

# Outcome of Ready to Use Food Therapy among Patients on HIV/AIDS Care in Mekelle Hospital, Northern Ethiopia: Retrospective Cohort Study

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## Abstract

**Background:** According to the World Health Organization (WHO), Nutritional support is an integral part of a comprehensive response to HIV/AIDS. Receiving appropriate nutrition can help improve the health and quality of life of HIV-infected individuals. So, Nutritional support is increasingly recognized as a critical part of the essential package of patients care among acquired immune deficiency syndrome (AIDS) patients. However, the outcome of ready to use nutritional support and factors affecting it among HIV/AIDS patients are not yet well investigated. So, this study aims to determine the nutritional outcome of ready-to-use food therapy (RUFT) and factors affecting it among peoples on HIV/AIDS care.

**Methods:** Retrospective cohort study was conducted among patients on food by prescription and HIV/AIDS care. Data was collected from a total of 531 patient records selected by systematic random sampling method using food by prescription registers as sampling frame. After determining the outcome of ready to use food therapy among HIV/AIDS patients on HIV care, Multivariate analysis was used to determine the independent predictors of outcome of food by prescription.

**Results:** In this study 62.2% of patients on ready to use food therapy were recovered. Severity of malnutrition Adjusted odds ratio [AOR (95% CI)]=2.594 (1.251-5.377)], sex [AOR (95%CI)=2.157 (1.340-3.473)], WHO stage [AOR (95% CI)=(3.345 (1.652-6.772)], education [AOR (95% CI) =1.820 (1.110-2.983)], and presence of opportunistic infection [AOR (95%CI)=2.791 (1.047-7.439)] were the independent predictors of outcome of ready to use food therapy.

**Conclusions:** In this study 62.2% of patients admitted to ready to use food therapy were recovered from malnutrition. The factors that affect Outcome of ready to use therapeutic food by prescription was severity of malnutrition, sex, WHO clinical stage, education, and opportunistic infection. For this reason, regular and comprehensive nutritional screening of patients on HIV chronic care and strengthening of nutritional adherence counseling for patients on ready to use therapeutic food is very crucial to improve the outcome of ready to use food therapy among HIV patients.

**Keywords:** Ready to use food; HIV/AIDS care; Food and HIV/AIDS

## Introduction

According to the World Health Organization (WHO), Nutritional support is an integral part of a comprehensive response to HIV/AIDS. Receiving appropriate nutrition can help improve the health and quality of life of HIV-infected individuals [1,2]. 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 [2].

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 [3].

HIV/AIDS and malnutrition are both closely interrelated. 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 [4]. HIV specifically affects nutritional status by increasing energy requirements, reducing food intake, and adversely affecting nutrient absorption and metabolism [5]. Malnutrition has been associated with progressive functional impairment, reduced immune competence and exacerbate the effects of HIV by increasing susceptibility to AIDS-related illnesses which leads to decreased rate of cure from opportunistic infections [6,7].

Low food intake combined with increased energy demands are the major factors in HIV-related weight loss and wasting. While there continue to be metabolic changes, once a patient is on Antiretroviral therapy (ART), progressive wasting and consequent morbidity can often be largely reversed and nutritional requirements may revert to normal [8,9].

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Antiretroviral therapy (ART) is essential to save lives, and clearly nutritional support alone cannot substitute for ART. However, food and nutrition plays an extricable role in the bioavailability (i.e. absorption, digestion, metabolism, and transportation) of drugs. Furthermore, there are metabolic complications associated with long-term ART use that have nutritional implications. Medications can affect nutrient absorption, metabolism, distribution, and excretion. In addition, medication side effects can negatively affect food consumption and nutrient absorption. For example, ART side effects like nausea and loss of appetite may reduce food consumption, and side effects such as diarrhea and vomiting may increase nutrient losses [10,11].

