EFFECTIVENESS OF NON-CASH INCENTIVES AND PSYCHOSOCIAL SUPPORT ON SIX-MONTHS RETENTION ON TREATMENT AMONG PEOPLE LIVING WITH HIV/AIDS IN KIBERA INFORMAL SETTLEMENT, NAIROBI, KENYA

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Effectiveness of Non-Cash Incentives and Psychosocial Support on Six-Months Retention on Treatment among People Living with HIV/AIDS in Kibera Informal Settlement, Nairobi, Kenya

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A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy in Epidemiology of the Jomo Kenyatta University of Agriculture and Technology

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other university

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DEDICATION

This work is dedicated to my parents, Mr and Mrs Opondo, my wife Mercy Mutua, my brothers and sisters for the unconditional support and love during my studies.

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ACRONYMS AND ABBREVIATIONS

3TC	Lamivudine
aHR	Adjusted Hazard Ratios
AIDS	Acquired Immunodeficiency Syndrome
aRR	Adjusted Risk Ratios
ART	Antiretroviral Therapy
CD4 +	T-Cells
Chi2	Chi-square
CHV	Community Health Volunteer
CI	Confidence Interval
CM	Contingency Management
COVID-19	Coronavirus disease
DTG	Dolutegravir
EAC	East African Countries
EFV	Efavirenz
EMR	Electronic Medical Record
ESRC	Ethics and Scientific Review Committee
HIV	Human Immunodeficiency Virus
IGAs	Income Generating Activities

ITT	Intention-To-Treat
IQR	Interquartile Range
KES	Kenya Shillings
LMIC	Low-and-Middle-Income Countries
LTFU	Lost to follow up
MDG	Millennium Development Goals
MOH	Ministry of Health
NASCOP	National AIDS and Sexually Transmitted Infections Control Program
NSDCC	National Syndemic Diseases Control Council
ODK	Open Data Kit
PEPFAR	The President's Emergency Plan For AIDS Relief
PI	Principal Investigator
PLHIV	People Living with HIV
RCT	Randomized Control Trial
SD	Standard Deviation
SDGs	Sustainable Development Goals
SSA	sub-Saharan Africa
STI	Sexually Transmitted Infections
TB	Tuberculosis

TDF	Tenofovir
UCT	Unconditional Cash Transfers
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGA	United Nations General Assembly
USA	United States of America
VL	Viral Load
WHO	World Health Organization

ABSTRACT

This study sought to determine the effectiveness of non-cash incentives combined with psychosocial support on retention during the first six months of HIV treatment among patients in informal settlement of Kibera in Nairobi, Kenya. The non-cash incentive consisted of a reminder at every clinic visit that the participants stand to receive free T-shirts of their favorite football team or free *Kiondos* based on preference if they made it to the sixth month visit without missing a treatment appointment. The study adopted an experimental design conducted at three study sites of Kibera Community Health Center, Kibera South Health Center and Silanga Dispensary, within Kibera informal settlement, where participants were randomly assigned to the intervention and control groups at a ratio of 1:1. Participants in the intervention group received a reminder at every clinic visit that they stand to receive the non-cash incentive if they made it to the sixth month visit without missing treatment appointment and attending all monthly psychosocial support group meetings. Participants in both intervention and control groups received the standard care. A total of 388 participants were recruited into the study and followed up for an average period of six months. The overall retention on treatment at six months was 93% (95% CI: 90 - 95%). Retention at six months among the intervention and control groups were 94% and 91% respectively (aRR: 1.03; 95% CI: 0.98 - 1.09; *p*-value=0.24). Predictors of patients' retention on treatment were being divorced, being widowed, time to clinic, participant weight category of 70-99 kg, being on 1st line regimen of TDF/3TC/EFV and other 1st line ART regimens which included ABC/3TC/EFV+AZT/3TC/LPV/r+AZT/3TC/NVP +D4T/3TC/EFV+TDF/3TC/NVP. Mortality and lost to follow-up rates were 1.6 and 13.5 per 100 person-years, respectively. The combination of non-cash incentives and psychosocial support was not effective in improving retention during the first six months of HIV/AIDS treatment. The study provided an important contribution to understanding the potential of non-cash incentives combined with psychosocial support to achieving epidemic control in resource limited settings. Further research investigating the long-term effects, cost-effectiveness, scalability and sustainability of such interventions are warranted.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

1.1.1 Global Picture of HIV/AIDS

Forty-one years ago, in June 1981, the human immunodeficiency virus (HIV) was first detected from Los Angeles in five young homosexual men diagnosed with Pneumocystis carinii pneumonia and other opportunistic infections (CDC, 1996). Within a decade the acquired immunodeficiency syndrome (AIDS) was killing millions of people around the world. The United Nations General Assembly (UNGA) convened its first ever special session on HIV in 2001 to establish a shared vision that pushed global efforts to reverse the progression of the pandemic (United Nations, 2001b). Despite tremendous progress that has been made in the fight against HIV/AIDS in the past 20 years, the enormous scale of the pandemic remains. World leaders convened at the 2021 UNGA High-Level meeting on AIDS and adopted a new, ambitious and achievable Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030. The declaration will guide the global HIV response over the next six years (United Nations General Assembly, 2021).

There were 39 million people globally living with HIV in 2022 of which 86% (33.6 million) knew their HIV status and 76% (29.8 million) were on Antiretroviral Therapy (ART) that were once deemed too expensive and too complicated for low resource settings. About 71% (27.7 million) were virally suppressed, while 9.2 million people with HIV did not have access to antiretroviral treatment (UNAIDS, 2023).

Figure 1.1 below shows the HIV treatment coverage for all ages. The graph compares the global, Eastern and Southern Africa and Kenya ART coverage from 2010 to 2022. The three lines show that ART coverage has steadily improved at global and Eastern and

Southern Africa region from an average of 25% in 2010 to 76% and 83% respectively in 2022. The same show an ART coverage shift in Kenya from 32% in 2010 to 94% in 2022.

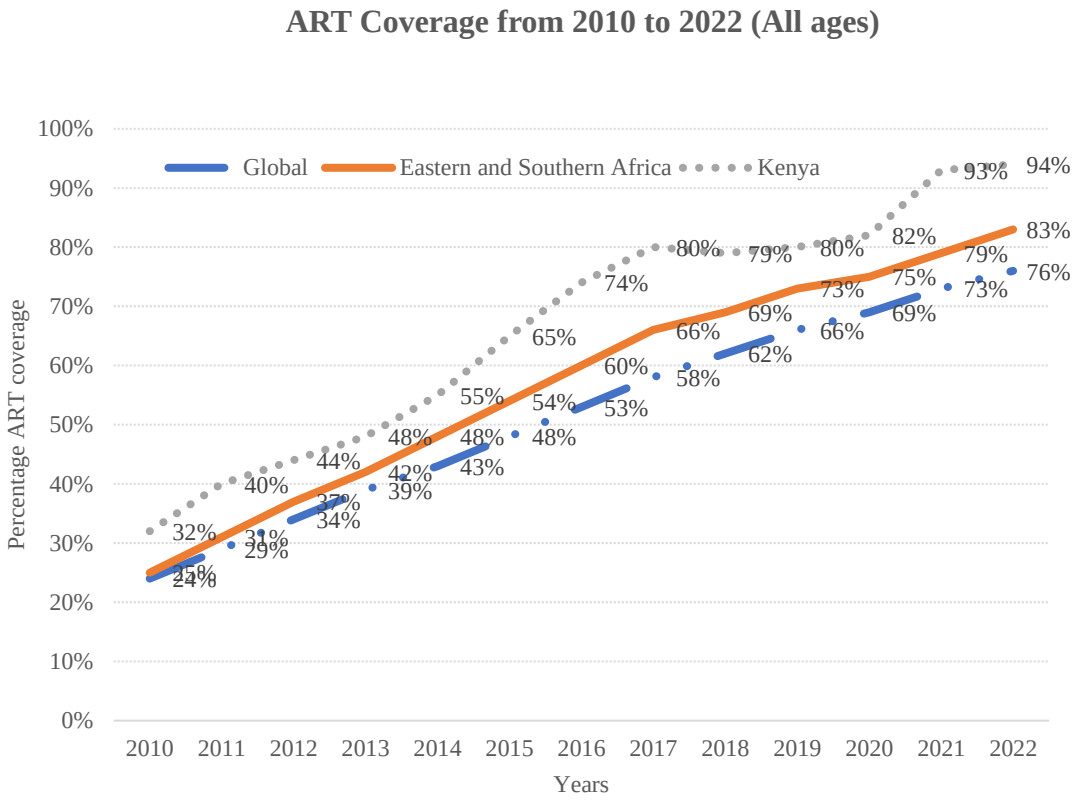

Figure 1.1: ART coverage for Global, Eastern and Southern Africa and Kenya- 2010 to 2022

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

Viral suppression enables people living with HIV to live long, healthy lives and to have zero risk of transmitting HIV to other people, however, viral load suppression in children was only at 46% in 2022 (UNAIDS, 2023) . Botswana, Eswatini, Rwanda, the United Republic of Tanzania and Zimbabwe, all in sub-Saharan Africa, have already achieved the 95–95–95 targets, and at least eight other countries in sub-Saharan Africa (Kenya, Malawi, Namibia, Lesotho, Zambia, Uganda, Burundi and Togo) are close to doing so.

Table 1.1 below shows the HIV testing and treatment cascade by age and sex for selected sub-Saharan countries in 2022. These are remarkable treatment successes which are underway in low income countries such as Malawi, which has introduced tailored interventions in districts where testing and treatment coverage were lagging behind. As a result, in 2022, an estimated 94% of people living with HIV in Malawi knew their HIV status, 92% of people who knew their HIV-positive status were receiving ART, and 86% of people on treatment were virally suppressed.

Table 1.1: HIV Testing and Treatment Cascade by Age and Sex, among Selected Sub-Saharan Countries, 2022

#	Country	Total Population living with HIV	Men (15+ years) living with HIV	Women (15+ years) living with HIV	Children (0-14 years) living with HIV
1	Eswatini	97-94-93	96-91-90	97-96-95	95-88-83
2	United Republic of Tanzania	95-94-92	93-91-89	98-97-95	72-72-66
3	Botswana	96-93-92	94-87-87	98-97-97	58-58-56
4	Zimbabwe	95-94-89	96-92-88	97-97-93	69-69-59
5	Rwanda	95-92-90	94-91-89	95-93-91	76-75-73
6	Kenya	94-94-89	93-89-84	95-95-92	84-84-74
7	Malawi	94-92-86	90-86-80	98-98-93	70-70-55
8	Namibia	94-91-86	91-86-80	97-94-90	76-76-68
9	Lesotho	93-85-84	92-80-79	95-89-88	81-81-75
10	Zambia	92-89-86	92-90-86	94-91-88	67-67-62
11	Uganda	89-84-79	88-80-75	92-87-83	71-71-60
12	Burundi	86-84-79	87-86-80	94-92-86	36-36-31
13	Togo	84-81-73	74-67-61	92-91-83	60-60-43

Reached the 95–95–95 testing and treatment targets (equivalent to 95–90–86 in this table)

Reached the 90–90–90 testing and treatment targets (equivalent to 90–81–73 in this table)

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

1.1.2 HIV/AIDS in Kenya

The first case of HIV/AIDS in Kenya was detected in 1984 to become one of the major causes of mortality and placed tremendous strain on the health system and the economy. Towards the end of 1987, HIV/AIDS began to spread rapidly and, by 1999, HIV/AIDS was declared a national disaster. In 2022, Kenya had the eighth and seventh largest epidemic in the world and Africa respectively. There were 1.4 million (1.2-1.6 million) people living with HIV (PLHIV) in the country (Figure 1.2) with an estimated prevalence of 3.7% (3.3 – 4.1) among adults aged 15 to 49 years (Figure 1.3). HIV/AIDS is more prevalent among women than men, 860,000 (770,000 – 1,000,000) women aged 15 years and above living with HIV compared to 450,000 (400,000 – 520,000) men and about 97% (86-100%) of women aged 15 years and above were receiving ART compared to 89% (80 - 100%) of men (UNAIDS, 2023). Therefore, more women compared to men were on HIV/AIDS treatment.

Population Living with HIV in Kenya (All ages), 1990 to 2022

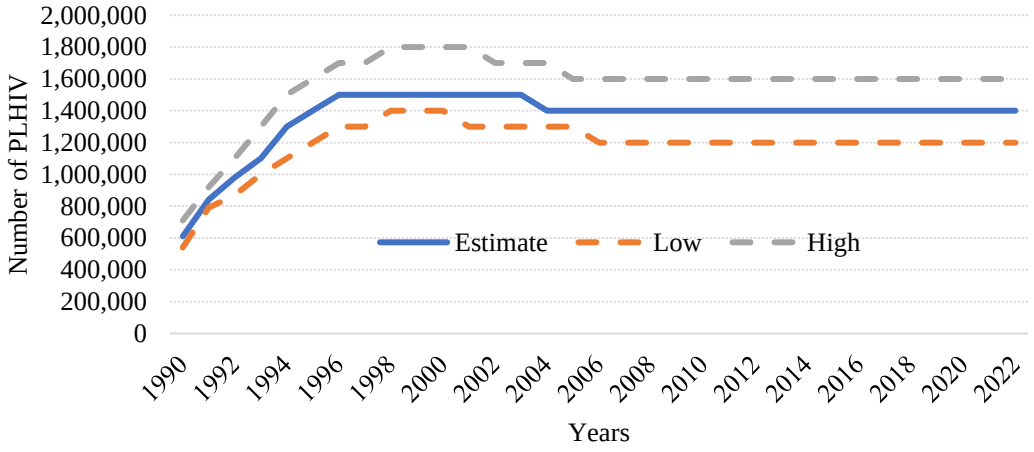

Figure 1.2: People of all Ages, Living with HIV in Kenya, 1990 to 2020

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

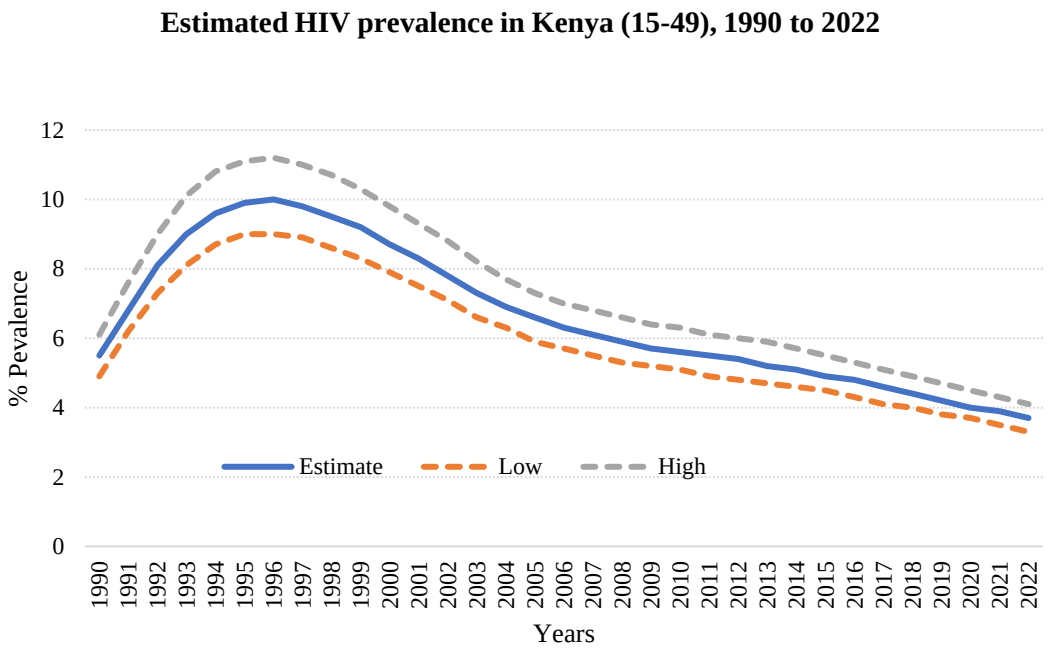

Figure 1.3: Estimated HIV Prevalence in Kenya, among 15-49-Year-Old from 1990 to 2022

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

The main modes of HIV/AIDS transmission in Kenya are mixed and includes sexual contact, mother-to-child transmission and injecting drug use (Ng'eno *et al*., 2018; Ogalo *et al*., 2018). There have been significant gains in the fight against HIV/AIDS in Kenya in recent years. The number of new HIV infections has fallen by more than half since 2009, and the proportion of people on ART has increased to about 95% (UNAIDS, 2023). However, there is still much work to be done. New HIV infections are still high at 22,000 and AIDS related deaths for all ages stood at 18,000 in 2022. HIV-related stigma and discrimination remain a major challenge, and access to HIV services is not yet universal.

Non-cash incentives are rewards offered to motivate people to change their behavior, but instead of money, other forms of recognition or benefits are used. This study examined the effectiveness of non-cash intervention combined with psychosocial support groups

among the newly tested HIV/AIDS positive clients seeking services at three health facilities within Kibera Informal Settlement in Nairobi, Kenya. The non-cash incentive consisted of a reminder at every clinic visit that the participants stand to receive free T-shirts of their favorite football team or free *Kiondos* based on preference if they made it to the sixth month visit without missing a treatment appointment.

1.2 Statement of the Problem

Since the beginning of the HIV/AIDS epidemic, 85.6 million [64.8 - 113.0 million] people have been infected with the HIV/AIDS virus and about 40.4 million [33.6 – 48.6 million] people have died from AIDS related illnesses. The colliding AIDS and Coronavirus disease (COVID-19), along with economic and humanitarian crises have placed the global HIV response under increased threat. In 2022 there were about 1.3 million [1.1 – 1.7 million] new HIV infections and about 630,000 [480,000 – 880,000] people died of AIDS related illnesses worldwide (UNAIDS, 2023) . If the current trends continue, then it is projected that 460,000 people will die of AIDS related causes by 2025. According to UNAIDS, about 4,000 people become infected with HIV every day, meaning that 1.2 million people will be newly infected with HIV in 2025. This will be three times more than the 2025 target of 370,000 new infections (UNAIDS, 2023). In Kenya, the estimated number of adults living with HIV has risen to an all-time high of 1.4 million [1.2 – 1.6 million] due to the recent introduction of "test and treat" strategy. Annual new HIV infections among adult patients aged 15 years and above have reduced dismally from 25,000 in 2018 to 18,000 in 2022. AIDS related deaths have increased from 17,000 in 2019 to 19,000 in 2021 and 18,000 in 2022 (UNAIDS, 2023).

