## The impact of integrating food supplementation, nutritional education and HAART (Highly Active Antiretroviral Therapy) on the Nutritional Status of Patients living with HIV/AIDS in Mozambique: Results from the DREAM Programme

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**Riassunto** Il programma DREAM (Drug Resources Enhancement against AIDS and Malnutrition) è un programma multiregionale attivo in Mozambico dal 2002, basato su un approccio olistico alla cura e alla prevenzione dell'epidemia da HIV/AIDS nel continente Africano.

DREAM, sin dall'inizio ha integrato la terapia antiretrovirale, la supplementazione e l'educazione alimentare. Al fine di conoscere lo stato di salute e di nutrizione di pazienti affetti da HIV/AIDS in terapia HAART (Highly Active AntiRetroviral Treatment) e non è stato condotto uno studio retrospettivo a braccio unico su un campione di 106 pazienti adulti di cui 84 in terapia HAART. Sono stati studiati i profili immunologici, virologici, l'indice di massa corporea (BMI), i livelli di emoglobina e l'adeguatezza della dieta del campione. Lo studio ha inteso indagare eventuali associazioni tra l'indice di diversità alimentare (DDS) e il miglioramento del BMI, la Carica Virale e il numero dei CD4.

I pazienti sono stati selezionali in maniera casuale in due centri di salute pubblici in Mozambico, dove è attivo il programma DREAM. Il programma fornisce gratuitamente la terapia HAART, il monitoraggio clinico e di laboratorio, l'integrazione alimentare e sessioni di educazione alimentare e sanitaria alla pari, ovvero, tenute da pazienti adeguatamente preparati. Sono stati misurati il BMI, l'emoglobina, la carica virale, la conta dei CD4 al momento dell'ingresso nel programma (T0) e dopo un anno (T1).

L'intake alimentare è stato valutato utilizzando il metodo del diario alimentare delle 24 ore con l'ausilio di un atlante alimentare locale e si è stimato anche l'indice di diversità alimentare (DDS) dopo un anno di assistenza (T1).Complessivamente la dieta dei pazienti appariva bilanciata. Nella coorte non in HAART il valore medio finale del BMI mostrava un aumento, sebbene non significativo, (valore iniziale  $21.9 \pm 2.9$ ; valore finale  $22.5 \pm 3.3$  n.s.) e un significativo aumento del valore dell'emoglobina (valore iniziale  $10.5 \pm 2.1$ ; valore finale  $11.5 \pm 1.7$  p< 0.024). Similmente, nella coorte dei pazienti in HAART, c'era un incremento significativo del valore medio dell'emoglobina (valore iniziale:  $9.9\pm 2.2$ ; valore finale  $10.8\pm 1.7 \text{ p} < 0.001$ ) e un incremento significativo del valore finale medio del BMI (valore iniziale  $20.7\pm 3.9$ ; valore finale:  $21.9\pm 3.3 \text{ p} < 0.001$ ), infine nella coorte in HAART i pazienti con un indice di diversità alimentare maggiore di 5 presentavano un significativo guadagno di BMI.

In conclusione i risultati dello studio confermano il miglioramento dello stato nutrizionale in entrambe le coorti evidenziando il ruolo della supplementazione e dell'educazione alimentare nei programmi di cura dell'HIV/AIDS in Africa. Il significativo guadagno di BMI nella coorte in HAART associato ad un elevato DDS sottolinea il ruolo sinergico della supplementazione alimentare, dell'educazione alimentare e della terapia HAART e mette in luce il ruolo complementare di una dieta adeguata e diversificata nella cura del paziente HIV/AIDS in paesi a risorse limitate.

