BODY FAT MALDISTRIBUTION AMONG HUMAN IMMUNODEFICIENCY VIRUS-INFECTED PATIENTS ATTENDING CARE AND TREATMENT CLINICS IN DAR ES SALAAM MUNICIPAL HOSPITALS

Marina Alois Njelekela (MD, PhD)

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By,

Marina Alois Njelekela

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Public Health of Muhimbili University of Heath and Allied Sciences

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CERTIFICATION

The undersigned certify that she has read and hereby recommend for Acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled **'*Body Fat Mal-distribution Among Human Immunodeficiency Virus-Infected Patients Attending Care And Treatment Clinics In Dar Es Salaam Municipal Hospitals*'** in fulfilment of the requirements for the degree of Master of Public Health of Muhimbili University of Health and Allied Sciences.

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Dr. Rose N. Mpembeni

(Supervisor)

Date: _____

DECLARATION

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I, **Marina Alois Njelekela**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature ……..…….. Date ……..

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DEDICATION

I wish to dedicate this work to my beloved parents, the late Mr. Alois Simon Njelekela and my mother Bernada Sunzi Kapinga for laying an excellent foundation for totality of my life including a successful career. What you invested in me was worthwhile. And to my beloved children Brenda Safia Chuma and Bianca Bernada Chuma for the tolerance they endured while I was pursuing the course.

ABSTRACT

Long term side effects of HAART such as body fat mal-distribution have not been reported in Tanzania, since care and treatment began in 2004. Likewise perceptions and attitude of HIV/AIDS patients on treatment on their body fat mal-distribution has not been studied previously. A cross sectional study was therefore conducted to determine the prevalence and most common risk factors for body fat mal-distribution among human immunodeficiency virus (HIV)-infected patients in Dar es Salaam and to assess the perceptions and attitudes these patients have on body fat mal-distribution. A total of 466 adult patients were interviewed during the study. Mean age of the participants was 41.1 ± 9.8 years, with men being more aged (46.1 ± 10.8 years) than women (39.6 ± 8.9 years) $p<0.0001$. Bivariate analysis showed significant association between body fat mal-distribution and sex ($p=0.03$), age ($p=0.003$), the use of HAART ($p=0.0001$) and the types of HAART (stavudine and efavirenz based ($p<0.0001$). In multivariate analysis the most important determinants of lypodystrophy in this population were stavudine based therapy (OR, 27.0, 95% CI 11.87-19.11, $p<0.0001$), efavirenz based therapy (OR, 8.5, 95% CI 3.8-61.50, $p<0.0001$), nevirapine based therapy (OR, 8.8, 95% CI 3.07-25.53, $p<0.0001$) and age group 41-50 years (OR, 4.3, 95% CI 1.18-16.14, $p=0.03$). Among the participants with lipodystrophy 15.8% felt strongly that their current body outlook/image is worse compared to the way they looked before and 10.5% reported to dislike their mirror image. On average 24.2% avoided wearing clothing that shows their body, 15.5% of participants felt they cannot attend outdoor activities, or meet new people (13.7%) or attend events that will have new people (12.6%). Based on these findings, we conclude that; there are a significant proportion of HIV positive patients who are on treatment with HAART that had lipodystrophy and stavudine, efavirenz, and nevirapine based therapies and increasing age were important determinants of lipodystrophy in this population. Negative perceptions and attitudes regarding ones' own body was also evident in this study. We recommend that, more efforts are required to have guidelines for care of patients with long term complications of HAART in Tanzania.

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LIST OF ACRONYMS

ABC	Abacavir
ACTG	AIDS Clinical Group Trial
AIDS	Acquired Immunodeficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Antiretroviral
BMI	Body Mass Index
CTC	Care and Treatment Center
d4T	Stavudine
ddi	Didanosine
DEXA	Dual Energy X-ray Absorptiometry
FRAM	Fat Redistribution and Metabolic Change in HIV Infection Study
HAART	Highly Active Antiretroviral Therapy
HDL-C	High Density Lipoprotein Cholesterol
HIV	Human Immunodeficiency Syndrome
LDCD	Lipodystrophy Case Definition Study
LDHIV	Lipodystrophy in HIV-infected Patients
LDL-C	Low Density Lipoprotein Cholesterol
MRI	Magnetic Resonance Imaging
mtDNA	Mitochondrial Deoxyribo Nucleic Acid
MUAC	Mid-Upper Arm Circumference
MUHAS	Muhimbili University of Health and Allied Sciences
NNRTIs	Non-nucleoside Reverse Transcriptase Inhibitors
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
PIs	Protease Inhibitors
PPRA-γ	Peroxisome Proliferator-Activated Receptor Gamma
RA	Research Assistant
RTIs	Reverse Transcriptase Inhibitors
SREBPs	Nuclear Transcription Factor
TC	Total Cholesterol

TDF	Tenofovir
TG	Triglycerides
WHR	Waist-Hip Circumference Ratio

OPERATIONAL DEFINITION OF TERMS

1) ***Body fat mal-distribution or lipodystrophy:*** One moderate or one severe subjective lipodystrophic feature (except for isolated abdominal obesity) apparent to both physician and patient.
2) Lipodystrophic feature include:
    a. Increased fat under the chin
    b. Increased fat on the back of the neck
    c. Increased abdominal girth
    d. Increased chest or breast fat
    e. Loss of fat in the face
    f. Loss of fat in the arms
    g. Loss of fat in the buttocks
    h. Loss of fat in the legs
3) ***"Primary Lipoatrophy"*** - at least one site with moderate or severe fat loss whereas
4) ***"Primary Lipohypertrophy"*** - at least one site with moderate or severe fat accumulation (except for isolated abdominal fat accumulation) and
5) ***"Mixed"*** - those associated with both lipoatrophy and lipohypertrophy as per above description
6) ***Normal:*** No such feature of any severity apparent to both physician and patient.

Non-assigned: Ambiguous are those with mild scores or with isolated abdominal fat accumulation which was moderate to severe apparent to both physician and patient.

CHAPTER ONE

1.0: INTRODUCTION

1.1 Background - Prevalence and incidence of HIV/AIDS:

UNAIDS estimates that there were 33.3 million [31.4 million–35.3 million] people living with HIV at the end of 2009 compared with 26.2 million [24.6 million–27.8 million] in 1999 a 27% increase[1]. Although the annual number of new HIV infections has been steadily declining (19%) since the late 1990s, this decrease is off-set by the reduction in AIDS-related deaths due to the significant scale up of antiretroviral therapy over the past few years[1].

Sub-Saharan Africa still bears an inordinate share of the global HIV burden. Although the rate of new HIV infections has decreased, the total number of people living with HIV continues to rise. In 2009, that number reached 22.5 million [20.9 million–24.2 million], 68% of the global total[1]. Sub-Saharan Africa has more women than men living with HIV. The largest epidemics in sub-Saharan Africa Ethiopia, Nigeria, South Africa, Zambia, and Zimbabwe have either stabilized or are showing signs of decline. The estimated 1.3 million [1.1 million–1.5 million] people who died of HIV related illnesses in sub-Saharan Africa in 2009 comprised 72% of the global total of 1.8 million [1.6 million–2.0 million] deaths attributable to the epidemic[1].

The epidemic in East Africa have declined since 2000 but are stabilizing in many countries. The HIV incidence slowed in the United Republic of Tanzania to about 3.4 per 1000 person-years between 2004 and 2008[2]. According to the data from Tanzania HIV/AIDS and Malaria Indicator Survey (THMIS) 2007 - 2008[3], the national prevalence among the sexually active populations (between 15 and 49 years of age) is reported to be 5.7 %. The data shows more women (6.6 %) are infected than men (4.6%). Compared with HIV prevalence data from the 2003-04 THIS, there has been a slight decrease in overall prevalence of HIV among sexually active population between 15 and 49 years of age from 7.0% (2003 -04) to 5.7% (2007 -08)[4]. There is also a decrease in prevalence

from 6.3% (2003-04), to 4.6% (2007-08) for men and 7.7% (2003-04) to 6.6% (2007-08) for women[3].

Body Fat Maldistribution and HIV Infection

The role of HIV infection alone in the development of body fat mal-distribution has remained controversial. The pathogenesis of fat abnormalities in HIV-infected individuals is not well understood, but research to date suggests that it is multifactorial and is associated with HIV-related immune depletion and immune recovery[5]. HIV also causes a generalized immune activation and leads to increased T cell turnover[6] which is perhaps linked to what has been referred to as microbial translocation, resulting early from depletion of CD4 lymphocytes in lymphoid tissue in the gut[7] which could have consequences for the speed of pathogenic processes leading to a variety of conditions of the cardiovascular and digestive system. Thinking specifically of CVD, whilst HIV infection seems to lead to a decrease in total cholesterol, it also causes decreases in HDL-cholesterol[8-9] and results in increases in markers of inflammation (e.g. C-reactive protein), endothelial activation and damage (e.g. intercellular adhesion molecule, ICAM, and vascular cell adhesion molecule, VCAM), and in fact also of coagulation (e.g. D-dimer) - factors which have been linked to increased risk of cardiovascular disease in the general population[10-12]. The development and severity of body fat mal-distribution have been positively associated with the duration of HIV infection, negatively associated with previous HIV viral load, and both positively and negatively associated with blood CD4 lymphocyte counts in various studies[13]. However, how these factors play a role in determining or modifying the development of LDHIV remains unclear[13].

Body Fat and Maldistribution and Antiretroviral Drugs

The introduction of Highly Active Antiretroviral therapy (HAART) provided HIV/AIDS patients with opportunities for life span improvement by inhibiting the replication of HIV [14-15]. Tanzania began to provide care and treatment services including the provision of anti-retroviral drugs (ARVs) in October 2004[16]. In Tanzania it was recommended a

triple therapy consisting of 2 NRTI + 1 NNRTI, 2NRTI + 1PI or 3NRTI's[16]. The default first line regimen in Tanzania is Zidovudine (AZT) 300mg/Lamivudine (3TC) 150mg twice daily and Efavirenz (EFV) 600 mg once daily at night[16]. The target for the first year was to cover 44,000 patients on ARVs. 96 care and treatment providing facilities were selected to initiate the services. By end of December 2007, a total of 263,000 patients were enrolled and among them 135,696 were on ART[16]. There are different classes of antiretroviral drugs which interferes the viral replication cycles[17]. The reverse transcriptase inhibitors (RTIs) adopted in the Tanzanian guidelines[18] includes the nucleoside reverse transcriptase inhibitors (NRTIs) e.g stavudine, zidovudine, lamivudine, abacavir, didanosine and more recently emtricitabine. The guideline has also included tenofovir, a nucleotide reverse transcriptase inhibitor[16,18]. The non-nucleoside reverse transcriptase inhibitors (NNRTIs) used are nevirapine and efavirenz [16,18]. Another group of ARVs involve inhibiting the activity of a protease enzyme responsible for virion maturation[19]. The protease inhibitors (PIs) that have been included in the Tanzania guideline are lopinavir/ritonavir, saquinavir/ritonavir, nelfinavir and more recently atanazavir has been proposed as a replacement of saquinavir [16,19]. Protease inhibitors are given with two nucleoside reverse transcriptase inhibitors the backbone being didanosine and abacavir [16]. Antiretroviral drugs are given in at least three combinations, mono or dual therapy is not recommended[18,20].

Side Effects of Using HAART

Various metabolic complications have been identified in HIV-infected patients.[21,22] Although these have been mainly associated with the use of HAART; HIV infection itself also has been implicated in the pathogenesis of these complications. Mitochondrial toxicity by HAART is associated with hyperlactatemia, lactic acidosis, hepatic steatosis, pancreatitis, body fat malformation, and peripheral neuropathy[21]. The proposed mechanism of mitochondrial toxicity is nucleoside reverse-transcriptase inhibitor (NRTI)–induced inhibition of mtDNA polymerase leading to derangements in oxidative phosphorylization and lactate homeostasis[21]. The complications of greatest concern are diabetes, dyslipidemia, body fat maldistribution (also known as

lipodystrophy or fat redistribution syndrome), lactic acidosis, osteopenia, osteoporosis, and avascular necrosis. These complications are of particular concern for at least two reasons: 1) HIV-infected patients are aging as a result of increased survival from HAART, and therefore these complications are more likely to lead to clinically significant disease; and 2) the development of these complications, especially if patients are not informed in advance, can lead to non-adherence to HAART. Clinicians should discuss the risk of these potential adverse events with their patients as part of routine care.

Fat Maldistribution

Lipodystrophy in HIV-infected patients (LDHIV) is part of a metabolic syndrome that includes dyslipidemias, insulin resistance and accelerated bone loss. LDHIV patients were first described in 1998[23]. The main clinical features are peripheral fat loss (lipoatrophy) in the face, limbs and buttocks, accompanied by central fat accumulation in the abdomen and breasts and over the dorsocervical spine (the "buffalo hump") and lipomas[24]. PI therapy has been most strongly linked to the body fat malformation syndrome, although NRTIs, especially stavudine, have also been associated with body fat malformation [25].

Factors Associated with Body Fat Maldistribution

The overall prevalence of at least one physical abnormality related to body fat malformation has been estimated at about 50% after more than a year of antiretroviral therapy [26]. PIs appear to be the strongest link to LDHIV; however, fat loss has been reported in some patients taking non-PI antiretroviral drugs[27]. Other factors, such as duration of HIV infection, age, and gender, may also contribute to the risk of development of LDHIV[27]. To our knowledge very few studies have determined the proportion of body fat maldistribution among HIV infected patients on treatment in Tanzania.

Nutritional Status, Age, Adiposity and Body Fat Maldistribution

Body adiposity before receiving PI-containing HAART may also affect features of LDHIV. For example, a cross-sectional study suggested that overweight men and women (body mass index, >28 kg/m^2) had a higher prevalence of buffalo hump and breast enlargement (women), but a lower prevalence of facial and gluteal fat loss compared with underweight subjects (body mass index, <20kg/m^2) [28]. Older people tend to have greater body fat mass, particularly intraabdominal fat [29-31], which may contribute to or modulate the body fat changes seen in LDHIV [32]. A disproportionately higher gain in fat mass relative to lean tissue was observed during refeeding after malnutrition and weight loss, although there is substantial individual variation [33]. HIV-infected patients with wasting syndrome (weight loss >10% of baseline body weight) lost more fat than lean body mass [34]. Thus, during recovery from wasting, body fat may accumulate disproportionately in certain areas. However, LDHIV can occur in patients without a previous history of wasting.