HIV/AIDS has affected economic growth worldwide by reducing availability of human capital. PLHIV are not only unable to work, but also require significant medical care that may most likely cause a strain in the health care system, especially in countries with significant AIDS population. The global, Eastern and Southern Africa and Kenya HIV prevalence stand at 0.7%, 5.9% and 3.7% respectively (UNAIDS, 2023). A 1% increase in the HIV/AIDS prevalence in sub-Saharan Africa (SSA) decreases growth in per capita

income by 0.47%. Given the high prevalence of HIV/AIDS in the East African countries, the impacts on economic growth has been felt more at 0.64% reduction in per capita income for every 1% increase in the prevalence of HIV/AIDS (Nketiah-Amponsah *et al*., 2019). In Kenya, the expenditure on HIV/AIDS as a percentage of public health spending was at one time as high as 50% and treating one AIDS patient for one year was as expensive as educating ten primary school students for one year (Stover & Bollinger, 1999).

Although a great deal of research has been done on the long-term retention of patients on treatment programs in SSA, early retention of patients on treatment has received comparatively less attention. Evidence from various studies have shown that ART is effective in preventing progression to AIDS and HIV transmission if treatment is started immediately (INSIGHT START Study Group *et al*., 2015; TEMPRANO ANRS 12136 Study Group, 2015). But not all patients remain on treatment under programmatic conditions. Some patients drop out of treatment and end up not restarting treatment elsewhere (Fox & Rosen, 2010; McCoy *et al*., 2017). These patients are at high risk of morbidity and death within a short time.

In addition, there is limited evidence from resource-constrained settings and SSA on interventions and strategies targeted at improving early retention of patients on treatment (Muhula *et al*., 2022; Wilkinson *et al*., 2015). It is depressing and even scandalous that after more than thirty years into the global HIV epidemic, effective methods to support treatment efforts remain limited to biomedical interventions and besides, researchers have conducted very few rigorous evaluations of such interventions (Bertozzi *et al*., 2010; Pettifor *et al*., 2012).

1.3 Justification

To address the research gaps, this randomized control trial (RCT) tested a novel intervention of non-cash incentive where participants in the treatment arm of the study received a reminder at every clinic visit that they stand to receive free T-shirts of their

favorite football team or free *Kiondos* based on choice if they made it to the sixth month visit without missing appointment. This was combined with enrolling the patients into and following them up to attend psychosocial support group meetings for the first six months of starting ART. The study was implemented in Kenya, within Kibera informal settlement in Nairobi with the focus on retaining patients on HIV treatment for the following reasons.

First, the third goal of the Sustainable Development Goals (SDGs) set by the United Nations is to ensure healthy lives and promote well-being for all at all ages. This research has the potential to contribute to this goal by expediting Kenya's progress towards the achievement of UNAIDS second and third Fast-Track targets by the year 2030.

Second, if the intervention is effective in retaining patients on treatment, then the research would contribute in reducing morbidity and mortality among PLHIV, which currently have remained high at 18,000 [16,000 – 35,000] AIDS related deaths recorded in Kenya in the year 2022 (UNAIDS, 2023). It is imperative for policymakers and governments to recognize the significance of achieving the Fast-Track Joint United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 targets by 2030. The 90-90-90 Fast-Track targets were partially achieved by 2020 indicating that the world is on a trajectory to end the AIDS epidemic by 2030 leading to aversion of 21 million AIDS-related deaths, 28 million HIV infections and 5.9 million infections among children (UNAIDS, 2020).

Third, early initiation of PLHIV on ART, retaining them on ART and ensuring virological suppression has significant clinical benefits on treatment and can eliminate HIV/AIDS transmission (Cohen, Shaw, *et al*., 2011). Several novel approaches that address structural and behavioral risk factors should therefore be considered at local levels for maximum impact on the epidemic (Bekker *et al*., 2015).

The choice of the non-cash incentive as an intervention in this study was informed by the fact that incentive-based programmes have been used with varying success in many areas of medicine to affect health-related behaviors, such as HIV testing, obesity management, and smoking cessation.

Kenyans are emotionally attached to English and local football premier leagues and this project intended to leverage the attachment to football to keep patients on HIV treatment. In addition, Kenya banned plastic bags in 2017, and so *Kiondos* would have been preferred by the participants as a durable shopping bag. The choice of psychosocial support was informed by a preliminary project that Amref Health Africa was implementing in two health facilities within the informal settlement of Kibera. In the project, patients were enrolled in the groups, and they had attended the psychosocial support groups, hence evidence that these were promising interventions worth exploring their effectiveness in combination with the non-cash incentives.

1.4 Hypothesis

1.4.1 Null Hypothesis

The proportion of patients on HIV treatment retained on treatment during the first six months of starting ART was not different between those who received non-cash incentives and got enrolled into psychosocial support groups and those who received standard care. i.e

$$H_0: p1 = p2$$

1.5 Research Questions

i. What is the effectiveness of non-cash incentives and psychosocial support on the retention of patients starting ART for the treatment of HIV in the first six months?
ii. What are the patient level predictors of retention on HIV treatment in the first six months of starting ART?
iii. What are the survival estimates for patients on treatment of HIV in the first six months of starting ART?

1.6 Objectives

1.6.1 Broad Objective

To determine the effectiveness of non-cash incentive (a reminder at every clinic visit that patients stand to receive free T-shirts of their favorite football team or free *Kiondos*) and psychosocial support on HIV retention in the first six months of antiretroviral therapy among patients in the informal settlement of Kibera in Nairobi, Kenya.

1.6.2 Specific Objectives

i. To determine the effectiveness of the intervention on retention of patients on HIV treatment in the first six months of starting ART
ii. To determine patient level predictors of retention on HIV treatment in the first six months of starting ART
iii. To determine survival estimates of patients on treatment after six months of starting ART

1.7 Conceptual Framework

The interventions in this study and socio-demographic factors are likely to affect the various patient-level factors which in turn determine the intermediate outcomes and subsequently affect the final study outcome. Figure 1.4 below displays these channels. When a patient tests HIV positive, s/he would either be enrolled in the intervention or control arms of the study. Those enrolled in the intervention arm received the non-cash incentives and got enrolled into psychosocial support groups and were asked to attend clinics as per schedule for ARVs refill and education sessions in the monthly support group meetings. The non-cash incentives and the education sessions together with the socio-demographic factors have the potential to modify patient behaviour and influence outcomes such as sexual choices (number of sexual partners one could have, condom use during sexual intercourse), HIV disclosure and labour market participation. These are likely to go further to determine retention of patients on HIV treatment. Patients who are

retained on treatment and adhere to taking their medication as prescribed end up with suppressed viral load in the body hence minimizing mortality among HIV positive patients.

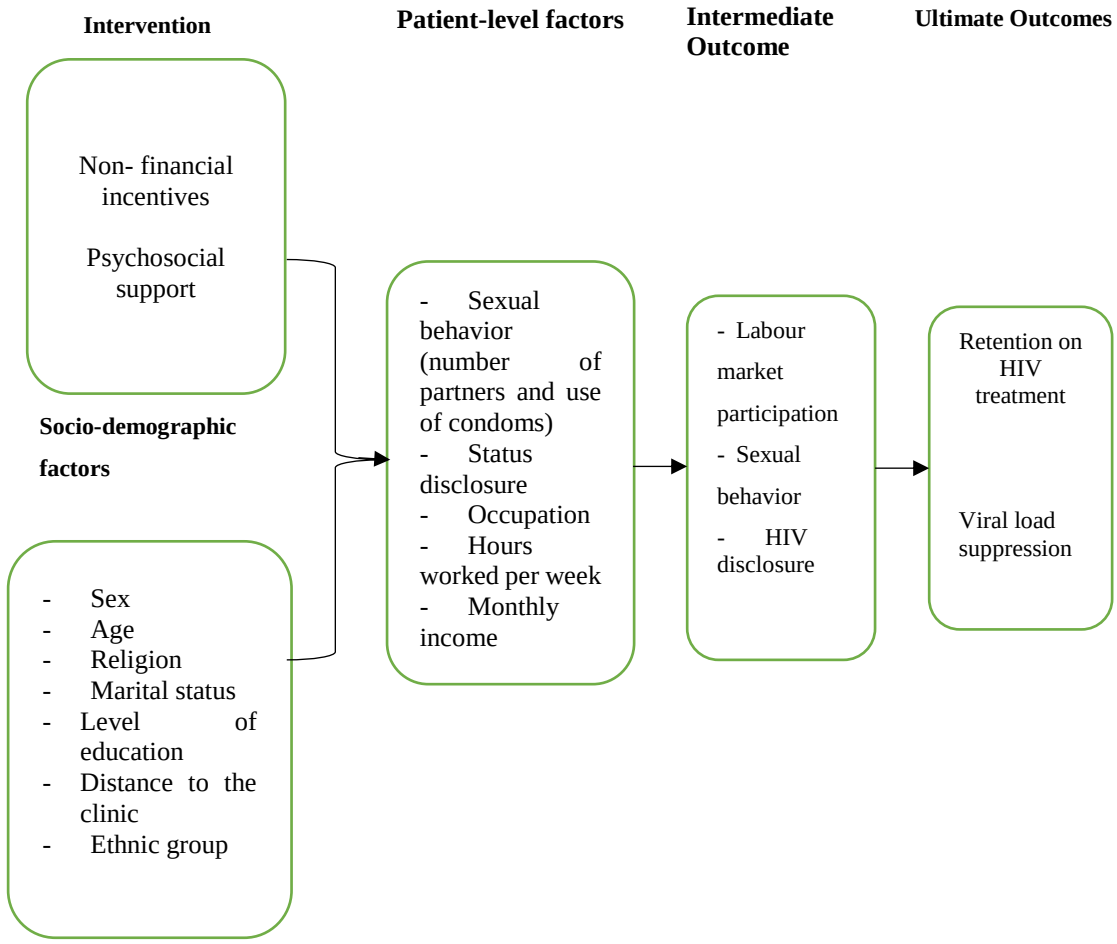

Figure 1.4: Conceptual Framework

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Early in the HIV/AIDS epidemic, there were few targets to guide the global response to HIV/AIDS pandemic. To date, these have increasingly developed into numerous and complex target frameworks.

The first global HIV/AIDS targets were first defined in the 2000 millennium development goals (MDGs). Though there were no specific quantitative targets, the MDGs stated an aim to 'halt and reverse' the epidemic (UNAIDS, 2010). In 2001, there was "The Declaration on Commitment" on HIV/AIDS which set out more timebound goals and targets, placing importance on transparency, accountability and ongoing reporting for concerted, determined civil society activism (United Nations, 2001a). Progress towards the 2001 Declaration's targets was reported in 2006, indicating underperformance on most of the targets apart from that of increasing HIV/AIDS funding for low-and-middle-income countries (LMICs) which had been achieved (United Nations, 2006).

Quantitative targets for ART coverage began with World Health Organization (WHO) commitment to enroll 3 million people on treatment by 2005. Later on, the Joint United Nations Programme on HIV/AIDS (UNAIDS) aimed to scale up and sustain ART coverage for 15 million people. This target was achieved ahead of time in March 2015 (UNAIDS, 2015).

In the 2011-2015 strategy, UNAIDS set a global vision to achieve Three Zeros – Zero new HIV infections, zero AIDS related deaths and zero discrimination (UNAIDS, 2011). Five years later, in 2015, the Three Zeros served as the basis for the development of the fast-track strategy, outlining 10 targets, one of which was the 90-90-90 target for 2020, which served as a very important pointer of progress for countries (UNAIDS, 2014). The 90-90-90 target aimed for 90% of PLHIV to be diagnosed, 90% of diagnosed people to be

on ART and 90% of people on ART to have a fully suppressed viral load (VL) by 2020. These targets were missed, but not by a big margin. At the end of 2020, 84% of PLHIV knew their HIV status, 87% of PLHIV who knew their HIV status were accessing ART and 90% of people under treatment were virally suppressed (UNAIDS, 2021b).

Figures 2.1 and 2.2 below show HIV testing and treatment cascades globally (from 2015 to 2022) and for Kenya (from 2010 to 2022) constructed from the UNAIDS epidemiological estimates of 2023. Both graphs show that not only has there been a steady improvement in performance against the 95-95-95 targets globally, this picture is also reflected in Kenya where performance against the 1st 95 improved from 71% in 2010 to 94% in 2022 while performance against the 2nd 95 improved from 45% in 2010 to 98% in 2022. The Kenya graph show missing data for the 3rd 95 from 2010 to 2018 and 2021, a reflection of under reporting being experienced by many countries across the globe. In 2020, Kenya's performance against the 3rd 95 was at 94%, one percentage point short of reaching the target of 95%. The 3rd UNAIDS target was achieved in 2022 at 95% and therefore the challenge is to maintain this achievement towards ensuring that every PLHIV who is on ART achieves viral suppression.

HIV treatment involves taking ART that work to control the virus. ART is recommended for everyone with HIV, and people with HIV should start ART as soon as possible after diagnosis, even on that same day. About 89% and more than 98% of PLHIV globally and in Kenya respectively knew their HIV status and on ART in 2022.

Generally, Kenya's performance as of 2022 seem encouraging across all the HIV testing and treatment cascade indicators, showing that the country is firmly on course to achieving the UNAIDS targets way before 2030. However, a cursory look at the absolute figures still show some gaps that need to be addressed such as about 18,000 AIDS related deaths among adults and children in 2022 and 22,000 adults and children newly infected with HIV in the same year. Similarly, there were an estimated 100,000 PLHIV who are not yet on HIV treatment (PEPFAR, 2020; UNAIDS, 2021a). These gaps are even larger within sub-populations, including children, young people and men.

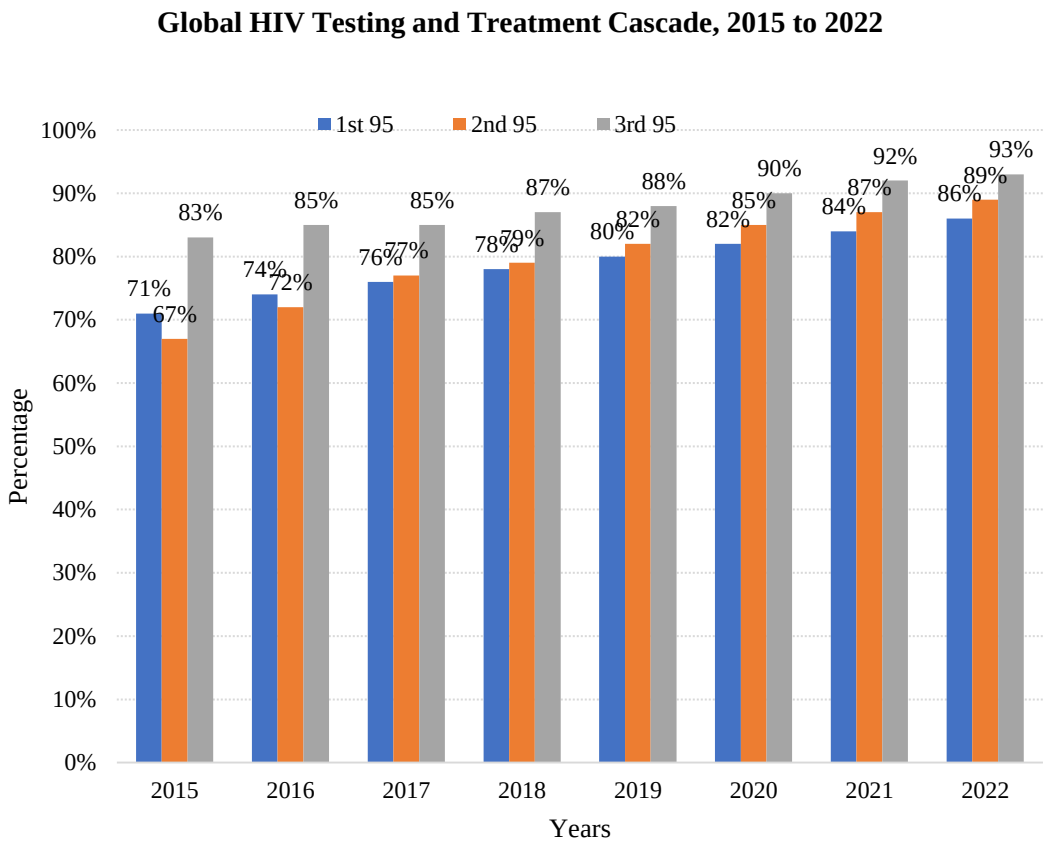

Figure 2.1: Global HIV Testing and Treatment Cascade

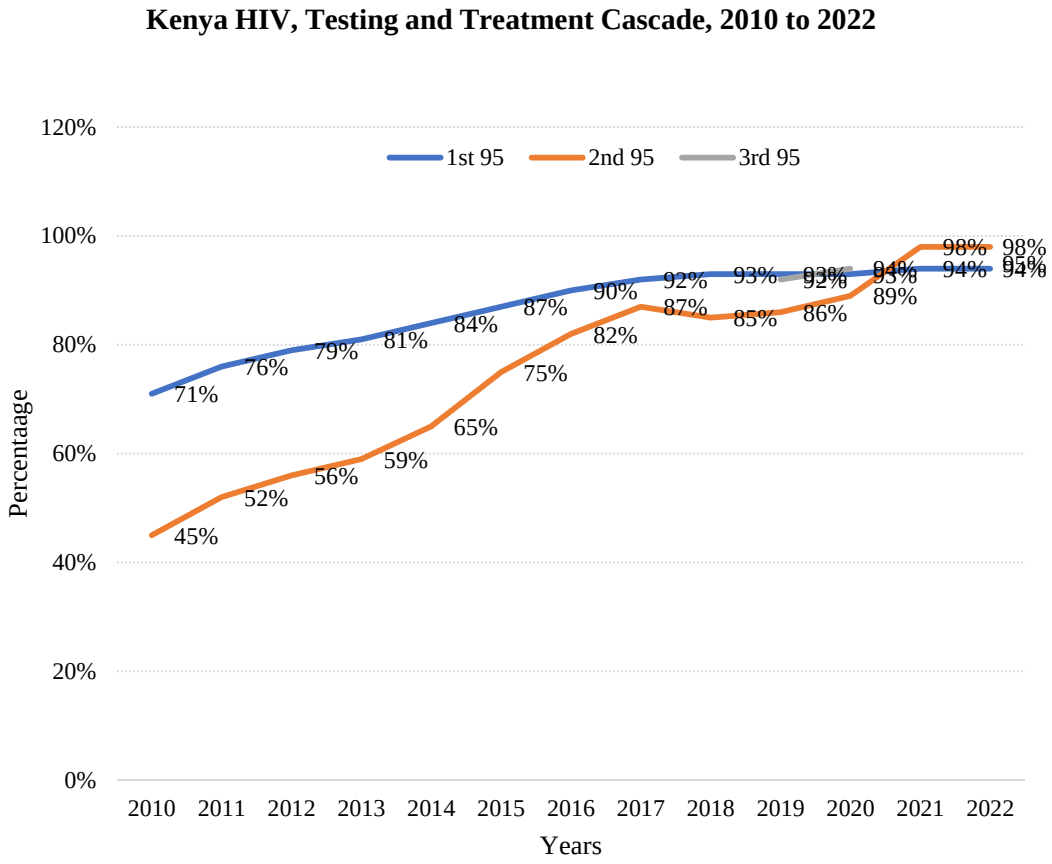

Figure 2.2: Kenya HIV, Testing and Treatment Cascade

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

Figures 2.3 show that AIDS related deaths in Kenya have reduced by 86% since the peak in 2003, 2004. In 2022, around 18,000 people died from AIDS related illnesses in Kenya, compared to 130,000 people in 2003 and 40,000 people in 2012 (10 years ago). Similarly, AIDS related mortality has reduced by 81% among children aged 0-14 years and by 45% among adults aged 15 years and above since 2012.

