AN ASSESSMENT OF THE EFFECT OF A PEANUT BASED READY-TO-USE NUTRITIONAL SUPPLEMENT ON HIV POSITIVE ADULTS ON ANTIRETROVIRAL THERAPY, ATTENDING THE 1000 HILLS COMMUNITY HELPERS CENTRE, DURBAN, KWAZULU-NATAL

BY

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PREFACE

The work within this dissertation was conducted in the School of Agricultural, Earth and Environmental Sciences at the University of KwaZulu-Natal. The supervisor was Professor Frederick J Veldman.

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As supervisor of the candidate I agree to the submission of this dissertation.

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Professor Frederick J Veldman (Supervisor)

DECLARATION

I, Mphilonhle Vuyani Sibongeleni Ncwane, identity number 8906205547086 and student number 207508697, declare that the work in this dissertation submitted to the University of KwaZulu-Natal, School of Agricultural, Earth and Environmental Sciences is my own independent work, except where otherwise stated. The work in this dissertation has not been submitted for any degree before to any tertiary institution by me or any other person. Data from other sources used in this dissertation has been appropriately acknowledged and referenced.

Signed: _____ Date _____

Mphilonhle Vuyani Sibongeleni (candidate)

ABSTRACT

Introduction: The aim of this study was to assess the nutritional effect of a peanut based ready-to-use food supplement (RUSF) [*Sibusiso*®] on HIV positive adults on antiretroviral therapy (ART).

Objectives: (1) To determine whether the BMI of HIV positive adults on ART supplemented with RUSF was improved after a three months supplementation period. (2) To determine the most predominant self reported disease symptoms experienced by HIV positive adults on ART at baseline assessment. (3) To determine whether predominant disease symptoms experienced by HIV positive adults in ART improved after supplementation with *Sibusiso*® RUSF. (4) To determine whether appetite, meal consumption and energy levels improved among HIV positive adults on ART supplemented with *Sibusiso*® RUSF. (5) To determine if there was any observed changes in body fat distribution in HIV positive adults on ART after being supplemented with *Sibusiso*® RUSF.

Materials and methods: This is a non randomised descriptive study whereby data was collected using a cross-sectional method. It included 50 HIV positive adults (between 20 and 78 years of age) on antiretroviral therapy, attending the 1000 hills community helpers' centre, Durban, KwaZulu-Natal. A monitoring tool was used to collect data on anthropometrical measurements (weight and height), disease symptoms experienced, disease conditions identified by the researcher/research assistants, level of appetite, meal frequency consumption and energy for each subject for a period of three consecutive months. Twenty participants were interviewed to assess the body fat distribution after using the supplement using a self reporting method.

Results and discussions: Study findings suggest that supplementation with RUSF for at least three months has a potential to gradually improve weight gain among HIV-positive adults on ART. The most self reported predominant disease symptom experienced before supplementation was fever, followed by nausea and persistent diarrhoea. This was in keeping with the results from other studies. After supplementation, there was a significant improvement in fever and gastroenteritis and steady but statistically significant decline in vomiting. However there was non-significant improvement in nausea and no change in persistent diarrhoea. RUSF in this study was also found to exert a beneficial effect on appetite, meal consumption and energy levels of participants. The study showed that short-term supplementation with RUSF is highly unlikely to result in lipodystrophy.

Conclusion: The administration of the nutrition supplement *Sibusiso*® RUSF for at least three months, in conjunction with the use of ART, was found to improve nutritional status in HIV patients under the controlled condition. *Sibusiso*® RUSF was able to improve the episode of fever which was most dominant disease symptom at baseline while improving gastroenteritis and vomiting. However it did not have an impact on reducing the episodes of nausea and persistent diarrhoea. *Sibusiso*® RUSF was also able to improve appetite, meal consumption and energy of participants after a three month period.

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This dissertation is dedicated to my late grandfather, uMgcinwa, u2-sheleni.

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CHAPTER 1
INTRODUCTION, THE PROBLEM AND ITS SETTING

1.1 Importance of the study

Human Immunodeficiency Virus (HIV) is a retrovirus that infects cells of the immune system and impairs the body's natural defence against disease and infection (United State Agency of International Developments [USAID] 2001). The most advanced stage of HIV is known as Acquired Immune Deficiency Syndrome (AIDS) (USAID 2001), which has become the most deadly disease mankind has ever faced (Joint United Nations Programme on HIV/AIDS [UNAIDS] 2001). This disease is currently not curable anywhere in the world, therefore, an individual diagnosed with HIV has a lifetime of disease to management (UNAIDS 2001). According to the UNAIDS (2013) report, worldwide, 35.3 (32.2–38.8) million people were estimated to be infected with HIV in 2012. However, the number of AIDS deaths had declined by 1.6 (1.4–1.9) million AIDS deaths in 2012, down from 2.3 (2.1–2.6) million in 2005. This report further stipulates that the Sub-Saharan Africa region host the world's worst HIV/AIDS epidemic and HIV is now defined as one of the major public health concerns in the region. This is despite the 34% reduction in an annual number of new infections in the region since 2001. Approximately 6.1 million of South African people were HIV infected in 2012, an increase from 4.3 million in 2002 (UNAIDS 2013), with young adults living in informal settlements being the most vulnerable group (UNAIDS 2013; O'Hara, Garbharran, Edwards & Smith 2003). Although there is a reported global decrease in estimated AIDS deaths, an estimated 240 000 deaths were reported in South Africa, an increase from 200 000 in 2001 (UNAIDS 2013).

The major identified challenges with HIV and AIDS is that it is often accompanied by poor nutritional status of those infected or affected (Anabwani & Navario 2006). Hence, the South African government developed an operational plan for comprehensive HIV/AIDS care management and treatment (DoH 2003). Nutrition care and support (NCS) was integrated into this plan with the purpose of improving nutritional status of HIV infected individuals (Ncayiyana 2007). This plan thus enabled South Africans to access a full array of interventions including nutrition related interventions (nutrition assessment and counselling,

and food supplements when it is necessary) at an early stage (DoH 2003). According to the recently updated guidelines emanated from the plan, antiretroviral therapy (ART) will be initiated in adults and adolescents with the CD4+ cell counts $\leq 350/mm^3$ (DoH 2010). According to the UNAIDS global report (2013) the number of people receiving antiretroviral treatment in South Africa reached more than 2.15 million in 2012.

Malnutrition, including both overnutrition and undernutrition, is a health problem directly and indirectly contributing towards high rates of morbidity and mortality globally, but more particularly in developing countries (Müller & Krawinkel 2005). South Africa is faced with a double burden of diseases, with a high prevalence of both under- and overnutrition (Vorster 2010; Faber & Wenhold 2007). In Sub Saharan Africa, HIV has been associated with worsening malnutrition, characterized by substantial weight loss and high prevalence of underweight (Nnyepi 2009). There are several other factors contributing to higher risk of undernutrition in people living with HIV/ AIDS (PLWHA) which include reduced food intake (due oral thrush and/or vomiting), physiological/functional changes, the presence of opportunistic infections, and side effects (such as loss of appetite, nausea, and diarrhoea) from the HIV/AIDS/TB medication (Maldey, Haile & Shumye 2014; Regional Centre for Quality of Health Care (RCQHC) 2004; Piwoz & Preble 2000; Semba & Tang 1999). Other factors, such as adverse socioeconomic conditions, poor housing conditions, water supply and sanitation also contribute to the problem of malnutrition (Hailemariam, Bule & Ayele 2013; Sguassero, Onis, Carroli 2010). South Africa is faced with a double burden of disease, with a high prevalence of both under- and overnutrition (Vorster 2010; Faber & Wenhold 2007). Although nutrition has a role to play in the overall management of HIV (Ncayiyana 2007), to date there are very little published scientific literatures on strategic interventions on the overall management of HIV. Therefore, the lack of nutrition related studies in South Africa targeting PLWHA is a concern.

Ready-to-use supplementary foods (RUSFs) were originally developed to reduce the incidence of malnutrition and treat malnutrition among children and adults (Scherbaum, Shapiro, Purwestri, Inayati, Novianty, Stütz, Yusran, Müller, Wirawan & Suryantan 2009; World Health Organization (WHO) 2007). RUSFs as a perceived solution to malnutrition worldwide (Scherbaum *et al* 2009), were made available in various forms such as compressed bars, biscuits and micronutrient powders, lipid-based nutrient supplements, and high-quality

vegetable oil and pastes (de Pee & Bloem 2009). A RUSF called *Sibusiso*® is a peanut and soya paste fortified with micronutrients and macronutrients that was developed by the South African non-governmental organization (NGO), the Gift of the Givers Foundation (GOTG) in more or less a decade ago (Gift of The Givers 2010). *Sibusiso*® RUSF was primarily used for prevention of weight loss and resulting malnutrition before the implementation of the first South African National Comprehensive HIV and AIDS Treatment programme. Even though there was no scientific backing to its success, there was a huge demand for it in the market (Pronsky, Meyer & Fields-Gardner 2001).

Since nutrition intervention remains important in the management of HIV, *Sibusiso*® ready-to-use supplementary food is still used. *Sibusiso*® RUSF has been claimed to benefit individuals under a variety of pathological conditions, including malnutrition, HIV and TB (GOTG 2010; Appendix A). However, up to now all evidence regarding its affectivity is anecdotal in nature. Besides that, several studies have been done on the effectiveness of pharmaceutical supplements (Friis 2005; Fawzi, Msamanga, Spiegelman, Kapiga, Villamor, Mwakagile, Mugusi, Hertzmark, Essex, Hunter 2004; Kupka & Fawzi 2002) and corn based supplements on nutritional status (Ndekha, van Oosterhout, Zijlstra, Manary, Saloojee & Manary 2009), but thus far there are still limited published studies on the impact of peanut/soya milk based pastes enriched with micronutrients supplements on HIV positive adults on ART. It is therefore important to scientifically determine the success of peanut based supplementation being implemented on HIV positive adults on ART. The present study will provide clinical evidence based on scientific research, under controlled condition and on adult population.

1.2 Background on the 1000 hills community helpers' centre

The 1000 hills community helpers' centre provides services to people of Inchanga, Fredville and surrounding areas. The 1000 hills community helpers' centre was established in 1989 initially as a community feeding programme. In 1990 it was realized that community members were in need of medical assistance due to the impact of HIV/Aids related illnesses. It was then decided to start up a basic clinic followed by an infant nutritional program. Medical volunteers were subsequently sourced to assist in providing this service, later joined by a pediatrician as well as five registered nursing sisters. In response to the needs of the

community, it was converted to community care centre in 2008 comprising of a health and wellness clinic, children's infirmary, education and development facility. The main services that are offered at present are HIV treatment, clinics, a feeding scheme, counselling, home-based care, and the support groups.

1.3 Statement of research problem

Sibusiso®, a peanut/soya based ready-to-use supplementary food with a potential to be a relevant and effective nutrition intervention for Africa, has been used widely with growing anecdotal evidence of it success. The main research question is whether giving *Sibusiso*® RUSF will have any beneficial effect on improving the disease condition on HIV positive adults on ART attending 1000 hills community helpers' centre, Durban, KwaZulu Natal. Supplementing HIV positive patients with a *Sibusiso*® RUSF was envisaged to help provide optimum nutrition, promote weight gain, and as a result alleviate the burden of malnutrition and complications that are associated with the poor nutritional status.

1.4 Study design

This research is a descriptive study whereby data was collected using a non-randomised cross-sectional method. The study was conducted in year 2012 on 50 participants. It included of forthy-four female and six male adults on antiretroviral therapy. Participants were between the age of 20 and 78 years living in Inchanga, Fredville and surrounding areas, KwaZulu-Natal, attending the 1000 hills community helpers' centre. Participants were supplemented with *Sibusiso*® RUSF for a period of three months.

1.5 Objectives of the study

The objectives of this study were to:

1.5.1 determine whether the Body Mass Index (BMI) of HIV positive adults on ART supplemented with *Sibusiso*® RUSF was improved after a three months supplementation period.

1.5.2 determine the most predominant self reported disease symptoms experienced by HIV positive adults on ART at baseline.

1.5.3 determine whether predominant disease symptoms experienced by HIV positive adults on ART improved after supplementation with *Sibusiso*® RUSF.

1.5.4 determine whether appetite, meal consumption and energy levels improved among HIV positive adults on ART supplemented with *Sibusiso*® RUSF.

1.5.5 determine if there was any observed changes in body fat distribution in HIV positive adults on ART after being supplemented with *Sibusiso*® RUSF.

1.6 Hypotheses

The hypotheses of this study were as follows:

1.6.1 *Sibusiso*® RUSF will contribute to an increase in the BMI of HIV positive adults on ART after a three months supplementation period.

1.6.2 Diarrhoea, nausea and vomiting will be the most predominant self reported disease symptoms experienced by HIV positive adults on ART at baseline as a result of the diseases.

1.6.3 *Sibusiso*® RUSF will improve the predominant disease symptoms experienced by HIV positive adults on ART improved after a three months supplementation period.

1.6.4 *Sibusiso*® RUSF will improve appetite, meal consumption and energy levels among HIV positive adults on ART after a three months supplementation period.

1.6.5 There will be no observable changes in body fat distribution in HIV positive adults on ART after being supplemented with *Sibusiso*® RUSF.

1.7 Study limitations

The limitations were imposed by the slightly poor adherence to the supplementary programme, nevertheless the study was planned as an "intention-to-treat" study. The majority of men were not compliant with the intervention to be part of the data to be analysed since their visits were inconsistent, non-consecutive and they withdraw early. This resulted in gender imbalance and a reduced sample size. Although the current study assessed the frequency of consumption of certain foods for the purpose of identifying dietary practices, it was unable to measure dietary intake at recruitment or during intervention. Hence, the current study did not have information on average intake of energy, the micronutrient and macronutrients composition of baseline diet or information on energy received from

household foods. This was going to reveal the extent to which normal eating pattern of the participants possible factored into weight gain.

1.8 Study parameters and general assumptions

In order for the hypotheses of this study to be tested successfully, it was assumed that:

- *Sibusiso*® RUSF was provided in addition to other meals and did not replace any of the meals in order to promote weight gain;
- Participants did not have any other disease conditions or symptoms other than that identified by the monitoring tool during the supplementation period; and
- None of the participants had nut allergies.

1.9. Operational Definitions

- **Antiretroviral drugs**: Drugs that act against a retrovirus by almost completely suppressing its replication at different stages of its life cycle (Stedman 2008).
- **Fever:** An abnormal elevation of body temperature in response to some disease or illness. A fever may be accompanied by symptoms such as shivering, headache, sweating, thirst, faster-than-normal breathing and a flushed face (Peters 2007).
- **Gastroenteritis:** Inflammation of the digestive track particularly the stomach and intestines, usually causing sudden upsets that last for two or three days. Appetite loss, nausea, vomiting and diarrhoea are the usual symptoms (Peters 2007).
- **Lipodystrophy:** a change in body fat distribution in the body which can be in two forms, which include lipohypertrophy which referred to a generalized fat gain in the specific area and lipoatrophy referred to a generalized fat wasting in the specific areas (Leach-Lemens 2009).
- **Macronutrients:** For the purposes of this study, macronutrients refer to carbohydrate, fat, and protein.
- **Malnutrition**: Imbalance, excess or lack of proper nutrient consumption leading to overnutrition or undernutrition [World Food Programme (WFP) 2012].
- **Nausea:** The uneasiness sensation of the stomach that perpetrates an urge to vomit (Peters 2007).

- **Nutritional status:** The nutritional health of a individual as determined by anthropometric measurements (weight, height, etc), biochemical measurements of nutrients, physical examination and/or a dietary analysis (DoH 2007).
- **Opportunistic infections:** Infections that are more frequent or severe due to immunosuppression, especially in the presence of diseases such as HIV (Aidsinfo 2008)
- **Oral thrush:** A fungal infection caused by *Candida albicans* that affects the mouth, characterized by painless, creamy white, plaque-like lesions of the tongue surface (Peters 2007).
- **Ready-to-use supplementary food**: High energy peanut based pastes fortified with high levels of nutrients during processing, higher than in the normal fortification process, it is used for the prevention of acute malnutrition or chronic malnutrition (Latham, Jonsson, Sterken & Kent 2011).
- **Ready-to-use therapeutic food**: A generic term of high energy and nutrient-dense food or food product designed to provide similar nutritional profile as that of the F-100 therapeutic milk. It is generally used in a rehabilitation treatment phase of severe acute malnutrition as a sole source of food except for water or breastmilk (Latham *et al* 2011; Collins & Sadler 2002).
- **Supplementary feeding**: The provision of extra food to children or families beyond the normal ration of their home diets (Sguassero, de Onis & Carroli 2005)
- **Medication side effects:** Any reaction to or consequence of a medication or therapy. Usually, although not necessarily, the effect is undesirable and may manifest itself as nausea, dry mouth, dizziness, blurred vision, discoloured urine or tinnitus (Anderson 2009).
- **Tuberculosis (commonly referred to as TB):** Occurs when a susceptible individual inhale a nuclei droplet containing the bacterium *Mycobacterium tuberculosis*. The primary infection is usually asymptomatic (Latent TB infection). Progressive infection in lungs causes coughing (sometimes with blood stained sputum), chest pain, shortness of breath, fever, night sweating, poor appetite and weight loss (Aidsinfo 2008; Peters 2007).

