Implementation and Impact of a Nutrition Assessment, Counseling and Support program on People Living with HIV in Accra, Ghana

A thesis presented to the faculty of the

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In partial fulfillment of the requirements of the degree of Doctor of Philosophy

Tufts University

December 2016

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ACKNOWLEDGEMENTS

First of all, I will like to thank Dr. Christine Wanke for her support not only to me but to my entire family before we left Ghana for Tufts and through our stay here.

I am thankful and appreciative of the guidance and support offered me by Drs. Fang Fang Zhang and Beatrice Rogers during this dissertation process. Your diverse expertise meant I learnt a lot of different things from each of you throughout this process.

Words cannot describe my appreciation to the faculty, staff, students and infectious disease fellows of the Nutrition and Infection Unit of the Department of Community Health and Medicine who became my American family and have been supportive through my stay.

Last but not the least, thank you Marjorie my wife for being there throughout this journey and Nuna for providing a different perspective on life.

ABSTRACT

Nutrition plays an important role in the management of HIV but has not been a routine and widely accessible part of HIV care in Ghana. To address nutrition-related issues in HIV care and management, U.S. Agency for International Development (USAID) collaborated with various National Health Authorities to introduce the Nutrition Assessment, Counseling and Support (NACS) framework into Ghana and other countries mostly in Sub-Saharan Africa to provide nutrition services and "improve the nutritional status of individuals and populations living with HIV (PLWH) and Tuberculosis". Since the introduction of NACS as part of Ghana's HIV control program, evaluation of its implementation and impact on health outcomes has not been carried out, and that is what this thesis sought to do.

The main objective of this thesis was to assess whether NACS was being implemented as planned and whether it led to a change in nutritional status as measured by body mass index (BMI), depression, and health related quality of life (HRQol) among PLWH in Accra, Ghana. Our first specific aim was to evaluate the implementation of NACS and whether the degree of implementation was associated with BMI among PLWH. Our second aim was to assess the impact of receiving care at a NACS HIV clinic on changes in BMI in a cohort of PLWH six months after enrollment into this study. Our final aim was to assess the impact of receiving care at a NACS designated HIV clinic on changes in depression symptoms and HRQol in that same cohort of PLWH.

To achieve Specific Aim 1, we conducted a cross-sectional study assessing indicators of NACS implementation in six HIV clinics (three NACS designated and three non-NACS). We collected HIV clinic level information and directly observed five counseling sessions

in each HIV clinic to ascertain the presence and content of nutrition counseling and provision of food support. To answer Specific Aims 2 and 3, we recruited 152 adult PLWH from the six HIV clinics (25 per clinic) and followed them prospectively for six months with data collected at baseline, three and six months after recruitment. At each study visit we administered a questionnaire collecting information on demographics, depression symptoms, and HRQol, and also measured subjects' weight and height.

For the first specific aim, we found poor implementation of NACS in the NACS designated HIV clinics; no nutrition assessments other than calculated BMI (in two NACS designated HIV clinics), no nutrition counseling being performed, and no food support available on site. In addition, a greater score on the NACS implementation scale was not associated with subjects' BMI. A fifth (20.5%) of all participants were obese; 26.5% were overweight; and only 3.3% were underweight.

For the second aim, we found that receiving care in a NACS designated HIV clinic did not predict change in BMI three or six months after enrollment into this study. Further, NACS implementation score was not associated with changes in BMI, irrespective of whether the hospital was designated as NACS or non-NACS.

For the third aim, we found that there was no significant difference in depression symptoms and HRQol between subjects receiving care in a NACS designated HIV clinic and those receiving care in a non-NACS clinic at three months after enrollment. However, between the three and six months follow-up, receiving care in a NACS designated HIV clinic was significantly associated with a reduction in depression symptoms and an increase in HRQol scores.

In summary, our results indicate that the NACS program components, including nutrition assessments, nutrition counseling, and food support, were not being implemented appropriately in NACS designated HIV clinics in Accra, Ghana. Although receiving care in NACS designated HIV clinics was not associated with changes in BMI, the lack of effect might be largely due to the poor implementation of the NACS program in these clinics. Receiving care in a NACS designated HIV clinic was associated with reduced depression symptoms and improved HRQol between three and six months of the follow-up. Such an impact is unlikely to be attributable to NACS implementation. Future studies are needed to further investigate factors hindering the implementation of NACS in Ghana and subsequently evaluate whether NACS represents a simple, cost-effective method to improve the nutritional status of PLWH living in Ghana. The high proportion of PLWH being overweight or obese also calls for future NACS programs to incorporate nutrition counseling or support that can reduce obesity risk in PLWH.

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LIST OF ABBREVIATIONS

AIDS;	Acquired Immune Deficiency Syndrome
AMPATH;	Academic Model Providing Access to Healthcare
ART;	Antiretroviral Therapy
ASSIST;	Applying Science to Strengthen and Improve Systems
BMI;	Body Mass Index
CAPI;	Computer-Assisted Personal Interview
CES-D;	Center for Epidemiologic Studies Depression Scale
CS;	Compound Symmetry
DRC;	Democratic Republic of the Congo
EQ-5D;	EuroQol Five Dimensions Questionnaire
EQ-VAS;	EuroQol Five Dimensions Questionnaire Visual Analogue Scale
FANTA;	Food and Nutrition Technical Assistance
FBP;	Food by Prescription
GHS;	Ghana Health Service
GHSERC;	Ghana Health Service Ethical Review Committee
HAART;	Highly Active Antiretroviral Therapy
HFIAS;	Household Food Insecurity Access Scale
HIV;	Human Immunodeficiency Virus
HRQol;	Health-Related Quality of Life
IQR;	Interquartile Range
IRB;	Institutional Review Board
I-TECH;	International Training & Education Center for Health
LIFE;	Leadership and Investment in Fighting an Epidemic
LIFT;	Livelihoods and Food Security Technical Assistance
LMIC;	Low-and Middle-Income Countries
MCHIP;	Maternal and Child Health Integrated Program
MOHSS;	Ministry of Health and Social Services
MUAC;	Mid Upper Arm Circumference
NACS;	Nutrition Assessment, Counseling and Support
NCST;	Nutrition Care, Support and Treatment
NHP;	Nutrition and HIV Program
PEPFAR;	US President’s Emergency Plan for AIDS Relief
PLWH;	People Living with HIV
RUSF;	Ready-to-Use Supplementary Food
RUTF;	Ready-to-Use Therapeutic Food
SPRING;	Strengthening Partnerships, Results, and Innovations in Nutrition Globally
SW;	Southwest
TB;	Tuberculosis
UNICEF;	United Nations Children's Fund
USAID;	U.S. Agency for International Development
WFP;	World Food Programme

CHAPTER 1: INTRODUCTION

Background

Of the 36.7 million people living with HIV (PLWH) worldwide, about 69% are living in Sub-Saharan Africa, and Ghana has about 260,000 adults and 19,000 children living with HIV [1, 2]. Ever since Highly Active Antiretroviral Therapy (HAART) was introduced, persons living with HIV (PLWH) are living longer [3, 4]. In spite of this, nutritional alterations in patients with HIV are common, with both undernutrition and over-nutrition present in HIV populations [5]. Rates of overweight and obesity among PLWH are approaching those of the non-HIV population [6]. This trend may be due to in part to the increased access and potency of antiretroviral therapy (ART) which has improved morbidity and mortality among PLWH [7]. In addition, early diagnosis programs mean PLWH are being diagnosed when they are visibly healthy, and the obesity present may reflect the general global obesity trend in the non-HIV population [6] and not HIV. Nutrition plays an important role in the management of HIV but hasn't been a routine and widely accessible part of management of HIV in Ghana [8, 9]. It has been shown that a well-nourished PLWH is more likely to maintain a stronger immune system to cope with HIV [10], and to achieve a better quality of life [11].