Perceptions and Attitudes of HIV Patients on Body Fat Malformation

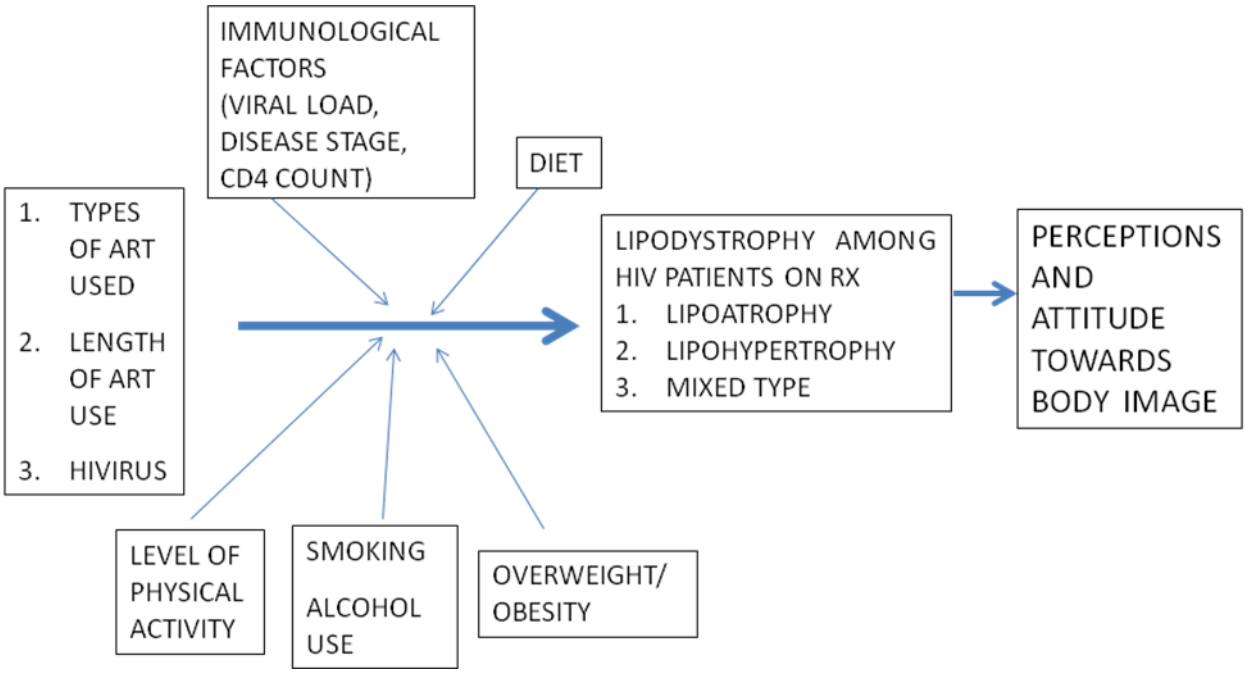
In addition some studies have documented that body fat changes may affect patients' psychosocial function[35]. There are several reasons why body changes due to body fat malformation may exert an impact on the lives of HIV-infected patients. Body changes may stigmatize patients, producing erosion of self-image and self-esteem, problems in social and sexual relations, and anxiety and depression[36]. For many patients, the benefit of survival outweighs the limitations produced by body fat malformation, but others may become depressed and lose interest in complying with the complex antiretroviral regimens, eventually leading them to discontinue control of their HIV infection[37]. This may in turn lead many patients to consider cessation of treatment. To our knowledge no African study has formally addressed the issue of the impact of these changes on the patient life, hence a significant knowledge gap exist on the issues of long term side effects of HAART. Such data are important for placing the findings of research studies into true clinical context.

1.2 Statement of the Problem

Since the advent of highly active antiretroviral drugs (HAART) globally in 1996 HIV related mortality has decreased dramatically[1]. Now patients are living longer but chronic health complications such as cardiovascular diseases and body fat malformation represent important health issues in this patient population. So the changes in body composition and any abnormalities with body metabolic pathways as a result of HAART or as a result of the disease itself, may lead to an emergence of cardiovascular diseases, which may be fatal to the patients and even shorten their lifespan. The magnitude of these complications is not known in Tanzania. Body fat changes stigmatize the bodies of patients infected with HIV giving them a similar look to that seen in HIV patients some years ago when the wasting syndrome was more prevalent and HIV infection was ultimately fatal. Routine assessment of body fat changes is ideally supposed to be conducted by clinicians taking care of HIV patients as part of routine monitoring of drug toxicity. Additionally treatment of body fat maldistribution needs to be instituted according to the severity of the complication. However, this is not routinely conducted.

The psychological impact of body fat changes may be severe enough to affect a patients' desire to continue with antiretroviral therapy. Also as exposure to HAART increases in the country, knowing the proportion of HIV related body fat malformation among HIV infected people on treatment will help to find interventions to minimize the risks. Knowing these complications will be of utmost importance because they can be severe and life threatening, disrupt adherence to antiretroviral therapy, limit options in therapy and profoundly affect lives of patients. It has been observed by other studies that patients with body fat malformation complications faces psychological trauma and feel stigmatized, and these may affect adherence to HAART[35, 37]. The psychological impact of body fat malformation has not been assessed.

Conceptual framework for understanding the possible causes of fat maldistribution among HIV positive people on treatment and not on treatment



The above conceptual framework indicates a relationship between various contributing factors to body fat maldistribution for HIV patients on treatment and not on treatment. According to the framework body fat maldistribution is interplay between types of antiretroviral drugs used and the length of treatment which can be modified by stage of disease, viral load, CD4 stage, dietary factors, level of physical activity, smoking, alcohol use and overweight/obesity. Studies are still going on to examine if HIV virus itself is linked with development of lipodystrophy in HIV infected individuals not on treatment.

1.3 Rationale of the Study

In order to convince the policy makers that body fat maldistribution need to be adequately addressed in the daily care of HIV infected patients it was important to conduct this study at this time. A more in-depth knowledge of the most common risk factors associated with body fat malformation in HIV-infected populations on treatment in Tanzania is needed first. The psychosocial consequencies of lipodystrophy have not been studied in Tanzania. Neither the most toxic drugs that cause lipodystrophy in Tanzania have not been studied. Hence finding these drugs will enable policy makers to be aware and recommend on the use of less toxic drugs in Tanzania. In addition, the findings of this study will help clinicians who are taking care of HIV patients on the following ways:

1. Clinicians will be able to educate patients receiving HAART about signs and symptoms of body fat malformation.
2. Clinicians will be able to recommend good nutrition and regular exercise to their patients.
3. Clinicians will be able to see the importance of screening patients who develop changes in body fat for depression at every visit and should be able to provide psychological support for patients who experience mood disorders secondary to body habitus changes.
4. Clinicians will see the importance of including an assessment for gynecomastia in the physical examination of men who are receiving HAART.

1.4 Research Questions

1. What is the magnitude of body fat malformation among HIV patients in Dar es Salaam?
2. What are the perceptions or attitudes on body fat malformation among HIV patients in Dar es Salaam?
3. What are the common risk factors that are associated with the observed prevalence of body fat malformation among HIV positive individuals in Dar es Salaam?

1.5 Research Objectives

1.5.1 Broad Objective

To determine the prevalence and associated factors of body fat malformation, and assess perceptions and attitudes towards body fat malformation among HIV infected individuals in Dar es Salaam.

1.5.2 Specific Objectives

1. To determine the proportion of HIV positive patients with body fat maldistribution (hypetrophy, atrophy and mixed types) in Dar-es-Salaam.
2. To assess the association between demographic factors and body fat maldistribution among HIV positive patients in Dar es Salaam.
3. To assess the association between use of HAART and body fat maldistribution among HIV positive patients in Dar es Salaam.
4. To assess the perceptions related to body fat maldistribution among HIV positive patients with lipodystrophy in Dar es Salaam.
5. To assess the attitudes related to body fat maldistribution among HIV positive patients with lipodystrophy in Dar es Salaam.

CHAPTER TWO

2.0: REVIEW OF LITERATURE

2.1 Body Fat Maldistribution

Body fat malformation is one of the long term side effects of HAART[23]. It is characterized by uniform subcutaneous and peripheral fat loss with relative preservation or increase in visceral fat, resulting relative central adiposity as well as fat accumulation in the neck and dorsocervical region[24]. There have been continued discussions on case definition of body fat malformation among scientists in the world to finally come up with two groups of "lumpers" and "spilitters". The lumpers include Dr Andrew Carr and his colleagues who published results from their body Lipodystrophy Case Definition Study (LDCD) in the Lancet in 2003[24]. In this study the patients were asked to report any noted change or changes in their body composition that was confirmed by a clinician. So they defined body fat malformation by grouping similar signs or symptoms (10 points scale) assuming the differences are not as important as similarities and their grouping model had a sensitivity of 78% and specificity of 80% for diagnosis of body fat malformation. On the other hand the splitters most notably Dr. Carl Grunfeld and his colleagues recently published much anticipated data from the Fat Redistribution and Metabolic Change in HIV Infection (FRAM) study[38], whereby lipoatrophy or lipohypertrophy was defined as concordance between participant report of change and examination and measuring regional adipose tissue volume by magnetic resonance imaging (MRI). Due to limitations of funds we will use the modified Carr's definition to define our body fat malformation case in an African setting. Several studies conducted in Africa have reported changes in body mass composition including alteration of central body fat stores by using different case definitions and different study designs[39-41].

The prevalence of body fat malformation has been determined by some few studies in Africa[40,41]. One recent study that was conducted in Benin found out that after a median follow-up of 23.2 months (interquartile range 22.3-23.7), 24 (30%) patients developed

body fat malformation (lipoatrophy 9%, lipohypertrophy 24% and mixed pattern 2.5%)[40]. Likewise another study that was conducted in Senegal reported a prevalence of moderate-severe body fat malformation to be 31.1% (95% confidence interval: 24.3 to 37.9), with 13.3%, 14.5%, and 3.3% for lipoatrophy, lipohypertrophy, and mixed forms, respectively[41].

2.2 Risk Factors For Body Fat Maldistribution

Several risk factors have been associated with development of body fat malformation among patients on HAART[42]. These include, effects of HAART, HIV itself and genetics and other host factors. The duration and type of HAART has been found to be associated with body fat malformation. Protease inhibitors have been associated with fat accumulation, and the nucleoside analogue reverse transcriptase inhibitors (nRTIs), stavudine, didanosine and zidovudine have been associated with fat loss[43,44]. Prospective studies investigating body composition in patients starting antiretroviral treatment for the first time [45-47], have demonstrated initial increases in limb fat during the first few months of therapy, followed by progressive decline during ensuing three years. In one study the decline was estimated to be 14 percent per year among white men receiving regimens containing stavudine or zidovudine with lamivudine and either a protease inhibitor or non-nucleoside reverse-transcriptase inhibitor[45]. Furthermore, one of these studies[45] demonstrated that 20-35% of patients developed body fat malformation about 12-24 months after initiated with HAART.

2.3 Antiretroviral Drugs

The use of protease inhibitors (PI) has been associated with development of lipoatrophy through inhibition of sterol response element binding proteins (SREBPs), which affect intracellular fatty acid and glucose metabolism and adipose tissue differentiation[48]. The PIs also downregulate peroxisome proliferator-activated receptor gamma (PPRA-γ), an important nuclear transcription factor that is affected by SREBPs and is necessary for adipocyte differentiation and function and fatty acid metabolism[48]. However, the use of

much newer PIs such as Atazanavir for 48 weeks was not associated with abnormal fat redistribution or metabolic disturbances[48]. Evidence suggests that the nucleoside analogue reverse transcriptase inhibitors (nRTIs) stavudine, didanosine and zidovudine may cause mitochondrial toxicity by inhibiting mitochondrial DNA polymerase-γ in fat and other tissues and thus interfering with respiratory chain complexes[43]. The result is impaired fatty acid oxidation and intracellular accumulation of triglycerides and lactate; which can enter the systemic circulation[44].

2.4 Other Contributing Factors to Body Fat Maldistribution

Other factors that contribute to body fat malformation include: nadir CD4+ cell count, as well as the viral load especially it has been found out that acute HIV infection has been associated with body fat malformation lending support to a direct viral role as well[43]. Potential host risk factors include age, sex, and race or ethnicity[49]. The pathogenesis of fat abnormalities in HIV-infected individuals is not well understood, but research to date suggests that it is multifactorial and is associated with HIV-related immune depletion and immune recovery, ARV medications, disregulation of fatty acid metabolism, hormonal influences, individual genetic predispositions, and factors that are not related to HIV such as diet and obesity[49-50]. Body fat maldistribution has been associated with lower nadir CD4 count as well as with gender (central lipohypertrophy may be more common in women) [38,43] and lipoatrophy in men [38,43]. Likewise body fat malformation is more common in elderly patients and those with longer exposure to ART. Recent studies have demonstrated racial/ethnic and gender differences in body fat distribution among HIV patients on treatment[49-52]. A genetic component is indicated by a recent analysis in AIDS Clinical Group Trial (ACTG) stufy 5005s[53], suggesting either predisposition or protection associated with mitochondrial DNA polymorphisms.

2.5 Psychosocial Effects of Body Fat Maldistribution

Studies that have been conducted in the West have shown that body-shape changes may affect patients' psychosocial function and quality of life. To my knowledge none of similar studies have been conducted in Tanzania. Shifts in body fat may cause significant emotional distress. Patients with body fat changes are more prone to develop depressive symptoms. In qualitative studies, body fat maldistribution has been associated with bodily discomfort, decreased self-esteem, interpersonal difficulties, social withdrawal, demoralization, and depression,[54,55] which, in turn, may lead to non-adherence to ARV therapy and ultimately to immunologic deterioration. Body fat maldistribution can cause the patient to feel stigmatized[54]. Psychological support from a trained mental health professional may be necessary to help the patient cope with these abnormalities. Patients report that clinicians minimize the importance of body fat changes. Patients who experience maldistribution of their body fat should be screened for depression at every visit and asked in a sensitive manner about its emotional impact on their lives[55]. Facial wasting may be particularly difficult for patients who are concerned that their appearance may reveal that they are infected with HIV. These patients may become extremely distressed if they believe that other people are able to discern their serostatus because of how they look[56]. Gynecomastia with and without other body fat changes has been reported in men receiving ARV therapy and is associated with social discomforts.[55-57] Body fat changes have also been associated with a higher incidence of high-risk sexual behavior; regardless of the patient's knowledge of viral load.[58,59]

Hence, in this study we are set to determine the prevalence of body fat maldistribution among HIV patients in three CTC clinics in Dar es Salaam. Furthermore, to examine the perceptions and attitudes of HIV patients on body fat maldistribution in Dare s Salaam. Other factors associated with body fat maldistribiution will also be determined.

CHAPTER THREE

3.0: METHODOLOGY

3.1 Study Design

The study design was cross sectional analytical study. This type of study utilizes different groups of people who differ in the variable of interest, but share other characteristics such as socioeconomic status, educational background, and ethnicity. Characteristically cross sectional studies: takes place at a single point in time, does not involve manipulating variables and allows researchers to look at numerous things at once (age, income, gender). They are often used to look at the prevalence of something in a given population as for this case the prevalence of body fat maldistribution. Researchers record the information that is present in a population, but they do not manipulate variables. This type of research can be used to describe characteristics that exist in a population, but not to determine cause-and-effect relationships between different variables. These type of studies are often used to make inferences about possible relationships or to gather preliminary data to support further research and experimentation. They are cost effective compared to follow up studies. Since this was a self-sponsored study and the time given for completion of the research was short, then cross sectional study design was the most appropriate choice.

3.2 Study Sites

The study was conducted in the three Municipal Hospitals of Ilala, Temeke and Mwananyamala. The three Municipal Hospitals were selected because they could offer a larger number of HIV patients attending clinics just for care (not on treatment yet) and those already on treatment. This allowed a much faster collection of data in the shortest period of time allowed for the data collection to be completed. Currently MUHAS, in collaboration with Dar es Salaam city council and Harvard School of Public Health are

managing a cohort of HIV patients in most of CTC clinics in Dar es Salaam. It has so far enrolled 75,000 HIV positive patients. Out of these about 40,000 are on medication[59].