1.10 Abbreviations

AI	Adequate intake
ART	Antiretroviral therapy
ARV	Antiretroviral drugs
BMI	Body Mass Index
CVD	Cardiovascular diseases
DoA	Department of Agriculture
DoH	Department of health
DRI	Dietary Reference Intake
FAO	Food and Agriculture Organization
GOTG	Gift of the Givers Foundation
FIVIMS	Food Insecurity and Vulnerability Information Mapping System
HAART	Highly Active Antiretroviral Therapy
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HSRC	Human Science Research Council
INP	Integrated Nutrition Programme
IRR	Incidence Rate Ratio
KZN	KwaZulu-Natal
LBM	Lean Body Mass
LDS	Lipodystrophy Syndrome
NGO	Non-Governmental Organisation
PEM	Protein-Energy Malnutrition
PLWHA	People Living With HIV/AIDS
RDI	Recommended Dietary Intake
REE	Resting Energy Expenditure
RUSF	Ready-To-Use Supplementary Food
RUTF	Ready-To-Use Therapeutic Foods
SPSS	Statistical Package for Social Sciences
StatsSA	Statistics South Africa
TB	Tuberculosis
UKZN	University of KwaZulu-Natal

UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	The United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WFP	World Food Programme

1.11 Summary

The prevalence of malnutrition in South Africa is high and impact greatly on mortality and morbidity. Confounding the problem of malnutrition is HIV infection which is highly prevalent among the poor and further contributes to poor survival. Appropriate nutrition interventions aimed at decreasing the rates of malnutrition are required. RUSFs among other benefits, have been found to have positive effects on weight gain among malnourished patients. Hence, this study aimed to determine whether a *Sibusiso*® RUSF produced by the Gift of the Givers Foundation would promote weight gain among HIV adults on ART. The participants included in this study were from a community of low socio-economic status. By supplementing PLWHA for a period of three months, the RUSF could promote weight gain, reduce disease symptoms, improve appetite, and thereby alleviate the burden of malnutrition.

1.12 Outline of the dissertation

The layout of the dissertation is as follows:
Chapter 1: Introduction, the problem and its setting
Chapter 2: Literature review
Chapter 3: Methodology
Chapter 4: Results
Chapter 5: Discussion
Chapter 6: Conclusions and Implications for further research

This dissertation was referenced according to the guidelines used in the Programme of Dietetics and Human Nutrition, University of KwaZulu-Natal, Pietermaritzburg.

CHAPTER 2
LITERATURE REVIEW

2.1. Introduction

In this chapter the prevalence of HIV globally and in South Africa, interaction between nutrition and HIV/AIDS, the factors that contribute to malnutrition, the nutritional status and nutritional needs of HIV infected patients will be reviewed. Available long and short term strategies developed to alleviate malnutrition in PLWHA will be reviewed. At the end, the effect of *Sibusiso*® RUSF on nutritional status, diseases symptoms and on body fat distribution will also be reviewed.

2.2. Prevalence of HIV globally, and in South Africa

UNAIDS (2013) reported that in 2012 an estimated 35.3 (32.2–38.8) million people were living with HIV globally. There was a notable sharp decline in new infections globally, from 3.4 (3.1–3.7) million in 2001 to 2.3 (1.9–2.7) million in 2012. At the same time the number of AIDS deaths also declined from 1.6 (1.4–1.9) million AIDS deaths in 2012, down from 2.3 (2.1–2.6) million in 2005. The report further stipulates that the far largest concentration of HIV/AIDS is in the developing world and Sub-Saharan Africa in particular where more than 70% of the population were affected in 2012. UNAIDS (2013) revealed that despite this devastating condition, sub-Saharan Africa has achieved a notable reduction (approximately 37%) in HIV prevalence between 2001 and 2012. Even with these favourable trends, HIV prevalence among young women remains more than twice as high as among young men throughout sub-Saharan Africa. UNAIDS (2013) further stipulates that in South Africa, HIV infection increased from 4.3 million to 6.1 million between 2001 and 2012. In addition, the number of HIV deaths increased from 200 000 to 240 000 between 2001 and 2012. Global AIDS response progress report (2012) documented that there is a wide variation in HIV/TB prevalence by age, race, gender, socio-economic status and geographical location. This report specified that in the past twenty years, among nine provinces of South Africa, KwaZulu-Natal was the most affected among the 15-49 year olds and the HIV prevalence remained stable at 39.5% on 2009 and 2010.

2.3. Food security, nutrition and HIV/AIDS

The HIV/AIDS epidemic is having an extensive effect on health, nutrition, food security and overall socioeconomic development in countries that have been greatly affected by the disease (WHO 2003). According to the South African government, food security "is achieved when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food, to meet their dietary needs and food preferences for an active and healthy life" (Department of Agriculture [DoA] 2002). In sub-Saharan Africa where HIV has reached epidemic, 400 million people were threatened by food insecurity by the turn of the 21st century (Hattingh, Walsh, Veldman, Bester 2007; Steyn & Walker 2000). In 2004, the Human Science Research Council (HSRC) as cited by [Development Bank of Southern Africa (DBSA) 2008] estimated that 14 million South Africans were food insecure. The HSRC (2005) reported on the survey conducted in Sekhukhune to pilot the development of a food insecurity and vulnerability modelling system (FIVIMS) for South Africa. The report revealed that South Africa is producing enough food to feed its population. However, there is still a large scale of hunger, even with a decline in South African households vulnerable to hunger over the past decade from 23.8 to 11.5 between 2002 and 2011 (Statistics South Africa [StatsSA] 2012). Furthermore, a number of households did not have a diet that is diverse to allow for optimal nutritional status (StatsSA 2012). In settings where poverty and lack of access to care prevails, malnutrition also becomes prevalent (Nnyepi 2009). WHO (2003) reported that the HIV/AIDS epidemic also seem to be disturbing in populations where malnutrition is already an endemic. Semba & Tang (1999) stipulated that HIV and poor nutrition form part of a typical vicious cycle compounded by the emergence of micronutrient deficiencies, malnutrition-related immune suppression, and oxidative stress increasing the susceptibility to faster disease progression and high mortality rate (See figure 2.1 below illustrating the cycle of HIV/AIDS and malnutrition).

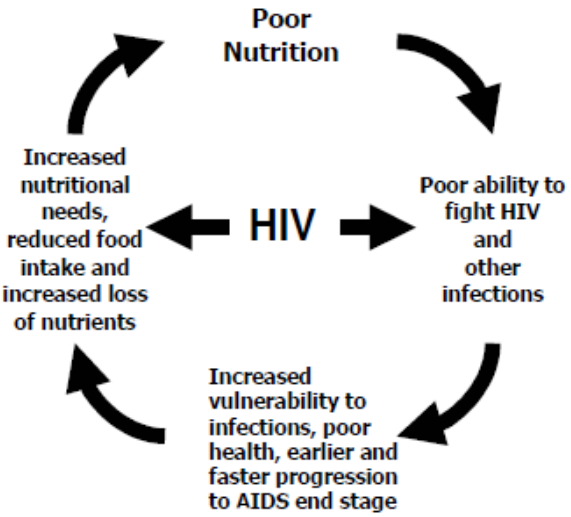


Figure 2.1: Cycle of HIV/AIDS and malnutrition (Semba & Tang 1999)

The HSRC (2005) report stipulated that in the post apartheid era, urbanisation and declining agrarian activities have been profound and had transformed the South African economy into a wage economy with most citizens accessing food via purchase rather than producing food for themselves. Even in rural areas, most households' access to food is partially or wholly reliant on household income. According to Polzer and Schuring (2003) malnutrition persists due to poor access to food by certain parts of the population and not as a result of overall shortage of food in the country. Among the poor who by definition are characterised by unemployment, the majority of income is accrued in the form of insecure/informal jobs, the government social welfare safety net of old age pensions and child support grants, and private transfers from working relatives and neighbours (DoA 2002). As a result, food security is largely influenced by direct or indirect access to cash in order to purchase food.

The persistence and severity of poverty and food insecurity is directly or indirectly aggravated by the HIV pandemic which in turn increases the risk of intergenerational malnutrition (Hailemariam *et al* 2013; Theodore 2009; Department of Health [DoH] 2007). An interwoven relationship between poverty and HIV/AIDS has been noted; they have a complex bidirectional relationship that has been proven over the years (Theodore 2009). The Food and Agricultural Organisation (FAO) (2008) stated that HIV/AIDS normally affects the household's most productive members first. When these individuals become ill, their ability to work, feed themselves and provide care to their families become compromised. When HIV has affected the family economy factor, food and nutrient intake consequently become adversely affected and the disease progresses even further (Hailemariam *et al* 2013). As the

disease progresses further, resources are drained. For example, valuable assets may need to be sold in order to pay for food and medical expenses, and adoption of harmful coping strategies such as children dropping out of school, all contribute to poverty advancement (Theodore 2009). As a result of living in poverty, individuals with HIV sometimes adopt risky behaviours such as sex work in order to generate income as another coping strategy which further exacerbates the spread of HIV and obviously malnutrition (FAO 2008).

In 2002 South Africa adopted an integrated food security strategy aimed at eradicating hunger, malnutrition and food security by 2015. One of the strategic objectives is to improve nutritional status (DoA 2002). WHO (2003) suggested that in spite of existing food insecurity, interventions aimed at improving the nutrition of PLWHA should be based on sound scientific evidence, local resources, and programmatic and clinical experience with the prevention, treatment, and management of the disease and related infections. WHO (2003) further acknowledged the gaps in available scientific knowledge regarding the interventions aimed at improving the nutrition of PLWHA. This justifies a need for the study on RUSFs since it is an intervention with a lot of resources invested in it.

2.4. Nutrition and immunity in HIV/AIDS

Nutrition has been a important factor in the management of HIV infection since early in the history of HIV/AIDS epidemic (Hattingh *et al* 2007). Hence, the relationship between nutrition and HIV has gained substantial attention from scientists and PLWHA. The main objective in the emphasis of nutrition in the management of HIV/AIDS is to maintain weight and strengthen the immune system (South African HIV Clinicians Society Expert Committee 2004). Malnutrition and HIV compromise the immune system which ultimately facilitates disease progression and affects the overall clinical outcome (Hailemariam et al 2013). Therefore, malnutrition plays a major role in HIV related mortality and morbidity, as well as the functional status and overall quality of life (Hailemariam *et al* 2013; Hattingh *et al* 2007). Conversely, optimal nutrition has been shown to have positive impact on immunity with some nutrients associated with antibody production and reducing susceptibility to co-infection such as HIV/Tuberculosis (TB) (Lategan, Steenkamp, Joubert & Le Roux 2010).

According to UNAIDS (2013), tuberculosis remains the leading cause of death among PLWHA. Globally, PLWHA accounted for 1.1 million (13%) of the estimated 8.7 million individuals who globally developed tuberculosis in 2012. Of the 2.8 million people with tuberculosis who received an HIV test result in 2012, 20% tested HIV-positive. The report further stipulates that 42% of those who tested HIV positive were from the sub-Saharan Africa. Frieden, Sterling, Munsiff, Watt and Dye (2003) reported that the increasing prevalence of HIV/TB co-infection is of concern in Africa with more than 60% contributed by Botswana, Zambia, Zimbabwe and South Africa. South Africa is the leading African country with 2 million co-infected adults which is double the number of the second leading country (WHO 2011). UNAIDS (2013) revealed that the world has made substantial progress towards reducing the prevalence of TB related mortality, with a notable 36% decline between 2004 and 2012. However in South Africa, change in TB related deaths among PLWHA during the same period was approximately 11.1%. In addition, TB was reported to be the leading cause of death for PLWHA in 2011.

South Africa's challenge of the HIV/TB co-infection pandemic is also coupled with malnutrition referred to as "triple trouble" (Chaparro & Diene 2009). Provinces which are most affected with a high percentage of co-infected individuals are; KwaZulu-Natal, Gauteng and Mpumalanga because of the fast-growing rate of the HIV infection (Fourie 2006). TB-related illnesses can also contribute to malnutrition due to increased nutrient requirements (Saunders, Smith & Stroud 2011). In South Africa HIV and TB services have been integrated (UNAIDS 2013). The number of PLWHA and receiving ARVs increased to more than 2.5 million in 2012 and all PLWHA received screening for TB at every clinic visit (UNAIDS 2013). Moreover, the best possible intervention that will address malnutrition, strengthen the immune system and reduce the risk of co-infection with opportunistic infections is fundamentally required.

2.5. Changes in anthropometric status and nutritional status of HIV infected adults

When HIV was first discovered, it was labelled a slim disease, since weight loss was a prominent feature of the disease (Marston & De Cock 2004). Weight loss is still associated with progression of HIV infection (Onyango, Walingo, Mbagaya & Kakai 2012; Wheeler, Gibert, Launer, Muurahainen, Elion, Abrams & Bartsch 1998). Bartlett, Hirsch & Mitty

(2013) reported that there is uncertainty whether weight loss is a cause of progression or a marker of disease severity. However, it has been suggested that weight loss/wasting cannot be an effect of HIV *per se* but an end result of opportunistic infections. Macallan, Noble, Baldwin, Foskett, McManus & Griffin (1993) stated that weight may remain stable even if the patient is not on ART. However, weight recovery is still achieved with the best possible treatment of infections.

Body mass index (BMI) is used to determine a healthy body weight and is calculated by dividing the patient's weight (kg) by height squared (m^2) (Venter, Gericke & Bekker 2009). The South African HIV Clinicians Society Expert Committee (2004) stated that a BMI of less than 18.5 kg/m^2 is an independent predictor of a high mortality risk. Hence, BMI is assessed and recorded at each clinic visit as part of malnutrition risk identification. Babameto & Kotler (1997) reported that weight loss is often the event that begins a vicious circle of increased fatigue and a decrease in physical activity, including the inability to prepare and consume food by the patient living with HIV/AIDS. A weight loss of more than 10% of initial body mass has been associated with a decline in physical performance, and 20% weight loss is associated with hospitalisation (South African HIV Clinicians Society Expert Committee 2004).

Weight loss and wasting in AIDS patients are multi-factorial in etiology, with inadequate intake, nutrient malabsorption and metabolic disturbance as most prominent determinants (South African HIV Clinicians Society Expert Committee 2004). HIV related wasting typically follows two patterns, which are the slow and persistent weight loss from anorexia and gastrointestinal disorders, and a rapid, intermittent weight loss from secondary infections (Macallan 1999).

The first type of HIV-related wasting syndrome is described as starvation-related wasting resulting from consistent voluntary or involuntary food deprivation in patients who have not manifested opportunistic infections (South African HIV Clinicians Society Expert Committee 2004). Patients presenting with this type of wasting react positively to nutrition support and feeding which typically reverse starvation (South African HIV Clinicians Society Expert Committee 2004).

The second type of HIV related wasting is typical of cachexia, characterized by a predominant loss of lean body mass caused by alteration of metabolism (South African HIV Clinicians

Society Expert Committee 2004). Cachexia has been described as one of the major causes of morbidity and mortality in relation to HIV infection (Castetbon, Kadio, Bondurand, Boka Yao, Barouan, Coulibaly, Anglaret, Msellati, Malvy & Dabis 1997). The South African HIV Clinicians Society Expert Committee (2004) described this type of wasting as a condition that prevails during stress states such as sepsis, trauma, or surgery. This is a type of wasting is irreversible by solely food intake or feeding as an intervention (South African HIV Clinicians Society Expert Committee 2004; Macallan 1999). Macallan (1999) stated that therapeutic strategies do not reverse depletion of lean body mass (LBM), but have been reported to mainly increase body fat and water.

According to Salomon, de Truchis and Melchior (2002), "It is critically important to identify and characterize early risk factors for wasting in HIV infected patients and to monitor wasting with a standardized set of strategies for diagnosis, surveillance and appropriate treatment"

2.6. Factors that contribute to HIV/AIDS related malnutrition

The following section will review the factors that lead to malnutrition in HIV/AIDS. These factors include decreased nutrient intake, nutrients malabsoption, metabolic alteration and depletion of antioxidant nutrients.

2.6.1. Insufficient nutrient intake and increased nutrient losses

In all stages of HIV infection, emphasis is placed on a healthy eating pattern and a balanced diet (WHO, FAO 2002; USAID 2001). An unbalanced diet deficient in macronutrients can result in a decreased energy intake (Macallan 1999) and ultimately weight loss (USAID 2001; Macallan 1999). Decreased food intake can result in severe loss of body cell mass and ultimately to death (Madley, Haile & Shumye 2014).

There are several reasons for an inadequate nutrient intake in HIV disease (Gramlich & Mascioli, 1995). MacArthur & DuPont (2012) reported that nausea and vomiting are common complications among patients with HIV infection and AIDS, since the gastrointestinal tract is a primary target during an episode of acute infection. According to WHO, FAO (2002), nausea and vomiting impede adequate food intake. Nausea is suggested to be caused by multiple factors, such as infection, dehydration, stress, certain foods and it can also be a side effect of certain medications including ARVs (WHO, FAO 2002). Other

serious gastrointestinal disorders such as pancreatitis and malignancies are very rare (MacArthur & DuPont 2012). Anorexia, central nervous system disease, dysphagia and odynophagia are among other factors that may affect micronutrient intake during HIV infection, resulting in failure to meet dietary requirements (USAID 2001; Semba & Tang 1999).

Fever is a common complication in HIV infected individuals, possibly caused by a compromised immune system due to infection (WHO, FAO 2002). In the study conducted by Ahoua, Umutoni, Huerga, Minetti, Szumilin, Balkan, Olson, Nicholas, Pujades-Rodríguez (2011) in Uganda and Kenya, findings were that at study enrolment, among the most frequently diagnosed opportunistic infections, fever of unknown aetiology was evident. WHO, FAO (2002) put forward the fact that fever increases the demand for energy and nutrients which are both fundamental in fighting the infection. However, fever and commonly occurring infections reduce the intake of food in HIV positive patients by altering the patient's appetite (USAID 2001). According to Saunders & Smith (2010), a reduction of food intake is the most distracting factor in the management of disease-related malnutrition. Reduction of food intake weakens the immune system and increase susceptibility to opportunistic infections such as TB. Opportunistic infection such as TB results in changes in the secretion of cytokines, glucocorticoids, peptides, insulin and insulin-like growth factors which also leads to loss of appetite and ultimately reduce food intake (Avert 2011; Saunders *et al* 2011; Suttajit 2007). In a study conducted by Castetbon *et al* (1997) in HIV-infected outpatients in Abidjan, Côte D'Ivoire, West Africa, 45 percent of symptomatic patients particularly reported appetite related problems. Patients who reported appetite related problems also demonstrated an impaired anthropometric status (Castetbon *et al* 1997).

