

Effects of an HIV-Care-Program on immunological parameters in HIV-positive patients in Yaoundé, Cameroon: a cluster-randomized trial

Germaine N. Nkengfack · Judith N. Torimiro · Jeanne Ngogang · Sylvia Binting · Stephanie Roll · Peter Tinnemann · Heike Englert

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Abstract

Objectives To measure the effects of an HIV-Care-Program, focusing on nutrition and lifestyle, which can be provided at scale to HIV-infected patients, on clinical and anthropometrical parameters, and health status.

Methods A cluster-randomized trial, including 5 health facilities randomized to intervention $n = 100$ (HIV-Care-Program) or control $n = 101$ (Usual-Care). The HIV-Care-Program consisted of counseling lessons for 6 months, on: nutrition, hygiene, coping with stigma and discrimination, embedded in practical activities. Outcome variables were CD4 count after 6 months and time to antiretroviral therapy (ARV) initiation, using analysis of covariance and Kaplan–Meier method, respectively.

Results After 6 months, CD4 count dropped by 46.3 cells (7.7 %) (intervention) and 129 (23 %) (control) ($p = 0.003$). Mean time to ARV; 5.9 months 95 % CI (5.9, 6.0) (intervention); 4.9 months 95 % CI (4.7, 5.2) (control)

($p < 0.004$). There was a partial correlation between CD4 count and initial viral load ($r = -0.190$, $p = 0.017$).

Conclusions The intervention provides a low-cost alternative improving health status, slowing down CD4 cell decline, delaying initiation of ARV and thus freeing local ARV capacities for patients in urgent need.

Keywords HIV · Nutrition · Counseling · Lifestyle · Cluster randomization

Introduction

The global HIV epidemic continues to pose one of the severest clinical and public health problems for large number of people in Africa. Out of the 34 million people living with HIV worldwide, 69 % come from sub-Saharan African countries alone (UNAIDS 2011).

Significant research efforts are ongoing to reduce the burden of HIV infection on individual persons and populations. These include: improving antiretroviral therapy and highly active antiretroviral therapy (ARV/HAARTS), or measuring supportive interventions such as nutrition optimization. ARV/HAARTS are known to suppress the viral replication and improve CD4 counts (Isanaka et al. 2012). However, ARV/HAARTS availability is still limited in sub-Saharan African settings and its use is associated with side effects including changes in distribution of body fat, insulin resistance, fatigue etc. Due to these side effects, patient's adherence to treatment has greatly been limited, thus leading to drug resistance (Ngondi et al. 2006; DaCosta DiBonaventura et al. 2012).

Meanwhile, there is increasing agreement that nutrition plays a vital role in the care and management of HIV and is fundamentally linked to immune system functions. HIV

G. N. Nkengfack (✉) · S. Binting · S. Roll · P. Tinnemann · H. Englert
Institute for Social Medicine, Epidemiology and Health Economics, Charité, Universitätsmedizin Berlin Center, Berlin, Germany
e-mail: mbonguegermaine@yahoo.com

G. N. Nkengfack · H. Englert
Muenster University of Applied Sciences, Muenster, Germany

G. N. Nkengfack
Department of Biomedical Sciences, University of Dschang, Dschang, Cameroon

J. N. Torimiro · J. Ngogang
Faculty of Medicine and Biomedical Sciences, University of Yaoundé I, Yaoundé, Cameroon

infection impairs the individual's immune system, contributes to malnutrition, resulting in further damages and disease progression to AIDS (Suttajit 2007; Shalini et al. 2012). Malnutrition is a result of changes in body metabolism, leading to a reduction in food intake, malabsorption and micronutrient deficiency (De Pee and Semba 2010). Micronutrient supplements have been proposed in several trials as an adequate strategy to improve clinical outcomes and to slow down the decline of CD4 cell counts in HIV-infected patients (Mugusi et al. 2004; Olaniyi and Arinola 2007). However, these supplements are mostly expensive and beyond the reach of the majority of HIV-infected patients in low-income countries (Lunney et al. 2008). Other studies show that excessive intake of supplements is accompanied by numerous side effects such as increased oxidative stress and HIV transmission from mother to child (Castetbon et al. 1997; van Gaalen and Lindi 2009; Birringer and Ristow 2012). Meanwhile, Cameroon is a country rich in cheap and locally available food, with a high potential of minerals, vitamins and antioxidants, which could contribute to improve the nutritional and immune status of HIV-infected patients (Holt et al. 2009).