3.2.1 Description of Study Sites

Ilala – According to the 2002 National Population Census, the population of Ilala District is about 634,924. The district has an area of 273 km^2 and is commonly referred to as 'Downtown Dar', where much of the commercial, banking, and Government offices are located. The district is divided into 3 divisions which are further subdivided into 22 wards. The Ilala municipall hospital CTC clinic has a total of 14,133 active clients of which 7,932 are on treatment and 3,431 are on care and monitoring.

Temeke – According to the 2002 National Population Census, the population of Temeke District is about 768,451. The district has an area of 786.5 km^2. The district is divided into 3 divisions which are further subdivided into 24 wards. The Temeke municipal hospital CTC clinic has a total of 16,350 active clients of which 8,871 are on treatment and 7659 on care and monitoring. The District of Temeke is on the outskirts of Dar es Salaam, with slightly less economic power and greater part of rural population.

Kinondoni – According to the 2002 National Population Census, the population of Kinondoni District is 1,083,913. The district has an area of 531 km^2. The district is divided into 4 divisions which are further subdivided into 27 wards. The Mwananyamala municipal hospital CTC clinic has a total of 17,746 active clients of which 9,193 are on treatment and 8,553 on care and monitoring. The District of Kinondoni is within as well as on the outskirts of Dar es Salaam, with significantly greater economic power and a good mix of rural and urban populations.

3.3 Study Population

HIV patients 18 years and above attending Municipal Hospitals care and treatment clinics for at least 24 months were targeted for this study. Adults were selected because they are able to give informed consent; also they constitute the majority in the 5.7% of the people with HIV in Tanzania[3].

3.4 Sample Size Determination:

The sample size was calculated using EPI INFO 6 Epi Table Calculator using the formula for estimating single proportions:

$$N = \frac{z^2 p(100-n)}{\varepsilon^2}$$

Where N = required minimum sample size

p = estimated prevalence of body fat maldistribution

ε = margin of error

z = standard normal deviate corresponding to 95% confidence level (=1.96)

The following assumptions were considered: expected prevalence of body fat malformation is (34% Rwanda) [41], among HAART users and non users. Significance level of 95% and desired precision of 5%.

$$N = \frac{1.96^2 34(100-34)}{5^2}$$

N = 342

Using the above assumptions a total of 342 patients were studied in the three municipal hospitals. We added 10% of patients to cater for non response, hence the final sample size was 376 patients.

3.5 Sampling Procedure and Eligibility

Simple random sampling (SRS) was used to enroll patients into the study. The daily appointment list of patients was obtained from the hospital CTC records one day in advance. From this list that contained patients both on HAART and not on HAART, the duration of attendance to CTC clinic for each patient was first determined. Only those patients who have been attending for at least 24 months met our study entry criteria. Practically from the list of patients who had been attending the clinics for 24 months and above we assigned them numbers beside each name of the patient according to the length of the list for that particular day. The numbers that were allocated to patients were then written in small pieces of paper that were cut specifically for this purpose and

mixed thoroughly. We used the lottery method to select participants who will be interviewed the following day. That is randomly 9-10 papers were picked and those names of patients bearing these numbers were the ones who were asked to take part in the study on that particular day. In case the patient refuses or did not attend CTC on that date to substitute a repeat procedure to randomly picking the numbers was conducted.

Inclusion criteria for the study was:

1. Men and women 18 years and above who were attending respective HIV/AIDS clinics in Dar es Salaam and had been attending the CTC at least for 24 months.
2. May be or may be not on prescribed antiretroviral drugs.
3. Alert patients with good general condition.
4. Have given signed informed consent.

Exclusion criteria will include:

1. Pregnant women.
2. Very sick patients – **Karnofky Score** of less than or equal to 40% [60].

3.6 Recruitment of Research Assistants

Six research assistants were recruited to assist during field work, one medical personnel one nurse in each CTC. Qualifications of these assistants included medical or nursing degree or diploma (all of them were Assistant Medical Officers and trained nurses), experience in working in the CTC clinic and involved with HIV/AIDS patients, and experience in interviewing respondents and good communication skills.

3.6.1 Training of Research Assistants

The research assistants were trained for one day. The emphasis was on the objectives of the survey such that, they should be well versed with the topic of lipodystrophy, they should be aware of the procedure of recruitment, the importance of ensuring data quality and minimizing missing data and finally they should know how to maintain

confidentiality of both respondents and the information collected. The team was also trained how to take and record measurements.

3.6.2 Pretesting of Interview Schedule

The pre-testing of the interview schedule was carried out by the principal investigator and the two research assistants at different days at Sinza Health Center. The pretesting aimed at checking how the target population was going to understand the tool and also give opportunity to research assistants to exercise flexibility in the wording of questions and probing. Review of the interview guide was done following the pretesting and necessary modifications were made.

3.7 Data Collection Procedures

Diagnosis of Lipodystrophy was done by a trained Doctor at each municipal hospital. However, before a clinical diagnosis a nurse asked the respondents if they have noticed any changes in their body composition that has alerted them (self – rated). The information by the patient was validated by the physician after conducting a thorough physical examination. The changes reported by the patient were confirmed by physical examination. Fat redistribution was scored as: None (score = 0), Mild (score = 1), Moderate (score = 2) and Severe (score = 3) for fat losses and accumulations separately[15,41]. Body fat malformation diagnosis was performed using one definition developed by Carr et al[24], which combines a clinical definition and one based on demographic, anthropometric and biochemical indicators (see below).

3.8 Study Variables

3.8.1 Dependent Variable

Body Fat Maldistribution:

Body fat maldistribution was assessed by a trained Doctor using the assessment tool basing on what was developed by Carr et al[24]. To characterize self-rated fat redistribution the patient was asked of his/her opinion if he/she has noted one of each of the following changes[24,41,43]:

i. Increased fat under the chin
ii. Increased fat on the back of the neck
iii. Increased abdominal girth
iv. Increased chest or breast fat
v. Loss of fat in the face
vi. Loss of fat in the arms
vii. Loss of fat in the buttocks
viii. Loss of fat in the legs

The information by the patient was validated by the physician after conducting a thorough physical examination.

Diagnosis of Body Fat maldistribution[24] was as is indicated below:

a. ***A case of body fat maldistribution or lipodystrophy:*** A patient with at least one moderate or one severe subjective lipodystrophic feature (except for isolated abdominal obesity) apparent to both physician and patient.
    a. ***"Primary Lipoatrophy"*** - at least one site with moderate or severe fat loss whereas
    b. ***"Primary Lipohypertrophy"*** - at least one site with moderate or severe fat accumulation (except for isolated abdominal fat accumulation) and
    c. ***"Mixed"*** - those associated with both lipoatrophy and lipohypertrophy as per above description

ii. Normal: A patient with no such feature of any severity apparent to both physician and patient.

iii. Non-assigned: Ambiguous patients will be those with mild scores or with isolated abdominal fat accumulation which was moderate to severe apparent to both physician and patient.

3.8.2 Independent Variables

i. Demographic and Other Characteristics

In this section variables included were age, sex, marital status, level of education, source of income, and kind of lifestyle (smoking, alcohol drinking, type of diet in the last 24 hours and physical activity). A quick assessment of level of physical activity was conducted using the same interview guide. The patients finally ranked themselves in terms of level of physical activity[61].

ii. Use or non use of HAART and Duration of Treatment

In this section participants were asked of the type and duration of the medication and if not on treatment for how long they have been diagnosed with HIV. The type of treatment and duration was further verified by the nurse from the patients' medical records.

iii. Change of Medication

It was also recorded if the participants' medication had been changed.

3.9 Quality Control

Collected data was edited during and after collection for consistency and completeness. Any noted errors were corrected before the patient left the clinic. The Principal Investigator (PI) supervised the data collection. .

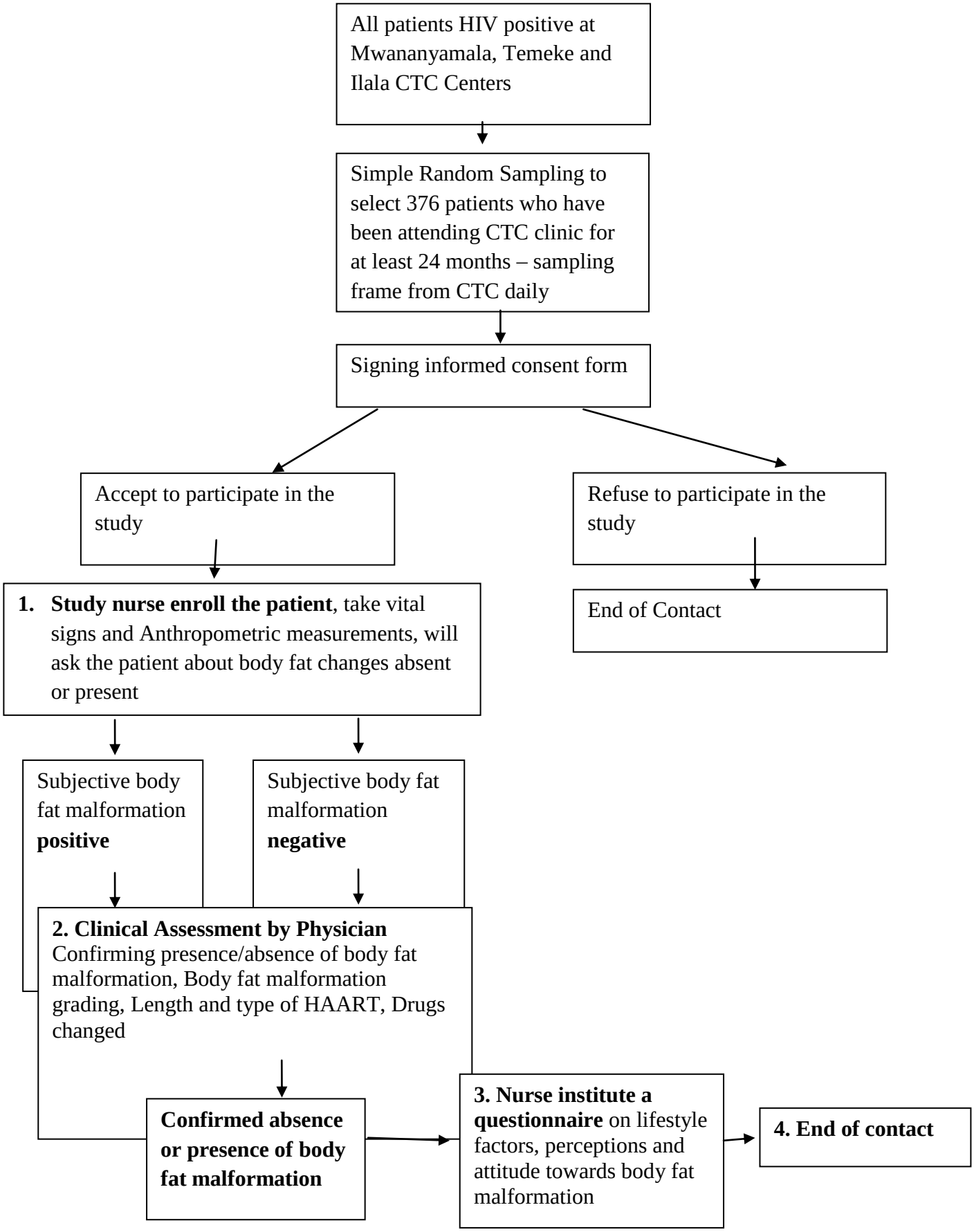
3.10 Data Analysis

Coding of open ended questions was done by the team and thereafter data was entered by the trained data entrant by using SPSS software. Data cleaning and analysis were done using Statistical Package for Social Sciences (SPSS) version 16.0[62] for windows. Frequency distribution was done to all variables to assess their distribution in the study population. Continuous variables were presented as Mean ± Standard Deviation (SD). To test for differences between means two sample t-test was used. Two-way tables were used to assess the association between dependent and independent variables by using the χ^2-test and $p< 0.05$ were considered statistically significant. Multiple logistic regressions were used to assess individual contribution of each independent variable in predicting body fat malformation while controlling for confounding variables.

3.11 Permission to the Study and Ethical Consideration

Ethical approval to conduct this study was obtained from Research Ethics Committee, Muhimbili University of Health and Allied Sciences. Permission to conduct the study in the study area was obtained from the Research Coordinators of the Municipalities. In addition to that, permission to carry out data collection was obtained from the Medical Officers Incharges who are overseers of these hospitals. The purpose for which the data are being collected, the expected duration of the participant's involvement, and a description of the procedures to be followed was explained to the participants who had signed informed consent. Description of any reasonably foreseeable benefits to the participant were explained based on the fact that they will contribute to enrichment of scientific knowledge that will pave way to recommendations to the government of best drugs for the HIV/AIDS patients. Participants were told of minimal or absence of risks or discomforts during the course of the study, for example longer duration of interviews; this was communicated in advance. Only those who agreed by signing informed consent were interviewed and were free to withdraw from the study during interview. Participants were ensured of confidentiality by assigning them with numbers instead of names.

3.12 Recruitment Plan



3.13 Limitations of the Study

There are a number of limitations expected out of this study.

1. First, the study has all the intrinsic limitations of a cross-sectional design which is not appropriate for a causal inference of parameters to be studied.
2. Also the patients we studied are only those who were attending the CTC clinics who may not be representative of all HIV positive patients.
3. However, the fact that the study area is Dar-Es-Salaam which is metropolitan and having residents from all over the country, this will make it possible for the findings to be generalised. Secondly, body fat changes were not assessed using specialized instruments such as dual energy X-ray absorptiometry (DEXA) or linear calipers. However, a recent study found a strong correlation of this type of assessment with DEXA.
4. Lack of laboratory measurements of blood glucose, lipid and lactate may have limited the exact definition of body fat malformation syndrome.

CHAPTER FOUR

4.0: RESULTS

4.1 Socio-demographic Characteristics of Study Sample

A total of 466 participants living with HIV/AIDS and attending Care and Treatment Clinics (CTCs) in Ilala, Temeke and Mwananyamala Municipal Hospitals were interviewed.

The mean age of the participants was 41.1 ± 9.8 years, with men being more aged (46.1 ± 10.8 years) than women (39.6 ± 8.9 years) $p<0.0001$. Findings showed that majority (43.5%) of the participants were in the age group 31-40 for females (47.0%). About three quarters (74.9%) were females. 47.4% of the participants were married or cohabiting.

With regards to education level, 73.5% attained primary education. The proportion of females who had no formal education (9.0%) was higher than that of males (7.0%).

Majority of participants (86.9%) responded that they are engaged in income generating activity, of which the source of income for majority of the participants was self employment (67.5%). Females had a higher proportion of respondents (70.9%) who were self employed compared to males (58.4%). Males (66.2%) reported to have a partner who is engaged in income generating activity while 97.4% of females reported the same concerning their male partners ($p<0.0001$).

There was a statistically significant difference in the number of participants in the three municipal hospitals with Kinondoni having more of respondents compared to other two hospitals ($p<0.0001$).