A RCQHC (2004) report stated that poor appetite can be a side effect of ARV drugs such as zidovudine (ZDV), lamivudine (3TC) and stavudine (d4T). Appetite can also be influenced by the perceived smell and taste of food, especially in older individuals since the sensitivity to sensory property declines with age (Zandstra & de Graaf 1998). Other conditions such as Herpes simplex, aphtous ulcers, or cytomegalovirus may lead to smell and taste alterations (Babameto & Kotler 1997), with physical impairments in the oropharyngeal or esophageal area (Fenton & Silverman 2004). Due to discomfort with chewing and swallowing, patients can limit their intake resulting in weight loss (Fenton & Silverman 2004; USAID 2001). For

example, some patients limit their food intake due to infection such as candidiasis, an infection caused by Candida yeast (USAIDS 2001).

According to MacArthur & DuPont (2012) diarrhoea is a frequent symptom of HIV/AIDS, with up to 60% of PLWHA reporting to being affected. In African adults, chronic diarrhoea has been used as a predictor of HIV-seropositivity (Wilcox, Wanke, Bartlett & Mitty 2013). In the HIV infected individuals, it remains a strong predictor of morbidity and mortality (MacArthur & DuPont 2012; Nel 2010). Diarrhoea has a multitude of aetiologies with HIV itself being a potential cause. The virus can infect the cells in the gastrointestinal tract and cause immune damage, especially to gut-associated lymphoid tissue [GALT] (Wilcox *et al* 2003). Other potential causes of diarrhoea include: consuming contaminated food as a result of inadequate food and water hygiene; infectious pathogens; some drug therapies (Wilcox *et al* 2003); and bacteria and protozoa such as *Cryptosporidium, Microsporidium, atypical Mycobacteria* (Sharpstone & Gazzard Gazzard 1996).

In South Africa, between 2005 and 2007, the Eastern Cape and KwaZulu Natal had the second lowest access to free potable water within a 200 meter radius (Barron, Day & Monticelli 2007). This poor access to safe water might be one of the factors contributing to diarrhoea among certain parts of the South African population. A decline in the incidence of infectious causes of diarrhoea has been noted in well resourced countries where HAART is freely available (Wilcox *et al* 2003). Even so, HAART (particularly protease inhibitor ritonavir) itself has been associated with medication-induced diarrhoea which may damage the intestinal epithelial barrier (leaky-flux diarrhoea) and/or alter chloride ion secretion (MacArthur & DuPont 2012). The interaction between diarrhoea and malnutrition is bidirectional, as diarrhoea leads to malnutrition while malnutrition exacerbates the increased risk of diarrhoea (MacArthur & DuPont 2012; Nel 2010; Wilcox *et al* 2003). The detrimental effect of diarrhoea is mainly due to increased nutrient losses, malabsorption, and the inflammatory response (Nel 2010). WHO, FAO (2002) revealed that diarrhoea also leads to water and mineral loss from the body. It can accelerate disease progression through dehydration, weight loss, nutrient malabsorption, and severe malnutrition if left unattended for a prolonged period (USAID 2001).

2.6.2. Malabsorption

Mason, Milovic, Lipman & Grover (2012) defined malabsorption as a condition of impaired nutrient absorption. Malabsoption is a common phenomenon of HIV infection (Jiménez-Expósito, Garcia-Lorda, Alonso-Villaverde, de Virgala, Sola, Masana, Arija, Izquierdo & Salas-Salvadó 1998), mainly due to usual episodes of diarrhoea experienced by patients infected with HIV/AIDS at some stage during the course of their illness (Fenton & Silverman 2004). HIV-related malabsorption has been associated nutritional deficiencies (Van der Hulst, von Meyenfeldt, van Kreel, Thunnissen, Brummer, Arends & Soeters 1998) and disease progression (Keating, Bjarnason, Somasundaram, Macpherson, Francis, Price, Sharpstone, Smithson, Menzies & Gazzard 1995). According to Mason *et al* (2012), malabsorption happens as an outcome of a defect in normal nutrient absorption. For example, defect in the luminal and brush border processing, or in the absorption into the intestinal mucosa or transport of nutrients into the circulation. Numerous researches have shows that nutrient malabsorption plays a major role in HIV-associated weight loss and wasting, regardless of sufficient energy consumption (Macallan 1999; Jiménez-Expósito *et al* 1998; Gramlich & Mascioli 1995; Lakshmipathi & Jastremski 1989).

Infection, either in the intestines or large bowel, can affect malabsorption of nutrients. Patients with intestinal infection of the small intestine have been recognized to suffer mostly from the malabsorption of carbohydrates, fats (Semba & Tang 1999; Jiménez-Expósito *et al* 1998) proteins, minerals, water and vitamins (USAID 2001). However, those with large bowel infections are allied with malabsorption of fluids and electrolytes (Fenton & Silverman 2004). The study conducted in San Francisco Hospital in United State of America found fat malabsorption (also known as steatorrhea) to be present in 50 percent of the sixty-one HIV-infected adults with or without diarrhoea (Koch, Garcia-Shelton, Neal, Chan, Weaver & Cello 1996). Since fat is the most energy dense nutrient, its malabsorption is a potential causative factor in weight loss (Mason *et al* 2012). Malabsorption of fat also reduces the absorption of the fat-soluble vitamins (vitamin A and E) which can compromise the immune system (USAID 2001; Semba & Tang 1999). Moreover, signs of nutrient deficiencies can manifest in some patients (Mason *et al* 2012). Therefore, malabsorption clearly can contribute to HIV-related malnutrition.

It is also worthwhile to mention that maldigestion is an established factor that interferes with nutrient absorption as it impairs the digestion of nutrients within the intestinal lumen or at the terminal digestive site of the brush border membrane of mucosal epithelial cell (Mason *et al* 2012).

2.7. Macronutrient requirements in HIV/AIDS infection

2.7.1. Energy

To maintain or achieve good health, an individual requires energy-providing nutrients. Macronutrients, namely carbohydrates, protein and fat are the main source of energy to the body. HIV positive patients have a markedly increased resting energy expenditure [REE] (Hattingh 2005), even when they are on ART (Mabaso 2012). According to Lakshmipathi & Jastremski (1989), inadequate macronutrient intake, malabsorption and metabolic disturbances in HIV are the underlying factors leading to increased REE which complicate the ability to meet energy requirement. These disturbances result in either a hypermetabolic state with active infection (Castleman, Seumo-Fosso & Cogill 2004; Food and Nutrition technical Assistance programme [FANTA] 2004; WHO 2003), or a higher mechanical workload, such as the increased use of energy for breathing in patients with respiratory discomfort (Hattingh 2005).

The WHO (2003) recommended that at the asymptomatic stage (WHO stage 1), energy requirements in PLWHA for maintaining body weight is 10% higher than that of healthy, uninfected individuals with the same energy variables, namely; age, gender and physical activity. During the period of illness (WHO stage 2 and subsequently AIDS), energy requirements are further increased by 20% - 30% more than that of healthy, uninfected individuals of the same age, gender and physical activity level (WHO 2003) to compensate for elevated REE (Avert 2011; FANTA 2004). Opportunistic infections can potentially increase energy requirements by 50 - 100% (Fawzi, Msamanga, Spiegelman & Hunter 2005). Hattingh (2005) stated that even though REE has been proven to increase, energy expenditure, studies showed no increase in overall total energy expenditure (TEE). Although the mechanism is not known, it is speculated that individuals compensate by reducing activity-related energy expenditure.

2.7.2. Protein

Diets that are adequate in protein may assist in improving a positive nitrogen balance and replenishing lean body mass (Onyango *et al* 2012). A suggested protein requirement of 1 to 1.4 g/kg body weight and 1.5 to 2 g/kg body weight are for weight maintenance, and to replenish lean body mass (excluding individuals suffering from severe hepatic or renal disease) is recommended respectively (Fenton & Silverman 2004). Malabsorption, common among PLWHA, has been proven to result in protein malnutrition and energy deficiency especially in underdeveloped countries (Lakshmipathi & Jastremski, 1989). Protein-energy deficiency is associated with an impaired immune system and increase disease progression (Onyango *et al* 2012). However, in spite of the above mentioned possible deficiency of protein among the HIV infected individuals, the WHO reported that there is insufficient evidence regarding protein requirements in HIV infected individuals. Hence, the protein requirements of PLWHA are the same as that of healthy, uninfected individuals with the same requirement factors such as age, gender and physical activity level (Avert 2011). The recommended protein intake is 12-15% of total energy (DoH 2007). Hattingh (2005) conducted a study on macronutrient intake of HIV seropositive and seronegative women of a low socio-economic status living in Mangaung, Free State Province, South Africa. The findings revealed that the median total protein intake of all women exceeded the dietary reference intake (DRI) of 46g/day. However, the results of protein intakes from other studies vary widely, ranging from inadequate to intake above recommended dietary intake (RDI). There was no intentional increase in protein intake due to HIV infection recommended because of insufficient scientific evidence to support it (WHO 2003).

2.7.3. Fats

The recommended 30-35 % of total energy needs (appropriately 80g) should come from fats as there are no special requirements for HIV infection (DoH 2007). The quality and type of dietary fat has been documented to either improve or suppress the immune function (Hattingh 2005). Antiretroviral (ARV) drugs may interact positively or negatively with foods that are high in fat (Pronsky *et al* 2001). Some studies have reported on the beneficial role of dietary fat, such as increasing the bioavailability of non-nucleoside reverse transcriptase inhibitor (NNRTI) drugs (WHO 2003). However, there is no data to suggest an increase in total dietary fat needs beyond normal requirements in HIV infected individuals (WHO 2003). In a

local study determining the macronutrient intake of HIV positive women, total fat intakes exceeded the DRI of less than 30 % of total daily energy intake (Hattingh 2005). This is not acceptable since excess intake of dietary fat has adverse effects on health. Hence, total fat intakes in HIV patients should be maintained as 30-35% of total energy with the exception of diarrhoea associated with more advanced stages of HIV infection (WHO 2003). Moreover, fat tolerance has also been suggested to vary amongst individuals (Fenton & Silvermann 2004). Thereby making special advice regarding fat intake for PLWHA is essential for better nutrient utilisation, metabolism, distribution or excretion and the effectiveness of specific drugs (Castleman *et al* 2004).

2.8. Micronutrient requirement in HIV/AIDS infection

According to Friis (2005), infection may lead to micronutrient deficiencies and micronutrient deficiencies may affect the risk of infectious disease morbidity. The role of micronutrients (vitamins and minerals) in the maintenance and functioning of the immune system and improvement of infectious disease is well established (Cunningham-Rundles, McNeeley & Moon 2005). However, the specific role of individual or/and multiple micronutrients in the prevention, care and treatment of HIV infection and related conditions merits further attention (WHO 2003). According to Hattingh *et al* (2007) moderate to severe micronutrient deficiency is common among HIV positive individuals, especially women. It has been documented that at the advanced stage of the HIV disease, deficiency of various vitamins dominate, leading to increased HIV progression, transmission and mortality (Kupka, Msamanga, Spiegelman, Morris, Mugusi, Hunter & Fawzi 2004). Despite the evidence that micronutrient requirements are likely to be reduced when the HIV patient initiates ART, micronutrient deficiencies may persist and may affect absorption and efficacy of the drugs (Friis 2005). Hence, HIV-infected people should consume diets that ensure micronutrient intakes at RDA levels (Castleman *et al* 2004; FANTA 2004). There is a possibility that the diet may not be sufficient to correct nutritional deficiencies in HIV infected individuals, even during the intake of ART due to a decreased food intake, increased nutrient needs and gastrointestinal malabsorption (Drain, Kupka, Mugusi & Fawzi 2007). Nutritional deficiency is noted especially in individuals from resource limited settings, as even before the infection set in, they consume an inadequate diet which fails to meet the nutritional requirements (FANTA 2004) and lack dietary diversification (DoH 2007).

Earlier studies from developed countries, before the use of ARV drugs, reported low serum levels of several micronutrient indicators such as vitamin A, carotenoids, vitamins B_6, vitamin B_{12}, vitamin C, vitamin E, folate, as well as selenium and zinc in adults (Friis 2005). In a study conducted in the Free State to investigate micronutrient intake among HIV positive individuals, the intake of fat soluble vitamins, folate and vitamin C was less than 67% of the RDI/adequate intake. In the same study, the intake of calcium, iron and selenium was also below 67% of the RDA (Hattingh *et al* 2007). This finding was probably due to the high consumption of carbohydrates sources such as maize meal, which contains low levels of these nutrients. Another study assessing nutrient intake and nutrient status of HIV seropositive individuals at Chulaimbo Sub-District Hospital, Kenya, the intake of vitamins and minerals was below the RDA (90%). This was with the exception of iron and thiamine, because of a high intake of vegetables in the region (Onyango *et al* 2012). In South Africa, the nutrient intake below RDAs can be expected because of low agrarian activities (HSCR 2005) and a lack of a dietary diversification (DoH 2007).

Abrams, Duncan & Hertz-Picciotto (1993), investigated the impact of dietary intake on disease progression though determining the relationship between dietary intake at baseline and the development of AIDS over a six-year period in HIV seropositive homosexual men. Findings of this study showed that a high nutrient intake was associated with a significantly reduced risk of developing AIDS. A reduced disease progression was statistically significantly associated with iron, vitamin E, riboflavin and the use of a multi-vitamin supplement. The study conducted by Fawzi *et al* (2004) in Dar es Salaam, Tanzania, also found that multivitamins (vitamin B complex, C and E) impacted on slowing down disease progression in HIV positive patients. Although serum selenium was also found to be low among HIV infected individuals (Friis 2005), however, there is inadequate evidence regarding the benefit of selenium supplements benefits (South African HIV Clinicians Society Expert Committee 2004). Therefore more research is required to substantiate the above findings. Results from other studies raised concerns that some micronutrient supplements such as vitamin A and zinc can produce adverse outcomes in HIV-infected individuals, increase disease progression and decrease survival if used with no evidence of deficiency (Fawzi et al 2004; Kupka & Fawzi 2002; Semba & Tang 1999).

According to FANTA (2004), optimal nutritional support for PLWHA play a critical role in survival of HIV infected individual (Castleman *et al* 2004). Hattingh *et al* (2007) stated that early assessment and nutrition intervention are required to support HIV infected patients. Lategan *et al* (2010) suggested food supplements enriched with macro- and micronutrients to complement the diet are essential to improve the nutritional status of HIV and TB infected people. However, there is insufficient published information on the effectiveness of food supplementation in HIV infected individuals.

2.9. Malnutrition management strategies in South Africa

Nutrition programmes have been in place in South Africa for a very long time. These programmes include supplementation with food (such as beans and maize meal) and promotion of gardening (DoH 1999). For several reasons, the programmes that have been implemented were not very effective in reducing malnutrition (DoH 1999). Malnutrition remained a key priority issue which the new government undertook to address post the apartheid era (Steyn & Labadarios 2002). The South African DoH developed a strategy aimed at solving nutrition problems in the country based on the recommendations of the Nutrition Committee which was appointed by the Minister of Health in 1994 (DoH 1999). The committee's fundamental reason for formulation of the strategy, the integrated nutrition programme (INP), was to replace the fragmented and mostly food based approach of the past that was proven to be less effective to meet the long term development and health needs of its population (DoH 1999). The INP strategy was formulated in 1995, and later became part of a broader integrated food security strategy [IFSS] (DoA 2002). The INP strategy applied the UNICEF conceptual framework for determinants of malnutrition as a model to ensure optimal nutrition, prevention and alleviation of malnutrition in South Africa (DoH 1999). There are eight focus areas of this strategy. However, three aimed at eliminating malnutrition among adults in the general public. Namely: contributing to household food security; disease-specific nutrition support, treatment and counselling; and micronutrient malnutrition control (DoH 2001).

The INP strategy to improve household food security placed considerable emphasis on food based income generation projects allowing communities to solve their own nutrition problems (DoH 2001). Due to constraints such as complex financial procedures, and lack of project management skills, the original intention of the INP to contribute to household food security

is still a challenge (DoH 2001). Disease specific nutrition support, treatment and counseling strategies still encompasses nutrition and dietary practices for the prevention and rehabilitation of nutrition related diseases and illness (DoH 2001). The Food and Nutrition Technical Assistance (FANTA) and World Food Program (WFP) (2007) reported that a disease specific nutrition support, treatment and counseling strategy incorporated into most national plans on comprehensive care and treatment of HIV, should be provided mainly through a clinical-model. Hence, nutrition assessment, education and counselling are integrated into the routine clinic visits of HIV-positive adults aiming at providing capacity to overcome constraints to healthy eating. Micronutrient malnutrition control addresses micronutrient deficiency in the population through a combination of strategies. This includes supplementation (vitamin A and multivitamins), food fortification and iodization, promotion of dietary diversification and related public health measures (DoH 2001). Food and nutrient supplementation, and therapeutic feeding are also provided to malnourished individuals, particularly those on anti-retroviral therapy (ART) as part of nutrition care and support (FANTA & WFP 2007; Anon 2003). A reduction in the impact of opportunistic infections and symptoms such as oral thrush, diarrhoea and fatigue has been reported due to the provision of supplements at clinics (Oketch, Paterson, Maunder & Rollins 2011). While the importance of NCS strategies is well recognized, there is paucity of information regarding their impact on nutritional status.