# The impact of integrating Food supplementation, Nutritional education and HAART (Highly Active Antiretroviral Therapy) on the Nutritional Status of Patients living with HIV/AIDS in Mozambique: Results from the DREAM Programme

Key words Hiv/Aids and nutrition; Haart; Nutritional assessment

**Summary** DREAM (Drug Resources Enhancement against AIDS and Malnutrition) is a multiregional health program active in Mozambique since 2002 and provides free of charge an integrating package of care consisting of peer to peer nutritional and health education, food supplementation, voluntary counseling and testing, immunological, virological, clinical assessment and HAART (Highly Active AntiRetroviral Treatment). The main goals of this paper are to describe the state of health and nutrition and the adequacy of the diet of a sample of HIV/AIDS patients in Mozambique on HAART and not.

A single-arm retrospective cohort study was conducted. 106 HIV/AIDS adult patients (84 in HAART), all receiving food supplementation and peer-to-peer nutritional education, were randomly recruited in Mozambique in two public health centres where DREAM is running. The programme is characterized by: provision of HAART, clinical and laboratory monitoring, peer to peer health and nutritional education and food supplementation. We measured BMI, haemoglobin, viral load, CD4 count at baseline (T0) and after at least 1 year (T1). Dietary intake was estimated using 24h food recall and dietary diversity was assessed by using the Dietary Diversity Score (DDS) at T1.

Overall, the patients'diet appeared to be quite balanced in nutrients. In the cohort not in HAART the mean BMI values showed an increases but not significant (initial value:  $21.9\pm2.9$ ; final value:  $22.5\pm3.3$ ) and the mean haemoglobin values (g/dl) showed a significant increases (initial value:  $10.5\pm2.1$ ; final value:  $11.5\pm1.7 \text{ p} < 0.024$ ). In the cohort in HAART, both the mean of BMI value (initial value:  $20.7\pm3.9$ ; final value:  $21.9\pm3.3 \text{ p} < 0.001$ ) and of haemoglobin (initial value:  $9.9\pm2.2$ ; final value:  $10.8\pm1.7 \text{ p} < 0.001$ ) showed a higher significant increase. The increase in BMI was statistically associated with the DDS in HAART patients.

In conclusion nutritional status improvement was observed in both cohorts. The improvement in BMI was significant and substantially higher in HAART patients because of the impact of HAART on nutritional status of AIDS patients. Subjects on HAART and with a DDS > 5, showed a substantial BMI gain. This association showed an additional expression of the synergic effect of integrating food supplementation, nutritional education and HAART on the nutritional status of African AIDS patients and also highlights the complementary role of an adequate and diversified diet in persons living with HIV/AIDS in resources limited settings.

#### Introduction

The majority of HIV-1- infected individuals live in sub-Saharan Africa where malnutrition and food insecurity are a widespread condition (1,2). Malnutrition and weight loss in patients with HIV/AIDS are known to accelerate disease progression, increase morbidity and reduce chances of survival, due to the well-documented impact of malnutrition on immunity (3,4).

The pathogenesis of AIDS related malnutrition and cachexia is multi-factored and includes food insecurity, reduced intake, malabsorption, reduced utilisation of nutrients, the elaboration of proinflammatory cytokines, and endocrine and metabolic alterations combined with increased nutritional needs (5,6). There is now clear evidence that malnourished individuals starting ARV therapy are far more likely to die in a given period than well-nourished individuals (7,8). Weight loss and wasting remain significant clinical problems even in the current era of Highly Active Antiretroviral Therapy (HAART) (9,10).

The role played by dietary intake in HIV patients in resource-limited settings, both in those who are on antiretroviral treatment and those who are not, has hardly been studied at all, although the need to integrate HAART with food supplementation – to improve the patients' diet – in areas of high food insecurity has been recognized (11,12).

Some authors in certain countries in sub-Saharan Africa, where the AIDS epidemic co-exists with chronic food insecurity, have indicated the benefits of programmes that aim to integrate the HAART therapy and food supplementation, in terms of weight increase, improved quality of life and a reduction of the adverse effects of the HAART therapy (13,14).

