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Effects of the Ready-to-Use Nutritional Supplement Plumpy Up on the Nutritional Status of People Living with HIV Monitored in the Pikine Health District

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Abstract: *Introduction*: Malnutrition is the second complication of HIV infection, and nutrition intervention programs should be a priority in the management of people living with HIV/AIDS (PLHIV). However, very few studies have looked at the dietary supplementation of PLHIV followed in ambulatory care. The general objective was to evaluate the effects of the daily consumption of dietary supplement Plumpy up on the nutritional status of adults living with HIV who are being monitored in an outpatient clinic in the Pikine Health District over a 12-week period. *Material and methods*: The study included 50 malnourished PLHIV patients enrolled at the beginning of antiretroviral therapy (ART) for some and in the course of ART for others in a single test group. The daily consumption of 200 g of ASPE Plumpy up was recommended over a period of 12 weeks. Anthropometric measurements (weight and height) were made at the beginning and end of the study. *Results*: Good acceptability of the RUSF by subjects was observed with 74% of respondents having appreciated the product. At baseline, 70% of patients had moderate acute malnutrition (MAM) and 30% severe acute malnutrition (SAM). After 3 months of supplementation with plumpy up, the nutritional status improved significantly ($p<0.0001$). Only 47% of patients had MAM and 6% had SAM. Almost half of the patients (47%) returned to a normal body mass index (BMI). Weight increased significantly from an average of 47.1 kg at baseline to 52.08 kg after three months. The BMI also showed a clear change from an average of 16.53 kg to 18.28 kg/m². *Conclusion*: Supplementation with 200 g of RUSF had a positive impact on individual weights, BMI, and thus on the nutritional status of the subjects.

Keywords: Malnutrition, PLHIV, Dietary Supplementation, RUSF, Plumpy Up

1. Introduction

Malnutrition has been an endemic problem in Africa for decades, complicated by a variety of factors, most recently HIV infection [1]. It is considered a cofactor in the progression of HIV infection to AIDS. Undernutrition, known as "wasting syndrome", has become one of the most common complications of the disease [2]. The nutritional impact of HIV infection was rapidly recognized as one of the fundamental characteristics of this disease and illustrates once again the interactions between immunodepression and malnutrition [3]. HIV infection led to immune deficiency and reduced nutrient absorption, resulting in malnutrition. Malnutrition is also known to affect the immune system, contributing to the rapid progression of HIV [4]. Malnutrition, through its negative effects on the immune system, aggravates HIV infection by increasing the risk of opportunistic infections and mortality [5]. Today, malnutrition and food insecurity are the main obstacles to successful treatment of people living with HIV (PLHIV) [6].

In the African context, where malnutrition is the second most common complication of HIV infection, nutritional intervention programs should be a priority in the management of PLHIV [7]. Recognizing the important role that food and nutrition interventions play in the overall response to the HIV pandemic, many countries have integrated food and nutrition components into their national response.

In Senegal, nutritional support for PLHIV is still the weakest link in the care chain, despite the fact that undernutrition is a frequent complication of HIV infection. Appropriate solutions must therefore be found to integrate nutritional management into the overall care package for PLHIV. In recent years, the plumpy nut therapeutic food produced by the French company NUTRISET, a world-renowned producer of nutritional solutions, has been introduced in Senegal as part of the care package for PLHIV. Its use has produced satisfactory results in the nutritional recovery process for PLHIV. However, as it is not specifically designed for the PLHIV target group, certain limitations have been noted in relation to plumpy NUT's coverage of certain micronutrients, notably vitamin A, zinc and iron [8].

In May 2009, a study entitled "Supplementary feeding with either ready-to-use fortified spread or corn-soya blend in emaciated adults starting antiretroviral therapy in Malawi: a blinded controlled trial" was set up by a group of researchers [9]. The aim of this study was to investigate the effect of two different supplement foods on body mass index (BMI) in HIV-positive Malawian adults starting antiretroviral therapy. It was found that after 14 weeks, patients receiving a fortified spread had an increase in BMI and fat-free body mass compared to those receiving a corn-soy blend. The mean BMI at enrolment was 16.5. They therefore concluded that supplemental feeding with the enriched spread resulted in a greater increase in BMI and lean body mass than feeding with a corn-soy blend.

