



## ORIGINAL ARTICLE



# Does *Moringa oleifera* Lam. leaves supplementation have an impact on the weight and bone mass index of people living with HIV that are on antiretroviral therapy? A double-blind randomized control trial

Aisha Gambo<sup>1\*</sup> | Nceba Gqaleni<sup>2</sup>

<sup>1</sup>Discipline of Public Health, School of Nursing and Public Health, College of Health Sciences, University of KwaZulu-Natal, Durban, South Africa.

<sup>2</sup>Discipline of Traditional Medicine, School of Nursing and Public Health, College of Health Sciences, University of KwaZulu-Natal, Durban, South Africa.

### Abstract

**Background.** HIV-related weight loss and wasting were the most common malnutrition and AIDS-defining conditions before HAART. HAART has led to more obese PLHIV. HIV-positive patients should eat micro- and macronutrient-rich foods to maintain optimal nutrition. This study examined whether *Moringa oleifera* Lam. leaf supplementation affects PLHIV receiving ART.

**Methods.** A randomized, double-blind, controlled trial was conducted. Two hundred patients with informed consent were randomly assigned to either the *Moringa oleifera* Lam. (MOG) group or the control group (COG). From baseline to six months of *Moringa oleifera* Lam. leaf supplementation, anthropometric parameters [weight; BMI] of the participants were assessed.

**Results.** One hundred seventy-seven patients completed the 6-month follow-up (89 MOG vs. 88 COG). During the study period, the MOG and COG had similar weights and BMIs ( $p > 0.05$ ). At baseline and six months, most participants in both study groups had a healthy BMI (18.5-24.9). Many participants were overweight; few were underweight ((BMI <18.5). MOG and COG BMI differences at baseline and six months were not significant ( $p > 0.05$ ). All experiments were 95CI.

**Conclusions.** *Moringa oleifera* Lam. leaf powder had no effect on HIV-positive adults receiving antiretroviral therapy, in accordance with this study.

Keywords: *Moringa oleifera* Lam., HIV, BMI, antiretroviral therapy.

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## INTRODUCTION

According to the 2019 UNAIDS report, there were 1,9 million HIV-positive individuals in Nigeria, with a prevalence of 1.5% among adults aged 15-49 [1]. Malnutrition and HIV/AIDS are inextricably linked [2]. During the pre-highly active antiretroviral therapy (pre-HAART) era, HIV-related weight loss and wasting were the most prevalent forms of malnutrition and AIDS-defining conditions [3]. This was marked by a significant decrease in body fat, lean mass, and bone mass [4]

The introduction of HAART has proven effective in reducing morbidity and mortality associated with HIV infection [5, 6] and in ameliorating the syndrome of wasting associated with HIV [5]. On the other hand, it has been documented that the prevalence of overweight and obesity increases among HIV-positive individuals receiving HAART [7], which may increase the risk of cardiovascular and metabolic diseases [8].

Diet is of the utmost importance for maintaining optimal nutrition and preventing these complications [4]. Patients infected with HIV are urged to consume diets rich in micro- and macronutrients necessary for normal body function [4]. Unfortunately, the diet and food consumption of PLHIV in low-income settings, such as Nigeria, need improvement [9].

The powdered leaves of *Moringa oleifera* Lam., which has been shown to have a high nutritional value [10-13], could be a valuable addition to the diets of PLHIV. *Moringa oleifera* Lam. is a member of the Moringaceae family [14]. The leaves are a rich source of both macro- and micronutrients [16] and act as a good source of natural antioxidants [17] due to their high concentration of minerals, vitamins, and other vital phytochemicals.

We have already conducted a study demonstrating the effect of *Moringa oleifera* Lam. leaves on the immune status [18] and the quality of life of PLHIV on ART [19], which have been reported elsewhere. Consequently, the purpose of this manuscript is to determine if supplementation with *Moringa oleifera* Lam. leaves affects the weight and BMI of PLHIV on ART compared to placebo at the S.S Wali Virology Centre, Aminu Kano Teaching Hospital, Kano State, Nigeria.

## MATERIALS AND METHODS

### Study location

The study location was the Sadiq Suleiman Wali, known as S.S Wali Virology Centre at Aminu Kano Teaching Hospital, Kano State (AKTH), Nigeria.

AKTH is a tertiary health institution and referral center that operates a daily HIV clinic (5 days a week). It also serves as a center for clinical evaluation, laboratory tests, HIV counseling and testing (HCT), treatment, and care supported by the Federal Government and the Institute of Human Virology, Nigeria (IHVN) in partnership with its global partners, including the Centers for Disease Control and Prevention (CDC) and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The center attends to all patients with HIV infection diagnosed within the hospital or referred from outside the health facility.