Table 1: Socio-demographic Characteristics of Participants by Gender

Characteristic	Sex of the Respondents			p-value
	Male N (%)	Female N (%)	Total	
***Age Group**				
≤ 30	5 (4.6)	46 (13.6)	**51 (11.4%)**	
31-40	35 (32.4)	159 (47.0)	**194 (43.5%)**	**0.0001**
41-50	35 (32.4)	99 (29.3)	**134 (30.0%)**	
≥ 51	33 (30.6)	34 (10.1)	**67 (15.0%)**	
Marital Status				
Single	24 (20.5)	63 (18.1)	**87 (18.7%)**	
Married/cohabiting	68 (58.1)	153 (43.8)	**221 (47.4%)**	**0.01**
Divorced/separated	13 (11.1)	68 (19.5)	**81 (17.4%)**	
Widowed	12 (10.3)	65 (18.6)	**77 (16.5%)**	
***Education Level**				
No formal education	8 (7.0)	29 (9.0)	**37 (8.5%)**	
Primary Education (up to 7y)	79 (69.3)	243 (75.2)	**322 (73.7%)**	**0.155**
Secondary Education and Above	27 (23.7)	51 (15.8)	**78 (17.8%)**	
***Occupation**				
Employee of government/parastatal	7 (6.2)	5 (1.7)	**12 (2.9%)**	
Casual labor which is not permanent	6 (5.3)	20 (6.8)	**26 (6.4%)**	**0.005**
Employed by private firm	27 (23.9)	37 (12.5)	**64 (15.6%)**	
Self employed	66 (58.4)	210 (70.9)	**276 (67.5%)**	
Farmer	7 (6.2)	24 (8.1)	**31 (7.6%)**	
District				
Ilala	29 (24.8)	123 (35.2)	**152 (32.6%)**	**<0.0001**
Temeke	44 (37.6)	111 (31.8)	**155 (33.3%)**	
Kinondoni	44 (37.6)	115 (33.0)	**159 (34.1%)**	
Total	**117 (25.1)**	**349 (74.9)**	**466 (100)**	

***Respondents are not adding to total due to missing values**

4.2 Proportion of HIV Positive Patients with Body Fat Maldistribution

Ninety five of the respondents (20.4%) were diagnosed by a doctor to have lipodystrophy or body fat maldistribution. By self rating 114 (24.5%) reported to have noted body fat maldistribution. More respondents reported a decrease or thinning of various parts of their body (17.5%) compared to those who reported increased parts of their body (14.0%). Proportion with body fat malformation was significantly higher among males (26.5%) compared to females with 18.3%, $p<0.04$. Table 2.

Table 2: Proportion of Respondents With Body Fat Maldistribution

Gender	**Body Fat Maldistribution**			
	Yes N (%)	**No N (%)**	**Total**	**p-value**
Male	31 (26.5)	86 (73.5)	**117 (25.1%)**	**0.04**
Female	64 (18.3)	285 (81.7)	**345 (74.9%)**	
Total	**95 (20.4)**	**371 (79.6)**	**466 (100%)**	

The type of body fat malformation that was diagnosed by a doctor is shown in Table 3. The most common type was Primary Lipoatrophy (49.5%) and Primary Lipohypertrophy was the least common type (12.6%). There was no difference on the types of lipodystrophy among males and females ($p=0.1$), Table 3; despite males suffering more of Lipoatrophy (64.5%), while females experienced more of mixed type (43.8%).

Table 3: Types of Body Fat Maldistribution by Gender

Gender	Body Fat Maldistribution				
	Primary Lipoatrophy N (%)	**Primary Lipohypertrophy N (%)**	**Mixed Type N (%)**	**Total**	**p-value**
Male	20 (64.5)	3 (9.7)	8 (25.8)	**31 (32.6%)**	**0.1**
Female	27 (42.2)	9 (14.1)	28 (43.8)	**64 (67.4%)**	
Total	**47 (49.5)**	**12 (12.6)**	**36 (37.9)**	**95 (100%)**	

Among those who were diagnosed by the Doctor, 85.3% of respondents had noted the changes themselves, with 83.9% reporting features of loss of body fat and 53.8% reporting feature of increase in body fat in one or more of their body parts. For respondents who reported severe loss of body fat; the commonest feature was thinning of buttocks among females (20.3%) compared to male (3.2%) p=0.02. While for respondents who had severe increase in body fat at any part of the body the commonest feature was the increase in abdominal circumference (7.8%) among female compared to male (3.2%) p=0.01.

4.3 Association Between Socio-demographic Factors and Body Fat Maldistribution.

Table 4 shows the association between socio-demographic factors and body fat maldistribution among respondents in the three municipal hospitals. Overall prevalence of body fat maldistribution was 20.4%. Male gender (27.4%) was found to be more affected than females (18.6%) p=0.03. Respondents in the age group 41-50 years (28.0%), had higher proportion of lipodystrophy compared to other groups (p=0.003). Those with secondary education and above had higher percentage of body fat maldistribution (24.4%) compared to the other categories, 21.5% and 5.6% respectively. There was no significant variation in body fat maldistribution with marital status (p=0.8) and occupation (p=0.9).

Table 4: Body Fat Maldistribution by Socio-demographic Characteristics of Participants

Characteristics	Body Fat Maldistribution		Total	p-value
	Yes N (%)	No N (%)		
Gender				
Male	31 (27.4)	82 (76.2)	**113 (24.7%)**	**0.03**
Female	64(18.6)	281 (81.4)	**345 (75.3%)**	
Age Group				
≤ 30	3 (5.9)	48 (94.1)	**51 (11.6%)**	**0.003**
31-40	32 (16.9)	157 (83.1)	**189 (43.2%)**	
41-50	37 (28.0)	95 (72.0)	**132 (30.1%)**	
≥ 51	17 (25.8)	49 (74.2)	**66 (15.1%)**	
Marital Status				
Single	20 (23.3)	66 (76.7)	**86 (18.8%)**	**0.8**
Married/cohabiting	41 (19.0)	175 (81.0)	**216 (47.2%)**	
Divorced/separated	17 (21.5)	62 (78.5)	**7 9 (17.2%)**	
Widowed	17 (22.1)	60 (77.9)	**77 (16.8%)**	
***Education Level**				
No formal education	2 (5.6)	34 (94.4)	**36 (8.4%)**	**0.05**
Primary Education (up to 7y)	68 (21.5)	248 (78.5)	**316 (73.5%)**	
Secondary Education and Above	19 (24.4)	59 (75.6)	**78 (18.1%)**	
***Occupation**				
Employee of government/parastatal	2 (16.7)	10 (83.3)	**12 (3.0%)**	**0.9**
Casual labor which is not permanent	5 (20.0)	20 (80.0)	**25 (6.2%)**	
Employed by private firm	13 (20.6)	50 (79.4)	**63 (15.7%)**	
Self employed	59 (21.9)	211 (78.1)	**270 (67.3%)**	
Peasant	8 (25.8)	23 (74.2)	**31 (7.7%)**	
Total	**95 (20.7)**	**363 (79.3)**	**458 (100%)**	

***Respondents are not adding to total due to missing values**

4.4 Association Between Use of Highly Active Antiretroviral Therapy (HAART) and Body Fat Maldistribution.

A total of 237 (50.9%) respondents were on combination therapy. On average respondents were on treatment for 40.8 ± 15.2 months in the three clinics. Table 5 shows an association between body fat maldistribution and use of HAART.

Table 5: Body Fat Maldistribution by Use of Highly Active Antiretroviral Therapy (HAART)

*Treatment	Body Fat Maldistribution			
	Yes N (%)	**No N (%)**	**Total**	**p-value**
Yes	85 (35.9)	152 (64.1)	**237 (50.9%)**	**0.0001**
No	10 (4.4)	215 (95.6)	**229 (49.1%)**	
Total	**95 (20.4)**	**371 (79.6)**	**466 (100%)**	

***All types of drugs**

Eighty five (35.9%) of patients who were using HAART had body fat maldistribution compared to only 4.4% among the non HAART users. Use of highly active antiretroviral therapy (HAART) was strongly associated with body fat maldistribution (p=0.0001).

Combination therapy was used as per National Care and Treatment Guideline that was revised in 2012[7]. For this population of patients' combinations were mainly the two groups of HAART, the Nucleotide Reverse Transcriptase Inhibitors (NRTI) and the Non Nucleotide Reverse Transcriptase Inhibitors (NNRTI). The use of Protease Inhibitors (PI) was nonexistent in this sample.

The association between type of HAART used and body fat maldistribution is shown in Table 5. In this analysis the clients were grouped according to combination therapy ever used not less than twelve (12) months of being initiated with therapy. In addition for

those who have been exposed to two combination therapies, the participant was grouped to the combination therapy that he/she had taken for a longer period. This was done so as to capture participants who had been on stavudine that were switched to efavirenz based therapy because of severe side effects that were associated with stavudine based drugs. The policy to phase out stavudine was effected from 2009. After this categorization majority of the respondents (49.4%) were on Combivir and Efavirenz combination, 38.8% were on Triomune 30 and 13.1% were categorized to be on Nevirapine based combination therapy. The type of HAART used was found to have a significant association with body fat maldistibution. Respondents receiving stavudine based combination had higher proportion of body fat maldistribution (53.3%) ($p<0.0001$). For those on Efavirenz based drugs 23.9% had body fat maldistribution and those on Nevirapine about 25.8% had lipodystrophy. Overall Efavirenz and Nevirapine based drugs were less notorious in causing lipodystrophy compared to Stavudine based drugs. Table 6.

Table 6: Body Fat Maldistribution by the Type of HAART Used

Regimens	**Body Fat Maldistribution**		**Total**	**p-value**
	Yes N (%)	**No N (%)**		
Stavudine Based[1]	49(53.3)	43(46.7)	**92(38.8)**	**<0.0001**
Efavirenz Based[2]	28(23.9)	89(76.1)	**117(49.4)**	**<0.0001**
Nevirapine Based[3]	8(25.8)	23(74.2)	**31(13.1)**	**0.146**
Total	**85(35.9)**	**152(64.1)**	**237(100)**	

1 Triomune 30 (Stavudine + Lamivudine + Nevirapine)

2 Atripla (Emtricitabine + Tenofovir + Efavirenz) = Trivada (Emtricitabine + Tenofovir) + Efavirenz, Combivir (Zidovudine+Lamivudine) + Efavirenz, Abacavir + Lamivudine + Efavirenz

3 Combivir (Zidovudine+Lamivudine) + Nevirapine = Duovir N (Lamivudine + Zidovudine + Nevirapine), Trivada + Nevirapine, Abacavir + Lamivudine + Nevirapine,

1,2,3 Participants have been exposed to these drugs at least 12 months before switching

The type of lipodystrophy according to type of HAART used did not differ significantly however, among those on stavudine based drugs 53.4% had lipoatrophy, 6.1% had lipohypertrophy and 40.8% had mixed type (p=0.1), when compared to those not using stavudine based drugs (results not shown). Efavirenz showed almost similar results though statistically were not significant. As for those on nevirapine based drugs, mixed type lipodystrophy was common compared to other types at 62.5% (p=0.03) (results not shown).

Apart from the use of HAART, 68 (71.6%) of the participants who had fat maldistribution at the time of interview, reported to be using other drugs than HAART compared to 27 (28.4%) who were using HAART exclusively. The types of medication used included, analgesics, immune modulators, traditional medicines, family planning pills, antidiabetics, antihypertensives (p=0.03), antibiotics, antifungal, antimalarial, antiacids and vitamins (p=0.05).

Participants who were on treatment with HAART and developed body fat maldistribution reported other forms of adverse effects compared to those who were not on treatment and had no lipodystrophy. The adverse effects included rashes 40% (p=0.3), sleeplessness 50% (p=0.002), headache 43.2% (p=0.02) mental confusion 37.5% (p=0.6), nausea and vomiting 46.3% (p=0.1), abdominal pain 50% (p=0.003), numbness of legs 46.2% (p=0.002), numbness in hands 42.4% (p=0.2), diarrhoea 48.5% (p=0.1), fatigue 37.2% (p=0.1) and jaundice 25% (p=0.5).

4.4.1 Association Between Body Fat Maldistribution and Duration of Treatment

The mean duration of treatment in this population was 40.8 ± 15.2 months. A higher proportion of respondents who were on treatment for more than 24 months had developed body fat malformation (80.3%) compared to those who were on treatment for 24 months (19.7%) p=0.054. Table 7.

Table 7: Body Fat Maldistribution by Duration of Treatment

Duration of Treatment Category	Body Fat Maldistribution			
	Yes N (%)	**No N (%)**	**Total**	**p-value**
24 Months	14 (19.7)	15 (10.6)	**29 (13.6%)**	**0.054**
>24 Months	57 (80.3)	127(89.4)	**184 (86.4%)**	
Total	**71 (33.3)**	**142(66.7)**	**213 (100%)**	

4.5 Determinants of Body Fat Maldistribution

Table 8 shows the results of multiple logistic regressions to determine the most important predictors of body fat maldistribution in this population. A model for this analysis contained covariates that attained a statistically significant difference of $p<0.05$ during bivariate analysis. These included sex, age, and type of HAART regimen. Participants that were on stavudine based therapy were twenty seven times more likely to develop lypodystrophy compared to HAART naïve participants (OR, 27.0, 95% CI 11.87-19.11, $p<0.0001$). Likewise for participants on efavirenz based therapy (OR, 8.5, 95% CI 3.8-61.50, $p<0.0001$) and nevirapine based therapy (OR, 8.8, 95% CI 3.07-25.53, $p<0.0001$). Another important determinant of lipodystrophy in this population was age 41-50 years. Participants in this age group were four times more likely to develop lipodystrophy compared to those below thirty years of age, (OR, 4.3, 95% CI 1.18-16.14, $p=0.03$). In this population, gender was not a predictor of body fat malformation, (OR, 1.4, 95% CI 0.74-2.50, $p=0.3$). (Table 8).

Table 8: Determinants of Body Fat Maldistribution

Covariates	β (OR)	95% CI		p-value
		Low	High	
Gender				
Male	1.00			
Female	1.36	0.74	2.50	**0.3**
Age				
≤ 30	1.00			
31-40	2.37	0.64	8.69	**0.2**
41-50	4.37	1.18	16.4	**0.03**
≥ 51	3.29	0.82	13.27	**0.1**
Type of HAART				
HAART Naïve	1.00			
Stavudine Based Therapy	27.04	11.87	61.50	**<0.0001**
Efavirenz Based Therapy	8.52	3.80	19.11	**<0.0001**
Nevirapine Based Therapy	8.85	3.07	25.53	**<0.0001**

4.6 Respondents Attitude Towards Change of Body Part(s).

Table 9 shows respondents attitude towards change of body parts. Increase in abdominal circumference (23.2%) was more experienced by the participants followed by breast enlargement (15.8%). However, majority of the participants did not experience any changes in their body composition.