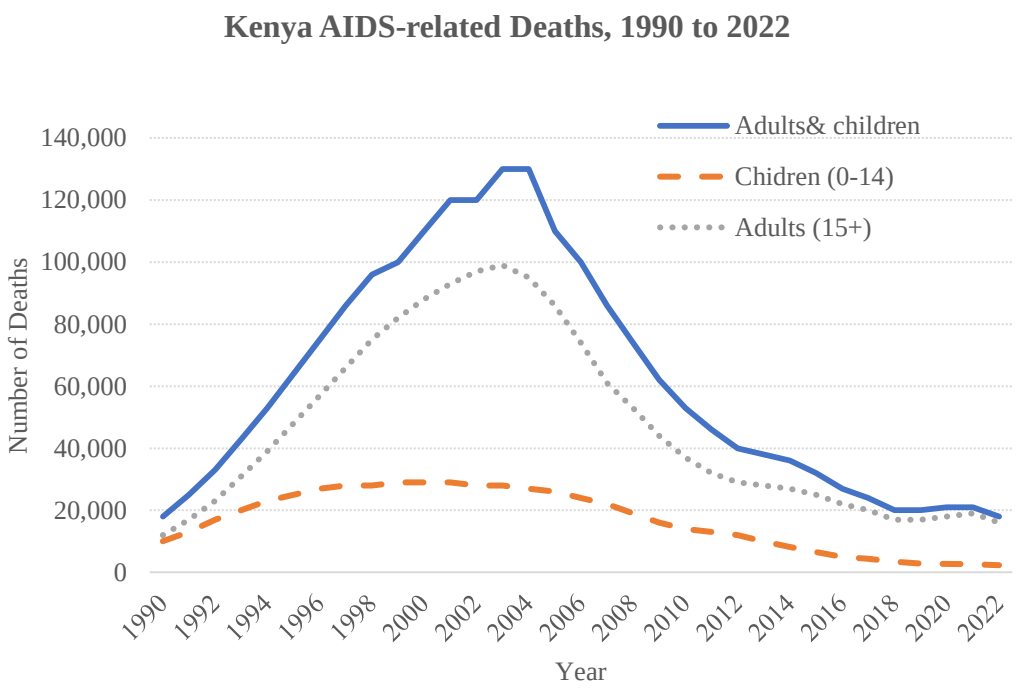

Figure 2.3: AIDS -Related Deaths in Kenya, from 1990 to 2022

Figure 2.4 below, show that new HIV infections in Kenya have reduced from its peak of 230,000 cases in 1993, to 22,000 cases in 2022. This is almost a 90% reduction in the new cases. The tremendous reduction in AIDS related deaths and new HIV infections is an indication that public health priorities such as focused prevention programs have prevailed in Kenya. These improvements, are underpinned by the strengthened community health systems and their benefits spill over beyond the public health realm and add to progress towards other SDGs.

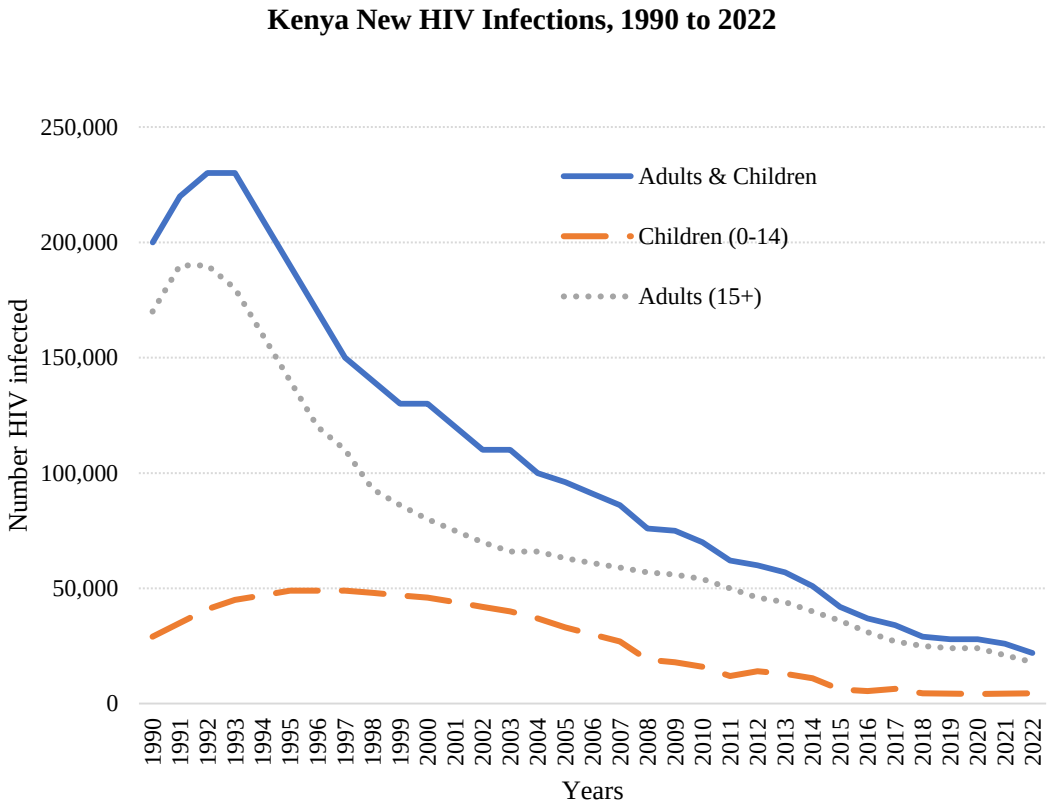

Figure 2.4: New HIV Infections in Kenya, from 1990 to 2022

Source: UNAIDS 2023 epidemiological estimates (https://aidsinfo.unaids.org/)

2.2 Incentives in HIV/AIDS Care and Other Programs

Incentives—cash/financial and non-cash/financial rewards—which are also referred to as contingency management (CM), have been used among individuals who misuse substances contigent upon objective evidence of abstinence (Petry, 2010). Such interventions have substantial evidence of efficacy in reducing drug use across a range of populations and settings and have been implemented throughout the United States of America (USA) and countries around the world (Garcia-Rodriguez *et al*., 2009; Peirce *et al*., 2006; Petry *et al*., 2005). CM are associated with among the largest effect sizes and have consistently engendered positive outcomes in treating substance use disorders (Dutra

et al., 2008). Zenner (Zenner *et al*., 2012) documented that patient financial incentives were effective in increasing chlamydia screening coverage among 15-24-year olds in England. In HIV/AIDS care, incentives have been used to encourage people to get tested, start treatment, and stay in care. Financial incentives, such as cash payments or vouchers, are the most common type of incentive used in HIV/AIDS care. Other types of incentives include transportation assistance, childcare, and food assistance. Incentive interventions that are appropriately implemented can increase HIV testing rates and voluntary male circumcision, and they can as well improve other HIV prevention and treatment outcomes in certain settings in the short term (Galárraga & Sosa-Rubí, 2019). A systemic review of seven studies documenting effects of incentives on HIV or STI testing uptake demonstrated a high uptake of HIV/STI testing among the incentivized group compared to the non-incentivised group (Lee *et al.,* 2014). Studies on incentive-based medication adherence interventions reported that incentives increased adherence by a mean of 20% points, with a positive relationship between the value of the incentive and the effect of the intervention. Post-intervention evaluations found that adherence effects diminish after the interventions are discontinued pointing to the challenge of developing sustainable and cost-effective long term interventions (DeFulio & Silverman, 2012). In addition, monetary incentive programs have been criticized as unethical, as they may exert undue influence on a person to get into a program depending on the amount on offer (Ostermann *et al.*, 2015). Gorin, however, argues that incentives have the potential not only to impact the health behavior of an individual but to affect communal cultural changes (Gorin & Schmidt, 2015). A paper by Sarah Baird of George Washington University examined the medium-term effects of a two-year cash transfer program targeting adolescent girls and young women and found significant declines in HIV prevalence, teen pregnancy, and early marriage among recipients of unconditional cash transfers (UCTs). These effects evaporated quickly two years after the cessation of transfers (Baird *et al*., 2016). Sandra evaluated the effectiveness of short-term cash and food assistance to improve adherence to ART and retention in care among PLHIV in Tanzania. The group that was receiving cash incentive demonstrated a 21.6% point difference in treatment adherence at six months compared to the control group. The six months adherence to treatment was also

significantly higher by 15.8% among the group that received food assistance versus the control group. At 12 months, the effect of cash incentive but not food on treatment adherence and retention was sustained (McCoy *et al*., 2017).

There are a number of reasons why incentives may be effective in improving HIV/AIDS care outcomes. First, incentives can help to offset the costs of care, such as transportation and childcare. Second, incentives can provide a motivation for people to start and stay in care, even if they are not feeling sick. Similarly, incentives can help to build trust between patients and healthcare providers (Iguna *et al*., 2022). Despite the potential benefits of incentives, there are also some potential drawbacks. For example, some people may feel that incentives are coercive or that they undermine the intrinsic motivation to stay healthy. Additionally, incentive programs can be expensive to implement.

Incentives—cash/financial and non-cash/financial are associated with among the largest effect sizes and they invariably led to pragmatic results in treating substance use disorders, HIV/AIDS or sexually transmitted infections (STI) testing uptake and medication adherence (Dutra *et al*., 2008; Lee *et al*., 2014). However, monetary incentive programs have been condemned as immoral, as they may apply inappropriate influence on a person to get into a program depending on the amount on offer (Ostermann *et al*., 2015). In addition, long term effects of such monetary incentive programs are not sustainable few years after cessation of the cash transfers (Baird *et al*., 2016). Businesses have noted that tangible, non-financial rewards do a better job of attracting and holding people's interest, getting them excited about possibilities, and motivating them to act in a way that meets business objectives (Quality Incentive Company, 2018). The theory is that, while cash is nice, and usually needed, the participant feels more "rewarded" when they receive something they have long wanted or may not have acquired otherwise.

Less is known about the potential effect of the use of non-cash incentives in HIV treatment. The saying "cash is king" has been repeated enough in many settings that it could qualify as a cliché. While there may be some truth to this statement in settings such as finance and economics, it is a poor philosophy when dealing with health incentive

programs. It may seem counterintuitive. Ask anyone whether they would prefer cash or a non-financial reward of the same value. The response is likely to be a resounding, “Cash!”. However, when it comes to tapping into the emotions that make incentive programs work, the results are very different.

2.3 Psychosocial Support in HIV/AIDS

People facing similar situations, especially adverse or unpleasant situations, often find comfort, support and strength in being together with other people in similar situations (World Health Organization, 2005b). HIV care and treatment, combined with psychosocial support as a community-based intervention are recommended by WHO as a standard practice and needed to reduce HIV related illnesses, deaths and a modality for addressing psychosocial needs of PLHIV (World Health Organization, 2016). Numerous studies have documented the usefulness and impact of psychosocial support groups in HIV patient care and support. A multicenter cohort study conducted in South Africa compared clinical, virological and immunological outcomes between children who received and who did not receive community-based adherence support from patient advocates. The study demonstrated significantly increased retention at 3 years (36 months) though the overall quality of evidence was low (Grimwood *et al*., 2012). A systematic review (Bateganya *et al*., 2015) of studies examining the evidence of impact of support groups on retention in HIV care among PLHIV residing in resource limited settings identified five studies (Decroo *et al*., 2011; Lamb *et al*., 2014; Muchedzi *et al*., 2010; Wouters *et al*., 2009). However, all these studies examined retention after six months of starting ART i.e 1 year, 2 years, 3 years or years later. Again, all the studies were observational, using either a cross sectional, cohort, qualitative or a mixed methods design. A more recent study conducted in Mozambique examined the effect of community ART groups on retention in care and found better 12 months and 24 months retention among patients in community ART groups 99.1% and 97.5% respectively compared to individual care 89.5% and 82.3% (Decroo *et al*., 2017).

As much as psychosocial support groups are recommended by WHO as a standard practice to HIV care, the implementation is varied. Some conduct meetings within the community, the target population varies, some have other added components that are dimmed important to the individuals served and even some have specific domains of focus such as social-recreation, psychotherapy, peer-modeling and psychoeducation (Elizabeth Glaser Pediatric AIDS Foundation, 2022; Kiambu People Living with HIV&AIDS, 2022; Machuka *et al*., 2020). In some places, the intervention is not practiced at all because of the challenges of making it attractive to PLHIVs to attend.

The status of implementation of psychosocial support in Kenya is mixed because of various challenges such as lack of funding. Psychosocial support is usually seen as an add-on to HIV care and treatment services and as a result, it is not adequately funded. Secondly, there is a shortage of trained psychosocial support providers in Kenya. This is due to a number of factors including the high cost of training, the lack of qualified trainers and the lack of incentives for people to become psychosocial support providers. The other challenge is stigma and discrimination which PLHIV continue to face. This makes it difficult for them to access psychosocial support services.

HIV infection affects all dimensions of a person's life: physical, psychological, social and spiritual. Counseling and social support can help people and their carers cope more effectively with each stage of the infection and enhances the quality of life. With adequate support, PLHIV are more likely to be able to respond adequately to the stress of being infected and are less likely to develop serious mental health problems. Assessment and interventions may be aimed at the acutely stressful phase following notification of HIV infection, the ensuing adjustment period, and the process of dealing with chronic symptomatic HIV infection and disease progression through to death.

HIV infection often can result in stigma and fear for those living with the infection, as well as for those caring for them, and may affect the entire family. Infection often results in loss of socio-economic status, employment, income, housing, health care, and mobility. For both individuals and their partners and families, psychosocial support can assist

people in making informed decisions, coping better with illness and dealing more effectively with discrimination. It improves the quality of their lives and prevents further transmission of HIV infection (Kaptein & Dekker, 2000).

A systematic review of non-specialist psychosocial support interventions for women living with HIV showed mixed evidence that psychosocial support may improve self-esteem, coping and social support, and reduce depression, stress, and perceived stigma (Beres *et al*., 2017). A report by Kaiser Family Foundation for a study conducted in the USA says that *"...those living with HIV hardly ever talk about it, even with those closest to them*" (Kaiser Family Foundation, 2017). This demonstrated how HIV infection affects all dimensions of a person's life: physical, psychological, social and spiritual, even in the developed countries and therefore counseling and social support can help people cope more effectively with each stage of the infection.

2.4 Implementation of "Test and Treat" Recommendation in Kenya

In implementing the WHO universal "test & treat" recommendation, the Kenya Ministry of Health through the National AIDS and Sexually Transmitted Infections Control Program, which is now referred to as The National Syndemic Diseases Control Council (NSDCC) launched a campaign dubbed "*Anza Sasa*" to encourage all those tested HIV positive to get ARV treatment regardless of their T-cels (CD4+) count. During the launch of the campaign in July 2016, the head of NSDCC pointed out two main aims of providing ART to all PLHIV as follows: 1) The treatment will enable the individual who is on ART to reduce the level of the virus circulating within their body to an undetectable level. As such ART will reduce further damage to their immune system and improve the body's ability to fight off infections averting unnecessary illnesses, disabilities and even deaths related to HIV. 2) With undetectable VL levels, further transmission to people who are uninfected with HIV will be minimized. Kenya, therefore launched new guidelines on the use of ARV drugs for treating and preventing HIV infection and is one of the countries in Africa which has moved to the use of VL testing as the preferred means of monitoring

people taking ART (NASCOP, 2016). The implementation of the WHO recommendation means that more people start ART earlier.

2.5 Differentiated Care for HIV/AIDS

Various innovative strategies to enhance adherence and improve retention among HIV positive clients have been piloted for over a decade now. Many implementing partners in different high prevalence countries have dedicated resources to test differentiated ART delivery models, especially for stable patients. Differentiated care is a client-centered approach that simplifies and adapts HIV services across the cascade to reflect the preferences and expectations of various groups of PLHIV while reducing unnecessary burdens on the health system. By providing differentiated care, also called differentiated service delivery, the health system is able to reallocate resources to those most in need (International AIDS Society, 2016). The objective of differentiated care is to provide quality, patient-centered care reflecting the preferences and expectations of the client while reducing unnecessary burden on the health system. It puts the client at the center of service delivery. The health system can refocus resources to those clients most in need by providing differentiated care. The central driver to adapting service provision is the client's needs. Differentiated care applies across the HIV continuum to all three of the 95-95-95 targets. This means that differentiated care focuses on all elements of 95-95-95 targets, from testing people unaware of their HIV status, ART delivery and viral suppression of HIV clients in care (International AIDS Society, 2016).

Differentiated ART delivery is, therefore, an element of differentiated care. It's main aim is to improve retention and viral suppression by optimizing models of drugs and care delivery focusing specifically on stable HIV clients who are on treatment (International AIDS Society, 2017).