### Research design

The study was a double-blind, randomized controlled trial conducted from December 2017 to November 2018. All research participants and research team members, including the principal investigator (PI), were blinded to the allocation of participants to study groups.

### Ethical consideration

The study was reviewed and approved by the ethics committee of Aminu Kano Teaching Hospital (AKTH) Kano State, Nigeria (reference number NHREC/21/08/2008/AKTH/EC/2012), and the Biomedical Research Ethics Committee of the University of Kwazulu-Natal, Durban, South Africa, (reference number BFC294/16). The study was registered in the Pan African Clinical Trial Registry

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**Supplementary information** The online version of this article ([Figures/Tables](#)) contains supplementary material, which is available to authorized users.

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**Corresponding Author:** *Aisha Gambo, Department of Public Health Medicine, School of Nursing and Public Health, College of Health Sciences, University of Kwazulu-Natal, Durban, South Africa, Email: [gamboaishatu@yahoo.com](mailto:gamboaishatu@yahoo.com)*

(identification number PACTR201811722056449).

Participants were informed about the aims of the study, and the study protocol was explained to them. This study was conducted in compliance with the principles enunciated in Helsinki's Declaration. All the study participants provided signed written informed consent or thumbprint if unable to sign. They were also informed of their right to withdraw from the study at any time.

### Participants

Participants were approached to participate in this study as they presented themselves to the clinic for any HIV services offered. The participants comprised of patients diagnosed with HIV infection receiving medical care at the S. S Wali Virology Center at the Aminu Kano Teaching Hospital (AKTH) Kano State, Nigeria.

*Inclusion criteria:* the inclusion criteria were an HIV diagnosis with CD4 counts  $\leq 500$  cells/mm<sup>3</sup>; 18 years or older; commenced ART at least for three months; on Tenofovir + Lamivudine + Efavirenz ART drug combination; male and female, and those who gave consent and complied with the study protocol.

*Exclusion criteria:* participants who had known allergy or intolerance to *Moringa oleifera* Lam. or placebo (cornstarch powder); pregnant women; active opportunistic infection; participants that took micronutrient or natural health product supplements within 30 days of screening and those that lived outside Kano State where the study was conducted were excluded.

### Sample size estimation

The sample size was calculated to be able to detect a medium effect size (Cohen's  $d=0.5$ ) or 0.5 standard deviation in mean weight or CD4 by randomised control trial (RCT) arm with 90% power ( $1-\beta$  [type 2 error probability]), and 95% confidence (or 5%  $\alpha$  error probability [type 1]) assuming a balanced 1:1 study design. A sample size of 172 patients was calculated, which was increased to 200 to give room for attrition.

Out of the 410 participants available for assessment of eligibility, 204 of the participants did not meet the inclusion criteria, 6 participants declined to par-

ticipate, and the remaining 200 participants were randomly assigned to either *Moringa oleifera* Lam. group (MOG) or the Control group (COG) with 100 participants in each group. Only 177 participants completed the study (Figure 1). The sample size was calculated using G\*Power version 3.1.9.2 [20].

### Randomization

Block randomization was used to balance the groups throughout the enrolment period. The randomization sequence was generated using PASS 12.0 software (Wei's Urn algorithm) by an independent person that was not part of the research team. As the recruited participants fulfilled the inclusion criteria and consented, a number was assigned to the patient and were randomly allocated into the MOG and COG groups. All research team members were blinded to the allocation of study participants to the respective study groups.

### Intervention - *Moringa oleifera* Lam. nutritional supplement

The fresh *Moringa oleifera* Lam. leaves were obtained from Prime Global Agricultural Industries Limited, Kano State, Nigeria. The fresh leaves were identified and authenticated by a Botanist at the Department of Biological Science, Bayero University Kano (BUK), Nigeria. Confirmation of the taxonomic identity of the plant was achieved by comparison with voucher specimens kept at the Herbarium of the Department of Biological Sciences BUK. It was processed, manufactured, and packaged at Dala Foods, Nigeria Limited, Kano State, Nigeria.

### Placebo

The placebo was obtained by colouring corn starch powder with chlorophyll [21]. It was also processed, manufactured, and packaged at Dala Foods Nigeria Limited Kano State, Nigeria.

Both the *Moringa oleifera* Lam. leaf powder and the placebo were similar in presentation and were identically packaged to be indistinguishable. The interventions were packaged into small (15 g) sachets each. Thirty (30) individual sachets were further packaged in a bigger green-colored plastic bag to be used as supplements taken together with meals for one month. It was sealed, labelled with the study code, visit no, subject no, and instructions on how

to take it, and stored in a dry place away from heat and humidity.

Patients were randomly assigned and were either given *Moringa oleifera* Lam. or the placebo. They were instructed to divide each sachet three times daily (5 g) and add it to their foods before eating [22,23].