2.10. Ready-to-use supplementary foods to alleviate malnutrition in HIV infected individuals

2.10.1 Background to the development of ready-to-use supplementary foods

Management of malnutrition in inpatient and outpatient settings, has been changing over time with every new scientific discovery. According to Briend (2001) in the WHO treatment protocol drawn up in 1999, the therapeutic milk WHO F100 was specifically developed for nutritional recovery of malnutrition in the nutritional rehabilitation of severe acute malnourished children. This therapeutic milk was used for inpatient care in therapeutic nutrition centres with medical supervision and not distributed directly to families (WHO 2007). There is evidence that therapeutic milk was successful in alleviating malnutrition and was effectively employed in hospitals (Scherbaum *et al* 2009; Maleta, Kuittinen, Duggan, Briend, Manary, Wales, Kulmala & Ashorn 2004).

Despite these successes, challenges were encountered with the reconstitution of this product, as there was the need for close supervision during reconstitution. This in turn increased demand for production capacity, as well as the need for access to clean safe water to minimize undesirable bacterial growth (Scherbaum *et al* 2009; WHO 2007; Briend 2001). The product was also used for treating severely malnourished children as the vitamin and mineral content was too high to treat moderately malnourished child (Isanaka, Roederer, Djibo, Luquero, Nombela, Guerin & Grais 2010; Briend 2001).

These above mentioned shortcomings led to the WHO amending the protocol for the management of severe malnutrition, encouraging the use of ready-to-use foods for inpatient and community-based management of undernutrition (Sunguya, Poudel, Mlunde, Otsuka, Yasuoka, Urassa, Mkop, Jimba 2012; WHO 2007). Hence, there was a need for the development of ready-to-use therapeutic foods (RUTFs) with the intended use to improve the nutritional status of children as it has been proven to be acceptable to children (Briend 2001) and effective in alleviating malnutrition (Prudhon, Briend, Prinzo, Daelmons & Mason 2006). This product was used as a supplement to local diets and in managing moderate malnutrition (Briend 2001). Examples of these ready to use therapeutic supplements include *Plumpy-nut* and *Plumpy 'doz* produced by Nutriset in France (Manary 2005). From these RUTFs, ready-to-use supplementary foods "RUSFs" suitable for adults were also developed (Isanaka *et al* 2010).

RUSFs are available in numerous forms such as compressed bars (de Pee & Bloem 2009), biscuits and pastes (de Pee & Bloem 2009; Manary 2005). RUSF reviewed in this dissertation is made up of peanut or soya paste, milk or whey powder protein, vegetable oil, sugar, minerals and vitamins, (Manary 2005; Maleta *et al* 2004). The ingredients used in the production of RUSF are energy dense and/or high in nutrients (Manary 2005). For several other reasons, the use of peanut based RUSFs is justified. It has low water activity which limits the risk of bacterial growth (Briend 1997). Even when unrefrigerated for months, the supplement can still be safe for human consumption (GOTG 2010). Since it requires no cooking, heat sensitive vitamins can be retained. Moreover, this validates no need for labour, fuel and water and justifies its suitability for developing countries such as South Africa where some population are rural and has no access to water (Barron *et al* 2007). In addition, the process of

producing this product is simple, uses basic technologies available in developing countries and is sustainable as the ingredients used in the manufacturing process is locally available (Diop, Dossou, Ndour, Briend & Wade 2003; Briend 2001). RUSFs has been said to be practical to implement in resource poor settings because its production is less costly compared to the production of RUTFs (Isanaka *et al* 2010).

Sibusiso® RUSF has been manufactured since 2004 from a Malawi produced groundnut by South African NGO, Gift of the Givers foundation. It has been used to prevent malnutrition during illnesses and natural disasters (GOTG 2010). Ingredients used in *Sibusiso*® also include soya milk extract, soya protein, oil (soya oil), sugar, vanilla flavouring and a vitamin and mineral premix (GOTG 2010). Hence, this RUSF has been shown to be energy dense, as well as high in protein and micronutrients. The use of soya improves the protein quality in a product as soya beans are known to have the highest protein content when compared to other cereals and legumes (Yeh, Resurreccion, Phillips & Hung 2002). With macronutrient breakdown, a 100g of *Sibusiso*® RUSF provides approximately 2352 kJ/100 g of energy, with carbohydrates contributing 34% of total energy (48 g/100 g), protein and essential amino acids contributing 11% of total energy (16 g/100 g), and fats contributing 55% of total energy (35 g/100 g) (GOTG 2010). *Sibusiso*® RUSF has been used by the South African Department of health as an effective nutrient supplement for individuals experiencing malnutrition, as is the case with TB, HIV and AIDS (Kindra, Coutsoudis & Esposito 2011).

2.10.2. Effect of ready-to-use supplementary foods

RUSF has been shown to be efficacious in improving childhood malnutrition in studies conducted in several countries such as Tanzania, Chad, Ethiopia, Senegal and Malawi (Sunguya *et al* 2012; Isanaka *et al* 2010; Maleta *et al* 2004; Collins & Sadler 2002). Maharaj (2012) also conducted a study in a South African setting which aimed to investigate whether supplementation with a RUSF (*Sibusiso*®) could promote weight gain in underweight children between one and ten years of age living in Cato Manor and Chesterville in Durban, KwaZulu-Natal. Underweight children who participated in the study were members of household food insecure families receiving food parcels supplied by the non-for-profit organisation Church Alliance for Social Transformation

(CAST). *Sibusiso*® RUSF was successful in promoting weight gain among underweight children and was able to improve the overall wellbeing of children by alleviating the burden of disease and infection symptoms, while improving appetite, meal consumption and energy levels.

Although there are numerous nutritional benefits to RUSF use observed in children on the African continent, evidence regarding its effectivity in adults is still lacking. A randomized controlled clinical trial conducted in KwaZulu-Natal on the effect of *Sibusiso*® RUSF on breastfeeding HIV positive mothers on maternal and child health revealed no significant changes of the anthropometric status when comparing the trial and control group of mothers except for LBM. This study also found that there were no significant differences in the incidence rate ratio (IRR) of opportunistic infections such as diarrhoea and candidiasis (Kindra *et al* 2011).

When RUSF was used in adults, the product, *Plumpy'nut*®, was proven to enhance the nutritional status of HIV infected adults in Malawi, Uganda, Kenya and Addis Ababa (see Table 2.1.below). To date there has been a lack of similar studies conducted in South Africa on adults with a focus on nutritional status and disease improvement with RUSF. Studies (Mabaso 2012; Mahlangu 2012) which have been conducted in South Africa regarding the acceptability of RUSF, substantiate the possibility of using RUSF to improve adult nutritional status. Therefore, it posed beneficial to investigate the effectiveness of RUSF in a South African community setting by specifically targeting HIV positive adults participating in a nutrition programme.

Table 2.1: Studies on the efficacy of ready-to-use supplementary foods in adults

Study	Location and population	Interventions	Major findings
Madley, Haile & Shumye 2014	Addis Ababa, Mekelle hospital, 1600 patients on ART	Adult HIV+ patients with moderate acute malnutrition (MAM) are provided with two sachets of RUSF (Plumpy'nut) daily until recovery from malnutrition or for a maximum of three months. Those with severe acute Mal-nutrition (SAM) are provided with four sachets daily until recovery or for a maximum of six months.	62.2% of patients on ready to use food therapy were recovered reached BMI above 18.5kg/m2. Out of 77 (14.7%) who were severely malnourished (BMI less than 16.0kg/m2) only 18 (23.4%) recovered. Out of 127 (24.2%) who were moderately malnourished (BMI 16.00-16.99 kg/m2) 56 (44.2%) recovered. 245 (79.4%) out of 320 (61.1%) who were mild malnourished (BMI 17.00-18.4 kg/m2) recovered. The therapy was most effective on people who were mildly malnourished.
Ahoua *et al* 2011	Uganda & Kenya, 1106 HIV infected malnourished adults with BMI <17 kg/m2 and initiated on ART	Patients received four sachets of RUSF (2000 kcal; Plumpy'nut ®, Nutriset, Malaunay, France) per day in the outpatient clinic, and were clinically assessed every two weeks or monthly. Duration: Patients stay no longer than 6 months on a programme.	After receiving nutritional treatment for a median of four months, 524 (47.4%) of patients achieved an average weight gain of 1.6 g/kg/day. 149 (13.5%) discharged before reaching a normal BMI of 18.5kg/m2, 250 (22.6%) defaulted from nutritional program care, 132 (11.9%) died, 26 (2.4%) transferred to another programme, and 25 (2.3%) stopped RUSF due to treatment intolerance or other reasons.
Ndekha *et al* 2009	Malawi 491 HIV-infected adults with BMI <18.5 kg/m2 initiating ART.	Experimental group: 245 patients, 260 g/day (1,360 kcal/day) of peanut-based Ready-to-use fortified spread (RUSF). Experimental group: 246 patients, 374 g/day (1,360 kcal/day) of corn-soya blend (CSB). Control group: none. Duration: 3.5 months	After 3.5 months, Patients in the RUSF group achieved mean overall weight gain of 5.6 kg, with median BMI of 19.0 kg/m2. Patients receiving RUSF, as compared to CSB, had a greater increase in BMI (2.2 ±1.9 vs. 1.7 ± 1.6 kg/m2 [difference 0.5 kg/m2 95% CI (0.2 - 0.8)] and fat free mass (2.9 ± 3.2 vs. 2.2 ±3.0 kg [difference 0.7 kg 95% CI [0.2 - 1.2]). No significant difference in mortality, immune reconstitution, HIV suppression or quality of life was observed between the groups.

2.11. HIV associated body fat distribution (lipodystrophy)

2.11.1. Background on lipodystrophy

Segatto, Freitas-Junior, Dos Santos, de Lima Ramos Pinto Alves, Barbosa, Filho & Monteiro (2012) stated that the introduction of highly active antiretroviral therapy (HAART) in the 1990's as a standard therapy to treat HIV/AIDS, resulted in a significant increase in survival and quality of life of PLWHA. These positive results are due to its action of fighting against infectious and opportunist diseases. However, pharmacological control of the disease has the secondary adverse side effect of altering body fat distribution, characterized by morphological changes (known as lipodystrophy syndrome [LDS]). Rossouw, Botes and Conradie (2013) explained the syndrome as being characterised by body habitus changes, most commonly a combination of lipoatrophy [loss of peripheral subcutaneous adipose tissue, usually in the face, limbs and buttocks] and lipohypertrophy [visceral adipose tissue accumulation, gynaecomastia and, in some cases, lipomatosis, especially in the dorsocervical area, known as a 'buffalo hump']. Nevertheless, even patients who are not on HAART present with lipodistrophy (Rossouw, *et al* 2013). It is not clear whether HIV lipodystrophy is caused by the HAART or indirectly caused by fat that was lost in the periphery and deposited in the alternative visceral sites (Rossouw *et al* 2013).

Metabolic changes include dyslipidemia, insulin resistance and lactic acidosis that are also common in PLWHA (Leach-Lemens 2009). These metabolic and morphological changes that are associated with excessive abdominal fat, increases the risk of early onset of cardiovascular disease (CVD), hypercholesterolemia, and diabetes mellitus (DM) in PLWHA (Domingo, Estrada, Lopez-Aldeguer, Villaroya, Martinez 2012; Segatto *et al* 2012). Leach-Lemens (2009) clinical review affirm that the adverse impact of HIV LDS is more than just on physical health but also associated with psychological impact including poor body image, anxiety, depression, and low self esteem. This clinical review further mentions that the body morphological change has been seen to be a new obvious HIV feature with the potential to disclose the status unintentionally. Hence, there is foreseen decrease compliance to treatment and reduced effectiveness of the treatment due to stigma.

Overweight and obesity are common problems in PLWHA, especially women (Segatto *et al* 2012). They are also associated with high risk of developing HIV LDS, dislipidemia and insulin resistance (Segatto *et al* 2012). This has raised a concern about the impact of RUSF if results show its potential for the significant improvement in weight. Therefore, HIV LDS should be routinely assessed, prevented and managed and more research should be done to identify potential causes and best management practices.

2.11.2 Lipodystrophy assessment methods

There are several methods used by researchers for assessing lipodystrophy due to lack of standardisation (Segatto *et al* 2012). These include self identification; assessment by physicians, anthropometric measurement, bioelectrical impedance analysis (BIA); computed tomography (CT) scan; magnetic resonance imaging (MRI); and dual energy X-ray absorptiometry (DEXA) (Segatto *et al* 2012; van Wyk 2009). Objectivity, accuracy, cost and standardisation of classification of the above mentioned methods varies widely (van Wyk 2009). Even though the best methods to assess lipodystrophy are those that give an exact image of body composition (MRI, CT scan and DEXA), they are not readily available in the clinical practice and they are too expensive (Segatto *et al* 2012). According to van Wyk (2009), self identification has been suggested by several studies to be also accurate and more economical. The method is simple relying on the responses of the participants. Wanke, Barlett & Bloom (2013) reported that the other methods offer no additional benefit to patient self report and physical examination as they are difficult to interpret and norms are not available. Some studies revealed that findings from the self reporting are matching to the results of the MRI scans showing that patients who self reported truncal enlargement had a significant excess visceral adipose tissue than those who reported no truncal enlargement (Engelson, Kotler, Tan, Agin, Wang & Pierson 1999).

2.12. Summary

PLWHA in resource-constrained settings such as sub-Saharan Africa are carrying a double burden of HIV and food insecurity and are therefore prone to nutritional deficiencies. Apart from food shortages, HIV infection is also frequently associated with malnutrition due to

causes such as lack of appetite, increased nutrient requirements due to increased metabolism; and decreased absorption due to opportunistic infections. Besides this, the REE in HIV infected individuals has been shown to be higher than that in their HIV uninfected counterpart. Hence, effective supplementary programmes are needed in order to decrease the incidences of malnutrition in PLWHA by providing adequate levels of energy and nutrients.

RUSF was initially designed to replace WHO F100 due to its shortcomings in the management of malnutrition. This was largely due to the fact that the ingredients used in the manufacturing of RUSF are energy dense and high in nutrients. RUSF are convenient and safe as they require no additional preparation, no addition of water and can be used safely in rural settings without the risk of bacterial contamination. RUSF are adaptable and sustainable as the ingredients and technology used to manufacture these spreads are simple. Locally produced RUSF have been found as effective as imported RUSF thereby reducing the cost of these supplements. The studies reviewed indicated positive outcomes of RUSF in prevention of malnutrition in children. However further studies are needed to investigate the effectiveness of RUSF such as *Sibusiso*® RUSF on HIV positive individuals, especially in the South African community setting.

Patients who are on HAART sometimes present with LDS, but even those who are not on HAART can still present with lipodystrophy. The cause of it is not clear, therefore, more research should be done to identify the potential causes. LDS is associated with excessive abdominal fat which increase the risk of CVD, hypercholesterolemia and DM. Hence, lipodystrophy should be routinely assessed, prevented and managed. There are several methods for assessing lipodystrophy syndrome. The studies reviewed indicated the subjective self reporting method as a reliable and more economical method in assessing lipodystrophy syndrome. .

CHAPTER 3
METHODOLOGY

This chapter provides a detailed explanation of the different methods used in addressing the research problem. The study design, study population and sample selection, methods and materials used in collecting and analysing the data are fully described**.**

3.1 Research design

The main purpose of this study was to determine the effect of a peanut based ready-to-use nutritional supplement [*Sibusiso*®], on HIV positive adults on antiretroviral therapy, attending the 1000 hills community helpers' centre, Durban, KwaZulu-Natal. The effect of this intervention was to be determined through identifying whether there was an improvement in BMI. The study aimed to determine whether there was an improvement in predominant disease conditions and symptoms experienced by HIV infected individuals. Furthermore, it determined if there was a general improvement of appetite, meal consumption and energy levels using a self reported method. Lastly, the study seeked to identify if there were any changes in body fat distribution in adults on ART after being supplemented with *Sibusiso*® RUSF. This research is a descriptive study whereby data was collected using a cross-sectional method. It includes 50 participants between the age of 20 and 78 years.

According to the Medical Research Council [MRC] (2010), in many circumstances, randomised controlled trials are the method of choice for evaluating interventions because randomisation, coupled with design features such as blinding provide the most robust ways of minimising biases. However, in the current study randomisation was difficult for practical reasons. It would have been unethical to randomly select a few at risk participants to receive *Sibusiso*® RUSF, taking into account that almost all of the HIV clients attending the centre have one or more factors that have been anecdotally suggested to improve with RUSF intake. In addition, this was an intention-to-treat study; therefore a control group was not included in the design, as it would also be impossible to exclude some of the PLWHA from any available dietary intervention.

3.2. Study population and sample selection

At the time of data collection, there were approximately 100 adults (over 18 years) attending the 1000 hills community helper's centre which provide ART to HIV infected participants. No sampling was done as all adults who were on ART were eligible for RUSF as part of clinical assistance sponsored by the Gift of the Givers. All participants were monitored at each visit. However, for the purpose of this study, the data for only those who met the inclusion criteria was used for analysis.

Hence the inclusion criteria for the study were;

- Being HIV positive
- Receiving ART from 1000 hills community helpers' centre
- Not pregnant
- Must attend at least four consecutive visits
- Be 18 years of age or older
- Not taking other supplements intended for enhancing weight gain.

Of the 100 adults receiving RUSF 50 were eliminated from participation in the study because they could not attend the community helper's centre for four consecutive visits due to reasons that included defaulting on treatment, migrating, and changing the site of collecting their medication. This resulted in a final number of 50 participants eligible for statistical analysis. We defined ART-treated HIV positive patients as those who's sero-status was confirmed to be positive using standard laboratory methods and taking ART according to the national guidelines of South Africa. The 50 adults included in the study still represented a sample of adults on ART attending the 1000 hills community helpers' centre.