Table 9: Percent Reporting Increased Body Parts

Scale – Extent of Change	Neck and chin (%)	Back of Shoulders (%)	Breast/Chest (%)	Abdomen (%)	Waist (%)
None	88 (92.6	83 (87.4)	71 (74.7)	66(69.5)	78 (82.1)
Very Little	2 (2.1)	2 (2.1)	7 (7.4)	7 (7.4)	2 (2.1)
On Average	4 (4.2)	8 (8.4)	14 (14.7)	21 (22.1)	10 (10.5)
Very Much	0 (0)	0 (0)	1(1.1)	1 (1.1)	1 (1.1)
Total	**94(100)**	**93(100)**	**95(100)**	**95(100)**	**95**

Table 10 shows respondents attitude towards change of body parts as percents reporting decreased body parts. Thinning of face (26.3%) and buttocks (25.3%) were more noticeable among the participants, with 6.3% and 7.4% respectively indicating that it was severe. Severe thinning of both upper and lower limbs (8.4%) was also reported.

Table 10: Percent Reporting Decreased Body Parts

Scale – Extent of Change	**Face (%)**	**Upper Limbs (%)**	**Lower Limbs (%)**	**Buttocks (%)**
None	53 (55.8)	49 (51.6)	49 (51.6)	54 (56.8)
Very Little	9 (9.5)	15 (15.8)	18 (18.9)	9 (9.5)
On Average	25 (26.3)	19 (20.0)	17 (17.9)	24 (25.3)
Very Much	6 (6.3)	8 (8.4)	8 (8.4)	7 (7.4)
Total	**93(100)**	**91(100)**	**92 (100)**	**94 (100)**

4.7 Perceptions Related to Body Image After Body Fat Maldistribution

Respondents' perception about their body image is shown in table 11. About 15.8% of the participants felt strongly that their current body outlook/image is worse compared to the way they looked before and 10.5% reported to dislike their mirror image. On average 24.2% of the participants with lipodystrophy avoided wearing clothing that shows their body and 7.4% do that much more often.

Table 11: Respondents Perceptions About Current Body Image

Scale of Perception	**Angry About Own Body (%)**	**Avoid Some Clothing (%)**	**Ashamed of Own Body (%)**	**Mirror Image Unhappy (%)**	**Conscious of Other People (%)**	**Bad Body than Before (%)**	**Afraid Mixing with People (%)**
No	60 (63.2)	50 (52.6)	63 (66.3)	49 (51.6)	69 (72.6)	50 (52.6)	76 (80.0)
Very Little	12 (12.6)	14 (14.7)	9 (9.5)	16 (16.8)	16 (16.8)	10 (10.5)	11 (11.6)
On Average	18 (18.9)	23 (24.2)	19 (20.0)	20 (21.1)	5 (5.3)	20 (21.1)	8 (8.4)
Very Much	4 (4.2)	7 (7.4)	4 (4.2)	10 (10.5)	1 (1.1)	15 (15.8	0 (0)
Total	**94 (100)**	**94 (100)**	**95 (100)**	**95 (100)**	**95 (100)**	**93 (100)**	**95 100)**

4.8 Perceptions of Participants with Regards to Their Social Life

Respondents' perceptions about their social life are shown in table 12. Despite the changes in body composition 11.6% of the participants did not worry much about going into gatherings, however, others felt they cannot go out for outdoor activities like swimming (15.5%), or meet new people (13.7%), or attend events that will have new people (12.6%).

Table 12: Respondents Perceptions About Their Social Life

Scale of Perception of Quality of Life	**Avoid Outdoor Activities (%)**	**Avoid Events where there will be many people (%)**	**Lack of Desire for Sexual Intercourse (%)**	**Afraid to be Introduced to New People (%)**	**Afraid to Enter a Room with New People (%)**	**Habit to Exclude himself from other people (%)**	**Go into parties without problems (%)**
No	67 (70.5)	76 (76.8)	73 (76.8)	73 (76.8)	79 (83.2)	82 (86.3)	61 (64.2)
Very Little	10 (10.5)	7 (7.4)	8 (8.4)	9 (9.5)	7 (7.4)	6 (6.3)	7 (7.4)
On Average	15 (15.8)	12 (12.6)	9 (9.5)	13 (13.7)	9 (9.5)	4 (5.3)	16 (16.8)
Very Much	2 (2.1)	2 (2.1)	3 (3.1)	0 (0)	0 (0)	1 (1.1)	11 (11.6)
Total	**95 (100)**	**95 (100)**	**95 (100)**	**95 (100)**	**95 (100)**	**95 (100)**	**95 (100)**

CHAPTER FIVE

5.0: DISCUSSION

This study aimed at determining the prevalence and associated factors of body fat malformation, and assessing the perceptions and attitudes towards body fat malformation among HIV infected individuals attending care and treatment at three municipal hospitals in Dar es Salaam. It is one of the few studies conducted in Tanzania that reports lipodystrophy as a complication of Highly Active Antiretroviral drugs. The study population comprised of 466 HIV positive patients of which 74.9% were women, which is in line with the recent data in Tanzania that women are more affected than men[3]. Furthermore in this study majority of the participants (43.5%) belonged to the 31-40 years age group which is also the highest affected age group in Tanzania[3]. The current prevalence of HIV/AIDS among adult women in Tanzania stands at 6.6% compared to that of adult men which is 4.6%[3]. As it is has been found in a previous study women were less educated compared to men[61]. Also from the three municipals, 466 interview schedules of HIV patients on treatment and not on treatment were analyzed so as to determine the prevalence of body fat maldistribution and the perceptions and attitudes towards body fat maldistribution.

5.1 Prevalence of Body Fat Maldistribution

Our study has revealed the prevalence lipodystrophy to be 20.7% in this population. Precisely defining lipodystrophy is important for comparison across studies and populations. The prevalence observed in this cohort was low compared to findings from studies conducted in the Western populations[51,63] especially given the fact that we onlu looked into body fat changes not including metabolic parameters that are usually considered in the diagnosis of lipodystrophy as a syndrome. These findings may also be contributed by the clinical diagnosis by the doctor that could have been subjective. Conversely, it was considerably higher than the 6.6% prevalence in African patients after 18 months of HAART that has been reported in an Italian study[52]. Other two

studies conducted in Africa demonstrated higher prevalence rates of lipodystrophy compared to this study[41,53].

5.2 Sociodemographic Factors and Body Fat Maldistribution

We have demonstrated in this study an association between body fat maldistribution and demographic characteristics such as gender, age, and education level. This is consistent with a similar study conducted in Rwanda where age and gender were significantly associated with lipodystrophy[41]. Several other studies have also found a similar association [53,64]. In African setting more women than men are generally obese[61,65] and obesity tends to increase with age[66] and level of education[67]. Hence the findings above characteristically tally with general observations among general populations in Africa.

5.3 Association Between the Use of HAART and Body Fat Maldistribution

While the use of HAART has improved survival and well being of HIV patients, in this study, the use of HAART was strongly associated with development of body fat maldistribution. Antiretroviral therapy both in naïve patients and in those who have previously received treatment involves the use of a combination of drugs[16]. In this study patients receiving stavudine based combination had higher proportion of body fat maldistribution (53.3%) and the results were statistically significant. For those on Efavirenz based drugs 23.9% had body fat maldistribution and those on Nevirapine about 25.8% had lipodystrophy. Overall Efavirenz and Nevirapine based drugs were less notorious in causing lipodystrophy compared to Stavudine based drugs. These findings are consistent with several other studies using stavudine based therapy[25,40,41,42,43,46,68]. Nonnucleoside reverse transcriptase inhibitors (NNRTIs), such as efavirenz, have been associated with in vitro altered deposition of triglycerides in the adipocyte, however its clear clinical implications is still being studied. Thymidine analogue nucleoside reverse transcriptase inhibitors (tNRTIs) are a risk factor for mitochondrial dysfunction associated with both dyslipidemias and lipoatrophy (particularly in subcutaneous adipocytes)[68]. Changing patients from thymidine analogs to NRTIs that don't have these effects has demonstrated beneficial effects on lipoatrophy[69,70]. Stavudine, the nucleoside

analog with the highest propensity for causing mitochondrial dysfunction, is relatively inexpensive and often has better availability in the developing world. Stavudine has also been found to cause lipodystrophy faster that is within six months of treatment compared to efavirenz[68]. Although reducing the dose of stavudine from 40 mg to 30 mg and shifting to AZT are possible options for the clinician, since toxicity is thought to be cumulative, these can only be but temporary measures. Hence the use of these drugs in the developing world will lead to mitochondrial toxicity and development of lipodystrophy as is shown in this study. Nevirapine based therapy was found to have limited impact on lipodystrophy in patients with HIV infection[71]. During our visits to CTC clinics, we did not encounter any treatment guidelines for patients with lipodystrophy.

5.3.1 Association Between the Duration of Treatment and Body Fat Maldistribution

We have demonstrated that majority of participants developed lipodystrophy after being on treatment for more than 24 months, however statistically was not significant. Recently reported studies on body fat maldistribution and the use of HAART have demonstrated a similar finding [41,72,73]. Prospective studies investigating body composition in patients starting antiretroviral treatment for the first time [47-48], have demonstrated initial increases in limb fat during the first few months of therapy, followed by progressive decline during ensuing three years. In one study the decline was estimated to be 14 percent per year among white men receiving regimens containing stavudine or zidovudine with lamivudine and either a protease inhibitor or non-nucleoside reverse-transcriptase inhibitor[31]. Furthermore, one of these studies[31] demonstrated that 20-35% of patients developed body fat malformation about 12-24 months after initiated with HAART.

5.4 Determinants of Body Fat Maldistribution

Several risk factors have been associated with development of body fat malformation among patients on HAART[44]. These include, effects of HAART, HIV itself and genetics and other host factors. The duration and type of HAART has been found to be associated with body fat malformation. Protease inhibitors have been associated with fat accumulation, and the nucleoside analogue reverse transcriptase inhibitors (nRTIs), stavudine, didanosine and zidovudine have been associated with fat loss[45,46]. In our model that contained sex, age, and type of HAART regimen, participants that were on stavudine based therapy were twenty seven times more likely to develop lypodystrophy compared to HAART naïve participantsThe other two regimens based on efavirenz and nevirapine were also important determinants of lipodystrophy in this population. Another important determinant of lipodystrophy in this population was age group 41-50 years. Participants in this age group were four times more likely to develop lipodystrophy compared to those below thirty years of age, however in this population, gender was not a predictor of body fat malformation. Several other studies therapy[25,40,41,42,43,46,68] have demonstrated similar findings with stavudine based therapy found to have a greater contribution to lipodystrophy compared to other drug combinations. In Tanzania phasing out stavudine based drugs began in 2010 due to high neurological toxicity that was encountered. We hereby further substantiate the phasing out of stavudine based drugs because of its long term side effects of lipodystrophy. Hence, the findings in this study will be useful to the policy makers as they work hard to continuously improve care and treatment services in the country.

5.5 Pyschosocial Effects: Perceptions and Attitude Towards Body Fat Maldistribution

In this study we have clearly demonstrated how respondents feel about their body image as a result of body fat maldistribution. Emotional feelings of the participants were diverse ranging from feeling worse than before, feeling of bad mirror image and patients avoided even to wear some dressing because of stigma. We did not explore the desire to stop treatment because of the change in body image. Other studies have explored the psychosocial effects of lipodystrophy among HIV patients on HAART[57,74]. Body fat

maldistribution could have substantial psychological repercussions with a subsequent negative impact on the patient's social life, emergence of depressive symptoms, or anxiety[74,75]. Moreover, body change status and the subsequent stigmatization could produce social isolation and distress, and even, a change in the beliefs about drugs and a decrease in adherence level.

In our study 12.7% of respondents with body fat maldistribution reported to isolate themselves from other people, 28.4% tended to avoid outside activities like swimming, others reported avoiding events that will have many people (22.1%) and a dimished desire to have sexual intercourse (21%). Other studies have also demonstrated altered social life among patients with lipodystrophy [76-78]. Although it is a common perception in the West that body-shape changes may affect patients' psychosocial function and quality of life and may lead to patients to consider cessation of treatment, few studies to date have formally addressed the issue of the impact of these changes on the patient. Hence this study demonstrates that there are significant variations in perceptions about body changes and the extent of compromise in the social life of these patients that need to be addressed in a larger and well designed study for that purpose.

CHAPTER SIX

6.0: CONCLUSION

From the findings of this study we can draw the following conclusions:

1. There is a significant proportion of HIV positive patients who are on treatment with HAART for at least 24 months that have lipodystrophy
2. The contribution of stavudine based therapy on development of lipodystrophy was higher compared to efavirenz and nevirapine therapy.
3. There are negative perceptions and attitudes regarding ones' own body especially that the changes in their body image was caused by the fact that the patients were using HAART.
4. Incidentally that there are no any treatment guidelines that exists for health care workers to use to treat patients with body fat malformation in CTC clinics in Dar es Salaaam.

Furthermore, there are some important operational implications linked to the observed prevalence of lipodystrophy in this population. First, although lipoatrophy may be considered a cosmetic problem, the condition is often associated with other metabolic abnormalities such as dyslipidaemias, hyperlactataemia and diabetes (though was not a scope of this study), which may all contribute to morbidity and mortality[47]. In resource-limited settings like Tanzania whereby availability of facilities for measurement of abnormalities of blood glucose, lactic acid and lipid metabolism can be challenging (as has been the case with this study), clinical assessment for lipodystrophy might be a 'red flag' indication of the overall syndrome, although this hypothesis needs to be assessed in more detailed studies. Second, lipodystrophy affects the overall appearance of individuals and in certain cultures this might be considered unacceptable and may contribute to stigma. Treatment modalities among patients with lipodystrophy was not a scope of this study, however if these patients were adequately treated their perceptions and attitudes against lipodystrophy could improve their psychosocial negativity. Finally, if the prevalence in our setting is anything to go by as a 'forecast' for other clinics across the country, then this problem might have a negative influence on ART adherence and the overall acceptability of ART as cohorts within the country become more mature

6.1 RECOMMENDATIONS

In order to treat on time lipodystrophy by the clinicians the Ministry of Health and Social Welfare should include assessment of lipodystrophy in the routine HIV assessment of patients in CTC clinics.

Treatment for lipodystrophy should be given due consideration by developing proper guidelines and conducting training to all health care providers in CTC clinics to be able to diagnose and treat lipodystrophy.

Prevention for the development of lipodystrophy should be well explained to the participants as part of health education in CTC clinics.

Guidelines for psychosocial evaluation of patients with lipodystrophy to be developed and used in all clinics in the country.

Efforts should be deliberately sought to incorporate management of longterm complications of HAART in Tanzania.

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8.0: APPENDICES

APPENDIX 1: INTERVIEW SCHEDULE (ENGLISH VERSION)

RESEARCH ON BODY FAT MALDISTRIBUTION AMONG HIV PATIENTS ATTENDING CTCs IN DAR ES SALAAM

INTRODUCTION:

I am a researcher from Muhimbili University of Health and Allied Sciences (MUHAS). We are conducting a study to assess the proportion of participants with body fat malformation. We will ask you several questions and we kindly request for your support. If in any occasion we will ask you a question that is not pleasant please bear with us.

Date of Interview: _____

Identity Number: _____

File Number: _____

Name of Interviewer (1st and 2nd Initials): _____

Clinic: _____

District: _____

Treatment Status: 1= On Medication 2=Not On Medication

Noted changes on body fat maldistribution: 1=Yes 2=No

INSTRUCTIONS (RA): PLEASE FILL IN EMPTY SPACES OR CIRCLE/TICK THE MOST CORRECT RESPONSE(S).

