

# Nutritional status of HIV-infected adults on antiretroviral therapy and the impact of nutritional supplementation in the Northern Cape Province, South Africa

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## Abstract

**Objectives:** The study aimed to describe the nutritional status and determine the impact of current nutrition intervention strategies on weight changes in adult HIV-infected patients on antiretroviral (ARV) therapy.

**Design:** A descriptive, prospective trial was performed.

**Setting:** The investigation was conducted at ARV roll-out centres in Kimberley, Upington, Kuruman, Prieska and Springbok in the Northern Cape Province of South Africa.

**Subjects:** Adult HIV-infected patients receiving ARV therapy were included in the study.

**Outcome measures:** Each participants's body mass index (BMI) was determined before and after a four-month intervention period of nutritional supplementation with an instant, enriched maize product.

**Results:** Data from 98 patients (mean age 39.7 years; standard deviation 8.9 years) were assessed. Prior to intervention, the median BMI was 20 kg/m<sup>2</sup> (range 12.6–29.7 kg/m<sup>2</sup>); the patients from Kuruman had a greater incidence of underweight compared to the other towns, with a median BMI of 17.9 kg/m<sup>2</sup>. Of the 87 patients assessed during the final week, 49.4% experienced weight gain and 40.2% lost weight. Eighteen (20.7%) patients gained more than 5% of their baseline weight, which was significant. Only eight (9.2%) patients lost more than 5% of their baseline weight. Twenty-two patients who presented with a BMI < 18.5 kg/m<sup>2</sup> at baseline had a median weight gain of 1.13 kg during the intervention period, while the group with a BMI > 18.5 kg/m<sup>2</sup> presented with no change in median weight.

**Conclusions:** Nutritional supplementation, provided according to provincial policy and combined with ARVs, nutritionally benefitted about half of the patients in the ARV programme in the Northern Cape.

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## Introduction

South Africa is home to the world's largest population (5.7 million) of people living with HIV, and 38% of all AIDS-related deaths occur here.<sup>1</sup> In 2008, 29% of women attending antenatal clinics were HIV-infected.<sup>2</sup> Baseline data from the National Food Consumption Survey indicated that the Northern Cape Province had the highest incidence of stunting and underweight among children in the country (27.7% and 38.3% respectively), and also the highest incidence of underweight among women (16.7%).<sup>3</sup> This province therefore shows the greatest potential risk for the development of nutritional problems across all age groups.

HIV infection can cause malnutrition, which contributes to immune dysfunction and a subsequent increased risk for opportunistic infections. HIV infection, nutritional status and immune function are closely related, with each of the factors influencing the others. The

dominant aspect in this relationship is the effect of HIV infection on nutritional status. In adults, this effect manifests itself primarily as wasting, especially in the absence of antiretroviral (ARV) therapy.<sup>4,5</sup>

In 1987, the HIV wasting syndrome was included by the Centers for Disease Control and Prevention (CDC) as an AIDS-defining illness. Wasting syndrome involves weight loss of more than 10% from baseline, with either diarrhoea or fever for more than 30 days.<sup>6</sup> The patient's body mass index (BMI) at the time of HIV diagnosis has been shown to be a strong, independent predictor of survival in HIV-infected adults in West Africa. Furthermore, it has been found that the degree of weight loss correlated with early death.<sup>7</sup>

Weight loss in HIV-infected individuals typically falls into two categories. Firstly, the individuals may experience slow and progressive weight loss or growth failure due to anorexia, gastrointestinal disturbances, psychosocial and economic factors,

and the adverse effects of treatment. Secondly, episodes of acute weight loss may result in wasting, which is usually associated with opportunistic infections.<sup>4,8</sup>

The studies summarised by Salomon et al<sup>9</sup> indicated that, despite several advances in the management of HIV infection, including ARV therapy, prophylaxis, treatment of opportunistic infections and psychosocial care, malnutrition remained an important prognostic factor, even in developed countries. Wasting, in particular the loss of lean body mass, has been associated with increased mortality,<sup>10</sup> accelerated disease progression,<sup>11</sup> and impairment of physical strength and functional status.<sup>12</sup>

Most HIV-positive patients need nutritional support at one stage or another. In poverty-stricken areas such as Africa, with a high prevalence of HIV infection and malnutrition, it is unlikely that at-risk individuals would be in a position where they have continuous access to an adequate diet. Therefore, a suitable food supplement is regarded as an ideal carrier for macro- and micronutrients to complement an insufficient dietary intake.