Combining improved nutrition with healthy lifestyle practices such as moderate physical activity, avoiding alcohol abuse and smoking etc. to care and management of HIV-infected persons is considered vital, when considering HIV infection as a chronic disease (Scandlyn 2000; Nigatu 2012). In several studies it has been demonstrated that these factors have the potential to influence immune cells and the progression of the HIV disease (Gomes and 2010; Wu et al. 2011; Kabalia et al. 2011).

Although each of these factors was investigated in isolation and already showed positive effects on immunological parameters, it could be assumed that combining them with education and counseling will have a stronger effect on a long-term, slowing down CD4 decline and retarding ARV initiation.

Therefore, we investigated the effect of modifying nutrition and lifestyle on treatment naïve HIV-infected patients in Yaoundé, Cameroon. This paper is the first publication presenting the 6 months results of a 30-month study.

Methods

Study population and recruitment

The intervention was conducted between June 2010 and December 2012 in Yaoundé, Cameroon. Considering the nature of the study, a cluster randomization by health facility was preferred, to minimize the risk of contamination through exchange of information between the

intervention and the control group during routine visits (Jewkes et al. 2006).

Inclusion criteria for health facilities included: health facility offering HIV care and/or treatment and a minimum of 100 HIV patients registered. Inclusion criteria for patients included: HIV-infected patients aged between 20 and 72, with CD4 >350 cells/ μ l, viral load <100,000 cells/ μ l, and not receiving ARV at the beginning of the study. Before returning their informed consent, patients were informed on study aim and procedure and given the possibility to ask questions. All the study participants provided a signed informed consent before the study started.

Ethical approval was obtained from the national ethics committee of Cameroon (Authorisation No. 106/CNE/DNM/08), the Institutional Review Board of the Cameroon Baptist Health Unit (IRB2010-02), and the Ministry of Public Health in Cameroon (Division de la Recherche Operationnelle en Santé), (Authorisation Administrative de Recherche: No. 631-0211).

Intervention phase

Participants in the intervention group (HIV-Care-Program) received

Individual counseling: participant's nutritional status, nutritional need and nutritional knowledge were assessed using a 3-day dietary protocol, a food frequency questionnaire (FFQ) and self-administered questionnaires. Two sessions of individual counseling took place during the first 2 weeks of the intervention phase and counseling duration was 30 min for each participant. Subsequently, the intervention group was divided into six groups (16–20 participants per group) for group counseling. Altogether 22 sessions of group counseling was provided during the intervention phase.

Group counseling: group counseling included the following four topics

HIV and Nutrition: effect of HIV on immune cells, effects of HIV on nutritional status, nutritional needs of HIV-positive patients, composition of a balanced diet (emphasis was laid on the consumption of "5 a day" intake of fruits and vegetables, high intake of carbohydrate, high intake of protein of plant origin e.g., kidney beans, soy bean etc., high intake of dairy products and water, low intake of fat), "one dollar shopping" (aimed to help participant buy the right food even with less financial resources), malnutrition (causes of malnutrition, use of nutrition to reduce effects of malnutrition), nutrition and ARV (interaction between food and ARV) and food preservation (adequate methods for food preservation, consequences of food preservation methods on nutrient content) (FAO. Living Well with HIV/AIDS: A manual on

nutritional care and support for people living with HIV/AIDS 2002).

HIV and Hygiene: personal hygiene, food and water hygiene and hygiene of the home (kitchen, toilet, home) (World Health Organization 2010).

Coping with stigma and discrimination: how to reconcile one's situation with one's self, reconciling with others, and reconciling with the society. Coping strategies were problem focused (e.g., joining a support group, seeking counseling etc.) and emotion focused (e.g., avoidance of problems, optimism, believing in God) (Collymore 2002, Inside out Research Report 2003).

