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# Outcome of Ready to use Food Therapy and its Predictor Among Adult Hiv/Aids Clients in Felege Hiwot Comprehensive Specialized Hospital, North West Ethiopia

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**BAHIR DAR UNIVERSITY COLLEGE OF MEDICINE AND  
HEALTH SCIENCE**

**SCHOOL OF PUBLIC HEALTH**

**DEPARTMENT OF EPIDEMIOLOGY AND BIostatISTICS**

**OUTCOME OF READY TO USE FOOD THERAPY AND ITS  
PREDICTOR AMONG ADULT HIV/AIDS CLIENTS IN  
FELEGE HIWOT COMPREHENSIVE SPECIALIZED  
HOSPITAL, NORTH WEST ETHIOPIA.**

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**A RESEARCH THESIS SUBMITTED TO DEPARTMENT OF  
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TITLE	OUTCOME OF READY TO USE FOOD THERAPY AND ITS PREDICTOR AMONG ADULT HIV/AIDS CLIENTS.
STUDY PERIOD	FROM NOVEMBER 30,2020 TO DECEMBER 30,2020.
STUDY AREA	FELEGE HIWOT COMPREHENSIVE SPECIALIZED HOSPITAL, BAHIR DAR

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## **ABSTRACT**

**Background:** - Malnutrition among people living with HIV remains a major challenge in achieving the full impact of interventions aimed at improving the quality of life, productivity and survival. However, the outcome of ready to use food therapy and factors affecting it among HIV/AIDS patients are not yet well investigated.

**Objective:** - This study aimed to assess the outcome of ready to use food therapy and its predictors among adults' HIV/AIDS patients at Felege Hiwot Comprehensive Specialized Hospital, North west Ethiopia, 2020.

**Methods:** - Retrospective cohort study was conducted among 636 adult HIV/AIDS patients on food by prescription at Felege Hiwot Comprehensive Specialized Hospital from November 30,2020 to December30, 2020. The study subjects were selected by systematic random sampling method using food by prescription registers as sampling frame. Data were entered and cleaned using Epidata version 3.1 then export to SPSS version 23 for analysis. Logistic regression was used to identify the association between dependent and independent variables. Variables with a p -value < 0.25 in bi-variable analysis were included into a multivariable logistic regression analysis to identify the predictor variable. Log Binomial logistic regression was used for a better estimation of RR. Variables with p-values less than 0.05 during Log Binomial logistic regression analysis was considered statistically significant with 95%CI.

**Results:** - In this study 36.8% of patients on ready to use food therapy were recovered. Severity of malnutrition at enrollment AOR (95% CI) =7.041 (3.719-13.331)], presence of opportunistic infection [AOR (95%CI) = 15.563 (6.417-37.745)] and Adherence to RUFT [AOR (95% CI) = 8.784 (1.314 -58.702)] were the predictors of outcome of ready to use food therapy.

**Conclusion and Recommendation:** -The recovery rate of this study was lower than the sphere standard. The factors that affect Outcome of ready to use food therapy were severity of malnutrition, opportunistic infection and adherence to RUFT. Regular and comprehensive nutritional screening of patients on HIV chronic care, early treating of OI and strengthening of nutritional adherence counseling for patients on RUFT is very crucial to improve recovery.

**Keywords:** -Food by prescription, Predictors, Treatment Outcome, Ethiopia

## **ACRONYMS AND ABBREVIATIONS**

AIDS	Acquired Immune Deficiency Syndrome
AOR	Adjusted Odd Ratio
ART	Anti-Retro viral Therapy
ARV	Anti-Retro Viral
BMI	Body Mass Index
CD4	Cluster Differentiation 4
CI	Confidence Interval
COR	Crude Odd Ratio
CNS	Central Nerve System
FAO	Food and Agriculture Organization
FBP	Food By Prescription
FMOH	Federal Ministry of Health
FHCSH	Felege Hiwot Comprehensive Specialized Hospital
HAART	Highly Active Anti-Retroviral Therapy
HIV	Human Immune deficiency Virus
MAM	Moderate Acute Malnutrition
NASC	Nutritional Assessment, Counseling, and Support
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH	People Living With HIV
RUTF	Ready to Use Therapeutic Food
RUSF	Ready to use Supplementary Food
SAM	Sever Acute Malnutrition
SPSS	Statistical Package for Social Science
USAIDS	United States Agency for International Development
WFP	World Food Program
WHO	World Health Organization

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# 1. INTRODUCTION

## 1.1 BACKGROUND

Malnutrition is defined as “the cellular imbalance between supply of nutrients and energy and the body’s demand for them to ensure growth, maintenance, and specific functions. It includes under nutrition, which results from less food intake and hard physical work and over nutrition results from excess food intake and less physical activities [1, 2].

The African Region is experiencing the double burden of malnutrition and if current trends continue, The number of undernourished people in sub-Saharan Africa rose from 181 million in 2010 to almost 222 million in 2016 [3].

The twin global epidemics of HIV infection and food scarcity disproportionately affect sub-Saharan Africa, and a significant proportion of patients who require antiretroviral therapy are malnourished because of a combination of HIV associated wasting and inadequate nutrient intake [4, 5].

Despite tremendous advances in care for human immunodeficiency virus (HIV) infection and increased funding for treatment, morbidity and mortality due to HIV/AIDS in developing countries remains unacceptably high[1, 2]. Receiving appropriate nutrition can help to improve health and quality of life of HIV-infected individuals. The current WHO recommendations for the nutrient requirements of people living with HIV/AIDS call for increases in energy over the intake levels recommended for healthy non-HIV-infected individuals of the same age, sex, and level of physical activity. Increased energy metabolism in asymptomatic adults requires 10-15 percent additional energy; this additional energy requirement is 20-30% in symptomatic adults[1].

The overall aim of nutritional programs in HIV care settings is to improve nutritional status, HIV treatment outcomes, and ART adherence for people living with HIV. The types of nutritional programs and mechanisms for their implementation vary widely across countries. Many nutritional programs in sub-Saharan Africa provide ready to use therapeutic foods (RUTF) or Ready to Use supplementary foods (RUSF) for a short period of time to tackle undernutrition amongst people living with HIV[6].

The food by prescription program is one of the strategies that addresses under nutrition among HIV infected people and their vulnerable family members through nutritional assessment, counseling, and support (NACS)[4, 7].

Ethiopia begins these programs in the summer of 2010 with technical assistance of Save the Children US. FMOH has launched a comprehensive National Nutritional program, which includes nutrition and HIV/AIDS as part of its complete service delivery. Ethiopia has integrated HIV and nutrition intervention based on the patient's nutritional status. Beneficiaries are those who have Moderate Acute Malnutrition (MAM) and Sever Acute Malnutrition (SAM). [7, 8].

HIV infected adults who present with malnutrition at participating health facilities are prescribed food rations according to their nutritional status. The rations are prescribed during monthly appointments together with client's ART medication, and are distributed directly from clinic pharmacies. Clients are monitored closely by health facility staff who are collecting both anthropometric and disease progression data during monthly appointments[8].