All the above procedure was performed by independent persons not part of the research. All the study participants were advised to maintain their regular diet from inception throughout the study. Additionally, they were also instructed not to consume *Moringa oleifera* Lam. in any form from other external sources throughout the study.

Compliance was monitored to evaluate adherence by self-report during biweekly telephone calls to the participants and monthly hospital visits.

#### **Nutritional contents of *Moringa oleifera* Lam. leaves powder**

The nutritional content of a 100 g *Moringa oleifera* Lam. leaf powder (Nigerian ecotype) was analyzed by a South African National Accreditation System (SANAS) [24] accredited laboratory ASPIRATA Food and Beverage Laboratory [25].

Accordingly, the nutritional content of *Moringa oleifera* Lam. leaf powder used in this study includes; 100 g contained an average of 28 g protein, 3.9 g total fat content (total saturated, monosaturated, and polysaturated fat), and 22 g carbohydrate. It contained 1791.82 mg calcium; 4879.26 mg potassium; 24 mg sodium; 2.88 mg Zinc and 37.78 mg iron.

#### **Data collection**

##### *Socio-demographic information*

At the beginning of the study, a questionnaire to determine each study participant's socio-demographic information was administered by a trained nurse at the virology clinic. This included age, marital status, educational level, occupation, family size, and monthly income.

##### *Anthropometric measurements*

Weight was measured to the nearest 0.1 kg using a digital weighing scale (Tanita HD-372, Tanita Corporation, Tokyo, Japan), with participants wearing light clothing and without shoes. Height was mea-

sured to the nearest centimeter using a stadiometer (Seca 217, Seca GmbH and co. KG., Hamburg, Germany). Body mass index (BMI) was calculated as the weight in kilograms divided by the square of height in meters. The BMI was categorised as underweight (BMI <18.5); normal weight (BMI 18.5-24.9); overweight (BMI 25.0-29.9) and obesity (BMI >30.0) [26]. A trained nurse conducted it at the virology centre at baseline and each monthly hospital visit under the supervision of the PI. Anthropometric measurements from baseline to the sixth month were used.

#### **Study outcomes**

The outcomes assessed were changes in anthropometric parameters (weight and body mass index [BMI]).

#### **Data processing and analysis**

All filled questionnaires were checked for completeness and consistency. The data input was done in Microsoft Excel and exported into SPSS version 26.0 and SAS version 9.4 statistical analysis software for further analysis. Continuous variables were described using the mean, standard deviation, and range, while categorical variables were reported mainly as frequency and percentage. Normality tests for the data were conducted using Kolmogorov-Smirnov and Shapiro-Wilk tests. The data that were not normally distributed were transformed through Box-Cox transformation. The weight was transformed through a lambda value -0.1 and BMI by lambda value -0.2. Repeated measures analysis of variance was deployed to determine significant changes in the mean of anthropometric parameters from baseline to the sixth month within each group. An independent t-test was used to determine the significant mean difference in anthropometric parameters between the two groups at each experiment stage. A linear mixed effect model analysis was deployed to determine the difference in anthropometrics parameters between the treatment groups over time to confirm variability between the two groups further. All statistical tests were performed at a 95% confidence level.

#### **Data Quality Control**

Data were collected by a trained nurse and trained research assistants after undergoing two-day intensive

training to all data collectors and supervisors at the virology clinic. Calibration of anthropometric measuring weight scale was checked at zero before and after each measurement following standard protocol.

## RESULTS

Figure 1 shows the flow chart of the participants' progress in both study groups. Four hundred and ten patients were screened and assessed for eligibility. Two hundred and ten patients were excluded [204 did not meet the inclusion criteria for the study, and six refused to participate]. Two hundred patients were randomized into two groups. One hundred patients were randomly selected and allocated to the group receiving *Moringa oleifera* Lam. (MOG), and 100 patients were randomly allocated to the group receiving the placebo (COG). In the MOG, eight patients were lost to follow-up, and three discontinued taking the intervention. In the COG, nine patients were lost to follow-up, and three discontinued taking the intervention. One hundred and seventy-seven (177) patients with the mean $\pm$ SD age of 41.57 $\pm$ 8.23 years completed the six months study, and their data were included in the analysis (89 in the MOG and 88 in COG) (Figure 1).