Still in the same vein, in May 2014, a group of researchers published a study carried out in Ethiopia entitled "Effects of nutritional supplementation in HIV-positive patients starting ARV treatment (ART): a randomized controlled trial in Ethiopia" [10]. Its aim was to determine the effects of lipid-based nutritional supplementation with both whey and soy in HIV-positive patients during the first 3 months of ART, but also to explore the effects of timing (timing of supplementation) by comparing supplementation at the start of ART and after 3 months of treatment.

Convincing results were obtained in both groups. There was a significant increase in:

1) a significant increase in lean body mass
2) grip strength gain
3) total weight
4) total CD3 count improved.

However, the effects of these two supplements (soy and whey) were not significantly different when compared directly. An exploratory analysis showed that lean body mass gain was achieved in patients with an undetectable viral load over three months. Patients receiving delayed supplementation had higher weight gain but lower gains in functional outcomes. The researchers therefore concluded that lipid-based nutritional supplements improve weight gain, lean body mass and grip strength in HIV patients starting ART. Whey-containing supplements are associated with improved immune recovery. Considering all the results obtained in these previous studies, the French company NUTRISET has started in 2019, the production of a ready-to-use nutritional supplement combining the different elements that have produced positive effects and that is specially designed for the nutritional reinforcement of PLHIV named plumpy up.

Plumpy up is a ready-to-use supplement food (RUSF) used in this study. It is a ready-to-eat peanut and soy-based nutritional supplement, specially designed for adult populations with HIV. RUSF contains the following ingredients: peanuts, vegetable oils (rapeseed, palm, soybean in variable proportions), sugar, soy protein isolate, defatted soy flour, maltodextrin, mineral and vitamin complex, stabilizer (totally hydrogenated vegetable fat, mono and diglycerides). May contain traces of dairy products and gluten. It has a high energy density, contains no water and is not susceptible to bacterial proliferation. It can therefore be stored easily and for a long time without refrigeration, even under less-than-optimal hygiene conditions.

It is against this backdrop that this study was set up to assess the effects of plumpy up supplementation on the nutritional status of PLHIV undergoing outpatient treatment at the Baye Talla DIOP health center in Pikine.

2. Materials and methods

2.1. Study Setting

The study took place in the Baye Talla Diop health center (BTDHC) in the Pikine health district, in the department of Pikine. The population is estimated at 412607 (2021).

The district boasts 13 health posts and 3 health huts and has been involved in HIV care since 2007. Several HIV-related projects have been carried out over the past decade, with very convincing results. These include the Presidential Emergency Plan for Aids Relief (PEPFAR) project, which provides care for PLHIV in general, and for key populations with the highest prevalence in particular. The service's activities focus on preventive strategies, putting patients on ART, psychosocial follow-up and support, medical follow-up and therapeutic management of opportunistic infections. Patients are treated on an outpatient basis.

2.2. Type and Period of Study

This is an experimental descriptive and analytical clinical cohort study evaluating the effect of the plumpy up nutritional supplement on the nutritional status of PLHIV. It took place over a 3-month period, from April 15 to July 15, 2021.

2.3. Study Population

Subjects were men or women living with HIV/AIDS at different stages of the WHO HIV classification and followed up on an outpatient basis at the Pikine CSBTD.

2.3.1. Inclusion Criteria

The criteria for inclusion in the study were as follows:

1) men or women living with HIV and undergoing outpatient care at the CSBTD.
2) mentally fit and able to ingest the food supplement
3) BMI less than 18.5 kg/m2

2.3.2. Non-Inclusion Criteria

1) diabetes
2) peanut or soy allergy
3) current user of dietary supplements
4) being pregnant or breastfeeding
5) not willing to participate in the study

2.4. Sampling

2.4.1. Sample Size

The sample size was exhaustive. All PLHIV meeting the inclusion criteria and in the health center's active file were recruited.

2.4.2. Selection of Statistical Units

The sample was composed of 50 men and women living with HIV at different stages of the WHO classification, all followed up at the Pikine health district.

Subjects were selected based on the eligibility criteria listed above.

2.5. Data Collection

2.5.1. Data Collection Method

Data are collected during an individual interview with the subject. Anthropometric measurements were collected simultaneously with the interview.

Anthropometric measurements were tracked throughout the study.

2.5.2. Data Collection Tools

An individual questionnaire was designed for this purpose and was used to collect the necessary information. An Excel database was also designed for this purpose to enable regular monitoring of anthropometric measurements throughout the study.

2.5.3. Data Collected

The following variables were collected:

Age: expressed in years

Sex: coded as "M" for male and "F" for female.

Weight: taken on an electronic scale with a maximum capacity of 200 kg and an accuracy of 100 g. The scale is checked and calibrated with a standard weight before each weighing session.