The nutrition assessment, counseling and support (NACS) framework and program were introduced to address various nutrition related issues in HIV care and management. NACS began as the Food by Prescription (FBP) program in 2006 in Kenya with the objective of preventing and addressing under-nutrition among PLWH [7, 12]. The name was later changed to NACS to reduce the emphasis on food distribution and to rather focus on

a more holistic range of interventions including nutrition assessment and nutrition counseling which together with food support will "identify, prevent and treat malnutrition" [7].

The main aim of NACS is to "improve the nutritional status of individuals and populations (with HIV/AIDS and Tuberculosis) by integrating nutrition into policies, programs, and the health service delivery infrastructure" [13].

Since its introduction, NACS has been implemented by about a dozen countries including Ghana, with assistance from the US President's Emergency Plan for AIDS Relief (PEPFAR) [7]. NACS was introduced into Ghana in October 2009 by the U.S. Agency for International Development (USAID) through the Food and Nutrition Technical Assistance (FANTA) Project and is now supposed to be offered in 42% of the health facilities that provide antiretroviral therapy (ART) services across the country [13, 14].

Rationale

Among PLWH, having a low BMI before ART starts is associated with HIV progression and death[7, 15]. At the same time, overweight and obesity among PLWH increase their risk of developing chronic diseases such as hypertension and type 2 diabetes [16]. ART has greatly improved health, survival and longevity among PLWH but has not eliminated the depression and quality of life issues they go through. PLWH suffer from depression more commonly than other populations, and this depression can lead to poor adherence in taking their ART medications [11, 17, 18]. A lower quality of life has been shown to be associated with a higher viral load among PLWH.

NACS when properly implemented (every PLWH receiving nutrition assessment and nutrition counseling based on that assessment and where necessary food support) could potentially improve these health outcomes, but ever since it was introduced into Ghana, its implementation and impact on these health outcomes – BMI, depression, and health-related quality of life (HRQol) - among PLWH has not been assessed.

Main objective

To assess whether NACS was being implemented as planned and whether it led to a change in nutritional status as measured by body mass index (BMI), depression, and health related quality of life (HRQol) among PLWH in Accra, Ghana

Main hypothesis

It was hypothesized that receiving care in a NACS designated HIV clinic will be associated with a greater change in BMI, lower depression scores, and higher HRQol scores. To achieve this overall objective, there were three specific aims.

Specific aims

Specific Aim 1: To evaluate the implementation of NACS and its association with BMI of PLWH in six HIV clinics in Accra, Ghana. The hypothesis was that HIV clinics designated to implement and provide NACS services will score higher on a NACS implementation scale, and better implementation will be associated with a lower odds of being overweight or obese (BMI>24.9 kg/m^2). A cross-sectional study design was used comparing indicators of NACS implementation in six HIV clinics (three NACS designated and three comparable non-NACS).

Specific Aim 2: To evaluate the impact of receiving care in a NACS designated HIV clinic on change in BMI of a cohort of PLWH six months after enrollment into this study. It was hypothesized that receiving care in a NACS designated HIV clinic will be associated with a greater change in BMI. One hundred and fifty two PLWH were recruited from six HIV clinics (used in specific aim 1) and prospectively followed for six months, with study measurements at baseline, three, and six months after recruitment.

Specific Aim 3: To assess the impact of receiving care in a NACS designated HIV clinic on change in depression symptoms and HRQol of a cohort of PLWH six months after enrollment into this study. It was hypothesized that receiving care in a NACS designated HIV clinic will be associated with lower depression symptom scores and higher HRQol scores over time. Depression and HRQol scores were measured among the study population recruited for specific aims 1&2 prospectively for six months with measurements at baseline, three and six months after recruitment.

Significance

The results of this study will provide valuable information to the Ministry of Health and Ghana Health Service on the state of implementation of the NACS program in some HIV clinics. It will provide them data on which components of the NACS program could be improved in order to observe an impact on various health outcomes among PLWH especially in the Greater Accra Region where this study took place. It will also describe the nutritional status (over and under-nutrition), depression symptoms and HRQol in an HIV population and how these change over time, and this can guide future interventions among this population.

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CHAPTER 2: REVIEW OF THE LITERATURE

The introduction of HAART in the late 1980's marked the beginning of HIV's transition from being a 'killer' disease to a chronic disease with lower mortality and increased length of life [1-3]. Access to ARTs in low- and middle-income countries (LMIC) in the last decade or two has been and is still increasing [4]. Despite these advances to health, both over-and- undernutrition continue to be present and affect health outcomes among PLWH, especially in resource limited settings [5-8]. Within Sub-Saharan Africa, one approach to help PLWH meet their nutritional needs is food-based supplementation or food by prescription (FBP) programs [7, 9].

Food by prescription programs

A pioneer program offering food assistance and support for PLWH was the Leadership and Investment in Fighting an Epidemic (LIFE) initiative which was launched in July 1999 by the Bill Clinton administration to help combat the AIDS pandemic. The LIFE initiative was targeted to PLWH in sub-Saharan Africa and India and among other goals sought to increase the proportion of households of PLWH with increased access to food. The LIFE initiative supported USAID to assist beneficiary countries using programs such as Food for Peace Title II [10].

Another program for PLWH with a strong food and nutrition component is the Academic Model Providing Access to Healthcare (AMPATH) formerly known as the Academic Model for the Prevention and Treatment of HIV/AIDS [11]. This is a partnership between the Moi Teaching and Referral Hospital, the Moi University School of Medicine and some medical schools in the United States led by the Indiana University School of

Medicine to tackle HIV in the west of Kenya, which began in 2001 [11, 12]. AMPATH, which serves about 50,000 PLWH, recognized the impact hunger had on retention of PLWH in care and made the decision to provide food support for six months for entire households of PLWH classified food insecure by a nutritionist [11]. An innovative approach of the AMPATH nutrition program is to incorporate food production, where they manage some irrigated farms and teach beneficiary PLWH how to increase their own food production [11].

The Ethiopian Ministry of Health, USAID, and Save the Children US collaborated to implement a FBP program for PLWH in 2010 [5]. This intervention provided Ready-to-Use Supplementary Food (RUSF) and Ready-to-Use Therapeutic Food (RUTF) assistance together with nutrition assessment and counseling to undernourished PLWH [5, 13]. This FBP program ended in 2014, and a final evaluation found that though it exceeded its targets of food supply, without resources being put into continuous training, the NACS component of the program, nutrition assessment and counseling, would be difficult to maintain [13]. A cross-sectional review of the adherence to RUTF was conducted in 34 health facilities in Addis Ababa, Ethiopia in 2013, with 630 adult PLWH [14]. This review found low adherence (36.3%) to RUTF, and some of the main factors contributing to this were poor education and knowledge of RUTF's benefits and how long it should be consumed for it to have benefits [14]. They recommended better counseling of PLWH before initiating RUTF in order to improve adherence.