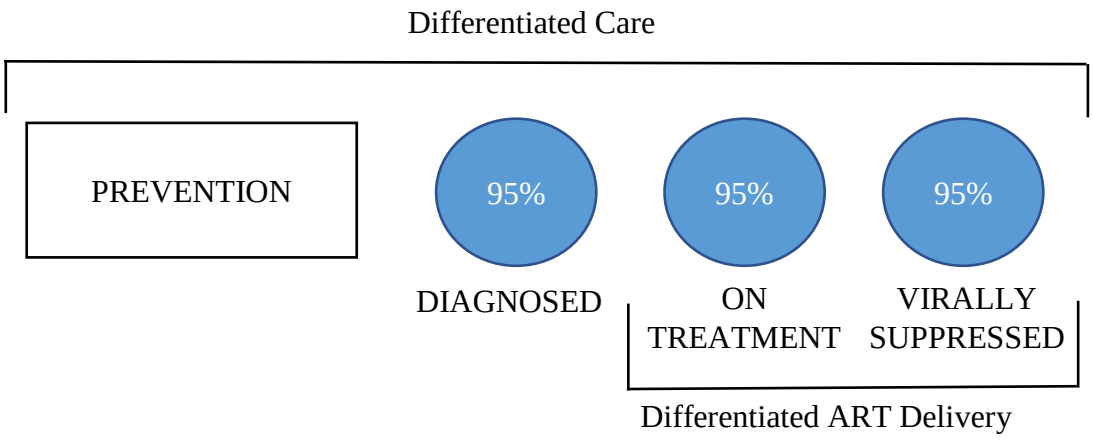

Figure 2.5: Principle of Differentiated Care

2.6 Retention on HIV Treatment and its Predictors

Retention in HIV care is the constancy of engagement in HIV treatment, care and support services which is vital to reducing morbidity and mortality associated with the infection as well as halting the development of resistance to ART. A large body of research conducted since 2008 had identified poor retention in HIV care, both before and after ART initiation, as one of the most important factors in determining the overall impact of HIV treatment. Systematic reviews conducted back in 2007 and 2010 estimated 24-month retention on treatment at 62% and 76% respectively (Fox & Rosen, 2010; Rosen *et al*., 2007). The one third to one quarter of all patients initiated on treatment were either known to have died or were lost to follow-up. The same authors later extended the systematic review to cover 2008 to 2013 and expanded the geographical coverage to LMICs. The unweighted average 24-month retention was 71%, lower than retention documented in earlier studies. The authors noted that studies with shorter follow-up periods report higher attrition at any given time point than studies with longer follow-up (MP & S, 2015).

In general, the average retention in SSA seemed to have improved with time but there seemed to have been substantial differences in the volume and methods of the articles

reviewed. It is therefore difficult to know whether the observed differences were real improvements or merely an object of research.

There have also been important changes in both WHO guidelines and national ART programs since 2008, which have been helpful to policy makers, funding agencies and program implementers in understanding and targeting their efforts.

A study in Northern Nigeria examined the levels of retention in HIV care and its predictors among men who have sex with men (MSM). About 38% of the participants were adequately retained in HIV care. Awareness of regular male partner's HIV status and financial difficulty were identified as predictors to adequate retention on HIV care (Afolaranmi *et al*., 2021). A retrospective study of PLHIV in Kinsasha Democratic Republic of Congo, compared adult patients who were at least 15 years old and initiating ART, before and after the implementation of "test and treat" strategy. Overall, retention in HIV care was 83% at twelve months and 77% after two years of follow-up. The risk of attrition increased with advanced HIV disease and the size of the HIV care center. Time to ART initiation greater than seven days after diagnosis and Cotrimoxazole prophylaxis were associated with a reduced risk of attrition (Id *et al*., 2022). Data from an observational cohort study in Kinsasha documented retention rates of 57% and 27% among PLHIV at 6- and 12-month follow-up. Retention was associated with low economic status, studying, daily/weekly internet access, previous HIV tests and aiming to share HIV test with partner (Carlos *et al*., 2021)

2.7 Survival Estimates of Patients on HIV/AIDS Treatment

Understanding the survival experience of patients on HIV/AIDS treatment, as well as the factors that influence survival, is important in increasing the understanding of the pathophysiology of the disease, clinical decision making, and planning health service interventions. A retrospective cohort study of HIV/AIDS patients receiving ART at the University of Gondar teaching hospital in Ethiopia found out that age and lack of formal education were associated with lower survival rates, whereas family size of one to two,

three to four, no alcoholic consumption, no smoking and chat use, baseline weight, current weight, baseline CD4 cell count, baseline hemoglobin, and no TB diseases were associated with longer survival rates (Teka *et al*., 2021). A hospital-based retrospective cohort study among HIV infected patients on ART at Kombolcha town in Ethiopia had 7.65% and 92.35% dead and censured respectively. Estimated median survival time after ART initiation was 32 months. Fair drug adherence, poor drug adherence, CD4 count < 50 cell/μL, CD4 count 50– 99 cell/μL, bedridden, opportunistic infections, weight < 60kg, WHO stage III, WHO stage IV were predictors of poor survival time (Siraj *et al*., 2022). In Central Kenya, a retrospective cohort study among patients initiated on ART between 2004 and 2012 demonstrated an overall retention rate of 68.8%, LTFU was 27.1% and mortality rate of 4.1%. Predictors of early mortality and LTFU included being male, single, separated or divorced, advanced WHO clinical stage, and among patients not on TB treatment (Wekesa *et al*., 2022)

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Sites and Area

The study participants were recruited from three health facilities of Kibera Community Health center, Kibera South Health Center and Silanga Dispensary, all situated within Kibera informal settlement, where the majority of the participants reside. The Kibera informal settlement is in Kibra and Langata sub-counties and is located 5 kilometers South West of Nairobi Central Business District. It is made up of 14 villages[1] with about 90 health facilities (Ministry of Health, 2020). The three study sites were selected because already they had Electronic Medical Records Systems which made it easier to access patients level data for this study.

Over the years, Kibera has grown to be a cosmopolitan society comprising of major ethnic communities in Kenya, and incorporating the two major religious groups in Kenya: Christians and Muslims (Mutisya & Yarime, 2011). It is one of the largest urban informal settlements in Africa, with an HIV prevalence of 12.6% compared to the country's HIV prevalence of 4.9% (NASCOP, 2020) and a 12-month patient HIV treatment retention of 81% (van der Kop *et al*., 2018). Residents in Kibera are highly mobile to and from upcountry, live in inhumane conditions with a lack of clean water, housing, health services and a lack of solid waste management facilities. In addition, Kibera slum dwellers face inadequate schooling facilities, unemployment, high crime rates, insecurity which has led to mass poverty, conflicts, contagious diseases and other social, ecological and economic risks (Mutisya & Yarime, 2011). Figure 3.1 below is a map of Kenya showing the position

[1] Kianda, Olympic, Soweto West, Gatwikira, Karanja, Kisumu Ndogo, Raila, Makina, Kambi Muru, Mashimoni, Lindi, Laini Saba, Silanga and Soweto East

of Kibera informal settlement, while Plate 3.1 below shows a picture of one of the study sites for an indication of the situation in Kibera informal settlment.

Participants recruitments at Kibera Community Health Center started on 4th February 2019 while recruitement at Kibera South Dispensary and Silanga Dispensary started on 1st April 2019.

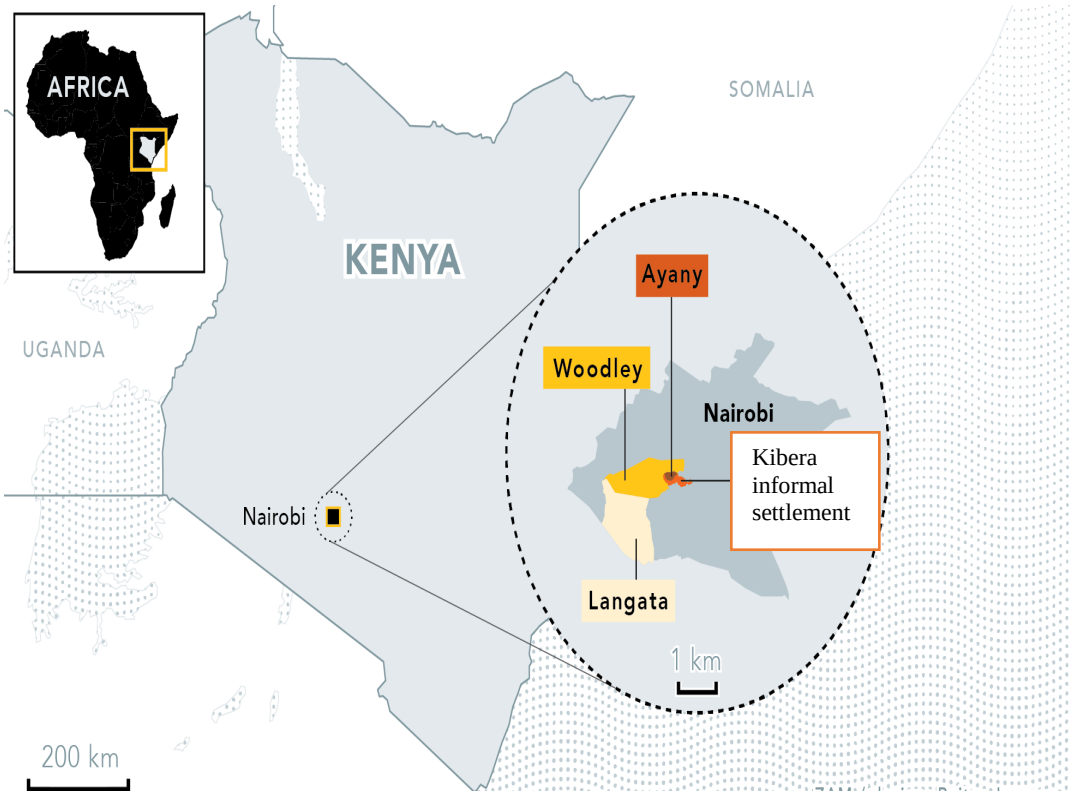

Figure 3.1: Kibera Informal Settlement

Plate 3.1: Kibera Community Health Center

3.2 Study Participants

Study participants included individuals who had newly tested HIV positive at the study sites.

Study participants recruitment and enrollment started in February 2019 at Kibera Community Health Center and two months later, April 2019 at Kibera South Dispensary and Silanga Dispensary. The last month of enrollment was August 2019 at Kibera South Dispensary, September 2019 at Silanga Dispensary and October 2019 at Kibera Community Health Center. The distribution of study participants enrollment varied by clinic as follows: Kibera Community Health Center, 56% (n=216); Kibera South Dispensary, 23% (n=91) and Silanga Dispensary, 21% (n=81). Kibera Community Health Center had the highest enrollment rate because of its bigger size and the fact that enrollment started two months earlier than the other two centers. Follow-up of the study participants continued until May 2020. See Table 3.1 below for details of the recruitment report.

Table 3.1: Participants Recruitment Report

Month/ Year 2019	Kibera Community HC	Kibera South [2] Dispensary	Silanga[3] Dispensary
	Starting ART	Starting ART	Starting ART
February	18		
March	15		
April	18	12	6
May	36	18	15
June	34	16	23
July	23	14	15
August	24	31	10
Sept	25		12
October	23		
November			
Total=388	**216**	**91**	**81**

A total of 504 HIV positive individuals were assessed for study eligibility, of which 388 (77%) eligible for the study were recruited, enrolled and randomly assigned to one of the two study arms after providing consent for study participation as shown in Figure 3.1 below. None of the study participants withdrew from the study. Out of the 504 HIV positive individuals who were assessed for study eligibility, 23% (n=116) were excluded from the study due to various reasons such as; Some declined to participate in the study (n=12) because it is their rite to either accept or decline participation, some were under age (less than 18 years of age) (n=2) and some had previously been enrolled in ART

[2] Recruitment started in April 2019 and ended in August 2019

[3] Recruitment started in April 2019 and ended in September 2019

programme (n=102) hence did not meet the inclusion criteria. See Figure 3.2: study profile for details.

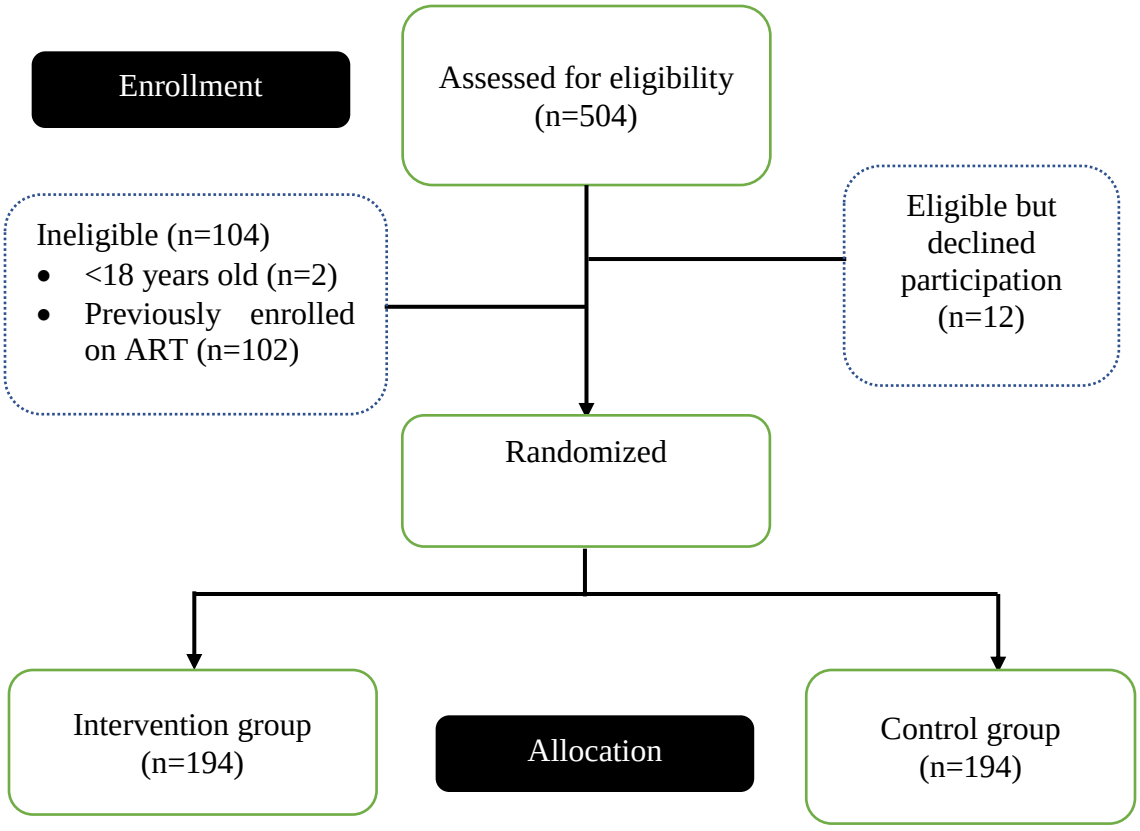

Figure 3.2: Study Profile

3.2.1 Inclusion Criteria

- Evidence of HIV infection
- 18 years and older
- Able and willing to provide informed consent to participate in the study.

3.2.2 Exclusion Criteria

Patients who previously enrolled on ART either at the study site or at any other health facility

3.3 Study Design

The study adopted an experimental design: a randomized control trial with control and intervention groups. Group 1 received the intervention in addition to the standard of care, while the control (group 2), received the standard of care only.

3.4 Study Procedures

A total of 10 peer educators and a team of health facility staff at the three study sites were trained by the principal investigator (PI), for two days, on the study procedures and the general details of the study protocol. These included the process of identification and consenting the participants, how to complete the baseline questionnaire using the handheld tablets, the study randomization process and the overall study protocol. The triage nurse connected the peer educators with newly diagnosed HIV positive patients to escort them to care and treatment service points and linked them to appropriate psychosocial support groups. The same peer educators traced the participants whenever they missed clinic appointments and made home visits where necessary.

Initially, the intervention group was to receive the following combination of interventions: (1) a thank you note issued at every clinic visit, thanking the participants for attending clinic appointments and providing them with a reminder of the next appointment date; (2) a reminder at every clinic visit that they would receive free T-shirts of their favorite football team or free *Kiondos* based on choice; (3) a certificate of appreciation if they made it to the sixth month visit without missing an appointment and (4) enrollment into psychosocial support groups.

To inform the choice of the intervention and specifically the incentives, the PI visited one psychosocial support group within Kibera Informal Settlement and sought their opinion on the proposed incentives. The majority were happy with the proposal to receive free T-shirts of their favorite football team or a free *Kiondo* but were completely unreceptive of the proposal to issue them with small thank you notes at every facility visit. They

suggested that the card would not be useful and that the clinicians could still appreciate them by word of mouth. They were also not receptive of the certificates of appreciation at the end of the sixth month visit.

This therefore reduced the intervention to a combination of: (1) a reminder at every clinic visit that the participants stand to receive free T-shirts of their favorite football team or free *Kiondos* based on choice if they made it to the sixth month visit without missing appointments; and (2) enrollment into psychosocial support groups of which meetings were held once a month.

Recruitment of participants into the study involved eligibility assessment and consenting at the three study sites. After clinical consultation, the clinical officers mentioned the study to all the newly diagnosed HIV positive patients and introduced them to the peer educators upon their expression of interest in the study. The peer educators then identified a quiet and private place and provided a detailed explanation of the study and sought informed consent. The participants were briefed on the randomization process for their understanding of the possibility of enrolling in either of the two study arms and also to understand the intervention. The peer educators then took the consented participants through baseline study procedures which included completing the baseline questionnaire.

3.5 The Intervention

Participants were randomly assigned to receive the intervention in addition to the standard of care or standard of care only. The non-cash intervention consisted of a reminder at every clinic visit that the participants stand to receive free T-shirts of their favorite football team or free *Kiondos* based on preference if they made it to the sixth month visit without missing a treatment appointment and attending all psychosocial support group meetings. Not missing a treatment appointment meant that the participant attended all clinic visits within one week before or after the appointment dates. The psychosocial group meetings were convened once a month on a weekend and structured in two parts. Part one took about an hour and involved experience sharing on how one was doing and health education

on various topics such as self-acceptance, nutrition, adherence, disclosure, hygiene, opportunistic infections, self-stigma, condom use, treatment failure, positive living and how to cope with HIV/AIDS. The second part of the meetings ran for about 30 minutes and involved discussions on how to improve participants' economic status through involvement in various income generating activities (IGAs). The meetings were held within the health facility compound. Tea and snacks were provided by the PI and prepared at the respective health facilities at a cost of about United States Dollar 6 per meeting.