In resource-limited settings where poverty and food insecurity are common, provision of therapeutic and supplementary food products is a critical component of comprehensive care and support interventions. Nutritional interventions have been successful in the management of HIV and AIDS, and many patients enrolled into such programs have markedly improved both their body weight and general health status [4, 5].

According to the sphere standard the discharged individuals from the FBP programme must be free from medical complications. In addition, they should have regained their appetite and have achieved and maintained appropriate weight gain without nutrition-relate edema (for example, for two consecutive weighing with BMI  $>18.5\text{Kg/m}^2$ . The standard for recovery from malnutrition is  $>75\%$ , Defaulted:  $<15\%$  and died:  $<10\%$ [9].

## **1.2 STATEMENT OF THE PROBLEM**

Malnutrition is a widespread problem, affecting the global population at some life stage. This public health epidemic targets everyone, but the most vulnerable groups are poverty-stricken people, young children, adolescents, older people, those who are with illness and have a compromised immune system, as well as lactating and pregnant women[10].

According to USAIDS Report of 2019, globally 38 million people currently living with HIV and adult population living with HIV globally constitute 35.1 million [29.6 million–41.7 million]. There were about 1.7 million new infections in 2019. 690 000 people have died of AIDS-related causes annually at the end of 2019 and 32.7 million [24.8 million–42.2million] people have died from AIDS-related illnesses since the start of the epidemic (end 2019) and more than 60% of all HIV infections in the world occurring sub-Saharan Africa. Up to 50% of PLWHA have malnutrition in many parts of the world, especially in sub-Saharan Africa[4, 11].

Over 850 million people worldwide and 200 million adults in Sub-Saharan Africa suffer from malnutrition. In 2014, approximately 462 million adults worldwide were underweight, while 1.9 billion were either overweight or obese[12].The 2018 Global Nutrition Report reveals that the global burden of malnutrition is unacceptably high and now affects every country in the world. But it also highlights that if we act now it is not too late to end malnutrition in all its forms. [13].

Today, nearly one in three persons globally suffers from at least one form of malnutrition: wasting, stunting, vitamin and mineral deficiency, overweight or obesity and diet-related NCDs. The developmental, economic, social and medical impacts of this global burden of malnutrition are serious and lasting, for individuals and their families, for communities and for countries[14]. The Africa region's adult population also faces a malnutrition burden. An average of 38.1% of women of reproductive age has anemia, and 8.1% of adult women have diabetes, compared to 7.9% of men. Meanwhile, 17% of women and 7% of men have obesity[15].

Malnutrition is considered to be the most common cause of immunodeficiency worldwide. It elicits dysfunctions in the immune system and promotes increased vulnerability of the host to infections[16].

Malnutrition among people living with HIV remains a major challenge in achieving the full impact of interventions aimed at improving the quality of life, productivity and survival. People living with HIV (PLWHA) are more likely to become malnourished due to reduced food intake, poor absorption of nutrients, and changes in the way the body uses nutrients it receives or has stored [17].

The synergism of HIV and under nutrition is unfortunate as one has a debilitating effect on the other, often in spite of access to ART. An HIV-positive person in a food insecure household would not consume an adequate diet consisting of nutrients required for maintaining a functional immune system to prevent opportunistic infections[18]. This situation usually leads to a rapid onset of AIDS, which causes a decrease in productivity due to illness and death. HIV-affected households are thus more likely to experience income losses, which in turn exacerbates food insecurity and low ART adherence, as difficult situations may arise such as choices between purchasing either food or treatment[19].

Up to 50% of PLWHA have malnutrition in many parts of the world, especially in sub-Saharan Africa. Their effects are interrelated and exacerbation of one another in a vicious cycle. Both HIV and malnutrition can independently cause progressive damage to the immune system and increased susceptibility to infection, morbidity and mortality through opportunistic infections such as fever, diarrhea, loss of appetite, nutrient malabsorption, and weight loss. Malnutrition and food insecurity have been associated with progressive functional impairment, reduced immune competence, increased mortality and poor clinical outcomes and exacerbates the effects of HIV by increasing susceptibility to AIDS-related illnesses which leads to decreased rate of cure from opportunistic infections[4, 20]. Evidence indicated that even relatively small losses in weight (5%) are associated with decreased survival rate [4].

In resource limited settings, many PLWHA lack access to sufficient quantities of nutritious foods, which poses additional challenges to the success of antiretroviral therapy. The combined impacts of food insecurity and HIV/AIDS place further strain on already limited household resources as affected family members struggle to meet household food needs[21, 22].

There are different strategies used to overcome malnutrition. Nutrition interventions like ready-to-use food therapy are critical components of a comprehensive response to the HIV pandemic.

In many conditions nutrition interventions can help break the infection and malnutrition cycle by helping people improving their immune function, reducing the incidence of complications associated with HIV infection, attenuating the progression of HIV infection, improving quality of life, and ultimately reducing mortality associated with HIV[23].

Study in west Africa(Senegal) showed Improving PLWH' diet with 100 g RUTF for a long period has a positive impact on muscle mass and anemia but not on the zinc status of the patients[24].

A meta-analysis done in Ethiopia revealed that the pooled percentage of under-nutrition among HIV-positive adults was 26% and the subgroup analyses of this study also indicated that the percentage of undernourishment among HIV positive adults is slightly higher in the Northern and Central parts of Ethiopia (27.5%) as compared to the Southern parts of Ethiopia (25%)[25].

A study conducted in Ethiopia showed that the recovery rate was 42%, study conducted in Mekele hospital showed that recovery rate was 62.4%, study conducted in Gonder university hospital showed that recovery rate was 24% and also study conducted in Amhara region showed that recovery rate was 41%[7, 26-28].

To overcome this problem Ethiopia began food by prescription program in 2010. Even if ready to use food therapy was launched and given for malnutrition HIV/AIDS clients in Ethiopia; treatment outcome of RUFT was low which is below the sphere standard (recovery rate >75%). Studies conducted in different place of Ethiopia at different times try to show the treatment outcome of RUFT and identify its predictor among adult HIV/AIDS clients, still there is information gap and also they did not include variables such as viral load status, disclosure status and comorbidity with chronic disease as predictors. And also, there is no similar study done in Felege Hiwot Comprehensive Specialized Hospital.

Therefore, this research aimed to fill the gap and also include those variables that are not included in the previous studies. And also, this study aimed to determine the treatment outcome of RUFT and its predictor among adult HIV/AIDS clients in FHCSH, and it will identify which of these factors have more pronounced impact on treatment outcome.



### **1.3 SIGNIFICANCE OF THE STUDY**

The result of this study is very important on identification of the predictors of treatment outcome of RUFT among adult ART clients.

The study will provide a base line data for hospital managers, ART clinic staffs, donors who are supporting the food by prescription (FBP) program in giving information about treatment responses and its predictors associated with the treatment outcome of FBP among HIV positive adult individuals based on the evidences generated from the study and that helps in improving quality of life of HIV infected people.