Physical activity (PA): moderate (PA) was defined as a 25–30 min walk per day, also equivalent to 2500–3000 steps in 30 min per day (i.e., 100 steps/minute on level land) (Marshall et al. 2009). Lessons were accompanied by practical activities such as shopping tours in local markets (participants were advised on when to go food shopping, quality of good food e.g., fruits and vegetables), cookery seminars on regional food, and workshops on healthy lifestyle. Food for cookery seminars was provided by the study team.

Transport cost was refunded for participants who attended the counseling meetings. Group counseling took place once a week over 6 months and the meeting duration was 3 h per group. During this phase, facilitators were trained according to a standardized curriculum for conducting the refresher sessions and support groups.

Participants in the control group were subjected to the general practitioner's choice of therapy (Usual-Care). In Cameroon, the usual care treatment for HIV/AIDS patients consists of periodic CD4 cell count and viral load check-up, and provision of family planning accessories and condoms.

Follow-up phase

The follow-up phases continued for 24 months. Participants in the intervention group received refresher sessions, lasting 3 h every 2 weeks for 12 months (follow-up phase I), and subsequently 3 h every 4 weeks for 12 months (follow-up phase II). All refresher sessions were carried out by trained facilitators, assisted by the study dietician and coordinator.

Sample size considerations

With 6 health facilities, each recruiting an average of 60 patients each, the study would have 80 % power to detect a difference between the two groups of 20 %, with a between-cluster variance of 0.005 (Thompson et al. 1997). A difference of 20 % was chosen as an estimate of clinically relevant change. To yield an average of 60 patients

per health facility and a 10 % drop out rate, a minimum of 100 patients per health facility were contacted. After 4 months of recruitment, instead of 1 month as previously planned, only about 100 participants were enrolled in each group, instead of 150 per group. For these reasons and others related to funding, the study management decided to begin the intervention with a sample sized of 100/101 study participant per group.

Randomization and masking of treatment allocation

Prior to study initiation, potential health facilities were assessed to determine the size, the number of HIV patients available, and then assigned to the intervention or control group, using a computer-generated random list. This was done by an investigator not involved in the study, and stratification was done by health facility size. The patient code was held only by the study coordinator and data bank manager during the trial. To preserve blinding, staff responsible for measuring and collecting health and socio-demographic outcomes, as well as clinicians involved in patient recruitment were unaware of group allocation.

Outcome measurements and data collection

Clinical and biochemical parameters: primary outcomes variables were change in CD4 cell count from baseline to 6 months, and time to ARV initiation. Secondary outcome variable was: observing if there was an association between CD4 count at 6 months and viral load at baseline. CD4 cell count was measured using the flow cytometry [FacsCalibur (Becton–Dickinson Immunocytometry system (BDIS), San Jose, CA, USA)]. Plasma HIV viral load was measured with real-time Abbot (Abbot Molecular Diagnostics, Wiesbaden, Germany), malondialdehyde (MDA) and albumin were measured using thiobarbituric acid (TBA) test and bromo-cresol green (BCG) colorimetric method, respectively.

Nutritional assessment: dietary intake was assessed with a 3-day dietary record; including all food and beverages consumed, portion size and method of preparation. Nutrient intakes were analyzed using a Nutrition Database, [Ernährungsanamnese-Beratungs-Informationen-System EBIS version 2011 (University of Hohenheim, Stuttgart, Germany)]. The complete dietary analysis contained 46 nutrients including carbohydrates, protein, fat, vitamin A, C, E, β -carotene, zinc and iron. A food frequency questionnaire was used to assess the frequency of food intake, grouped in nine major categories (meat, fish, vegetables, fruits, starchy food, dairy products, fats and oils, local dishes, miscellaneous).

Anthropometric measurements: height was measured to the nearest centimetre with a stadiometer and weight to the

nearest 0.1 kg with a standard scale (Seca 216 and 792, Hamburg, Germany).

