varied responses indicating either improvement or worsening of their depressive condition.

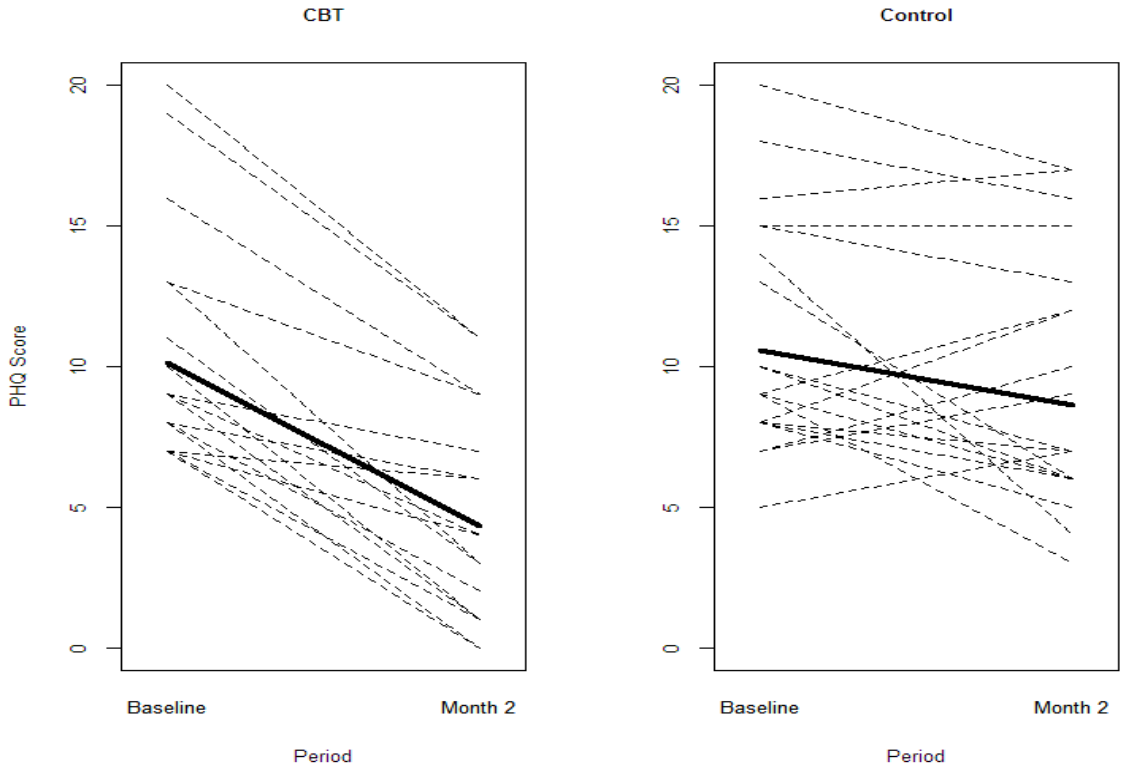


Figure 4. Depression Score Trajectories for the CBT and Control Groups

An assessment of the findings of Figure 4 reveals that depression score trajectories for all participants in the CBT arm had a downward trend from baseline to posttest time points. This is

an indication that PLHIV who participated in CBT were less likely to be depressed due to significant reduction in their depression score which depicts good symptom remission. The graph reveals that there were participants who had similar baseline depression scores but ended up with different depression scores at the month-2 post treatment assessment, an indication that CBT treatment did work differently for each of them. The overall mean trajectory (thick black line) has a downward (negative) slope indicating that generally, the treatment was effective in reducing symptoms of depression among the participants in the CBT cohort. In comparison, PHQ-9 score trajectories show that participants in the control group responded in varied directions. Some had their depression levels reduced while others had higher depression levels at two months posttest assessment. A visual inspection of Figure 4 reveals that there was a downward trend in the overall mean trajectory (thick black line), an indication that though the participants were not on treatment they had an inherent ability to improve their well-being. This could be attributed to either personal resilience or change in situations/circumstances that were triggers for their depression. On the overall, mean trajectory for those who were in the CBT arm was steeper compared to those in the control arm. This shows that there was a higher rate of change among participants in the CBT arm than those in the control arm.

4.3.5 Pre-and Posttest Change in Median Depression Levels by Treatment Arms

Figure 5 presents the results of pre-and post-treatment analysis of change using box plots. The results revealed changes in the median depression scores (thick middle lines in the box) at baseline and at month-2 post treatment in each arm of the study. The median depression at month-2 post intervention among those in the CBT arm, 4.0 (IQR: 1.0, 6.0), was significantly lower than that of the baseline, 9.0 (IQR: 7.3, 12.5), p <.0001. Similarly, the drop in depression levels among participants in the control arm was statistically significant, median depression score at month-2: 6.5 (IQR: 6.0, 12.0) vs. 9.0 (IQR: 8.0, 13.5), p = .021. The significant result noted in the control group was however attributed to the fact that a few participants in the group did experience a sharp decrease in PHQ-9 scores thereby pulling down the group median score.

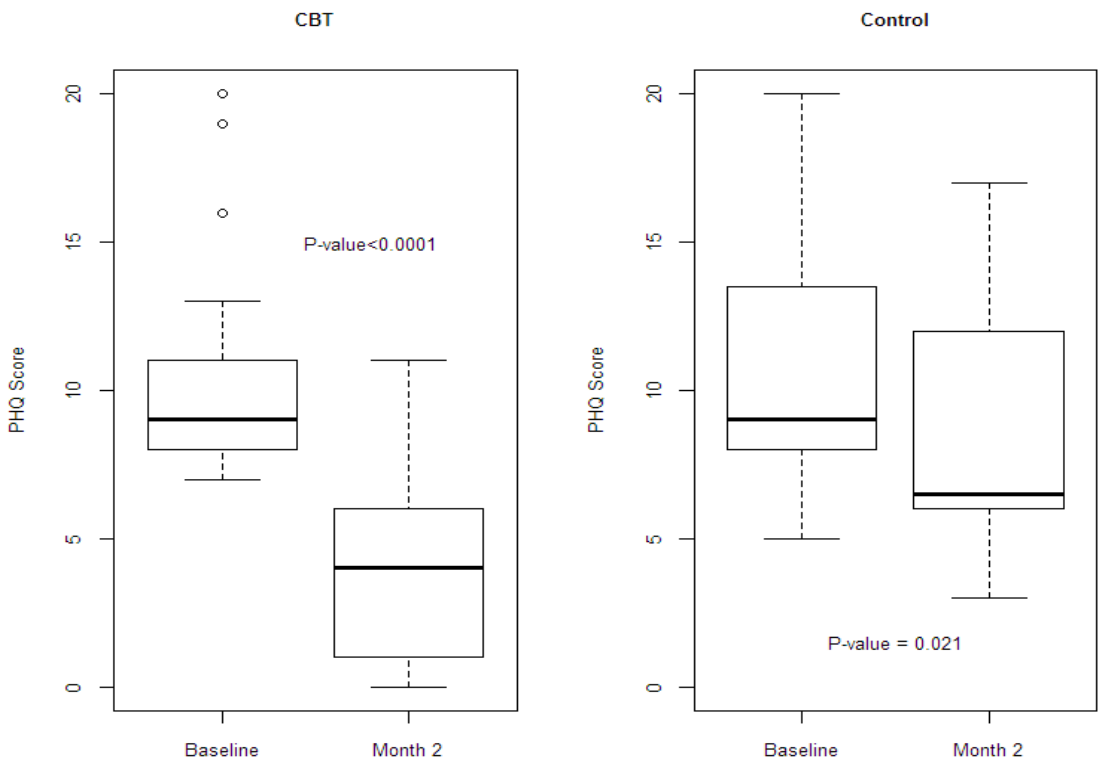


Figure 5. Comparison between Pre- and Post-Treatment Depression Scores for CBT and Control Groups

4.3.6 Modelling the Effect of CBT on Depression Symptoms

Figure 6 presents results of Generalised Estimating Equations (GEE) model that was used to show the effect of CBT on depression. GEE model was considered appropriate for this study because of its flexibility to work with many types of data including continuous and ordinal categorical data. GEE also controlled for pretest measures as covariates in reporting change due to the intervention. From this regression model, the overall mean depression score for the participants in the control arm was 10.65, 95% CI [10.41, 10.89]. Participants in the CBT arm had a lower average by 0.07, 95% CI [-0.27, 0.40] at pre-treatment phase of the study. However, the difference between the two groups was not statistically significant (95% CI, since the mean difference crossed zero). An assessment at two months follow up revealed that the participants in the control arm had lower depression scores by 1.96, 95% CI [0.60, 3.32] in comparison to the baseline. Nevertheless, participants in the CBT arm had a significantly higher mean change in depression scores compared to the control arm, -3.85, 95% CI [-5.61, -2.09]. The trend revealed by the regression model shows that CBT was effective in reducing depression severity among participants in the treatment arm.

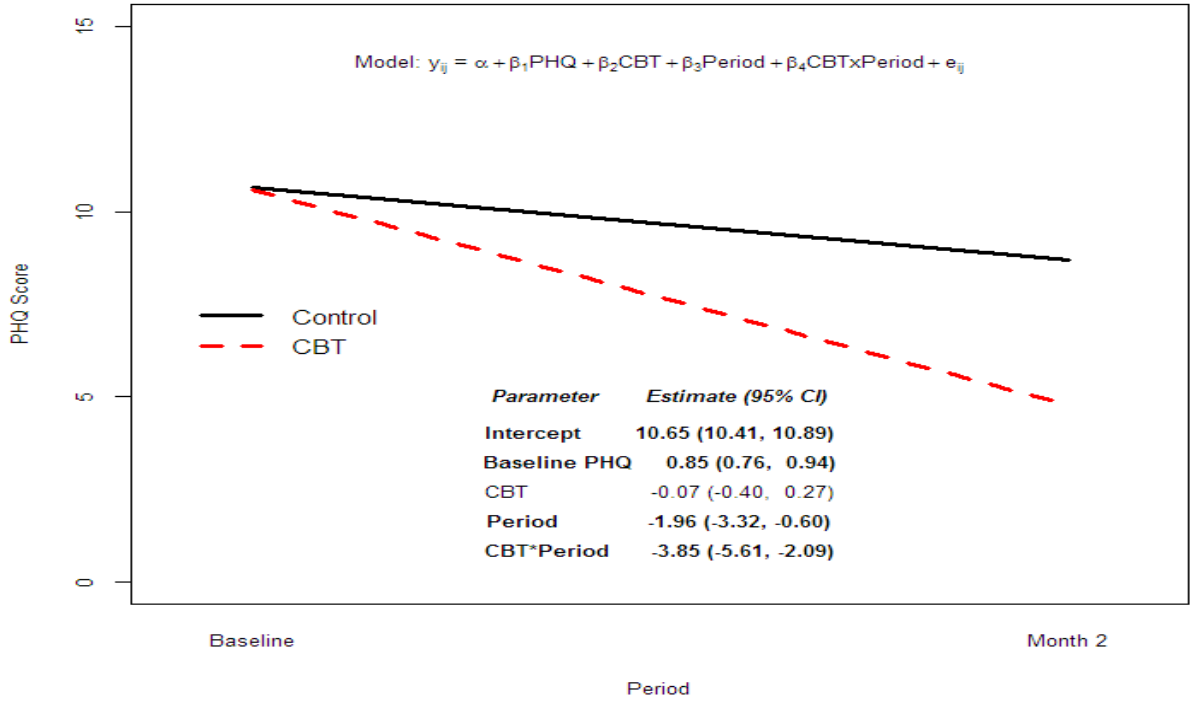


Figure 6. Modelled Effect of CBT on Depression using GEE

The results presented in Figure 6 indicate the magnitude of the effect of CBT intervention on depression severity among participants in the experimental group relative to those in comparison group. The findings reveal that mean PHQ-9 score for the study conditions could be explained at baseline and posttest assessment points using a regression model presented in equation 1.

$Y_{ij} = \alpha + \beta_1 PHQ + \beta_2 CBT + \beta_3 Period + \beta_4 CBT*Period + \varepsilon_{jj}$ ……..equation 1

Where:

Y = Rate of change in PHQ-9 score for depressive symptoms at month-2 posttest

α = Intercept

PHQ = Baseline depression score

CBT = Treatment condition

Period = Predictor time (Baseline = 0, Month-2/follow up =1)

*CBT*Period* = Interaction between treatment condition and time

ε_{ij} = Error effect

4.3.7 Hypothesis Testing and Treatment Effect Size

A non-parametric Mann-Whitney *U* test statistic was used to test the first study hypothesis that, there was no statistically significant difference between CBT and control groups on depression level at posttest. Table 9 presents the results of a two-tailed Mann-Whitney *U* test that was used to establish the difference in depression scores between the two groups at the 2-month post treatment assessment. The results revealed that there was a statistically significant difference between CBT group (*Mdn* = 4.00, *n* = 21) and control group (*Mdn* = 6.50, *n* = 24), *U* = 108, *Z* = -3.305, *p* = .001. From the results, CBT group had a lower overall median score than control group. Lower median score implies that participants in the CBT had a significant reduction in depression severity compared to their counterparts in the control since both groups were deemed equivalent at pre-treatment. The results could also imply that participants who enrolled in CBT programme had a marked positive change from baseline to follow up time point and a significant relief from depression symptoms. Overall, CBT participants had a significantly lower levels of depression as compared to control group participants at posttest. Thus, the null hypothesis was rejected.

Table 9

Results of the Mann Whitney U Test to Compare the Groups' Posttest Depression Symptom Scores

Groups	***N***	**Mean Rank**	**Sum of Ranks**	***U***	***Z***	***p***
Experimental Group	21	29.00	696.00	108.00	-3.305	.001*
Control Group	24	16.14	339.00			

* The difference is significant at $p < .01$

Note. Based on a $\boldsymbol{Z}$ value of 3.305 ($\boldsymbol{N}$ = 45), computed treatment effect size yields, $\boldsymbol{r}$ = .5

To evaluate the strength of the effect of CBT intervention on depression symptomatology among participants in the treatment group in relation to those in the control group, an effect size showing the magnitude of change was calculated at month-2 post intervention. Effect size is the difference between the posttest means of two groups that is, treatment and no-treatment groups divided by the pooled sample of both groups (Hans & Hiller, 2013). To account for variance in depression scores due to CBT intervention at post treatment assessment, both Pearson's *r* and Cohen's *d* were computed. This was done as an objective and standardized way to measure the magnitude of the

observed difference between the groups. Field (2005a) observed that researchers use effect sizes as a means to provide a standardised measure of an importance of an effect, and as an objective way to compare different groups on a specific variable in a study. In the current study, effect size, *r* was calculated by dividing the *Z* value with the square root of the total sample size on which *Z* value was based. From Mann Whitney *U* test and post hoc analysis, a *Z* value of 3.31($N = 45$) and an effect size of, $r = .5$ were obtained. An effect size value of .5 reported in the current study is considered relatively large and sufficient to account for variance due to CBT treatment effect based on Cohen's (1988) criteria of, .1= small effect, .3 = medium effect, and .5 = large effect.