### Demographic characteristics of the participants

Table 1 shows the baseline demographic assessments of the 177 participants (89 in the MOG and 88 in the COG). The participants in both groups had similar baseline measures regarding gender, age, marital status, religion, ethnicity, level of education, family size, occupation, and monthly income. The majority of the participants were between 30 to 39 years, with a predominantly female population in both groups [MOG=70 (78.7%); COG=67(76.1%)]. Most of the participants were married [MOG= 42 (47.2%); COG= (38 (43.2%)] with Islam being the predominant religion [MOG= 64 (71.9%); COG= (66 (75%)). More than half of participants belong to Hausa/Fulani ethnicity [MOG= 55 (61.8%); COG= 47 (53.4%)]. A few of the participants in both groups were without any form of education [MOG= 15 (16.9%); COG= 16 (18.2%)] and majority earned a monthly income below the minimum wage of □

30,000 (US \$ 78.23) [MOG= 67 (75.3%); COG= 66 (75%)] (Table 1).

Table 2 shows the baseline anthropometric parameters [weight; BMI] of the study participants in MOG and COG. The means of weight (kg) for both groups were [MOG= 63.8 ( $\pm$ 14.8); COG= 61.9 (12.5)]. The mean BMIs for MOG and COG were 24.84 ( $\pm$ 4.76) and 23.75 ( $\pm$ 3.82), respectively. More than half of the study participants had BMI within the normal range of 18.5- 24.9 in both groups [MOG= (51.7%); COG= (58%)] while a considerable number were overweight with BMI values of 25.0- 29.9 [MOG= (30.3%); COG= (31.8%)] for both study groups (Table 2).

Table 3 shows the comparison of BMI of participants at baseline and sixth month between MOG and COG. At both baseline and sixth month, most of the participants in both study groups had normal weight (BMI = 18.5-24.9). Only a few of the participants were underweight (BMI<18.5) or obese (BMI $\geq$ 30.0). A considerable number were overweight. These differences in BMI categories at both baseline and sixth month were not found to be statistically significant ( $p > 0.05$ ) in both MOG and COG. The descriptive analysis showed that the overall mean ( $\pm$ SD) BMI for MOG at baseline was 24.84 ( $\pm$ 4.78) and 25.16 ( $\pm$ 4.93) at 6th month while that of the COG was 23.75 ( $\pm$ 3.82) and 24.19 ( $\pm$ 4.09) at 6th month (Table 3).

Table 4 shows the result of repeated measures ANOVA to determine changes in anthropometric parameters within each study group. At six months follow-up, the difference in mean weight and BMI observed in the MOG was not statistically significant ( $P > 0.05$ ). However, a statistically significant ( $P < 0.05$ ) increase was observed in both the mean of weight and BMI of participants in the COG at the fifth and sixth months of the study (Table 4). Nonetheless, no significant ( $P > 0.05$ ) difference was observed in both the weight and BMI when compared between the MOG and COG using the independent-sample test from study inception to the 6<sup>th</sup> month (Table 5).

A linear mixed-effect model was used to further assess for variability in anthropometric parameters between the MOG and COG. Table 6 shows the

linear mixed effect model results showing the differences in weight and BMI between the two groups over the study period.

An unstructured correlation matrix was assumed for the model analysis. Estimate of fixed effects between MOG and COG showed that both the weight ( $p=0.5556$ ) and BMI ( $p=0.5145$ ) were not significantly ( $p>0.05$ ) different over the study period.

Figure 2 shows the mean measurements of BMI and weight of study participants in both MOG and COG groups over the study period. The mean BMI and weight of both study groups were relatively constant throughout the study (Figure 2).

## DISCUSSION

This manuscript reports a double-blinded randomized controlled trial conducted to determine the six-month impact of *Moringa oleifera* Lam. leaf powder supplementation on the weight and BMI of adult HIV patients receiving ART care at S. S Wali virology centre, AKTH, Kano State, Nigeria.

Over the study period, the *Moringa oleifera* Lam. leaf powder supplementation intervention did not impact the weight and BMI of the patients compared to the COG. However, a significant increase in weight and BMI was observed within the COG at the fifth and sixth months of study. The lack of significant change in weight and BMI observed in MOG could be attributed to the type of participants included in the study. At study inception, we observed that most of our study participants had a normal BMI. A considerable number were overweight, while only a few were underweight. As inclusion criteria, the study should have recruited underweight participants with BMI  $<18.5$  kg/m<sup>2</sup>. This class of patients would probably have benefitted more in terms of improvement in weight and BMI from the *Moringa oleifera* Lam. leaves supplementation due to the vast amounts of nutrients constituted [27]. This is a limitation of our study. Alternatively, *Moringa oleifera* Lam. has been reported to control weight gain due to its low calorific content; as such, its use is advocated in obese individuals [28]. This factor could have also been attributed to the lack of change in weight and

BMI observed in the MOG.

On the other hand, Tshingani et al. reported an opposite effect of *Moringa oleifera* Lam. leaves. According to their findings, *Moringa oleifera* Lam. increased BMI in patients with physical activity. They reported a significant increase in BMI in patients with physical activity in the third and sixth months of taking *Moringa oleifera* Lam. leaves supplementation [29].