Height: the height of subjects is measured standing on a centimeter-scale, to an accuracy of 0.1 cm, following standardized procedures.

BMI: body mass index is calculated as the ratio of weight in kilograms to the square of height in meters (kg/m2).

Marital status, occupation and level of education: these variables were asked directly of the subject when the questionnaire was administered.

HIV profile: the profile was determined through the medical record; it was coded as follows: HIV 1, HIV 2 or HIV 1&2.

WHO clinical stage: the WHO clinical stage was also determined on the basis of the patient's medical record, and was coded as follows: stage 1, stage 2, stage 3 and stage 4.

Subjects' diet during the study: During the study, the 50 subjects received a daily dosage of 200 g of plumpy up at a rate of 2 sachets per day for a period of 12 weeks. There were no specific times set for taking ASPE, the main recommendation being the daily consumption of 200 g of it. However, to facilitate intake and avoid forgetfulness, subjects are asked to take 1 sachet (100 g) in the morning and another in the evening. The ration is given to the subjects every 10 days at the health center, so that regular monitoring of food intake can be carried out. Every 10 days, subjects receive 20 sachets of plumpy up, and compliance is assessed through the sachets returned at the next appointment.

2.6. Data Entry and Analysis

Data entry was carried out using Kobocollect, Excel 365. Data analysis was carried out at two levels:

2.6.1. Descriptive Part

Qualitative variables are described by their frequencies and 95% confidence intervals. Quantitative variables are expressed by their mean and standard deviation.

2.6.2. Analytical Part

The relationship between the dependent variable, i.e. nutritional status, and the other explanatory variables transformed into qualitative variables is studied using the chi2 test and Student's t test, depending on their applicability. A difference is considered significant if $p<0.05$.

2.7. Ethical Aspects

Before starting the study, the approval of the ethics committee of the Ministry of Health and Social Action was obtained. Informed consent was also obtained from the subjects prior to any inclusion in the research. At the end of the study, the participants were reconvened by the managing physician and the study manager to share the results of the study.

3. Results

3.1. Evolution of Sample Size

The study involved 50 PLHIV (28 women and 22 men) in a single test group. During the 3 months of supplementation, 4 deaths (3 women and 1 man) and 1 drop-out were recorded. The 4 deaths occurred in the first and second months of supplementation. In the end, 45 subjects followed supplementation correctly from start to finish. Therefore, the analysis at the end of the 3 months of supplementation concerns only these 45 subjects.

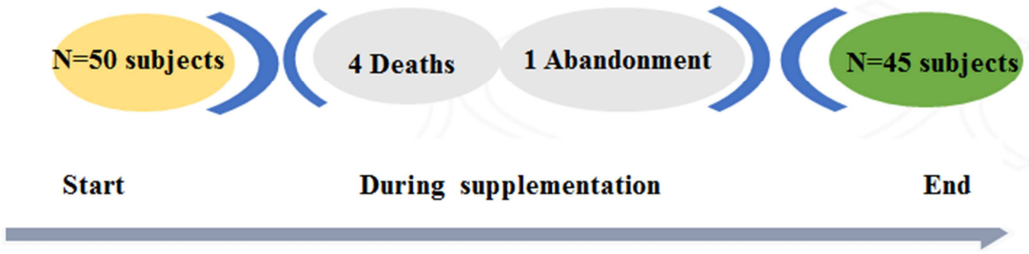

Figure 1. *Evolution of sample size over the course of the study.*

3.2. Socio-Economic Characteristics of Patients

Table 1. *Patients' socio-economic characteristics at entry N=50.*

Age (in years)[1]	**38±12**	
Min – Max	***20; 68***	
Gender	**(n)**	**%**
Men	17	34
Female	33	66
Marital status	**(n)**	**%**
Married	17	34
Single	20	40
Divorced	05	10
Widowed	08	16
Study level	**(n)**	**%**
Primary	13	26
Secondary	09	18
Higher	02	04
No education	26	52
Sector of activity	**(n)**	**%**
income-generating activity	31	62
Unemployed	29	38
Sexual orientation and/or practice	**(n)**	**%**
Heterosexuals	34	68
Homosexuals	12	24
Sex workers	04	08

[1]= values expressed as mean ± standard deviation
Min -Max: Minimum and maximum values

3.3. Clinical Characteristics of Patients at Admission

Table 2. *Clinical characteristics of patients at admission (N=50).*

HIV profiles	**n**	**%**
VIH1	47	94
VIH2	02	02
VIH1&2	01	04
Clinical stage		
Stage 1	27	54
Stage 2	10	20
Stage 3	09	18
Stage 4	04	08
Opportunistic infections		
Tuberculosis	12	24
ART	**50**	**100**
ART duration		
< 6 mois	22	44
> 6 mois	28	56

3.4. Assessment of Plumpy up Acceptability

During the supplementation period, subjects were asked to answer questions designed to assess plumpy up acceptability at each weighing session.