Given that this was an experimental study involving two groups between which a comparison was drawn at posttest, Morris' (2008) formula for computing effect size in pre-and posttest control group design was used to determine and corroborate CBT's effect on depression. The computation yielded a strong effect size, $d_{ppc2} = 1.0$, which conformed to an *r* value of .5. This effect size was statistically significant in favour of CBT over active control group ($p = .001$). Study results suggest that patients treated with CBT for depression in the study improved significantly from pretest to the time when they completed treatment. Most importantly, by computing effect size the researcher was able to control for confounding variables like maturation and remission of symptoms due to passage of time among participants. Such confounding variables are often a common occurrence in experimental studies (Hunsley, Elliot, & Therrien, 2013) and may undermine the accuracy of study outcomes due to overestimation of the true treatment effect size. The study findings are consistent with that of a meta-analysis by Cape *et al*. (2010) on comparing brief psychotherapies (that is, 6-7 sessions) with treatment as usual in a primary care setting which revealed significant effects favouring outpatient CBT for depression ($d = 1.13$).

4.3.8 Discussion on the Outcome of CBT for Depression

In the first research objective, the researcher endeavoured to establish the treatment effect which CBT intervention had on depression among PLHIV in Turbo Sub-county. This was achieved by comparing change in depression score outcome between CBT participants and the untreated control group participants. The study results show that CBT was more effective than control in reducing symptoms of depression and increasing general functioning of HIV-infected patients at month-2 post-treatment assessment. It was established that participants in CBT had significantly lower levels of depression than their counterparts in the control group. This was revealed by a

major drop of 5.8 points on the level of depression severity score from pretest to posttest among CBT participants. The findings on the effectiveness of CBT in reducing depressive symptoms support that of previous studies conducted among HIV-infected population in similar settings (Andersen *et al*., 2016; Safren at al., 2012; Jayasvasti *et al*., 2011). With an average drop of about 6 points in depression scores, 71.4% of participants enrolled in CBT programme were deemed to have moved at least one level down (to a lower category) in the depression severity ladder. This finding implies that patients who participated in the treatment experienced a remarkable remission of depressive symptoms and improvement in mood. The findings of the current study concur with that of a systematic review on psychological interventions for common mental disorders for PLHIV in low- and middle-income countries, which found that CBT was effective in reducing common mental disorders (like depression) symptoms at 6 weeks to 12 months follow-up of study participants (Chibanda, Cowan, Healy, Abas, & Lund, 2015). The trend observed in the current study is vital in recommending the use of CBT as an effective psychotherapy for depression treatment in a busy HIV-outpatient clinic in the peri-urban setting of western Kenya.

The study results further revealed that all patients that participated in the CBT treatment had some positive change in depression severity though at varied levels. At posttest, CBT participants reported a drop in PHQ-9 score ranging from -1 to -10 points in the scoring continuum. A drop in PHQ-9 score is an indicator of positive improvement on participant's depressive status. Change in depression scores for participants in the CBT group from pretest to postest is depicted in Figure 7.

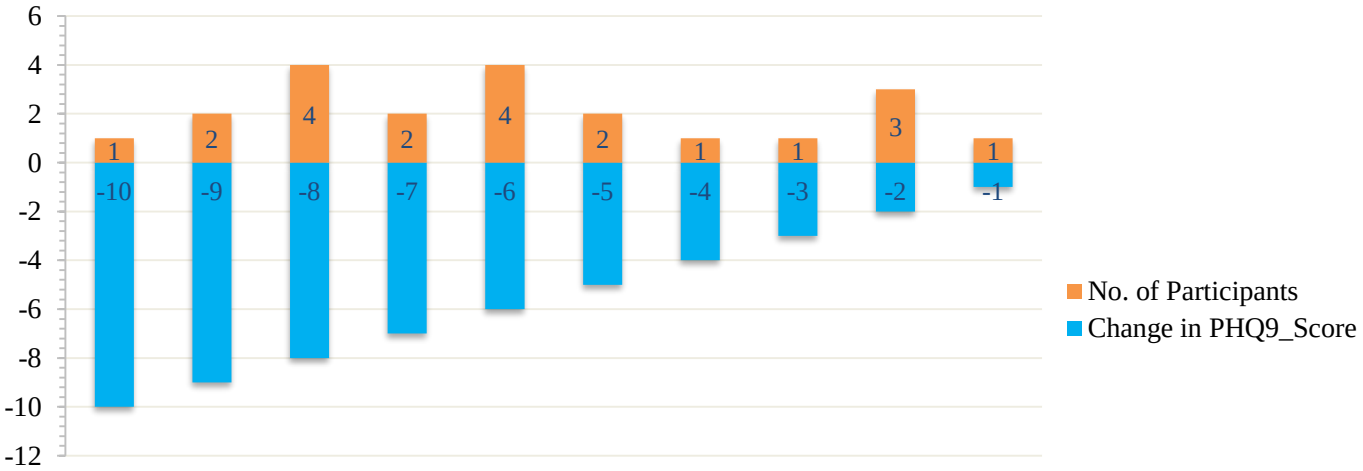


Figure 7. Change in PHQ-9 Scores for CBT from Baseline to Posttest

The observed difference in PHQ scores at posttest explains the unique way in which patients responded to the treatment. The varied responses could partly be attributed to participants' level of education which as expected might have influenced the pace at which they grasped the key concepts of CBT. Overtime, it has been observed that CBT may only work well with people of average intellectual capacity. Client's level of education in the application of CBT intervention has been correlated with intellectual capacity and abstract thinking (Epstein *et al*., 1988). Results of the current study revealed that a majority of participants had an average of 10 years of formal education which may be considered reasonable for logical thinking. Difficulty in thinking conceptually may present as an impediment to the therapeutic process and limit the efficacy of CBT techniques, particularly for clients with low intellectual capacity and/or with rigid thought processes (Epstein *et al*., 1988). The varied response to CBT could also be explained in terms of participants' ability to internalise intervention principles responsible for mediating change in depression levels. Just like previous authors (Sanders & Wills, 2005), the researcher noted that clients may report a good understanding of the principles of CBT on an intellectual level, but may not seem to apply them in real life situation in a way that promotes practical change. Nevertheless, study findings showed a positive treatment outcome in favour of CBT for depression thus suggesting that the intervention may be adopted locally as an effective psychotherapy among HIV-infected patients with average level of education.

In line with the conceptual framework upon which the study was embedded and in the context of the study findings, CBT intervention seemingly had a demonstrable significance of providing a viable, less costly, brief and effective treatment for depression in PLHIV who might not access and afford the cost of pharmacological intervention. In the current case, CBT delivered by psychotherapists may present the advantage of being a better alternative to psychiatric intervention given that Kenya like other less developed countries faces serious shortage of psychiatrists. Presently, there are only 54 practising psychiatrists in Kenya against a population of 43 million people of whom 4% suffer from serious mental illnesses (Marangu, Sands, Rolley, Ndetei, & Mansouri, 2014; Ndetei *et al*., 2009). Moreover, all the 54 Kenyan psychiatrists are based in health facilities and institutions found exclusively in major urban settings far beyond the reach of depressed PLHIV seeking treatment in primary health care outpatient clinics. Furthermore, the notable change reported in the experimental group at the two months posttest has the value of elucidating the clinical significance of CBT to alleviate depression and consequently making

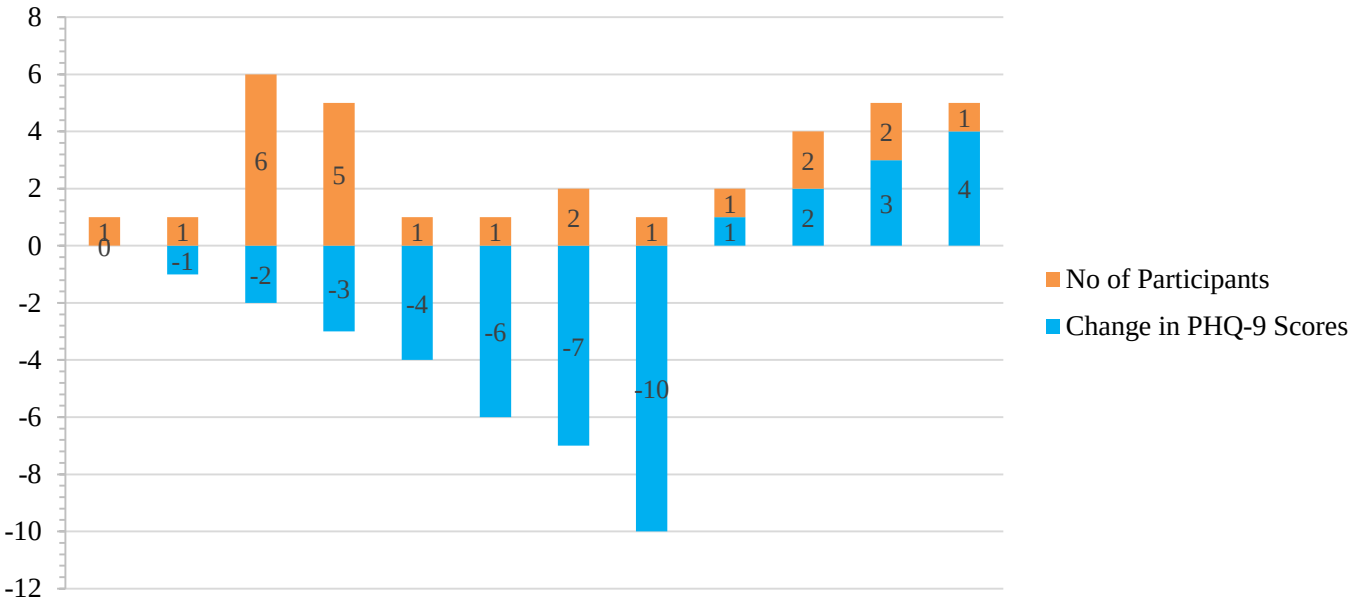
PLHIV experience improvements in emotional wellbeing. These findings are consistent with those of related studies conducted in South Africa which concluded that all participants exposed to CBT intervention showed significant reductions in depressive symptoms combined with improvements in functioning and quality of life at post-treatment phase (Andersen, 2009; Andersen *et al*., 2016).

The treatment effect size reported in Table 9, $r = .5$ (or $d = 1.0$) which corresponds to a large effect size of CBT for depression at posttest assessment was surprisingly unprecedented. Previous studies conducted among different patient populations scarcely reported effect sizes of such magnitude for CBT at the critical month-2 post-treatment assessment. The study findings contrast that of a meta-analysis and meta-regression done by Cape *at al.* (2010) which found that CBT for depression only had a minimal effect size at posttest (d -0.33, 95% CI -0.6 to -0.06), and that of van Straten, Geraedts, Verdonck-de Leeuw, Andersson, and Cuijpers, (2010) which found that CBT intervention only had a small effect in the treatment of depression. Relatively, the study findings are in tandem with that of Butler *et al.* (2006) which found large effect sizes for CBT in the treatment of depression; and somewhat consistent with that of Himelhoch, Medoff, and Oyeniyi (2007) on efficacy of group CBT to reduce depressive symptoms among HIV-infected individuals which reported a significant pooled effect size for group CBT of 0.18–0.56 (95% CI).

Of interest to note is that the large effect size reported in the current study may be an indication that participants adequately responded to the intervention and thus emphasised the fact that a considerable proportion of clients usually respond to CBT within the first few sessions of therapy as previously observed (Miller & Berman, 1983; Elkin *et al*., 1989). This experimental large treatment effect size could also validate CBT as evidence-based psychotherapy for depression with a high potential for application and replication in both research and clinical settings at the local and regional levels.

The study results also revealed that on average, participants in the control group reported a drop of 1.9 points in PHQ-9 scores at posttest with only 4 out of 24 participants recording a drop of $\geq$ -5 points as shown in Figure 8. Though marginally significant, this reduction in score on depression symptoms severity among participants in control group at the two months posttest assessment only favoured a few individuals. The findings imply that only 16.7% of participants in the control group could be deemed to have moved to a lower level of depression severity which required a drop of at least 5 points based on the PHQ-9 scoring cut-offs (Spitzer *et al*., 1999). The

improvement noted in control group could possibly be attributed to either personal attributes of psychological resilience, passage of time and/or change in situations which did constitute the triggers for their depression. Change in depression scores reported in Figure 8 shows that participants in the control group had mixed outcomes in their depressive status. Some participants had positive and others negative change in PHQ-9 scores. The positive change in depression score implied a deteriorating depressive condition and vice versa for the negative score at posttest assessment.



Note. Change in PHQ-9 score is the difference between posttest and pretest depression scores

Figure 8. Change in PHQ-9 Scores for Control Group from Pre-to-Posttest

Comparatively, the study established that CBT intervention was superior to control group in reducing symptoms of depression at post treatment assessment as demonstrated by the proportion of participants who reported a drop of at least 5 points in PHQ-9 score, 71.4% (CBT) vs. 16.7% (control) as presented in Table 8. This outcome compares favourably with the findings reported in previous studies across diverse settings (Gloaguen *et al*., 1998; Hollon *et al*., 2005; Wilson *et al*., 2008; Beltman *et al*., 2010; & McHugh *et al*., 2013). Current findings offer suggestive evidence to consider CBT as an acceptable treatment option within the local primary health care setting

where patients are usually limited to pharmacotherapy as a singular treatment for depression. And as observed, there is cause to believe that local patients may benefit from CBT delivered by professional therapist just as much as they could from the use of antidepressants since the two options have been found to have similar effect on depression in studies comparing pharmacotherapy with CBT (Vos, Haby, Barendregt, Kruijshaar, Corry, & Andrews, 2004). Additionally, CBT has been recognised for being as effective and with more long lasting effects than medication in the management and treatment of depression (Hollon *et al*., 2005; McHugh *et al*., 2013). For depressed PLHIV seeking care in the local primary health care settings, CBT presents the advantage of being a cheaper and easily accessible treatment option. In addition, CBT offers the much needed alternative to the use of antidepressants for depression which could cause adverse side effects due to drug interaction for patients already on antiretroviral drugs (Gibson *et al*., 2014).

4.4 Effect of Cognitive Behavioural Therapy on Antiretroviral Treatment Adherence

This section presents the findings on the second objective of the study that tests the hypothesis which sought to establish if there was any significant difference in the degree of ART adherence between participants enrolled in CBT and their counterparts in the control group consequent to study intervention. Firstly, the section describes the trend of change in the degree of adherence to ART from pre-intervention to post-intervention phase of the study. Second, a comparison is drawn between the treatment group (CBT) and the control group using inferential statistics to allow for determination of treatment effect size and hypothesis testing. Finally, the section presents the results of logistic regression used to model the effect of CBT on enhancing ART adherence and discussion on the overall findings on CBT for antiretroviral therapy.