Another food distribution program in Sub-Saharan Africa was the Kenya FBP which began in 2006. This FBP was launched in line with Kenya's "National HIV/AIDS Strategic Plan and the National Health Sector Strategic Plan (2005-2010)" with support

from PEPFAR, with the aim of treating moderate and severe undernutrition [7, 15]. This program provided fortified blended flour to eligible PLWH and exited them when they attained a set improvement in nutritional status [7, 15]. This FBP program was later replaced by the Nutrition and HIV Program (NHP) which took the FBP to scale across the country [16]. A 2009 review of the FBP program revealed that though nutrition assessment and counseling was supposed to be an integral part of the intervention, it faced challenges such as inadequate space to offer counseling [15]. Another review of the NHP found that despite Kenya producing a surplus of trained nutritionists, there was a shortfall of nutritionists employed in health facilities due to budgetary constraints [16]. This Kenya FBP was adopted by other countries supported by PEPFAR, and to promote nutritional assessment and counseling's equal importance to preventing and managing malnutrition, PEPFAR sometime in 2009 began to use NACS instead of FBP [7].

NACS programs in Africa

NACS is made up of three components. Comprehensive nutritional assessment is the first component of the program, whereby nutritional assessment is to be provided to all PLWH patients [17]. Nutrition assessment should involve anthropometric measures, biochemical measures, dietary assessments and food security assessments [17]. The nutritional counseling aspect of NACS then utilizes the information obtained from the nutritional assessment to develop a feasible plan to improve nutritional status of the clients[17]. The last component in NACS is to provide nutritional support that includes the provision of therapeutic foods and micronutrient supplements to treat or prevent certain nutritional conditions identified during the nutritional assessment and counselling components[17].

Namibia, which had a high level of stunting and one of the highest adult HIV prevalence rates worldwide, began the implementation of NACS in 2010. This was implemented under the leadership of the Ministry of Health and Social Services (MOHSS) with assistance from the FANTA III project, the International Training & Education Center for Health (I-TECH), UNICEF/Namibia, and the World Food Programme (WFP) [18]. Within a year or two of the initiation of NACS, 32 of the country's 34 health districts were implementing NACS [18].

A review of NACS in Namibia conducted using qualitative and quantitative data collection tools in a cross-sectional design found that in spite of the wide coverage of NACS, no facility surveyed had all the items needed for proper implementation of the program [18]. Training shortfalls and lack of close supervision also affected the implementation of NACS. The review found that most NACS facilities only conducted nutrition assessment of PLWH who visibly looked undernourished due to the high patient to staff ratio [18]. Though most NACS facilities recorded anthropometric measurements in patient records, only 50% of them explained the results of those nutrition assessments to clients during counseling [18]. Only one third of NACS facilities surveyed during this evaluation provided nutrition counseling to all clients, and barriers to this were lack of counseling materials and time [18].

Uganda has an adult HIV prevalence of 7.1% and is at the same time among the top 20 countries with a high burden of undernutrition [19, 20]. In response to the nutrition related issues in the country and among PLWH, a USAID funded Strengthening Partnerships, Results, and Innovations in Nutrition Globally Project in Uganda (SPRING/Uganda) was initiated in 2011. SPRING/Uganda used the NACS framework to achieve its nutrition

goals in the southwest (SW) region of Uganda [19]. Two reviews of NACS in SW Uganda carried out in 2013 and 2014 found an improvement in the integration of nutrition assessment over the two review periods and the wide availability of equipment such as weighing scales and mid upper arm circumference (MUAC) tapes in health facilities surveyed [19, 21]. The 2014 review found that weighing scales were not being calibrated routinely, making accuracy of nutrition assessments a problem [21].

The reviews showed an improvement in individual nutrition counseling across facilities [21]. Understaffing, training and retraining challenges, and infrastructure were identified as barriers to optimal implementation of NACS [19]. It was recommended that mentorship and training in NACS should target nursing assistants, nurses and midwives who dominated the health workforce and had the most contact with patients, in order to ensure better integration of NACS in the healthcare system [21]. As in the Kenya review, the impact of NACS on health outcomes was not evaluated.

Malawi, which has an adult HIV prevalence of 9.1%, established the Nutrition Care, Support and Treatment (NCST) program (their version of NACS) in 2005 to help tackle the negative effect of undernutrition on HIV [22]. The NCST over the years faced implementation and effectiveness problems due to lack of data to budget and project the need for RUTF food support. The lack of RUTF in NCST facilities led to health workers stopping nutritional assessment of PLWH [22].

To help address this issue, USAID's FANTA projects, Applying Science to Strengthen and Improve Systems (ASSIST) and Livelihoods and Food Security Technical Assistance (LIFT) began to support the Malawi health authorities in 2013 to improve nutrition care

for PLWH and in so doing generate data and good practices that could be used to empower the national NCST program [22]. Based on this assistance, data has been generated to allow the inclusion of nutrition assessment indicators into the Malawi Health Management Information System [22].

The Democratic Republic of the Congo (DRC) has an HIV prevalence of 1.3%, with about 41% of the population being chronically undernourished as a result of years of conflict [23]. To help address nutrition issues among PLWH and the general population, FANTA together with the Livelihoods and Food Security Technical Assistance II (LIFT) program and ASSIST collaborated with the DRC Ministry of Health to use NACS as a vehicle of integrating nutrition into HIV management [24]. This intervention started in 2014 in some health facilities in Kinshasa and Lubumbashi to serve as "learning sites," and has the three USAID projects working on various aspects of the program [24].

Since the initiation of this NACS project, some successes include the increase in nutrition assessment from 0% to 96% in 2015 [24]. Of the PLWH who received nutrition assessment services, those offered nutrition counseling increased from 0-96% [24]. The program was able to refer PLWH who received NACS services to local savings and loans association for loans which they could use to start businesses to improve their livelihoods. It was able to refer its clients to organizations such as the World Food Programme (WFP) offering food support including corn soy blend and legumes [24]. Currently, plans to expand NACS services to other parts of the country are being explored in light of the increasing peace and stability [24].

Zambia has an adult HIV prevalence of 13% and in 2013 started a pilot NACS program in eight sites in the Kitwe District with the assistance of the USAID ASSIST Project, FANTA III and LIFT II [25, 26]. We couldn't identify a formal review, but a progress report after three months of NACS implementation found among others that not all PLWH in NACS clinics were offered nutrition assessment services [25]. These and more problems were addressed by quality improvement teams which came up with various interventions to address those challenges. Through this iterative process of refining the intervention, improvements were observed, and the proportion of NACS PLWH clients who received nutritional assessment for example rose from almost 30% in August 2014 to about 80% in September 2015 [25]. As a next step, NACS services have been scaled up and expanded into another district in Zambia in August 2015 [25, 26]. In addition, the process to embed nutrition indicators into the medical records and health data system of the country is planned to be initiated soon [26].