Although dietary counselling or the provision of an optimal diet is important in the management of HIV-infected patients, this is generally not a feasible solution in the developing countries that harbour the majority of the world's HIV-infected individuals. Even in the technically developed world, maintenance of optimal nutritional health is exceedingly difficult. The guidelines proposed by the US National Task Force on Nutrition in AIDS emphasise the prevention of protein-energy malnutrition (PEM) as one of the major goals in individuals testing positive for HIV. These guidelines are, however, not readily applicable to impoverished communities, where PEM is prevalent and often precedes the onset of HIV infection.<sup>13</sup>

One of the challenges in developing countries, such as South Africa, is to identify appropriate, affordable interventions to timeously prevent and treat malnutrition. When a staple food (or supplement based on a staple food) is used to prevent or treat malnutrition, a high coverage rate can be achieved due to good compliance by the target group.

In the Northern Cape Province, the nutrition protocol for the optimal management of HIV-infected patients includes supplementation with enriched maize meal and a soy-based drink, as well as a multivitamin supplement. Although it is difficult to demonstrate the benefits of nutritional support regarding clinical outcome in HIV-infected children or adults, research has shown that nutritional status, and thus nutritional support, may affect both the progression of HIV disease as well as the survival of HIV-infected individuals.<sup>4,14</sup> Efforts should therefore be made to determine the impact of such interventions as part of the ARV roll-out plan.

Despite the nutrition intervention strategies implemented by government as noted above, few attempts were made in the past to determine the nutritional status of HIV-infected adults in South Africa, and the outcome of supplementation on the nutritional status

of patients participating in ARV programmes. In a small, descriptive study ( $n = 44$ ) amongst HIV-infected adults in KwaZulu-Natal, a mean weight gain of 2.4 kg for patients below 50 kg and 6.2 kg for patients above 50 kg was demonstrated, following a nutrition intervention programme utilising enriched maize meal (Mnise SE, unpublished data). The question needs to be asked whether these results could be replicated in other parts of South Africa. The aim of this study was to describe the nutritional status and determine the impact of existing nutrition intervention strategies on weight changes in adult HIV-infected patients on ARV therapy in the Northern Cape Province.

## Methods

The study was approved by the Ethics Committee of the Faculty of Health Sciences, University of the Free State (ETOVS 132/07). To ensure confidentiality, all forms used for data capturing referred only to record numbers, with no reference to the personal information of the participants. For illiterate patients, the information was explained in their home language and the consent form was signed by two witnesses.

The study was performed as a descriptive prospective trial. The initial study was planned to compare two different enriched porridges containing the same macro- and micronutrient content, but, due to limited patient numbers, the groups were combined to describe the effect of supplementation on nutritional status. HIV-infected adults older than 18 years of age, on ARV therapy at ARV roll-out centres in Kimberley, Upington, Kuruman, Prieska and Springbok, who gave written consent to participate, were included in the study. Patients with active tuberculosis, known allergy to soy protein, those refusing to consume the supplement, and pregnant and lactating women were excluded. All dropouts, as well as those who passed away during the trial, were recorded and documented. All new patients in the ARV programme were included in the study during the study period, but due to severe budgetary restraints in the Northern Cape, the number of new patients admitted at the particular ARV sites was much lower than expected.

Before the initiation of the study, a pilot study, comprising the first data collection, was performed with ten HIV-infected adults distributed between the sites to standardise forms and techniques.

A nutritional risk assessment form was completed by a registered, trained dietitian for each of the patients. The participants were weighed and measured using standardised equipment, and this information was used to calculate the BMI of each individual.