There is no similar study done in Felege Hiwot Comprehensive Specialized Hospital. So knowing treatment outcome of ready to use food therapy and its predictor among HIV/AIDS patients is important to improve the service delivery process and will also help to clearly picture the problem of outcome of ready to use food therapy and its predictors associated with nutritional intervention programs. And also, may be used by health program planners, organizations working on food by prescription program and researchers who are interested to conduct research in this area may use it as a reference.

## 2. LITERATURE REVIEW

### 2.1. OUTCOME OF READY TO USE FOOD THERAPY

A Retrospective cohort study done in Sub-Saharan Africa showed that 47.4% of patients were cured after ready to use food therapy[6].

Another study conducted in Sub-Saharan Africa stated that patients who took ready to use food therapy were a 13% weight increase as compared to a control group who took food supplementation containing corn–soya blend with a 10 % increase[5].

Randomized controlled pilot study done in South Africa shows that nutritional supplementation taken concurrently with ART for 6 months resulted in an increase in BMI, CD4 count, hemoglobin, red blood cell and white blood cell count and improvement in physical activity[23].

A study done in Mangochi health district of Malawi about effective therapeutic feeding with chickpea sesame based ready-to-use therapeutic food (CS-RUTF) in ;wasted adults with confirmed or suspected AIDS stated that 49.4% of patients were discharged recover ,38.5% of study participants died[24].

Other retrospective cohort study conducted in Kenya showed that only 13.1% of clients attain a BMI of > 20 and 22.2% attaining BMI > 18.5[29].

Prospective quasi-experimental study done in Uganda showed that food assistance over 12 months, significantly increased body mass index by 0.6 kg/m<sup>2</sup>[30].

A partnership study between Tufts University and save the children US in Ethiopia stated that 32.6% achieved BMI >= 18.5 at least once during treatment in the FBP group, compared to 18.8% in the comparison group. A study conducted in Ethiopia on impacts of FBP showed that recovery rate was 42%, and non-response rate was 58%[7].

A retrospective cohort study done in Mekele hospital reveal that about 62.4% patients on ready to use food therapy were recovered or graduated from malnutrition,29.6% of patients were non-respondents (didn't recover) according to the predefined RUFT exit criterion, 5.9% defaulted from the food therapy and 1.9% had died. The overall failure rate including non-respondent, defaulter and death were 37.6%[26].

A mixed quantitative and qualitative study done in Tigray region stated that 55.3% were recovered from malnutrition, 19% did not complete the program, and 21% completed the program but failed to recover from malnutrition[31]. A cross sectional study conducted in Gondar University Hospital reveal that 24% were recovered (graduated) from malnutrition,25.6% of patients were non-responders (didn't recover) according to the FBP exit criteria, 48.8% were defaulted from the FBP program and 1.7% were died during the intervention period. The overall failure rate including non-responders, defaulter and death were 76 % [27].

A Retrospective Cohort Study conducted in Amhara National Regional State showed that about 41% of patients achieved normal BMI after three months of treatment[28].

A cross sectional study done in Gonder University Hospital about retention and treatment outcomes of an undernutrition program for HIV patients (children and adults) involving Ready-to-use Therapeutic Food showed that 44.2% recovered after 4-6 months of follow-up and the overall defaulted cases were found to be 24.8% and not responded cases comprise 18.6% [32].

## **2.2. SOCODEMOGRAPHIC FACTORS**

A Retrospective cohort study done in Sub-Saharan Africa showed that being male sex were found to be significant predictors for poor nutritional treatment outcome[6].

Other retrospective cohort study conducted in Kenya showed that male patient were more likely to attaining BMI > 20 as compared to female and younger age were more likely to attain BMI >20 than other older age group[29].

A partnership study between Tufts University and Save the Children US in Ethiopia stated that being female was more likely to recover from malnutrition after ready to use food therapy than men[7].

And also case control study done in Bahir Dar showed that being male sex were found to be significant predictors for poor nutritional treatment outcome[33].

A retrospective cohort study done in Mekele hospital showed that being male sex and illiterate patient were found to be significant predictors for poor nutritional treatment outcome[26].

In contrast to this a cross sectional study conducted in Gondar University Hospital revealed that males were higher to recover than females[27].

A Retrospective Cohort Study conducted in Amhara National Regional State revealed that male patients were more likely to achieve normal BMI status compared with females[28].

### **2.3. PREDICTOR OF OUTCOME OF READY TO USE FOOD THERAPY**

A longitudinal Retrospective cohort study done in Sub-Saharan Africa stated that patients who were eligible for and started on ART at or after NP admission were less likely to fail nutritional therapy than patients who never initiated therapy despite being eligible and patients not eligible for ART at NP admission were both at increased risk of NP failure[6].

A study done in Mangochi Health District of Malawi about Effective Therapeutic Feeding with Chickpea Sesame Based Ready-to-Use Therapeutic Food (CS-RUTF) in Wasted Adults with Confirmed or Suspected AIDS stated that being on HAART and adhering to the number of visits were associated with increased chances of nutritional status improvement while the occurrence of episodes of acute diarrhea, and complaint of poor appetite during supplementation negatively affect nutritional improvement[24].

A randomized controlled trial conducted in Malawi about Supplementary feeding with either ready-to-use fortified spread or corn-soy blend in wasted adults starting antiretroviral therapy stated that patients receiving fortified spread had a greater increase in BMI than those receiving corn-soy blends[34].

Other retrospective cohort study conducted in Kenya showed that higher nutritional status at base line and compared to patients receiving HAART, patients who did not qualify for and therefore did not receive HAART during the study period had an increased rate of attaining BMI > 20[29].

A partnership study between Tufts University and Save the Children US in Ethiopia stated that recent commencement of ART, being moderately rather than severely malnourished, having a CD4 count higher than 200 cells/microliter, and coming from a food insecure household increased chance of recovery from malnutrition[7].

A retrospective cohort study done in Mekele hospital stated that patients in clinical stage 1 and 2 at enrolment to ready to use therapeutic food were more likely to respond to the therapy than patients at WHO clinical stage III and IV, patients without opportunistic infection at enrolment to the therapeutic food were more likely to recover than those who had opportunistic infection and patients who diagnosed as moderate and mild malnutrition during entry had more likely to respond to the therapeutic food than severe malnutrition[26].

A cross sectional study conducted in Gondar University Hospital reveal that patients who were moderately malnourished at base line were more likely for recovery as compared with those who were severely malnourished at entry. And patients who had opportunistic infections like diarrhea, mouth ulcer/oral thrush, pneumonia, meningitis, and CNS toxoplasmosis were less likely to recover from malnutrition as compared to those who had no opportunistic infections at entry[27].