4.4.1 Comparison of ART Adherence at Pre-Treatment between CBT and Control arms

To establish if there were any inherent differences in antiretroviral treatment adherence between participants enrolled in CBT and those in the control group of the study at post-randomisation, descriptive statistics were used to summarize general findings on degree of adherence. Adherence levels were assessed using *Patient Adherence Record* (a combination of self-reporting and visual analogue scale) and the aggregate scores categorized into three (3) levels; High (≥ 95%), Moderate (75-94%), Low (< 75%). To assess for the difference between the two groups, Fisher's exact test

was performed since Pearson Chi Square test assumptions were violated and statistical test results presented in Table 10.

Table 10

Pretest Antiretroviral Treatment Assessment for Control and Experimental Groups

Variable	**Category**	**Control (n =27)**	**CBT (n =26)**	***P*(95%CI)**
Antiretroviral Treatment (ART) adherence	Low	10 (37.1%)	7 (26.9%)	0.714[f]
	Moderate	5 (18.5%)	6 (23.1%)	
	High	12 (44.4%)	13 (50.0%)	

Note. [f] = Fisher' exact test, not significant since $p > .05$

As is evident from Table 10, there was no statistically significant difference in ART adherence rates between participants enrolled in control and experimental groups ($p = .714$) at pre-treatment. It was also clear from the descriptive statistics that majority of the participants (CBT = 50% and Control = 55.6%) had sub-optimal adherence to ART at pretest. Such observations could imply that a huge proportion of HIV-infected persons seeking clinical care at Turbo Sub-County Hospital might not be getting maximum benefit from their ARV medications. This unfortunate occurrence among this cohort of patients could perhaps be attributed to the presence of depression as a comorbid condition to HIV infection since all study participants had a diagnosis of some degree of depression. In comparison, it should be noted that non-adherence to drugs is not unique to patients in the current study but rather it is a common phenomenon globally. Poor adherence to medication has been seen in many cases of chronic diseases involving patients from developing countries like Kenya where adherence rates are thought to be lower than that of developed countries which averages 50% for chronic illnesses (WHO, 2003).

The study findings further revealed that up to 34% of the participants had experienced some difficulty in remembering their medication, and half (50%) of the participants had missed some doses of their medicines in the last 30 days. Nevertheless, none of the participants took a break from their medication. The results confirm the findings of other studies which have shown that more than 10% of patients report missing one or more medication doses on any given day, and

more than 33% report missing doses in the past two to four weeks (Chesney, 2000). Non-adherence to ART coupled with clinical depression may lead to certain adverse health outcomes like higher viral loads and lower CD4 counts among HIV positive individuals (Leserman, 2008). Thus, it is vitally important that HIV positive patients adhere to medication since successful viral suppression requires close to 95% adherence to ART (Chesney, 2003).

Poor adherence to ART and lack of retention in HIV care among PLHIV emerge as fundamentally widespread challenges in sub-Saharan Africa where only 67% of those active in care show optimal adherence levels (Ortego *et al*., 2011) and only 60% of people are retained in care one year after ART initiation (Nachega *et al*., 2010). This observation renders it obvious that many patients in the region could be experiencing difficulty in following their treatment regimen. Furthermore, literature reviewed on antiretroviral therapy reveals that levels of adherence to ARV medication usually varies between 37 and 83 percent, depending on the drug under study (Stein, Rich, & Maksad, 2000). The trend observed in the current study regarding ART adherence is in tandem with the aforementioned range of statistics (between 37% and 83%) on the degree of adherence. It is important to note that non-adherence in the current study was taken to mean missed dose(s) for a timeframe spanning more than 2 days in a month. However, in the strict sense of its definition, non-adherence means not taking medications at prescribed time intervals, and non-compliance to dosing instructions regarding dietary or fluid intake (Paterson, Swindells, & Mohr, 2000).

As mentioned earlier, non-adherence to medication among PLHIV is an obstinately persistent problem which ART programmes face in diverse settings with as many patients being reported as lost to follow up on any given occasion. Recent studies have observed that about 40% of patients usually go unaccounted for three years after starting ARVs (Odindo & Mwanthi, 2008; Mayston *et al*., 2012). This hapless phenomenon could pose a serious threat to the war against HIV and therefore requires urgent remediation. Part of the intervention measures which may help stem the problem of lost to follow up in care might include the use of psychotherapy. Psychological intervention comes in handy since ART adherence is a learnt behaviour (Steel *et al*., 2007) which must be consistently sustained overtime otherwise it may wane with time if not well reinforced. As established in the study, CBT could be one of the critical intervention strategies that may help PLHIV remain active in care since it is founded on theoretical orientations which are accredited for behaviour change and reinforcement.

4.4.2 ART Adherence at Post-Treatment

Table 11 presents results of ART adherence across the treatment arms at two months posttest assessment. Participants assessed in the analysis were, $n = 46$ after filtering out non-completers (8 participants). Participants in both control and the CBT arms demonstrated some change in the degree of adherence to ART treatment. There was an increase in the proportion of participants who attained moderate level of adherence from 20.8% at baseline to 33.33% at month 2 follow up among those in the control arm (that is, adherence level of 75-94%). Similarly, there was an increase in the proportion of participants who attained ≥95% adherence level from 45.5% at baseline to 76.2% at month 2 in the CBT arm. Overall, there were 10 (22.2%) participants who transitioned from a lower adherence level to a higher adherence level. The CBT arm had a significantly higher rate of transition, 7 (30.0%), compared to the control arm, 3 (12.5%), $p = .030$. Notably, the study findings revealed that there was an upward trend in the proportion of participants who attained optimal adherence to antiretroviral treatment. However, the gain was only reported among participants in the intervention group (30.7% increase). In comparison, the control group did not register any significant difference in the degree of optimal adherence to ART at month-2 post treatment assessment.

Table 11

Adherence Level across Time Stratified by the Treatment Arms

Adherence level	**Control (*n* = 24)**		**CBT (*n* = 21)**	
	Baseline	**Month 2**	**Baseline**	**Month 2**
Low	9 (37.5%)	6 (25.0%)	6 (27.3%)	0 (0.0%)
Moderate	5 (20.8%)	8 (33.3%)	6 (27.3%)	5 (23.8%)
High	10 (41.7%)	10 (41.7%)	10 (45.5%)	16 (76.2%)
Total	24 (100.0%)	24 (100.0%)	22 (100.0%)	21 (100.0%)

4.4.3 Effect of CBT on Antiretroviral Treatment Adherence and Hypothesis Testing

4.4.3.1 Effect of CBT on Enhancing Medication Adherence

To establish the effect of CBT intervention on the degree of adherence to ARV medication among study participants, an assessment on transition from one lower level of adherence to a higher one was conducted using ordinal logistic regression model and the results presented in Table 12.

Table 12

Ordinal Logistic Regression Model Assessing the Effect of CBT on Adherence Levels

Parameter	***β*(95%*CI*)**	***SE***	***OR***	***P***
Intercept1	-0.52(-1.35, 0.32)	0.43	-	0.226
Intercept2	0.77(-0.03, 1.57)	0.41	-	0.058
CBT	0.87(-0.13, 1.87)	0.51	2.39 (0.87, 6.59)	0.089
Time	0.76(0.27, 1.24)	0.25	2.14 (1.31, 3.46)	0.002*

Note. β, coefficients; * Significant at $p < .01$

An examination of findings in Table 12 reveals that the rate of ART adherence across all the levels of ART adherence was not significantly different between the control and CBT arms at baseline, *OR* = 2.39, 95% CI [0.87, 6.59]. However, at month two post treatment assessment, the rate of transition from a lower level of ART adherence to a higher level among participants in the CBT arm was statistically significant, *OR* = 2.14, 95% CI [1.31, 3.46]. That is, at month-2 post treatment assessment, there was a twofold improvement in the ART adherence level among participants in CBT. The findings show that CBT for medication adherence was more effective at helping participants transition to a higher level of adherence than the control group.

4.4.3.2 CBT Treatment Effect Size(r)

Table 13 shows the results of an inferential statistical analysis that was used to test the second hypothesis, that there was no statistically significant difference between CBT and control groups on ART adherence level at posttest. The effect of treatment on ART adherence was assessed and a Mann-Whitney *U* test revealed a statistically significant difference in the ART adherence levels between CBT participants (*Md* = 4.76, *n* = 21) and control group participants (*Md* =4.04, *n* =24),

U = 150, Z = -2.62, p = .009. In addition, post hoc analysis findings revealed that CBT had a treatment effect size of, r = .4 (d = .85) which was considered a medium effect size using Cohen (1988) criteria of .1=small effect, .3=medium effect, .5=large effect. Study findings in Table 13 confirmed that the significant difference between CBT and control groups on adherence levels at posttest was as a result of CBT intervention, and that the reported difference was not due to chance. Thus, it was concluded that there was a statistically significant difference between CBT and control groups on ART adherence level, and the null hypothesis rejected.

Table 13

Results of the Mann Whitney U Test to Compare the Groups' Posttest ART Adherence Level

Groups	***N***	**Mean Rank**	**Sum of Ranks**	***U***	***Z***	***p***
Experimental Group	21	27.86	585.00	150.00	-2.623	.009*
Control Group	24	18.75	450.00			

* The difference is significant at $p < .05$ or $p < .01$

Note. Based on a ***Z*** value of 2.623 (***N*** = 45), computed treatment effect size yields, ***r*** = .4

4.4.3.3 Comparison of experimental and control groups on ART optimal adherence at posttest

Table 14 presents the results of statistical analysis comparing CBT and control programmes on the effectiveness to enhance optimal adherence to ART. The results established that at month two follow up, a significantly higher proportion of participants in the CBT arm of the study (76.2%) had optimal ART adherence level of 95% and above compared to those in the control arm (41.7%), OR = 3.7, 95% CI [1.1, 12.9]. Pearson's Chi square test revealed a statistically significant difference between CBT and control groups (p = .034). Study findings provide a quantitative evidence in favour of CBT as an effective psychological intervention which may be adopted to enhance the degree of medication adherence among PLHIV enrolled in ART programmes in the outpatient primary healthcare clinics of western Kenya region.

Table 14

Comparison of Optimal ART Adherence at Posttest between CBT and Control Arms

Variable	Category	Control	CBT	Total	*P* (95%CI)
ARV	No	14 (58.3%)	5 (23.8%)	19 (43.5%)	
adherence	Yes	10 (41.7%)	16 (76.2%)	26 (56.5%)	0.034*
>95%	Total	24 (52.2%)	21 (47.8%)	46 (100.0%)	

*Significant at p< .05

Note. Optimal adherence means taking ≥95% of monthly prescribed medication

4.4.4 Discussion on the Outcome of CBT for ART Adherence

Study findings established that CBT intervention had a significant effect of increasing the degree of ART adherence among HIV-infected adults seeking care in Turbo Sub-County Hospital. This observation may support the view by Steel *et al.* (2007) that ART adherence is a learnt behaviour which may wane with time and therefore requires targeted intervention to help maintain optimal adherence. CBT is globally recognised for helping individuals learn healthier skills and habits that give yield to more adaptive behaviours like adherence to antiretroviral treatment. Thus, the study findings are crucial in presenting CBT as a behaviour change intervention with an evidence base for enhancing ART adherence and potential to help keep PLHIV in active care as well as ensuring optimal adherence to medication.

With regard to the study results on the treatment effect size of CBT for ART adherence, it was found that CBT intervention delivered in a brief group therapy format was significantly effective at the critical 2-month post-treatment assessment. The treatment effect size of $r = .4$ or $d = .85$ reported in the study has the implication that CBT intervention had a critical medium effect on improving patients' behaviour to adhere to medication. Most importantly, this behaviour change among CBT participants was manifestly sustained at the two-month outcome assessment thus signifying the potential and suitability of CBT for ART adherence in a primary care setting. This finding is consistent with that of Safren *et al*. (2009) which established that individuals who received CBT demonstrated much greater improvements in adherence to treatment, and that the treatment gains were generally maintained at post-treatment assessments. The current study also established that CBT was a superior intervention compared to the untreated control in enhancing

medication adherence among PLHIV at posttest assessment. This finding is in concurrence with that of a previous study which found that at the 3-months outcome assessment participants who received cognitive behavioural therapy exhibited significantly greater improvements in medication adherence relative to the comparison group (Safren *et al*., 2009).

The study findings that CBT may offer a solution to poor medication adherence among PLHIV in the local setting bears the significance of giving hope to many care providers in the ART programmes. Currently, data on ART uptake reveal that on the overall 60.5% of all HIV-infected adults and adolescents in Kenya enrolled to ART are on medication (NACC & NASCOP, 2014). This means that more patients are expected to be enrolled in ART programmes across the country, and with increase in enrolment on ART, more patients will be expected to remain on ARVs for life. And as expected, optimal adherence to medication among PLHIV enrolled in ART is of utmost importance in the provision of care, and disease management. Antiretroviral drugs are known for their value in sustaining individuals in good health conditions thereby yielding longevity to PLHIV. Good adherence to ART is known to lengthen and revitalize life in persons affected by the HIV epidemic (Thames *et al*., 2012; Babson, Heinz, & Bonn-miller, 2013). Most importantly, antiretroviral treatment adherence is one of the key mechanisms that help delay the emergence of resistant strains of the virus and enhances durability of the current regimens (Steel, *et al*., 2007). In like manner, it should be noted that the wellbeing of a person living with HIV is correlated with high levels of ART adherence of more than 90-95%. It has been estimated that a very high level (95%) of adherence to antiretroviral therapy must be attained for optimal effectiveness of the drugs to be realised in the body (Paterson *et al*., 2000). The current study is vitally important in elucidating the use of CBT as a quantitatively validated psychotherapy for ART adherence in the local primary care setting.

The quest to find a solution to poor adherence is supported by the World Health Organization's (WHO, 2011) report that if an HIV-positive person adheres to an effective ART regimen, the risk of transmitting the virus to their uninfected sexual partner can be reduced by 96%. Thus, the use of ART is not only important in suppressing the replication of the virus in the human body but it also reduces significantly the transmission risk of HIV between sexual partners. The power of ART is in how it works when treatment regimen is optimally followed. ART works by reducing HIV viral load and increasing CD4 cells count as well as delaying the HIV clinical staging to AIDS

stage thus reducing mortality (Egger *et al*., 2002; Wood *et al*., 2004a). A survey done by Kenya' Ministry of Health (NACC & NASCOP, 2014) reported a higher correlation between ART adherence and viral load suppression. The report indicated that persons living with HIV adhering to ART had a 78.5 % rate of viral load suppression (defined as ≤1,000 copies/ml). However, as revealed in the study, non-adherence still remains a major concern among PLHIV since only 76.2% and 41.7% of participants in CBT and control groups respectively had optimal ART adherence as shown in Table 14. These findings present the challenge that a non-adherent patient may become vulnerable to drug resistance, and perhaps spread such resistant strains through sexual contact even to HIV negative individuals as has been observed before (Akena *et al.*, 2013; Vlahov & Celentano, 2006; Wainberg & Friedland, 1998).