Both the intervention and control groups received the standard care as defined in the ministry of health test & treat guidelines (NASCOP, 2016). These included the following seven components: (i) ART[4]; (ii) Positive health, dignity and prevention[5]; (iii) screening for and prevention of specific opportunistic infections; (iv) CD4 + cell count at baseline and VL testing at six months; (v) screening for and management of non-communicable diseases; (vi) mental health screening and management and (vii) participants tracing by peer educators through phone calls and home visits in cases of missed appointments. Patients who did not attend a clinic appointment were called one day after a missed appointment, a second time three days later and a final time seven days later, after which the peer educators could make a home visit to find out why the client had not attended clinic appointment. See figure 3.3 below, intervention and control study arms.

[4] All PLHIV qualify for ART irrespective of CD4+ cell count or percentage, WHO clinical staging, age, pregnancy status or comorbidities; ART initiated as soon as the patient is ready to start, preferably within two weeks from time of HIV diagnosis subject to patient readiness

[5] All PLHIV provided with health education and counselling on disclosure of HIV status, partner/family testing and engagement; condom use; family planning, sexually transmitted infections and treatment adherence

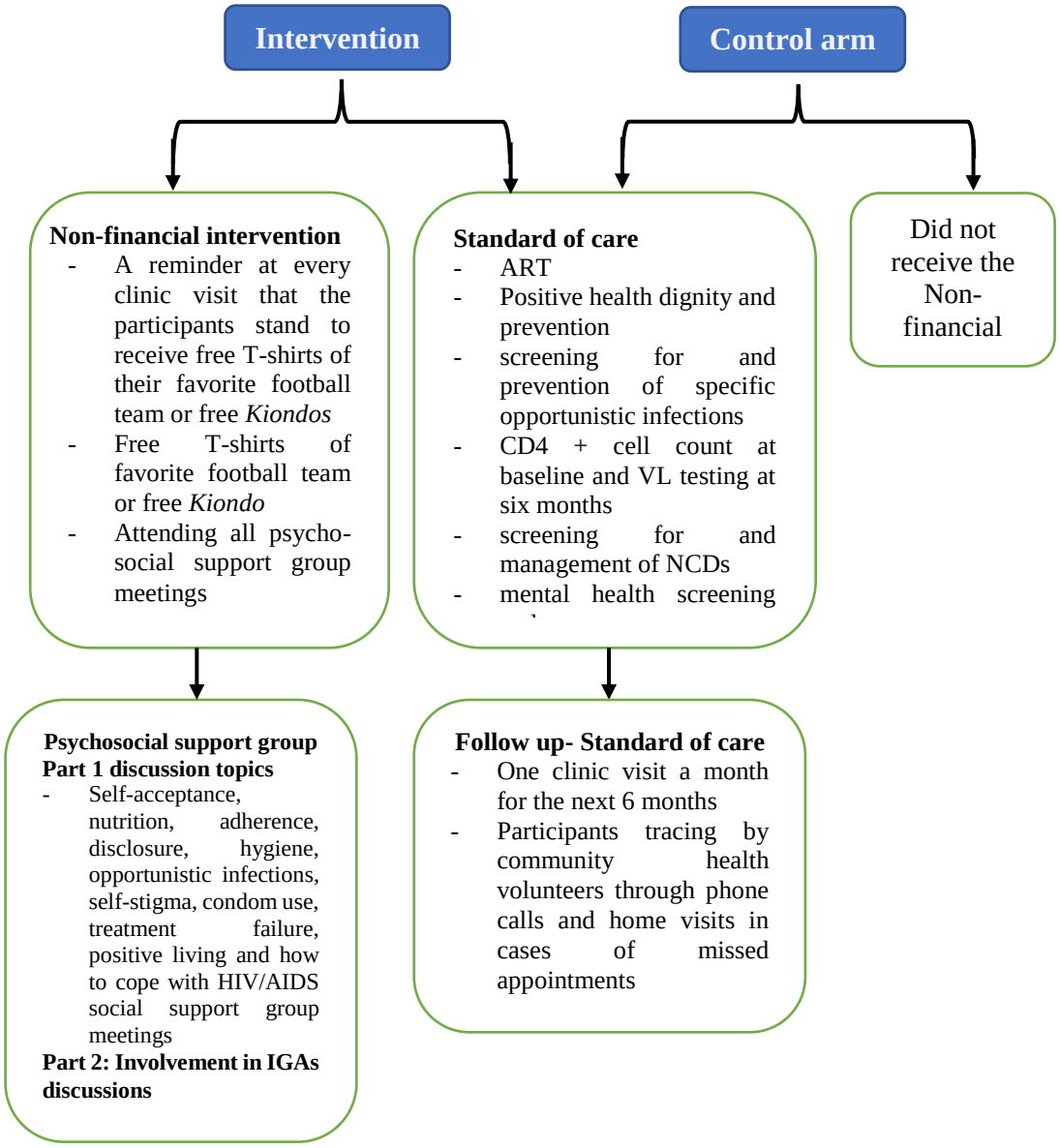

Figure 3.3: Intervention and control study arms

3.6 Sample Size Determination

In estimating power for a two sample proportions test using Pearson's Chi-square (chi2) test with six months of patients' retention as the primary outcome variable, the hypothesis tested was:

The proportion of patients on HIV treatment retained on treatment during the first six months of starting ART was not different between those who received non-cash incentives and got enrolled into psychosocial support groups and those who received standard care. i.e

$$H_0: p1 = p2$$

Assuming a statistical confidence level of 0.05 with a six months retention of 83% in the control group, study power of 80% to detect a minimum effect size of 10% at six months period.

Using a sample size calculation formula based on statistical superiority for retention on treatment which is dichotomous (Zhong, 2009).

$$n = \frac{[(a+b)^2 (p_1q_1+p_2q_2)]}{x^2}$$

Where;

n= is the required sample size in each of the groups
p1= the proportion of patients retained on treatment in the control group
p2= the proportion of patients retained on treatment in the intervention group
q1= proportion of patients not retained on treatment in the control group
q2= proportion of patients not retained on treatment in the intervention group
x= minimum detectable effect size at six months
a= conventional multiplier for alpha= 0.05
b= conventional multiplier for beta= 0.80

$$n = \frac{[(1.96+0.842)^2 (0.83*(1-0.83)+(0.93*(1-0.93))]}{0.1x0.1}$$

$$= 161.9 \simeq 162$$

Adjusting for 20% attrition as documented in one of the studies conducted within Kibera informal settlement, where the probability of retention in the program at six months was 0.83 (Unge *et al*., 2009)

n=194 sample required in each of the two groups

Participants distribution among the three health facilities was random and based on capacity to recruit.

3.7 Randomization and Allocation of Study Participants

Participants were randomly assigned to the intervention and control groups at a ratio of 1:1. Randomization assignments were listed in opaque sealed envelopes and after consenting, the participants were asked to select one envelop and to break the seal to reveal the randomization assignment group. The study team involved in administration of the treatment were blinded (Single blinding) to the intervention assignment to avoid potential bias. The participants were not blinded to the intervention assignment for logistical purposes and to reduce on drop-out rates.

Concerns of patients in the control arm feeling disenfranchised and transfer out to other health facilities if they realized that patients on the intervention arm of the study were receiving incentives could have led to high dropout rates. This was, however, mitigated by clearly informing the participants of the study procedures and involving them in the randomization process where they selected one randomization envelop and revealed the assignment to a study nurse not involved in the assignment process. The other concern was a possibility of spillover of the information gained from the psychosocial support groups to those in the control group. This was addressed by ensuring that patients in the control group were scheduled for appointment visits on separate days from those in the intervention group.

3.8 Sampling Strategy

All the newly diagnosed HIV positive patients were introduced by the clinical officers to the peer educators/community health volunteer (CHV) upon their expression of interest in the study, for assessment of study eligibility, consenting and enrollment. Participants were randomly assigned to the intervention and control groups at a ratio of 1:1.

3.9 Data Collection and Management

Peer educators conducted participants' eligibility screening assessment, looking at inclusion, exclusion criteria and obtained consent for study enrolment. If a patient was eligible and willing to participate in the study, the peer educator went through the consent form with the participant and collected either written consent for the literate participants or a thumbprint with a witness signature if illiterate. The peer educators then administered a piloted, validated questionnaire programmed in Open Data Kit (ODK) to capture participants' socio-demographic characteristics, HIV care, social life and labor market involvement data. The participants had the choice of conversing in English or Kiswahili.

A health facility data extraction tool was used to extract additional data from health facility electronic medical records (EMR) systems. The data elements extracted were patient identification number, health facility where first positive HIV test was done, date confirmed HIV positive, ART start date, CD4+ count, VL count, WHO staging (Appendix 1), Tuberculosis (TB) screening outcome, patient outcome, exit reason, exit date.

At six months, study specific follow-up questionnaires (electronic) were administered to all participants who returned to the clinic. At the end of the study, a tracing report form (Appendix 2) was filled out for all participants, indicating whether they returned to the clinic or if they did not, what type of tracing was undertaken to ascertain their status (telephone or home visits). This form captured the participants' final outcome i.e transferred out, died or lost to follow-up (LTFU).

The 10 peer educators used tablets in all data collection. All the data was in soft copy and kept under password protected files with only the PI having access to the records. The study questionnaire was pre-tested at Kibera Community Health Center before starting data collection.

Quality control was ensured by strictly adhering to the study protocol to ensure consistency and minimize errors during data collection. The study team (10 peer educators and a team of health facility staff at the three study sites) was comprehensively trained on the study protocol, including data elements, data collection methods and instructions for data entry.

The tools were piloted before starting the main data collection to identify any potential issues and challenges in data collection procedures and refine the study intervention. This helped refine the study protocol, identified ambiguities and ensured clarity of instructions.

The study team was closely supervised and regularly monitored during data collection, feedback on any issues identified was provided and questions that arose during the process adequately addressed.

Data validation and cleaning was done both in excel and in Stata version 15 to identify missing data, logical checks, outliers, and inconsistencies before analysis was started. Logical checks were done to ensure data accuracy. Data analysis plan was developed prior to starting data analysis.

3.10 Ethical Considerations

The study protocol was reviewed and approved at the Amref Health Africa in Kenya Ethics and Scientific Review Committee (ESRC) before starting data collection. Ethical approval was renewed annually, for two years to allow for completion of data collection. The approval was granted on 3rd December 2018 and renewed on 3rd March 2020, with a reference number: AMREF-ESRC P550/2018.

Informed consent was sought from all study participants in the language in which they were most comfortable in, English or Kiswahili including being informed about the study risks and benefits and measures in place to ensure anonymity and confidentiality of the data collected. Each participant was given the opportunity to ask questions before providing written consent. Once signed, each participant was provided with a copy of the informed consent form. Illiterate participants provided consent in the presence of a literate witness and provided thumbprints instead of signatures.

All data obtained from electronic medical records systems were stripped of personal identifiers and assigned unique identifiers. Under no circumstances were any identifying information on individual participants made public. Strict adhere to relevant data protection regulations and ethical guidelines such as restricted access to the data by the study PI only and conducting regular data backups to prevent data loss or unauthorised access.

3.11 Outcomes

The primary outcome was retention on HIV treatment at six months, defined as the proportion of participants retained on treatment at six months from treatment enrollment and measured by whether the participant attended a follow-up appointment within the 5 to 7-month timeframe from treatment enrollment. Participants confirmed to be active on treatment at some other health facilities were considered retained on treatment. Participants not reachable over the phone were physically traced within the community by peer educators to ascertain the final status. Those not traced through phone calls or physically were considered LTFU.

The secondary outcomes were viral suppression, labour market participation, HIV disclosure, sexual behavior and survival on treatment. Table 3.2 below summarises the study outcomes, the measures and analysis method.

Table 3.2: Study Outcomes

Outcome	Outcome measure	Method of analysis
6 month retention	Attended 6th-month clinic appointment at the clinic of enrollment or active on treatment elsewhere (5-7 months timeframe)	i) Descriptive statistics ii) Risk ratios to determine differences in the two study arms iii) Logistic regression to examine the predictors of patients'retention on treatment
Viral suppression	VL below 1000 copies/mL	i) Descriptive statistics ii) Risk ratios to determine differences in the study arms iii) Logistic regression to examine the predictors of viral suppression
Labour market participation	Mean hours worked per day	i) Descriptive statistics ii) Risk ratios to determine differences in the study arms iii) Logistic regression to examine the predictors of missing work for a whole day or more
HIV disclosure	Disclosed HIV status	i) Descriptive statistics ii) Risk ratios to determine differences in the study arms iii) Logistic regression to examine the predictors of disclosing HIV status
Sexual behavior	Used condoms for sex with unofficial partner[6]	i) Descriptive statistics ii) Risk ratios to determine differences in the study arms iii) Logistic regression to examine the predictors of using condoms for sex with unofficial partner
Time/ survival on treatment		Kaplan-Meier survival analysis

3.11 Statistical Analysis

Data analysis was performed according to the intention-to-treat (ITT) principle where all study participants were analysed according to their initially assigned study arm at baseline, regardless of adherence to study protocol. Paticipants who died, were LTFU, were confirmed as retained at the clinic of recruitment and those confirmed to have transferred to other clinics and continued to be on ART were included in the ITT analysis. This

[6] Unofficial partner is someone who is romantically or sexually involved with a person who is already in a committed relationship with someone else, popularly known as "side chick" or "side partner".

approach was preferred over per-protocol analysis because it preserves the benefits of randomization, maintaining the comparability of groups and minimizing bias due to non-compliance or drop-out. ITT analysis provides a conservative estimate of treatment effect, reflecting real-world clinical practice where not all patients adhere perfectly to treatment protocols. Per-protocol analysis may overestimate the treatment effect compared to ITT analysis because it excludes participants who did not adhere to the treatment protocol, potentially introducing selection bias.

Baseline characteristics were reported per randomization arm to enable comparison of groups. Dichotomous variables were summarised as a proportion of patients with the count divided by the total number of evaluated patients. Continuous variables were summarised as mean with standard deviation (SD) in case of normal distribution and as median with interquartile range (IQR) in case of non-normal distribution. For continuous variables a footnote stating the number of evaluated participants was included.

The primary outcome, 6-month retention on HIV treatment, was assessed using adjusted risk ratios (aRR), with the differences in proportions among the treatment and control group presented with a 95% confidence interval (CI) along with the *p*-value associated with the aRR. Secondary outcomes were similarly assessed and presented with a 95% CI for the differences in the two groups. Adjusted hazard ratios (aHR), 95% CI and *p*-values were calculated to estimate the association between retention and variables at an individual level. Univariable analyses were performed to assess the strength of the association between each individual factor and the probability of the secondary outcomes. Variables were then included in an initial multivariable model if they had a univariable *p*-value <0.05 or were considered important based on prior evidence. In the final adjusted models, variables were selected based on a significant threshold of *p*-value <0.05. For a time-to-event outcomes, i.e., the effect of the interventions on the time to retention (remaining on treatment after ART initiation i.e the time between study enrollment and the last scheduled visit) was examined with a Kaplan-Meier plot; equality of survival functions was tested using the log-rank test. The individual factors associated with retention on HIV treatment were examined using a Cox proportional hazards model and

presented hazard ratios for each time interval and 95% CIs. Mortality and LTFU rates were calculated per 100 person-years.

3.12 How Bias was Reduced in the Study

Selection bias refers to a situation where the randomization process is not effectively distributing participants equally between the treatment groups, leading to systematic differences between the groups at baseline. In an RCT, the goal is to randomly assign participants to different treatment groups to ensure that any observed differences in outcomes are due to the treatment itself and not to other factors. However, selection bias can occur for various reasons:

i. Non-compliance: Some participants may not adhere to the assigned treatment and switch groups, leading to a lack of true randomization.
ii. Dropout or attrition: If participants drop out of the study or are LTFU at different rates between treatment and control groups, it can introduce bias.
iii. Eligibility criteria: If certain participants are excluded from the study based on specific criteria, this could lead to a non-representative sample.
iv. Self-selection: In some cases, participants may have the option to self-select into a particular treatment group, leading to biased results.
v. Randomization errors: Despite efforts to randomize, errors can occur, leading to imbalances between treatment and control groups.

In this study, selection bias was minimized by randomly assigning the participants into the study groups, where they were asked to pick and break opaque sealed envelope to reveal the group. The eligibility (inclusion and exclusion) criteria were clearly defined and consistently applied in all the participants. Additionally, the attrition rate was minimized through adherence to follow-up procedures where peer educators traced the participants from day one of missed appointment. Finally, adoption of ITT as analysis technique helped mitigate the impact of non-compliance and dropouts.

Attrition bias is also known as dropout bias or LTFU bias and occurs when participants in a study drop out or are LTFU at different rates between the treatment groups. Attrition bias can be problematic because it can lead to an overestimation or underestimation of the treatment effect, depending on the reasons for dropout. If participants who experience positive outcomes are more likely to drop out from the treatment group, it may falsely inflate the apparent effectiveness of the treatment. Conversely, if those experiencing negative outcomes drop out more often, it may lead to an underestimation of the treatment effect. In this study, attrition bias was minimized by clearly informing the participants of study procedures and being involved in the randomization process. None of the participants withdrew from the study apart from those who died and those who were LTFU.

Reporting bias also known as publication bias occurs when the publication or non-publication of research findings is influenced by the nature or direction of the results. It refers to the tendency of researchers, journals, or other parties to publish or emphasize studies with statistically significant or positive results, while neglecting or suppressing studies with non-significant or negative results.