A Retrospective Cohort Study conducted in Amhara National Regional State revealed that those patients who adhered to RUTF treatment were more likely to achieve normal BMI compared to those who did not adhered to the RUTF treatment, those patients who were moderately malnourished were more likely to achieve the desired BMI compared with those who were severely malnourished at the time of enrolment and those patients who adhered to Antiretroviral treatment (ART) were more likely to regain the desired BMI compared to those who did not adhered[28].

A case control study conducted in Bahir Dar town stated that patients who were diagnosed to have SAM at base line were more likely not to respond to therapeutic food than patients who had a diagnosis of mild malnutrition. Similarly, patients who were diagnosed to have moderate malnutrition were at higher risk of not recovering than did those with mild malnutrition. Participants who had a CD4 count below 100 were more likely not to respond to therapeutic food than participants who had a CD4 count above 350. Furthermore, patients who failed to have regular follow up, WHO clinical stage three, hemoglobin level below 10mg/dl were also associated with increased risk of no recovery from malnutrition[33].

### 3. CONCEPTUAL FRAMEWORK

The conceptual framework was developed after reviewing different literatures with proposed to outcome of ready to use food therapy and its predictors among adult HIV/AIDS clients. This study conceptualizes outcome of ready to use food therapy as the result of the interaction of different factors, which have direct and indirect relation to outcome of ready to use food therapy.

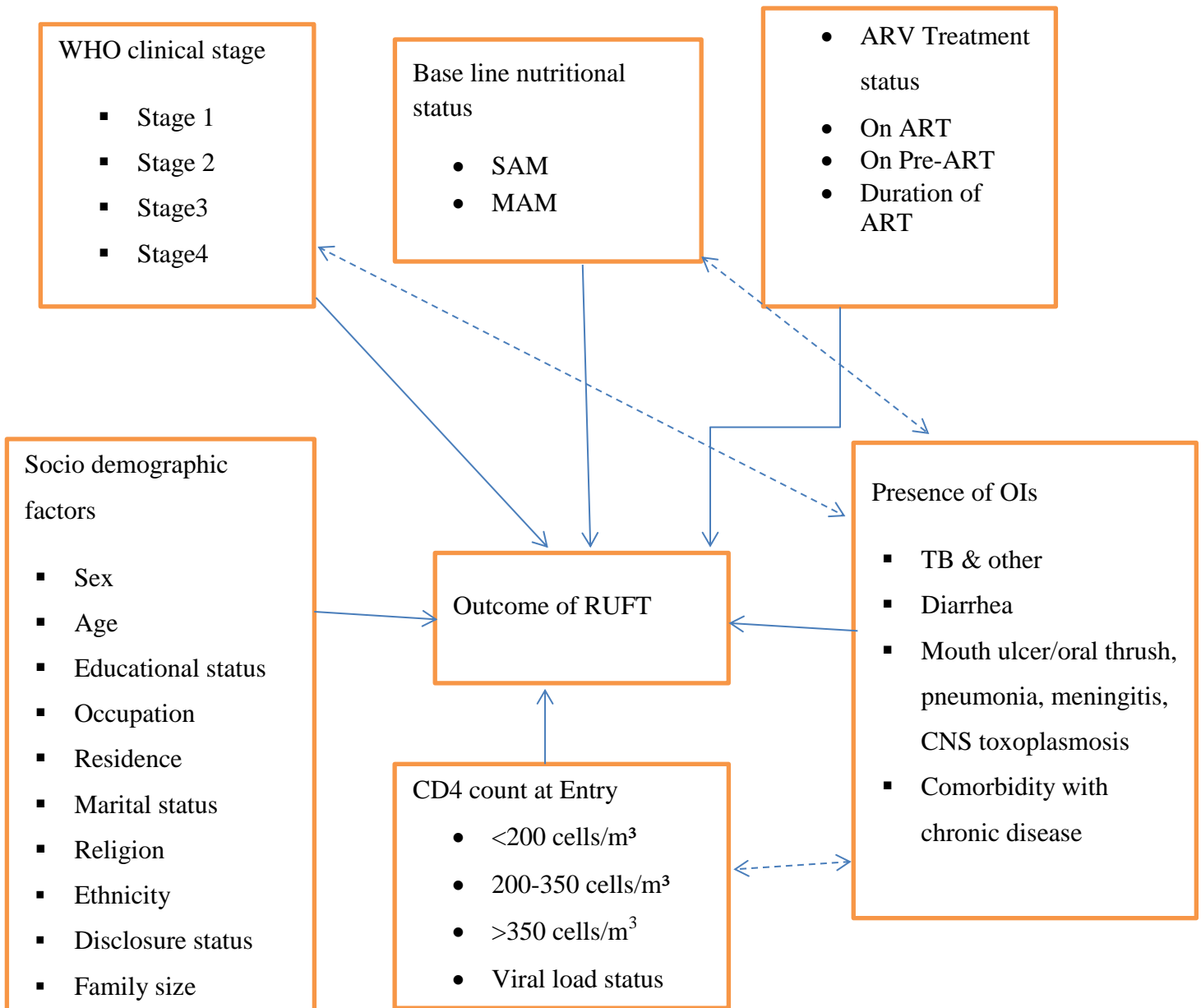


Figure 1 conceptual framework of outcome of ready to use food therapy and its predictor among adult HIV/AIDS clients which is taken from different literature [5-7, 23-25, 27, 29-33]

## **4. OBJECTIVES**

### **4.1. GENERAL OBJECTIVE**

The aims of this study was to determine the outcome of ready to use food therapy and its predictor among adult HIV/AIDS clients in FHCS Hospital, 2020.

### **4.2. SPECIFIC OBJECTIVES**

- To determine the outcome of ready to use food therapy among adult HIV/AIDS patients in FHCS hospital.
- To identify predictor of outcome of ready to use food therapy among adult HIV patients in FHCS Hospital.

## **5. METHODS AND MATERIALS**

### **5.1. STUDY DESIGN**

Retrospective cohort study design was conducted among adults on HIV/AIDS care treated for malnutrition by ready to use food therapy.

### **5.2. STUDY AREA AND PERIOD**

The study was conducted in Felege Hiwot comprehensive specialized hospital from November 30, 2020 to December 30, 2020.

Felege Hiwot comprehensive specialized hospital serves as a referral hospital for Amhara region and neighboring regions (Benishangul Gumez and Oromia) with a catchment population of 10 million.

Felege Hiwot comprehensive specialized hospital is found in the capital of Amhara regional state Bahir Dar which is located 560 km far from Addis Ababa. The FBP nutritional treatment program was started since 2011 in the Felege Hiwot Referral Hospital (FHRH). Felege Hiwot Referral Hospital serves about 15,961 PLHIV, of whom 7273 were enrolled into the FBP nutrition treatment program.

### **5.3. STUDY POPULATION AND SOURCE POPULATION**

#### **5.3.1. SOURCE POPULATION**

All adult HIV positive individuals who have follow up in Felege Hiwot Comprehensive Specialized hospital were considered as source population.