So far there are few data on the direct effect of dietary intake on nutritional outcome in HIV-positive people particularly in developing countries. Some studies on specific nutrients and combination of nutrients suggest that disease progression, nutritional status, well-being and survival can be improved, but these studies have not resulted in specific recommendations for dietary modification beyond the recommendation for increased energy intake. For this reason, this study aims to assess the nutritional outcomes among HIV infected adults receiving RUTF and identify associated factors among people on HIV/AIDS chronic care.

## Methods

### Study design and setting

Retrospective cohort study design was conducted among patients on HIV/AIDS chronic care treated for mal-nutrition by ready to use food therapy from Nov. 2010 to Oct 2012. The study was carried out in Mekelle hospital which is located 784 kms Northern of Addis Ababa. Mekelle Hospital serves as a referral hospital for Tigray region and neighboring regions (Afar and Amhara) with a catchment population of 8 million. Ready to use therapeutic food has been started since 2010 in Ethiopia. In Mekelle hospital a total of 1600 patients were on ART and ready to use food therapy (RUTF).

### Ready to use therapeutic food program (RUTF)

HIV-infected adults who present with malnutrition to health institutions are prescribed food rations according to their nutritional status (MAM, Body mass index (BMI)<18.5 or SAM, BMI<16) [12]. Adult HIV+ patients with moderate acute malnutrition (MAM) are provided with two sachets of RUTF 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. The rations are prescribed during monthly appointments, together with clients' ART medications, and are distributed directly from clinic pharmacies. Clients are monitored closely by health facility staffs who collect both anthropometric and disease progression data during monthly appointments.

Ready to use therapeutic food is a Plumpynut®-based paste in a plastic wrapper for treatment of malnutrition. The ingredients in Plumpy'nut include "peanut-based paste, with sugar, vegetable, fat and skimmed milk powder, enriched with vitamins and minerals" with energy 2,100 kJ (500) kcal in 92 grams [12].

The program is aligned with the national protocol for treatment of HIV, and used outcomes for individual participants at the time of program exit according to the following definitions [12]:

**Graduated/Recovered:** Participant reached a BMI of 18.5 for two consecutive visits within three or six months, depending on nutritional

status at baseline (MAM or SAM respectively).

**Non-response/Unrecovered:** Participant who did not reach a BMI of 18.5 for two consecutive visits within three (MAM) or six (SAM) months.

**Defaulter:** Participant did not reach a BMI of 18.5 and dropped out of the program before the end of three (MAM) or six (SAM) months.

**Died:** Participant died during course of program participation, and death was documented by clinic staff in the register book.

### Study population and sampling techniques

Sample size was determined using the formula of two population proportion estimation using Epi-info stat calc for un matched case control with the assumption of 95% certainty level, 5% precision, 80% power, 1:1 control to case ratio and considering the odds ratio to be detected between the two groups as 2.0. Based on this the required sample size was calculated to be 531 including 10% possible incompleteness.

The sample size was estimated using the formula for two populations to determine predictors of outcome of ready to use nutrition therapy among patient on HIV/AIDS chronic care. Mekelle Hospital was selected by purposive sampling method because most patients receive ART at Mekelle hospital and has better record handling. Selection of each record of patients was done by systematic random sampling method using the longitudinal RUTF registers as sampling frame until the determined sample size was obtained.

### Data collection and quality control

A standard checklist was used for extracting information from data base and patient cards. This form is developed using the standardized RUTF follow up form employed by the ART clinic. The laboratory results of CD4 count recorded before starting ART were used as a base line values. If there is no pre-treatment laboratory test, however, results obtained within one month of ART initiation/enrolment in to RUTF were considered as baseline values. Four experienced ART nurses who were trained on comprehensive HIV care, RUTF and involved in patient follow ups collected the data and data collection was supervised by two trained supervisors. During the data collection process the filled checklist was checked for their completeness, consistency and accuracy by the principal investigators every day. Mode, median and mean values was used to address incompleteness, inaccuracy and inconsistencies. The data were entered and cleaned before analysis using SPSS.