3.3 Study methods and materials

The supplement was a peanut/soya milk spread enriched with 6 micronutrients and came packaged in plastic tubs. At each visit the participant was given 3 tubs of *Sibusiso*® ready-to-use supplementary food as a monthly supply. Participants were instructed to take a daily serving of 4-6 heaped teaspoons of the nutrition supplement. Trained professional nurses from the centre were responsible for collecting data at each visit with the researcher present on some days for monitoring the process. Intensive training of the centre nurses on

interviewing technique and taking anthropometric measurements for the purpose of standardizing the procedure was done by the consulting dieticians of the Sibusiso® Product (Pty) Ltd. The researcher assisted with ongoing monitoring of the data collection process. The nurses who served as field-workers were fluent and literate in English and isiZulu, and had experience in nutritional monitoring of HIV infected adults. The monitoring tool used in this study was an amended one used in a similar local study on children (Maharaj 2012). Although the monitoring tool was originally designed to be used in severely malnourished children under the age of five years, it was adapted to be able to facilitate the collection of insightful and relevant information to answer the research question.

Data collection days were strategically planned on the same day that ART was collected in order to ensure a high attendance rate and convenience to participants. On the first visit, information on the socio-environmental conditions of the subject was captured. This included employment, and availability of water, electricity, indoor flushing toilets and a fridge. The baseline information also assessed the frequency (daily, weekly or monthly) of consumption of different food groups. All baseline information aimed at identifying the risk of malnutrition in participants that were included in the study. Thereafter, on a monthly basis data on anthropometrics (BMI), symptoms, appetite changes, and disease conditions was recorded on the monitoring tool (see Appendix B). Towards the end of the study the researcher conducted an interview with each participant to assess the body fat distribution of participants after using the supplement using a self reporting method (see Appendix C).

Variables included in the study

3.3.1. Anthropometric measurements

Anthropometric measurements included weight and height of participants. All measurements were repeated twice as per ISAK (International Society for the Advancement of Kinanthropometry) to two decimal places by a researcher or a research assistant to enhance reliability but only a mean value was recorded. If the two measurements differed significantly, the third reading was measured and the median used. BMI was calculated by dividing weight of a subject by height squared (kg/m^2).

- Weight gain or loss

The weight (kg) of the participants was measured on each day of supplement collection. Any change in weight was documented, and indicated as an increase or decrease in weight from the previous weight recorded.

Procedure of weight measurement

The following method was used:

- The electronic scale was recalibrated before each measure
- The electronic scale was placed on an even surface in the clinic
- The electronic scale was turned on and the nurse waited until it read 0.00 kg
- The participant was asked to remove shoes, socks and any other clothes or object that that could contribute to extra weight. Hence they were weighed wearing light indoor clothing
- The participant was asked to stand in the middle of the scale with their weight evenly distributed on both feet and with hands on their sides.
- The weight was recorded in kilograms into 2 decimals
- The weight was measured twice and the average was recorded. The third reading was measured if the first two readings differed significantly, and median recorded.

- Height

The height (m) of participants was measured using a stadiometer at baseline.

Procedure of height measurement

- The stadiometer was placed on a level surface
- The participant was asked to remove shoes, socks and hair, if tied up, was untied
- The participant was asked to stand with heels together, arms to the side, legs straight, shoulders relaxed, head in a Frankfort horizontal plane and buttocks and shoulders touching the stadiometer
- Just before the measurement was taken the subject was asked to take a deep breath and hold it while maintaining an erect posture

- The sliding headpiece was then lowered upon the highest point of the head with adequate pressure to compress the hair
- The sliding headpiece was then locked in place and the reading was taken
- The height measurements were read into 2 decimal places in metres and two readings were taken, an average was then recorded. The third reading was done if the first two measurements varied significantly and a median recorded.

3.3.2 Diseases symptoms

Participants were interviewed if they presented with symptoms as per the monitoring tool. Symptoms included nausea, diarrhoea, fever or vomiting. Participants had to respond either yes or no to these questions. It was important to identify if the participants had experienced any of these symptoms since it could affect food intake or absorption of nutrients and ultimately weight gain.

3.3.3 Disease conditions

Gastroenteritis: A subject was identified by the research assistant as having gastroenteritis, if they presented with symptoms regarding loss of appetite, nausea, vomiting and diarrhoea.

Diarrhoea: A working definition of diarrhoea used was the abnormal passage of ≥3 unformed stools per day or a liquid stool (MacArthur & DuPont 2012).

Diarrhoea (past 2 weeks): The duration of diarrhoea was also considered to determine whether acute or chronic. Diarrhoea with a duration of 2 weeks was considered as chronic.

Dehydrated: A subject was identified as being dehydrated if they presented with symptoms such as extreme thirst, dry lips and tongue, an increase in heart rate and breathing rate, dizziness, confusion and lethargy or mucous membranes.

Mouth sores: The researcher/research assistant assessed participants for mouth sores by inspecting the mouth.

Oral thrush: The researcher/research assistant assessed oral thrush by inspecting the mouth of participants for fungal (candidia) infection that present itself as creamy white lesion with cottage cheese appearance on the tongue, roof of mouth, gums and tonsils (Peters 2007).

ART: Each subject was asked if he/she has initiated ART, and this was confirmed by checking their clinic card.

TB: Each subject was asked if he/she had been tested for TB and was confirmed by the Directly Observed Treatment Short-course (DOTS) card. Test results were noted on the monitoring tool.

3.3.4 Appetite

Participants were questioned about their appetite. Appetite was rated as either being poor or good. For the purpose of this study, good appetite was defined as always having a natural desire to enjoy your food at meal times. Poor appetite was defined as frequently having no desire to eat at meal times.

3.3.5 Meal consumption

Meal consumption was measured by asking subject how much food they were consuming on average at each meal. Using a standard bowl (about 500ml) as a reference, patients were asked to rate the amount of food consumed as ¼, ½ or a full bowl of food.

3.3.6 Energy levels

Participants were asked to rate their level of energy at each visit. Energy levels were classified as being very weak, weak, fine or full of energy. For the purpose of this study, the following definitions were used:

Very weak: - being fully dependent of assistance for normal duties such as to walk, cook, clean the house due to a lack of strength.

Weak: - not having adequate strength to perform normal household physical duties, partially depend on assistance.

Fine/fair: - having a fair strength to perform normal physical household duties

Full of energy: - being able to perform strenuous physical duties without a struggle.

3.3.7 Other supplements

On the first day that participants received a supplement, they were asked whether they were receiving a multivitamin, or any therapeutic porridge. This was done in order to eliminate them from taking supplements with a potential of influencing nutritional status. Therefore, ensuring that the study findings are a true reflection of the impact of the RUSF supplementation.

3.3.8 Body morphological changes

Morphological change assessment was done using a subjective self reporting method. Morphological change assessment was defined as an accumulation or

wasting of fat in certain body areas including neck, breast, abdomen, face, arms and buttocks. Lipohypertrophy referred to a generalized fat gain in the specific area, while lipoatrophy referred to a generalized fat wasting in specific areas. The severity was scored and recorded as mild (slightly noticeable), moderate (readily obvious), or severe (obvious). Cases with morphological changes were defined as participants with one or more moderate and/or severe features of lipohypertrophy and/or lipoatrophy (see Appendix C).

3.4. Ethical Considerations

Ethical approval for the study was obtained from the Human and Social Ethics Committee, University of KwaZulu-Natal, Reference Number HS/0373/011M. All participants were requested to sign a written consent form before participating in the study. The study was explained to them in their home language and it made clear that they can withdraw at any point in time.

3.5 Data analysis

Statistical data analysis of the variables are discussed in this section. Data was entered into a Microsoft database (©MS Excel 2010). It was rechecked for any missing information and entry errors. A unique subject identification number was used to maintain confidentiality. Data was transferred to and analysed using SPSS (Statistical Package for Social Science), version 18.0 (SPSS Inc., Chicago, III, USA) which is a statistical analysis computer program. Statistical significance was set at a *P-value* of less than or equal to 0.05.

Sub-problem one: To determine a change in BMI of HIV positive adults on ART supplemented with *Sibusiso*® RUSF.

Anthropometric measurements between subsequent visits for each patient was analysed using the software, SPSS (Statistical Software for Social Sciences) version 18. Basic descriptive statistics (means ± standard deviations) were used to describe the characteristics of participants at each visit. Comparisons were made between mean BMI in visit 1 (before any supplementation was given), and subsequent visits. A paired t-test was used to measure differences in BMI between subsequent visits. Pearson correlation was used to identify relationship between BMI changes and other factors that could possible contribute to this

change, such as availability of vegetable gardens. A p-value of less than or equal to 0.05 was considered significant.

Sub-problem two: To determine the most prevalent symptoms and disease condition of patients on ART.

At each supplementation day, data was collected regarding the disease symptoms which were being experienced by participants. Symptoms included nausea, diarrhoea, fever and vomiting. Disease conditions were diarrhoea (past 2 weeks), dehydration, mouth sores, oral thrush, gastroenteritis, TB and HIV. The frequencies of these symptoms or conditions were calculated by adding the number of diseases and symptoms that participants presented with on each data collection day. The disease condition that the participants presented with throughout the period of data collection was identified as being the predominant disease condition experienced among participants.

Sub-problem three: To determine whether symptoms and disease condition of patients improved after supplementation.

Cross tabulations and chi square t-test were used to compare the symptoms from the first visit to the last participant visit.

Sub-problem four: To determine whether appetite, meal consumption and energy levels improved among ART patients after supplementation with *Sibusiso*® RUSF and possible contributing factors.

On each supplementation day, data was collected regarding level of appetite, meal consumption levels and energy levels of participants observed in the past month. At the end of the three month supplementation period, data collected was analysed to identify whether there was any overall improvement in appetite, meal consumption and energy levels. To determine improvement in appetite and energy levels, cross tabulations and chi square t-test were used to compare the appetite and energy levels from the first visit to the last patient visit. Pearson correlations were conducted to determine contributing factors to appetite and energy level.

Sub-problem five: To determine change in body fat distribution of adults after being supplemented with *Sibusiso*® RUSF.

Morphological change assessment was done using a subjective self report method at the end of three months of supplementary period. Cases were defined as participants with one or

more moderate and/or severe features of lipohypertrophy and/or lipoatrophy. Data was analysed by adding the number of confirmed cases after the end of assessment period. Pearson correlation was used to determine relationship between BMI change and lipoatrophy or lipohypertrophy.

3.6 Summary

In this non randomised intervention, 50 HIV positive adults on antiretroviral therapy, attending the 1000 hills community helpers' centre, Durban, KwaZulu-Natal participated in the study. A monitoring tool was used to obtain data and anthropometric measurements of the supplemented participants at each of the four consecutive visits by a researcher and/or the trained nurse (research assistant) at the research site. Data was then analysed to determine the effect of the intervention by identifying whether there was an improvement in participant BMI. The improvement in predominant disease conditions and symptoms experienced by HIV infected participants was also investigated. Data analysis also showed whether there was any general improvement in appetite, meal consumption and energy levels. Lastly, the study seeked to identify if there were any changes in body fat distribution on adults on ART after being supplemented with *Sibusiso*® RUSF.

CHAPTER 4
RESULTS

Chapter four presents the results of the study according to the sub problems outlined in chapter one.

4.1. Sample characteristics

A total of 50 adults on ART were supplemented for a period of three months with *Sibusiso*® RUSF. No control group was used in this study. Table 4.1 depicts sample characteristics if the participants. The average age of the participants was 40 years. Majority of participants (n = 32) were over the ages of 35 years. The study consisted of 88% (n = 88%) females and 12% (n = 6) males. All participants were of an African origin. Average weight of participants was 60.02 kilograms and the average height 1.63 metres.

Table 4.1: Sample characteristics of study participants.

Variables	N (%)*	Variables	N (%)*
Age		**Race**	
18-25	05 (10)	African	50 (100)
26-35	13 (26)		
36-45	16 (32)	**Health status**	
46 and above	16 (32)	HIV/TB	07 (14)
Average age (40 years)		HIV	43 (86)
Gender		Average weight (60.06kg)	
Male	06 (12)	Average height (1.63m)	
Female	44 (88)		
TOTAL	**50 (100)**		

* % of total sample (*n* = 50)

Figure 4.1 illustrates the background of participants by showing the resources that they have access to at home. Seventy-four percent (n=37) of participants had access to a stove, 68% (n=34) had access to running water, 16% (n=8) had access to indoor flushing toilets, 54% (n=27) had access to a fridge and 78% (n=39) had access to electricity. Of the 50 participants surveyed, only 24% (n=12) had a vegetable garden at home.

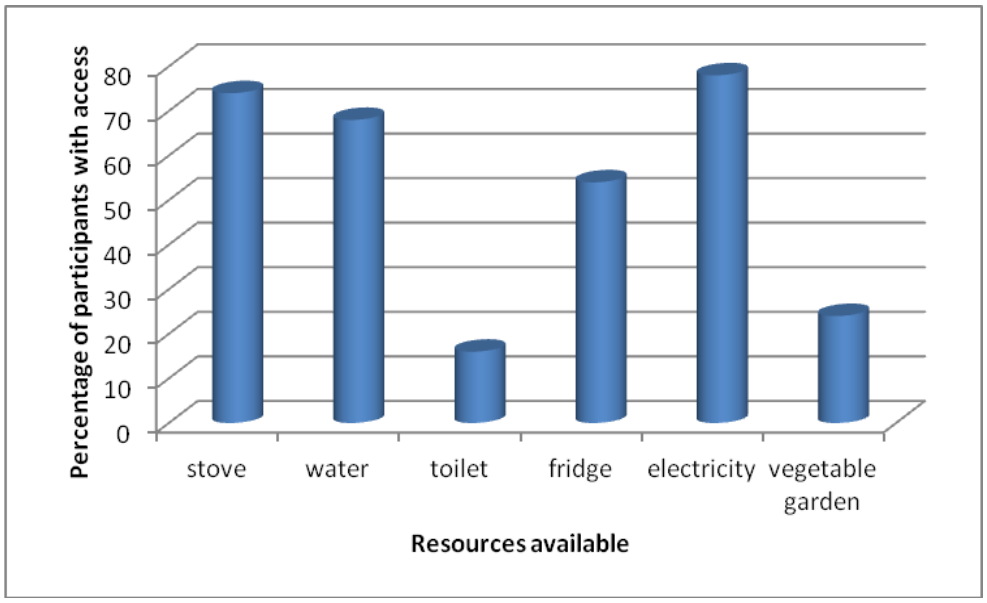


Figure 4.1: Resources available to participants with a potential to influence nutritional status.

Figure 4.2 illistrates the frequency of foods consumed at by participants at baseline assessment. Water, bread/potatoes/phutu and porridge were consumed on a daily basis. Eggs, milk, meat/chicken/fish and fruits were consumed on a monthly basis.

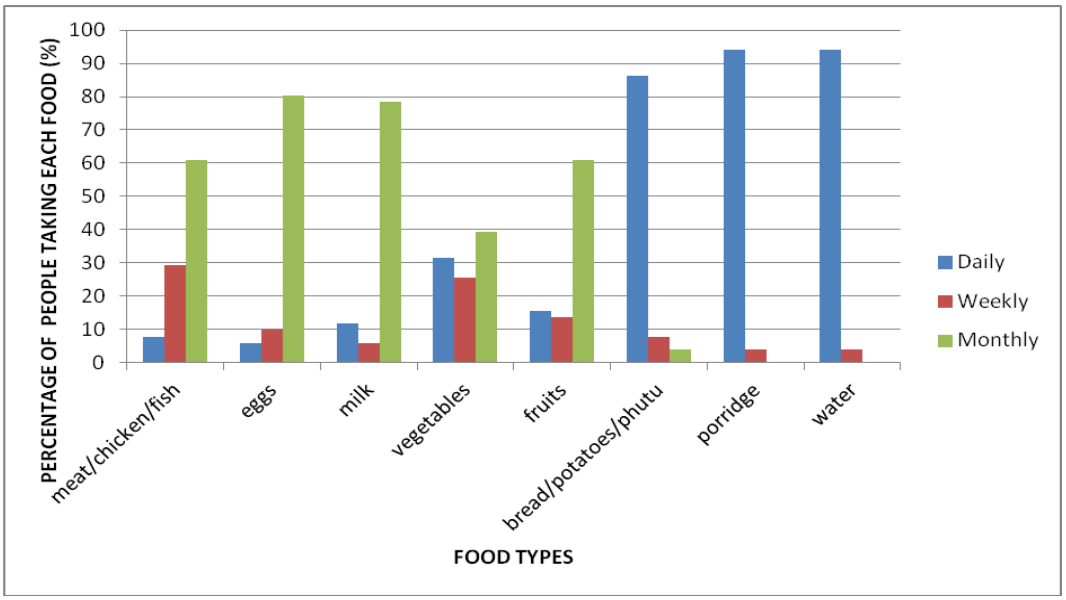


Figure 4.2: Frequency of food consumed by the participants at baseline assessment

4.2. Nutritional and health effects of *Sibusiso*® RUSF on HIV positive adults receiving ART

4.2.1 To determine whether the BMI of HIV positive adults on ART supplemented with Sibusiso® RUSF *improved after a three months supplementation period.*

The mean BMI values from visit one (baseline) to visit four were compared to the initial BMI. This was done to determine how the supplement has impacted on the BMI of participants in the course of the study. Table 4.2.below shows the results.