Although *Moringa oleifera* Lam. leaves intervention did not affect the weight and BMI of the participants in this study, previous research done by the same author reported a significant increase in the CD4 cell counts [18] and quality of life domains [19] of the participants in the MOG after six months of *Moringa oleifera* Lam. leaves supplementation.

The introduction of HAART has increased the prevalence of overweight and obesity in PLHIV [7] as seen in our study participants. This may increase the risk of cardiovascular and metabolic diseases [18]. Additionally, Takarinda et al. reported a study conducted to determine the prevalence of malnutrition among HIV – positive patients that are enrolled in HIV treatment in Zimbabwe. The study reported that the majority of their study participants had a normal BMI (63.6%). Also, a high prevalence of overweight and obesity was observed amongst the study participants. The study suggested that HIV may change from a highly fatal infectious disease into a chronic manageable disease due to the high prevalence of obesity observed in the HIV population on ART. This is associated with an increased risk of cardiovascular-related conditions such as hypertension and diabetes mellitus [30]. A similar result was reported in a hospital-based cross-sectional study conducted to assess the nutritional status among people living with HIV in Nepal, where most of the study participants were overweight or obese. The study also highlights the importance of nutritional programs being an integral part of the HIV/AIDS continuum of care [31]. Therefore, to address the burden of malnutrition, the use of *Moringa oleifera* Lam. could be advocated in PLHIV that are taking ART to control weight gain and reduce the risk of cardiovascular and metabolic diseases.

This being a double-blind, randomized placebo trial, a gold standard of intervention studies, gives strength and credence to the findings of this study. Some limitations of the study have been noted. The lack of inclusion of participants that were underweight as well as the sixth month duration of the study and not longer for any significant observable differences. *Moringa oleifera* Lam's distinguishable taste could be a source of bias, including patients who were only on one ART regimen (tenofovir + lamivudine + efavirenz drug regimen) limits the generalizability of our study findings. Lastly, compliance, which was monitored by the self-reporting of the study participants, is a further limitation of the study.

## CONCLUSIONS

This study revealed that *Moringa oleifera* Lam. leaf supplementation did not have impact on the weight and BMI of our study participants at sixth month.

## INFORMATION

**Acknowledgments.** The authors wish to acknowledge all the patients who participated in this study. We wish to acknowledge and convey our sincere appreciation to the management and staff of Dala Foods Nigeria Limited, Kano State, who assisted in producing the interventions. Lastly, we wish to acknowledge Marothi Peter Letsoalo of the Centre for the AIDS Programme of Research in South Africa (CAPRISA) and Tesleem K. Babalola for assisting with the statistical data analysis.

**Trial registration number:**  
PACTR2018117220-56449

**Authors' Contributions.** Aisha Gambo conceived the study. Aisha Gambo and Nceba Gqaleni drafted the manuscript. Both authors reviewed the manuscript for important intellectual content, and read and approved the final manuscript.

**Conflict of Interest Statement.** The authors declare they have no conflict of interest.

**Data Availability.** Data will be made available on reasonable request.

**Funding sources.** This study has been funded by the Department of Science and Innovation of South Africa. (Contract No. DST/CON 0196/2011) and College of Health Sciences, University of Kwazulu-Natal, Durban, South Africa.