A common theme of the various evaluations reviewed here is that the impact of NACS on clinical health outcomes was not assessed. This could be due to the cost and logistical challenge of conducting a formal research study. It could also be due to difficulty in implementing NACS in its entirety, especially the nutrition counseling aspect.

NACS in Ghana

As of 2015, Ghana had an adult HIV prevalence rate of 1.6%, with about 19,000 children living with HIV [27]. The prevalence of HIV among female sex workers and men who have sex with men is far higher than the general population (11% and 17% respectively) [28]. The incidence of HIV in the general population has been decreasing since 1996, but

limited resources to increase coverage and availability of ART's, together with high stigma and discrimination, are barriers to the control of the epidemic [28, 29].

To improve the nutritional status of PLWH and tuberculosis in Ghana, USAID through FANTA assisted the Ghana Health Service (GHS) in 2009 to introduce and integrate NACS into the health delivery system [30]. This was done through training of health workers, development of manuals, and the establishment of a NACS technical working group made up of government and non-governmental agencies involved in the management of HIV and TB [30]. NACS was integrated into routine HIV and TB services and the strategic plans for both diseases [30]. As of 2013, 83 health facilities in 77 districts throughout the country that offer ART services were also offering NACS services, and 18,688 PLWH had received nutritional assessment and counseling [30]. Nurses and midwives are the most abundant group of health workers and spend the most time with PLWH, and FANTA, together with the Maternal and Child Health Integrated Program (MCHIP), has been able to include NACS in the curriculum of nurses and midwives [30].

In an evaluation study to assess NACS's impact on nutrition knowledge among PLWH in Ghana, NACS clients and HIV clinic staff were interviewed. In addition, nutrition counseling sessions were observed and the equipment readiness of NACS designated HIV clinics assessed [31]. A cross-sectional design using eight conveniently selected ART sites over six regions was utilized in this study.

This evaluation found that no routine individual nutrition counseling was offered at any of the study sites except when a PLWH appeared visibly wasted [31]. For such PLWH, direct observation of the counseling sessions found that it was of good quality, providing

adequate nutrition advice. Group counseling sessions, which took place whilst the PLWH awaited their turn to see the nurse or doctor, focused mainly on ART adherence with only an occasional mention of nutrition [31]. In terms of nutritional knowledge, this study found that whilst 89% of PLWH sampled knew enough to eat three meals a day, about 81% of them did not know how to increase their energy intake. Almost all study sites were not well equipped to provide NACS services [31].

Impact of NACS interventions on various health outcomes

Although there are few studies that have assessed all three components of NACS on health outcomes, most have evaluated the impact of the food support or distribution component of NACS on health outcomes [7]. The health outcomes focused on are BMI, HRQol, food insecurity, dietary diversity, morbidity, mortality and retention in care.

Food Insecurity and Dietary Diversity

Food insecurity and HIV have a bi-directional relationship, with food insecurity increasing a person's vulnerability to risky practices that can lead to HIV, and HIV and its stigma also contributing to food insecurity [32]. Three studies which examined the impact of food assistance on food security found a positive relationship [33-35]. A systematic difference in baseline food security status between participants receiving food assistance and the 'controls' was a limiting factor in one of the three studies [34]. In one of these three studies where food assistance was provided to PLWH for 12 months, no impact on dietary diversity was found [35].

HIV specific outcomes

Tang et al., 2015 in their review identified seven studies with a NACS intervention and mortality as an outcome and concluded that NACS had an uncertain impact on mortality [7]. Using change in $CD4^+$ cell count as a proxy for morbidity, they found 12 NACS intervention studies utilizing various study designs and came to the conclusion that NACS would have an uncertain impact on morbidity [7]. The authors also identified five other studies with other morbidity outcomes such as hemoglobin, severe clinical events, and HIV related outcomes and came to the same conclusion regarding the impact of a NACS roll out on them [7].

Tang et al., 2015 in their review found seven NACS intervention studies with retention in care as an outcome and came to the conclusion that NACS rollout would have an uncertain impact on adherence to ART, which was a proxy outcome for retention in care [7].

BMI

Various studies have shown that provision of food support in the form of food rations (such as beans, cereal and oil or RUTF) was associated with an improvement in BMI when the recipients were underweight at baseline (BMI < 18.5 kg/m^2) [16, 33, 35-43]. A majority of these studies had a single arm where before-and-after analysis was done on the impact of food assistance on BMI [33, 35, 37-39, 42]. The rest compared the impact of one type of food assistance to another [36, 40, 41]. Two studies where PLWH had a BMI >18.5 kg/m^2 at baseline did not observe a significant increase in BMI with the provision of food support [44, 45]. These two studies concluded that it was possible recipients of these food rations were sharing within their families and this could affect the amounts they consume.

In addition, it may have been difficult to see a significant improvement of BMI among a group not severely malnourished when the intervention was for a short duration.

Quality of Life

A recently published systematic review on the effect of NACS interventions on various outcomes found 7 studies which looked at the food support aspect of NACS and its effect on quality of life measures [7]. The authors concluded that NACS interventions "will have an uncertain impact in quality of life" measures [7] and called for more well designed studies evaluating this outcome. This conclusion was due to several factors among which was the variability in study designs (2 single arm studies, 2 randomized controlled trials and 2 cohort studies). In addition, quality of life was assessed differently across the studies, and divergent outcomes were obtained.

Conclusion

This review found that there was a serious lack of peer-reviewed publications on the implementation and impact of FBP and NACS programs available. The majority of the publications available were country reports prepared for the funders of these interventions rather than peer-reviewed publications, and they focused on meeting program targets rather than measuring the impact of the interventions on health outcomes.

There are also very few studies available that examined the impact of all three components of NACS on health outcomes, and this could be because NACS in its entirety was not being implemented well or implementation was not a research and evaluation focus. In spite of the pivot from FBP to NACS to enhance the nutrition

assessment and nutrition counseling components of the program, most studies reviewed focused on the food support aspect. For this review, we only found one unpublished study which evaluated the implementation of NACS. A lack of focus on the implementation of NACS as a whole could also contribute to the inconsistency of results obtained.

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CHAPTER 3: IMPLEMENTATION OF THE NUTRITION ASSESSMENT, COUNSELING AND SUPPORT PROGRAM IS NOT ASSOCIATED WITH BODY MASS INDEX AMONG PEOPLE LIVING WITH HIV IN ACCRA, GHANA

Abstract

Objective: To evaluate the level of implementation of NACS in six HIV clinics in Accra, Ghana, and to assess whether the level of implementation of NACS is associated with the BMI of PLWH.

Design: A cross-sectional analysis of baseline data from a prospective cohort study.

Setting: The HIV clinics of six hospitals (3 NACS designated and 3 non-NACS) in the Greater Accra Region of Ghana.

Subjects: 152 PLWH between 18 and 65 years; and at least 6 months on ART. PLWH were excluded if they were pregnant, breastfeeding, or unable to stand upright to have their weight and height measured.

Results: On a NACS implementation scale ranging from 0-8, with a higher score indicating better NACS implementation, NACS implementation was not different between designated NACS and non-NACS HIV clinics (5 vs 4, p=0.14). A higher NACS implementation score was not significantly associated with an overweight or obese BMI (BMI >24.9 kg/m^2) after adjusting for age, monthly income, time since HIV diagnosis and sex.