Table 3. *Plumpy up acceptability.*

Number of respondents	**Percentage In the sample**	**Comments on the acceptability of plumpy up**
34	68%	Feeling thirsty after taking ingesta
13	26%	The plumpy up texture is too pasty and consistent, making it difficult to swallow.
01	2%	Decrease in sexual libido after 2 months of intake
04	8%	Diarrhea at the start of supplementation
15	30%	Too much food, preventing them from eating their daily meals.
05	10%	Sleeping food
37	74%	Pleasant taste, practical packaging, easy to eat

3.5. Evolution of Subjects' Nutritional Status

Table 4. *Changes in nutritional status of study subjects.*

Nutritional status	**Inclusion**		**After 3 months**		**P**
	n	**%**	**n**	**%**	
MAM	35	70	21	47	
SAM	15	30	03	06	0.0001
Normal	00	00	21	47	
Total	50	100	45	100	

3.6. Changes in Anthropometric Parameters

Table 5. *Anthropometric parameters of subjects.*

Parameters	**Inclusion**	**After 3 months**	***P***
Weight (kg)[1]	47.1 ± 6.07	52.08 ± 4,98	0.002
Min -Max	*33; 60*	*40; 61*	
Height (m)[1]	1.68 ± 0.08	-	-
Min- Max	*1.50; 1.88*	-	
BMI (kg /m²) [1]	16.53 ± 1.39	18.28 ± 1.46	0.002
Min -Max	*12.65; 18.37*	*15.06; 21.10*	
Weight gain [1]	-	4.2 ± 2.74	
Min – Max	-	*1; 8*	

[1]= values expressed as mean ± standard deviation.
P <0.05 Student's t-test for comparison of means
Min -Max: Minimum and maximum values

4. Discussion

The present study was conducted in the Pikine health district over the period from April to July 2021. It involved 50 PLHIV, all malnourished and followed up as outpatients in the Pikine health district.

Subjects were recruited in collaboration with the patients'

attending physicians, depending on whether they met the inclusion criteria and agreed to take part in the study. The average age of the subjects was 38 and the sex ratio M/F was 1.27, with 66% women. This confirms the trend of the disease in Senegal with a feminization that is observed and confirmed by the 2012 demographic health survey [11]. The feminization of the epidemic is a major trend. Currently, 50% of PLHIV worldwide are women, with this rate reaching 59% in sub-Saharan Africa, the region most affected by the epidemic [12].

One of the specific features of this study is the inclusion of key populations (men who have sex with men and sex workers) in the sample. In 2016, outside sub-Saharan Africa, key populations and their sexual partners accounted for 80% of new HIV infections; concerning sub-Saharan Africa, key populations accounted for 25% of new infections for the same period [13]. In our sample, 32% are part of the key population, with 28% MSM (homosexual) and 8% female sex workers. The nutrition of these vulnerable groups has so far not been the subject of in-depth research in Senegal. The prevalence of malnutrition is very high among these key populations, and therefore requires greater attention.

Clinically, 100% of subjects were on ARVs, with HIV-1 serology still dominant in 94% of cases. Worldwide, HIV-1 represents at least 90% of circulating viruses [14].

Twenty-four percent of patients were suffering from TB/HIV co-infection and were in the course of or at the end of treatment. 12% of patients had already had an episode of TB and were completely cured.

In the clinical and therapeutic guidelines for curative programs in hospitals and clinics, tuberculosis has been heralded as the first opportunistic infection that can reveal the presence of HIV infection; and in some countries, up to 70% of tuberculosis patients are co-infected with HIV [15].

In addition, the acceptability of plumpy up was assessed during the course of the study. Ready-to-use supplement food (RUSF) are increasingly used in HIV programs, but little is known about how they are used and perceived by patients. We used a qualitative questionnaire to explore the use, and acceptability, of plumpy up among study subjects. Participants were generally highly motivated to take RUSF and considered it beneficial, in line with the patient study carried out in Ethiopia [15]. According to this study, RUSF was described as a means of making up for nutritional deficits, "rebuilding the body" and protecting it from the harmful effects of antiretroviral treatment. Acceptance of our RUSF plumpy up was motivated by a strong desire to get well on the part of all subjects, who showed a firm commitment to compliance and plumpy up from the outset.