ART adherence trends reported among the study participants are of lower proportions (CBT, 76.2% and Control, 41.7%) compared to the general population of HIV infected persons on ART in Kenya. The Kenya AIDS Indicator Survey of 2014 reported an average adherence rate of 83.7% for the past 30 days (NACC & NASCOP, 2014). The low adherence rates revealed by the study could generally be attributed to the interplay between depression and adherence. Depression is known for its tendency to compromise adherence to antiretroviral therapy since it often renders its victims lethargic to routines like taking medication daily. A meta-analysis published in 2011 established strong links between depression and poorer adherence to ART across all populations affected by HIV, in both developed and less developed settings (Gonzalez, Batchelder, Psaros, & Safren, 2011).

The study findings on the effect of CBT on ART optimal adherence was significantly noticeable with more participants enrolled in CBT moving from low levels of adherence to higher levels. The degree of change revealed in the study portrays CBT as an effective intervention for poor adherence to medication among PLHIV in resource-poor primary care settings. And even though there is not a single behavioural intervention that has been established as the gold standard for improving ART adherence in Kenya among HIV-infected population, a few studies have demonstrated CBT as a behaviour change intervention among PLHIV (Papas *et al*., 2010; Papas *et al*., 2011).

In sum, the current study was intended to investigate the effectiveness of CBT intervention to enhance HIV medication adherence delivered in a group format within a primary care clinic for

HIV positive adults living in a large peri-urban area. The study findings revealed more favourable outcomes for CBT than control. On the effectiveness of CBT interventions for antiretroviral treatment adherence, the study found a treatment effect size of medium proportion. This is fairly consistent with findings from meta-analytic reviews on CBT for ART adherence which found that the treatment had between small to medium effect sizes at post-treatment assessment (Amico, Harman, & Johnson, 2006; Simoni, Pearson, Pantalone, Marks, & Crepaz, 2006). The study findings provide hope in the use of CBT as an effective behavioural intervention for improving ART adherence in the local HIV-outpatient clinics just like in other settings including the United States (Koenig *et al*., 2008; Simoni *et al*., 2009). Evidently, the study portrayed CBT intervention an effective and a feasible therapy model that could be integrated into primary HIV care in Kenya to help buttress ART adherence among PLHIV. To this end, CBT may be of great clinical significance to ART care programmes in Kenya following the release of new ART guidelines which stipulates that all persons newly diagnosed with HIV must be initiated on ART upon enrolment and sustained in care for long term (MoH/NASCOP, 2016).

4.5 Effect of Cognitive Behavioural Therapy on HIV/AIDS-related Stigma

This section presents the findings on the third objective of the study that tested the hypothesis which sought to establish if there was any significant difference in the level of HIV stigma between participants enrolled in CBT and their counterparts in the control group consequent to study intervention. Thus, the section describes the trend of change in levels of stigma from pretest to posttest phase of the study. In addition, a comparison is drawn between CBT group and control group using inferential statistics, and a regression model showing the effect of CBT on stigma level is presented.

4.5.1 Baseline Assessment of HIV/AIDS Stigma among the Study Participants

HIV/AIDS stigma description was on a 4 point Likert-type scale ranging from strongly disagree (1) to strongly agree (4). Participants were asked to indicate the extent to which they agreed with the scale items. To assess the level of stigma, descriptive statistics were used to summarize general findings on the magnitude of all stigma items at baseline. Overall, the results of descriptive statistics presented in Table 15 revealed that 62.3% of the participants did not agree that being HIV positive made them feel dirty, up to 86.8% felt no shame because of their HIV status, and another 86.8% did not agree that they were guilty because of being HIV positive. More than a quarter of the participants (28.3%) felt worthless because they were HIV positive, and 50% of them hide their HIV status from others. Up to 11.3% of the participants felt that people with HIV/AIDs were cursed, and another 11.3% felt it difficult to tell people about their HIV infection. Less than 10% of the participants thought that people with AIDS should expect some restrictions on their freedom, and another 18.9% thought that people who have HIV should be isolated.

Table 15

Baseline Assessment of HIV/AIDS Stigma among the Study Participants

Variable	Response	n (%)
Being HIV positive makes me feel dirty	Strongly disagree	26 (49.1%)
	Disagree	7 (13.2%)
	Agree	13 (24.5%)
	Strongly agree	7 (13.2%)
I am ashamed that I am HIV positive	Strongly disagree	38 (71.7%)
	Disagree	8 (15.1%)
	Agree	5 (9.4%)
	Strongly agree	2 (3.8%)
I feel guilty that I am HIV positive	Strongly disagree	43 (81.1%)
	Disagree	3 (5.7%)
	Agree	2 (3.8%)
	Strongly agree	5 (9.4%)
I sometimes feel worthless because I am HIV positive	Strongly disagree	37 (69.8%)
	Disagree	1 (1.9%)
	Agree	10 (18.9%)
	Strongly agree	5 (9.4%)
I hide my HIV status from others	Strongly disagree	23 (44.2%)
	Disagree	3 (5.8%)
	Agree	11 (21.2%)
	Strongly agree	15 (28.8%)
People who have AIDS are cursed	Strongly disagree	45 (84.9%)
	Disagree	2 (3.8%)
	Agree	4 (7.5%)
	Strongly agree	2 (3.8%)
It is difficult to tell people about my HIV infection	Strongly disagree	44 (83.0%)
	Disagree	2 (3.8%)
	Agree	3 (7.5%)
	Strongly agree	3 (5.7%)
People who have AIDS must expect some restrictions on their freedom	Strongly disagree	47 (88.7%)
	Disagree	2 (3.8%)
	Agree	2 (3.8%)
	Strongly agree	2 (3.8%)
People who have HIV should be isolated	Strongly disagree	41 (77.4%)
	Disagree	2 (3.8%)
	Agree	6 (11.3%)
	Strongly agree	4 (7.5%)

4.5.1.1 Baseline Assessment of HIV/AIDS Stigma across the Study Arms

Tables 16 presents the results on HIV stigma stratified as enacted and internalised for both arms of the study. A comparison of the baseline scores across the treatment arms did not reveal any significant differences except for the item assessing whether the participants hide their HIV status from others. The results showed that the participants in the control arm were more likely to agree with hiding their status from others compared to the CBT arm, $p = .04$. Of the 53 participants enrolled in the study, 8 (15.1%) became lost to follow up. There was no statistically significant difference in the proportion of participants lost in both arms, 3(CBT) vs. 5(control), $p = .467$. Participants in both groups were considered equivalent at baseline thus providing a good statistical basis to conduct a pre- and-posttest assessments and to draw conclusion on treatment outcomes.

Table 16

Pretest Assessment of HIV/AIDS Stigma across the Treatment Arms

Variable		Control, 27 (50.9%)	CBT, 26 (49.1%)	Fisher's exact P
Internalized stigma				
Being HIV positive makes me feel dirty	Strongly disagree	12 (44.4%)	14 (53.8%)	
	Disagree	4 (14.8%)	3 (11.5%)	0.800
	Agree	8 (29.6%)	5 (19.2%)	
	Strongly agree	3 (11.1%)	4 (15.4%)	
I am ashamed that I am HIV positive	Strongly disagree	20 (74.1%)	18 (69.2%)	
	Disagree	4 (14.8%)	4 (15.4%)	0.900
	Agree	2 (7.4%)	3 (11.5%)	
	Strongly agree	1 (3.7%)	1 (3.8%)	
I feel guilty that I am HIV positive	Strongly disagree	21 (77.8%)	22 (84.6%)	
	Disagree	1 (3.7%)	2 (7.7%)	0.700
	Agree	1 (3.7%)	1 (3.8%)	
	Strongly agree	4 (14.8%)	1 (3.8%)	
I sometimes feel worthless because I am HIV positive	Strongly disagree	17 (63.0%)	20 (76.9%)	
	Disagree	1 (3.7%)	0 (0.0%)	0.700
	Agree	6 (22.2%)	4 (15.4%)	
	Strongly agree	3 (11.1%)	2 (7.7%)	
I hide my HIV status from others	Strongly disagree	8 (29.6%)	15 (60.0%)	
	Disagree	1 (3.7%)	2 (8.0%)	0.040
	Agree	6 (22.2%)	5 (20.0%)	
	Strongly agree	12 (44.4%)	3 (12.0%)	
Enacted Stigma				
People who have AIDS are cursed	Strongly disagree	21 (77.8%)	24 (92.3%)	
	Disagree	2 (7.4%)	0 (0.0%)	0.300
	Agree	2 (7.4%)	2 (7.7%)	
	Strongly agree	2 (7.4%)	0 (0.0%)	
It is difficult to tell people about my HIV infection	Strongly disagree	21 (77.8%)	23 (88.5%)	
	Disagree	1 (3.7%)	1 (3.8%)	0.800
	Agree	3 (11.1%)	1 (3.8%)	
	Strongly agree	2 (7.4%)	1 (3.8%)	
People who have AIDS must expect some restrictions on their freedom	Strongly disagree	23 (85.2%)	24 (92.3%)	
	Disagree	1 (3.7%)	1 (3.8%)	0.900
	Agree	1 (3.7%)	1 (3.8%)	
	Strongly agree	2 (7.4%)	0 (0.0%)	
People who have HIV should be isolated	Strongly disagree	18 (66.7%)	23 (88.5%)	
	Disagree	1 (3.7%)	1 (3.8%)	0.100
	Agree	4 (14.8%)	2 (7.7%)	
	Strongly agree	4 (14.8%)	0 (0.0%)	

Note. Strongly disagree=1, disagree = 2, agree = 3, strongly disagree = 4

4.5.2 Post -Treatment Assessment of HIV Stigma by Treatment Arms

Table 17 presents the results of post-treatment stigma scores disaggregated by stigma type for both CBT and control arms of the study. Stigma is usually categorised based on the direction and perspective of how it is interpreted. Enacted stigma is perceived from the perspective of the non-affected person whereas internalised stigma is perceived from the perspective of the affected person (Rensen, Bandyopadhyay, Gopal, & Van Brakel, 2010). These two aspects of stigma are usually interconnected and may have an effect on the self-efficacy, community participation, personal well-being and self-esteem of the affected person (Katz *et al*., 2013).

There were five items within the HIV/AIDS stigma scale that targeted internalised stigma and four items for enacted stigma as presented previously in Table 16. The results of Fisher's Exact Test presented in Table 17 show that there was a statistically significant difference between PLHIV who participated in the CBT intervention and those in the control arm, in their perception and feeling about being HIV positive at the 2-months outcome assessment. Study participants in the CBT intervention were more likely to disagree that being HIV positive made them feel dirty, $p = .043$. They were also more likely to disagree that they were ashamed of their HIV status, $p = .044$. Moreover, participants in the CBT arm no longer found it difficult to tell people about their HIV status, $p = .029$, and they were more likely to disagree that people with HIV should be isolated, $p = .023$. Though not statistically significant, the participants in the CBT arm were less likely to feel guilty of their HIV status, less likely to hide their status from others, less likely to perceive that people with HIV are cursed, and less likely to expect people with AIDS to have restricted freedom. These findings reveal that CBT was somewhat effective in responding to certain aspects of HIV stigma within the acute two months assessment period. And unlike the control group, participants in the experimental group seemingly had some degree of relief from the experience of the damaging feelings of stigmatising beliefs associated with HIV/AIDS at posttest.

Table 17

Posttest Assessment of Internalised HIV/AIDS Stigma across Treatment Arms

Variable		Control, 24 (53.3%)	CBT, 21 (46.7%)	Fisher's exact *P*
Internalized stigma				
Being HIV positive makes me feel dirty	Strongly disagree	11 (45.8%)	9 (42.9%)	
	Disagree	3 (12.5%)	3 (14.3%)	0.043*
	Agree	4 (16.7%)	9 (42.9%)	
	Strongly agree	6 (25.0%)	0 (0.0%)	
I am ashamed that I am HIV positive	Strongly disagree	14 (58.3%)	18 (85.7%)	
	Disagree	0 (0.0%)	1 (4.8%)	0.044*
	Agree	6 (25.0%)	2 (9.5%)	
	Strongly agree	4 (16.7%)	0 (0.0%)	
I feel guilty that I am HIV positive	Strongly disagree	16 (66.7%)	19 (90.5%)	
	Disagree	2 (8.3%)	1 (4.8%)	0.287
	Agree	4 (16.7%)	1 (4.8%)	
	Strongly agree	2 (8.3%)	0 (0.0%)	
I sometimes feel worthless because I am HIV positive	Strongly disagree	17 (70.8%)	11 (52.4%)	
	Disagree	1 (4.2%)	4 (19.0%)	0.260
	Agree	3 (12.5%)	5 (23.8%)	
	Strongly agree	3 (12.5%)	1 (4.8%)	
I hide my HIV status from others	Strongly disagree	9 (37.5%)	12 (57.1%)	
	Disagree	2 (8.3%)	3 (14.3%)	0.080
	Agree	7 (29.2%)	6 (28.6%)	
	Strongly agree	6 (25.0%)	0 (0.0%)	
Enacted Stigma				
People who have AIDS are cursed	Strongly disagree	17 (70.8%)	19 (90.5%)	
	Disagree	2 (8.3%)	1 (4.8%)	0.477
	Agree	3 (12.5%)	1 (4.8%)	
	Strongly agree	2 (8.3%)	0 (0.0%)	
It is difficult to tell people about my HIV infection	Strongly disagree	18 (75.0%)	19 (90.5%)	
	Disagree	0 (0.0%)	2 (9.5%)	
	Agree	5 (20.8%)	0 (0.0%)	0.029*
	Strongly agree	1 (4.2%)	0 (0.0%)	
People who have AIDS must expect some restrictions on their freedom	Strongly disagree	18 (75.0%)	18 (85.7%)	
	Disagree	1 (4.2%)	1 (4.8%)	0.831
	Agree	4 (16.7%)	2 (9.5%)	
	Strongly agree	1 (4.2%)	0 (0.0%)	
People who have HIV should be isolated	Strongly disagree	16 (66.7%)	15 (71.4%)	
	Disagree	0 (0.0%)	4 (19.0%)	0.023*
	Agree	8 (33.3%)	2 (9.5%)	
	Strongly agree	0 (0.0%)	0 (0.0%)	

*significant at $p < .05$

4.5.3 Pre – and Posttest Comparison of Internalised Stigma within Treatment Arms

To assess for any changes on the level of internalised stigma, a statistical analysis was conducted comparing the median baseline and 2-months outcome scores of internalised stigma within CBT and control arms of the study. The findings revealed no inherent differences between the baseline and the follow up internalised stigma scores across the two arms of the study ($p > .05$). The median baseline internalised stigma scores for CBT and control groups were 7.0 (IQR: 6.0, 9.5) and 9.0 (*IQR*: 7.5, 11.5) respectively. Similarly, the month two follow up internalised stigma scores for the CBT and control arms were 7.0 (*IQR*: 6.0, 10.0) and 9.0 (*IQR*: 5.0, 13.0) respectively. The grouped scores of internalised stigma were compared and the results were as shown in Table 18.