Table 4.2: The average BMI values from visit one to visit four at clinic

Visits	Mean BMI (kg/m2)	SD	P-VALUES	
Visit 1 (Baseline assessment)	22.62	4.57	**Visit 1- 2** 0.019	
Visit 2	23.31	4.60	**Visit 2 - 3** 0.128	**Visit 1 - 4** 0.000
Visit 3	23.83	5.26	**Visit 3 - 4** 0.084	
Visit 4	24.23	5.20		

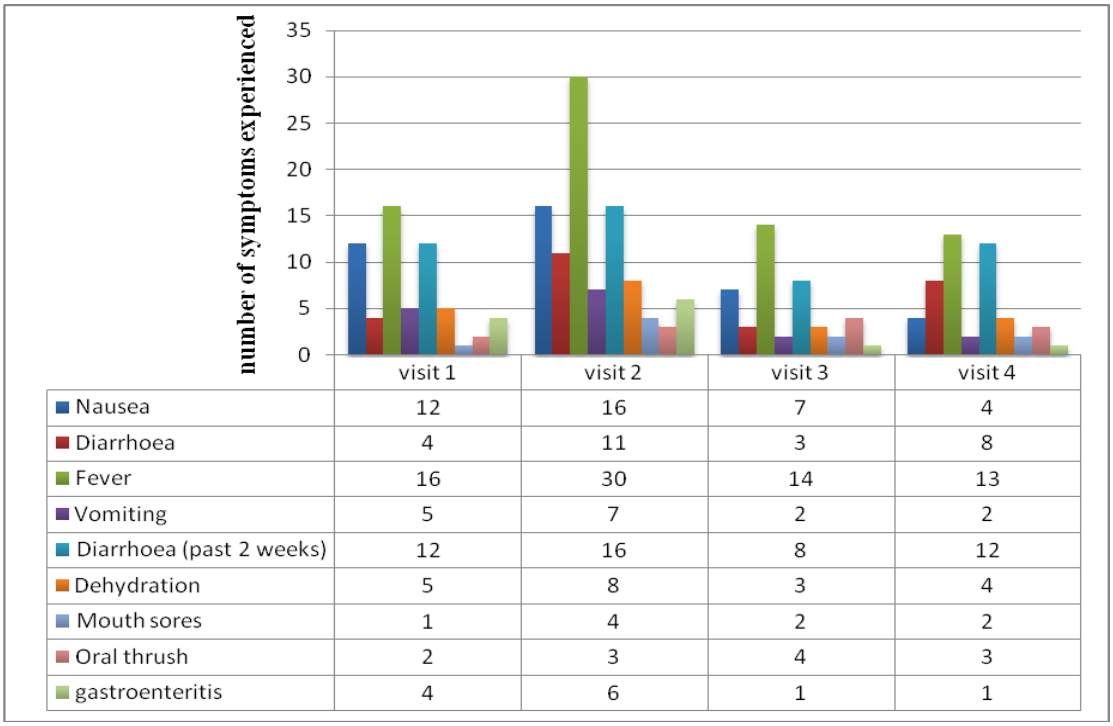
P-level (two-tailed) of <0.05 considered to be significant

There was a gradual increase in the mean BMI of participants from the first to the last date of supplementation. Based on the paired-sample-t-test, comparing visit 1 and visit 2, a significant increase in BMI was noted ($p<0.05$). Between visit 2 and visit 3, a non-significant increase in BMI was noted ($p>0.05$). A non-significant increase in BMI was also noted from visit 3 to 4 ($p>0.05$). However, when comparing the initial BMI of the participants to their final BMI, a significant improvement was noted ($p< 0.05$). Twelve percent of participants at the end of supplementation did not manage to achieve a normal BMI considered to be above 18.5kg/m^2 to 24.99kg/m^2. There was no significant correlation between the baseline BMI and BMI changes. Yet, there was a weak positive correlation between baseline weight and having a vegetable garden ($r^2=0.409$; $p=0.004$). However, there was no correlation between having a vegetable garden and vegetable consumption ($r^2=0.001$; $p=0.994$). Instead, a weak positive

correlation was measured between the change in BMI between the baseline to end of supplementation and having access to running water (r^2=0.379; p=0.009).

4.2.2. To determine whether predominant symptoms experienced by adults on ART improved after supplementation with Sibusiso® RUSF.

The symptom with the highest prevalence at the start of supplementation was fever, followed by nausea and diarrhoea (past 2 weeks). However, even though by the fourth visit most symptoms were still present, the frequency of nausea had declined. Participants also reported to experience significantly fewer episodes of fever between the first and the last visit [$\chi 2$ (1, n=47) =3.993; p<0.005]. As depicted in Figure 4.3, from visit 1 to visit 4, participants reported a steady but significant decline in vomiting [$\chi 2$ (1, n=47) =11.937; p=0.001]. There was also a significant improvement in the presence of gastroenteritis [$\chi 2$ (1, n=45) =6.648; p=0.05]. There was however, no change/ improvement reported in episodes of diarrhoea two weeks prior to the clinic visit when comparing the first and the last visit. There was a non-significant improvement in nausea after a three months supplementation. A non-significant increase in prevalence of symptoms was observed in the second visit among participants.



	visit 1	visit 2	visit 3	visit 4
Nausea	12	16	7	4
Diarrhoea	4	11	3	8
Fever	16	30	14	13
Vomiting	5	7	2	2
Diarrhoea (past 2 weeks)	12	16	8	12
Dehydration	5	8	3	4
Mouth sores	1	4	2	2
Oral thrush	2	3	4	3
gastroenteritis	4	6	1	1

Figure 4.3: Most prevalent disease symptoms experienced by the participants at baseline, and changes in episodes throughout the supplementation period.

4.2.3. To determine whether appetite, meal consumption and energy levels improved among adults on ART supplemented with Sibusiso® RUSF

An improvement in appetite was observed among participants from visit 1 to visit 4 (Figure 4.4). When observing the trend in appetite a general improvement was noted during the supplementation period.

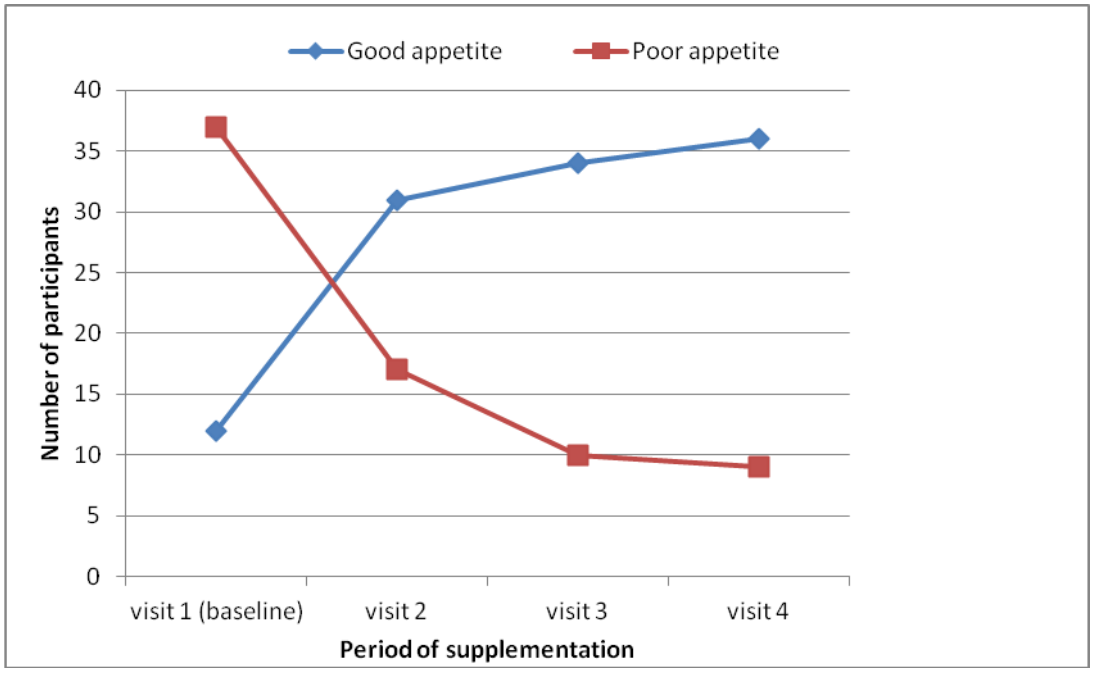


Figure 4.4: Appetite level of participants during supplementation period

There was weak positive correlation between appetite levels and meal consumption measured from the baseline to the second visit, and a moderate positive correlation between appetite levels and meal consumption measured in the second to the last forth visit. There was also a weak to moderate positive correlation between appetite levels and also improved energy levels (Table 4.3 below)

Table 4.3: Correlation between appetite levels and other variables

Variable 1	Visits	Variable 2	Visits	R^2	P
Appetite level	baseline	Meal consumption	baseline	0.366**	0.010
	2		2	0.643**	0.000
	3		3	0.647**	0.000
	4		4	0.517**	0.000
	baseline	Energy Level	baseline	0.094**	0.522
	2		2	0.397**	0.006
	3		3	0.405**	0.007
	4		4	0.526**	0.000

R^2: Pearson Correlation coefficient; ** Pearson's correlation is significant at the 0.01 level (2-tailed) * Pearson's correlation is significant at the 0.05 level (2-tailed)

There was a general improvement in meal consumption by the participants (Figure 4.5). In the first visit (at baseline) 60% (n=30) of the participants reported to consume a 1/4 bowl of food at most meals. However, by the fourth visit, only 18 % (n=9) of participants reported to consume a 1/4bowl of food. Twenty-four percent (n=12) of participants reported to consume a ½ bowl at baseline assessment, this number dropped to 10% (n=5) after a month of supplementation in the second visit. The number of participants consuming a ½ bowl then started to rise again the third visit to 20% (n=10) and then reached 26% (n=13) by the forth visit. The number of participants consuming a full bowl of food had increased from 14% (n=7) in the first visit (at baseline) to 52% (n=26) in the third visit and decreased slightly to 46% (n=23) in the last visit. Overall, from the first to the last visit, there was a two third improvement in the total number of those who consumed a full bowl of food.

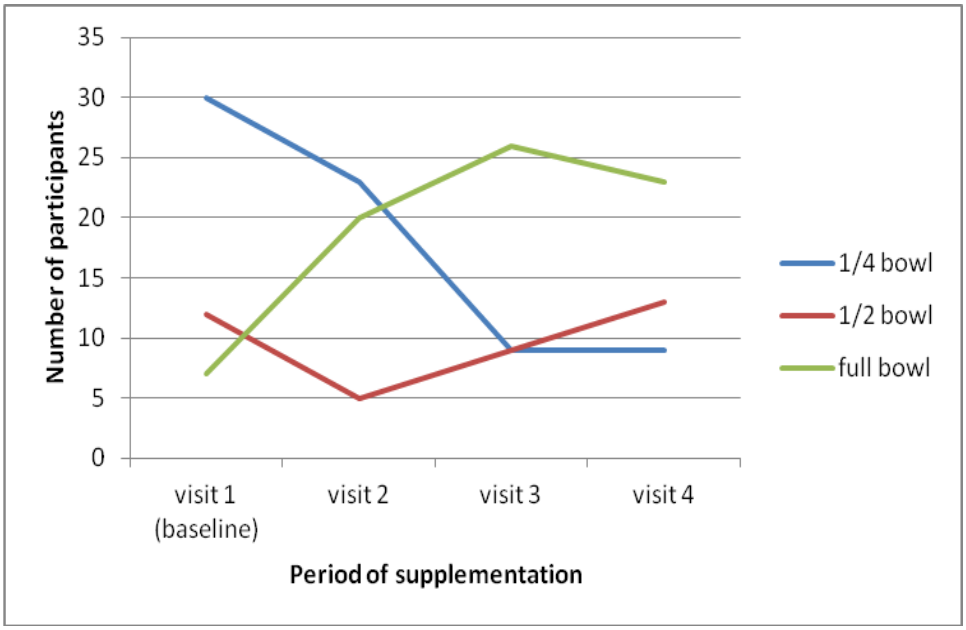


Figure 4.5: Meal consumption by the participants

From Figure 4.6 it can be seen that there was a general improvement in energy levels of the study participants. Only 2% (n=1) of the participants rated themselves as being very weak in the last visit, which was a sharp decrease from the 28% (n=14) in the first visit. Twenty four percent (n=12) of the participants reported to have a weak amount of energy by the end of the study, representing a decrease from 70% in the first visit. Fifty four percent (n=27) reported a fair amount energy by the end of the fourth visit.

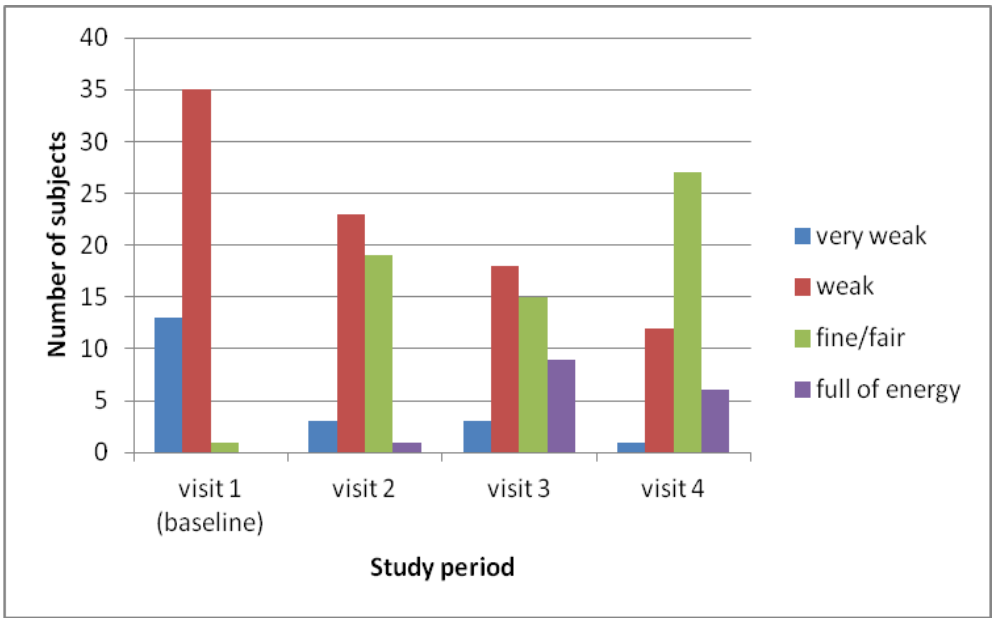


Figure 4.6: Energy levels of participants during the course of supplementation

There was a weak negative colerration between energy level and reported cases of gastroenteritis. This was reported for baseline, visit two and at the last visit. There was no correlation in visit 3, and is depicted in table 4.4. There was a weak negative correlation beween energy level and reported cases of fever in the second and third visit. However there was no correlation identified between energy level and fever episodes at baseline and on the last visit. There was no correlation between energy level and reported cases of persistant diarrhoes (more than two weeks) at baseline and in the second visit. However, a weak negative correlation was measured in the third and the forth visit.

Table 4.4: Correlations between energy levels and gastroenteritis,fever, and diarrhoea (previous two weeks)

Variable 1		Variable 2		R^2	P
Energy level	(Baseline)	Gastroenteritis	(Baseline)	-0.326*	0.025
	2		2	-0.428**	0.003
	3		3	-0.289	0.054
	4		4	-0.407**	0.005
	(baseline)	Fever	(Baseline)	-0.146	0.318
	2		2	-0.308*	0.033
	3		3	-0.489**	0.001
	4		4	-0.125	0.406
	Baseline	Diarrhoea (past two weeks)	Baseline	-0.191	0.189
	2		2	-0.285	0.055
	3		3	-0.329*	0.027
	4		4	-0.422**	0.003

R^2: Pearson Correlation coefficient; ** Pearson's correlation is significant at the 0.01 level (2-tailed) * Pearson's correlation is significant at the 0.05 level (2-tailed)

4.2.4 To determine if there was any observed changes in body fat distribution on adults on ART after being supplemented with Sibusiso® RUSF.

A group of 20 study participants participated in assessment of morphological changes during the supplementary period (Table 4.5). Of the 20 participants, 20% participants had

lipodystrophy. Ten percent of the positive cases experienced moderate lipohypertrophy, 5% in the breast and the other 5% in the waist. The other 10% liposystrophy positive cases reported having severe lipohypertrophy both in the waist and abdominal area. Few cases of mild lipohypertrophy were reported, mainly in the breast and waist; and mild lipoatrophy was reported for numerous body part. However, mild lipohypertrophy/lipoatrophy was not counted as cases of lipodystrophic syndrome. There was no correlation between BMI change and lipoatrophy or lipohypertrophy.

Table 4.5: Distribution of body fats in the participants over the three months period

	Lipohypertrophy			**Lipoatrophy**			
	Neck	Breast	Waist	Face	Arms	Buttocks	Legs
Mild	10%	20%	15%	5%	10%	10%	10%
Moderate		5%	5%				
Severe			10%				

4.3 Summary

Sibusiso® RUSF was able to gradually promote weight gain among HIV positive participants supplemented for a period of three months. The most predominant symptoms experienced before supplementation was fever followed by nausea. Persistent diarrhoea was the most predominant disease condition reported by participants at baseline. Appetite and meal consumption increased during the three months supplementation period. The energy levels among supplementation participants were found to increase during the period of supplementation, with the majority of participants reported to have fair to full energy levels on the last visit. Out of twenty HIV positive participants 20% reported moderate lipodystrophy after three months of supplementation. In the following chapter the results will be discussed.

CHAPTER 5
DISCUSSION

The main purpose of this study was to assess the effect of *Sibusiso*® RUSF on HIV positive adults on ART, attending the 1000 hills community helpers' centre, Durban, KwaZulu-Natal. In Chapter 4, results were reported for changes in BMI; predominant disease conditions and symptoms; change in appetite, meal consumption and energy levels; and also body fat distribution for adults on ART after being supplemented with *Sibusiso*® RUSF. The results will be discussed in this chapter, with special emphasis on the study objectives and reflection on past research within the context of each of these.