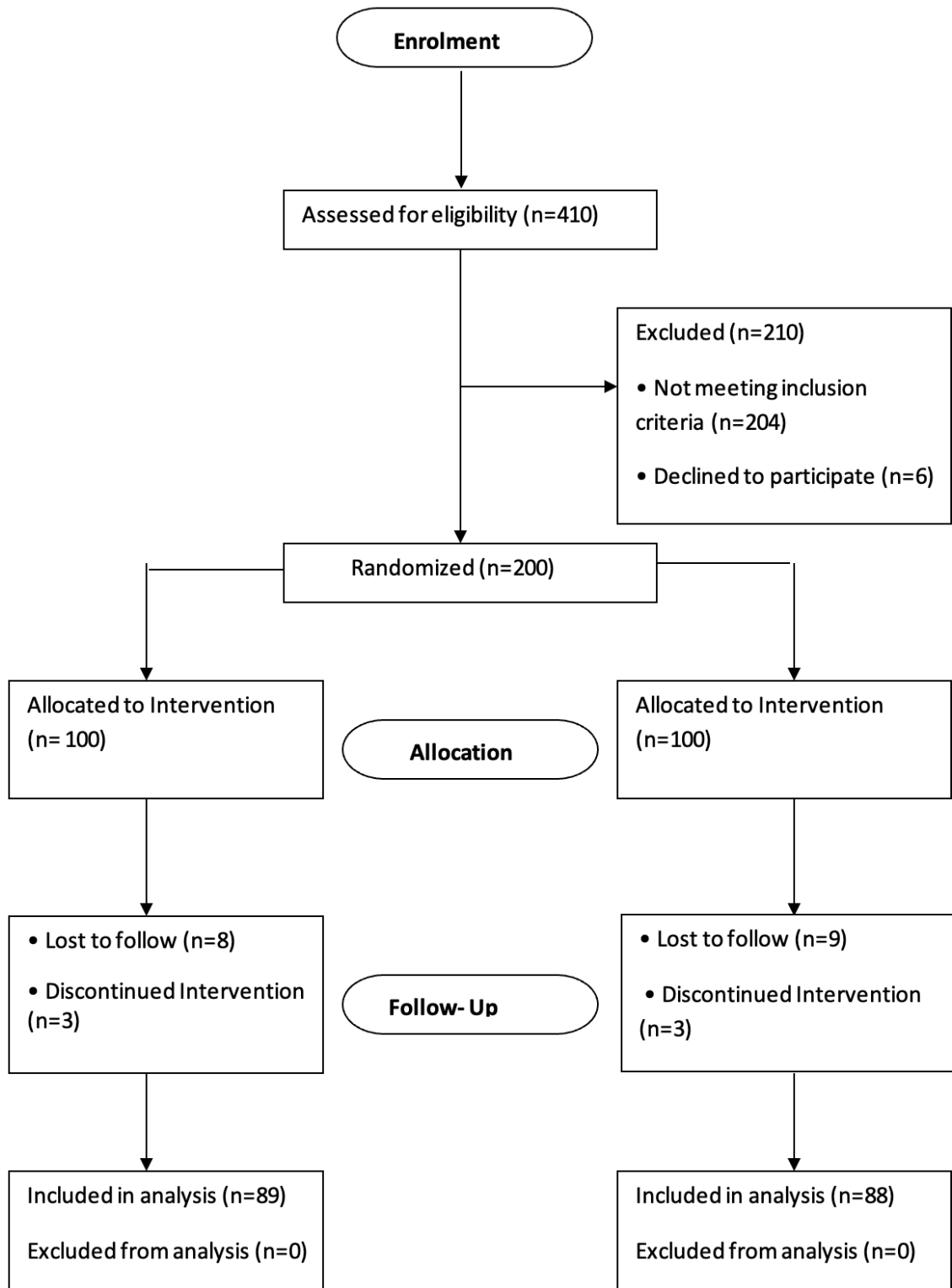


FIGURE 1: Flow chart of participants.



**TABLE 1:** Socio-demographic characteristics of participants.

Variables	MOG (%) (N=89)	COG (%) (N=88)	P-value
<b>Gender</b>			
Males	19 (21.3)	21 (23.9)	0.689
Female	70 (78.7)	67 (76.1)	
<b>Age (years)</b>			
< 20	3 (3.4)	1 (1.1)	0.737
20-29	24 (27.0)	21 (23.9)	
30-39	37 (41.6)	36 (40.9)	
40-49	20 (22.5)	22 (25.0)	
50-60	5 (5.6)	8 (9.1)	
<b>Marital Status</b>			
Married	42 (47.2)	38 (43.2)	0.838
Single	12 (13.5)	10 (11.4)	
Divorced	19 (21.3)	20 (22.7)	
Widowed	16 (18.0)	20 (22.7)	
<b>Religion</b>			
Islam	64 (71.9)	66 (75.0)	0.642
Christianity	25 (28.1)	22 (25.0)	
<b>Ethnicity</b>			
Hausa/Fulani	55 (61.8)	47 (53.4)	0.511
Yoruba	13 (14.6)	15 (17.0)	
Igbo	9 (10.1)	15 (17.0)	
Others	12 (13.5)	11 (12.5)	
<b>Educational Level</b>			
Primary	14 (15.7)	12 (13.6)	0.971
Secondary	27 (30.3)	24 (27.3)	
Tertiary	20 (22.5)	21 (23.9)	
Quranic	13 (14.6)	15 (17.0)	
None	15 (16.9)	16 (18.2)	
<b>Occupation</b>			
Entrepreneur	15 (16.9)	10 (11.4)	0.840
Trader	23 (25.8)	25 (28.4)	
Civil Servant	15 (16.9)	17 (19.3)	
Artisan	19 (21.3)	17 (19.3)	
Unemployed	17 (19.1)	19 (21.6)	
<b>Family Size</b>			
2-5	38 (42.7)	32 (36.4)	0.557
6-10	26 (29.2)	25 (28.4)	
>10	25 (28.1)	31 (35.2)	
<b>Monthly Income (₦)</b>			
Not Indicated	11 (12.4)	6 (6.8)	0.672
< 30,000	67 (75.3)	66 (75.0)	
30,001-60,000	6 (6.7)	10 (11.4)	
60,001-90,000	1 (1.1)	1 (1.1)	
90,001-120,000	3 (3.4)	2 (2.3)	
>120,000	1 (1.1)	3 (3.4)	

Statistical test = Chi-square test.