### Data analysis

Data was coded and entered in to SPSS version.16 software. Descriptive analysis (Frequencies distribution, Mean ( $\pm$ SD), median, interquartile range and percentages was calculated to describe each socio demographic variable. Percentage was used to describe RUTF. The outcome measure of RUTF was recovered and unrecovered (failure to respond+defaulter+death). Based on this, Bivariate logistic regression was done to investigate associations of outcome of RUTF and different independent variables. Factors which were found to be significant at P-Value<0.05 was taken to multivariate logistic regression to see the independent predictors of outcome of RUTF. Odds ratio with 95% CI was used to interpret and show the strength of relationship between the independent variables and outcome of ready to use food therapy.

### Ethical statement

The study used the routine existing ready to use food therapy data. Ethical Approval was obtained from Mekelle University College of Health Science Ethical Review Committee with reference number

ERC0197/2013. In Ethiopia in the existing system, there is no way to communicate with the patients once they get the service. As such, informed consent from the patients is not obtainable. As it was conducted based on the ready to use therapeutic food records and was not sensitive, the consent relied on the ethical board's approval. No patient identifying information was recorded to maintain the anonymity of the information.

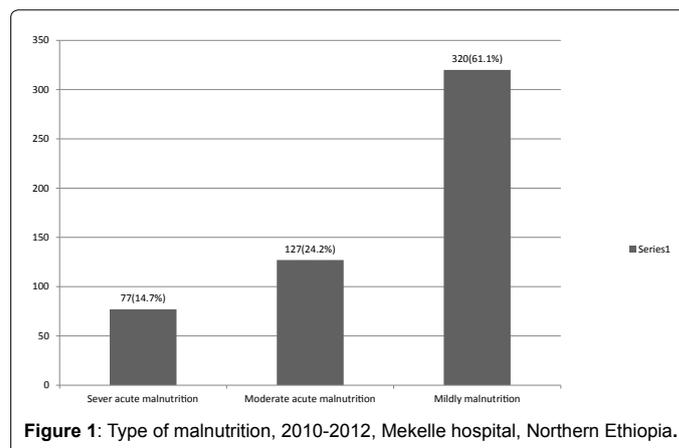
## Results

### Participant characteristics

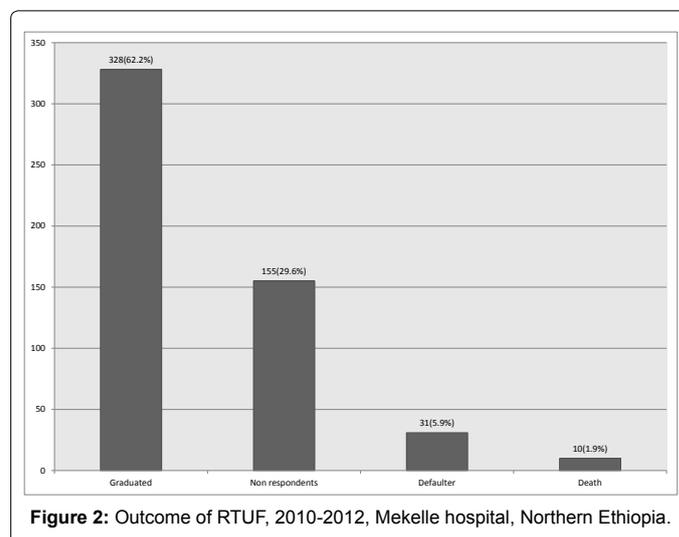
The study included a total of 524 eligible patient records on ready to use therapeutic food. Among those patients, three hundred sixty (68.7%) of them were females and the mean ( $\pm$ SD) age of patents was 34.98 ( $\pm$ 0.10) years. Regarding the marital status, 178 (34%) of patients were married and 94 (17.9%) of them were in union. As to educational status, 138 (26.3%) were illiterate and the rest 386 (73.3%) had attended at least formal education. Out of the total respondents, 483 (92.2%) were Orthodox Christian followers. Most 436 (83.2%) of study subjects were unemployed. Out of the total study subjects, 88.5% of them were urban residents (Table 1).