Questionnaire: a self-administered questionnaire included demographic information (age, region of origin, educational level, occupation, marital status and socioeconomic status) as well as personal evaluation of program relevance.

Assessments of all parameters and collection of data were conducted at baseline, after 3, 6, 12, 18, 24, and 30 months in the intervention group, and at baseline, after 6, 18, and 30 months in the control group.

At the end of each weekly meeting in the intervention group, participants were asked to sign a register, including the number of weekly meetings attended.

Data analysis

Statistical analysis was carried out using SPSS statistics 20 (IBM Corporation, 2011). Baseline characteristics in both groups were compared using analysis of covariance (ANCOVA) and Chi-square test. After 6 months, outcome variables in the two groups were compared using ANCOVA for continuous variables, and logistic regression for categorical variables, adjusting for clusters and baseline

variables. The time to ARV initiation was calculated using the Kaplan–Meier method, adjusting for clusters. Data that were not normally distributed were log transformed before analysis.

Finally, we also examined whether changes in CD4 cell count after 6 months were associated with baseline viral load, unadjusted using Pearson correlation, and then partial correlation, controlling for clusters. All analyses were conducted according to the intention-to-treat population and values were significant at $p < 0.05$ without adjusting for multiple testing.

Results

Study population

The trial profile is shown in Fig. 1. All five health facility completed the trial. Of the 201 enrolled participants, 190 were evaluated for outcomes after 6 months. The number of participants lost to follow-up was ten (10 %) in the intervention and one (1 %) in the control group. The program was well attended with more than 90 % of the