Conclusion: There was poor implementation of NACS at baseline in the NACS designated HIV clinics surveyed, and neither being a NACS designated HIV clinic nor having a better score on the NACS implementation scale was associated with an overweight or obese BMI among the study population.

Keywords: HIV; NACS; Ghana; BMI; Implementation; Nutrition; Counseling

Introduction

Among other factors, advances in treatment have led to a growing population living with HIV (PLWH) worldwide, now estimated to be 36.9 million at the end of 2014[1]. Approximately 260,000 adults and 19,000 children are living with HIV/AIDS in Ghana [2]. Nutrition plays an important role in the management of HIV but hasn't been a routine and widely accessible part of management of HIV in Ghana [3, 4]. Under-nutrition as indicated by low BMI at ART initiation has been shown to be positively related to progression of HIV and death [5, 6]. Among PLWH with low BMIs, weight gained after initiating ART has been associated with better survival [7]. A person with a better nutritional status is more likely to have and maintain a stronger immune system to cope with HIV [8].

To address nutrition-related issues in HIV care and management, USAID through FANTA developed the nutrition assessment, counseling and support (NACS) approach to provide nutrition services to PLWH [9]. NACS began as the FBP program in 2006 in Kenya. The name was later changed to NACS to reduce the emphasis on food products and to rather focus on a wider range of interventions including nutrition assessment and counseling, which together with food support will "identify, prevent, and treat malnutrition" [6].

The main aim of NACS is to "improve the nutritional status of individuals and populations living with (HIV/AIDS and tuberculosis)" [9]. NACS works by "integrating nutrition into policies, programs, and the health service delivery infrastructure" [9]. NACS is made up of three components. Comprehensive nutritional assessment is the first component of the program, where basic nutritional assessment is provided to all PLWH [9]. Nutrition assessment should involve anthropometric measures, biochemical measures, dietary assessments and food security assessments [9]. The nutritional counseling aspect of NACS then follows. Counseling utilizes the information obtained from the nutrition assessment to develop a feasible plan to improve nutritional status for the clients[9]. With the rising trend of increasing overweight and obesity among PLWH [10], nutrition counseling should seek out not only underweight PLWH but also those overweight and obese and guide them to achieve a healthy weight. This trend could be partly due to more effective ART medications leading to less HIV associated wasting [11-13] and the global nutrition transition to cheaper more calorically dense foods. The third component in NACS is to provide therapeutic foods and micronutrient supplements to those found to be either moderately or severely undernourished during the nutrition assessment and counseling phases of NACS [9]. NACS has been implemented by a dozen countries, (mostly in Africa and supported by the US President's Emergency Plan for AIDS Relief (PEPFAR)) [6]. In Ghana, NACS was introduced in October 2009 and is now offered in 83 health facilities that provide ART services across the country [14].

Since the introduction of NACS as part of Ghana's HIV control program, evaluation of implementation characteristics and outcomes has not been carried out. Thus the effect of the program on clinical outcomes such as BMI is unknown. This study was conducted to

evaluate the fidelity of implementation of NACS in six HIV clinics in the Greater Accra Region of Ghana, and to assess whether the level of implementation of NACS is associated with the BMIs of the program recipients. The results of this study should provide the NACS program office in the Ghana Health Service with some information on the status of the NACS program and how to improve its implementation and impact. It will also provide them quantitative data on the nutritional status (measured using BMI) of PLWH in Accra.

Methods

Study design:

A cross-sectional analysis was carried out using baseline data from a prospective cohort study of PLWH in the Greater Accra Region of Ghana. The pilot study was conducted in the HIV clinics of six hospitals (3 NACS designated and 3 non-NACS HIV clinics). An HIV clinic is classified as a NACS HIV clinic by the NACS program office in the Ghana Health Service. To protect the identities of the staff of the HIV clinics who participated in the study, the names of their institutions have been de-identified. The six HIV clinics were chosen for this study because they had an HIV clinic for non-pregnant women and men and also had patients from similar catchment areas with similar socioeconomic status.

All PLWH who received care in the six HIV clinics were invited to participate in this study if they met the following inclusion criteria: (1) being HIV positive adults; (2) between 18 and 65 years; and (3) at least 6 months on anti-retroviral therapy (ART) drugs

(initiation of ART's is associated with some weight gain) [15]. PLWH were excluded if they were pregnant, breastfeeding, or unable to stand upright to have their weight and height measured. Recruitment and data collection took place between October and December 2015 and lasted about two weeks in each HIV clinic.

Ethics statement:

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and approved by the Tufts Health Sciences IRB (IRB Number: 11905) and the Ghana Health Service Ethical Review Committee (GHSERC) (IRB Number: GHS-ERC: 11/09/15). Written informed consent was obtained from all subjects (patients and HIV clinic staff).

Study Procedures:

Permission was first sought from the Regional Health Directorate of the Ghana Health Service (GHS) to conduct this study. In each HIV clinic, a member of the research team approached PLWH who were waiting for medical care and briefly explained the purpose of the study. Among those who expressed interest, an informed consent form was administered and the individual screened to determine study eligibility.

Questionnaires:

A structured questionnaire (collecting data on demographics, socioeconomic status, medical history and food insecurity) was interviewer-administered to participants using

the laptop-based CAPI (Computer-Assisted Personal Interview) software system[16] or a paper alternative when there was no electricity.

All study related activities took place in the HIV clinics where everyone coming for care was HIV positive and so there were no confidentiality issues regarding the HIV status of study participants. Interviews were done in a separate room within the HIV clinic where available or a corner of the clinic where other PLWH could not hear responses by the person being interviewed.

Anthropometry:

A digital scale and stadiometer were used to measure the weight and height of screened participants to the nearest 0.1kg and 0.01m respectively by a trained research team member. Body Mass Index (BMI) was calculated using the formula: weight (kg) / [height (m)]^2.

NACS Implementation:

To assess NACS implementation, a checklist (developed from the training manual used to train health workers in Ghana) was used to collect information on patient load, HIV clinic staff size, and the availability of equipment and materials needed for proper implementation of NACS[17]. Five random counseling sessions in each HIV clinic were directly observed by a member of the research team to ascertain the content of nutrition counseling provided to clients as stipulated in the NACS training manual (after the clinic staff consenting)[17].

Eight indicators were created to quantify the level of NACS implementation. The eight indicators were:

1. Is there a functioning weighing scale
2. Is there a height board/stadiometer
3. Is there at least one adult MUAC tape
4. Is there food support (Plumpy nut/corn soya blend) available in the HIV clinic for distribution to HIV clients who need them
5. How many of 5 patients directly observed had their weight measured
6. How many of 5 patients directly observed had their weight correctly measured.
7. How many of 5 patients directly observed had ever had their height measured before
8. How many of 5 patients directly observed were offered nutrition counseling

A score of 1 was assigned to a particular indicator if the condition is met and a score of 0 was assigned otherwise. For indicators 5-8, a score of 0.2 was assigned for each patient directly observed. Five patients were directly observed in each HIV clinic, giving a maximum score of 1 for indicators 5-8. A summary score was created by summarizing scores from all eight indicators and had a range from 0 to 8, with a higher score indicating better implementation.