Variables	No	Percentage
<b>Sex</b>		
Male	164	31.3
Female	360	68.7
<b>Age</b>		
16-29	151	28
30-44	290	55.3
$\geq$ 45	83	15.8
<b>Residence</b>		
urban	460	88.5
Rural	60	11.5
<b>Marital status</b>		
Single	94	17.9
Married (Union)	178	34
Married (Separated)	88	16.8
Divorced	83	15.8
Widowed/widower	81	15.5
<b>Religion</b>		
Orthodox	483	92.2
Muslim	32	6.1
Protestant	5	1.0
Catholic	4	0.8
<b>Educational status</b>		
No education	140	26.7
Primary	181	34.5
Secondary	171	32.6
Tertiary	32	6.1
<b>Employment</b>		
Employed	94	18.25
Unemployed	421	81.75

**Table 1:** Socio-demographic characteristics (2010-2012) in Mekelle Hospital, Northern Ethiopia.



**Figure 1:** Type of malnutrition, 2010-2012, Mekelle hospital, Northern Ethiopia.



**Figure 2:** Outcome of RTUF, 2010-2012, Mekelle hospital, Northern Ethiopia.

### Patients nutritional and HIV/AIDS related characteristics during enrolment

The mean ( $\pm$ SD) BMI of patients at baseline were 16.8 ( $\pm$ 1.05). Severe malnutrition was highest among females 70.1% (54/77). At baseline, 77 (14.7%) were on severe malnutrition (BMI<16.00 kg/m<sup>2</sup>), 127 (24.2%) moderate malnutrition (BMI 16.00-16.99 kg/m<sup>2</sup>) and 320 (61.1%) mildly malnutrition (BMI 17.00-18.4 kg/m<sup>2</sup>) (Figure 1). To this effect, the mean ( $\pm$ SD) hemoglobin level of patients at admission was 13.55 g/dl. Hemoglobin level of most, 401 (76.5%) patients were 12 g/dl and more but 108 (20.6%) patients had anemia with hemoglobin level below 12 g/dl. Additionally, Most patients admitted to RUTF program 260 (49.6%) and 142 (27.1%) were on WHO clinical stage 3 and 4 respectively.

Almost all, 519 (99%) of HIV-positive adults didn't have oedema during enrolment in to RUTF and 468 (89.3%) patients on RUTF were taking ART.

### Outcome of ready to use food therapy

From a total of 524 patients enrolled into the RUTF 328 (62.4%) were recovered or graduated. One hundred fifty five (29.6%) of patients were non respondents (didn't recover) according to the predefined RUTF exit criterion, 31 (5.9%) defaulted from the food therapy and 10 (1.9%) had died. The overall failure rate including non respondent, defaulter and death were 196 (37.6%) (Figure 2).