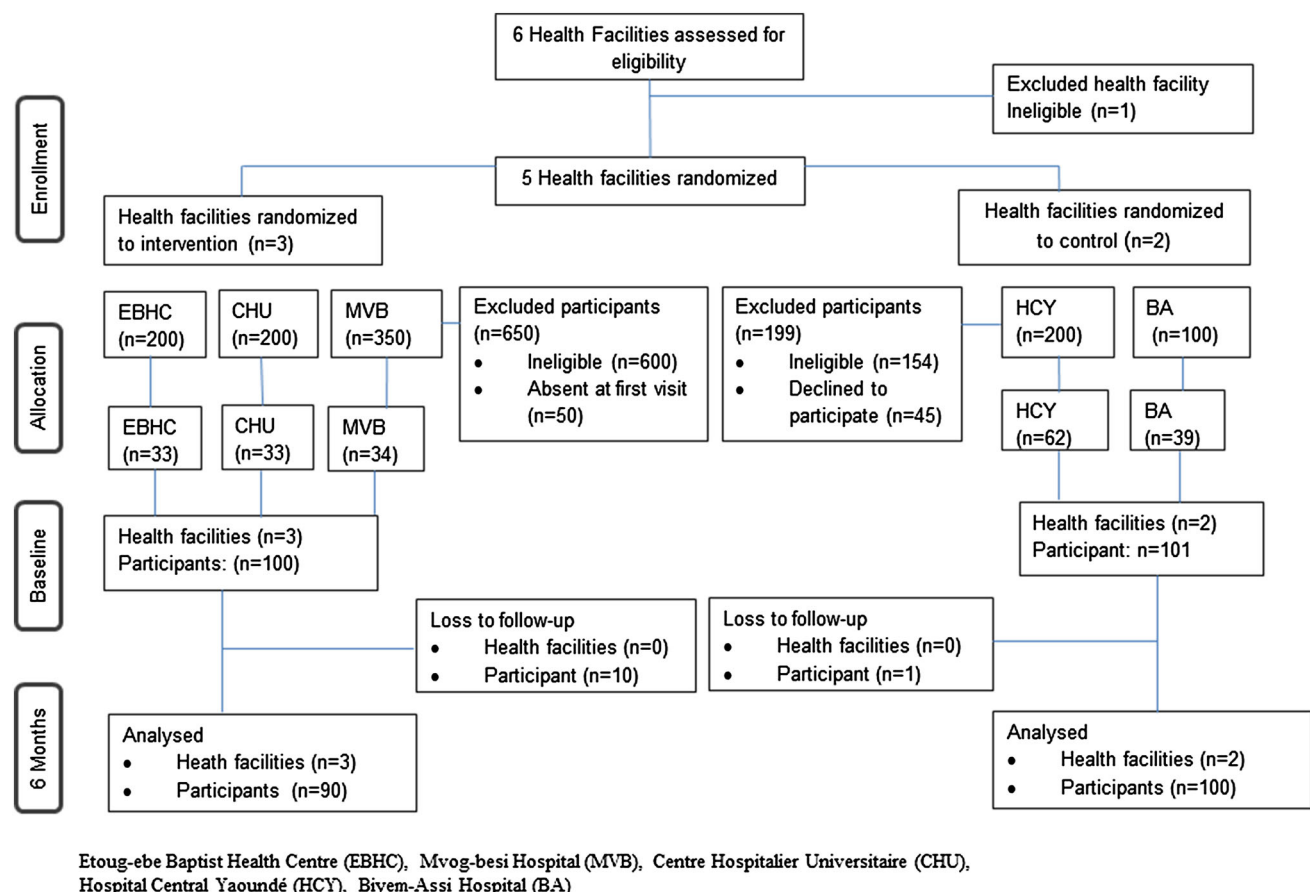


Fig. 1 The flow diagram of clusters and individuals through the cluster-randomized trial, Cameroon, Yaoundé, HIV-Care-Program 2010–2012

participants in the intervention group evaluating the program as being relevant and useful for their health.

Differences at baseline between the intervention and control group were not significantly different at baseline with respect to their age, sex, marital status and years since HIV infection; weight, BMI, CD4 count and MDA (Table 1). Average weekly alcohol intake was 13 glasses of alcoholic beverages in the intervention group compared to seven glasses in the control group. Macro -and micronutrient intake recorded from the dietary record at baseline was statistically different between both groups (Table 2). The highest level of education in both groups was secondary education and most patients belonged to the lowest socioeconomic strata with an average monthly income of 100,000 frs CFA (about 165 €).

Comparison of CD4 cell counts between intervention and control group at 6 months

After 6 months, the mean absolute CD4 cell count dropped from 603.6 cell count to 557.3 cell count 95 % CI (477.9; 636.8) in the intervention group and from 561.4 cell count to 432.4 cell count 95 % CI (370.6; 494.3) in the control group (Table 3). That is a difference of 46.3 cells 95 % CI (36.8; 55.7) (7.7 %) in the intervention versus 129 cells 95 % CI (125.2; 132.8) (23 %) in the control group.

There was no correlation between CD4 cell count after 6 months and baseline viral load for both groups, ($r = -0.143$, $p = 0.037$), but after adjusting for clusters, there was a partial negative correlation between CD4 cell count and initial viral load for both groups ($r = -0.190$, $p = 0.017$). Also, a partial correlation was observed between CD4 after 6 months and baseline viral load in the intervention group alone ($r = -0.253$, $p = 0.030$) and after adjusting for clusters, ($r = -0.247$, $p = 0.036$). In the control group, no correlation was observed between CD4 at 6 months and baseline viral load, ($r = -0.142$, $p = 0.017$) and after adjusting for clusters, ($r = -0.139$, $p = 0.211$).

Initiation to ARV at 6 months

After 6 months, 44 participants of the 201 who started the study without taking ARV were initiated to ARV, 9 (10 %) in the intervention group compared to 35 (35 %) in the control group ($p < 0.001$). Mean time to ARV initiation was 5.9 months 95 % CI (5.9, 6.0) in the intervention group and 4.9 months 95 % CI (4.7, 5.2) in the control group ($p < 0.004$) (Fig. 2).

Compliance

Based on the number of weekly meetings attended in the intervention group, compliance was good with about 65 %

participation at each meeting, over the 6 months intervention period.