All new patients admitted to the ARV programme from 1 September to 31 December 2007 were screened according to the criteria. The BMI was used to describe the degree of adiposity by determining the relationship of weight to height. BMI was calculated by dividing weight (kg) by height squared ( $m^2$ ). To interpret BMI, the patients were classified as underweight ( $< 18.5 \text{ kg}/m^2$ ), normal ( $18.5\text{--}24.9 \text{ kg}/m^2$ ), overweight ( $25.0\text{--}29.9 \text{ kg}/m^2$ ), obese class 1 ( $30.0\text{--}34.9 \text{ kg}/m^2$ ), obese class 2 ( $35.0\text{--}39.9 \text{ kg}/m^2$ ), and obese class 3

(> 40 kg/m<sup>2</sup>).<sup>15</sup> For the purpose of this study, weight changes were indicated as a percentage of the initial body weight (as measured at baseline), and a loss of 5% or more was regarded as significant weight loss. Weight gain of 5% or more of body weight measured at baseline was regarded as significant weight gain.

The researchers consulted with the patients on a monthly basis at their local clinic and provided the supplement as part of the routine ARV treatment programme. The amount of supplement handed out was sufficient to provide 100 g of dry product per person per day, supplying approximately 1 800 kJ, 14 g protein, 15 g fat and 61 g carbohydrates. This amount of supplement also provided 100% of the recommended dietary allowance (RDA) for vitamins and minerals per day. Food supplementation still forms part of the ARV programme in the Northern Cape Province, and anthropometric data are continuously recorded with the aim of improving service delivery and programme success.

Compliance was ensured and monitored by issuing the supplement as part of the medical treatment of the patient, and training and monitoring the patient during each monthly follow-up. After an intervention period of four months, the researchers collected the end data, which entailed precisely the same procedure as during the baseline data collection.

Data were entered into a Microsoft Excel spreadsheet and statistical analysis was done by the Department of Biostatistics at the University of the Free State. Frequencies and percentages were used to summarise the categorical data. Means and standard deviations, or percentiles as appropriate, summarised baseline numerical characteristics. Changes from baseline to follow-up were summarised similarly. Subgroup comparisons were done using chi-squared or Mann-Whitney tests, as appropriate.

## Results

From the initial group of 158 patients enrolled in the ARV programme at the five sites during the study period, only 98 patients attended the ARV clinic on a regular basis over the four-month intervention period, which amounts to a 38% dropout rate from the ARV programme. Most of the dropouts occurred within the first six weeks. Kimberley, where the highest number of new patients was initially enrolled, experienced the highest dropout rate (55%), followed by Kuruman (48%), while no dropout occurred in Springbok (Table I).

The mean age of the 98 patients that were followed up was 39.7 years (standard deviation [SD] 8.9 years), and 66 participants (67.4%) were female. At baseline, patients had a median BMI of 20 kg/m<sup>2</sup> (ranging between 12.6 kg/m<sup>2</sup> and 29.7 kg/m<sup>2</sup>). Twenty-seven (27.6%) participants had a baseline BMI of lower than 18.5 kg/m<sup>2</sup> (Table II). No participants with a BMI in the obese category (BMI ≥ 30 kg/m<sup>2</sup>) were identified.

No significant difference was observed between the median BMI values of males and females (19.7 kg/m<sup>2</sup> and 20.1 kg/m<sup>2</sup>

Table I: Study population according to area

Site	Baseline (n)	End (n)	% Dropout
Kuruman	25	13	48.0
Kimberley	67	30	55.2
Prieska	32	25	21.9
Springbok	13	13	0
Upington	21	17	19.0
Total	158	98	38.0

Table II: Distribution of patients' body mass index (BMI) at baseline

BMI (kg/m <sup>2</sup> )	Interpretation <sup>15</sup>	Number of patients (n = 98)	Percentage
< 18.5	Underweight	27	27.6
18.5–24.9	Normal	63	64.3
25.0–29.9	Overweight	8	8.2

respectively). Patients from Kuruman presented with the lowest median BMI (17.9 kg/m<sup>2</sup>) at baseline, while median values for the other four sites were in the normal weight classification (Table III). Kuruman was the only area where the BMI data differed from the other areas ( $p = 0.08$ ).

The results of the initial nutritional risk assessment are summarised in Table III. According to these findings, 53 (54.1%) patients reported unintentional weight loss prior to the onset of the study. Approximately one quarter (25.5%) of the patients suffered from loss of appetite, while 11 (11.2%) presented with secondary infections at baseline. No significant association was observed ( $p = 0.38$ ) between baseline BMI and whether or not nutritional problems (as indicated by the patients, for example constipation, diarrhoea or nausea) were experienced.