However, disclosure of HIV status and breaking the chain of confidentiality were obstacles to the acceptability of plumpy up. These results confirm those of the study carried out by Olsen et al. in Ethiopia, who described patients whose main concern with RUSF was the risk of HIV disclosure and its social consequences [16]. Despite the motivation to improve health, keeping their "secret" remains the priority for the subjects in our sample.

Notwithstanding the fact that the packaging of the plumpy up supplement is trivialized and makes no mention of HIV, all subjects brought their entire rations (empty sachets) back to the health center to "remain as discreet as possible". Several subjects declined the invitation to take part in this study, despite the advantages described, on the grounds of confidentiality. This is an important aspect to consider, and we need to think more carefully about it.

The 50 subjects were divided into a single test group. The recommended daily intake was 200g of plumpy up. RUSF was consumed on its own, without being mixed with any other food. No specific diet was imposed on the subjects in this study. During supplementation, four subjects died, respectively at the first (2 subjects) and third month (2 subjects), giving a mortality rate of 8%. One drop-out was recorded, bringing the total number of subjects to 45. According to the attending physician, the reasons for the deaths were linked to the advanced stage of the disease (3 subjects who died were at stage 4 AIDS) and to an opportunistic infection that attacked the lungs of the fourth subject who died during supplementation. The reason for discontinuation was a reported drop in sexual appetite, which led to the decision to discontinue supplementation.

The sample was composed of subjects starting ART less than 6 months ago (44%) and those on ART for more than 6 months (56%). Weight gain was observed on both sides, irrespective of the timing of supplementation. However, the highest weight gain (8 kilos) was recorded in a subject starting ART in a situation of advanced undernutrition, in contrast to the results obtained following the study conducted by Olsen et al. in Ethiopia, which aimed to determine the effects of nutritional supplementation with either whey or soy protein in HIV-infected patients during the first three months of antiretroviral treatment, by comparing supplementation at the start of ARV treatment and after three months on ART [10]. In this study, the greatest weight gain was observed in a subject receiving delayed supplementation.

In our study, out of 45 subjects, 43 recorded weight gain (difference between entry weight and exit weight) after daily consumption of 200g of plumpy up per day over a 3-month period. Two subjects lost between 2 and 4 kilos during supplementation. The reasons for these weight losses were attributable to other causes, mostly linked to other related pathologies in the subjects.

The average weight gain was 4.2 kilograms, and the highest gain was 8 kilograms, in contrast to the study carried out by Diouf in Senegal, where lean mass gains of less than 3 kilograms were recorded in both groups. The lowest weight gain recorded was 1 kilogram [17].

At inclusion, all 50 subjects in our study were malnourished (severe or moderate acute) with a BMI $<18.5 kg/m^2$. After plumpy up supplementation, 47% had a normal BMI and were therefore no longer malnourished. The mean BMI after 3 months rose from 16.53 ± 1.39 to 18.28 ± 1.46, with minimum and maximum values of $15.06 kg/m^2$ and $21.10 kg/m^2$ respectively.

In the same vein, the results obtained support those of the study entitled Effects of nutritional supplementation on PLHIV starting ART: a randomized control trial, which aimed to study the effect of two different food supplements on body mass index (BMI) in emaciated HIV-positive Malawian adults

starting antiretroviral therapy [9].

The findings show a marked improvement in body mass index between inclusion and the end of 3 months' supplementation, with an increase of 2.2 points (SD 1.9) on the initial mean BMI of 16.5kg/m².

5. Conclusion

In conclusion, the results of this study show that plumpy up has a significant positive impact on subjects' weight and therefore naturally on BMI after 3 months of use.

Consumption of 200 g of plumpy up /day over a 3-month period enabled 95% of subjects to record a very significant weight gain, enabling some to return to a normal BMI and others to increase their BMI. Overall, the study also showed that plumpy up was well accepted by the patients who adopted it.

Clearly, then, ready-to-use nutritional supplements are an effective means of recovering from and/or preventing the onset of malnutrition in infected subjects.

In view of the high rates of malnutrition combined with growing poverty in Senegal, their integration into the HIV treatment circuit is a necessity.

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Conflicts of Interest

The authors declare no conflicts of interest.

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