5.1. Significant findings in relation to the study objectives

5.1.1 BMI of HIV positive adults on ART supplemented with Sibusiso® RUSF was improved after a three months supplementation period.

Weight management is crucial in an individual living with HIV (DoH 2007). However a change in weight in HIV is multifactorial in its aetiology (South African HIV Clinicians Society Expert Committee 2004). The mean BMI values from visit one to visit four was compared to determine how *Sibusiso*® RUSF has impacted on the BMI of participants. Results showed that there was a gradual increase in BMI in the course of supplementation. This was sustained throughout the study. The RUSF in this study has therefore, promoted weight gain among HIV adult participants aged 20 to 78 years. These findings are similar to the findings from studies conducted by Ahoua *et al* (2011) and the study by Ndekha *et al* (2009), who both demonstrated that RUSF improved weight gain in adult participants. Several other studies documented similar findings (Sunguya *et al* 2012; Maharaj 2012; Isanaka 2010; Maleta *et al* 2004; Collins & Sandler 2002; Bried *et al* 1999), even though they were conducted on children. These results are in contrast to a study conducted on HIV positive mothers in KZN where RUSF had no impact on nutritional status (Kindra, Coutsoudis & Espisito 2011). Yet, it is not suggested that the results should be interpreted as controversial. Many factors should be taken into consideration here (such as poor acceptance and poor adherence), that in most cases now, are well understood and clarified after intense scientific scrutiny.

In addition, the increase in mean BMI could have been due to the high energy content of *Sibusiso*® RUSF, which is approximately 2352 kJ/100g. This is supported by the scientific backing that increased energy intake is the main contributor to weight gain, particularly sourced from dietary fat. RUSF provide additional energy the local diet (Isanaka *et al* 2010). Keeping in mind the average age of participants (40 years) and the daily recommended dose of *Sibusiso*® RUSF (4-6 heaped teaspoons), it can be reasoned that the energy provided by the RUSF only, falls well below the RDA. However, the additional energy and nutrients improves dietary intake, hence participants are more prone to meeting the RDAs as was pointed out by Maleta *et al* (2004). Besides, Maleta *et al* (2004) reported that the micronutrients in RUSF improve micronutrient status, which in turn improves appetite. Furthermore, improved appetite improves food intake which promotes weight gain. It is highly likely that in the current study, patients gained weight via the same mechanism. However, this will be discussed in more detail later on in this chapter.

As previously mentioned, *Sibusiso*® RUSF has been reported to be highly acceptable in HIV infected patients (Mahlangu 2012; Mabaso 2012). It is speculated that this could have improved adherence to the supplementation programme. Yet, there was no measure of acceptance in our study, even though none of the volunteers complained about the product. However, this is in contrast to the findings from the study conducted by Kindra *et al* (2011) who reported poor adherence to RUSF with mothers not consuming the daily amount of supplement according to protocol. There were even occasional days when they did not use the supplement. In this study, participants reported the unacceptable sweet taste of the product to affect their compliance. It can therefore be assumed that a positive weight gain suggests that in the current study, there was a better acceptability and adherence to the treatment by the study participants.

No significant association was found between the starting weight (at baseline) and changes in BMI (r^2=0.003; p=0.982). In some instances, studies have shown that the response to treatment, in HIV infected individuals starting ART, to some extent, depend on the baseline nutritional status of the individual (Ciliberto, Sandige, Ndekha, Ashorn, Briend, Ciliberto, Manary 2005). The findings of our study show that the RUSF can be used in patients at different stages of disease progression, regardless of their BMI.

It cannot be overlooked that twelve percent (n=6) of the participants did not manage to achieve a normal BMI (18.5-24.9kg/m^2) at the end of the intervention period. A weak

positive correlation between the changes in BMI and running water (r^2=0.379; p=0.009) was measured. Poor access to water (68%, n=34) was noted in the community, in general. The above mentioned finding substantiate that the success of RUSF in improving BMI can be determined by external factors, such as those outlined in the UNICEF conceptual framework (DoH 1999). Also, it is suspected that the persistent diarrhoea that dominated in this study, could have for instance contributed to poor weight gain. A small portion (18%) of participants reported a low food intake on the last visit, even though their overall food consumption improved. It is expected that an improved food intake would have a beneficial impact on weight gain, which in this study, was the case.

5.1.2. Predominant symptoms experienced by adults on ART improved after supplementation with Sibusiso® RUSF.

Nutrition and immunity have a synergistic relationship and deficiencies in either can have serious health implications (Lategan *et al* 2010). Inadequate diet which fails to meet the nutritional requirements can cause nutrient deficiencies and compromise the immunity in HIV positive people. The results from a current study showed a lack of dietary diversity, characterised by high intake of carbohydrates rich foods with low levels of other nutrients and less frequent consumption of other foods (Figure 4.2). It is therefore also important to acknowledge that the improvement in disease symptoms documented in this study, is independent of dietary practices. Apart from lack of dietary diversity, food shortages (FAO 2008) and increased nutrient requirements due to increased metabolism (Lakshmipathi & Jastremski 2005), there are also other factors that can affect weight gain in PLWHA. HIV infection is frequently associated with malnutrition due to causes such as difficulties with eating (WHO 2002) and decreased absorption due to opportunistic infections (van der Hulst *et al* 1998). Hence, it is crucial to investigate the disease symptoms experienced by PLWHA that can potentially affect their nutritional status. In this study, the most predominant symptoms experienced among participants before supplementation was fever, followed by nausea and diarrhoea (past 2 weeks). The predominance of fever is possibly caused by a compromised immune system due to infection as suggested by WHO (2002) and USAID (2001). This predominance of fever is in line with the findings of Ahoua *et al* (2011) who also reported that the most frequently diagnosed opportunistic infections in PLWHA is fever of unknown aetiology. There was a significant improvement in the incidence of fever between the first and the last visit ($\chi 2$=3.993, p<0.005). Therefore, it is suggested that

Sibusiso® RUSF provided additional nutrients that improved the compromised immunity of participants due to infection and reduction in food intake.

Other crucial findings from the study were an increase in the severity of all disease symptoms noticeable in the second visit. However, the cause of that was unknown. It should be noted that poverty and hunger prevail in this community, and these symptoms may be aggravated by side-effect from over-consuming RUSF due to a lack of any other available food. This is even more specific to diarrhoea which is known to be aggravated by fat intake (WHO, FAO 2002), as RUSF has a high fat content according to the nutritional information on the label (see Appendix A). It is also possible that this suspected initial overdosing with RUSF could have been triggered by HIV stigma and perceiving RUSF as a fast method to overcome thinness which is a perceived obvious sign of HIV infection.

Nausea and vomiting are common in PLWHA (WHO, FAO 2002). Therefore a high percentage of participants with nausea (24%) was not surprising. Based on the evidence that nausea can be caused by multiple factors including being a side effect, could also explain the increase in this symptom on the second visit. As shown in Figure 4.3, from visit 1 to visit 4, there was a steady but significant decline in vomiting ($\chi 2=11.937$; $p=0.001$). There was also a significant improvement in the incidence of gastroenteritis ($\chi 2=6.648$, $p=0.05$). No change/improvement was shown in those who reported to have had chronic diarrhoea (two weeks prior to the clinic visit) when comparing the first and the last visit. In a local study conducted on HIV positive breastfeeding mothers, RUSF did not make any impact on crude incidence of opportunistic infections, including diarrhoea (Kindra, Coutsoudis & Espisito 2011). This evidence is also crucial and in accord with the findings from this study where RUSF did not impact on reducing the prevalence of diarrhoea.

According to Wilcox *et al* (2003), diarrhoea has a multitude of aetiologies with HIV itself being a potential cause. Poor access to water (68%, n=34), indoor flushing toilet (16%, n=8) and fridges (54%, n=27) might have increased the risk of diarrhoea. In addition, other daily consumed foods could be contaminated with diarrhoea-causing pathogens. These findings indicate that the beneficial effects of *Sibusiso*® RUSF on eliminating symptoms and improving disease condition might be suppressed by other external factors, such as unhygienic drinking water. Hence, a need for more intense education on personal hygiene is crucial. MacArthur & DuPont (2012), Nel (2010) and Wilcox *et al* (2003) mentioned that the

interaction between diarrhoea and malnutrition is bidirectional. Diarrhoea leads to malnutrition while malnutrition exacerbates the increased risk of diarrhoea. Breaking this cycle is therefore, very important to support good health.

5.1.3. Appetite, meal consumption and energy levels improved among adults on ART and simultaneously supplemented with Sibusiso® RUSF.

HIV/AIDS has been associated with loss of appetite (WHO, FAO 2002). This was noticeable in the findings from this study. The cause of loss of appetite was unknown but it is suspected that it is multifactorial, as a result of possible side-effects of the medication, as well as the high prevalence of fever reported at the first visit. Fever and opportunistic infections reduce the intake of food in HIV positive patients by altering the patient's appetite (USAID 2001). Patients also regularly experience smell and taste alterations with physical impairments in the oropharyngeal or oesophageal area, resulting in a loss of the desire to eat (Fenton & Silverman 2004). This often requires medical intervention, using drugs that stimulate appetite. GOTG (2010) claimed that *Sibusiso*® RUSF improved patient appetite. However, this has been anecdotal. In this study, an improvement in appetite was noted among participants throughout the duration of the study from the first to the fourth visit. There was a dramatic change between the first two months of supplementation. These findings confirm the results from other studies where RUSF use also improved appetite (Maharaj 2012; Maleta *et al* 2004; Manary *et al* 2004). Saunders *et al* (2011) also stated that illness normally reduce appetite. There was a positive correlation between appetite level and meal consumption. This suggests that as participants' appetite improves the amount of food they consume also increase. There was also a positive correlation between appetite levels and energy levels. Possible explanation for this finding could be the good appetite possible led to increased meal consumption, thus to better energy levels of the participants.

An improvement in meal consumption was documented between the first and the last visit. The number of participants that were consuming a ¼ bowl of food had decreased while the number of subject that were consuming a full bowl increased. Even though the number of participants consuming a ½ bowl decreased on the second visit and then increased steady in the following visits. Overall improvement in illness (Saunders *et al* 2011) and fever in particular (USAID 2001), probably had an impact on improving meal consumption as these

have been suggested to affect food intake. These findings are also in agreement with Maleta *et al* (2004) who reported that an improvement in appetite lead to an improvement in food intake. Hence, it is speculated that the increase in appetite and disease-related symptoms observed during the period of supplementation contributed to increased meal consumption in the course of the study.

GOTG (2010) claimed that *Sibusiso*® RUSF improves low energy levels, but this assumption was based on anecdotal evidence. A general improvement in energy levels was observed among participants monitored during the supplementation period in this current study. As indicated in figure 4.6, at the end of the intervention period only 2% of the study population reported to be very weak. This is a substantial decrease from 26% of the participants who reported to feel very weak during the first visit. Twenty-eight percent of the participants still felt weak during the last visit, which however represented a decrease from 70% of subjects who reported to feel weak during the first visit. Collectively, 66% of the participants had a fair to full amount of energy in the last visit, which was an increase from 2% during the first visit. Consumption of a well balanced diet is essential to provide energy that the body needs to maintain weight, fight infection and compromise for the elevated resting energy expenditure associated with HIV infection (WHO, FAO 2002). When the body receives inadequate energy from food, it becomes weak and uses its muscle (lean body mass) for energy, which results in weight loss (WHO, FAO 2002). Babameto & Kotler (1997) reported that weight loss is often the event that triggers a vicious cycle of increased fatigue and a decrease in physical activity, including the inability to prepare and consume food by PLWHA. There was a negative correlation between energy level of participants and their experience of disease symptoms such as gastroenteritis, fever and diarrhoea. However, there is no overwhelming evidence to suggest that the presence of gastroenteritis, fever or persistent diarrhoea can sometimes compromise the energy levels of PLWHA. The correlations were not very strong and were not identified throughout the course of the study but on certain visits, as seen in Table 4.4. This is despite the suggestion that fever increases the demand for energy (WHO, FAO 2002) and alters appetite (USAIDS 2001), where as diarrhoea increase nutrient loss (Nel 2010).

5.1.4 Body fat distribution in adults on ART after supplementation with Sibusiso® RUSF.

HIV lipodystrophy can have adverse effects on PLWHA. These include early onset hypercholesterolemia, CVD and DM (Domingo *et al* 2012). Segatto *et al* (2012) reported that the HIV LDS causes are multifactorial, including a positive family history, current history of severe immune suppression, gender (especially females), the presence of opportunistic infections, AIDS diagnosis (stage 4 disease or CD_4^+ less than 200 cells/mm^3) duration of HAART and type of HAART. Especially stavudine (NRTI), ritonavir, and indinavir (PI) are prone to induce LDS. Domingo *et al* (2012) stated that chronic ART can bring about additional metabolic side-effects, including dyslipidaemias, insulin resistance, and abnormal body fat re-distribution (lipodystrophy). Overweight and obesity are common problems in PLWHA especially women (Segatto *et al* 2012). If women are also associated with a high likelihood of developing HIV lipohypertrophy (Domingo *et al* 2012; Segatto *et al* 2012), this is cause for concern regarding the impact of RUSF if the results highlight its potential for the significant improvement in body weight. Rossouw et al (2012) reported that there is a lack of data on the cost-effective measures to treat lipoatrophy and lipohypertrophy. Therefore, prevention and sound scientific research on the potential causes remain important. A prospective population-based study reported that an estimated 20% of individuals on HAART will experience fat redistribution in the first two years of treatment. In the current study, ten percent of the HIV positive participants suffered moderate lipohypertrophy, five percent in the breast and the other five percent in the waist. Ten percent other cases experienced severe hyperlipotrophy in the waist and abdomen. However, no association between changes in BMI and the presence of lipoatrophy or lipohypertrophy were measured. It can therefore be concluded that it is highly unlikely that the presence of lipodystrophy in this study population has not been affected by short-term supplementation with RUSF. However, it is suspected that the presence of lipodystrophy in this study population can be ascribed to the other factors, such as those mentioned previously. Furthermore, no similar studies were found of which the results of this study could be compared to. This serves as a motivation for further study, especially when taking into consideration the positive findings on weight gain.

5.2 Shortcomings of the study

The shortcoming of this study included the following:

- Both genders were not equally represented in the study: the majority of men were not compliant to participate, as their visits were inconsistent, non-consecutive and they withdrew early. Assessment of attitude and perception towards supplementation programmes should be considered in future studies;
- The frequency of intake of certain foods was measured. The foods used were the commonly used foods in KwaZulu-natal rural areas and there are a representative of all food groups. However, it was not possible to quantify the exact nutrient intakes, which would have provided a more comprehensive understanding of dietary habits of the population group. A diet history could have served as an appropriate tool for this purpose;
- This study did not include the use of a placebo, as it is not an ethical choice;
- Macallan (1999) documented that therapeutic strategies do not reverse depletion of LBM, but instead have been reported to mainly increase body fat and water. A loss of lean body mass is a prognostic marker in HIV infection and changes in body composition are more sensible in testing intervention outcomes. Weight gain in this study could not be classified, based on whether it is associated with a desirable gain in lean body mass or undesirable increase in body fat;
- Additional follow-up visits of participants should be conducted to observe whether the weight gain and improvement in disease symptoms were sustainable;
- The assessments of body/morphological changes were conducted on only a small number of participants. It is suggested that the study should be repeated using a much larger study sample.
- Future studies should assess the impact of RUSF by also including changes in blood parameters, such as CD4 counts, full blood counts, lipid profiles, etc.

CHAPTER 6
CONCLUSION

The aim of this study was to determine the impact of a locally produced ready-to-use supplementary food, *Sibusiso*®, on BMI and on the improvement of disease symptoms identified at baseline assessment of HIV positive adults receiving ART. It also aimed to determine the impact of this supplementary food on lipodystrophy in HIV positive adults receiving ART. In this chapter, the main conclusions of this study and implications for future research will be discussed.

6.1 Conclusion

Within the context of the hypotheses stated in Chapter 1 of this thesis, the following conclusions can be made:

- The administration of the nutrition supplement *Sibusiso*® RUSF, in conjunction with the use of ART, might increase the likelihood of nutritional recovery in malnourished HIV patients. Findings from this study support the hypothesis that supplementation with RUSF at least for three months has the potential to gradually improve BMI among HIV-positive adults on ART in clinical settings. RUSF is high in energy and supplementation with it likely contributes to an improved energy intake, even though it is unable to meet full RDA requirements for either energy or macronutrients. This study reported no association between the starting weight and BMI changes after three months of supplementation. It is hypothesised that in this finding lies a possible benefit, in the sense that *Sibusiso*® RUSF can be used effectively in patients with HIV, regardless of their BMI. It is not certain whether this also holds true for the different stages of disease progression, as it has been reported that disease progression influences treatment outcome, also in terms of ART. This is the basis for the decision of local authorities to start treatment at an earlier phase of disease progression (DoH 2010).

- The most predominant disease symptom and disease conditions experienced by the subject population before supplementation was initiated, were fever followed by nausea and persistent diarrhoea. Fever was unexpected but the predominance of nausea and diarrhoea support the hypothesis that the contamination of the environment in poor

communities increases the risk of PLWHA to contract these symptoms. No support however was found for the hypothesis that vomiting predominated. The predominance of the earlier mentioned symptoms was also keeping with the results from other previous studies.