The first aim of this paper is to describe the main characteristics of the state of health and of nutrition and the adequacy of the diet of a sample of 106 HIV/AIDS patients in the DREAM programme in Mozambique, on HAART and not, all of whom were included on the food supplementation programme. The other aim is to evaluate whether there are any associations between Dietary Diversity and the restoration of the Body Mass Index, and immunological and virological parameters such as the CD4 count and the viral load.

#### Materials and methods

#### The DREAM Model

Drug Resource Enhancement against AIDS and Malnutrition (DREAM) is a public health programme created by the Community of Sant'Egidio to fight HIV

and AIDS in sub-Saharan Africa, which includes prevention of the HIV transmission in the general population and of mother-to-child transmission, through Community Care and Home Care and Child Prevention and Care. The programme is characterized by a holistic approach: the provision of HAART is combined with good clinical practice and laboratory tests including CD4 count and viral load. The DREAM model includes nutritional evaluation, health education, peer to peer support and education, and food supplementation as its chief strategy. The entire programme is offered free of charge.

As far as food supplementation is concerned, DREAM has chosen to donate food to fight malnutrition and improve adherence. The eligibility criteria for adults' enrolment in DREAM's food assistance programme are: BMI < 18.5, presence of the wasting syndrome, TB co-infection, insufficient access to food, CD4 count < 200. At the time of the study 36% of the DREAM patients were receiving food supplementation.

Another key element of the programme is the involvement of the patients in the process of their own care and that of other patients. Patients who so wish can become programme activists. The DREAM activist is a new human and professional figure that combines the role and the jobs of the community health worker and cultural intermediary. Their contribution is essential for the efficacy of the DREAM model, particularly in the field of nutrition.

These patients carry out specific training courses on the following: basic aspects of the prevention and treatment of AIDS, principles of food hygiene, the vicious circle of HIV, malnutrition and infection, principles of a balanced diet, principles of infant feeding.

After their training, the activists become peer to peer health and nutrition educators and they are particularly involved in supporting adherence to the therapy and promoting food hygiene and a balanced diet.

Brief health education sessions are held by activists for the patients at the DREAM Centres while they are waiting for their appointments, or at the patients' home with the involvement of family members and neighbours. The brief education session includes a cooking demonstration on how to prepare a balanced meal with food distributed by the programme.

Nutrition education plays an important role in adherence to the therapy in that it makes patients aware that the HAART needs to be associated with a balanced

diet. This message, conveyed by the activists, also by describing their personal experience, becomes effective and introduces the complementary role of HAART and good nutrition in a HIV/AIDS patient in a positive way.

Further and more detailed information about the programme's methodology can be found in previous papers (15,16).

#### Study Design

This is a single-arm retrospective cohort study. The immunological, virological, anthropometrical and clinical information regarding 106 patients (27 males and 79 females) was recorded at time of registration (Time 0) and also when the 24 hour food recall was carried out (at least 12 months after registration) (Time 1). At the time of the survey (T1), 84 patients (79.2 %) had been on HAART for at least six months, while 22 subjects were not on treatment.

All participants provided informed consent for participation in the study. Pregnant and breastfeeding women, patients on home care or hospitalised were excluded.

Subjects were randomly recruited among the patient population, which because of their social, clinical anthropometric and economic vulnerability, were receiving a food supplementation from the programme. The supplementation was provided regularly and with no interruptions during the whole period of the study.

Enrolment took place on the day of delivery of the food package.

The food package consisted of a ration of cereals (rice or corn) of around 15kg; pulses (5kg); peanuts (3kg); sugar (2kg); sunflower seed oil (3Lt.); at least 7kg of fortified corn soy blend. For years, the World Food Program has contributed with a significant portion of these rations and has also controlled the quality of the food (17). The dietary assessment was conducted via a single 24-hour food recall, using food models and images of portion sizes to enhance the accuracy of recall (18).