CHAPTER FOUR

RESULTS

4.1 Socio Demographic and Clinical Characteristics of Study Participants

The mean age of the study population was 34 years (SD 9.9), and 57% (221) were male. The majority (45%) were aged between 25-34 years, followed by those aged between 35-44 years at 25%. Almost all (98%) of the participants were Christians and majority (60%) were married to either one or more than one partner. Majority (96%) had at one time or another ever attended school and 52% (200) completed primary school, 15% (59) completed secondary school and 4% (14) completed tertiary school. One-third (30%) of the study participants did not have formal education. Twenty percent (20%), twenty three percent (23%), thirty five percent (35%), sixteen percent (16%) and six percent (6%) of the households were made up of one, two, three, four and more than five people, respectively. Fifty six percent (56%), twenty three percent (23%) and twenty one percent (21%) of the participants received HIV services at Kibera Community Health Center, Kibera South Health Center and Silanga Dispensary respectively. The majority (89%) were residents within the Kibera informal settlement. Ninety percent (90%) walked to the clinics as a mode of transport, spending a medium time of 30 minutes (IQR 15-30) to access health services. Majority of the respondents in the two groups (intervention group- 37% and control group- 36%) were not certain of their average household monthly income. However, among those who could identify a range, a higher proportion were either earning Kenya Shillings (KES) 5001 to 10,000 (21%) or KES 10,001 to 20,000 (21%). Unemployment rates among study participants were at 21% (80), 24% (95) were casual laborers, 19% (72) were self-employed or small business owners and 36% (141) were in formal/salaried employment. All (99%) the study participants were HIV asymptomatic i.e WHO HIV Clinical stage 1 and either received first line ART fixed-dose combination of Dolutegravir/lamivudine/tenofovir (DTG/3TC/TDF- 51%) or Tenofovir/lamivudine/ Efavirenz (TDF/3TC/EFV-48%). The median CD4+ count was 394.5 cells/ul (IQR 172-639), while the mean weight was 64.6 kg (SD 19.7) with 47% of

the participants' weights documented, majority (78%) of which weighed between 40 and 69kg. Participant characteristics between the two groups were balanced based on the *p*-values of which none was less than 0.05 to warrant rejection of the null hypotheses. See Table 4.1 below for details.

Table 4.1: Baseline Characteristics of Study Participants

Variable	**Intervention group (n=194)**	**Control group (n=194)**	**Total (n=388)**	**Test statistic**	***p*-value**
Sex (Male=1)				chi2=0.29	0.59
Male	108 (56%)	113 (58%)	221 (57%)		
Female	86 (44%)	81 (42%)	167 (43%)		
Age (Years)					
Mean (SD)	33.5(9.4)	34.6(10.3)	34.0 (9.9)⁑	t=1.08	0.28
18-24	30 (15%)	27 (14%)	57 (15%)		
25-34	84 (43%)	89 (46%)	173 (45%)		
35-44	55 (28%)	41 (21%)	96 (25%)		
>45	25 (13%)	37 (19%)	62 (16%)		
Religion				chi2=0	1
Christian	190(98%)	190(98%)	380(98%)		
Muslim	4(2%)	4(2%)	8(2%)		
Marital status				chi2=3.73	0.29
Married	109(56%)	123(63%)	232(60%)		
Divorced	37(19%)	27(14%)	64(16%)		
Never married/Single	23(12%)	26(13%)	49(13%)		
Widowed	25(13%)	18(9%)	43(11%)		
Ever attended school				chi2=0.29	0.59
Yes	186(96%)	188(97%)	374(96%)		
No	8(4%)	6(3%)	14(4%)		
Education completed				chi2=1.56	0.67
No formal education	56(29%)	59(30%)	115(30%)		
Primary completed	104(54%)	96(49%)	200(52%)		
Secondary completed	29(15%)	30(15%)	59(15%)		
Tertiary completed	5(3%)	9(5%)	14(4%)		
House hold size				chi2=1.58	0.66
One person	43(22%)	36(19%)	79(20%)		
Two people	39(20%)	50(26%)	89(23%)		
Three people	65(34%)	69(36%)	134(35%)		
Four people	35(18%)	26(13%)	61(16%)		
Five and above people	12(6%)	13(7%)	25(6%)		
Financial support to				chi2=2.61	0.86
One person	13(7%)	12(6%)	25(6%)		

Variable	Intervention group (n=194)	Control group (n=194)	Total (n=388)	Test statistic	*p*-value
Two people	9(5%)	9(5%)	18(5%)		
Three people	50(26%)	50(26%)	100(26%)		
Four people	53(27%)	61(31%)	114(29%)		
Five and above	70(36%)	60(31%)	130(34%)		
Clinic				chi2=0.20	0.91
Kibera Community Health Center	110(57%)	106(55%)	216(56%)		
Kibera South Health Center	45(23%)	46(24%)	91(23%)		
Silanga dispensary	39(20%)	42(22%)	81(21%)		
Predominant mode of transport to clinic				chi2=3.62	0.16
Walking	169(87%)	180(93%)	349(90%)		
Matatu	24(12%)	13(7%)	37(10%)		
Boda Boda	2(1%)	1(1%)	2(1%)		
Residence Status				chi2=0.92	0.34
Kibera	169(87%)	175(90%)	344(89%)		
Outside Kibera	25(13%)	19(10%)	44(11%)		
Occupation				chi2=1.52	0.68
Salaried employment	75(39%)	66(34%)	141(36%)		
Self employed/Business person	37(19%)	35(18%)	72(19%)		
Casual Labour	46(24%)	49(25%)	95(24%)		
Unemployed	36(19%)	44(23%)	80(21%)		
Time to Clinic (Minutes)					
Median (IQR)	30(15)	30(15)	30(15)‡	t=0.13	t=0.89
Average HH monthly income				chi2=6.82	0.34
Less than KES 1,000	2(1%)	0(0%)	2(1%)		
KES 1,001-5,000	11(7%)	18(13%)	29(10%)		
KES 5,001-10,000	34(23%)	25(19%)	59(21%)		
KES 10,001-20,000	30(20%)	29(22%)	59(21%)		
More than 20,001	14(10%)	14(10%)	28(10%)		
Not willing to disclose	2(1%)	0(0%)	2(1%)		
Not certain	54(37%)	49(36%)	103(37%)		
CD4+ Cells per ul					
Median (IQR)	394.5(467)	395.5(506)	394.5(467)	t=0.20	0.84
Weight categories (Kg)					
Mean (SD)	65.9(20.9)	63(18.2)	64.6(19.7)ǂ	t=-1.02	0.308
40-69	74(78%)	70(79%)	144(78%)		
70-99	15(16%)	16(18%)	31(17%)		
100-129	3(3%)	1(1%)	4(2%)		
130-159	1(1%)	2(2%)	3(2%)		
160 and above	2(2%)	0(0%)	2(1%)		
WHO HIV Clinical staging				chi2=4.99	0.08
Stage 1	179(97%)	181(100%)	360(99%)		
Stage 2	4(2%)	0	4(1%)		
Stage 3	1(1%)	0	1(0.3%)		
1st Line ART original regimen				chi2=2.05	0.36
TDF/3TC/DTG	101(52%)	93(49%)	194(51%)		
TDF/3TC/EFV	87(45%)	96(50%)	183(48%)		
Other^{+}	5(3%)	2(1%)	7(2%)		

4.2 Effectiveness of the Intervention on Study Outcomes

A total of 388 study participants were randomly assigned to the intervention and control arms and were followed up for an average period of six months. Of these, 360 (93%) were retained on treatment including three (3) participants who transferred out to other health facilities and continued to receive treatment. Among the 28 (7%) participants not on treatment, three (3) had died and 25 could not be traced after exhaustive tracing attempts (lost to follow-up). Figure 4.1: Study participants as included in the analysis.

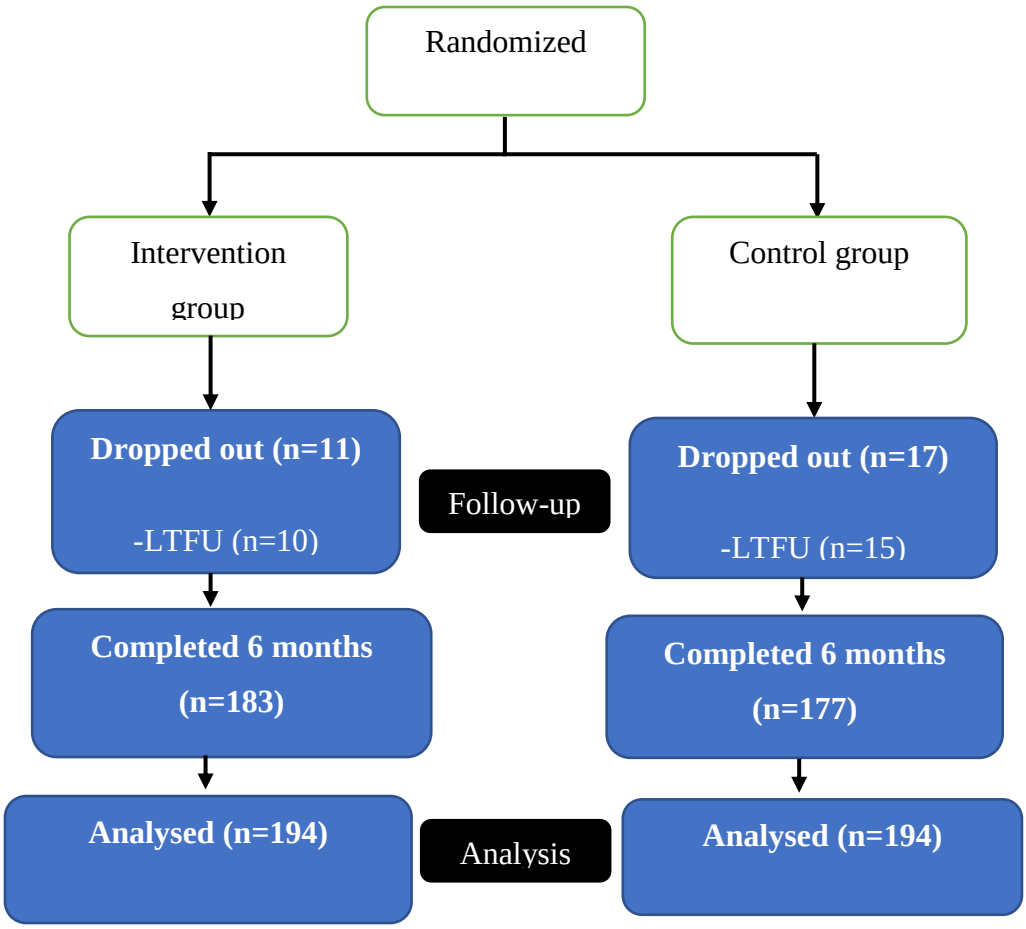

Figure 4.1: Study Participants as Included in the Analysis

Table 4.2 shows a summary of the effects of the intervention on all the outcomes measured in this study at six months. Retention on treatment at six months among the intervention and control groups was 94% (95% CI: 90 - 97%) and 91% (95% CI: 86 - 95%) respectively. The risk of the participants being retained on treatment was 1.03 times as high in the intervention group compared to the control group over a six-month period (aRR: 1.03; 95% CI: 0.98 - 1.09; *p*-value=0.24).

The viral suppression rate at six months was 93% (95% CI: 87 - 96%) among the intervention group, compared to 97% (95% CI: 92 - 99%) among the control group. The risk of viral suppression was 0.96 times as high in the intervention group compared to the control group over a six-month period (aRR: 0.96, 95% CI: 0.91 - 1.01; *p*-value=0.12). The overall VL suppression rate at six months was 95% (95% CI: 91- 97%).

Labor market participation rates for the intervention and control groups were 40% (95% CI: 32 - 49%) and 43% (95% CI: 35 - 52%) respectively. The risk of missing work for a whole day or more was 0.93 times as high in the intervention group compared to the control group over six-month period (aRR: 0.93, 95% CI: 0.71 - 1.24; *p*-value=0.63). Based on this result, there was no significant difference in the risk of missing work for a whole day or more between the intervention and control groups over the six-month period examined. However, the intervention group showed a slightly lower risk compared to the control group, although this difference was not statistically significant. The overall labor market participation rate was 42% (95% CI: 36 - 48%).

HIV status disclosure rates were at 71% (95% CI: 64 - 77%) and 73% (95% CI: 66 - 79%) among the intervention and control groups respectively. The risk of participants disclosing their HIV status was 0.97 times as high in the intervention group compared to the control group over a six-month period (aRR: 0.97, 95% CI: 0.86 - 1.10; *p*-value= 0.65). There was no significant difference in the risk of participants disclosing their HIV status between the intervention and control groups over the six-month period examined. The intervention group showed a slightly lower risk compared to the control group, but this difference was

not statistically significant. The overall HIV status disclosure rate was 72% (95% CI: 67 - 76%).

Unofficial partner is someone who is romantically or sexually involved with a person who is already in a committed relationship with someone else, popularly known as “side chick” or “side partner”. The reported condom-use rates the last time a participant had sex with an unofficial partner were 79% (95% CI: 66 - 88%) and 82% (95% CI: 69 - 90%) among the intervention and control groups respectively. The risk of using a condom with unofficial partner was 0.97 times as high in the intervention group compared to the control group over a six-month period (aRR: 0.97, 95% CI: 0.81 to 1.17; *p*-value=0.77). This showed that there was no significant difference in the risk of using a condom with an unofficial partner between the intervention and control groups over the six-month period examined. The intervention group showed a slightly lower risk compared to the control group, but this difference was not statistically significant. The overall reported condom use rate was 80% (95% CI: 72 - 87%).

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Table 4.2: Summary of the Effects of the Intervention on Study Outcomes at Six Months

Outcomes	Overall (n=388)	Intervention (n=194)	Control (n=194)	Adjusted Risk Ratio (95% CI)	*p*-value
Primary outcome					
Retained on treatment	360 (93%)	183 (94%)	177 (91%)	1.03 (0.98 to 1.09)	0.24
Secondary outcomes					
Virally suppressed	280 (95%)	136 (93%)	144 (97%)	0.96 (0.91 to 1.01)	0.12
Labor market participation	113 (42%)	56 (40%)	57(43%)	0.93 (0.70 to 1.24)	0.63
Disclosed HIV status	278 (72%)	137(71%)	141(73%)	0.97(0.86 to 1.10)	0.65
Used Condoms for sex with unofficial partner	86 (80%)	42 (79%)	44 (82%)	0.97 (0.81 to 1.17)	0.77

CI=Confidence interval
p-value<0.05

4.3 Predictors of Patient Retention on Treatment

Predictors of patients' retention on treatment were estimated. Table 4.3 shows the final multivariate model and the adjusted hazard ratios for each of the factors associated at *p*-value<0.05. The predictors of patients' retention on treatment were being divorced (aHR: $2.9x10^{10}$, 95% CI: $1.36x10^{9}$ - $6.19x10^{11}$; *p*-value<0.000), widowed (aHR: 16.49, 95% CI: 5.03 - 54.01; *p*-value<0.000), time to clinic (minutes) (aHR: 2.41, 95% CI: 2.41 - 2.42; *p*-value<0.000), participant weight of between 70-99 kg (aHR: 104.20, 95% CI: 15.77 – 688.27; *p*-value<0.000), being on 1st line ART regimen of TDF/3TC/EFV (aHR: 0.00, 95% CI: 0.000 – 0.001; *p*-value<0.000 and other 1st line ART regimens which include ABC/3TC/EFV+AZT/3TC/LPV/r+AZT/3TC/NVP+D4T/3TC/EFV+TDF/3TC/NVP (aHR: 3.22×10^{20}; 95% CI: 9.55×10^{19} - 1.09×10^{21}; *p*-value<0.000).

Table 4.3: Predictors of Patients' Retention on HIV Treatment

Characteristics of Study participants	N (%)	Retained (%)	Hazard Ratio (95% CI)	*p*-value	Adjusted Hazard Ratio (95% CI)	p-value
Total, *n(%)*	388 (100%)	360 (100%)				
Marital status						
Married[†]	229 (59%)	213 (59%)	1		1	
Divorced	64 (17%)	62 (17%)	0.30 (0.04- 2.44)	0.261	$2.9x10^{10}$ ($1.36x10^{9}$ - $6.19x10^{11}$)	0.000
Never married/Single	46 (12%)	40 (11%)	1.81 (0.51 - 6.39)	0.356	$3.08x10^{6}$	
Widowed	49 (13%)	45 (13%)	1.22 (0.41 - 3.60)	0.725	16.49 (5.03 - 54.01)	0.000
Time to clinic (minutes)	388 (100%)	360 (100%)	0.99 (0.99 - 1.01)	0.811	2.41 (2.41 - 2.42)	0.000
Weight categories (Kg)						
40-69	242 (67%)	223 (66%)	1		1	
70-99	104 (29%)	103 (30%)	0.11(0.01-0.88)	0.037	104.20(15.77-688.27)	0.000
100-129	12 (3%)	12 (4%)	$1.30x10^{-15}$($5.61x10^{-16}$-$3.02x10^{-15}$)	0.000	1	
130-159	1 (0%)	1 (0.3%)	$4.41x10^{-15}$($2.20x10^{-16}$-$8.83x10^{-14}$)	0.000	1	
1st Line ART original regimen						
TDF/3TC/DTG	194 (51%)	180 (51%)	1		1	
TDF/3TC/EFV	182 (48%)	170 (48%)	0.82 (0.32 - 2.14)	0.686	0.00 (.000 - 0.001)	0.000
Other[+]	7 (2%)	5 (1%)	4.93 (1.04 - 23.34)	0.044	$3.22x10^{20}$ ($9.55x10^{19}$ - $1.09x10^{21}$)	0.000

[+] Other=ABC/3TC/EFV+AZT/3TC/LPV/r+AZT/3TC/NVP+D4T/3TC/EFV+TDF/3TC/NVP; CI= Confidence Interval; [†]Married includes monogamous and polygamous

4.4 Predictors of Secondary Study Outcomes

Getting and keeping an undetectable viral load is important for people with HIV to stay healthy. Testing the probability of a patient's viral load being suppressed as a function of various predictor variables found out that school attendance was a negative and significant predictor of the probability of viral suppression (b=-2.39, 95% CI: -4.74 - -0.03; *p*-value=0.047). The study suggested that higher levels of school attendance are associated with decreased likelihood of achieving viral suppression.