Statistical analysis:

Various characteristics of the study population were summarized using means ±SD's or median (IQR) (Interquartile range) for continuous variables and percentages for categorical variables. Differences between NACS designated and non-NACS HIV clinics

were analyzed using independent samples t-tests for continuous variables and chi-squared tests for categorical variables. Median NACS implementation scores were compared between the NACS designated and non-NACS HIV clinics using a Mann Whitney U test.

Two logistic regression models were then used to measure the association between NACS and the odds of having an overweight/obese BMI. The first used the NACS implementation score as the main independent variable whilst the second model used NACS status (that is, whether a PLWH received care in a NACS designated HIV clinic or not). A binary BMI outcome variable (normal BMI [18.5-24.9 kg/m^2] or overweight/obese BMI [>25 kg/m^2] was created by eliminating the data from the five participants who were underweight (BMI<18.5 kg/m^2). This was done in order not to combine them with any other weight category, which would distort the analysis. Both logistic regression models adjusted for age, sex, monthly income and years since HIV diagnosis. NACS implementation score, age and time since HIV diagnosis were analyzed as continuous variables. Sex and monthly income were treated as categorical variables, with income defined as (0-299 Ghana cedis/month and >299 Ghana cedis/month). SAS 9.3 software (SAS Institute Inc.) was used for all data analyses, and a p-value of 0.05 considered significant when testing hypothesis.

Statistical Power: Assuming a type I error of 0.05, and a 15% dropout rate, 150 participants needed to be recruited to ensure there was at least 80% statistical power to detect a BMI difference of $1kg/m^2$ between NACS and non-NACS participants, and we ended up recruiting 152 participants.

Results

Table 1 describes some characteristics of the 6 HIV clinic study sites. No staff member of the non-NACS HIV clinics had been trained in the provision of NACS and one NACS designated HIV clinic had no HIV clinic staff member trained in NACS as well.

Table 1 Characteristics of participating hospitals

Hospitals*	NACS hospital	Average number of HIV patients accessing care weekly	Number of staff who work in HIV clinic	Number of staff trained in NACS
Hospital 1	Yes	70	5	0
Hospital 2	Yes	90	3	2
Hospital 3	Yes	100	2	1
Hospital 4	No	80	7	0
Hospital 5	No	90	2	0
Hospital 6	No	80	3	0

*Hospital names anonymized to protect identity of staff in the HIV clinic. NACS, Nutrition Assessment Counseling and Support.

There was no statistically significant difference in the median NACS implementation score of the NACS designated HIV clinics when compared to those of the non-NACS HIV clinics (5 vs 4 respectively) (p=0.14) (Table 2). Of the five counselling sessions directly observed in each of the six HIV clinics, no nutrition counseling was offered, and there was no food support available in any of the study sites (Table 2).

Table 2 NACS implementation score by HIV clinic

NACS implementation scale indicators	NACS designated HIV clinics			Non-NACS HIV clinics		
	Hospital 1*	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6
1. Is there a functioning weighing scale†	1	0	1	1	1	1
2. Is there a height board/stadiometer†	1	0	1	1	1	0
3. Is there at least one adult MUAC tape†	0	0	0	1	0	0
4. How many of 5 patients directly observed had their weight measured‡	1	0	1	1	1	1
5. How many of 5 patients directly observed had their weight correctly measured‡	1	0	1	1	1	1
6. How many of 5 patients directly observed have ever had their height measured before‡	1	1	1	1	0	0
7. How many of 5 patients directly observed were offered nutrition counseling‡	0	0	0	0	0	0
8. Is there food support (Plumpy nut/corn soya blend) available in the HIV clinic †	0	0	0	0	0	0
NACS implementation score (out of 8)	5	1	5	6	4	3
NACS implementation score by NACS category, median (IQR)§	5(4)			4(3)		
Overall NACS implementation score, , median (IQR)	4.5(2)					

NACS, Nutrition Assessment Counseling and Support; MUAC, Mid Upper Arm Circumference; IQR, Interquartile Range.

*Hospital names anonymized to protect identity of staff in the HIV clinic

†Score of 1 where present and 0 where absent

‡Score of 0.2 for each patient directly observed

§No significant difference in NACS implementation score between NACS and non-NACS hospitals

The demographic and anthropometric characteristics of study participants are summarized in Table 3. The study population had a mean BMI of 25.8kg/m^2 with 26.5% of them being overweight and 20.5% being obese (Table 3). The study participants had a mean age 40 years, 84% were female, and almost 70% had an individual monthly income range of 0 – 299 cedis ($0-77 US Dollars) (Table 3). There were no statistically significant differences between participants recruited from NACS designated HIV clinics compared to those from non-NACS HIV clinics.

Table 3 Demographic and anthropometric characteristics of study participants by study group

	Overall		NACS		Non-NACS		P
	Mean	SD	Mean	SD	Mean	SD	
N	152		77		75		0.87
Age, y	40.0	9.0	38.8	8.5	41.1	9.4	0.13
Interval from HIV diagnosis, y	3.5	3.4	3.5	4.1	3.6	2.4	0.5
Household size	4	2.4	4	3	4	2	0.6
BMI, kg/m^2	25.8	5.7	25.1	4.8	26.6	6.5	0.11
	n	%	n	%	n	%	
BMI categorized							
Underweight (BMI<18.5 kg/m^2)	5	3.3	2	2.6	3	4.1	
Normal weight (BMI= 18.5-24.9 kg/m^2)	75	49.7	40	52.0	35	47.3	0.07
Overweight (BMI= 25-29.9 kg/m^2)	40	26.5	25	32.5	15	20.3	
Obese (BMI>30 kg/m^2)	31	20.5	10	12.9	21	28.3	
Female	127	84	65	84.4	62	82.7	0.8
Married	70	46.0	31	44.3	39	55.7	0.19
Main breadwinner of the home	83	54.6	41	53.3	42	56.0	0.7
Highest level of education completed							
None	21	13.8	15	19.5	6	8.0	
Primary school	29	19.1	9	11.7	20	26.7	
Junior/Senior high	89	58.6	46	51.7	43	57.3	0.06
Polytechnic/Community college	7	4.6	3	3.9	4	5.3	
University	6	3.9	4	5.2	2	2.7	
Monthly income							
GHS0-299 (equivalent of US$0-77)	78	66.7	39	65.0	39	68.4	0.69
>GHS300 (equivalent of US$78 or more)	39	33.3	21	35.0	18	31.6	

NACS, Nutrition Assessment Counseling and Support; BMI, Body Mass Index; GHS, Ghana cedis.

About a third of the study participants had not disclosed their HIV positive status to immediate family (defined here as spouse or children) (Table 4). Only a small subset of the study population ever reported having ever smoked cigarettes or used illicit drugs like cocaine or marijuana (Table 4).

Table 4 Medical history of study participants by study group

	Overall		NACS		Non NACS		P
	n	%	n	%	n	%	
I have disclosed my HIV status to immediate family	101	66.5	50	64.9	51	68.0	0.69
I have ever been diagnosed with tuberculosis	21	13.8	10	13.0	11	14.7	0.76
I have ever been diagnosed with pneumonia	4	2.6	1	1.3	3	4.0	0.36
I have ever smoked cigarettes	5	3.3	3	3.9	2	2.7	1.0
I have ever used cocaine or marijuana	4	2.6	2	2.6	2	2.7	1.0

NACS, Nutrition Assessment Counseling and Support.