PART I: SOCIODEMOGRAPHIC AND OTHER CHARACTERISTICS

Now let us begin our discussion by getting important information concerning you:

1. Gender: 1= Male
   2= Female ☐

2. What was your date of birth (date and year) _____

3. How old are you now? _____ (years)

4. Please tell me about your marital status:
   1= Married and living with my husband of different sex in the same house
   2= Not married
   3= Divorced ☐
   4 = Widowed
   5 = Living together without formal marriage
   6= Separated
   7=Others (Mention): _____

5. are you a follower of which religion? ☐
   1=Islam
   2= Christian
   3=Others (Mention) _____ ☐
   4=Other concerns: _____

6. In total how nmany years have you spent in formal education?
   _____(years) ☐

5. What is your level of education?

1=I have not been to school at all

2=I haven't finished primary education

3=I have finished primary education

4=I haven't finished secondary education

5=I have finished secondary education

6=I have not finished advanced secondary education

7= I have finished advanced secondary education

8= Higher learning – college, university

6. Do you have any job that brings income to you?

1=Yes

2=No

7. If the answer above is yes: what is this job?

1=Employee of government/parastatal

2=Casual labour which is not permanent

3=Employed by private firm

4= Privately employed

5=Farmer

6=Others (Mention) _____

8. If you are not working, is your partner employed?

1= Yes

2= No

9. If the answer above is yes: what is his job?

1=Employee of government/parastatal

2=Casual labour which is not permanent

3=Employed by private firm

4= Privately employed

5=Farmer

6=Others (Mention) _____

PART II: INFORMATION ABOUT PAST MEDICAL HISTORY

10. Have you ever been told by the doctor that you have any of the following diseases? (Mention all that is true)

1=Hypertension

2=Diabetes Mellitus

3=Obesity

4=Heart Disease

5=Stroke

6= Others (Mention) _____

11. Have you ever been told that your parents are/were suffering from any of the following diseases? (Mention All that are correct)

1=Hypertension

2=Diabetes Mellitus

3=Obesity

4=Heart Disease

5=Stroke

6= Others (Mention) _____

PART III: PATIENT INFORMATION ON HIV/AIDS:

12. In which year were you first diagnosed with HIV/AIDS? *(Year)*

_____

13. Where was it? *(Mention name of clinic)* _____

14. Are you currently using ARV Drugs? 1=Yes 2=No.

15. If the answer above is yes what is the name(s) of ARV drugs you are using now?

_____

16. For how long have you been using the drugs? *Mention that is most correct for you.*

Years=_____

Months=_____

17. Have the drugs you are using ever changed?

1=Yes 2=No

18. If the answer above is yes, which drugs were you using first? *Mention.*

_____

19. For how long did you use the firs drug(s)? *Mention that is most correct for you.*

Years=_____

Months=_____

20. Are you currently using any other types of drugs than ARVs?

1=Yes 2= No ☐

21. If the answer is yes what type of drugs? *Circle all that is correct and if possible mention the name of the drug*

1=Analgesics for pain: _____ ☐

2=Immune modulators: _____

3=Traditional medicines: _____

4=Family planning pills/injectables: _____

5=Antidiabetic drugs_____

6=Antihypertensives _____

7=Antibiotics_____

8=Antifungal drugs_____

9=Antimalarial_____

10=Drugs for peptic ulcer/dyspepsia_____

11=Vitamins_____

12=Others (Mention)_____

PART IV: LIFESTYLE HISTORY

22. Are you currently using any type of tobacco?

1=Yes, ☐

2=No *(Go to question number25)*

23. If Yes, predominantly what type do you use? *Circle the most correct*

1=Cigarette: _____

2=Tobacco Roll: _____

3=Tobacco Sniffing: _____ ☐

4=Tobacco Pipe: _____

24. How many cigarettes/Rolls/Sniffing/Pipe do you use per day? Circle appropriate tobacco use.

1=Less than 5

2=5 – 20 _____ ☐

3=21 – 40

4=More than 40

For those who have responded no question 22 above.

25. Have you ever used tobacco before?

1=Yes 2=No ☐

26. If the answer is yes, when did you stop using tobacco?

(Year?_____ ☐

27. Do you drink alcohol?

1= Yes 2=No *(Go to question number 31)* ☐

28. If Yes, what type? *Mention all that you use*

1= Beer: _____

2=Whisky: _____ ☐

3=Wine: _____

4=Local brew: _____

29. How many units of alcohol do you drink per day?

1=A lot until I get drunk

2=Average amount

3=Very little

(One unit is equivalent to 341 ml of Beer with 5% alcohol).

---

30. Do you use any other type of alcoholic drinks or sniffs?

1= Narcotic drugs ☐

2=Bhang

3=Mirungi

4=Others *(Mention)* _____

31. Are there any types of food stuffs that you have been advised not to eat?

1=Yes ☐

2=No

32. If the answer above is yes please explain what type of food stuffs were you advised not to eat?

_____

_____

33. Do you usually do physical exercise?

1=Yes 2=No *(Go to question 41)*

34. If the answer above is yes how many times and for how long do you exercise in a week?

1=Once a week about, time spent per session_____

2=More than once a week, time spent per session_____

3=More than three times a week, time spent per session_____

4=Others (Mention)_____

35. What type of exercise do you conduct?

1=Jogging

2=Lifting Heavy Weights

3=Gymnasium

4=Others (Mention)_____

36. Do you take physical exercise to be beneficial to you?
    1=Yes 2=No 3=I do it as routine

37. What reasons make you not to do physical exercise?
    1=I feel weak

    2=I have no time

    3=I don't like doing it

    4=Others (Mention)_____

38. Please rate yourself in terms of physical exercise?
    1=Average

    2=Below Average

    3=Above Average

PART V: INFORMATION ON SIDE EFFECTS OF HAART

39. Have you experienced any problems since you started Anti retroviral drugs?
    1=Yes 2= No ☐

40. Have you experienced one or more of the following side effects since you started Antiretroviral Drugs?
    1= Rashes

    2=Insomnia ☐

    3=Head ache

    4=Confusion

    5=Nausea/Vomitting ☐

6=Abdominal discomfort

7=Numbness in lower limbs

8=Numbness in upper limbs

9=Diarrhoea

10=Fatigue/general body malaise

11=Yellow discoloration of eyes

12=Others

41. Have you noted any changes in your body shape/composition since you started treatment?

1=Yes

2=No

42. Have you noticed any of the following changes on respective body parts? Tick all that is applicable (√).

1= Increasing waist/abdominal girth: _____

2= Increasing chest mass: _____

3=Breasts enlargement: _____

4= Increasing size of back of neck (Buffalo lump): _____

7=Increased fat under the chin

8=Thinning of legs: _____

9=Thinning of arms: _____

10=Thinning of face: _____

11=Thinning of buttocks: _____

PART VII: MEASUREMENTS

A: Anthropometric Measurements

Measurements	**Cm**
Weight (cm)	
Height (cm):	
Waist Circumference (cm)	
Hip Circumference (cm):	
Left Mid Upper Arm Circumference (cm):	
Left Mid Thigh Circumference (cm):	
Shoulder Width(Buffalo Hump) (cm)	
Bust line (cm)	

B: Blood Pressure and Heart Rate Measurements

BP Measurements	**mmHg**
SBP1 (mmHg)	
SBP2 (mmHg)	
SBP3 (mmHg)	
DBP1 (mmHg)	
DBP1 (mmHg)	
DBP1 (mmHg)	
HR1	
HR2	
HR3	

"THANK YOU VERY MUCH FORYOUR TIME"

APPENDIX 2: INTERVIEW SCHEDULE (SWAHILI VERSION)

UTAFITI KUHUSU MATATIZO YA MABADILIKO YA MWILI YANAYOWAPATA WAGONJWA WA VVU

UTAMBULISHO:

Mimi ni mtafiti kutoka Chuo Kikuu cha Sayansi za Tiba na Afya Shirikishi ,Muhimbili. Tunafanya utafiti kuhusu athari za muda mrefu zinzowapata wagonjwa wa ukimwi. Tutakuuliza maswali kadhaa na tunakuomba sana ushirikiano wako. Kama maswali mengine yatakuudhi, tafadhali tusamehe ni sehemu tuu ya utafiti.

Tarehe ya mahojiano: _____

Namba ya Utambulisho ya Mshiriki: _____

Namba ya Faili: _____

Herufi za Majina mawili ya mwanzo ya Msaili: _____

Kliniki: _____

Wilaya: _____

MAELEKEZO: TAFADHALI JAZA SEHEMU ILIYO WAZI AU ZUNGUSHIA JIBU LILILO SAHIHI.

SEHEMU YA I: TAARIFA ZA BINAFSI NA SIFA NYINGINEZO

Sasa tuanze mazungumzo yetu kwa kupata taarifa muhimu kuhusu wewe binafsi

1. Jinsia: 1= Mwanaume
   2= Mwanamke ☐

2. Ulizaliwa lini (tarehe na mwaka) _____ Una umri wa miaka mingapi: _____

3. Nieleze hali yako ya ndoa:
   1= Nimeoa/olewa naishi na mwenzi wangu wa jinsia tofauti nyumba moja
   2= Sijaoa/olewa
   3= Tumetalikiana ☐
   4 = Mjane
   5 = Tunaishi pamoja bila ndoa
   6= Mtalaka/tumetengana ☐
   7=Mengineyo: _____

4. Wewe ni muumini wa dini gani?: ☐
   1=Muislamu
   2= Mkristu
   3=Nyingine, taja _____ ☐
   4=Mengineyo: _____ ☐

5. Kwa ujumla umesoma miaka mingapi?

_____(miaka)

6. Je umesoma mpaka darasa la ngapi?

1=Sijaenda shule kabisa

2=Sikumaliza elimu ya msingi

3=Nimemaliza elimu ya msingi

4=Sikumaliza elimu ya sekondari

5=Nimemaliza Elimu ya Sekondari

6=Sikumaliza elimu ya juu ya sekondari

7=Nimemaliza elimu ya juu ya sekondari

8=Elimu ya juu/chuo

6. Je una shughuli yoyote ikuingiziayo kipato?

1=Ndiyo

2=Hapana

10. Kama jibu ni ndiyo, Je ni shughuli gani hukuingizia fedha/kipato?

1=Nimeajiriwa na serikali/shirika la umma

2=Kazi za kubabaisha/zisiso z a kudumu/kibarua

3=Mfanyakazi wa Sekta Binafsi

4=Nimejiajiri

5=Mkulima

6=Nyinginezo _____

11. Kama hufanyi kazi, je mwenzi wako anafanya kazi?

1= Ndiyo ☐

2= Hapana

9. Kama Jibu ni Ndiyo je anafanya kazi gain?

1=Nimeajiriwa na serikali/shirika la umma

2=Kazi za kubabaisha/zisiso z a kudumu/kibarua

3=Mfanyakazi wa Sekta Binafsi

4=Nimejiajiri

5=Mkulima

6=Nyinginezo _____

SEHEMU YA II: Maelezo ya Magonjwa yaliyopita:

43. Umeshawahi kuambiwa na Daktari kuwa una moja ya magonjwa yafuatayo? (Taja yote yaliyo sahihi)

1= Shinikizo la Damu

2= Kisukari ☐

3= Unene kupita kiasi

4= Ugonjwa wa moyo

5= Kiharusi

6= Mengineyo (Taja) _____

44. Je mmoja au wote kati ya wazazi wako ana moja au zaidi ya magonjwa haya? (Taja yote yaliyo sahihi)

1= Shinikizo la Damu

2= Kisukari

3= Unene kupita kiasi

4= Ugonjwa wa moyo

5= Kiharusi

6= Mengineyo (Taja) _____

SEHEMU YA III: Hali ya Mgonjwa Kuhusu Tiba ya VVU:

45. Ni mwaka gani uligunduliwa kuwa una VVU? *(Mwaka)* _____

46. Uligunduliwa wapi? *(Taja jina la kliniki)* _____

47. Je kwa sasa unatumia dawa za VVU? 1=Ndiyo 2=Hapana.

(KAMA JIBU HAPANA NENDA SWALI NAMBA 20)

48. Kama jibu hapo juu ni ndiyo, je ni aina gani ya dawa?

_____

49. Je ni kwa muda gani sasa unatumia aina hii ya dawa? *Taja iliyo sahihi kwako.*

Miaka=_____

Miezi=_____

50. Je umewahi kubadilishiwa dawa za VVU?

1=Ndiyo 2=Hapana

(KAMA JIBU HAPANA NENDA SWALI NAMBA 20)

51. Kama jibu ni ndiyo ulikuwa unatumia dawa gani kwanza? *Taja.*

_____

52. Ni kwa muda gani ulitumia dawa hiyo? *Taja iliyo sahihi kwako.*

Miaka=_____

Miezi=_____

53. Je unatumia aina nyingine yoyote ya madawa zaidi ya za kurefusha maisha?

1=Ndiyo 2= Hapana ☐

54. Kama ndiyo aina gani? *Zungushia yote sahihi.*

1=Dawa za maumivu: _____ ☐

2=Dawa za kuongeza kinga ya mwili: _____

3=Dawa za kienyeji: _____

4=Dawa za uzazi wa mpango: _____

5=Dawa za Kisukari_____

6=Dawa za Presha _____

7=Dawa za maambukizi_____

8=Dawa za Fangasi_____

9=Dawa za malaria_____

10=Dawa za Vidonda vya Tumbo_____

11=Vitamini_____

SEHEMU YA IV: Maelezo ya Aina ya Mtindo wa Maisha ya Msailiwa:

55. Je unatumia aina yoyote ya Tumbaku?

1=Ndiyo, ☐

2=Hapana *(Nenda swali la 58)*

56. Kama ndiyo aina gani unatumia?. *Zungushia unachotumia.*

1=Sigara: _____ ☐

2=Msokoto: _____

3=Tumbaku ya kunusa: _____ ☐

4=Kiko _____

57. Kwa wanaotumia Sigara/ Msokoto/ Tumbaku ya Kunusa/ Kiko. Je ni kiasi gani kwa siku? *Zungushia unachotumia.*

1=Chini ya 5 ☐

2=5 – 20 _____

3=21 – 40

4=Zaidi ya 40

Kwa waliojibu Hapana namba 22 hapo juu.

58. Je ulishawahi kutumia tumbaku siku za nyuma?

1=Ndiyo 2=Hapana ☐

59. Kama jibu ni ndiyo je uliacha matumizi ya tumbaku mwaka gani?_____ ☐

60. Je unatumia kilevi chochote?

1= Ndiyo 2=Hapana *(Nenda swali 64)*

61. Kama ndiyo je unatumia aina gani ya kilevi? *Taja vyote unavyotumia.*

1=Bia: _____

2=Pombe Kali: _____

3=Mvinyo: _____

4=Pombe ya kienyeji: _____

62. Je kwa kawaida unakunywa kiasi gani cha pombe kwa siku?

1=Sana hadi nilewe

2=Pombe kiasi tuu

3=Kidogo sana

(Uniti moja ni sawa na ml341 za bia yenye asilimia 5% za pombe).