#### **5.3.2. STUDY POPULATION**

The study population were all adult PLHIV above the age of 19 years whose BMI was  $<18.5$  kg/m<sup>2</sup> and who were enrolled in to the FBP nutritional treatment program between November 1, 2017 to September 1, 2020.



## **5.4. INCLUSION AND EXCLUSION CRITERIA**

### **5.4.1. INCLUSION CRITERIA**

Adult HIV positive individuals age greater than 19 years, who had nutritional intervention and registered in the food by prescription registration book from November 1, 2017 to September 1,2020.

### **5.4.2. EXCLUSION CRITERIA**

- Those who were transferred out to other health facility without completing the treatment.
- Those clients who were defaulter and death without completing the treatment were excluded.

## **5.5. VARIABLES OF THE STUDY**

### **5.5.1. DEPENDENT VARIABLE**

- Outcome of ready to use food therapy

### **5.5.2. INDEPENDENT VARIABLES**

#### **Socio demographic factors**

- Sex
- Age
- Educational status
- Occupation
- Residence
- Religion
- Marital status
- Disclosure status
- Family size

#### **Base line Nutritional status**

- Sever Acute malnutrition
- Moderate Acute malnutrition

**ARV Treatment Status**

- On ART
- On Pre ART
- Duration of client on ART

**CD4 count at Admission**

- <200 cells/m<sup>3</sup>
- 200 – 350 cells/m<sup>3</sup>
- > 350 cells/m<sup>3</sup>
- Viral load status

**Presence of Opportunistic Infections**

- Tuberculosis, TB & other OI
- Diarrhea, mouth ulcer/ oral thrush, pneumonia, meningitis, CNS toxoplasmosis
- Comorbidity with chronic disease (DM, Chronic cardiac disease)

**WHO clinical stage**

- stage 1
- stage 2
- stage 3
- stage 4

## 5.6. OPERATIONAL DEFINITIONS

**Good outcome (Graduated/ Recovered):** Patients reached a BMI of 18.5kg/m<sup>2</sup> for two consecutive visits within 3 months for MAM and within 6 months for SAM.

**Poor outcomes (Non-response/ Unrecovered):** Participants who did not reach a BMI of 18.5kg/m<sup>2</sup> for two consecutive visits within 3 months for MAM and within 6 months for SAM.

**Defaulter:** Participants did not reach a BMI of 18.5kg/m<sup>2</sup> and dropped out of the program before the end of treatment.

**Died:** Participant died during the course of treatment and his/her death is documented in the registration book.

**Severe Acute Malnutrition (SAM)** is malnutrition with BMI <16 kg/m<sup>2</sup>.

**Moderate Acute Malnutrition (MAM)** is malnutrition with BMI ≥16 kg/m<sup>2</sup> to <18.5).

**Normal nutrition** is BMI ≥18.5 kg/m<sup>2</sup> to < 24 kg/m<sup>2</sup>,

**Overweight** is BMI ≥25 kg/m<sup>2</sup> to <30 kg/m<sup>2</sup>.

**Ready to Use Food (RUF)** includes both RUTF and RUSF, which are nutrient dense food packed in sachets.

**GOOD Adherences for ART** - If the client takes greater than 95% of the prescribed ART drug or, missing only 1 out of 30 doses or missing 2 from the 60 doses.

**FAIR** - If the client takes 85-94% of the prescribed ART drug adherence, i.e., missing 2-4 doses out of 30 doses or 4 to 9 doses from 60 doses.

**POOR**- If the client takes less than 85% of the prescribed ART drug, i.e. missing >5 doses out of 30 doses or > 10 doses from 60 doses.

## 5.7. SAMPLE SIZE DETERMINATION AND SAMPLING PROCEDURE

The sample size was determined using Epi Info Stat-Calc calculator for two populations by selecting power of 80%, a significance level of 5%, unexposed to exposed ratio of 1: 1. The sample size was calculated by two different ways; by outcome of ready to use food therapy and by associated factors based on this the maximum sample size was taken. Taking female as a risk factor of recovery in the study conducted in Amhara region with AOR 1.73 for the proportion of unexposed among recovered subjects of 23.7% [28]. Based on the above assumption, the total sample size required including 10% anticipated dropouts was 636.

**Table 1** sample size determination from different literature

Explanatory variables		Ratio(unexposed: exposed)	BMI improved		AOR	sample size	Reference
			Yes	No			
Sex	Male	1:1	87(53.0%)	77 (47.0%)		388	[26]
	Female		241(67.0%)	119(33%)	2.157		
ART adherence status	Good	1:1	133 (30.9%)	151 (35%)	2.14	218	[28]
	Poor		42 (9.7%)	105 (24.4%)			
Sex	Female	1:1	102 (23.7%)	177 (41.1%)		578	[28]
	Male		73 (16.9%)	79 (18.3%)	1.73		

**Table 2** Sample size determination by proportion

Dependent variable	Proportion	Sample size	Reference
Recovery	40.6%	370	[28]
Recovery	62.4%	360	[26]
Recovery	42%	374	[7]

## **5.8. SAMPLING PROCEDURE**

Selection of each record of patients was done by systematic random sampling method using the food by prescription registers as sampling frame until the determined sample size was obtained.

There were 1782 total HIV infected patients who were enrolled in to FBP program from November 2017 to July 2019.

$N = 1782$        $n = 636$

$N/n = 1782/636 = K = 2.8 = 3$

So sample was taken every 3<sup>rd</sup> interval until the determined sample size was obtained.

## **5.9. DATA COLLECTION PROCEDURE**

### **5.9.1. DATA COLLECTION INSTRUMENT METHOD**

Data was extracted by document review using a structured checklist prepared in English adapted from Ethiopian Federal Ministry of Health ART clinic food by prescription registration book, patient ART follow up card and from previous studies.

### **5.9.2. DATA COLLECTION PROCESS**

Data collectors and supervisors were trained for one day about the objectives of the study, contents of tools and how to collect the data before the data collection. The data was collected by experienced ART care providers who were trained on comprehensive HIV care and RUTF that work at ART clinic. Two runners were used for bringing cards from the card room. The principal investigator and the supervisors were closely monitored the whole data collection process on a daily basis. The laboratory results of CD4 count recorded before starting ART was used as a base line. If there was no pre-treatment laboratory test, however, results obtained within one month of ART initiation/enrolment in to RUTF was consider as baseline values.

## **5.10. DATA ANALYSIS**

Data was entered in to Epi-Data version 3.1 statistical software and then exported to SPSS version 23 for analysis. Before analysis data cleaning, coding and recoding was done. Descriptive statistics was used to describe demographic and clinical characteristics of patients. Binary logistic regression analysis was carried out for independent variables with an outcome variable to select candidate variables for multivariable analysis. Variables with a p value  $< 0.25$  in bivariable analysis were included into a multivariable logistic regression analysis to identify the independent predictors of outcome of ready to use food therapy. But the odd ratio obtained from multivariable logistic regression is exaggerated, since the study is a cohort study the measure of strengthen of association is explained by relative risk (RR). In order to overcome this problem log binomial logistic regression was used. The final model was assessed for goodness-of-fit by using Hosmer–Lemeshow test. Finally, variables with significant associations for outcome of ready to use food therapy among HIV /AIDS clients were identified based on the adjusted odd ratio (AOR) with a 95% CI and p-value  $< 0.05$ .