Neither the NACS implementation score nor whether a PLWH received care in a NACS designated HIV clinic were associated with a higher odds of having an overweight/obese BMI (BMI>24.9 kg/m^2) after adjusting for age, time since diagnosis with HIV, sex, and monthly income (Table 5). Compared to those who earned more than 300 Ghana cedis a month, those who reported earning less had a lower odds of having an overweight/obese BMI (OR; 0.34 95% CI; 0.14, 0.86 and OR; 0.32 95% CI; 0.13, 0.80) (Table 5). Age was also marginally associated with a higher odds of being overweight/obese (OR: 1.05 95% CI; 1.002, 1.10 and OR; 1.05 95% CI; 0.13, 0.80) (Table 5).

Table 5 Logistic regression analysis of the association between NACS implementation score and odds of being overweight/obese

	Outcome: Odds of being overweight/obese (BMI > 24.9 kg/m^2)		
	OR (95% CI)[1]		OR (95% CI)[1]
NACS implementation score	1.29 (0.99, 1.68)	NACS status (Yes vs No)	1.05 (0.48, 2.32)
Age (in years)	1.05 (1.002, 1.10)	Age (in years)	1.05 (1.002, 1.10)
Time since HIV diagnosis (in years)	1.04 (0.93, 1.16)	Time since HIV diagnosis (in years)	1.03 (0.92, 1.14)
Sex (female vs male)	1.57 (0.49, 5.09)	Sex (female vs male)	1.81 (0.56, 5.80)
Monthly income[2] (Low vs High)	0.34 (0.14, 0.86)	Monthly income[2] (Low vs High)	0.32 (0.13, 0.80)

NACS, Nutrition Assessment Counseling and Support; OR, Odds Ratio.

[1] Adjusted for NACS implementation score or NACS status, age, time from HIV diagnosis, sex and monthly income.

[2] Low (0-299 GH Cedis) High (>300 GH Cedis). One Ghana cedi equivalent to 0.25USD (as at October 2016)

Discussion

In this study, there was poor implementation of NACS in the HIV clinics of the NACS designated hospitals. The lack of difference in the level of implementation between NACS designated and non-NACS HIV clinics was primarily due to the fact that the HIV clinics in the NACS hospitals were not offering nutrition counseling to PLWH seeking care and did not have food support or MUAC tapes. Informal interviews with some of the facility managers revealed that food support was no longer being supplied from the national program office. Some NACS trained staff felt overwhelmed with the large patient numbers and so did not prioritize nutrition counseling and did not feel qualified enough to do it despite their training. This result aligns with previous work done in Ghana which showed that in NACS hospitals, the emphasis during counseling was more on adherence to the antiretroviral therapy (ART) medications rather than nutrition[18]. The finding that those whose monthly income fell in the lower bracket were less likely to have an overweight or obese BMI is unsurprising in light of the fact that more than half of the study population were overweight and obese and having more money may lead to more food purchases and consumption which could lead to higher BMI.

There was not enough trained staff who could offer NACS services in the NACS designated HIV clinics with Hospital 1 having no trained staff at post and Hospital 3 having one trained staff. This unavailability of trained staff was also identified during a review of NACS implementation in Namibia and South-Western Uganda[19, 20] and this is an important factor that could negatively influence the implementation of NACS.

Another contributing factor to the non-implementation of NACS could have been the lack of trained nutritionists and dietitians permanently based in the NACS designated HIV

clinics. Anecdotally some of the nurses in the NACS designated HIV clinics were not confident in their ability to provide counseling and wished the health authorities would recruit nutritionists or dietitians to be permanent members of staff in their respective HIV clinics. Ghana has about four universities producing nutritionists and more recently dietitians annually but due to financial difficulties by the government, they are not being employed into the health service system. A similar situation was identified in Kenya where it was shown that despite Kenya producing a surplus of trained nutritionists, there was a shortfall of nutritionists in employment in health facilities due to budgetary constraints [21]. A cost-effective solution to this may be to employ a trained dietitian or nutritionist and assign that individual to a cluster of HIV clinics to provide nutrition services to PLWH and also provide ongoing training to the nursing staff and other non-nutrition health workers who interact with the patients more often.

Another alternative will be to re-examine the nutrition training offered to NACS practitioners and to simplify the message enough that they will be able to provide basic nutrition counseling to their patients. Currently there is no financial motivation for a health worker to take on the additional burden of providing nutrition counseling and this may be a de-motivator to some health workers in NACS designated HIV clinics who do not consider nutrition their core responsibility. Addressing this innovatively in a resource limited environment can be challenging but not inhibitive. For example discharging NACS duties well may be a promotion booster. In addition, NACS practitioners could be given special T-shirts or lapel pins to identify them and boost their pride in the program. The fact that a majority of the PLWH visibly looked healthy and even obese could also have led the staff not to prioritize nutrition counseling. If this is so, it calls for re-training

of health workers offering NACS services on the need to assess and provide nutrition counseling to both overweight and underweight PLWH.

The NACS implementation scale revealed that none of the HIV clinics had all the necessary equipment and tools to fully implement NACS. No NACS designated HIV clinic had an adult MUAC (Mid Upper Arm Circumference) tape on site. This finding mirrors those from the NACS implementation evaluations conducted in Namibia and South-Western Uganda[19, 20]. The poor performance of the NACS designated HIV clinics especially with regard to the provision of nutrition counseling and availability of food support is not surprising considering the fact that the "NACS program has been scaled down by the authorities"[22].

On average the study participants had a BMI of 25.8kg/m^2. A contributing factor to this relatively high BMI could have been a consequence of the inclusion criteria of being on ART's for at least 6 months. ART initiation has been associated with initial weight gain [15]. When categorized according to the BMI guidelines, 47% of the entire study population were either overweight (26.5%) or obese (20.5%). This supports earlier work done in Accra, Ghana which showed a 35% of population of PLWH surveyed being overweight or obese[23]. The level of overweight and obesity observed in this study are similar to those reported in other studies done among non-HIV Ghanaian populations (30.5% overweight among women; 21.3% overweight and 14% obese) [24, 25]. This makes overweight and obesity an important public health concern in PLWH living in Ghana. Being overweight or obese in PLWH increases their risk of developing chronic non-communicable diseases like type 2 diabetes and hypertension[26]. The levels of overweight and obesity observed among the PLWH in this study matches the nutrition transition sweeping the continent

including Ghana with an increased transition to more processed foods with high caloric density that promotes weight gain [27-29]. Anecdotal evidence gathered from the study participants indicated that weight gain for them was a way of protecting themselves from HIV related stigma, since a thin figure could be associated with the HIV disease. An earlier study by Wiig and Smith found a similar mindset among PLWH in Ghana [30]. It is very important to mention the very low levels (3.3%) of underweight observed in this population. This is also indicative of the change in trend from HIV being associated with wasting to now becoming characterized by overweight and obesity globally.