Variables	Outcome of ready to use food therapy		COR(95% CI)	AOR(95% CI)
	Recovered N (%)	Not recovered N (%)		
<b>Sex</b>				
Male	87(53.0)	77 (47.0)	1	1
Female	241(67.0)	119(33)	1.792(1.229-2.614)**	2.157(1.340-3.473)**
<b>Education</b>				
No education	70 (50.7)	68(49.3)	1	1
Educated	258 (66.8)	128(33.2)	1.958(1.319-2.907)**	1.820(1.110-2.983)*
<b>Religion</b>				
orthodox	308(63.8)	175(36.2)	1	1
Muslim	14(43.8)	18(56.2)	0.442(0.215-0.910)*	0.683(0.269-1.730)
Protestant	3 (60.0)	2(40.0)	0.852(0.141-5.150)	0.849(0.095-7.602)
Catholic	3(75.0)	1(25.0)	1.705(0.176-16.512)	6.905(0.374-127.639)
<b>Type of malnutrition</b>				
Sever acute malnutrition	18 (23.4)	59 (76.6)	1	1
Moderate malnutrition	56 (44.1)	71 (55.9)	2.585(1.34-8.71)**	2.594(1.251-5.377)*
Mild malnutrition	254(79.4)	66 (20.6)	12.6(6.970-22.8)***	14.25(7.074-28.742)***
<b>WHO stage</b>				
WHO stage 1 and 2	102 (83.6)	20 (16.4)	3.420(1.905-6.139)***	3.345(1.652-6.772)**
WHO stage 3	141 (54.2)	119 (45.8)	0.795(0.525-0.203)	0.743(0.442-1.247)
WHO stage 4	85 (59.9)	57 (40.1)	1	1
<b>CD4 admission</b>				
<100	26 (63.4)	15 (36.6)	2.347(0.735-7.493)	1.193(0.481-2.960)
100-200	40 (44.4)	50 (55.6)	3.688(1.965-6.922)***	0.575(0.302-1.096)
200-350	109(63.4)	63 (36.6)	0.795(0.525-1.20)	0.820(0.489-1.374)
>350	153(69.5)	67 (40.5)	1	1
<b>Hgb admission</b>				
<10g/dl	17 (42.5)	23 (57.5)	1	1
10-11.99g/d	31 (60.8)	20 (39.2)	2.097(.904-4.867)	1.568(0.546-4.502)
>=12g/dl	272 (65.1)	146 (34.9)	2.521(1.305-4.869)**	1.779(0.761-4.158)
<b>OI admission</b>				
None	318(64.6)	174(35.4)	4.021(1.862-8.684)***	2.791(1.047-7.439)*
Yes	10(31.25)	22(68.75)	1	1

\*P< 0.05 , \*\*P<0.01      \*\*\*P<0.001

**Table 2:** Bivariate and multivariate analysis of baseline predictors (2010-2012) Mekelle Hospital, Northern Ethiopia.

### Factors associated with treatment success among adults receiving RUTF

In bivariate analysis sex, religion, education, type of malnutrition, WHO stage, CD4 count, hemoglobin and presence of opportunistic infection (OIs) was significantly associated with outcome of RUTF at p-value<0.05 (Table 2).

In multivariate analysis female sex, higher educational status, type of malnutrition, clinical WHO stage, and presence of opportunistic infection (OIs) were found to be the independent predictors. Females were 2 times higher to recover than males following ready to use therapeutic food. Patients who were educated were 1.8 times higher to respond to therapeutic food than those illiterate one. Additionally, patients in clinical stage 1 and 2 at enrolment to ready to use therapeutic food were 2 times higher 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 2.7 times higher to recover than those who had opportunistic infection. Finally Patients diagnosed as moderate and mild malnutrition during entry had 2.5 and 14 times higher to respond to the therapeutic food than severe malnutrition (Table 2).

### Discussion

This study reported that 62.2% of patients enrolled in to ready to use therapeutic food were recovered. This is higher than a study conducted in Ethiopia that reported only 58% of HIV/AIDS patients enrolled in to ready to use therapeutic food were recovered [13]. This is almost similar though there is high defaulter rate in the Ethiopian study. Additionally, when recovery rate of this study is compared with a study done in sub-Saharan Africa, it is slightly higher (47.4%) [14]. This difference in cure rate among our study and the sub-Saharan African study was due to a difference in type of malnutrition at enrolment that 85.3% of HIV patients on ready to use therapeutic food in this study was in mild and moderate malnutrition. However, 50% of patients on ready to use therapeutic food in the sub Saharan African study were on severe acute malnutrition who had lower chance of recovery. Other reason why recovery rate was high in our study may be due to integrated services of ART and ready to use therapeutic food program.

Ninety eight percent of patients in this study were on integrated ART and ready to use therapeutic food. This was very high when compared with 12% patients on ART enrolled to ready to use therapeutic food according to a study done in Sub-Saharan African [14]. The best nutritional outcome of ART and ready to use therapeutic food

integration was also mentioned in other study that says combination antiretroviral therapy and ready to use therapeutic food increases the chances of nutritional recovery in those high-risk patients. The observed result was 4.5 fold increased risk of nutritional therapy failure, including death, compared with patients already on ART [15].