Discussion

The huge burden of HIV in sub-Saharan Africa imparts great significance to the question of interaction between immune status, nutrition and lifestyle. There is substantial evidence that adequate nutrition as well as a modified lifestyle interventions coupled with or without education and counseling can improve the immunological status of HIV patients (Rabeneck et al. 1998; Boppa et al. 2004; Buller et al. 2008).

The authors tested the hypothesis that an HIV-Care-Program, based on nutritional education and lifestyle modification, would increase CD4 cell count in the intervention group compared to the control group after 6 months. However, in this study, we observed a decrease in CD4 cell counts in both groups. Several investigators reported increasing CD4 cell counts after micronutrient supplementation in HIV-infected patients (Fawzi et al. 2004; Koletar et al. 2004; Kaiser et al. 2006). Contrary to our study, those participants were receiving HAART and/or micronutrient supplements. So far, only a limited number of studies have been conducted in sub-Saharan Africa examining the diets based on local foods and its effects on HIV progression. These studies mostly report the effectiveness of local food in improving nutritional status of HIV patients (Zotor and Amuna 2008; Kuria 2009; Nkengfack et al. 2012).

It was assumed that the rate of decline of CD4 cells in the intervention group might have been slowed down by the intervention. This assumption could be supported by the higher number of participant being initiated to ARV after 6 months in the control group (35), compared to the intervention group (9). Contrary to our results, Kuria (2009), after using a low nutrient diet, observed no effect on CD4 cell count and viral load in HIV asymptomatic patients. However, in Kuria's study, a low nutrient diet with little variety was used and lifestyle was not addressed.

The absence of expected increase in CD4 cell count could be linked to the relatively higher levels of average CD4 cell count observed at baseline, 603.6 cells/ μ l in the intervention group and 555.2 cells/ μ l control group, respectively. Jiampton and co-workers (2003) after administering micronutrient supplement observed the most pronounced positive effects in HIV patients with CD4 counts < 200 cells/ μ l.

van Gaalen and Lindi (2009) also suggest that excessive supplementation of antioxidants could cause fluctuating CD4 cell concentration, meanwhile moderate doses could temporarily boost uninfected CD4 cell concentration, and

Table 1 Baseline characteristics of study participants: clusters, demographic, anthropometric and clinical parameters. Cameroon, Yaoundé, HIV-Care-Program 2010–2012

Characteristics	Intervention group (<i>n</i> = 100)	Control group (<i>n</i> = 101)	<i>p</i> value
Health facilities randomized (<i>n</i> %)	3 (60)	2 (40)	
Cluster size <i>n</i> (%) ^a			
EBHC	33 (16.4)	0 (0)	
CHU	33 (16.4)	0 (0)	
MVB	34 (16.9)	0 (0)	
HCY	0 (0)	62 (30.8)	
BA	0 (0)	39 (19.4)	
Demographic parameters			
Age (years) mean ± SD	33.0 ± 8.3	34.4 ± 10.0	0.224
Sex <i>n</i> (%)			
Male	31 (31.0)	35 (34.7)	
Female	69 (69.0)	66 (65.3)	
Region of origin <i>n</i> (%)			–
Centre, South, East	32 (32.0)	54 (53.5)	
South West, Littoral	10 (10.0)	10 (9.9)	
West, North west	53 (53.0)	30 (29.7)	
Adamaoua, North, far North	5 (5.0)	7 (6.9)	
Marital status <i>n</i> (%)			–
Married	38 (38.0)	42 (41.6)	
Unmarried	58 (58.0)	50 (49.5)	
No response	4 (4.0)	9 (8.9)	
Education <i>n</i> (%)			–
None	8 (8.0)	16 (15.8)	
Primary	36 (36.0)	32 (31.7)	
Secondary	37 (37.0)	38 (37.6)	
University	19 (19.0)	14 (13.9)	
No response	0	1 (1.0)	
Employment <i>n</i> (%)			–
Yes	37 (37.0)	29 (28.7)	
No	59 (59.0)	69 (68.3)	
No response	4 (4.0)	3 (3.0)	
Monthly income (frs CFA) <i>n</i> (%) ^a			–
<100.000	58 (58.0)	36 (35.6)	
100.000–200.000	13 (13.0)	5 (5.0)	
>200.000	5 (5.0)	3 (3.0)	
No response	24 (24.0)	57 (56.4)	
Clinical and anthropometrical parameters (mean ± SD)			
Weight (kg)	70.1 ± 13.0	69.7 ± 14.7	0.849
BMI (kg/m ²)	26.1 ± 4.2	25.9 ± 5.0	0.798
CD4 (cells/μl)	603.8 ± 213.6	555.2 ± 198.2	0.081
Viral load (log)	4.5 ± 4.6	4.3 ± 4.4	0.005
Albumin (g/dl)	2.1 ± 1.0	3.4 ± 1.1	<0.001
MDA (μmol/l)	3.3 ± 1.7	3.5 ± 2.7	0.438
Years since HIV disease was diagnosed	3.1 ± 2.1	3.7 ± 2.2	0.059