_____

63. Je ni kilevi gani kingine unachotumia badala ya pombe au sigara?

1= Madawa ya kulevya

2=Bangi

3=Mirungi

4=Nyingine *(Taja)* _____

64. Je kuna vyakula vyovyote ambavyo umekatazwa kula baada ya kuanza dawa?

1=Ndiyo ☐

2=Hapana

65. Kama jibu juu ni ndiyo tafadhali elezea ni aina gani ya vyakula ambavyo umekatazwa kula.

_____

_____

66. Je katika siku za karibuni umepata matatizo ya kupata chakula cha kutosha kwa matumizi yako? ☐

1= Ndiyo 2=Hapana *(Nenda swali 69)*

67. Kama jibu ni ndiyo taja aina tatu za vyakula ambavyo ni vigumu kwako kuvipata.

1) _____

2) _____

3) _____

68. Kwa nini ni vigumu kupata vyakula hivyo hapo juu? Taja sababu angalau mbili:

1) _____

2) _____

69. Je huwa unafanya mazoezi ya viungo?

1=Ndiyo 2=Hapana *(Nenda swali 41)*

70. Kama jibu ni ndiyo unafanya mazoezi mara ngapi kwa wiki?

1=Mara moja kwa wiki

2=Zaidi ya mara moja kwa wiki, taja tafadhali_____

3=Mara nyingi mfululizo

71. Ni aina gani ya mazoezi huwa unafanya?
1=Kukimbia kimbia

2=Kunyanyua uzito

3=Mazoezi ya viungo mbalimbali

4=Nyingine (Taja)_____

72. Je unachukulia mazoezi ya viungo kuwa ya manufaa kwako?
1=Ndiyo 2=Hapana 3=Nafanya tuu kama utaratibu

73. Je ni vitu gani vinakuzuia usifanye mazoezi ya viungo?
1=Najisikia dhaifu

2=Sipati muda

3=Sipendi

74. Je unaweza kujiweka katika kiwango gani cha ufanyaji wa mazoezi ya viungo?
1=Wastani

2=Chini ya Wastani

3=Juu ya Wastani

SEHEMU YA V: Maelezo ya Awali Kuhusu Mabadiliko ya Mwili

KABLA YA KUANZA MASWALI HAYA TIKI INAYOHUSIKA

1= NATUMIA DAWA ZA VVU

2=SITUMII DAWA ZA VVU

75. Je umeshawahi kupata moja au zaidi ya matatizo haya hapa chini?

1=Vipele

2=Kukosa usingizi ☐

3=Kichwa kuuma

4=Kuchanganyikiwa akili

☐

5=Kichefuchefu/kutapika

6=Maumivu ya tumbo

7=Ganzi kwenye miguu ☐

8=Ganzi kwenye mikono

9=Kuharisha

10= Mwili kuchoka/kutokuwa na nguvu ☐

11=Macho kugeuka rangi ya njano

12= MENGINEYO _____

_____

76. Je umeona mabadiliko yoyote katika ukubwa wa sehemu yoyote ya mwili wako?

1=Ndiyo ☐

2=Hapana *(Nenda swali 30)*

77. Kama jibu ni ndiyo je umeona mabadiliko gani? Weka alama ya (√).

1=Kuongezeka ukubwa wa kiuno:_____ ☐

2=Kuongezeka ukubwa wa tumbo: _____

3=Kuongezeka ujazo wa kifua: _____

4=Matiti kujaa/kuvimba: _____ ☐

5=Kuongezeka ujazo sehemu ya mabega na shingo (Buffalo Hump): _____ ☐

6=Kuvimba kidevu

7=Miguu kuwa myembamba: _____ ☐

8= Mikono kuwa myembamba: _____

9= Uso kusinyaa na kukonda: _____ ☐

10=Makalio (buttocks) kusinyaa/kukonda: _____

SEHEMU YA VI: Vipimo Mbalimbali Vya Msailiwa:

A: Vipimo vya Mwili:

Vipimo	**Kiasi**
Uzito (cm)	
Urefu (cm):	
Kiuno(waist) (cm)	
Mapaja (hips) (cm):	
Mzunguko wa Mkono wa kushoto (cm):	
Mzunguko wa Paja la kushoto (cm):	
Upana wa mabega (Buffalo Hump) (cm)	
Upana wa Kifua (bust line) (cm)	

B: Vipimo vya Shinikizo la Damu na Mapigo ya Moyo:

Vipimo	**Kiasi**
SBP1 (mmHg)	
SBP2 (mmHg)	
SBP3 (mmHg)	
DBP1 (mmHg)	
DBP1 (mmHg)	
DBP1 (mmHg)	
HR1	
HR2	
HR3	

"ASANTE SANA KWA KUSHIRIKI UTAFITI HUU"

APPENDIX 3: CONSENT FORM (ENGLISH VERSION)

RESEARCH ON BODY FAT MALDISTRIBUTION AMONG HIV PATIENTS ATTENDING CTCs IN DAR ES SALAAM

Introduction

This study is performed by investigators from **Muhimbili University of Health and Allied Sciences**. It is based at Mwananyamala, Temeke, and Ilala Municipal Hospitals.

The research is set to determine the prevalence and most common risk factors for body fat mal-distribution among human immunodeficiency virus (HIV)-infected patients in Dar es Salaam and to assess the perceptions and attitudes these patients have on body fat maldistribution.

This document gives you information regarding the purpose, how to participate, what it entails by participating, and benefits of participating as well as potential risks. This will therefore enable you to make informed decision as to whether to participate or not.

Purposes

The purposes of this research are:

1. To determine the proportion of HIV positive patients with body fat maldistribution (hypetrophy, atrophy and mixed types) in Dar-Es-Salaam.
2. To assess the perceptions related to body fat malformation among HIV positive patients with lipodystrophy in Dar es Salaam.
3. To assess the attitudes related to body fat malformation among HIV positive patients with lipodystrophy in Dar es Salaam.
4. To assess the association between use of HAART and body fat malformation among HIV positive patients in Dar es Salaam.
5. To assess the association between demographic factors and body fat malformation among HIV positive patients in Dar es Salaam.
6. To assess the relationship between immunological factors (CD4 Count, Viral load) and body fat malformation among HIV positive patients in Dar es Salaam.

The study

The study has received ethical clearance from the Muhimbili National Hospital Research and Publication Committee.

The Study Protocol

The study will be conducted at CTC clinics at the three Municipal Hospitals. There will be four sets of data to be collected:

1. **Initial assessment by the nurse:** The study nurse at the clinic will enrol the patients and enquire and record demographic characteristics. She will take vital signs (blood pressure and heart rate). The nurse will also take physical measurements: height, weight, waist circumference, hip circumference, mid-upper arm circumference (MUAC), and mid-thigh circumference. The nurse will ask the patient about body fat changes if absent or present and will record it in the questionnaire. Thereafter, the patients will be sent to the doctor for clinical evaluation.

2. **Clinical Evaluation:** Next the patient will be seen by the attending physician who will fill in a specific enquiry form to evaluate body fat malformation according to body changes (new fat repartition) as reported by the patient and validated by the physician familiar with the patient file. The most common sites for accumulation or loss of body fat that will be assessed by the physician are: face, neck, dorsocervical spine, breast, abdomen, buttocks, arms and legs. The physician will do a clinical examination to assess loss of body fat from the cheeks (facial), upper limbs, buttocks and lower limbs. Also accumulation of fats will be assessed from the neck, dorsocervical spine, breast and abdomen. For each of these 8 body sites the physician will document the grade of the changes as: None – Absent (score = 0), Mild - Noticeable on close inspection (score = 1), Moderate - Readily noticeable by patient/physcian (score = 2) and Severe - Readily noticeable to a casual observer (score = 3) for both fat losses and accumulations separately. At this point the physician will be asked to seek second opinion of fellow physician if he is not sure of any of the changes. The Body fat malformation Assessment Score (LAS) will then be determined by totalling the subscores of body changes from these 8 areas. For regional clinical severity scores lipohypertrophy (fat accumulation) will be assigned a positive value, and lipoatrophy responses a negative value (bidirectional scale). The body fat malformation assessment score will be calculated via addition of absolute value scores in each area, thus they all be assigned a positive value. Thus, a higher body fat malformation assessment score will indicate a greater severity of body fat malformation (inclusive of both lipohypertrophy and lipoatrophy) and will range from 0 to 24. After complete evaluation by the physician the research assistant will institute the interview guide to the patient.

3. **Questionnaire:** Patients will respond to questions on socio-demographic factors (age, gender, level of education, professional activity, marital status, religion, place of residence), lifestyle factors (diet - 24-hr food recall system, physical activity, smoking), alcohol consumption, number of term pregnancies (for women) and presence of other chronic diseases. Only patients who will be diagnosed by the doctor that they have body fat malformation they will respond

to psychosocial assessment questionnaire. Trained research assistant will conduct the interviews.

RESULTS

You will be receiving the results of the measurements as the study goes on and in case of side effects you will be notified.

Ethical Clearance

This study obtained ethical clearance from MUHAS Research and Publication Committee.

Potential risks associated with participating in this Study

There are no potential risks expected for participating in this study. However you may experience the following:

1. Some of the questions you may be asked may bring in an abnormal feeling to you and the time taken to complete the questionnaire may be longer than what you expected.
2. We do not expect that the responses you will give in the questionnaire will be known to anybody who is not involved in the study. Efforts to maintain confidentiality will be implied like the use of numbers as identifiers. Thus your responses will be recorded in the questionnaire and not linked to your name.

Potential Benefits

By taking part in this research study, you will have personally contributed to the global and national initiatives to an HIV research such that those on treatment are enjoying good quality life with no worries of severe side effects and therefore improve adherence to ARVs. Your health will also be thoroughly examined and investigated by experienced medical personnel. Altogether, the knowledge to be gained from in this study is likely to be of assistance to millions of people in Tanzania and elsewhere.

Confidentiality

Your research records will be confidential to the extent permitted by law. You will be identified by a code, and not by name. Personal information from your records will not be released without your written permission. You will not be personally identified in any publication about this study.

In addition, please note that:

1. Your participation in this research is **ENTIRELY VOLUNTARY**.
2. You may decide not to take part or to withdraw from the study at any time without losing the benefits of your standard medical care normally availed to HIV patients in respective health care services.

Research-Related Injury

If you are injured as a result of participation in this study, the study clinic will give you immediate necessary treatment for your injuries. The cost of this treatment (ordinary patient) will be born by the study. You will then be told where you may receive additional treatment for injuries.

Persons to Contact in case of Problems or Questions

If you ever have questions about this study or in case you are injured as a result of participation in this research study, you should contact any of the following:

1. Dr. Marina Njelekela- Principal Investigator, Simu namba - 0713 291 323 or you can see her at Muhimbili University of Health and Allied Sciences, MPL Building 2nd Floor Room number 43.

Study office contacts:

Postal address: Body Fat Malformation Project,

Attn: Dr Njelekela M.

Muhimbili University of Health and Allied Sciences,

P.O. Box 65001,

Dar es Salaam.

Consent Form

Body Fat Maldistribution Among Human Immunodeficiency Virus-Infected Patients Attending Care and Treatment Clinics in Dar es Salaam Municipal Hospitals

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without jeopardy.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THIS FORM AND AGREE TO PARTICIPATE IN THIS STUDY. I ALSO UNDERSTAND THAT ALL INFORMATION IN THIS STUDY WILL BE CONFIDENTIAL.

IN CASE YOU HAVE QUESTION YOU CAN CONTACT ANY OF THE FOLLOWING

1. Dr. Marina Njelekela- Principal Investigator, Simu namba - 0713 291 323 or you can see her at Muhimbili University of Health and Allied Sciences, MPL Building 2nd Floor Room number 43.

_____
_____

Signature of Participant Date

_____
_____

Signature of Investigator Date

APPENDIX 4: CONSENT FORM (SWAHILI VERSION)

UTAFITI KUHUSU MATATIZO YA MUDA MREFU YANAYOWAPATA WAGONJWA WA UKIMWI

Utangulizi

Utafiti huu unafanywa na watafiti kutoka Chuo Kikuu cha Sayansi za Tiba, Muhimbili.

Utafiti huu unataka kuangalia ukubwa na sababu zinazopelekea watu kupata tatizo la mgawanyiko tofauti wa mafuta katika mwili wa wagonjwa wa VVU hapa Dar es Salaam na pia kutafiti kuhusu mtazamo na hisia zao kisaikolojia kuhusu hali hiyo.

Kabrasha hili litakupatia habari kuhusu madhumuni ya utafiti na namna ya kushiriki, faida na madhara ya kushiriki kwenye utafiti. Hii itakuwezesha wewe kuamua kushiriki au kutoshiriki kwenye utafiti.

Dhumuni

Madhumuni ya utafiti huu ni: -

1) Kutafuta idadi ya wagonjwa wa VVU wenye mgawanyiko tofauti wa mafuta katika mwili katika hospitali za Manispaa, Dar es Salaam.
2) Kutathmini hisia za wagonjwa wa VVU kuhusu mabadiliko ya shepu ya mwili wao katika hospitali za Manispaa, Dar es Salaam.
3) Kutathmini mitazamo ya wagonjwa wa VVU kuhusu mabadiliko ya shepu ya mwili wao katika hospitali za Manispaa, Dar es Salaam.
4) Kuangalia uhusiano uliopo kati ya utumiaji wa dawa za VVU na mabadiliko ya shepu ya mwili au mrundikano tofauti wa mafuta kwa wagonjwa wa VVU Dar es Salaam.
5) Kuangalia uhusianao uliopo kati ya mgawanyiko tofauti wa mafuta katika sehemu mbalimbali za mwili na sababu za kidemografia kati ya wagonjwa wa VVU Dar es Salaam.
6) Kutathmini uhusiano kati ya mambo ya kiimunologia (CD4 Count, Viral load) na mgawanyiko tofauti wa mafuta katika sehemu mbalimbali za mwili kwa wagonjwa wa VVU Dar es Salaam.

Utafiti

Utafiti umepata ruhusa kutoka katika kamati ya maadili ya utafiti ya Chuo Kikuu cha Afya na Tiba Muhimbili na pia kutoka katika Ofisi za Waganga Wakuu wa Manispaa za Ilala, Mwananyamala na Temeke.

Kuhusu Utafiti

Utafiti huu utafanyika katika hopitali kuu tatu za Manispaa yaani Ilala, Mwananyamala na Temeke. Tutakusanya aina nne za takwimu katika utafiti huu kama ifuatavyo:

3. **Ukaguzi wa Awali na Muuguzi:** Muuguzi atawaalika wagonjwa kujiunga na utafiti na atawauliza na kunakili taarifa zote zinazohusu umri, jinsia na kadhalika. Pia atachukua vipimo vya msukumo wa damu (pressure) na mapigo ya moyo pamoja na kupima vipimo mbalimbali vya mwili kama vile urefu, uzito, kiuno, mapaja, na mzunguko wa paja na mkono. Muuguzi atamuuliza mgonjwa kama ameona mabadiliko yoyote katika mwili wake kuhusu mrundikano wa mafuta ulio tofauti na atanakili katika sehemu husika katika dodoso. Baada ya hapo mgonjwa ataelekezwa kwa daktari kufanyiwa uchunguzi wa mwili wake kubaini kama ana mabdiliko yoyote ya mrundikano tofauti wa mafuta katika mwili.