This study tested the probability of a patient working for a whole day or more as a function of various predictor variables. The health facility or clinic that the patient attended was a positive and significant predictor of the probability of working for a whole day or more (b=0.69, 95% CI: 0.33 – 1.05; *p*-value<0.000). Male patients had a higher probability of working for a whole day or more without missing compared to females (b=0.98, 95% CI: 0.25 – 1.70; *p*-value=0.008). Patient age was a positive and significant predictor of the probability of working for a whole day or more (b=0.04, 95% CI: 0.006 - 0.07; *p*-value=0.023). This meant that older patients had a higher probability of working for a whole day or more without missing compared to younger patients. In addition, monthly income was a positive and significant predictor of the probability of working for a whole day or more (b=0.34, 95% CI: 0.10 - 0.58; *p*-value=0.006). Those with higher monthly income had a higher probability of working for a whole day or more without missing compared to those with less income per month.

The study tested the probability of a patient disclosing their HIV status as a function of various predictor variables and found out that the health facility or clinic that the patient attended was a positive and significant predictor of the probability of disclosing HIV status (b=0.52, 95% CI: 0.11 - 0.92; *p*-value=0.012). Again, fare spent to and from the clinic was a positive and significant predictor of the probability of a patient disclosing HIV status (b=0.0052, 95% CI: 0.001 - 0.01; *p*-value=0.022). Meaning that the probability of disclosing HIV status increased significantly with the increasing fare spent to and from the clinic.

Patient education level was a positive and significant predictor of the probability of using a condom when having sex with unofficial partner (b=1.07, 95% CI: 0.08 - 2.05; *p*-value=0.034). The probability of using a condom when having sex with unofficial partner increased significantly with the increasing levels of education among the patients (Table 4.4: Predictors of secondary outcomes)

Table 4.4: Predictors of Secondary Outcomes

Independent variables	(1) Virally suppressed	(2) Missed work for whole day or more	(3) Disclosed HIV status	(4) Used Condoms for sex with unofficial partner
Arm	-0.537	-0.329	0.219	-0.309
	(0.689)	(0.301)	(0.303)	(0.552)
Age [Years]	-0.0107	0.0399*	-0.00382	-0.00662
	(0.0312)	(0.0175)	(0.0172)	(0.0265)
Clinic [KCHC=1]	-0.0585	0.687***	0.516*	
	(0.375)	(0.184)	(0.206)	
Sex [Male=1]	0.910	0.975**	0.160	-0.527
	(0.757)	(0.368)	(0.355)	(0.566)
Religion [Christian=1]	-1.976	-0.188	-0.205	
	(1.318)	(0.828)	(1.311)	
Marital status [Married =1]	0.240	0.0136	-0.0123	-0.304
	(0.294)	(0.115)	(0.103)	(0.197)
Weight [kg]		0.00886	0.0209	
		(0.0116)	(0.0116)	
Ever attended school [Yes=1]	-2.388*	-1.909	-0.394	
	(1.202)	(1.484)	(0.938)	
Education [No formal education=1]	0.0744	-0.324	0.116	1.068*
	(0.432)	(0.201)	(0.203)	(0.503)
Household Size [2=1]	0.157	0.143	0.328	-0.325
	(0.331)	(0.173)	(0.183)	(0.270)
Financial support [<=1=1]	0.434	-0.123	0.172	
	(0.282)	(0.132)	(0.125)	

Independent variables	**(1)** **Virally suppressed**	**(2)** **Missed work for whole day or more**	**(3)** **Disclosed HIV status**	**(4)** **Used Condoms for sex with unofficial partner**
Residence status [Kibera=1]		-1.668	-0.0130	
		(1.369)	(0.115)	
Time to clinic [Minutes]	-0.000493	0.0126	-0.00873	0.00138
	(0.0139)	(0.00950)	(0.00942)	(0.00345)
Predominant mode of transport to clinic [Walking=1]		0.327	-1.384	
		(1.395)	(1.053)	
Fare to and from clinic [Kshs]		0.00323	0.00518*	
		(0.00215)	(0.00226)	
Occupation [Salaried employment=1]	0.264	-0.0980	0.194	-0.264
	(0.384)	(0.187)	(0.209)	(0.276)
Monthly income [<1000=1]	0.0604	0.339**	0.00707	
	(0.204)	(0.124)	(0.131)	
1st Line Original Reg [TDF/3TC/DTG]	-0.506	-0.00126	-0.538	0.631
	(0.557)	(0.289)	(0.287)	(0.593)
Constant	4.213	-1.985	-0.220	1.641
	(3.543)	(2.310)	(2.181)	(2.227)
Observations (N)	199	246	257	105
R-sq	0.049	0.178	0.041	0.129
adj. R-sq	-0.002	0.13	0.002	-0.014
rmse	0.227	0.461	0.451	0.402

Standard errors in parentheses

* p-value<0.05, ** p-value<0.01, *** p<0.001

4.5 Survival in HIV/AIDS Treatment

The overall retention on treatment at three (90 days) and six (180 days) months were 98% (95% CI: 96 - 99%) and 93% (95% CI: 90 - 95%) respectively (Figure 4.2). The overall attrition rate was 14.7 drop-outs per 100 person-years among the 388 participants. This meant that there will be on average 14.7 drop-outs if 100 patients were followed-up for one year. The mortality rate was 1.6 per 100 person-years, and the LTFU rate was 13.5 per 100 person-years.

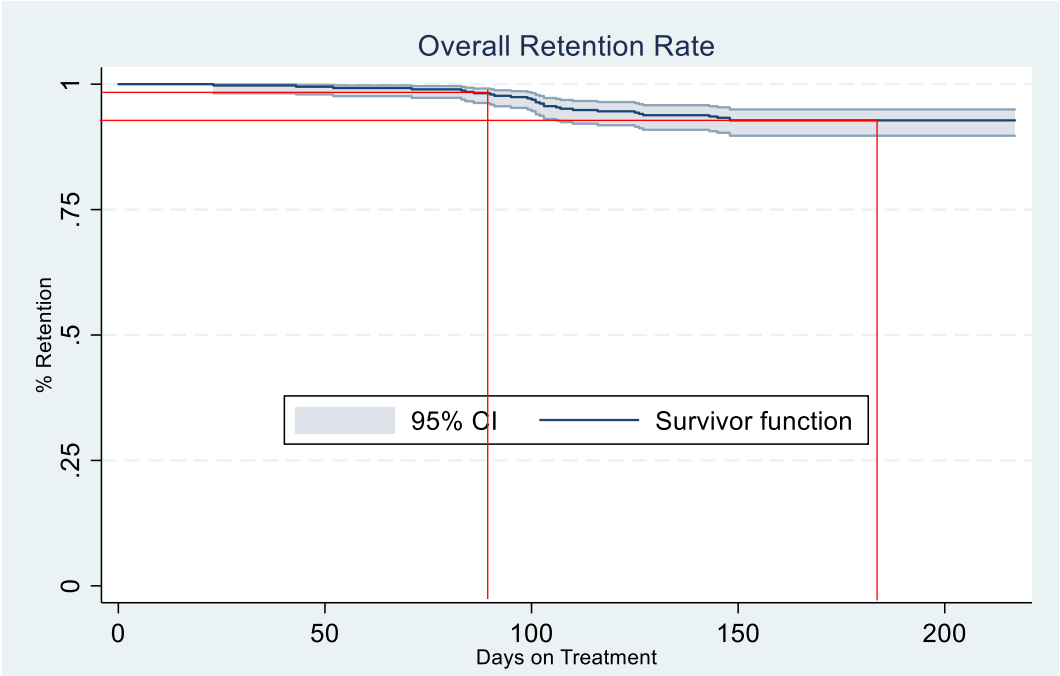


Figure 4.2: Kaplan-Meier overall Retention Rate

The retention rate among the control and intervention groups were 97% (95% CI: 94 - 99%) and 98% (95% CI: 95 - 99%) at three months and 91% (95% CI: 86 - 95%) and 94% (95% CI: 90 - 97%) at six months (Figure 4.3).

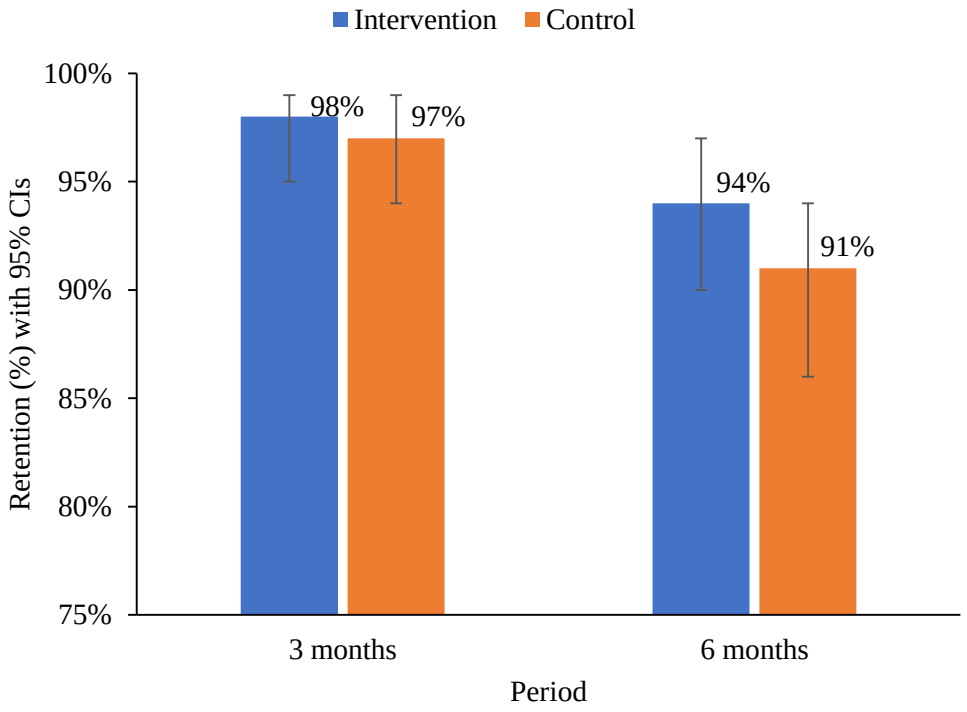
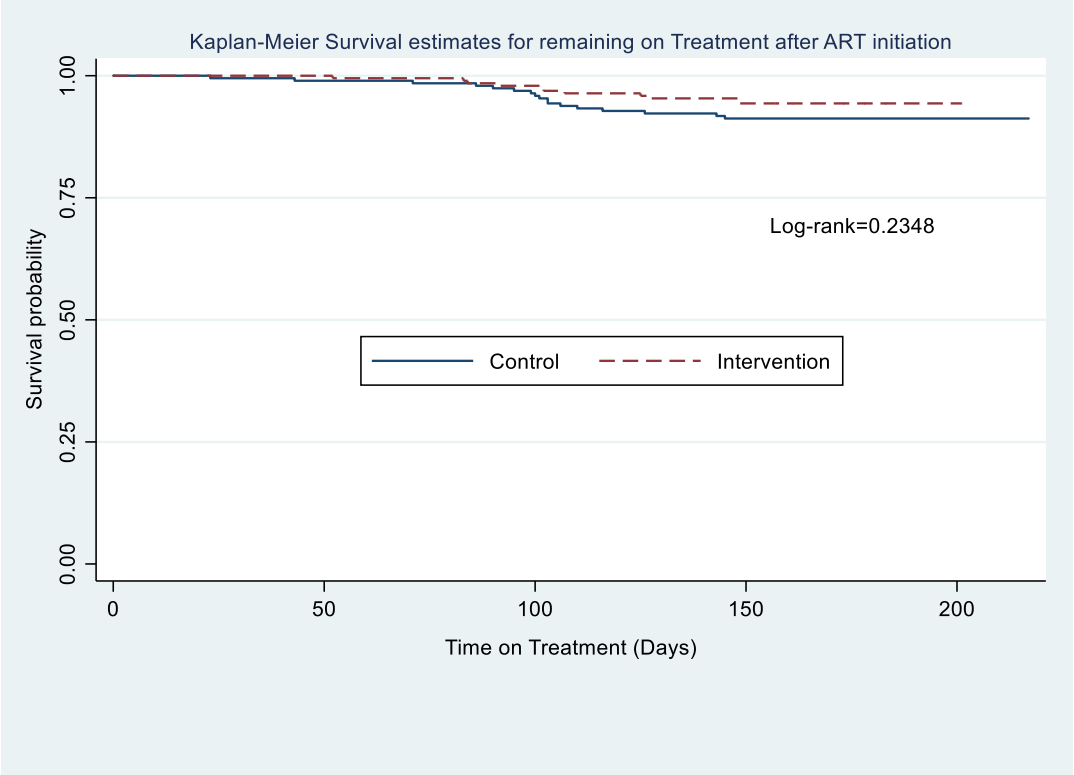


Figure 4.3: Retention rates for Intervention and Control groups at Three and Six Months

A test of equality of the two groups using a log-rank test indicated that the survival functions for the treatment and control groups were not any different (equal) ($\chi^2(1) = 1.41$, *p*-value=0.2348) (Figure 4.4).



At risk by group

Control:194	193	187	178	174
Intervention: 194	194	191	185	179

Figure 4.4: Kaplan-Meier Survival Estimate for Remaining on Treatment after ART Initiation

CHAPTER FIVE

DISCUSSION

5.1 Early Retention on HIV Treatment

This study evaluated whether promising patients newly initiated on ART that if they stayed on treatment for six months, then they would be provided with free T-shirts of their favorite football team or free *Kiondo* on condition that they attended all psychosocial support group meetings. The intervention was evaluated as to whether it would improve retention on HIV/AIDS treatment among resource limited populations in the Kibera informal settlement in Nairobi, Kenya.

The choice of the primary outcome, early retention on treatment, underscores its vitality in reducing transmissions, morbidity and mortality, preventing new infections and achieving viral suppression (Auld *et al*., 2014; Cohen, Chen, *et al*., 2011). Although retention on treatment has been explored in studies of adults in HIV services, very few have measured early (at six months from start of ART) retention on HIV programs (Muhula *et al*., 2022; Wilkinson *et al*., 2015). To the author's knowledge, no study in Kenya of an RCT design has explored strategies to improve early retention on treatment among adult HIV positive clients.

The finding was that the intervention was not effective in retaining the patients on ART during the first six months of treatment. Even though the intervention was not effective, the retention rate of 93% at six-months was high and consistent with data from a study conducted in Tanzania which documented the six months retention rate at 93.5% (McCoy *et al*., 2017). This was much higher than data documented from studies conducted in Western Kenya (Fayorsey *et al*., 2019), Coastal Kenya (Hassan *et al*., 2015) and within the same locality of Kibera informal settlement *(Unge et al*., 2009). The documented overall six-month retention on treatment in this study (93%), was not any different from retention in the clinics (92%), given that only three participants were confirmed to have

transferred to other health facilities and continued to receive treatment. Similarly, retention on treatment was not any different among adults randomized to the intervention (94%) compared with the control (91%). It is, however important to consider clients who are active on treatment in other health facilities when quantifying retention on treatment, hence the need to put in place adequate structures for tracing patients who miss clinic appointments. Of note, all participants who could not be traced for a period of three months (90 days) were subsequently documented as LTFU from HIV/AIDS treatment. It is part of the standard practice for health facilities to trace participants who miss clinic appointments and therefore this was done by all the clinics involved in the study in addition to offering other support services that might had helped to engage and retain participants on treatment. This could be one of the reasons why retention among the intervention and control groups remained high with no clear statistical differences but with a possibility of public health significance. It could also be that a reward that is not given until six months of treatment has been completed does not have much impact on behavior in the early months of HIV treatment.

The study posited that by integrating interventions, multiple barriers to engagement along the HIV treatment cascade challenges could be addressed, particularly concerning the early retention of patients in treatment, with a focus on those residing in slum areas. Retention at 94% of participants on treatment at six months in the intervention arm is within the range of studies that have evaluated the effect of single interventions at 6 months in SSA (Muhula *et al*., 2022). Only two studies were identified that have assessed combination interventions aimed at enhancing retention at six months in HIV treatment (Fayorsey *et al*., 2019; Graves *et al.,* 2018). Retention being a predictor of viral suppression, an achievement of 94% could be an indication that Kenya is well on course to the UNAIDS target of achieving viral suppression for 95% of those on HIV treatment by 2030.

Retention on HIV treatment depended on being divorced, being widowed, time to clinic, patient weight of between 70 and 99 kg, being on 1st line ART regimen of TDF/3TC/EFV and other 1st line ART regimens of ABC/3TC/EFV+AZT/3TC/LPV /r+AZT/3 TC/NVP+

D4T/3TC/EFV+TDF/3TC/NVP. Patients who are divorced or widowed are at a higher risk of attrition from HIV treatment compared to those who are married as they may lack the needed social and psychological support to adequately deal with the stigma and overall economic and social burden associated with HIV infection. They were therefore more prone to attrition from HIV treatment, which is consistent with previous work done in Kenya, South Africa and India (Machuka *et al*., 2020; Shisana *et al*., 2016; United Nations General Assembly, 2021). Patients with higher weights (between 70 to 99kg) were at a higher risk of attrition from HIV treatment compared to those with lesser weights, consistent with findings from studies conducted in Haiti and Kinshasa in the Democratic Republic of Congo (Domercant *et al*., 2017; Id *et al*., 2022). Patients with longer travel times to clinic were at a higher risk of attrition from treatment as they may lack the motivation to walk long distances to the clinics or may not have the money to pay fares to and from the clinics (Alvarez-Uria *et al*., 2013; The World bank, 2021; Zerbo *et al*., 2020), which support the early initiative by the Ministry of Health to decentralize ART treatment sites to lower level health centers and dispensaries to reduce time and costs associated with travelling to and from hospitals (Ministry of Health, 2009).

5.2 Viral Suppression, Labor Market Participation, Disclosure of HIV Status and Knowledge about HIV/AIDS Prevention and Transmission

The proportion of patients who had achieved viral suppression (< 1000 copies/µL) at 6 months was higher among the control group (97%) compared to the intervention group (93%) though not significantly different, depicting that the risk of viral suppression was 0.96 times as high in the intervention group compared to the control group over 6 months period. These findings may explain the interdependence between retention and viral suppression and the need to examine these together in the race to achieving the 2nd 95 and 3rd 95 UNAIDS targets by 2030.

The study did not find any significant differences in labor market participation among the intervention (40%) and the control (43%) groups (*p*-value=0.63). These proportions are however lower than the general population in Kenya that end up missing work for a day

or more (67%) due to illness (Kenya National Bureau of Statistics, 2016). The health facility or clinic that the patient attended, being male, being older in age and higher monthly income were all independently associated with a higher probability of working for a whole day or more without missing.