Of the initial 98 patients who attended the ARV clinic for a period of at least three months, 87 (88.8%) patients visited the clinic during the final week of the study. The data of the patients who did not return have therefore been excluded from the results described further in this paper.

Weight changes for the group ( $n = 87$ ) varied between a weight loss of 8.35 kg (minimum) to a weight gain of 18.36 kg (maximum), with a median change of 0 kg (25% -1 kg; 75% +2.15 kg). Results with regard to weight changes during the study period are shown in Table IV. Eighteen (20.7%) participants gained more than 5% of their baseline weight, which, for the purpose of this study, was classified as significant. Only eight (9.2%) patients lost more than 5% of their baseline weight, also classified as significant weight loss. As with the baseline data, no significant correlation could be demonstrated between nutritional problems and weight changes.

No weight change occurred in patients who reported nutritional problems at baseline ( $n = 19$ ), while patients with no nutritional problems had a median weight gain of 0.5 kg. However, no significant difference was observed between the two groups ( $p = 0.56$ ).

Table III: Baseline nutritional risk assessment of patients at the onset of the study

Site	No of patients attending ARV clinic*	Median BMI (kg/m <sup>2</sup> )	Secondary infections n (%)	Unintentional weight loss prior to study n (%)	Loss of appetite n (%)	Nutritional problems n (%)
Kuruman	13	17.9	0 (0)	9 (69.2)	4 (30.8)	1 (7.7)
Prieska	25	21.0	6 (24.0)	15 (60.0)	3 (12.0)	3 (12.0)
Springbok	13	20.8	1 (7.7)	3 (23.1)	1 (7.7)	1 (7.7)
Upington	17	19.8	4 (23.5)	9 (52.9)	6 (35.3)	3 (17.6)
Kimberley	30	20.1	0 (0)	17 (56.7)	11 (36.7)	11 (36.7)
Total	98	20.0	11 (11.2)	53 (54.1)	25 (25.5)	19 (19.4)

\*Attendance of at least three months was required for inclusion in the study.

Table IV: Weight changes after nutritional supplementation

Site	Number	Median weight change in kg (min; max)	Weight gain n (%)	Weight loss n (%)	No change n (%)
Kuruman	8	1.4 (-0.2; 18.4)	7 (87.5)	1 (12.5)	0 (0)
Prieska	25	-0.4 (-8.4; 6.7)	11 (44.0)	14 (56.0)	0 (0)
Springbok	9	0.7 (-2.9; 5.4)	5 (55.6)	4 (44.4)	0 (0)
Upington	15	1.8 (-4.1; 8.8)	10 (66.7)	5 (33.3)	0 (0)
Kimberley	30	0 (-8.0; 12.3)	10 (33.3)	11 (36.7)	9 (30.0)
Total	87	0 (-8.4; 18.4)	43 (49.4)	35 (40.2)	9 (10.3)

Twenty-two patients who initially presented with a BMI of lower than 18.5 kg/m<sup>2</sup> had a median weight gain of 1.13 kg during the intervention period, while the group with a higher BMI presented with no change in median weight. Although no significant difference could be demonstrated between the two groups ( $p = 0.31$ ), the nutritional status of the malnourished group seemed to benefit more from being included in the ARV programme with supplementation than the group with normal weight. In Kuruman, the area with the lowest median baseline BMI, seven (87.5%) patients gained weight, and the amount of weight gained was considered as significant in three of these patients.

## Discussion

Despite the nutrition intervention programme being run as part of the ARV roll-out programme and managed by registered dietitians, a 38% dropout rate occurred – not only from nutrition intervention, but also from the ARV programme. The highest dropout rate occurred in the larger towns, with no dropouts in Springbok, where, as reported by the field worker, more personal follow-up was possible. According to a meta-analysis by Rosen et al<sup>16</sup> between 9.6% and 32.8% of patients were lost to follow-up or died at six ARV roll-out sites in South Africa where patients were monitored for at least one year. The dropout rate in our study was higher than that reported at other sites, and ways to improve retention should be investigated. In addition to the initial dropouts, a further 11.2% of patients (11/98) did not attend their scheduled follow-up in the final week of the intervention programme.