Table 18

Comparison of Median Pretest and Posttest Internalised Stigma Scores within Groups

Intervention	**Pretest**	**Posttest**	***P***
	***Md*(*IQR*)**	***Md*(*IQR*)**	
Control	9.0 (7.5, 11.5)	9.0 (5.0, 13.0)	0.889*
CBT	7.0 (6.0, 9.5)	7.0 (6.0, 10.0)	0.860*

*Not significant, $p > .05$

An examination of the findings presented in Table 18 reveals the results of Chi Square test applied to assess if there was any inherent difference in the median level of internalised stigma from pre-to-posttest among PLHIV enrolled in experimental and control groups. The result was not statistically significant implying that neither treatment nor passage of time had a positive impact of reducing the level of internalised HIV stigma among the majority of study participants during the intervention period.

To assess for the direction of change in the levels of internalised stigma scores, graphical method of analysis was used to show the score trajectories from pretest to posttest. The internalised stigma score trajectories appeared to rise from those of the baseline to higher values at month-2 post intervention assessment for most of the participants in the control arm. The overall median trajectory (thick black line) for the control arm had a modest slope while that of the CBT arm was

flat, indicating that there was no significant change in the level of HIV stigma at post treatment phase of the study as demonstrated in Figure 9. The upward trajectories notwithstanding, a further statistical analysis was done to establish if there was any change in levels of internalised HIV stigma among study participants during follow up, and the Chi Square (χ^2) test for treatment effect of CBT on internalised stigma scores at month two outcome assessment was found to be marginally significant, $p = .051$.

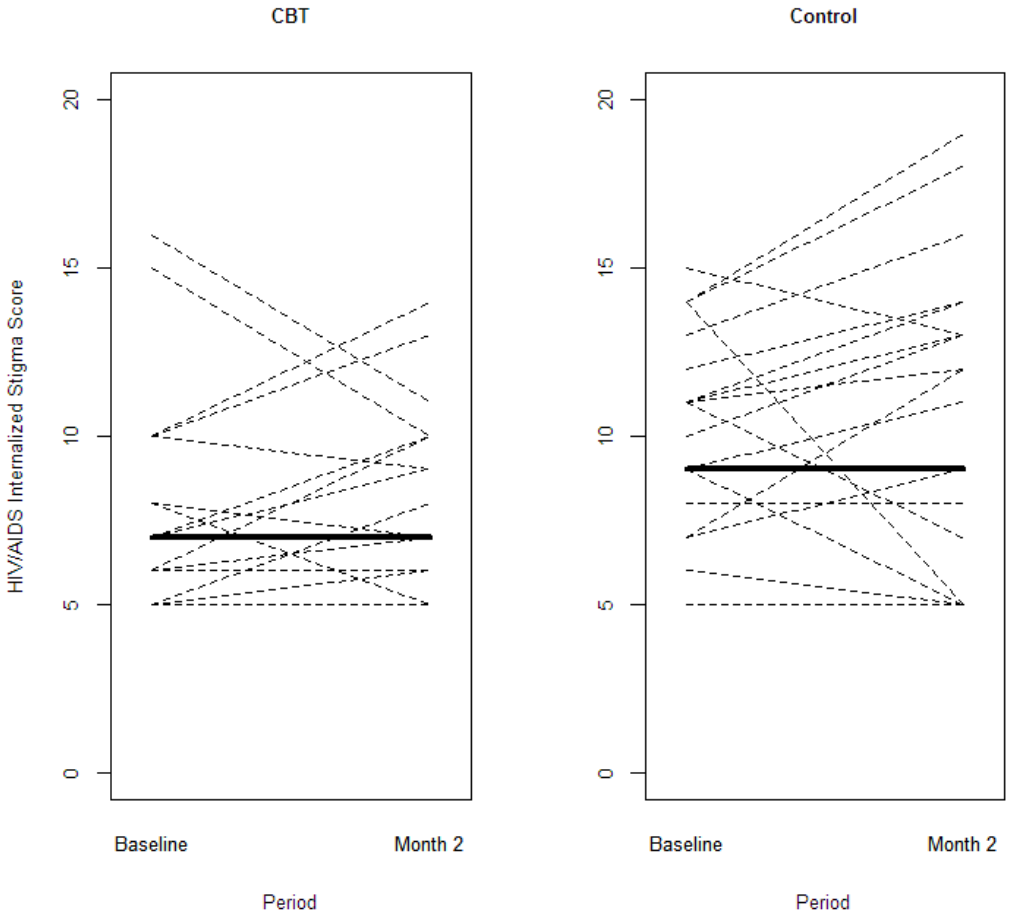


Figure 9. HIV/AIDS Internalised Stigma Score Trajectories

4.5.4 Pre – and-Posttest Comparison of Enacted Stigma by Treatment Arms

From the graphical assessment presented in Figure 10, the study established that all the 26 participants in the CBT arm had trajectories that are rising. Most of them with overlapping enacted HIV stigma scores. Similarly, most of the participants in the control arm had rising enacted stigma scores. The overall median for enacted stigma scores were rising for both CBT and control arms.

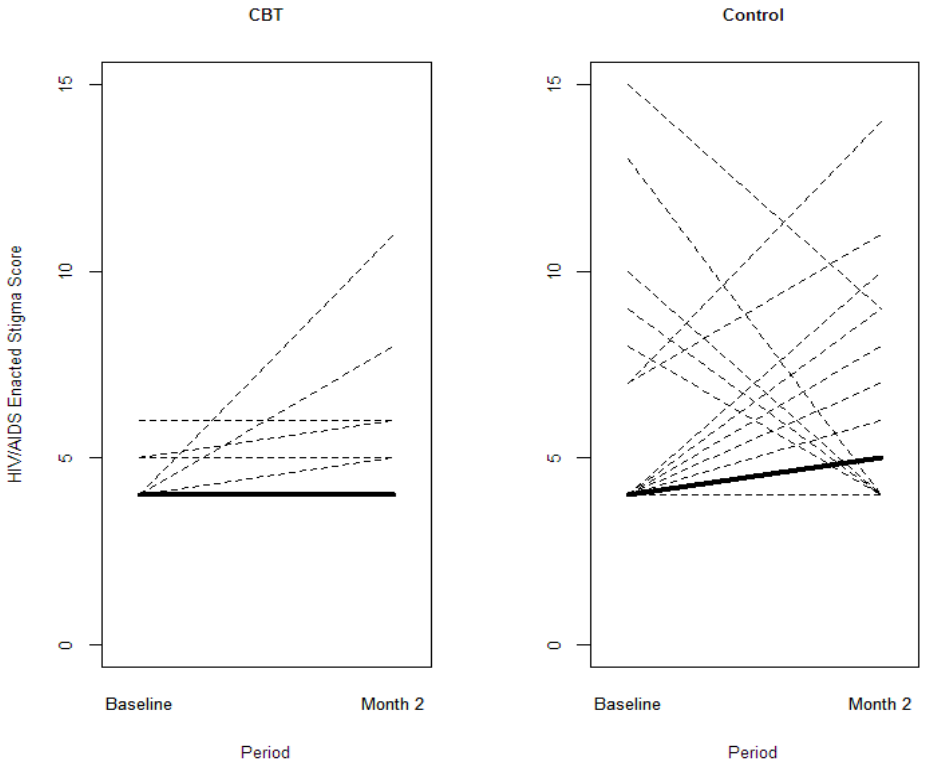


Figure 10. HIV/AIDS Enacted Stigma Score Trajectories

Further assessment was conducted to ascertain whether there was a significant change in the level of enacted stigma scores from the baseline to month-2 follow up. Evidently, from the box plot in Figure 11, the CBT arm is simply a line at baseline. This means that the participants had tight baseline scores except for a few outliers. The median enacted score at baseline is similar to the median enacted stigma score for month 2 follow up, 4.0 (IQR: 4.0, 4.0) vs. 4.0 (IQR: 4.0, 5.0), p =.251. The baseline median score for enacted stigma in the control arm was lower than that of the month 2 follow up, 4.0 (IQR: 4.0, 7.0) vs. 5.0 (IQR: 4.0, 8.3). This difference is consistent with the positive slope seen in Figure 10 for the control group. Nevertheless, the difference in enacted

stigma scores at baseline and month 2 outcome assessment for control group was not statistically significant, p = .381 as shown in Figure 11. In addition, a statistical analysis comparing the two arms of the study was conducted using Chi Square test to determine whether there was change in the level of enacted stigma due to treatment effect. The test result revealed that CBT for stigma did not have a significant effect on enacted stigma at month-2 follow up period, p = 0.349.

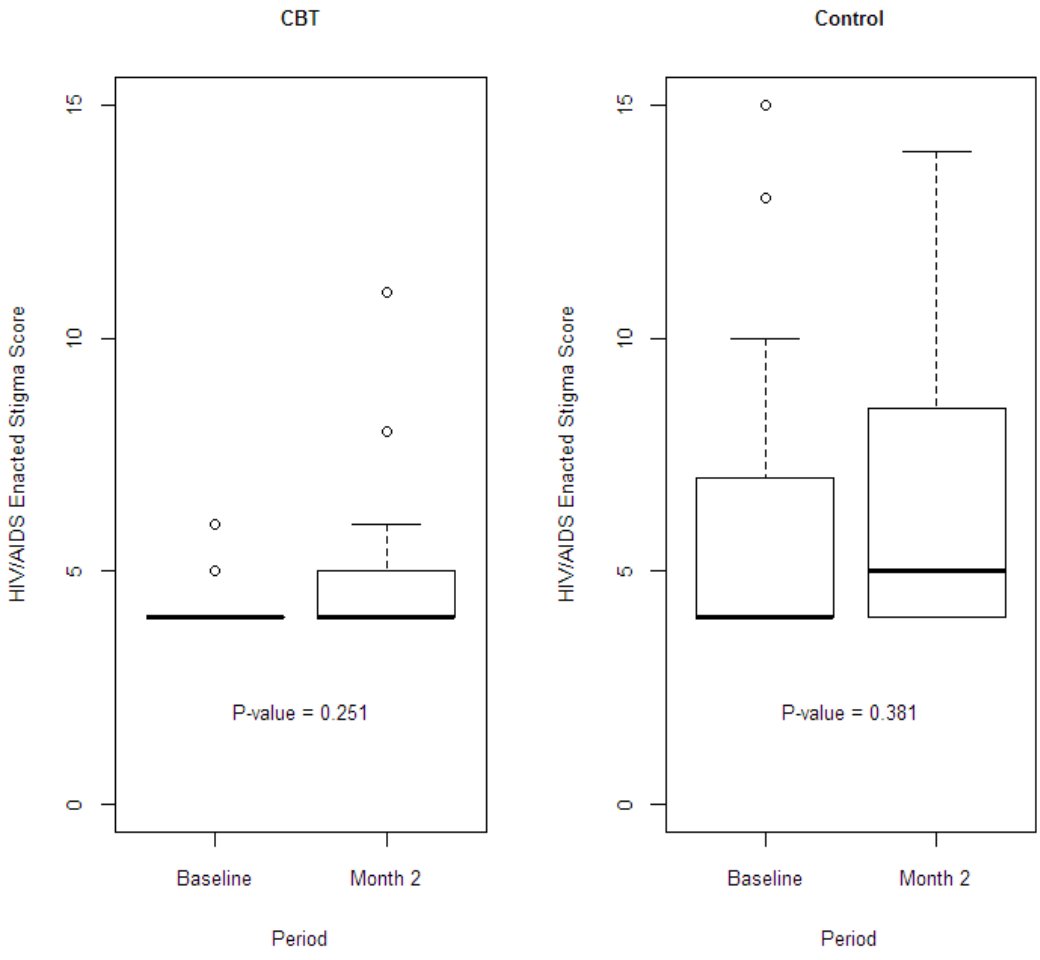


Figure 11. Comparison of Pretest and Posttest Enacted Stigma Scores Stratified by Study Arms

4.5.5 Effect of CBT on HIV-related Stigma and Hypothesis Testing

4.5.5.1 CBT Treatment Effect on HIV Stigma

A comparison of the pretest and posttest stigma scores for the participants in both arms of the study showed that the median stigma scores at month 2 were relatively similar to those of the baseline, 11.0 (*IQR*: 10.0, 14.0) vs. 11.0 (*IQR*: 10.0, 13.8), p = .692, and 14.5 (*IQR*: 11.0, 19.8) vs. 14.0 (IQR: 12.0, 18.5), p = .809 for CBT group and control group respectively. Figure 12 presents results of generalised estimating equations (GEE) that was used to model the effect of CBT on HIV stigma. The average HIV stigma score for the participants in the control arm was 12.50, 95% CI [10.39, 14.61] at baseline. The CBT arm had a lower but statistically non-significant average HIV stigma score by 1.91, 95% CI [-0.64, 4.45]. By month 2 follow up, the control arm had HIV stigma score that was higher than the baseline average by 1.33, 95% CI [-1.22, 3.89]. The CBT arm had an average change in HIV stigma score that was relatively lower than the change among the control arm participants. However, this difference was not statistically significant, -0.70, 95% CI [-3.61, 2.21]. Model comparisons showed that inclusion of the interaction effect in this model was important, p = .041 even though treatment effect was not statistically significant. The increase in levels of stigma among participants in the control group at post-treatment could suggest that CBT was effective in containing HIV stigma. Even though the treatment effect was quite minimal, estimated over time, CBT could be said to be clinically significant since the participants never experienced an increase in stigma levels.

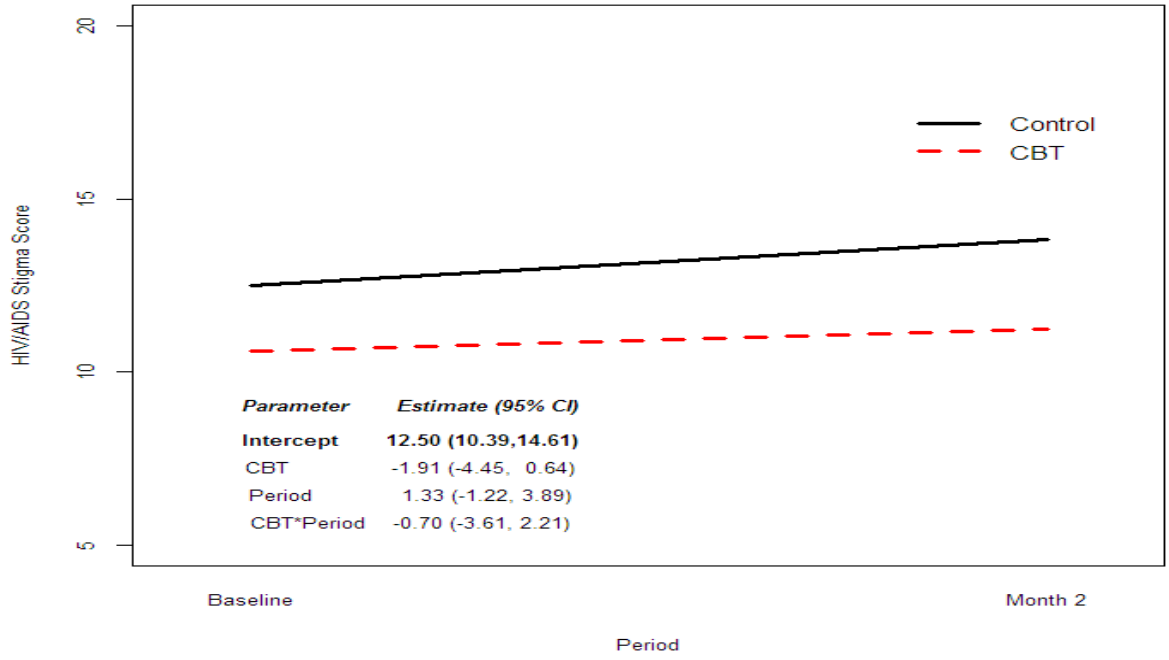


Figure 12. Estimating the Effect of CBT on HIV/AIDS Stigma

4.5.5.2 Hypothesis Testing

In order to test the study hypothesis that there was no statistically significant difference in the level of HIV-related stigma between HIV-infected outpatients enrolled in the CBT group and their counterparts in the control group, the posttest HIV stigma scores of the participants in the experimental and control conditions were compared using the Mann Whitney *U* test, a non-parametric statistical technique.