4. **Uchunguzi wa Mwili na Daktari:** Daktari atamuona mgonjwa na kumpima kama ana mabadiliko yoyote ya mrundikano wa mafuta au mabadiliko ya shepu ya mwili wake na kunakili katika fomu maalumu. Sehemu ambazo daktari ataangalia ni zile ambazo mara kwa mara zinapata mabadiliko hayo nazo ni: usoni, shingoni, nyuma ya mabega, matiti, tumbo, makalio, mikono na miguu. Daktari ataangalia sehemu ambazo mafuta hupotea kama kwenye uso, makalio, mikono na miguu na pia ataangalia sehemu za mwili ambako mafuta hurundikana kama: shingoni, nyuma ya mabega, matiti na tumboni. Kwa kila badiliko Daktari atarekodi kiwango au daraja la mabadiliko kama: Hakuna (0), Kidogo sana – inaonekana kama ukiangalia kwa karibu (1), Wastani – inaonekana mara moja ukiangalia (2) na Sana – inaonekana wazi mtu au mgonjwa akitazama (3). Daktari ana uhuru wa kumuuliza Daktari mwingine mtazamo wake kama atakutana na wagonjwa wasiokuwa na mabadiliko ya wazi au yenye utata.

   Kiambatanisho Namba Sita – Uchunguzi wa Daktari na Kiwango cha Mabadiliko kitatumika kujumlisha daraja zote za mabadiliko katika maeneo hayo nane ya mwili. Yale mabadiliko ya kurundikana mafuta yatapewa alama ya chanya (+) na yale yanayoashiria kupoteza mafuta yatapewa alama ya hasi (-). Kwa kupata tathmini ya mwisho kama mgonjwa ana tatizo hilo, Daktari atajumlisha madaraja yote kwa kila mgonjwa na skoa itaonyesha udogo au ukubwa wa tatizo hili na italenga pointi 0-24. Baada ya vipimo hivi vya kina Daktari atamwelekeza mgonjwa kwa mtafiiti msaidizi kwa ajili ya kujaza dodoso.

4. **Dodoso:** Mgonjwa atajibu maswali kutoka katika dodoso yanayohusu taarifa muhimu za mgonjwa: umri, jinsia, kiwango cha elimu, kazi anayofanya, hali ya ndoa, dini, mahali aishipo, hali ya maisha: chakula – ripoti ya masaa 24-kuhusu chakula alichokula, kiwango cha mazoezi ya viungo, na uvutaji wa tumbaku),

kiwango cha matumizi ya pombe, jumla ya watoto alionao au kuzaa na uwezekano wa kuwapo aina nyingine ya magonjwa sugu. Ni wale tuu ambao Daktari atathibitisha kuwa wana mabadiliko katika miili yao ndio wataendelea na dodoso la tathmini ya kisaikolojia. Mtafiti msaidizi/muuguzi atafanya kazi hiyo.

Ruhusa ya Kufanya Utafiti

Utafiti huu umepata ruhusa ya kufanyika kutoka katika kamati ya maadili ya utafiti ya Chuo Kikuu cha Sayansi za Afya na Tiba cha Muhimbili.

Faida Zinazoweza Kupatikana

Kwa kushiriki kwenye utafiti huu, wewe binafsi utakuwa umechangia kwenye juhudi za kitaifa na duniani kote za kuzuia tatizo la mrundikano tofauti wa mafuta kwa wagonjwa wa VVU; tatizo ambalo linahusishwa na kuongezeka kwa matatizo ya magonjwa sugu kama ya moyo hasa kwa wale wanaotumia dawa za VVU. Pia utafaidika kwa kufanyiwa uchunguzi wa kina wa afya yako kuhusiana na madhara ya muda mrefu ya VVU. Vile vile, matokeo ya mambo tutakayojifunza kwenye utafiti huu yatakuwa na msaada mkubwa kwa mamilioni ya Watanzania na watu wengineo duniani kote katika kuinua hali ya afya ya wagonjwa wa VVU.

Usiri na Uaminifu

Kumbukumkbu za utafiti zinazokuhusu zitahifadhiwa kwa usiri mkubwa kwa kuzingatia taratibu za kisheria. Kumbukumbu hizo zitahifadhiwa kwa kutumia namba maalum na siyo majina ya wagonjwa husika. Taarifa binafsi kutoka kwenye kumbukumbu zako hazitatolewa bila ya ruhusa maalum ya maandishi. Wagonjwa watakaoshiriki hawatotambulishwa kwa namna yoyote kwa kutumia majina yao au kwa taarifa zao binafsi kwenye machapisho yoyote ya utafiti huu.

Kwa nyongeza, tafadhali zingatia:

a. Ushiriki wako kwenye utafiti huu **NI WA HIARI.**
b. Unaweza kuamua kutoshiriki au kusitisha ushiriki wako kwenye utafiti huu wakati wowote.

Madhara yanayohusiana na utafiti huu

Iwapo utapata madhara yoyote kutokana na kushiriki kwenye utafiti huu, kliniki itakupatia huduma zinazostahili kwa muda muafaka.

Kwa Matatizo au Maswali Yanayohusu Utafiti Huu, Tafadhali Wasiliana na:

Dr. Marina Njelekela – Mtafiti Mkuu, Simu – 0713 291 323 au unaweza kumuona kwenye Chuo Kikuu cha Muhimbili, jengo la MPL, Ghorofa ya 2, Idara ya Fisiolojia.

Anwani za Ofisi za Utafiti wetu ni:

Anwani ya Posta: Body Fat Maldistribution Study,

Attn: Dr Njelekela M.

P.O. Box 21765,

Dar es Salaam.

Hiari ya Mshiriki

Umepewa nakala ya waraka huu wa hiari ya mshiriki kwa kumbukumbu zako.

USHIRIKI WAKO KWENYE UTAFITI HUU NI WA HIARI. Una haki ya kusitisha ushiriki wako katika hatua yoyote ya utafiti huu bila masharti au matatizo yoyote.

KWA KUWEKA SAHIHI KWENYE WARAKA HUU WA RIDHAA YA MSHIRIKI KUNATHIBITISHA KWAMBA UMEELEWA NA UMEKUBALI KUSHIRIKI KWENYE UTAFITI HUU.

_____ _____

Sahihi ya Mshiriki Tarehe

_____ _____

Sahihi ya Mtafiti Tarehe

APPENDIX 5: CLINICAL ASSESSMENT (ENGLISH VERSION)

LIPODYSTROPHY STUDY – MWANANYAMALA, TEMEKE, AMANA

CLINICAL EVALUATION AND GRADING BY PHYSICIAN

PATIENT ON HAART: 1. YES 2. NO

SNO	BODY FAT CHANGE	SCORES			
	LIPOHYPERTROPHY **1. YES 2. NO**	**0=NONE**	**1=MILD**	**2=MODERATE**	**3=SEVERE**
1.	Increased fat under the chin				
2.	Increased fat on the back of the neck				
3.	Increased abdominal girth				
4.	Increased chest or breast fat				
	LIPOATROPHY **1. YES 2. NO**	**0=NONE**	**-1=MILD**	**-2=MODERATE**	**-3=SEVERE**
1.	Loss of fat in the face				
2.	Loss of fat in the arms				
3.	Loss of fat in the buttocks				
4.	Loss of fat in the legs				

PATIENT HAS THE FOLLOWING DIAGNOSIS – CIRCLE THE MOST APPROPRIATE DIAGNOSIS

7) ***A case of body fat maldistribution or lipodystrophy:*** A patient with at least one moderate or one severe subjective lipodystrophic feature (except for isolated abdominal obesity) apparent to both physician and patient.
    a. ***"Primary Lipoatrophy"*** - at least one site with moderate or severe fat loss whereas
    b. ***"Primary Lipohypertrophy"*** - at least one site with moderate or severe fat accumulation (except for isolated abdominal fat accumulation) and
    c. ***"Mixed"*** - those associated with both lipoatrophy and lipohypertrophy as per above description
8) ***Normal:*** A patient with no such feature of any severity apparent to both physician and patient.
9) ***Non-assigned:*** Ambiguous patients will be those with mild scores or with isolated abdominal fat accumulation which was moderate to severe apparent to both physician and patient.

APPENDIX 6: CLINICAL ASSESSMENT (SWAHILI VERSION)

ID NUMBER:_____

FOMU YA DAKTARI - LIPODYSTROPHY STUDY – MWANANYAMALA, TEMEKE, AMANA

KIAMBATANISHO NAMBA 6: UCHUNGUZI WA DAKTARI NA KIWANGO CHA MABADILIKO

MGONJWA ANATUMIA DAWA ZA UKIMWI: 1. NDIYO 1ST/2ND
2. HAPANA

SNO	MABADILIKO YA MWILI	KIWANGO			
	KUONGEZEKA (+ve) **2. NDIYO 2. HAPANA**	**0=HAKUNA**	**1=KIDOGO SANA**	**2=WASTANI**	**3=SANA**
5.	Kuvimba kidevu kwa chini shingo				
6.	Kuongezeka ujazo sehemu ya mabega na shingo (Buffalo Hump)				
7.	Kuongezeka ukubwa wa tumbo				
8.	Kuongezeka ujazo wa kifua na matiti				
	KUPUNGUA (-ve) **2. NDIYO 2. HAPANA**	**0=HAKUNA**	**1=KIDOGO SANA**	**2=WASTANI**	**3=SANA**
5.	Kukonda usoni hasa mashavuni				
6.	Kukonda katika mikono				
7.	Kukonda katika miguu				
8.	Kusinyaa/kukonda makalio				

PATIENT HAS THE FOLLOWING DIAGNOSIS – CIRCLE THE MOST APPROPRIATE DIAGNOSIS

10) ***A case of body fat maldistribution or lipodystrophy:*** A patient with at least one moderate or one severe subjective lipodystrophic feature (except for isolated abdominal obesity) apparent to both physician and patient.
    a. ***"Primary Lipoatrophy"*** - at least one site with moderate or severe fat loss whereas
    b. ***"Primary Lipohypertrophy"*** - at least one site with moderate or severe fat accumulation (except for isolated abdominal fat accumulation) and
    c. ***"Mixed"*** - those associated with both lipoatrophy and lipohypertrophy as per above description
11) ***Normal:*** A patient with no such feature of any severity apparent to both physician and patient.
12) ***Non-assigned:*** Ambiguous patients will be those with **mild scores (0-1)** or **with isolated abdominal fat accumulation** which was moderate to severe apparent to both physician and patient.

APPENDIX 7: PSYCHOSOCIAL ASSESSMENT (ENGLISH VERSION)

PSYCHOSOCIAL ASSESSMENT (THIS PART SHOULD ONLY BE FILLED WITH ONLY THOSE PARTICIPANTS WITH BODY FAT MALDISTRIBUTION)

SNO	QUESTION	none (0)	Mild or some (1)	Moderate (2)	Very Much (3)
I	**BODY IMAGE PERCEPTION**				
	Rate from 0 (none) to 3 (very much), the changes that you believe have occurred in your body shape				
A.	**INCREASING (+)**				
	Neck				
	Back of Shoulders				
	Breasts				
	Abdomen				
	Waist				
B.	**DECREASING (-)**				
	Face				
	Upper Limbs				
	Lower limbs				
	Buttocks				

II	**YOUR PERCEPTIONS ON BODY FAT DISTRIBUTION**				
	You feel angry when he / she examines your figure?				
	You avoid wearing clothes that enhance your figure?				
	You are is ashamed of your body?				
	When you look at the mirror you feel bad about your body/figure?				
	You take special care/awareness of your companions?				
	You are very careful that you are accompanied by who.				
	You feel your body is worse than before				
	If invited to go out you become anxious to mix with people				
III	**QUALITY OF LIFE**				
	Avoid situations where other people may have seen your body (swimming pool, changing rooms)?				
	Avoid social gatherings because people feel bad about your shape?				
	Decreased sexual activity because you feel wrong with your figure?				
	You are tense and nervous when you are introduced to other people?				
	If a room is full of strangers, you can enter it?				

	You have a tendency to isolate people?				
	You usually go to any social engagement you have?				
	You often make excuses to avoid social engagements?				

APPENDIX 8: PSYCHOSOCIAL ASSESSMENT (SWAHILI VERSION)

ID NUMBER:_____

TATHMINI YA KISAIKOLOJIA (SEHEMU HII IJAZWE KWA WENYE MABADILIKO YA MWILI TUU)

I.	**MTAZAMO WAKO KUHUSU MABADILIKO YA MWILI**				
Kiwango cha kutoka 0 (hakuna) mpaka 3 (sana), kuhusu mabadiliko ambayo unaamini yametokea katika sehemu za mwili wako zilizoorodheshwa hapa chini					
		Hapana (0)	**Kidogo sana (1)**	**Wastani (2)**	**Sana (3)**
A.	**KUONGEZEKA UKUBWA**				
	Shingo				
	Mabega kwa nyuma				
	Matiti				
	Tumbo				
	Kiuno				
B.	**KUPUNGUA/ KUKONDA**	**Hapana (0)**	**Kidogo sana (1)**	**Wastani (2)**	**Sana (3)**
	Uso				
	Mikono				
	Miguu				
	Makalio				

II.	**HISIA ZAKO KUHUSU MABADILIKO YA MWILI WAKO**				
		Hapana (0)	**Kidogo sana (1)**	**Wastani (2)**	**Sana (3)**
	Je unajisikia hasira wakati mwenzi wako akichunguza mwili wako?				
	Je unaepuka kuvaa nguo zinazoonyesha mwili wako?				
	Je unaona aibu kuhusu mwili wako				
	Je ukijiangalia katika kioo unajisikia vibaya kuhusu mwili wako?				
	Je unakuwa mwangalifu sana kuwa umeambatana na nani?				
	Je umejiona una mwili mbaya kuliko ilivyokuwa zamani?				
	Je ukipata mialiko kwenda matembezi ya jioni na unakuwa na wasiwasi kuchanganyika na watu wengine?				
III.	**UBORA WA MAISHA**	**Hapana (0)**	**Kidogo sana (1)**	**Wastani (2)**	**Sana (3)**
	Je unaepuka mazingira yanayofanya mwili wako uonekane na watu wengine? kama vile kuogelea				

	Je unaepuka mikusanyiko kwa sababu unajisikia vibaya kuhusu mwili wako?				
	Kutokana na kuuona mwili wako kuwa mbaya je umepunguza hamu ya kufanya tendo la ndoa?				
	Je unakuwa mwenye mawazo na wasiwasi unapotambulishwa kwa watu wengine?				
	Je unakuwa mgumu na mwenye wasiwasi kuingia mahali/chumba ambacho kina watu wapya kwako?				
	Je unakuwa na tabia ya kujitenga na watu wengine?				
	Je unakwenda katika mikusanyiko yoyote ya kuburudika bila wasiwasi?				
	Je unatoa udhuru mara kwa mara ukialikwa katika mikusanyiko ya burudani?				
	Je unapata ugumu wa kujiburudisha au unasikitika endapo unagundua kuwa watu wana wasiwasi kuhusu mwili wako?				