## **5.11. DATA QUALITY ASSURANCE**

Data was collected using trained health professionals and regular follow-up were carried out during data collection period by principal investigator. During the data collection process the filled checklist were checked for their completeness, consistency and accuracy by the principal investigators and supervisor every day during data collection period. The collected data were cleaned before the analysis.

## **5.12. ETHICAL CONSIDERATION**

The study was conducted after getting ethical clearance from research and ethical committee of the Health Science College of Bahir Dar University. Permission was obtained from Felege Hiwot Comprehensive Specialized hospital after verifying about the study. The information was collected from the food by prescription register and patient ART follow up card was used only for the research purpose and kept confidential. No patient identifying information was recorded to maintain the anonymity of the information.

## **6. RESULTS**

### **6.1. SOCIO-DEMOGRAPHIC CHARACTERISTICS**

The study included a total of 636 eligible patients on ready to use therapeutic food. Three hundred seventy (58.2%) of them were females and the mean ( $\pm$ SD) age of clients was 36.49 inter-quartile range ( $\pm$ 9.345) years. Two hundred seventy-four (43.1%) of clients were married and three hundred ninety-seven (62.4%) of clients had attended primary and above education. Out of the total respondents, 578 (90.9%) were Orthodox Christian followers. Five hundred fifty (86.5%) of clients were unemployed and Five hundred seventy-five (90.4%) of them were urban residents.

**Table 3 Socio-Demographic Characteristics of study participants at FHCSH Adult ART clinic.**

<b>Characteristics</b>		<b>Number</b>	<b>Percentage</b>
<b>Sex</b>	<b>Male</b>	<b>266</b>	<b>41.8</b>
	<b>Female</b>	<b>370</b>	<b>58.2</b>
<b>Age</b>	<b>19-24</b>	<b>54</b>	<b>8.5</b>
	<b>25-34</b>	<b>197</b>	<b>31.0</b>
	<b>35-44</b>	<b>253</b>	<b>39.8</b>
	<b>45-54</b>	<b>104</b>	<b>16.4</b>
	<b>&gt;55</b>	<b>28</b>	<b>4.4</b>
<b>Residence</b>	<b>Urban</b>	<b>575</b>	<b>90.4</b>
	<b>Rural</b>	<b>61</b>	<b>9.6</b>
<b>Marital status</b>	<b>Married</b>	<b>274</b>	<b>43.1</b>
	<b>Single</b>	<b>121</b>	<b>19.0</b>
	<b>Divorced</b>	<b>179</b>	<b>28.1</b>
	<b>Widowed</b>	<b>62</b>	<b>9.7</b>
<b>Religion</b>	<b>Orthodox</b>	<b>578</b>	<b>90.9</b>
	<b>Muslim</b>	<b>44</b>	<b>6.9</b>
	<b>Protestant</b>	<b>11</b>	<b>1.7</b>
	<b>Catholic</b>	<b>3</b>	<b>0.5</b>
<b>Educational Level</b>	<b>No Education</b>	<b>239</b>	<b>37.6</b>
	<b>Primary</b>	<b>225</b>	<b>35.4</b>
	<b>Secondary</b>	<b>129</b>	<b>20.3</b>
	<b>Diploma and above</b>	<b>43</b>	<b>6.8</b>
<b>Employment</b>	<b>Employed</b>	<b>86</b>	<b>13.5</b>
	<b>Unemployed</b>	<b>550</b>	<b>86.5</b>



## 6.2. NUTRITIONAL AND HIV/AIDS RELATED CHARACTERISTICS

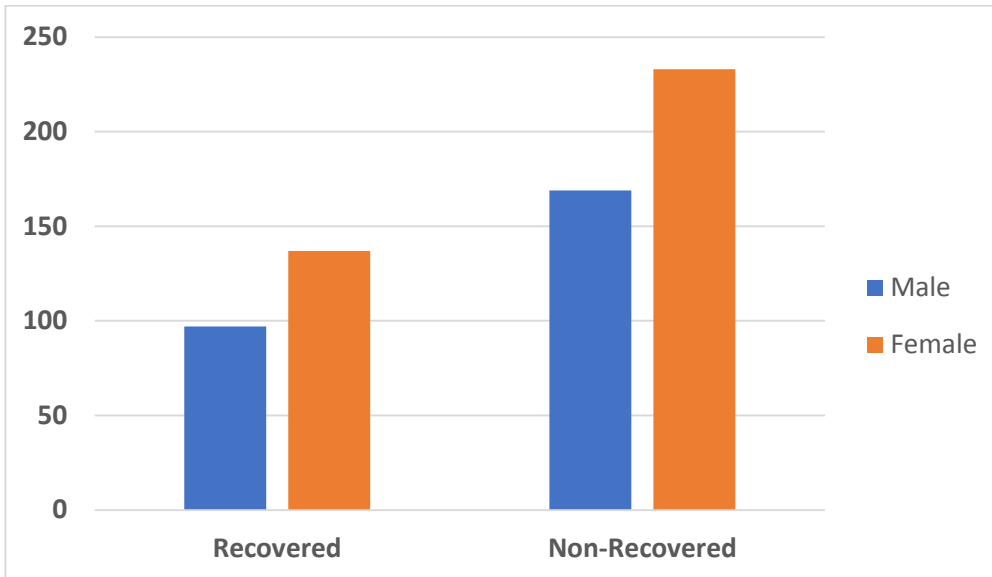
At base line, 222 (34.9%) of them were on Sever Acute Malnutrition. Two hundred thirty-five (36.9%) of them were on WHO clinical stage one and 199 (31.3%) were on WHO stage three. Two hundred eighty- four (44.7%) had CD4 count of less than 200 cells/m<sup>3</sup>, 236(37.1%) had opportunistic infections. From this 43(18.2%) clients had TB, 65(27.5%) of clients had diarrhea, 46(19.5%) of clients had mouth ulcer/oral thrush and 80(34.7%) of clients had other OI like, pneumonia, meningitis and CNS toxoplasmosis.

**Table 4. Nutritional and HIV/AIDS related characteristics of clients.**

<b>Variable</b>		<b>Frequency</b>	<b>Percent</b>
<b>Reside within the catchment</b>	Yes	498	78.3
	No	138	21.7
<b>Viral load status</b>	<1000copies	525	82.5
	>1000copies	111	17.5
<b>Disclosure</b>	Yes	559	87.9
	No	77	12.1
<b>Adherence to RUFT</b>	Good	599	94.2
	poor	37	5.8
<b>Adherence to ART</b>	Good	619	97.3
	Fair	7	1.1
	Poor	10	1.6

### 6.3. OUTCOME OF READY TO USE FOOD THERAPY AMONG ADULT HIV/AIDS CLIENTS

Two hundred thirty-four (36.8%) of them were recovered according to the predefined RUFT exit criterion.