Table 19

Results of the Mann Whitney U Test to Compare the Groups' Posttest HIV Stigma Level

Groups	**N**	**Mean Rank**	**Sum of Ranks**	***U***	***Z***	***p***
Experimental Group(CBT)	21	19.48	409.00	178.00	-1.699	.089*
Control Group	24	26.08	626.00			

* The difference is not significant at $p > .05$

An assessment of findings in Table 19 reveals the results of Mann Whitney *U* test for the posttest HIV stigma scores of the participants in the experimental and control groups. The results did not show any significant difference (Z=1.699; p=.089, p-value >.05). Overall, the study results showed that the change in stigma levels within and between the two study arms was not considerably different at the month-2 post treatment assessment. Thus, it was concluded that there was no statistically significant difference between CBT and control groups on HIV stigma level at posttest, p = .089 and thus, null hypothesis failed to be rejected.

4.5.6 Discussion on the Outcome of CBT for HIV Stigma

The study findings that there was no statistically significant difference in the levels of HIV/AIDS stigma between baseline and post treatment assessments among CBT participants contrast findings by Tshabalala and Visser (2011) in the study done in South Africa on the model of cognitive behavioural therapy (CBT) for HIV positive women which found a significant reduction in HIV stigma at post-treatment assessment. The South African study was however different from the current study in various aspects like, it only had women participants; participants were offered more therapy sessions; and CBT approach was individual-based. This could denote that HIV-infected persons usually experience HIV stigma in a highly personalised way which could only be addressed at an individual level through one-on-one therapy approach as opposed to group setting where privacy is often in dearth.

In spite of the current study showing that CBT did not have a significant effect on the overall stigma levels at the 2-months outcome assessment, there was however a significant reduction of stigma perception on specific indicators for both internalised and enacted stigmas. The reduction was seen in two items for each category of stigma in the HIV/AIDS stigma scale for the experimental group (see Table 17). The items include; (1) Being HIV positive makes me feel dirty, (2) I am ashamed that I am HIV positive, (3) It is difficult to tell people about my HIV infection, and (4) People who have HIV should be isolated, $p < .05$. Items 1 and 2 are indicators of internalised stigma while items 3 and 4 are for enacted stigma. These findings clearly proved that CBT could be effective in reducing levels of stigma and in helping PLHIV deal with stigma in a primary care setting. Nevertheless, it is worth noting that for patients to realise maximum benefit from the effect of CBT intervention on stigma, the participants may have to go through more treatment sessions than in the current study.

The consistent pattern of unrelenting stigma tendencies among a majority of the participants as revealed in the study could be a demonstration that HIV stigma is both persistent and prevalent among the HIV-infected population in Turbo Sub-county, Kenya. The HIV/AIDS stigma score trajectories were rising for most of the participants in the control arm from pretest to posttest. Some participants however had decreasing score trajectories in both CBT and control arms. Some participants did not experience any change at all. The overall median trajectories also had a positive slope but the rate of change for the control group was steeper than that of the CBT arm. This perhaps could be attributed to commonality of shared experiences among study participants in terms of social and personal factors linked to HIV stigma, for instance, cultural practices, belief systems, life stressors, and relationship networks.

Consequently, the study findings may in a salient manner suggest that HIV/AIDS is still perhaps the most stigmatised medical condition in the region and that stigma could still be one of the most serious obstacles in the fight against HIV/AIDS in the local primary care setting. Boon *et al*. (2006) emphasised that HIV/AIDS is known to be associated with stigma. It has also been observed that HIV-related stigma is more highly damaging than any other disease-related stigma (Oyediran, Oladipo, & Anyanti, 2005) due to inaccurate links with maladaptive behaviours like sexual promiscuity, commercial sex work, homosexuality and religious views attributing it as a punishment from God (Genberg *et al*., 2009). Additionally, stigma levels revealed in the study confirm the position that HIV stigma is still prevalent in developing countries such as Kenya; where just like Nigeria HIV stigma has resulted in break-up of families, social rejection and violation of human rights (Monjok, Smesny, & Essein, 2009). The present study findings revealed that up to 22.6% of participants were either separated or divorced, with 33.3% of those in control group expressing agreement that people with HIV should be isolated, a phenomenon which may partly be attributed to HIV stigma.

In comparison, studies conducted in diverse settings on HIV stigma have consistently revealed similar trends of high prevalence. For instance, in a study conducted by Lee, Kochman, and Sikkema (2002) in the USA on the impact of internalised AIDS stigmas, they found that 63% of participants sampled in two US cities reported that they were embarrassed by their HIV infection and 74% stated that it was difficult for them to tell others that they were HIV positive. Another study conducted in southwest Ethiopia reported that 79.4% of participating individuals did not

want to disclose their HIV-positive status due to fear of stigma (Deribe, Woldemichael, Wondafrash, Haile & Amberbir, 2008). Further, a survey conducted by Simbayi *et al*. (2007), in Cape Town South Africa among 1063 respondents living with HIV/AIDS found that 40% of the respondents had experienced discrimination because of being HIV-positive and 20% had lost either a place to stay or a job for being HIV-infected. From the same survey, more than 33% of participants reported feelings of being dirty, ashamed, or guilty because of their HIV status.

HIV stigma among PLHIV has been associated with serious outcomes in terms of adverse behavioural and emotional ramifications including: inability to seek treatment and care services, unsafe sexual practices, isolation and emotional distress, and self-hatred (Lee *et al*., 2002; Simbayi *et al*., 2007). This observation could be explained from the basis that HIV-infected persons usually conceal their HIV status and avoid treatment for fear of being known and stigmatised (Parker, Bajanja, Karamagi, & Tindyebwa, 2007). HIV-related stigma therefore remains a significant impediment to the treatment and prevention of HIV/AIDS (Sambisa, Curtis, & Mishra, 2010). Stigma has also been linked with negative health outcomes for PLHIV including, more severe AIDS related symptoms, and decrease in health care satisfaction (Bird, Bogart & Delahanty 2004). This inescapable reality makes it imperative that interventions aimed to reduce HIV-related stigma should target manifold levels of influence (internal and external) in order to guarantee optimal clinical care in ART programmes in the local healthcare setting. Katz *et al*. (2013) found that HIV-related stigma compromised participants' abilities to successfully adhere to ART, and recommended that interventions for stigma should target intrapersonal, interpersonal and structural influences for maximum ART adherence to be realised.

The study findings make it abundantly clear that HIV stigma does not present without other health related outcomes which either precipitate or exacerbate stigma. Even though the study did not examine the correlation between stigma and other study variables like ART adherence and depression, related studies have found such associations. For example, studies conducted by Downshen, Binns, and Garofalo, (2009); and Simbayi *et al*. (2007) revealed a positive correlation between stigma and levels of depression. In particular, negative self-image attributable to HIV-infection was found to be the main predictor of depression. Negative self-image resulting from HIV infection could precipitate HIV stigma that may lead to poor self-esteem and lack of self-confidence which are the hallmarks of depression as observed by Kumar and Clark (2009). Thus,

the way an individual views himself following HIV diagnosis could be a cause for depression. Furthermore, internalised stigma has been found to significantly predict cognitive–affective depression among HIV positive population (Simbayi *et al*., 2007). On the relationship between HIV stigma and ART adherence, a study done in the US found that HIV patients with high stigma concerns were 3.3 times more likely to not adhere to antiretroviral therapy regimen (Dlamini *et al*., 2009).

Arguably, the study findings suggest that HIV stigma may be at the centre of the salient emotional reactions and psychological distress which often-times present among many PLHIV in the local primary care setting. High stigma burden that comes with HIV infection may potentially affect all dimensions of a person's physical, psychological, and social life. To alleviate the problem posed by stigma, there is need to institute a powerful public health argument for investing in psychological support services for people living with HIV. Psychotherapy like CBT intervention may offer the much needed support to help PLHIV to cope more effectively with the negative effects of stigma. With appropriate psychological support, PLHIV are less likely to miss medication, less likely to feel depressed and/or engage in unsafe sex which increase the risk of onward HIV transmission to other people.

Subsequently, a look into the relationship between HIV stigma and other correlates like poor ART adherence and depression renders a compelling urge to design an appropriate intervention that would psychologically empower HIV-infected individuals to inculcate a sense of positive self-image and embrace a positive attitude towards HIV infection. This may have the advantage of helping to curtail or significantly reduce the rampant incidences of stigma and depression as psychological sequelae to HIV infection among PLHIV. Overall, the study findings undoubtedly portrayed a positive outlook for use of CBT in the management of HIV-related stigma. Notably, CBT intervention was instrumental in containing the escalation of enacted HIV stigma as well as marginally reducing internalised HIV stigma. In sum, study results elucidated that a larger longitudinal randomised controlled trial (RCT) with extended assessment points is warranted to investigate whether CBT for HIV-related stigma is effective and efficacious enough to be adopted in primary health care settings in Kenya.

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents summary, conclusions and recommendations based on the findings from the study. The chapter summarises the effect of Cognitive Behavioural Therapy (CBT) on clinical depression, ART adherence and HIV stigma among PLHIV in Uasin Gishu County, Kenya; the methodology of the study and the key findings. The chapter also draws conclusions in response to the three research hypotheses which set out to establish the effect of CBT on levels of depression, HIV/AIDS related stigma and ART adherence among the study participants. The chapter also provides recommendations to address and further understand CBT as an intervention for depression and its psychosocial correlates among PLHIV in a primary health care setting in Kenya.

5.2 Summary

The purpose of this study was to establish the effect of cognitive behavioural therapy on clinical depression, and its psychosocial correlates among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya. The study also aimed at presenting an evidence-based psychotherapy for clinical depression in a primary care setting in Kenya. The study had the following objectives:

i. To establish the effect of Cognitive Behavioural Therapy on clinical depression among HIV-infected outpatients attending Turbo Sub-County Hospital in Kenya.

ii. To determine the effect of Cognitive Behavioural Therapy on antiretroviral therapy adherence among HIV-infected outpatients attending Turbo Sub-County Hospital in Kenya.

iii. To establish the effect of Cognitive Behavioural Therapy on HIV stigma among HIV-infected outpatients attending Turbo Sub-County Hospital in Kenya.

The research design adopted in this study was an experimental research design. Data on dependent variables were collected on two time points of pre- and post-treatment phases of the study for the period between July and November 2016.

The population of this study included all the 3000 patients in Turbo Sub-County Hospital HIV-outpatient clinic. Purposive sampling was used to select the study site and systematic random sampling was used to select 393 participants from a total of 3000 patients attending HIV-outpatient clinic in Turbo Sub-County Hospital. The sample size of the participants was based on a powered sample-size calculation using the formula given by Morgan and Case (2013). Data for this study were collected using Patient Health Questonnaire-9 (PHQ-9) for depression, HIV stigma scale for HIV stigma, and Patient Adherence Record for ART adherence. The data were analysed using descriptive statistics, and inferential statistics including Mann-Whitney *U* test, Chi Square test, Generalised estimating equations and Ordinal Logistic Regression. Violation of Gaussian assumptions were assessed using both Normal Q-Q Plot and Shapiro-Wilk *W* test for normality. The effect of CBT on depression was modelled using Generalised estimating equations model. The key findings and conclusions of this study are based on the responses to the following hypotheses:

i. There is no statistically significant difference in the levels of depression between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

ii. There is no statistically significant difference in the degree of adherence to antiretroviral therapy between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

iii. There is no statistically significant difference in the level of HIV stigma between HIV-infected outpatients enrolled in CBT group and those in the control group at month-2 posttest in Turbo Sub-County Hospital, Kenya.

The findings of the study showed that;

i. Cognitive behavioural therapy (CBT) was effective in reducing clinical depression among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya. The data collected provided evidence to prove that CBT delivered in group formats for PLHIV in primary care setting is both feasible and effective in helping patients with depression move at least one level down the ladder of depression severity at two months post treatment. On average, participants in the CBT had a significant drop of >5 points in depression score at two months follow up assessment with 71.4% of CBT participants (versus 16.7% in control group) reporting a drop of between 5 and 10 points on PHQ-9 score. This is indicative that study participants responded well to the CBT treatment, and that the treatment was effective in the remission of symptoms of depression as a comorbid condition in HIV infection. The study results revealed a relatively large effect size (r =.5) for CBT intervention on depression at two months posttest assessment thereby lending credence to the effectiveness of CBT group therapy and the replicability of the findings in similar settings.

ii. Cognitive behavioural therapy (CBT intervention) was effective in enhancing antiretroviral treatment (ART) adherence among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin Gishu County, Kenya. The study found that participants enrolled to the CBT had a twofold improvement in the ART adherence level OR = 2.14, 95% CI [1.31, 3.46] at two months posttest assessment. Similarly, a significantly higher proportion of participants in the CBT arm had optimal adherence level (≥ 95%) compared to those in the control arm, 76.2% vs. 41.7%, p = .024. The results showed that CBT intervention had a moderate effect size r =.4 (or d =.85) in enhancing medication adherence at the acute 2-months assessment. This evidence on the treatment effect size suggests that CBT could be adopted in a primary care setting as a viable intervention for poor ART adherence among HIV-infected outpatients. The study finding further confirmed that adherence to ARV medication for persons suffering from chronic illnesses like HIV-infection is a learnt behaviour which could only be enhanced through a psychological behaviour-change intervention like CBT programme.

iii. Cognitive behavioural therapy (CBT) was not effective in reducing HIV stigma on the overall among HIV-infected outpatients attending Turbo Sub-County Hospital in Uasin

Gishu County, Kenya. However, the study results on treatment effect showed that; the effect of CBT on the internalised stigma scores at month-2 follow up period was marginally significant, $p = .051$, and the effect of CBT on the enacted stigma scores was not significant at month two follow up period, $p = .349$. Notably, a reduction in internalised stigma among CBT participants was considered pivotal in eliminating self-stigmatising beliefs which have often been identified as barriers to healthcare-seeking behaviours and a serious hindrance to accessing care among PLHIV in ART programmes. Thus, participants in CBT may be expected to exhibit improved uptake of healthcare services than their counterparts in the control group due to truncated levels of internalised stigma as a result of the treatment. Even though CBT was not effective in reducing HIV stigma on the overall, data collected on HIV stigma provided evidence that there was a statistically significant difference between participants in the CBT arm and those in the control arm of the study in their perception about being HIV positive at the month-2 outcome assessment. Those in the CBT arm were more likely to disagree that being HIV positive made them feel dirty, $p = .043$; that they were ashamed of their HIV status, $p = .044$. Similarly, participants in the CBT arm no longer found it difficult to tell people about their HIV status, $p = .029$, and they were more likely to disagree that people with HIV should be isolated, $p = .023$. Furthermore, participants in the CBT arm were less likely to feel guilty of their HIV status, hide their status from others, perceive that people with HIV are cursed, and less likely to expect people with AIDS to have restricted freedom. These findings demonstrated that CBT was effective in controlling for the escalation of HIV stigma among CBT participants. Notwithstanding, the findings showed a likelihood of HIV stigma being deeply rooted among PLHIV, and that HIV stigma presents lingering effects with a possibility of worsening off if not intervened for as seen in the case of participants in the control group, who had a steady rise in the level of HIV stigma during the intervention period.