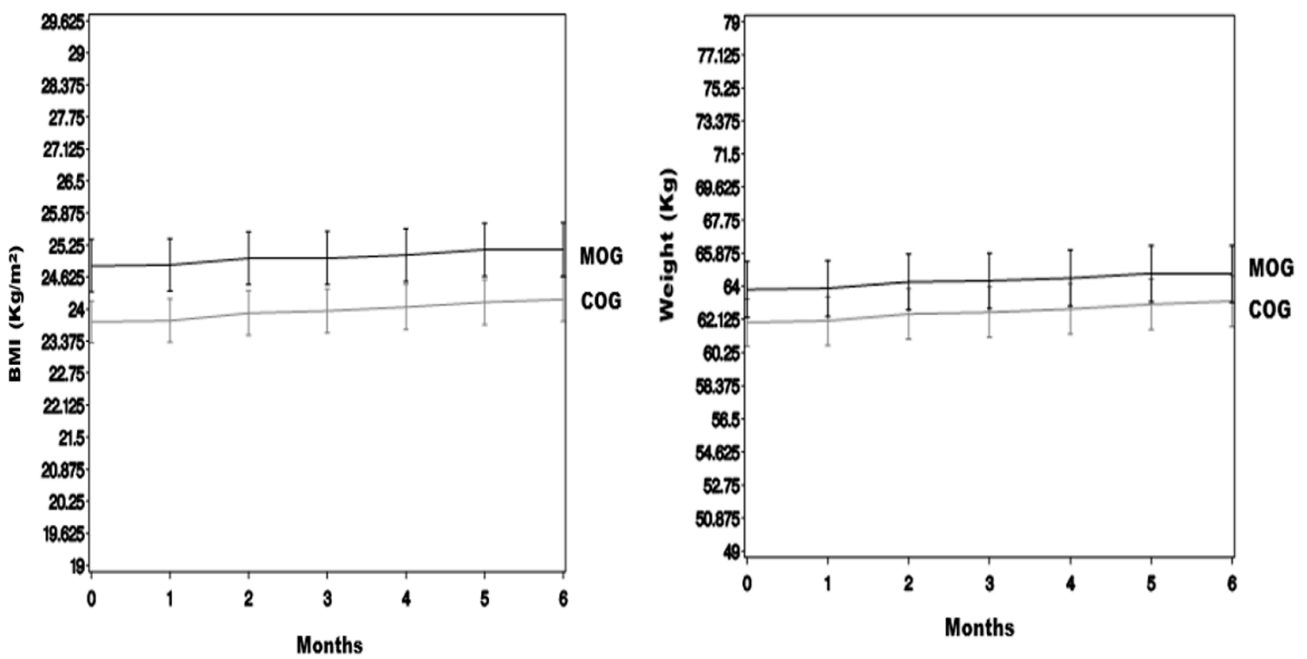


FIGURE 2: Charts showing mean measurements of BMI and weight in MOG and COG over the study period.

**TABLE 2:** Description of baseline anthropometric parameters between MOG and COG.

Parameters	Baseline		p value
	MOG (n = 89) Freq. (%)	COG (n = 88) Freq. (%)	
<b>Anthropometrics</b>			
<b>Weight (Kg)</b>			
Mean ( $\pm$ SD)	63.8 ( $\pm$ 14.8)	61.9 ( $\pm$ 12.5)	0.361
<b>BMI (Kg/m<sup>2</sup>)</b>			
Underweight (<18.5)	5 (5.6)	5 (5.7)	
Normal (18.5 – 24.9)	46 (51.7)	51 (58.0)	
Overweight (25.0 – 29.9)	27 (30.3)	28 (31.8)	
Obese (> 30.0)	11 (12.4)	4 (4.5)	
Mean ( $\pm$ SD)	24.84 ( $\pm$ 4.8)	23.75 ( $\pm$ 3.8)	0.093

Statistical test = independent sample t-test.