**Figure 2 Recovery status of adult HIV/AIDS clients by sex disaggregation**

**Table 5. Bivariable and multivariable analysis of baseline predictors (November 1, 2017-September 1,2020) FHCSH Hospital, North west Ethiopia.**

Variable	Outcome of RUFT				
		Recovered	Not Recovered	COR (95% CI)	AOR (95% CI)
<b>Resides within the catchment area</b>	Yes	194	304	1.344(1.012-1.784)	1.197 (0.952-1.505)
	No	40	98	1	1
<b>Base line Nutritional status</b>	SAM	9	213	1	
	MAM	225	189	13.406(7.026-25.577)	7.041 (3.719-13.331)
<b>OI</b>	Yes	5	231	1	
	No	229	171	27.022(11.306-64.584)	15.563 (6.417-37.745)
<b>Viral load status</b>	<1000 Copies	206	319	1.556(1.110 – 2.180)	1.046 (0.844-1.296)
	>1000 Copies	28	83	1	
<b>Comorbidity</b>	Yes	4	23	1	
	No	230	379	0.731(0.617-0.865)	1.077 (.534-2.170)
<b>Baseline CD4</b>	<200	86	199	1	1
	200-300	69	147	1.059(0.814-1.377)	0.822 (0.686- 0.986)
	300-350	79	56	1.939(1.546-2.433)	1.048 (.904-1.215)
	>350				
<b>Adherence to RUFT</b>	Good	233	366	14.392(2.077-99.743)	8.784 (1.314-58.702)
	Poor	1	36	1	
<b>Disclosure status</b>	Yes	212	347	0.869(0.744-1.015)	0.655(0.388-1.105)
	No	22	55	1	1
<b>Residence</b>	Urban	216	359	0.886(0.744-1.054)	1.046(0.841-1.569)
	Rural	18	43	1	1

## **6.4. FACTOR ASSOCIATED WITH OUTCOMES OF READY TO USE FOOD THERAPY**

In bi-variable analysis presence of opportunistic infection (OIs), viral load, baseline nutritional status, residence, adherence to RUFT, disclosure status, reside within catchment area, baseline CD4 and clients with comorbidity were significantly associated with outcome of RUTF at p-value <0.25.

In multivariable analysis presence of opportunistic infection (OIs), baseline nutrition and adherence to RUFT were found to be the predictors of recovery.

Patients without opportunistic infection at enrolment to the therapeutic food were 15 [AOR = 15.563, 95% CI (6.417, 37.745)] times more likely to recover than those who had opportunistic infection. Patients diagnosed as moderate malnutrition during entry were 7 [AOR =7.041,95%CI (3.719 ,13.331)] times more likely to recover than severe malnutrition.

Patients with good adherence to RUFT were 9 [AOR =8.784, 95%CI (1.314, 58.702)] times more likely recovered than poor adherent to RUFT.

## 7. DISCUSSION

In this study 36.8% of participants enrolled in to food by prescription program were recovered. This is lower than a study done in different region of Ethiopia [[7](#), [26](#), [28](#), [31](#)].

This study also lower than a study conducted in Sub Saharan Africa and Malawi [[6](#), [24](#)]. This variation might be due to the study conducted in Mekele included mildly malnourished study clients. But in this study only severely malnourished and moderately malnourished patient were included. In other hand the variation b/n this study and Sub Saharan Africa and Malawi might be due to the difference in socio-demographic characteristics of patients', economic status of patients, clinicians' skill of treatment & health facilities set up.

However this finding is higher than a study done in Gonder University Hospital and a study conducted in Kenya [[27](#), [29](#)]. The difference might be due to the quality of service that had provided and health professional skill.

Factors associated with recovery among adult HIV/AIDS clients who were enrolled in food by prescription program were baseline nutritional status at enrollment, presence of opportunistic infections and adherence to RUFT.

This study showed that the recovery rate of moderate malnourished clients is 7 times higher than severely malnourished clients. This study is in line with a study done in different region of Ethiopia and study done in Sub-Saharan Africa [[7](#), [26-28](#), [33](#)].

The possible reason could be severely malnourished clients have a weakened immune system that may lead to increased susceptibility to opportunistic infections, this may lead to a slow rate of healing from illnesses, possibly fast progression of the HIV disease state to AIDS stage and poor response to treatment of RUFT. Additionally, being severely malnourished could be increase the incidence, severity and length of infections. Symptoms that accompany infections such as loss of appetite, diarrhea and fever lead to further reduced food intake, poor nutrient absorption, nutrient loss and altered metabolism. And also, being severely malnourished takes more time for recovery than moderately malnourished ones. This might lead to poor treatment outcome to ready to use food therapy.

This study showed that Patients without opportunistic infection at enrolment to the therapeutic food were 15 times more likely to recover than those who had opportunistic infection. The finding of this study is in line with a study conducted in Mekele and Gonder university hospital and a study done in Malawi [24, 26, 27]. In contrary to this, study done in Sub-Saharan Africa and Kenya showed that there were no association between opportunistic infection and the outcome of RUFT[6, 29].

The reason could be, those who had opportunistic infections during the nutritional intervention period had poor intake of therapeutic food due to poor appetite, mouth ulcers and mal absorption. due to the presence of OI patients' immune system would weakened which further exacerbates the malnutrition status and end up with poor response to nutritional supplement (RUFT).

The finding of this study also showed that those patients who were good adherence to RUFT were 9 times more likely to recover compared to patients with poor adherence to RUFT. This study is consistent with a study conducted in Amhara region and a study done in Malawi[24, 28]. But study done in Gonder University Hospital, Bahir Dar, Mekele and in Sub Saharan Africa and Kenya had no association with adherence of RUFT and outcome of RUFT[6, 26-29].

The possible reason might be patients who have poor adherence may be interrupted their monthly prescribed sachet of RUFT, take RUFT improperly, discontinued and moreover, they may be shared their prescribed RUFT for their families. And also, they may not get nutritional counseling that is provided by the health workers per clinical visit. And also, an opportunistic infection affects their eating behavior and reduces their swallowing capacity that potentially leads to poor adherence to the nutritional support program. This may lead to poor treatment outcome.

## **8. STRENGTH AND LIMITATION OF THE STUDY**

### **8.1 LIMITATION**

Since this study was used a secondary data (retrospective study), so it missed variables such as hygiene and sanitation, food sharing at house hold level and family income.

## **9. CONCLUSIONS**

In conclusion, the recovery rate of under nutrition patients was low as compared to the sphere standard. The factors that affect Outcome of ready to use food therapy were severity of malnutrition, poor adherence to RUFT and opportunistic infection.

## **10. RECOMMENDATIONS**

### **For FHCSH adult ART Clinic**

- Regular and comprehensive nutritional screening of patients on HIV chronic care should be implemented.
- Strengthening of nutritional adherence counseling for patients on ready to use therapeutic food.
- Early identification and early treating of patients with opportunistic infection.