Subsequently, it may be deduced from the findings of this study that with a significant reduction of depression symptoms and internalised stigma as well as increase in ART adherence, CBT participants may experience improved immunity and medical stability due treatment effect of antiretroviral medication. These benefits would accrue through overcoming barriers to accessing care, and embracing adaptive behaviours that support strict adherence to antiretroviral treatment regimen. In this respect, participants in the CBT programme may eventually have better health

outcomes than their counterparts in control group because of possessing skills necessary to resolve negative effects of internalised stigma and depression symptoms as well as espousing positive attitude towards ART.

5.2.1 Implications of the Study

In this study, the researcher reports on how CBT as a behaviour-change intervention may be applied in a primary healthcare setting to reduce depressive symptoms and enhance medication adherence among depressed HIV-infected outpatients. This is significant because Kenya is one of the countries in sub-Saharan Africa (SSA) with high HIV prevalence and escalating new HIV infections which can only be reversed through strict adherence to antiretroviral therapy. Cases of non-adherence to treatment, high rates of depression among the HIV infected population in Kenya and patients getting lost from care are some of the key areas that have been investigated locally. Nonetheless, non-adherence to antiretroviral therapy (ART) remains disproportionately high in HIV care programmes especially at this point when the ministry of health has unveiled a new ART guideline which requires every person diagnosed HIV positive to be initiated on ARVs immediately. Locally, HIV care programmes have overtime relied upon medication counselling offered by clinicians to help optimise treatment benefits. So far, the outcome of such efforts has not generated any considerable difference in improving ART adherence. This gives a compelling cause to devise a strategy that may help intervene for poor medication adherence as a means to ensuring that patients are virally suppressed and thus prevent new infections. And since medication adherence is a learnt behaviour, psychological approach would aptly apply. CBT is one such intervention that is credited for behaviour change and has the evidence base for helping patients learn healthier skills and habits like medication adherence. However, its feasibility and use in enhancing ART adherence is yet to be established in the local setting. Therefore, study findings are useful in ventilating the potential of CBT as a medication adherence-enhancer and alternative treatment for depression especially among outpatients in busy HIV clinics in the resource constrained setting of western Kenya.

5.3 Conclusions

The conclusions of this study are derived from a review of the findings. The study concluded that;

i. CBT as a psychotherapy for depression can be administered to depressed HIV patients using group therapy approach and help patients achieve remission of depressive symptoms in a relatively short period of time in the local primary healthcare settings.

ii. CBT intervention has the potential to help HIV infected patients who are on medication improve on their degree of adherence and to derive optimal benefit from antiretroviral treatment offered in the local HIV care clinics.

iii. Although CBT intervention has not been clearly demonstrated to have significant effect on HIV related stigma in the short term, it still offers a promise of being viable intervention to contain the escalation of HIV stigma.

iv. Further, group CBT may be adopted and delivered by the local mental health practitioners as an alternative treatment in response to clinical depression among patients with chronic and terminal illnesses for remission of symptoms within a short time.

v. HIV-infected patients seeking clinical care in resource-constrained settings are likely to respond well to a brief CBT intervention provided that they have at least average level of high school education.

5.4 Recommendations

This study lays out two sets of recommendations including options for addressing CBT psychotherapy and HIV management among PLHIV in a primary healthcare setting as well as areas for further investigations.

5.4.1 Recommendations Addressing CBT (psychotherapy) and HIV Care

i. The Ministry of Health should make necessary policy reforms that would support efforts to adopt the use of psychotherapy (specifically, CBT) to help improve mental health and emotional wellbeing of PLHIV.

ii. Organizations offering ART programmes should consider setting up mental health divisions within HIV-outpatient clinics to help assess, diagnose and treat mental illnesses that present alongside HIV infection.

iii. The Agencies implementing ART programmes in Kenya should consider employing the services of psychologists and counsellors with CBT expertise to intervene for poor treatment adherence which is a learnt behaviour and a barrier to quality health outcomes in HIV care.

iv. Institutions running HIV management programmes should consider training clinical care providers on the basics of administering psychological assessments for common neuropsychiatric disorders like depression to allow for timely diagnosis and intervention.

5.4.2 Suggestions for Further Research

The main aim of the study was to establish the effect of CBT on clinical depression, ART adherence and HIV stigma among HIV-infected outpatients. The study findings are thus vital in recommending relevant policies geared towards utilization of psychotherapy in achieving improved HIV care outcomes in Kenya. However, the study proposes future research;

i. In similar settings and for generalizable findings, a multi-site randomised controlled trial should be conducted to determine both the efficacy and the effectiveness of CBT for depression and ART adherence among HIV-infected persons in Kenya. The current study was only intended to determine treatment effectiveness and not efficacy of CBT. Of note is the fact that a good treatment or intervention must be both effective and efficacious.

ii. There is need to conduct further studies to compare CBT and other psychotherapies for depression among PLHIV attending HIV clinics in Kenya with a view to determining which psychotherapy has a more significant clinical effect.

iii. Depressed persons living with HIV in Kenya have in the past relied solely on antidepressant medication for treatment. However, from the findings of the study it is evident that CBT is highly effective in reducing symptoms of depression among PLHIV. This creates the urge to conduct further studies that will elucidate the effect of integrated use of CBT and antidepressants for depression among PLHIV in Kenya.

iv. The study findings revealed that CBT was only effective in preventing the escalation of HIV stigma among participants within the acute period of 2-months outcome assessment. Hypothetically, this demonstrated that CBT may have the potential to reduce HIV stigma if extensively applied. To establish the effectiveness of CBT for HIV stigma, there is need to conduct a further study involving more CBT sessions than the current six, and possibly include additional one-on-one booster sessions in the intervention since the experience of HIV stigma is highly idiosyncratic.

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APPENDICES

Appendix A: Informed Consent for Participants

Title of Study

Effect of Cognitive Behaviour Therapy on Clinical Depression and Its Psychosocial Correlates among HIV-infected Outpatients in Turbo Sub-county, Kenya

Investigator

Japheth O. Adina, PhD Candidate, Faculty of Education and Community Studies, Egerton University
Cell phone: 0710-799779

Purpose of the Study

The purpose of this study is to develop a treatment intervention to guide the implementation of the concept of Cognitive Behavioural Therapy in the management of HIV-infected outpatient adults seeking care in primary healthcare settings in Kenya. This intervention has been practiced and evaluated in the developed world with many benefits; nevertheless so far there is no clear documentation on how it can be implemented in the Kenya.

Description of the Research

I am kindly inviting you to participate in this study. This treatment is part of a research study to look at ways to help participants to overcome clinical depression and its effects on treatment adherence and HIV stigma. This study has three parts. First, you will work with the research assistant, who will ask you questions about your condition and your life before treatment. The questionnaires will take approximately 30 minutes. During treatment, you will learn ways to help you to deal with depression. Each treatment session will be in a group setting and will last 2 hours. The total number of sessions will be six, and sessions will be done on a weekly basis, that is, one session per week. After the last treatment session, we will ask you to stay longer to talk about what you liked about treatment and didn't like about treatment and what was helpful. Note that, you will be given a transport reimbursement fee based on distance travelled during the 6 sessions of treatment.

Access to Research Information

The data collected will be kept under lock and key and will not be accessed by any unauthorized individuals. The information will only be accessible to the research team comprising of the principle investigator, the supervisors and the examiners. The filled questionnaires and any recorded information will be locked up for a period of five years after the study pending to be destroyed.

Potential Harm, Injuries, Discomforts or Inconvenience

This being a non-invasive-experimental research, you will not be exposed to any harm, injuries or discomforts. There may be some slight emotional distress in terms of expressing inner feeling in a group therapy setting but I request you to bear with it since its part of the therapeutic process.

Potential Benefits

You may benefit immediately from participating in this study since it will be professionally conducted by an experienced CBT therapist and even thereafter from the skills and techniques acquired during therapy sessions.

Confidentiality

 Confidentiality will be respected and no information that discloses your identity will be released or published without consent unless required by law.

 For the Group sessions, confidentiality of information is guaranteed but I can't promise that the other participants will observe each other's privacy.

Participation

Participation in research is voluntary. If you choose to participate in this study you may withdraw at any time. If you do not wish to participate, you do not have to provide any reason for your decision not to participate.

Contact:

If you have any questions about this study, please contact:

Principal Investigator,
Faculty of Education and Community Studies,
Egerton University,
P.O Box 536, Egerton.
Cell phone: 0710799779

I understand that I have the right to refuse to participate in this study. I also understand that if I do agree to participate, I have the right to change my mind at any time and stop my participation. My signature below indicates that I have given my informed consent to participate in the above described study. My signature also indicates the following:

- I have been given opportunity to ask questions about the described study and my participation in it.
- My questions have been answered to my satisfaction.
- I have been permitted to read this document and have been given a signed copy of it.
- I am at least 18 years old and legally able to provide consent.

Participant' signature: _____ Date: _____

Researcher' signature: _____ Date: _____

Appendix B: Participant's Socio-Demographic Questionnaire

Date: _____

Participant ID: _____ Age: _____ Sex: _____F/M

I would like to ask you a few general questions concerning your life. Please feel free to answer as honest as you can.

1. What is your highest level of education?
   - Primary: Level…….
   - Secondary: Level……..
   - College/University: Level……
2. What is your current marital status?
   - Single
   - Cohabiting
   - Separated/Divorced
   - Married
3. How long ago did you get tested for HIV?
   - Less than six months ago
   - One year ago
   - Two years ago
   - More than three years ago
4. Did you ever receive any professional counselling services following HIV diagnosis?
   - No
   - Yes
5. What is your current employment status
   - Unemployed
   - Self-employed
   - Employed
6. Are you able to speak and write in Kiswahili language?
   - No
   - Yes
7. Are you currently on ARV medication? (Interviewer: If participant endorses **No** for **#7**, do not proceed to the next set of questions. Thank the participant and terminate the interview)
   - No
   - Yes

Appendix C: Patient Health Questionnaire (PHQ-2)

(Mini scale used in Screening for Depression)

PARTICIPANT NO: _____ DATE: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?

(Use "√" to indicate your answer)

		Not at all (0)	**Several days (1)**	**More than half the days (2)**	**Nearly every day(3)**
1	Little interest or pleasure in doing things				
2	Feeling down, depressed, or hopeless				

Appendix D: Patient Health Questionnaire (PHQ-9) Scale

PARTICIPANT NO: _____ DATE: _____

Interviewer: I would like to ask you a few questions concerning your life. I will read out each statement and then you will answer from the options I will read after each statement.

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use "√" to indicate your answer)

		Not at all (0)	**Several days (1)**	**More than half the days (2)**	**Nearly every day(3)**
1	Little interest or pleasure in doing things				
2	Feeling down, depressed, or hopeless				
3	Trouble falling or staying awake				
4	Feeling tired or having little energy				
5	Poor appetite or overeating				
6	Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
7	Trouble concentrating on things, such as reading the newspaper or television				
8	Moving or speaking slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
9	Thoughts that you would be better off dead, or of hurting yourself in some way				
	Add columns:				

Total Score: _____

NB: For the interviewer: If a participant endorses positive for item 9 and/or scores > 20 fill the participant referral form (For psychiatric intervention purposes).

Appendix E: ART Adherence Tool

Patient Adherence Record

HIV Diagnosis: _____years ago / Duration of ART (Date Started)_____ Months/years

I would like to ask you a few questions concerning your history on antiretroviral medication.

A: Self Report

A. Do you sometimes find it difficult to remember to take your medication? Yes□ No□

B. When you feel better, do you sometimes take a break from your medication? Yes□ No□

C. Thinking back over the past 30 days, have you missed any of your doses? Yes □ No□

D. Sometimes if you feel worse when you take the medicine, do you stop taking it?

Yes□ No□

B. Visual Analogue Scale

Now I'm going to ask some questions about your HIV medications.

Most people with HIV have many pills or other medications to take at different times during the day. Many people find it hard to always remember their pills or medicines. For example:

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to all the instructions, such as "with food" or "on an empty stomach," "every 8 hours," or "with plenty of fluids."
- Some people decide to skip pills to avoid side effects or to just not take pills that day.

We need to understand what people with HIV are really doing with their pills or medicines. Please tell us what you are actually doing. Don't worry about telling us you don't take all your pills or medicines. We need to know what is really happening, not what you think we "want to hear."

Q. Have you been prescribed for antiretroviral medications within the last 30 days? **Yes/No**

NB: Interviewer**:** If **Yes,** list codes/names for all Antiretrovirals that Participant was prescribed to take in last 30 days-where applicable

DRUG A		DRUG B	

Interviewer: Now I am going to ask you some questions about these drugs. Please put an "X" on the line below at the point showing your best guess about how much **(DRUGS A and/or B)** you have taken in the last three to four weeks. **Give Instrument and pen to respondent**

e.g. **0%** means you have **taken no (DRUG A)**

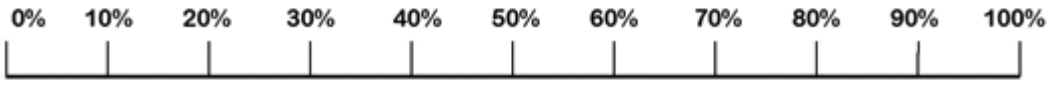
25% means you have **taken quarter of your**

50% means you have **taken half your**

75% means you have **taken three quarters your**

100% means you have **taken every single dose of**

A1. (DRUG A)



B1. How About (DRUG B) ?