More than 25% of the patients in this study presented with a baseline BMI of lower than 18.5 kg/m<sup>2</sup>, and were thus malnourished

prior to enrolment in the ARV programme. Unlike other data<sup>17</sup> on HIV-infected individuals in South Africa, no significant difference could be demonstrated between the BMI values of the male and female patients. The median BMI (20.0 kg/m<sup>2</sup>) observed in this group of patients in the Northern Cape Province was similar to the median BMI of an immunocompromised group of HIV-infected patients from the Free State Province, who presented with a median BMI of 19.7 kg/m<sup>2</sup>.<sup>18</sup> Patients enrolled in Kuruman presented with the lowest median BMI from all the sites monitored in the Northern Cape Province, which corresponded to unemployment data indicating this area as having the highest unemployment rate (38.3%) of the five towns.<sup>19</sup>

At baseline, 54.1% of the patients reported unintentional weight loss prior to the onset of the study, while 25.5% experienced loss of appetite. Considering that the participants had to comply with the entry criteria to be enrolled in the ARV programme (that is, having a CD4<sup>+</sup> cell count of < 200 cells/mm<sup>3</sup>), and therefore were severely immunocompromised, the weight loss and loss of appetite reported by this group were to be expected.

Half (49.4%) of the patients gained weight during the intervention period, of whom 42% gained a significant amount of weight. This finding indicates that the ARV programme, in combination with nutritional supplementation with an instant, enriched maize meal ensuring 100% RDA of micronutrients, had a positive impact on a large group of patients enrolled in this programme. However, despite supplementation according to provincial policy, 40.2% of the patients still lost weight during the four-month intervention period.

No significant association could be demonstrated between weight changes and the presence of nutritional problems. The results from this study showed that patients with a BMI < 18.5 kg/m<sup>2</sup>, reflecting underweight, had better weight gain than the group with a normal BMI. The median weight gain, however, did not differ significantly between patients with an initial body weight lower than 50 kg (41; 47%) (median 0 kg gain) when compared to patients with an initial body weight of more than 50 kg (46; 53%) (median 0.2 kg gain) ( $p = 0.33$ ). These results do not correspond with the findings of a study performed in KwaZulu-Natal, where better weight gain was demonstrated in patients weighing more than 50 kg compared to those weighing less (Mnise SE, unpublished data).

The limitations of this study were the relatively small sample size, and the high dropout rate. It was not possible to evaluate the impact of nutritional supplementation without taking the impact of ARVs into account, thereby making it impossible to determine whether the medication or the supplements were the primary reason for weight gain. It was considered unethical to withhold nutrition support from a group of patients at nutritional risk in order to have a comparative control group. Consequently, the impact of ARVs alone on weight change could not be determined.

The nutritional support, as provided to patients as part of this study, may seem suboptimal. However, it should be interpreted in the context of existing severe budget restrictions at the time of the study, when very limited nutritional support or supplementation was available in the Northern Cape. Dietitians were forced to employ counselling as a major resource to impact on the nutritional status, and no options in terms of specialised nutritional supplements were available to those patients losing weight or starting the programme in a malnourished state. The authors believe that it is important that dietitians and other health care professionals in South Africa should be made aware that not all health professionals and patients are in the fortunate position to participate in ARV programmes at tertiary institutions, or in provinces/districts where sufficient funding is channelled towards nutrition intervention strategies, and where specialised nutritional support is available. The best possible treatment available was provided to the participating patients. The treatment even included home visits and searches for patients not returning to the clinic, which was beyond the normal call of duty.

Evidence from this study suggests that nutritional supplementation according to provincial policy, in combination with ARVs, nutritionally benefited approximately half of the patients retained on the ARV programme in the Northern Cape. As these immunocompromised patients clearly need both ARV therapy and nutritional support, it seems superfluous to try to establish which of the interventions will make more of a difference in terms of nutritional status. It is recommended, however, that more aggressive supplementation should be investigated to increase the success rate in terms of weight gain. This will only be possible once sufficient funding becomes available for sustainable supplementation programmes.

It is further recommended that the reasons for the high dropout rate from ARV programmes be investigated to determine whether nutritional status plays any role in programme retention, and to ensure that retention measures are put in place.

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