The FAO Food Composition Table for Africa (19) and for Mozambique (20), was used as a reference for carrying out the dietary assessment. A value of less than 75% of the FAO Recommended Dietary Allowances (21) was considered inadequate, in agreement with other authors (22). It must be noted, however, that the nutrient requirements of HIV/AIDS patients are higher owing to the nature of the disease, which includes hypermetabolism, anorexia and malabsorption. (23). Therefore, since the exact nutritional requirements of such patients, especially of those on HAART, are subject to debate, the FAO/WHO RDA for

the general population adapted for Mozambique have been used as a standard of reference (19,20,21,24).

In order to evaluate the adequacy of nutrition, the Dietary Diversity Score (DDS) was used, in line with reports in relevant literature (25,26), using the 12 food groups derived from FAO Food Composition Table for Africa (19). In the data analysis, the value of the DDS was dichotomized into < 5 or > 5 groups.

The 24-hour food recall was conducted by properly trained DREAM activists.

The weight and height of DREAM patients were monitored. BMI values of less than 18.5 were considered to be indicative of malnutrition, according to the WHO classification.

It is a recognized fact that in HIV patients, BMI is a very powerful indicator – almost as much as viral load – of disease progression, and it is also a useful prognostic indicator of survival (27).

The computerised clinical files of the DREAM programme contained all the patients' socio-demographic, medical and anthropometrical data. Specifically, it was possible to access immunological and virological parameters such as the CD4 count and viral load, indicative of disease progression. Diagnostic, therapeutic and laboratory methods used by the DREAM programme have already been described (8, 15).

#### Statistics

Data were analysed using the Statistical Package for Social Sciences software (SPSS for Windows, version 14.3, 2006, Chicago, Illinois). The mean differences of dietary intake (energy, proteins, lipids and carbohydrates) and of clinical, virological and immunological parameters were analysed using the paired sample t-test (CL 95% calculation included). The Wilcoxon non-parametric test was also used to compare the paired values. BMI changes and DDS differences were explored using the Levene Test for Equality of Variance and the Independent t-test for Equality of Means between the 2 sub-populations, HAART and non-HAART. Logistic binary regression models were developed to test potential associations.

#### **Results and discussion**

Table 1 lists the main demographic, social and housing features of the cohort. Table 2 lists the characteristics of their dietary intake. Overall, the patients' diet

	Total	SD	HAART	SD	Non-HAART	SD
Subjects	106		84		22	
Age	32.9	±8.3	33.8	±8.7	29.3	±5.6
Females	79		64		15	
Illiteracy rate	12.3%		10.7%		18.2%	
Primary school	57.5%		56%		63.6%	
Unemployment rate	14.2%		15.5%		9.1%	
Householder	24.5%		25%		22.7%	
Access to drinking water	30.2%		28.6%		36.4%	
Other Hiv+family members	53.8%		53.6%		54.5%	
Observation time (T1-T0 in days)	391.3	±28.8	391.7	±30.5	389.7	±21.8
Exposure time of HAART			273.6	79.8		

Table 1 – Demographic, social and housing features of HIV/AIDS patients in total and sub-divided into HAART and non-HAART

appeared to be quite balanced in nutrients: the protein percent of calories was 10.9% of which 2% was of animal origin, while the lipid percent of calories amounted to 23.2% in line with other authors (28, 29). With regard to dietary adequacy, Table 2 shows that 65% of patients did not reach the 75% FAO/WHO Recommended Dietary Allowances quota, with a difference noted between HAART patients (lower in 54.7% of cases) and non-HAART patients (81.8%). As for protein intake, it was insufficient in 33% of patients, with a higher quota among non-HAART patients (41%). The high percentage of subjects experiencing low dietary intake in term of energy was probably influenced by the timing of the nutrition survey. In fact the survey was carried out on the day of delivery of the food package, hence at the time when the patients were experiencing the most severe food shortage. This way the influence of the programme's food supplementation on the diet is partially eliminated and the condition of poor access to food of the HIV patients on the study is better highlighted.