**TABLE 3:** Changes in BMI of participants at baseline and 6th month in MOG and COG.

BMI	Baseline			6th month		
	MOG n. (%)	COG n. (%)	P	MOG n. (%)	COG n. (%)	P
Underweight (<18.5)	5 (5.6)	5 (5.7)	0.357	5 (5.6)	7 (8.0)	0.549
Normal Weight (18.5 – 24.9)	46 (51.7)	51 (58.0)	0.781	41 (46.1)	46 (52.3)	0.600
Overweight (25.0 – 29.9)	27 (30.3)	28 (31.8)	0.576	29 (32.6)	27 (30.7)	0.872
Obese (≥ 30.0)	11 (12.4)	4 (4.5)	0.130	14 (15.7)	8 (9.1)	0.248
Mean [±SD] (Kg/m <sup>2</sup> )	24.84 [±4.78]	23.75 [±3.82]		25.16 [±4.93]	24.19 [±4.09]	
Minimum (Kg/m <sup>2</sup> )	16.82	16.03		15.62	16.44	
Maximum (Kg/m <sup>2</sup> )	37.97	34.68		39.84	35.67	

Statistical test = independence sample t-test; SD=standard deviation.

**TABLE 4:** Repeated measures ANOVA analysis of anthropometric parameters within each study group.

			MOG			COG		
			Mean	Std.	P	Mean	Std.	P
			Diff (I-J)	Error		Diff (I-J)	Error	
BMI	Baseline (I)	1st month	-0.018	0.072	0.999	-0.028	0.051	0.999
		2nd month	-0.148	0.097	0.999	-0.179	0.073	0.336
		3rd month	-0.150	0.118	0.999	-0.215	0.089	0.366
		4th month	-0.212	0.128	0.999	-0.293	0.102	0.106
		5th month	-0.313	0.143	0.665	-0.390*	0.106	0.009*
		6th month	-0.317	0.141	0.568	-0.446*	0.113	0.003*
Weight	Baseline (I)	1st month	-0.045	0.181	0.999	-0.091	0.133	0.999
		2nd month	-0.427	0.224	0.999	-0.500	0.193	0.238
		3rd month	-0.483	0.282	0.999	-0.602	0.233	0.238
		4th month	-0.640	0.306	0.827	-0.784	0.267	0.089
		5th month	-0.899	0.342	0.213	-1.045*	0.283	0.008*
		6th month	-0.876	0.343	0.259	-1.216*	0.301	0.002*

\*Statistically significant.

**TABLE 5:** Independent – sample analysis showing the differences in anthropometric parameters between MOG and COG.

Study groups	n	Admission	Mean weight (SD)					
			1 <sup>st</sup> month	2 <sup>nd</sup> month	3 <sup>rd</sup> month	4 <sup>th</sup> month	5 <sup>th</sup> month	6 <sup>th</sup> month
MOG	89	63.83 (14.77)	63.88 (14.89)	64.26 (14.76)	64.31 (14.93)	64.47 (14.93)	64.73 (15.00)	64.71 (15.07)
COG	88	61.94 (12.54)	62.03 (12.92)	62.44 (13.26)	62.55 (13.36)	62.73 (13.37)	62.99 (13.38)	63.16 (13.49)
Diff (CL at 95%)		1.89	1.85	1.82	1.76	1.74	1.74	1.55
p (interaction)	> 0.001							
Study groups	n	Admission	Mean BMI (SD)					
			1 <sup>st</sup> month	2 <sup>nd</sup> month	3 <sup>rd</sup> month	4 <sup>th</sup> month	5 <sup>th</sup> month	6 <sup>th</sup> month
MOG	89	24.84 (4.76)	24.86 (4.84)	24.99 (4.82)	24.99 (4.88)	25.06 (4.87)	25.16 (4.93)	25.16 (4.93)
COG	88	23.75 (3.82)	23.78 (3.93)	23.92 (4.02)	23.96 (4.04)	24.04 (4.10)	24.14 (4.08)	24.19 (4.09)
Diff (CL at 95%)		1.09	1.08	1.07	1.03	1.02	1.02	0.97
p (interaction)	> 0.001							

**TABLE 6:** Linear mixed effects model showing the differences in anthropometric parameters between MOG and COG over the study period.

		Estimates of Fixed Effects				95% CI	
	Parameter	Estimate	Std. error	t	Sig.	Lower Bound	Upper Bound
<b>Weight</b>	Intercept	61.92	1.47	42.02	0.0001	61.43	63.65
	MOG	-0.05	0.08	-0.59	0.5556	-0.20	-0.11
	COG	0	0	-	-	-	-
<b>BMI</b>	Intercept	23.73	0.47	50.98	0.0001	23.61	24.32
	MOG	-0.02	0.03	-0.65	0.5145	-0.08	-0.04
	COG	0	0	-	-	-	-

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**How to cite this article:** Gambo A., Gqaleni N. **Does *Moringa oleifera* Lam. leaves supplementation have an impact on the weight and bone mass index of people living with HIV that are on antiretroviral therapy? A double-blind randomized control trial.** *Journal of Public Health in Africa*. 2022;13:2126. <https://doi.org/10.4081/jphia.2022.2126>