### **For Researchers**

Since this research is a retrospective study, it did not include factors such as hygiene and sanitation, food sharing and other factors.

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## 12. APPENDIXES

### Annex 1. Consent form

The consent form will be needed for ART focal person

Good morning/afternoon/evening.

My Name is -----

I am from the research team of Bahir Dar University School of public health, which is currently carrying out study on **Outcome of ready to use food therapy and its predictor among adult HIV/AIDS patients in Felege Hiwot Comprehensive Specialized Hospital**. As part of this study we are collecting your information, socio-demographic, clinical and nutritional data. The finding of this study will be used to improve the quality of nutritional treatment outcome and to identify the predictors.

Name of data extractor-----Signature-----Date-----

Name of supervisor.....signature..... date

health facility -----

Please direct any questions or problems you may encounter during this study to

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Mobile +251 0910579163

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**Annex 2. Data extraction format/check list**

This data extraction format was prepared for the collection of socio-demographic, nutritional and HIV/AIDS related information that was important for the assessment of outcome of ready to use food therapy and its predictor among HIV/AIDS clients.

All this information was retrieved from the food by prescription register book and patient card without mentioning the names of the patient. This information was collected by the health care providers who were working in the ART clinic at Felege Hiwot Comprehensive Specialized Hospital.

Mr./Sr.....(Nurse/Health Officer) is/are requested to extract the existing data as you are participating in this Research project.

### Annex 3. English Questioner

**Table 6 Socio- demographic characteristics**

S.No	Questions	Coding Categories	Skip Pattern
101	Sex	1. Male 2. Female	
102	Age in years (enter number)	-----years	
103	Residence	1. Urban 2. Rural	
104	Ethnic group	1. Amhara 2. Tigre 3. Oromo 4. other specify	
105	Religion	1. Orthodox 2. Muslim 3. Protestant 4. Catholic 5. other specify_____	
106	educational level	1. No education 2. Primary 3. Secondary 4. Technical and vocation/Diploma and above	
107	Occupation	1. Employed 2. Unemployed 3. Farmer 4. Merchant 5. Daily laborer 6. Other (specify	
108	marital status	1. Currently married 2. Cohabiting 3. Never married 4. Divorced 5. Widowed 6. Other (specify)_____	

**Table 7 General Information (Nutritional and HIV/AIDS related Characteristics)**

QID	Questions	Response Options	Skip Pattern
201	Base line Nutritional status	1. SAM 2. MAM	
202	WHO clinical stage	1. Stage1 2. Stage2 3. Stage3 4. Stage4	
203	Baseline CD4 count	1. <200cells/m <sup>3</sup> 2. 200- 350 cells/m <sup>3</sup> 3. >350cells/m <sup>3</sup>	
204	ART treatment status	1. On ART 2. On Pre-ART	
205	Why the client is not start ART timely?	1.On OI management 2. On adherence preparation	
206	Duration of ART treatment	1. <12month 2. > 12 Month	
207	Is there presence of OI?	1.Yes 2. No	If No, go to Q207
208	Which OI Present?	1. TB 2. Chronic diarrhea 3. Mouth ulcer/Oral Thrush 4. Other OIS	
209	Adherence to ART	1. Good 2. Fair 3. Poor	
210	Adherence to RUTF	1.Good 2. Poor	
211	Treatment out come	1. recovered 2.not recovered	
212	Has source of external support for food	1. yes 2.no	
213	Baseline Hgb	-----	
214	Functional status of clients	1. Working 2. Ambulatory 3. Bedridden	
215	Nutritional counseling	1.Yes 2. No	
216	Regular follow-up	1. Yes 2. No	
217	Duration on the nutritional program	1. < 3month 2. > 3month	
218	Prescribed RUTF for SAM	1. 4 sachets/day 2. <4 sachets/day	

219	Prescribed RUTF for MAM	1. 2 sachets/day 2. 1 sachets/day	
220	Does the client refuse to take RUTF product?	1. Yes 2. No	
221	The number of families in the house?	-----	
222	Disclosure status at enrollment	1. Disclosed 2. Not disclosed	
223	Viral load status	1. <1000 copies 2. >1000 copies	
224	Does the client reside within the catchment area?	1. Yes 2. No	
225	Is there presence of comorbidity?	1. Yes 2. No	
226	Which comorbidity present? Specify	-----	

## **Annex 4: Declaration Form**

### **BAHIR DAR UNIVERSITY COLLEGE OF MEDICINE AND HEALTH SCIENCE SCHOOL OF PUBLIC HEALTH**

#### **DEPARTMENT EPIDEMIOLOGY AND BIostatISTICS**

#### **Declaration Form**

I, the under signed, declared that this is my original work, has never been presented in this or any other University, and that all the resources and materials used for the research, have been fully acknowledged.

Principal investigator

Name: Wudineh Arega \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

#### **Advisors**

Name: Kebadnew Mulatu \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

#### **Co-Advisors**

Name: Taye Abuhay \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_



**Annex 5: Advisor’s approval form**

**BAHIR DAR UNIVERSITY  
COLLEGE OF MEDICINE AND HEALTH SCIENCES**

**SCHOOL OF HEALTH SCIENCES**

**DEPARTMENT OF EPIDEMIOLOGY AND BIostatISTICS**

**APPROVAL OF THESIS FOR DEFENSE**

I hereby certify that I have supervised, read, and evaluated this thesis report titled “Outcome of RUFT and its predictors among adult HIV/AIDS clients in Felege Hiwot Comprehensive Specialized Hospital, Bahirdar town, Ethiopia” prepared by Wudineh Arega under my guidance. I recommend the thesis be submitted for oral defense.

Mr. Kedadnew Mulatu \_\_\_\_\_

Advisor’s name

Signature

Date

Mr. Taye Abuhay \_\_\_\_\_

Co-Advisor’s name

Signature

Date

Mr. Abebayehu Bitew \_\_\_\_\_

Department Head

Signature

Date

**Annex 6: EXAMINERS' APPROVAL FORM**

**BAHIR DAR UNIVERSITY**

**SCHOOL OF PUBLIC HEALTH**

**DEPARTMENT OF EPIDEMIOLOGY AND BIostatISTICS**

**APPROVAL OF THESIS FOR DEFENSE RESULT**

As members of the board of examiners, we examined this thesis entitled “Outcome of Ready To Use Food Therapy and its predictors among adult HIV/AIDS clients in Felege Hiwot Comprehensive Specialized Hospital Bahir Dar town, Ethiopia” by **Wudineh Arega**. We hereby certify that the thesis/dissertation is accepted for fulfilling the requirements for the award of the degree of Masters in Epidemiology.

**BOARD OF EXAMINERS**

_____	_____	_____
External examiner’s name	Signature	Date

_____	_____	_____
Internal examiner’s name	Signature	Date

_____	_____	_____
Chair person’s name	Signature	Date