The HIV status disclosure rates were high at 71% and 73% among the intervention and control groups respectively. The high disclosure rates in the study population indicate the gains made in HIV/AIDS prevention and treatment efforts, especially as a first step in gaining HIV-specific social support (Hays *et al*., 1993; Zea *et al*., 2005) and, under some circumstances, can help prevent seroconversion of HIV-negative individuals and facilitate adherence to ARV medications (Spire *et al*., 2008). These proportions are higher than those earlier reported (men 55% and women 37%) in KDHS 2014 (Kenya National Bureau of Statistics, 2015). The health facility or clinic that the patient attended, fare spent to and from the clinic were all independently associated with a higher probability of disclosing HIV status.

A higher proportion of the study population had comprehensive knowledge about HIV/AIDS prevention and transmission measures i.e 79% in the intervention and 82% in the control groups reported having used condoms the last time they had sexual intercourse with unofficial partners. This is higher than the proportions reported through KDHS in 2014 at 56% women and 66% men, indicating the positive strides being made in universal awareness of AIDS in Kenya (Kenya National Bureau of Statistics, 2015). Patient education level was independently associated with a higher probability of using a condom when having sex with unofficial partner.

5.3 Survival in HIV/AIDS Treatment

The attrition rate among the 388 patients on ART was 14.7 per 100 person-years, much better than 23 per 100 person-years that was document at a rural HIV/AIDS clinic in Coastal Kenya and within the same locality of Kibera informal settlement (Hassan *et al*.,

2015; Unge *et al*., 2009). Mortality and LTFU incidence rates were 1.6 and 13.5 per 100 person-years respectively.

5.4 Strengths and Limitations of the Study

This trial advances knowledge gained from previous studies in several important ways. To the knowledge of the author, this was the first study in a resource-limited setting to test whether an incentive of this nature (free T-shirts of a favorite football team or a free *Kiondo*) combined with psychosocial support improved retention within the first six months of starting ART in a general population with HIV. This study was designed to evaluate a relatively simple implementation model that is feasible to administer in real-life clinical settings. The conditions for providing the incentives were relaxed provided that the patients attended clinic regardless of timeliness, in order to further simplify implementation and to avoid excluding disadvantaged participants facing the greatest obstacles to keeping appointments.

Additionally, this study specifically recruited individuals initiating ART based on evidence of increased risk of attrition from treatment in the first six months of treatment (MP & S, 2015). The focus on this group was also driven by the increased clinical, social and economic vulnerability of patients at this time and the potential to influence formation of habits early in treatment for long lasting effects (Gary Charness & Uri Gneezy, 2009; Whetten *et al.,* 2008). The findings suggest that non-cash incentives offered to adults initiating ART were ineffective at least in the short-term, though more work is needed to understand the long-term effects.

Other key strengths of this study were its high participation rate and low deaths which minimized the possibility of non-participation or attrition biases. Only 2% of those assessed for eligibility declined to participate in the trial, less than 1% of the participants died and none of the participants withdrew from the trial. By tracing participants who did not return to the clinic and categorizing those confirmed to be receiving care in other health facilities as transfer outs was a more valid assessment of retention in treatment than

solely using retention in clinics of study as a proxy measure for retention on treatment. The randomized design, inclusion of a comparison group and the focus on ART initiates, eliminated the pathway to presentation to care with advanced HIV/AIDS.

This study had important limitations. First, some data were missing from the electronic medical records system. However, these were not differential by study arm and would not likely result in the underestimation of retention in treatment. Some known predictors to retention such as history of TB and immunosuppression could not be assessed due to unavailability of some data such as TB status and CD4+ counts (Decroo *et al*., 2014; Gupta *et al.,* 2011).

Second, the study clinics already had mechanisms in place to support patient retention on treatment, such as calling patients who missed appointments, however these were not optimally implemented due to inadequate resources. The intervention might have been more likely to show an effect on retention on HIV treatment and other secondary outcomes if tested in settings without these support mechanisms.

A small number of participants could not be located to confirm the final outcome after exhaustive tracing and were therefore classified as LTFU. Although this study followed gold standards as per Ministry of Health and PEPFAR indicator guidelines, misclassification might have occurred if patients did not have a documented facility transfer. The proportion of untraceable participants among those not retained on treatment, did not significantly vary by study arms, suggesting that potential misclassification might be non-differential by study arm.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

1) The findings demonstrated that the combination of non-cash incentives of a reminder at every clinic visit that participants will receive free T-shirts of their favorite football team or free *Kiondos* based on preference if they made it to the sixth month visit without missing a treatment appointment and psychosocial support was not effective in improving retention during the first six months of HIV treatment.
2) The predictors of patient retention on HIV treatment were being divorced, widowed, time to clinic, weight of between 70-99kg, 1st line ART regimen of TDF/3TC/EFV and other 1st line ART regimens.
3) Evidence suggests that there was no statistically significant difference in survival estimates between the treatment and control groups.

6.2 Recommendations

1) Although this combination intervention did not demonstrate statistical significance between the intervention and control groups, from a public health significance perspective, it warrants consideration along with other proven interventions as part of a comprehensive package of support at the time of treatment for the following reasons: (1) the intervention had no known risks of harm or adverse effects to study participants; (2) its simplicity in implementation makes it worth considering.

2) To enhance early retention of patients in HIV treatment, strategies should be piloted to reach divorced and widowed patients earlier and support them to remain on treatment.
3) Efforts should also be made to further decentralize ART treatment to reduce costs and time associated with traveling to and from hospitals.
4) The study provided an important contribution to understanding the potential of non-cash incentives combined with psychosocial support to achieving epidemic control in resource limited settings and therefore further research investigating the long-term effects, cost-effectiveness, scalability and sustainability of such interventions are warranted

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APPENDICES

Appendix I: Revised WHO Clinical Staging of HIV/AIDS for adults and adolescents

Primary HIV infection

Asymptomatic

Acute retroviral syndrome

Clinical stage 1

Asymptomatic

Persistent Generalized Lymphadenopathy (PGL)

Clinical stage 2

Moderate unexplained weight loss (<10% of presumed or measured body weight)

Recurrent respiratory tract infections (RTIs, sinusitis, bronchitis, otitis media, pharyngitis)

Herpes zoster

Angular cheilitis

Recurrent oral ulcerations

Papular pruritic eruptions

Seborrhoeic dermatitis

Fungal nail infections of fingers

Clinical stage 3

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

Severe weight loss (>10% of presumed or measured body weight)

Unexplained chronic diarrhoea for longer than one month

Unexplained persistent fever (intermittent or constant for longer than one month)

Oral candidiasis

Oral hairy leukoplakia

Pulmonary TB diagnosed in last two years

Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or

joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Conditions where confirmatory diagnostic testing is necessary

Unexplained anaemia (<8 g/dl), and or neutropenia (<500/mm3) and or thrombocytopenia (<50 000/ mm3) for more than one month

Clinical stage 4

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

HIV wasting syndrome

Pneumocystis pneumonia

Recurrent severe or radiological bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration)

Oesophageal candidiasis

Extrapulmonary TB

Kaposi's sarcoma

Central nervous system (CNS) toxoplasmosis

HIV encephalopathy

Conditions where confirmatory diagnostic testing is necessary:

Extrapulmonary cryptococcosis including meningitis

Disseminated non-tuberculous mycobacteria infection

Progressive multifocal leukoencephalopathy (PML)

Candida of trachea, bronchi or lungs

Cryptosporidiosis

Isosporiasis

Visceral herpes simplex infection

Cytomegalovirus (CMV) infection (retinitis or of an organ other than liver, spleen or lymph nodes)

Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis, penicilliosis)

Recurrent non-typhoidal salmonella septicaemia

Lymphoma (cerebral or B cell non-Hodgkin)

Invasive cervical carcinoma

Visceral leishmaniasis

(World Health Organization, 2005a)

Appendix II: Data Collection Questionnaire

STUDY AREA: KIBERA INFORMAL SETTLEMENT

TARGET RESPONDENTS: PERSONS AGED ABOVE 18 YEARS OLD AND CONFIRMED TO BE HIV POSITIVE

Note: Administer the tool in Kiswahili, unless the respondent understands and speaks English

Please identify a private setting for the interview

IDENTIFICATION	
Health facility name	
Date of interview (dd/mm/yyyy)	
Study ID	
Patient ID	
Community Health Volunteer name	

Start time:

SECTION 1: RESPONDENT SOCIO-DEMOGRAPHIC INFORMATION				
NO	**QUESTIONS AND FILTERS**	**RESPONSES**	**CODES**	**SKIP TO**
100	Sex of the respondent *Jinsia ya mhojiwa*	Male Female	1 2	
101	When is your date of birth? *Ulizaliwa lini?*	Month Year Don't Know	☐☐ ☐☐ 88	
102	How old were you on your last birthday? *Ulikuwa na miaka ngapi ulipoadhimisha*	[Age in complete years]	☐☐	

	kumbukumbu yako ya mwisho ya kuzaliwa?	[Compare and correct Q101 and/or Q102 if inconsistent]		
103	What is your religion? *Je, wewe ni mshiriki wa dini gani?* [Probe if Christian to identify Catholic or protestant/other christians]	Catholic Protestant/other Christian Muslim No religion Other (specify)_____	1 2 3 4 5	
104	What is your marital status? *Je, hali yako ya ndoa ni gani?*	Monogamous Polygamous Divorced Separated Never married/Single Widowed	1 2 3 4 5 6	

105	Have you ever attended school? *Je, uliwahi kuenda shule?*	Yes No	1 2	 →Q.107
106	What is the highest level of school you completed? *Je, ulihitimu kiwango kipi cha juu cha elimu?* [Probe to get specific education level completed]	Nursery Primary Post-primary/vocational Secondary College University Don't know	1 2 3 4 5 6 88	
107	How many people do you reside with, excluding yourself? *Je, ni watu wangapi unaishi nao bila kujihesabu wewe mwenyewe?*	Number of people	☐☐	
108	Of the above, how many are children? *Kati ya hawa, wangapi ni watoto?*	Number of children	☐☐	

109	What is the nature of the relationship to those you reside with? *Ni uhusiano gani ulioko kati yako na wale unaoishi nao?* [You may check more than one option]	Wife/husband Children Friends Relatives Other (Specify)_____	1 2 3 4 5	
110	How many people are you supporting financially, excluding yourself *Ni watu wangapi unaowakimu kifedha, bila kujihesabu?*	Number of people	☐☐	
111	Are you living in Kibera? *Unaishi Kibera?*	Yes No	1 2	→Q.113 →Q.114
112	If no, where do you live? *Unaishi wapi?*	_____		
113	How long have you been living in Kibera? *Umeiishi Kibera kwa muda gani?*	Months OR Years	☐ ☐	

114	How long does it take you to reach the clinic from your residence? *Wewe huchukua muda wa kiasi gani kufika kliniki ukitoka kwako?*	Minutes OR Hours	☐ ☐	
115	How do you get to the clinic (main mode of transportation) e.g walking, public transport? *Je wewe hufika kliniki kwa njia gani (njia ya usafiri ambayo wewe hutumia kwa kawaida)kwa mfano kutembea, usafiri wa umma na kadhalika?*	Please specify _____		
116	How much do you usually pay for return travel to the clinic? *Wewe hulipa pesa ngapi, kwenda na kurudi kutoka nyumbani hadi kliniki?*	KES	☐	
117	What is your ethnic group/tribe? *Je, wewe ni wa kabila gani?*	Kikuyu Luo Kamba Luhya	1 2 3 4	

		Kisii Somali Nubian Other (Specify)_____	5 6 7 8	

END

SECTION II: LABOUR MARKET PARTICIPATION				
NO	**QUESTIONS AND FILTERS**	**RESPONSES**	**CODES**	**SKIP TO**
200	What is your present main occupation? *Je, ni shughuli ipi saa hizi **muhimu** ya kuleta mapato unajishughulisha nayo?*	Salaried employment Self-employed/Businessperson Casual labor Unemployed	1 2 3 4	 →END

		Other (Specify)_____	5	
201	How many hours do you work per day and how many days do you work per week? *Ni masaa mangapi wewe hufanya kazi kwa siku na ni siku ngapi wewe hufanya kazi kwa wiki?*	Hours per day Days per week	☐ ☐	
202	How much time do you have to miss from work to attend the clinic? *Ni muda kiasi gani wewe hukosa kazi ili kuhudhuria kliniki?*	Less than 2 hours Up to half a day A whole day More than one day	1 2 3 4	
203	How much do you earn in a month?	<Kes. 1,000 Kes. 1,000-5,000	1 2	

	Unapata hela ngapi kila mwezi kutokana na kazi yako?	Kes. 5,000-10,000 >Kes. 10,000 Not willing to disclose Not certain	3 4 5 6	
204	What is your average household income per month? *Kwa ujumla mapato ya familia yako ni hela ngapi kwa mwezi?*	<Kes. 1,000 Kes. 1,000-5,000 Kes. 5,000-10,000 Kes. 10,000- 20,000 >Kes.20,000	1 2 3 4 5	

		Not willing to disclose	6	
		Not certain	7	

END

SECTION III: HIV CARE AND SOCIAL LIFE				
NO	**QUESTIONS AND FILTERS**	**RESPONSES**	**CODES**	**SKIP TO**
300	Overall, how do you feel about the HIV care that you have received so far at this clinic? *Kwa ujumla, unahisi vipi juu ya huduma ya afya ambayo umepokea katika hii kliniki hadi sasa?* [Please circle one]	Completely dissatisfied Mostly dissatisfied Somewhat dissatisfied Mixed feelings Somewhat satisfied	1 2 3 4 5	

		Mostly satisfied Completely satisfied	6 7	
301	When did you receive your first positive HIV result? *Ni lini ulipokea matokeo ya kwanza yaliyoonyesha kwamba una virusi vya ukimwi?*	Today Earlier (Specify)_____	1 2	→Q.305
302	Which health facility did you get your first positive HIV test done? *Ni wapi [Kituo cha afya] ambapo ulipata kujua kwamba una virusi vya ukimwi mara ya kwanza?*			
303	Have you disclosed your HIV status to anyone?	Yes	1 2	 →Q.305

	Je umefichulia hali yako ya virusi vya ukimwi kwa mtu yeyote?	No		
304	If yes, who have you disclosed your status to? *Kama ndio, ni nani umemueleza juu ya hali yako?*	Husband/Wife Parents Siblings Friends Colleague(s) at work Other (Specify)_____	1 2 3 4 5 6	
305	How often do you find someone to turn to for suggestions about how to	None of the time A little of the time	1 2	

	deal with a personal problem when you need it? *Ni mara ngapi unaweza pata usaidizi kutoka kwa mtu atakayekupa mapendekezo kuhusu jinsi ya kukabiliana na tatizo la kibinafsi?* [Please circle one]	Some of the time Most of the time All of the time	3 4 5	
306	How often do you have a drink containing alcohol? *Je, Ni mara ngapi wewe hunywa vinywaji vyenye pombe?*	Never Once a month Two to three times a month Two to four times a month	1 2 3 4 5	

		Four or more times a month		
307	Have you ever used drugs such as Heroin, Bang, Cocaine, Khat/Miraa, Kuber, Glue? *Je, umewahi kutumia madawa za kulevya kama heroin, bangi, cocaine, miraa, kuber, glue?* [Mention the drugs to the respondent]	Yes No	1 2	 →Q.309
308	Have you ever used any of the following drugs? *Umewahi kutumia madawa za kulevya zifuatazo?*			
a)	Heroin	Yes No	1 2	

b)	Marijuana/Bang	Yes No	1 2	
c)	Cocaine	Yes No	1 2	
d)	Khat/Miraa	Yes No	1 2	
e)	Kuber	Yes No	1 2	
f)	Glue	Yes No	1 2	

g)	Other (Specify)	_____		
309	In the last three months, have you had sex with an unofficial sexual partner(s) (excluding your official partner)? *Je, kwa miezi mitatu iliyopita umeshiriki ngono na mpango wa kando? (ukiondoa mke au mume wako)* [Check with Q104]	Yes No Not willing to disclose	1 2 3	
310	Did you use a condom when you last had sex with your unofficial sexual partner? *Je, ulitumia Condom mara ya mwisho ulishiriki ngono na mpango wako wa kando?*	Yes No Not willing to disclose	1 2 3	

END

THANK YOU FOR TAKING PART IN THE STUDY

END TIME: _____

Appendix III: Data Extraction Tool

Data extraction tool from Health facility Electronic medical records systems OR Patient charts

Study ID	PID	HF where first positive HIV test is done?	Date confirmed HIV positive	ART Start date	CD4 Count	Date of baseline CD4 count	Viral load test	Date of Viral load test	WHO staging	TB screening outcome	TB screening date	Appointment schedule date	ARV dispense date	Patient status	Exit reason	Exit date

Appendix IV: Tracing Report Form

Date (dd-mmm-yyyy) / Tarehe: ☐☐-☐☐☐-☐☐☐☐

This form is to be filled at the end of follow-up (6-months if patient attended 6-month visit).

Participant Study ID No.	Site (Please check)
☐☐☐☐	Kibera CHC ☐ Kibera South Disp ☐ Silanga Disp ☐

6-month follow-up: Did the patient attend their 6-month visit? (the 12-month visit must fall between 5 months and 7 months of their baseline visit)

1. Yes / Ndio ☐ 2. No / Hapana ☐

If patient attended their 6-month follow-up, no further action is required (once they have completed the questionnaire).

If patients did not attend their 6-month visit, please indicate their status

Death	☐
Formally transferred care and active in care at new facility	☐
Formally transferred care and NOT active in care at new facility	☐

Unknown – requires participant tracing ☐

Other: Please specify _____

Does the participant require tracing to ascertain their status?

1. Yes / Ndio ☐ 2. No / Hapana ☐

Participant traced by telephone?

1. Yes / Ndio ☐ 2. No / Hapana ☐

Participant traced through home visit?

1. Yes / Ndio ☐ 2. No / Hapana ☐

Additional comments:

_____

_____

_____

_____

Staff initials

Appendix V: Publications

Publication 1: Interventions to Improve Early Retention of Patients in Antiretroviral Therapy Programmes in Sub-Saharan Africa: A Systematic Review

Publication 2: Six-Months Retention on Treatment and Attrition Risk Factors among People Living with HIV/AIDS in Kibera Informal Settlement, Nairobi, Kenya