- Unexpectedly, participants reported an increase in severity of these symptoms from the baseline to the second visit, but the reason for this finding was unknown. However, it is suspected that overconsumption of the supplement could have contributed to possible side-effects. Reason for overconsumption could be a lack of other available food sources due to poverty or perceiving RUSF as a fast method to overcome the stigma associated with thinness. Yet, the increased presence of some of the symptoms could possibly have metabolic origins, similar to that when a patient with HIV commences ART. However, but this is purely based on speculation.

- There was a significant and beneficial improvement in fever and gastroenteritis; steady but significant decline in vomiting and no change in persistent diarrhoea, from the beginning of supplementation to subsequent visits. The findings of this current study support the hypothesis that supplementation with the RUSF will provides participants with more nutrients that will help in the improvement of symptoms experienced by participants. Despite the low water content of RUSF combined with a low risk of contamination with pathogens, intense education on personal hygiene is crucial to break the cycle of diarrhoea and malnutrition in people infected with HIV, especially in poverty stricken areas.

- Other conditions such as lack of appetite and fatigue were present at the beginning of supplementation. Loss of appetite was probably a result of fever or alteration of taste and smell due to illness. In this study *Sibusiso*® RUSF was also found to exert a beneficial effect on appetite, meal consumption and energy levels of participants. These results support the hypothesis that because of the high nutrient and energy density of *Sibusiso*® RUSF, there will be improvement in these conditions in participants receiving supplementation. Even at the second visit when participants reported an increase in disease symptoms, they also reported an improvement in appetite, meal consumption and energy levels. These three factors are expected to complement each

other in order to improve nutritional status in this population group, if it is assumed that the individuals have access to appropriate food and supplements such as RUSF.

- Lipodystrophy was reported by 20% HIV positive participants who were receiving *Sibusiso*® RUSF for three months. However, one cannot unreservedly reject the hypothesis that *Sibusiso*® RUSF will not induce lipodystrophy. It is highly unlikely in this study, that lipodystrophy in the participants were affected by supplementation with RUSF. Yet, it is uncertain whether these results are conclusive, in the sense that it requires more long-term epidemiological studies to see whether RUSF-induced weight gain, is associated with an improvement in lean body mass, or whether the weight gain is as a result of increased body fat stores, which is not desirable.

In conclusion, *Sibusiso*® RUSF was not only successful in promoting weight gain among participants, but was also able to improve the overall wellbeing of participants by alleviating the burden of disease conditions and infectious symptoms while improving appetite, meal consumption and energy levels without inducing any morphological changes. It is therefore important to consider scaling up the RUSF intervention at the same pace as ART programs in high HIV prevalence areas dominated by poverty and malnutrition.

6.2 Implications for further research

The administration of the nutrition supplement *Sibusiso*® RUSF, in conjunction with the use of ART, might increase the chances of nutritional recovery in malnourished HIV patients. Findings from this study suggest that supplementation with RUSF for at least three months has the potential to gradually improve weight gain among HIV-positive adults under ART in the clinical settings. It is suggested that future research investigates whether *Sibusiso*® supplementation sustains weight gain in HIV positive patients for longer periods of time. If so, then the use of *Sibusiso*® should be promoted, especially in areas of low socio-economic status where the prevalence of HIV has reached epidemic proportion. Yet, it remains a priority to investigate whether *Sibusiso*® promotes an increase in body fat stores, or whether it promotes an improvement in lean body mass, as this would finally establish whether the product should be promoted for public use.

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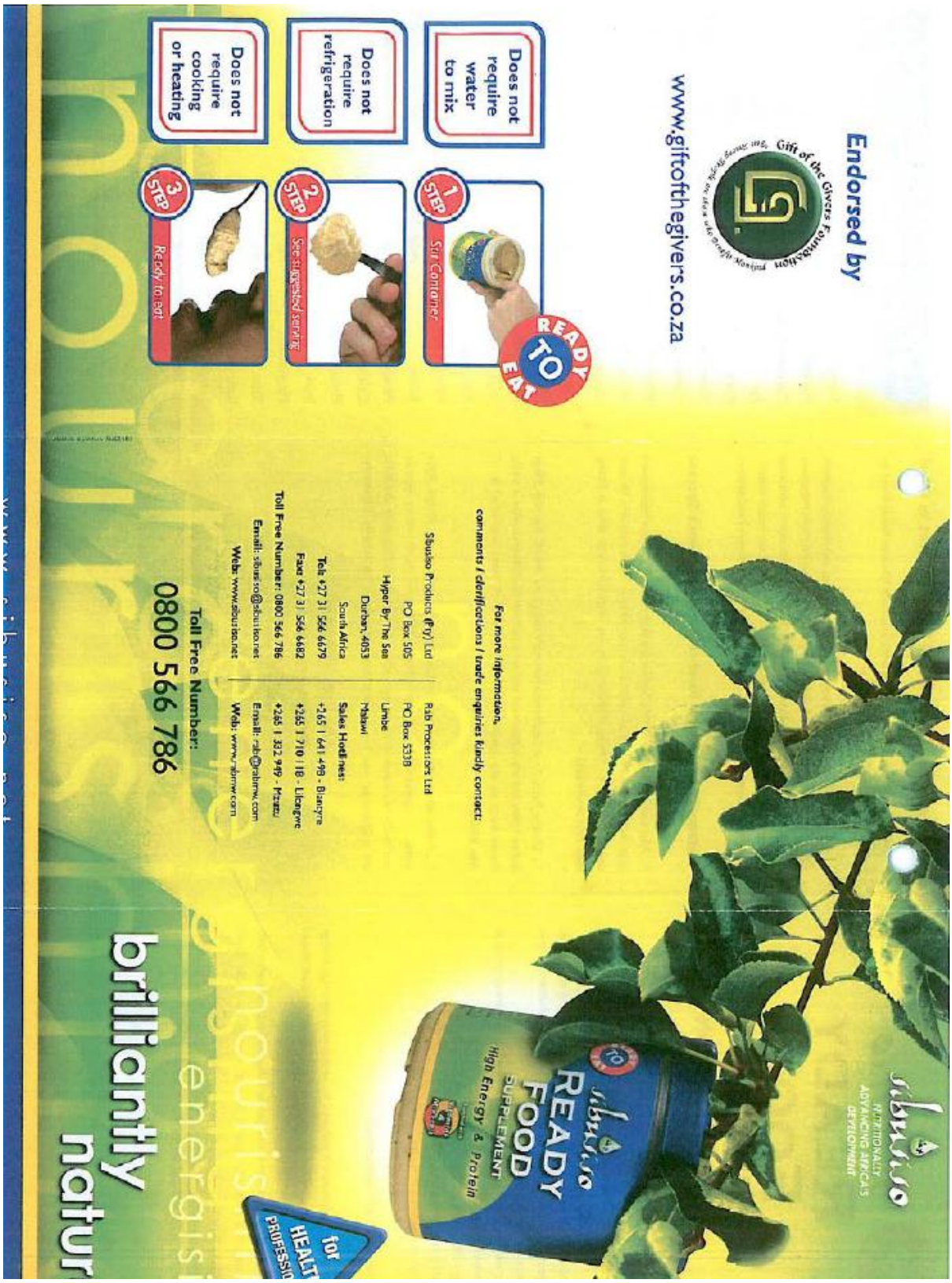
APPENDIX A: *Sibusiso*® Ready food supplement information leaflet



READY TO EAT

sibusiso

READY FOOD SUPPLEMENT

High Energy & Protein

What are the qualities of this product?

- This product is READY to eat, it does not require cooking, heating or dilution;
- Sibusiso Ready Food can be used as a stand alone product directly from the bottle, as a spread, or added to porridge;
- This energy and nutrient dense product has a sweet nutty flavour, which is quite different to flavours of other food supplements;
- High energy – 100g SRFS 2352kJ;
- Protein – SRFS 16 g / 100g;
- It is free of lactose, wheat and gluten.

When is this product indicated?

- Sibusiso Ready Food Supplement is indicated for people who have high energy needs (for example, due to infection), but who find it difficult to meet these needs through a mixed diet.
- Sibusiso Ready Food Supplement is additionally indicated for people who have decreased appetite and who battle to eat enough to meet their nutritional requirements.

Enriched with Vitamins & Minerals

What are some of the results of this product to date?

- Some of the testimonials of people who have used Sibusiso Ready Food to supplement their diets are as follows:

"Having carried out independent laboratory tests and obtained feedback on a range of people utilising the product, the Gift of the Givers Foundation is satisfied that Sibusiso Ready Food Supplement has shown substantial promise in the provision of energy, weight gain and improved nutritional status". ***Dr Imtiaz Sooliman MB.Ch.B. – Chairman: Gift of the Givers Foundation.***

Testimonials of Sibusiso Ready Food Supplement's Success

"…After taking Sibusiso Ready Food Supplement, there has been a marked improvement in his health and he has gained weight. He is now taking an active interest in life once again…" ***– Ms C. Shaw, (referring to an acquaintance who is living with HIV and AIDS).***

"…Sibusiso Ready Food Supplement has really helped my son. He was only 39kgs before I gave him the supplement and we could see the difference after a week. Please keep up the good work for the sake of all those who need it…," ***Mrs Withers.***

"…Before taking Sibusiso Ready Food Supplement, I weighed only 32 kgs. After taking the supplement, I had gained 6.5kgs within the first month and my appetite and health had improved. I now weigh 40kgs. My four year old daughter also takes the supplement and her appetite has improved…," ***Michelle Kennedy.***

Losing Weight !
Poor Appetite !
Muscle Wasting !
Low Energy Levels !
Weakness and Illness !
Nutritionally Challenged !

The Solution is

www.sibusiso.net

NUTRITIONAL INFORMATION

Nutrients		Per 100g	Per 50g daily serving	% RDA* per 5 daily ser
Energy	- kJ	2352	1176	
Protein	- g	16	8	
Carbohydrate	- g	48	24	
Fat	- g	35	17.5	
Fibre	- g	1.9	0.95	
Vitamin A	- mcg RE	1200	600	75
Vitamin D	- mcg	10	5	83
Vitamin E	- mg	30	15	100
Vitamin K	- mcg	50	25	
Vitamin C	- mg	150	75	100
Vitamin B1	- mg	2.2	1.1	79
Vitamin B2	- mg	2.2	1.1	69
Vitamin B3	- mg	20	10	56
Vitamin B6	- mg	2.6	1.3	50
Folic acid	- mcg	600	300	75
Vitamin B12	- mcg	3.6	1.8	60
Biotin	- mcg	60	30	100
Pantothenic acid	- mg	8	4	80
Calcium	- mg	2000	1000	91
Phosphorus	- mg	1400	700	80
Iron	- mg	28	14	100
Magnesium	- mg	160	80	23
Zinc	- mg	10	5	33
Iodine	- mcg	300	150	100
Selenium	- mcg	110	55	100
Sodium	- mg	< 580	<290	
Potassium	- mg	1150	575	
Copper	- mcg	1400	700	

*Percentage Recommended Dietary Allowance Adults and Children older than 10 ye

APPENDIX B: Monitoring Tool

Nutritional Assessment of Patient receiving Sibusiso Ready Food Supplement (SRFS)

Patient Details:

Name: _____ Patient no.: _____

Age (yrs):		No. of people in household:	
Starting weight (kg):		No. of children < 13 yrs in household:	
Height (m):		Grant (specify):	

Sex(m/f): _____

Background Information:

Please tick the applicable answer

	Yes	No
Employed		
Vegetable garden		
Electricity		
Fridge		
Indoor flushing toilet		
Running water		
Stove		

Food Frequency			
	Daily	Weekly	Monthly
Meat/chicken/fish			
Eggs			
Milk			
Vegetables			
Fruit			
Bread/potatoes/phutu			
Porridge			
Water			

Medication & Supplements		
	Yes	No
TB medication		
ARV medication		
Multivitamin		
Porridge		
Other (specify):		

Nutritional Information:

Please fill in necessary details and tick correct column

		VISIT 1	VISIT 2	VISIT 3	VISIT 4	VISIT 5	VISIT 6	VISIT 7	VISIT 8
	Date								
	Weight (kg)								
	Wt Gained (kg)								
	Wt Lost (kg)								
	Ht (m)								
Symptoms	Nausea								
	Diarrhoea								
	Jaundice								
	Fever								
	Vomiting								
Disease Conditions	Diarrhoea (past 2 wks)								
	Dehydrated								
	Mouth sores								
	Oral thrush								
	Kwashiorkor								
	Marasmus								
	Gastro								
	TB								
	HIV +								
Appetite	Poor								
	Good								
Meal consumption	1/4 bowl								
	1/2 bowl								
	Full bowl								
Energy levels	Very weak								
	Weak								
	Fine								
	Full of energy								

This form was compiled by: Dietitian ☐ Nurse ☐ Other(specify) ☐

Remember:

At first visit: Fill in all patient details, background information and food frequency and other supplements received

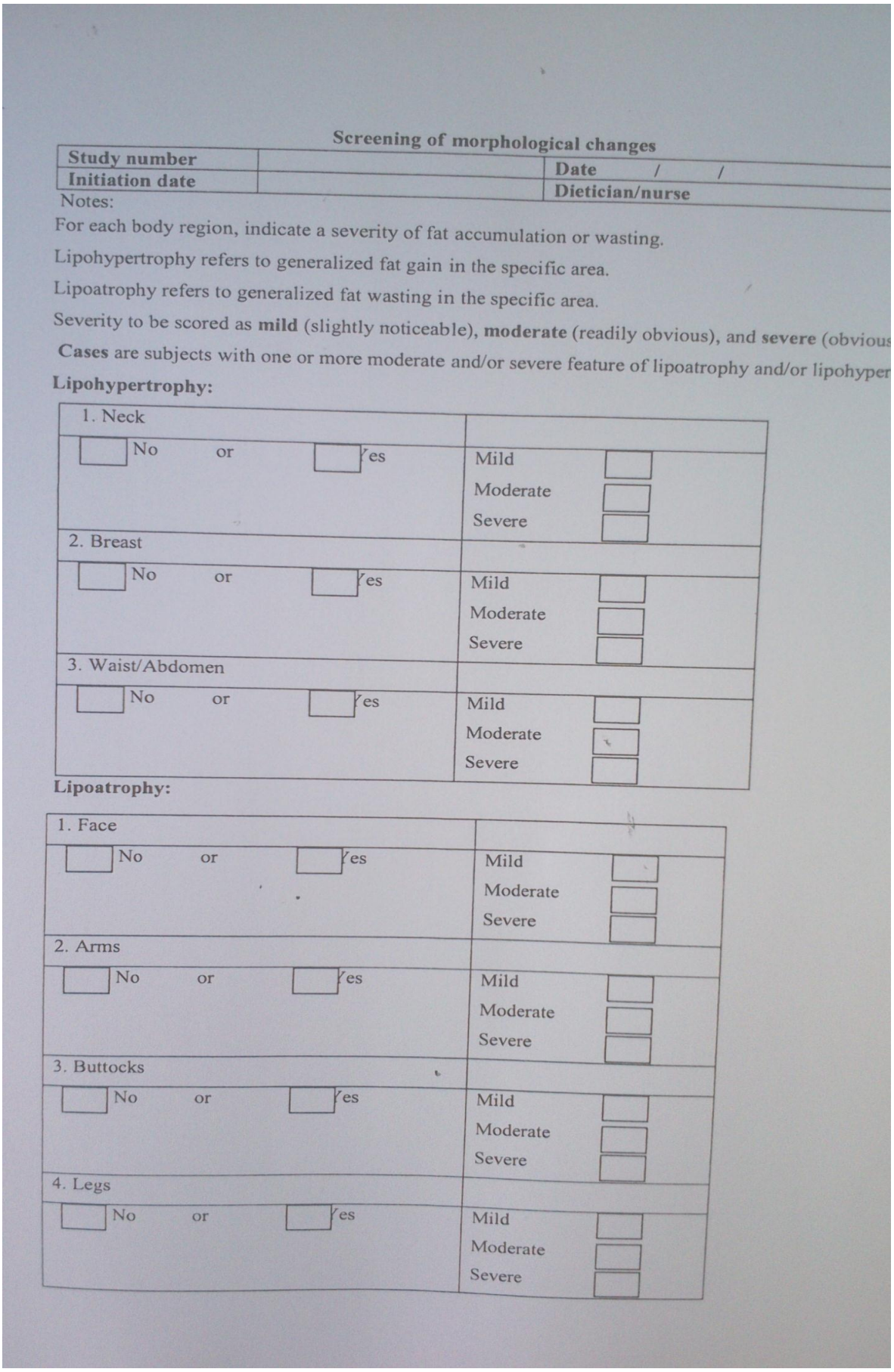
At every visit: Fill in weight and tick appropriate boxes for weight gained or lost, symptoms of disease, disease conditions, appetite, food consumption and energy levels

Issue every adult with 3 tubs of Sibusiso at each visit
Every adult must have 4-6 heaped teaspoons of Sibusiso daily

Many thanks for the time and effort taken to fill in this form.

Philippa Barnard and Angie Steyn - Consulting Dietitians for Sibusiso Products (Pty)Ltd

APPENDIX C: Screening tool for morphological changes



Screening of morphological changes

Study number		**Date** / /	
Initiation date		**Dietician/nurse**	

Notes:

For each body region, indicate a severity of fat accumulation or wasting.

Lipohypertrophy refers to generalized fat gain in the specific area.

Lipoatrophy refers to generalized fat wasting in the specific area.

Severity to be scored as **mild** (slightly noticeable), **moderate** (readily obvious), and **severe** (obvious

Cases are subjects with one or more moderate and/or severe feature of lipoatrophy and/or lipohyper

Lipohypertrophy:

1. Neck		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐
2. Breast		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐
3. Waist/Abdomen		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐

Lipoatrophy:

1. Face		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐
2. Arms		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐
3. Buttocks		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐
4. Legs		
☐ No or ☐ Yes	Mild	☐
	Moderate	☐
	Severe	☐