Statistical estimates were based on an F-test and a Chi-square test

MDA Malondialdehyde, EBHC Etoug-ebe Baptist Health Centre, CHU Centre Hospitalier Universitaire, MVB Mvog-besi Hospital, HCY Hospital Central Yaoundé, BA Biyem-assi Hospital

^a 100,000 FRS CFA = 165 €

Table 2 Baseline characteristics: lifestyle, Cameroon, Yaoundé, HIV-Care-Program 2010–2012

Characteristics	Intervention group (n = 100)	Control group (n = 101)	RDA
Nutrition (mean ± SD)			
Energy (Kcal)	2,114.9 ± 496.9	2,457.5 ± 966.1	2,127.5
Protein (g)	68.1 ± 22.2	84.8 ± 44.8	57.1
Fat (g)	81.7 ± 32.4	101.2 ± 49.9	65.6
Carbohydrate (g)	266.5 ± 70.8	288.8 ± 123.1	276.1
Vitamin A (µg)	1,974.8 ± 1,255.4	2,907.1 ± 4,381.3	800.0
β-Carotene (mg)	10.6 ± 7.6	9.6 ± 5.6	8.0
Vitamin C (mg)	143.2 ± 100.2	159.8 ± 128.1	100.0
Vitamin E (mg)	11.8 ± 5.2	17.9 ± 14.1	12.0
Calcium (mg)	479.5 ± 253.5	482.2 ± 221.8	1,000.0
Zinc (mg)	8.8 ± 3.2	9.9 ± 5.2	12.0
Iron (mg)	12.2 ± 4.0	14.2 ± 5.8	15.0
Alcohol intake n (%)			
Yes	41 (41)	45 (44.6)	
No	53 (53)	27 (26.7)	
No response	6 (6)	29 (28.7)	
Smoked in the past n (%)			
Yes	9 (9)	7 (6.9)	–
No	79 (79)	69 (68.3)	
No response	12 (12)	25 (24.8)	
Physical activity in the past n (%)			
Yes	68 (68)	61(60.4)	–
No	20 (20)	8 (7.9)	
No response	12 (12)	32 (31.7)	

Energy value for HIV positive patients increased by 10 % compared to HIV negatives, thus [1,934.1 + 1,93.4 = 2,127.5 (RDA)]

RDA Required daily allowance, SD standard deviation

Table 3 Comparison of outcome at 6 months in both groups, Cameroon, Yaoundé, HIV-Care-Program 2010–2012