With regard to dietary balance, the cohort evaluated in the study presented a better balance compared to the latest available data for the Mozambican population (30).

In order to evaluate the diversity of the diet and hence its quality, the calories from the various food groups consumed were calculated. The energy quota attri-

	Total	SD	HAART	SD	Non-HAART	SD			
Total energy (kJ/24h)	6923.3	±1559.4	7068.4	±1485.4	6368.5	±1736.4			
Total energy (Kcal/24h)	1654.7	±372.7	1689.4	±355.0	1522.1	$\pm 415.0$			
Total protein (g/24h)	45.1	±13.9	45.7	±13.5	42	±15.5			
Animal protein (g/24h)	8.3	±9	8.3	±9.2	8.3	±8.2			
Vegetable protein (g/24h)	36.7	±11.5	37.4	±11	34.2	±13.1			
Fat (g/24h)	42.6	$\pm 12.7$	43.9	±12.5	37.6	±12.5			
Carbohydrate (g/24h)	287	±72.2	292.3	±71.4	266.5	±73.2			
Protein	10.9		10.7		11.1				
Fat (%)	23.2		23.2		22.2				
Carbohydrate (%)	65.9		66.2		66.7				
Percentage of patients with nutrient intakes lower than 75% of RDA (Who/Fao/Onu/1985)									
Total energy (<75% RDA)	65%		54.7%		81.8%				
Total protein (<75%RDA)	33%		31%		41%				
DDS	5.4	±1.3	5.5	±1.3	5.1	±1.2			

Table 2 – Dietary intake and food security information with percentage of patients with nutrient intakes lower than 75% of RDA (WHO/FAO/ONU 1985) of HIV/AIDS patients in total and sub-divided into HAART and non-HAART

butable to cereals prevailed, due to many factors, like cultural practices, greater availability, and also as an effect of one of the principles of the nutritional education, which is based on encouraging the patient to consume a portion of cereals at every meal. However one can also observe a certain variety in diet: nearly 15% of total calories were from foods of animal origin. This amount can also be attributed to the principle of nutritional education that encourages regular consumption, at least twice a week, of foods of animal origin. The presence of 4% of total calories attributed to fruit and vegetables certainly reflects the indication that comes from the nutritional education, that is, that one should consume several portions of fresh fruit and vegetables every day.

The distribution of patients according to the DDS confirmed considerable food diversity in the sample: 74 patients (70%) consumed more than 5 food groups daily.

Further, the DDS turned out to be significantly related to the energy and protein intake of patients (r=0,42; p<0.01, r=0,44;p<0.01).

The mean values of BMI, haemoglobin, CD4 count, viral load and the percentage of BMI < 18.5, both at the time of registration (T0) and when the food

Table 3 – Mean values of Body Mass Index, Haemoglobin (g/dl), Viral Load (copies/ml) and CD4 count (cells/ml),
BMI gain in HIV/AIDS patients in HAART and non-HAART at the time of enrolment (T0) and at time of survey
(T1)

	HAART 84 Subjects				NON-HAART 22 Subjects					
	то		T1		р	то	то			р
		SD		SD			SD		SD	
BMI (Kg/Mt)	20.7	±3.9	21.9	±3.3	p1<0.001	21.9	±2.9	22.5	±3.3	NS
Hb (g/dl)	9.9	±2.2	10.8	±1.7	p1<0.001	10.5	±2.1	11.5	±1.7	p1<0.024
Viral Load	110	±145	7.8	±25	p1<0.001	45	±106	16	±29	NS
(*1000 copies/ml)										
VL proportion < 400	6%		73%		p <sup>3</sup> <0.001	9.1%		27.3		NS
CD4 (cells/ml)	285	±270	389	±220	p1<0.001	612	±306	640	±354	NS
BMI<18.5	27/84		11/84		p <sup>2</sup> <0.005	2/22		0/22		NS
	(32.1%)		(13.1%)			(9.1%)		(/)		
BMI gain			1.2	±2.4				0.7	±1.9	