Including 5.9% defaulter and 1.9% death, a total of 37.4% of patients failed to respond for ready to use therapeutic food. Similarly, findings from studies done in sub-Saharan African and Ethiopia reported that failure to respond to ready to use therapeutic food among HIV patients on HIV/AIDS chronic care was 48% and 89% respectively. The reason for this low failure compared with the studies done in sub-Saharan Africa is that only 14.7% of patients in this study had severe malnutrition where as 50% of patients admitted to ready to use therapeutic food had severe malnutrition at admission to the therapy in other studies done in sub-Saharan Africa, Ethiopia and Uganda [13,14,16,17]. In general 37% of patients were failed to respond to ready to use therapeutic food. This failure may be due to HIV positive adults have higher energy requirements than healthy non-HIV-infected individuals and increased resting energy expenditure. Presence of fever infection, diarrhea, vomiting, and the need for growth and weight recovery also contribute to failure of ready to use therapeutic food [14,18,19].

Females were 2 time more likely to recover than males. Similar studies in Ethiopia and sub-Saharan African countries showed that men were 1.5 times more likely to fail to respond for ready to use therapeutic food than females [13,14]. The fact that men tend to access HIV care at a more clinically advanced stage of disease than women has been documented elsewhere and is likely to explain this finding. Additionally it could also be due to good compliance to nutrition and ART among females [13,18].

Patients who are illiterate were 2 times more likely to fail to respond to ready to use therapeutic food than those educated. Similar study conducted in Botswana on the risk of developing malnutrition in people living with HIV/AIDS reported similar event that AIDS patients who had low educational attainment were associated with failure to respond to ready to use therapeutic food [18]. This is because people with better educational status had better awareness about adherence to ready to use food therapy and medication.

WHO clinical stage I and II had four times more likely to respond to ready to use therapeutic food than patients on WHO stage III and IV. Majority (76.6%) of patients admitted to ready to use therapeutic food were in WHO clinical stage III and IV. Similar study conducted in Ethiopia, Sub-Saharan African and rural district of Malawi showed that WHO clinical stage III and IV at admission was one of the risk factor for failure to respond to ready to use therapeutic food [14,19,20].

Failure to respond to ready to use therapeutic food was 2.7 times higher in patients with opportunistic infection during enrolment than those who did not have opportunistic infection. In other similar studies, the most common OI was tuberculosis. This showed tuberculosis and malnutrition has been a vicious cycle problem and Co infection with TB complicates the care of severely malnourished patients. This association was consistent with the finding from studies in Ethiopia, Sub-Saharan Africa, Malawi, South Africa and China that showed significant relationship between opportunistic infections and nutritional outcome of ready to use therapeutic food [4,14,20-22].

Patients with the diagnosis of severe malnutrition at enrolment to ready to use therapeutic food has higher treatment failure than moderate malnutrition. Similar study conducted in Sub-Saharan African countries and rural Malawi showed that severely malnourished

patients had two times increased risk of failure to respond to ready to use therapeutic food [14,20]. Similar study from Malawi and Ethiopia had supportive evidence for this finding that individuals who were severely malnourished [body mass index (BMI)<16.0 kg/m<sup>2</sup>] had six times higher risk of dying in the first 3 months on HIV care and nutritional care [20,13].

The main weakness of the study was being retrospective cohort study design may limits our ability to gather data about factors that may influence failure to respond to ready to use food therapy, for example factors such as food sharing at household level, Number of dependent children, additional source of income etc.

In conclusion, 62.2% of patients admitted to ready to use therapeutic food were recovered from malnutrition. The factors that affect Outcome of ready to use therapeutic food was severity of malnutrition, sex, WHO clinical stage, education, and opportunistic infection. For this reason, regular and comprehensive nutritional screening of patients on HIV chronic care and strengthening of nutritional adherence counseling for patients on ready to use therapeutic food is very crucial to improve the outcome of ready to use therapeutic food among patients on chronic HIV care.

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