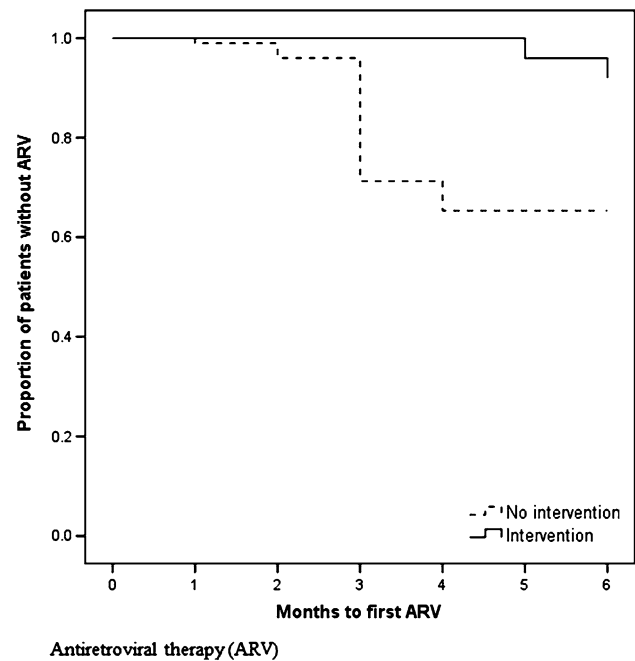
Parameters	Intervention group (n = 90)	Control group (n = 100)	p value [†]
CD4* (cells/µl)	557.3 (477.9, 636.8)	432.4 (370.6, 494.3)	0.003
No. patients on ARV (n) %	9 (10)	35 (35)	<0.001

ARV Antiretroviral therapy

* Values shown are mean (confidence interval)

[†] Statistical tests (ANCOVA) and logistic regression, adjusted for clustering and baseline parameters

slow disease progression. In our study, the intake of antioxidants was promoted through the “5 servings of fruit and vegetable a day” program (Buller et al. 2008). Also, the

**Fig. 2** Kaplan–Meier Estimates of Duration to first antiretroviral therapy, Cameroon, Yaoundé, HIV-Care-Program 2010–2012

intake of locally cultivated soybean, a rich source of antioxidant in form of Isoflavones aglycones was well encouraged (Pandey and Rizvi 2009; Cheng et al. 2010). Analysis of the 3-day dietary record showed intakes of dietary antioxidants high above the required daily allowance (Table 2). This could explain the decrease in CD4, although the quantity of antioxidant consumed through the local food was not directly measured.

Also, after adjusting for clusters, a partial negative correlation was observed in both groups between CD4 after 6 month and baseline viral load. This result indicates that the higher the viral load, the lesser the CD4 cell count and thus confirms the use of CD4 and viral load as surrogate indicators to monitor HIV disease progression. This result is similar to that of (Fawzi Mehta (2007), who observed after supplementation with micronutrient in HIV/AIDS patients a negative correlation between changes in CD4 and viral load.

Limitations

some limitations of our study should be taken into consideration. The trial design influenced the ability to detect significant changes. Cluster randomisation generally reduces the units available for allocation of trial groups. This trial originally included relatively small cluster of six health facilities, but due to the 1-year delay observed in starting the intervention, potential participants from one

health facility were completely lost, since CD4 count decreased during this period to values below 350. Thus, this health facility could no longer take part in the study. Also, the overall small number of health facility is a result of the limited number of health facilities involved in the care and/or treatment of HIV/AIDS patients in Yaoundé. A larger trial would have allowed a more precise estimation of the intervention and detection of smaller differences between groups. Further, during the period between study design and implementation, changes in the global recommendations for initiation of HIV patients to ARV were made, changing the criteria for ARV initiation from 250 to 350 cells/ μ l, limiting the number of health facilities as well as patients fulfilling our study criteria (UNAIDS 2010).

The subjective approach (questionnaire) used to collect data was based on self-reporting. Therefore, participants' responses on delicate issues may be inaccurate, reflecting what participants feel the investigator may wish to hear or think about them. In this case, recall bias could be introduced (Holtgraves 2004). Finally, the fact that the study was not blinded also serves as a further limitation.

Conclusions

This study provides evidence that an intervention based on nutrition and lifestyle modification for ARV naïve HIV-infected patients in a sub-Saharan low-/middle income country settings is possible and can slow down the rate of CD4 decline 6 months after intervention. Slowing down CD4 decrease through the analyzed nutrition and lifestyle modification thus contributes to delays in the onset of ARV therapy initiation. The long-term effects of the intervention after 24 months will be documented in a future article.

However, despite the benefit that can be obtained from nutritional and or lifestyle modification interventions, it is still important to make ARV accessible and affordable for all HIV-infected patients in developing countries.

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