 $P^1 = T$  Test/Wilcoxon

 $P^2$  = Fisher's Exact Test

 $P^3 = Chi Square$ 

survey (T1) was carried out, were obtained for the two groups of patients (Table 3). In the cohort not in HAART the mean BMI values showed an increases but not significant (initial value:  $21.9 \pm 2.9$ ; final value:  $22.5 \pm 3.3$ ) and the mean haemoglobin values (g/dl) showed a significant increases (initial value:  $10.5 \pm 2.1$ ; final value:  $11.5 \pm 1.7 \text{ p} < 0.024$ )

It is important to observe that in the subgroup of subjects in HAART there is a sharp decline in the viral load, from a mean of 110,000 copies to 7,800 copies. On the other hand the percentage of subjects with less than 400 copies rises from 6% to 73%. The data express good overall adherence of the sample to the treatment, as already reported in a previous paper (31).

The improvement in nutritional status between these two points in time was quite evident, and in the HAART group it was accompanied by a significant increase in subjects with viral load <400 copies. Upon enrolment into the programme, the nutritional status of patients was highly compromised. One third of HAART patients (32.1%) had BMI values below 18.5 at entry. This value dropped

Table 4 – Binary Logistic Regression Analysis between dietary diversity (DDS), antiretroviral therapy and nutritional status in HAART patients

Binary Logistic	Dependent Variable	Variable in the equation	В	Exp (B)	Р
Regression	BMI gain	DDS	0.368	1.445	0.045
Regression	BMI T1 ( 18.5)	Log Viral Load	0.439	1.551	0.013

to around 13% after 12 months, probably related to the joint effect of HAART, food supplementation and health and nutrition education.

All the other parameters turned out to be significantly improved.

In order to evaluate the interplay between dietary diversity, antiretroviral therapy and nutritional status, we carried out a binary logistic regression (stepwise forward conditional model) with HAART patients. The dietary intake and immunological and virological variables were included in the analysis. The dependent variable was the dichotomized (<1.2 or >1.2 BMI gain points) BMI gain. The final model excluded all the variables except the dichotomized DDS score (DDS <5 vs. DDS >5), as shown in table 4.

This result was confirmed by the means comparison. In fact, in the group with the high DDS score, the BMI gain was significantly higher : 0.03 (DDS < 5) vs. 1.72 (DDS > 5) (Levene's Test: NS; t-test= -2.9; p=0.004).

When binary logistic regression was performed using the BMI dichotomized at <18.5/>18.5 as the dependent variable, the role of viral load emerged significantly (table 4), in agreement with other authors (32, 33). In other words, when the infection was not well controlled by treatment and consequently the viral load was not undetectable, the likelihood of remaining in a low nutritional status was noticeably higher.

No association between BMI and DDS was observed among non-HAART subjects. Overall, the increase in BMI among non-HAART subjects was much less than that reported for subjects on treatment.

#### Conclusions

Nutritional status improvement were observed in both cohorts, HAART and not in HAART. The improvement in BMI was significant and substantially higher in HAART patients because of the impact of HAART on nutritional status of AIDS patients. Subjects on HAART and with a DDS > 5, showed a substantial BMI gain. This association showed an additional expression of the synergic effect of integrating food supplementation, nutritional education and HAART on the nutritional status in African AIDS patients and also highlights the complementary role of an adequate and diversified diet in person living with HIV/AIDS in resources limited settings.

Nutritional education and supplementation, in the context of a highly endemic HIV/AIDS situation such as that of Sub-Saharan Africa, should be prioritized and should be integrated into good clinical practice and laboratory monitoring.

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