Appendix F: AIDS-Related Stigma Scale

Item description	Respondent's responses			
	Strongly disagree(1)	Disagree	Agree	Strongly agree(4)
1. Being HIV positive makes me feel dirty				
2. People who have AIDS are cursed				
3. I am ashamed that I am HIV positive				
4. It is difficult to tell people about my HIV infection				
5. People who have AIDS must expect some restrictions on their freedom				
6. I feel guilty that I am HIV positive				
7. People who have HIV should be isolated				
8. I sometimes feel worthless because I am HIV positive				
9. I hide my HIV status from others				

Note. Assembled AIDS-related stigma scale

Original Versions of AIDS-related Stigma Scales

English Version of the AIDS-Related Stigma Scale

Please answer whether you agree or disagree with the following statements		
1. People who have AIDS are dirty.	I AGREE	I DISAGREE
2. People who have AIDS are cursed.	I AGREE	I DISAGREE
3. People who have AIDS should be ashamed.	I AGREE	I DISAGREE
4. It is safe for people who have AIDS to work with children.	I AGREE	I DISAGREE
5. People with AIDS must expect some restrictions on their freedom.	I AGREE	I DISAGREE
6. A person with AIDS must have done something wrong and deserves to be punished.	I AGREE	I DISAGREE
7. People who have HIV should be isolated.	I AGREE	I DISAGREE
8. I do not want to be friends with someone who has AIDS.	I AGREE	I DISAGREE
9. People who have AIDS should not be allowed to work?	I AGREE	I DISAGREE

Kalichman *et al*., 2005

HIV Internalised Stigma Scale

ITEMS	I AGREE	I DISAGREE
1.It is difficult to tell people about my HIV infection		
2. Being HIV positive makes me feel dirty		
3. I feel guilty that I am HIV positive		
4. I am ashamed that I am HIV positive		
5. I sometimes feel worthless because I am HIV positive		
6. I hide my HIV status from others		

Kalichman *et al*., 2009

Computation of AIDS-Related Stigma Scale-Internal Consistency

Case Processing Summary

		N	%
Cases	Valid	10	100.0
	Excluded[a]	0	.0
	Total	10	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.788	.774	9

Item Statistics

	Mean	Std. Deviation	N
Stigma1	2.0000	1.15470	10
Stigma2	1.6000	1.07497	10
stigma3	1.4000	.96609	10
stigma4	1.6000	1.26491	10
stigma5	1.7000	1.25167	10
stigma6	2.2000	1.39841	10
Stigma7	2.3000	1.41814	10
Stigma8	2.1000	1.28668	10
Stigma9	3.1000	1.19722	10

Inter-Item Correlation Matrix

	Stigma1	Stigma2	stigma3	stigma4	stigma5	stigma6	Stigma7	Stigma8	Stigma9
Stigma1	1.000	.090	-.199	-.456	-.384	.206	.136	-.150	.161
Stigma2	.090	1.000	.385	.196	.396	.355	.452	.032	-.570
stigma3	-.199	.385	1.000	.600	.570	.428	.308	.322	.058
stigma4	-.456	.196	.600	1.000	.968	.678	.632	.573	.176
stigma5	-.384	.396	.570	.968	1.000	.736	.682	.504	.022
stigma6	.206	.355	.428	.678	.736	1.000	.863	.235	.119
Stigma7	.136	.452	.308	.632	.682	.863	1.000	.408	.046
Stigma8	-.150	.032	.322	.573	.504	.235	.408	1.000	.353
Stigma9	.161	-.570	.058	.176	.022	.119	.046	.353	1.000

Summary Item Statistics

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance	N of Items
Inter-Item Correlations	.276	-.570	.968	1.538	-1.700	.123	9

Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Squared Multiple Correlation	Cronbach's Alpha if Item Deleted
Stigma1	16.0000	45.778	-.100	.	.836
Stigma2	16.4000	40.711	.269	.	.792
stigma3	16.6000	38.489	.512	.	.765
stigma4	16.4000	33.156	.741	.	.728
stigma5	16.3000	32.900	.772	.	.723
stigma6	15.8000	31.067	.804	.	.713
Stigma7	15.7000	31.122	.785	.	.716
Stigma8	15.9000	36.544	.473	.	.768
Stigma9	14.9000	42.767	.087	.	.817

Scale Statistics

Mean	Variance	Std. Deviation	N of Items
18.0000	45.556	6.74949	9

Appendix G: Summary of CBT Intervention

CBT Session 1: Outline

- Welcome – 5 minutes
- Group members introductions-10 minutes
- Overview of treatment/expectations – 15 minutes
- HIV/Depression Psycho-education – 60 minutes
- Introduction to CBT – 30 minutes

CBT Session 2: Outline

- Check-in and Homework Review– 30 minutes
- CBT Model of depression – 60 minutes
- Automatic Thoughts → Feelings and Behaviours -30 minutes

CBT Session 3: Outline

- Check in, practice exercises – 30 minutes
- CBT model – 30 minutes
- Analysis of behaviour – 60 minutes

CBT Session 4: Outline

- Check in, practice exercise – 45 minutes
- Cognitive Distortions and alternative thoughts – 75 minutes

CBT Session 5: Outline

- Check in – 30 minutes
- Thought Evaluation – 40 minutes
- Problem-solving – 50 minutes

CBT Session 6: Outline

- Check in practice exercise – 30 minutes
- Stigma coping skills – 60 minutes
- Develop a long term plan; and wrap up –30 minutes

CBT Material Content

Session 1

i. Setting of group norms-discussions on issues of confidentiality; respect; teamwork; attendance; and support for each other.
ii. Psycho-education – presentation on issues forming treatment building blocks. These include,
- Definition of HIV and AIDS
- HIV Transmission
- HIV and Human health
- Depression symptomatology
- Depression and HIV/ARVs
- Depression and Stigma
- Depression and suicidality
- Introduction to Cognitive Behavioural Therapy
- Home assignment (at least 3 things that make clients see life positively)

Session 2

i. Reviewing previous session's practice exercise
ii. CBT model illustration – introducing clients to; triggers/thoughts/emotions
-Automatic thoughts
-Thoughts and emotions
-Characteristics of negative thoughts-negative emotion
-Monitoring automatic thoughts
-Homework assignment (exciting/upsetting situations and the multiplier effect)

Session 3

i. CBT Model
- Thought record
- Putting the CBT Model together
In-depth analysis of triggers, thoughts, emotions, behavior and consequences-stigma/depression/poor adherence
- Homework assignment

Session 4

i. Cognitive distortions
ii. Skills of dealing with cognitive distortions
- Questioning automatic thoughts
- Distraction
- Thought stopping

- Positive self-talk
- Homework assignment on identifying situations causing negative thoughts leading to stigma/depression/poor adherence and generating realistic replacements

Session 5

i. Coping strategies
ii. Thought evaluation
iii. Problem solving
iv. Homework-situations/events leading to irrational decisions and generating alternative rational decisions.

Session 6

i. Stigma coping skills
ii. Developing long term plans
iii. Treatment wrap up and follow up schedule.

Appendix H: Data used in pretesting of study instruments

Pilot Data for Reliability Tests

Depression Scale		HIV-Stigma scale		Patient Adherence Record	
Test_PHQ9	**Retest_PHQ9**	**Test_Stigma**	**Retest_Stigma**	**Self_Report**	**VAS**
16	14	12	16	3	3
9	11	21	19	2	3
8	10	30	23	3	3
13	15	18	15	3	2
8	9	22	24	3	3
7	13	32	29	2	2
10	7	17	20	2	2
12	13	12	15	1	1
8	7	33	29	3	3
16	19	24	29	2	2

Test_PHQ9 * Re_Test_PHQ9 Crosstabulation

Count

		Re_Test_PHQ9								Total
		7.00	9.00	10.00	11.00	13.00	14.00	15.00	19.00	
Test_PHQ9	7.00	0	0	0	0	1	0	0	0	1
	8.00	1	1	1	0	0	0	0	0	3
	9.00	0	0	0	1	0	0	0	0	1
	10.00	1	0	0	0	0	0	0	0	1
	12.00	0	0	0	0	1	0	0	0	1
	13.00	0	0	0	0	0	0	1	0	1
	16.00	0	0	0	0	0	1	0	1	2
Total		2	1	1	1	2	1	1	1	10

Correlations

		Test_PHQ9	Re_Test_PHQ9
Test_PHQ9	Pearson Correlation	1	.739*
	Sig. (2-tailed)		.015
	N	10	10
Re_Test_PHQ9	Pearson Correlation	.739*	1
	Sig. (2-tailed)	.015	
	N	10	10

*. Correlation is significant at the 0.05 level (2-tailed).

Test_Stigma * Re_Test_Stigma Crosstabulation

Count

		Re_Test_Stigma							Total
		15.00	16.00	19.00	20.00	23.00	24.00	29.00	
Test_Stigma	12.00	1	1	0	0	0	0	0	2
	17.00	0	0	0	1	0	0	0	1
	18.00	1	0	0	0	0	0	0	1
	21.00	0	0	1	0	0	0	0	1
	22.00	0	0	0	0	0	1	0	1
	24.00	0	0	0	0	0	0	1	1
	30.00	0	0	0	0	1	0	0	1
	32.00	0	0	0	0	0	0	1	1
	33.00	0	0	0	0	0	0	1	1
Total		2	1	1	1	1	1	3	10

Correlations

		Test_Stigma	Re_Test_Stigma
Test_Stigma	Pearson Correlation	1	.854**
	Sig. (2-tailed)		.002
	N	10	10
Re_Test_Stigma	Pearson Correlation	.854**	1
	Sig. (2-tailed)	.002	
	N	10	10

**. Correlation is significant at the 0.01 level (2-tailed).

Self_Report * VAS Crosstabulation

			VAS			Total
			1.00	2.00	3.00	
Self_Report	1.00	Count	1	0	0	1
		% within Self_Report	100.0%	0.0%	0.0%	100.0%
	2.00	Count	0	3	1	4
		% within Self_Report	0.0%	75.0%	25.0%	100.0%
	3.00	Count	0	1	4	5
		% within Self_Report	0.0%	20.0%	80.0%	100.0%
Total		Count	1	4	5	10
		% within Self_Report	10.0%	40.0%	50.0%	100.0%

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Interval by Interval	Pearson's R	.773	.179	3.443	.009[c]
Ordinal by Ordinal	Spearman Correlation	.700	.220	2.772	.024[c]
Measure of Agreement	Kappa	.655	.228	2.583	.010
N of Valid Cases		10			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

c. Based on normal approximation.

Pretest Depression Assessment for Study Completers

Ranks

	Programme	N	Mean Rank	Sum of Ranks
PHQ9_Pretest	Control	24	24.38	585.00
	CBT	22	22.55	496.00
	Total	46		

Test Statistics[a]

	PHQ 9_PreTest
Mann-Whitney U	243.000
Wilcoxon W	496.000
Z	-.469
Asymp. Sig. (2-tailed)	.639

a. Grouping Variable: Programme

Posttest Comparison of Depression Scores across Treatment Arms

Ranks

	Programme	N	Mean Rank	Sum of Ranks
PHQ9_Score	Control	24	29.00	696.00
	CBT	21	16.14	339.00
	Total	45		

Test Statistics[a]

	PHQ9_Score
Mann-Whitney U	108.000
Wilcoxon W	339.000
Z	-3.305
Asymp. Sig. (2-tailed)	.001

a. Grouping Variable: Programme

Appendix I: Formal Approval Letter

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

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

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2016/174
Approval Number: 0001699

3rd August, 2016

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
03 AUG 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Mr. Japheth Owuor Adina,
Egerton University,
P.O. Box 536-20115,
EGERTON-KENYA.

Dear Mr. Adina,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has received your request for approval of your study titled:

"Cognitive Behaviour Therapy and Its Effect on Clinical Depression and Related Outcomes among HIV-Infected Outpatients in Turbo Sub- County, Kenya".

On the basis of your study review and approval by the Egerton/Research Ethics Review Committee (ERC), IREC is glad to inform you that your study has been granted a Formal Approval Number: **FAN: IREC 0001699** on 3rd August, 2016. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 2nd August, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:
	Principal	-	CHS
	CEO	-	MTRH
	Dean	-	SOM
	Dean	-	SPH
	Dean	-	SOD
	Dean	-	SON

Appendix J: Data Collection Permission Letter

Academic Model Providing Access To Healthcare
Telephone: 254 53 2033471/2P.O. BOX 4606, ELDORET Fax: 254 53 2060727

RESEARCH

Ref: RES/STUD/8/2016 **August 16, 2016**

Japheth Adina
Egerton University
P.O Box 536-20115
Eldoret- Kenya

Dear Mr. Adina,

RE: PERMISSION TO CONDUCT RESEARCH AT AMPATH

This is to kindly inform you that your study *"Cognitive Behaviour Therapy and its Effect on Clinical Depression and Related Outcomes among HIV infected Outpatients in Turbo Sub- County Kenya "* has been reviewed by the AMPATH Research Program Office. Permission is therefore granted to begin collecting your data at AMPATH.

Please note that your research activities should not in any way interfere with the care of patients. This approval does not support access to AMRS data at AMPATH.

You are required to submit a final report of your findings to the AMPATH Research Program Office.

Should you wish to publish your research findings, permission has to be sort from AMPATH Publications Committee. Please contact the AMPATH Research Office in case of any enquiry regarding this matter.

Thank you,

AMPATH CENTRE RESEARCH 16 AUG 2016 P.O. Box 4606-30100 Eldoret

Jepchirchir Kiplagat
Assistant Program Manager - Research.

CC: Chief of Party, AMPATH
Deputy Chief of Party, Research and Training

Appendix K: Ethical Approval Letter

EGERTON UNIVERSITY

TEL: 051-2217808
Fax: 051-2217942
e-mail: dvcre@egerton.ac.ke
website: www.egerton .ac.ke

P. O. BOX 536-20115
EGERTON

RESEARCH ETHICS REVIEW COMMITTEE

EU/RE/DVC/009 **26th July, 2016**

Japheth Owuor Adina,
P.O. Box 8602-30100,
ELDORET.

Dear Mr. Adina,

RE: APPLICATION FOR ETHICAL APPROVAL OF RESEARCH PROJECT

Reference is made to your application for Ethical clearance of your Research Project entitled: **"Cognitive Behaviour Therapy and its Effect on Clinical Depression and related Outcomes Among HIV-Infected Outpatients in Turbo Sub-County, Kenya".**

It was observed that you have addressed all the ethical issues that were raised in a committee meeting held on 15th June, 2016. Your proposal has therefore been approved for implementation.

Please further note that the Standard Operating Procedures (SOPs) requires that you submit progress and final reports of your study to the Committee. You are also required to obtain Research permit from NACOSTI.

Prof. J. K. Kipkemboi
CHAIRMAN – RESEARCH ETHICS COMMITTEE

JKK/ejc

Appendix L: Map of AMPATH ART Clinics in Western Kenya