The over-representation of women in the study is due to the opt-out strategy to HIV testing during pregnancy adopted by Ghana where all pregnant women are routinely offered HIV testing with the right to refuse [31]. This has led to more women being diagnosed HIV positive, but some are unable to inform their spouses or partners due to the threat of being kicked out of their homes and abandoned by their spouses and immediate relatives if their HIV positive status was known. This accounts for the skewed distribution of women in this study where 33.5% of them had not informed their immediate relative (defined as spouse or children) of their HIV positive status. Anecdotally, two study participants told us they had been put out of their marital homes when they informed their husbands of their HIV positive test.

Neither receiving care in a NACS designated HIV clinic nor the NACS implementation score of an HIV clinic was associated with higher odds of being overweight or obese. This was expected in light of the poor implementation of NACS in the NACS designated HIV clinics which failed to distinguish them from non-NACS HIV clinics. The only nutrition assessment done was BMI (except in one NACS designated HIV clinic whose

scale was damaged at the time of the study) with none offering dietary or food security assessments. None of the clinics provided nutrition counseling, and only one (non-NACS) had an adult MUAC tape. Implementation of NACS per protocol is supposed to prevent and treat malnutrition whilst at the same time providing nutrition counseling to prevent and manage overweight and obesity which increases the risk of disease for PLWH [9].

The main limitation of this study is its cross-sectional design in that causation cannot be inferred. However, since this is the baseline analysis of an ongoing prospective cohort study, more detailed analysis can be done at the end of the entire study since it has a longitudinal design. Another limitation is that the high BMIs observed could be due to the inclusion criterion of having to be on ART use for at least six months. This could distort the picture, since ART initiation is associated with initial weight gain [15]. Finally including more hospitals may have improved the variability in NACS implementation observed.

In spite of these limitations, this study also has many strengths. There was a natural control group of HIV clinics and PLWH who had not yet been exposed to the NACS program. The implementation of NACS was even measured in HIV clinics officially designated non-NACS to rule out the possibility of the NACS program being implemented unofficially through “program leakage”. To our knowledge this is the first study to score the implementation of NACS and measure the association between level of implementation of the program and BMI of program recipients. Scoring the level of implementation of NACS enabled the use of a continuous variable in the analysis instead of a yes/no variable for NACS.

Conclusion

This pilot study showed that there was poor implementation of NACS in the NACS designated HIV clinics surveyed. The study found that neither the NACS implementation score of an HIV clinic nor receiving care in a NACS designated HIV clinic was significantly associated with BMI in PLWH. PLWH living in Ghana experience a high prevalence of being overweight or obese. As a result of these findings, we recommend that efforts should be put in place by the GHS and Ministry of Health to ensure that NACS is being implemented as per-protocol. Even though preventing and reversing under-nutrition seems to be the main driver behind the NACS program, the increase in overweight and obesity observed among PLWH makes the nutrition assessment and counseling sections of NACS ever more relevant. There should be universal nutrition assessment to enable the targeted nutrition counseling to be provided to help program recipients achieve and maintain a healthy weight. This detailed nutrition counseling will either require more comprehensive training of health workers in the HIV clinics or the employment of dietitians or nutritionists in these facilities to provide these much needed services.

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CHAPTER 4: RECEIVING CARE IN AN HIV CLINIC DESIGNATED TO IMPLEMENT THE NUTRITION ASSESSMENT COUNSELING AND SUPPORT PROGRAM IS NOT ASSOCIATED WITH THE BODY MASS INDEX OF A COHORT OF PEOPLE LIVING WITH HIV IN ACCRA, GHANA SIX MONTHS AFTER ENROLLMENT INTO A STUDY

Abstract

Background: Ever since the nutrition assessment, counseling and support (NACS) program was introduced into Ghana in 2009 to improve the nutrition care received by people living with HIV (PLWH), its impact on clinical outcomes such as body mass index (BMI) has not been assessed. This chapter aimed to evaluate whether receiving care in a HIV clinic designated to provide NACS was associated with changes in BMI among PLWH after six months of follow up.

Method: A prospective cohort of 152 adult PLWH were recruited from six HIV clinics (3 NACS designated and 3 non-NACS) with demographic and anthropometrical data collected at baseline, three and six months after recruitment. Repeated measures models were used to estimate the associations between NACS status and changes in BMI between baseline and three-month study visits and between three- and six- month study visits.

Results: Almost 80% of participants returned at both follow-up visits, with similar rates of loss to follow-up between both groups. Participants had a mean age of 40 years and 84% were female.

At baseline, the mean BMI was 25.8kg/m^2, with 3.3% being underweight, 26.5% being overweight, and 20.5% being obese. Change in BMI at three-month follow-up was 0.2 kg/m^2 and 0.01 kg/m^2 in NACS designated vs. non-NACS HIV clinics (p=0.77 and 0.99 respectively) and change in BMI at 6-month follow-up was 0.6 kg/m^2 and 0.1 kg/m^2 in NACS designated vs. non-NACS HIV clinics (p=0.55 and 0.89 respectively). Overall, no significant trend in BMI was observed among PLWH from either NACS designated or non-NACS HIV clinics (p=0.36 and p=0.87 respectively). Receiving care in NACS designated HIV clinics was not associated with changes in BMI at 3 months (β = -0.05, 95% CI: -0.27, 0.17) or 6 months (β= -0.05, 95% CI: -0.41, 0.32), after adjusting for age, sex, monthly income, time from HIV diagnosis, and baseline BMI. NACS implementation score was not associated with changes in BMI at 3 months or 6 months.

Conclusions: This study showed that receiving care in a NACS designated HIV clinic was not associated with changes in BMI over 6 months Given the poor NACS implementation scores in these clinics, the lack of association could be due to lack of nutrition counseling and support provided to PLWH. Further research on overcoming barriers to the implementation of NACS is needed to improve its implementation and assess its impact on weight status of PLWH.

Keywords: NACS, nutrition assessment counseling support, Ghana, HIV, BMI

Introduction

The introduction of Highly Active Antiretroviral Therapy (HAART) has significantly improved the survival of people living with HIV (PLWH) [1, 2]. However, it has also brought the recognition that the nutritional status of PLWH is suboptimal, with both

undernutrition and over-nutrition present in the same population. [3] In particular, increases in the prevalence of overweight and obesity among PLWH add additional risks to the already elevated risk of cardiovascular diseases in this population [4].

A Food by Prescription (FBP) program was introduced in 2006 in Kenya to help address undernutrition among PLWH, [5]. The aim of the FBP program was to "provide energy and nutrient-dense food products along with nutrition assessment, counseling, and clean, safe water to PLWH who were undernourished or at risk of malnutrition" [6]. PLWH who met the criteria were given fortified blended flour (FBF) which was a mix of precooked corn-soy flour fortified with micronutrients [6]. This FBP program, which was quickly adopted by other countries, was the foundation of Nutrition Assessment Counseling and Support (NACS). The US President's Emergency Plan for AIDS Relief (PEPFAR) changed the name from FBP to NACS to promote a more holistic set of interventions such as nutrition assessment and counseling rather than focusing on food distribution or food support [5].

NACS's main objective is to "improve the nutritional status of individuals and populations (HIV/AIDS and Tuberculosis) by integrating nutrition into policies, programs, and the health service delivery infrastructure" [7]. There are three components of NACS; nutrition assessment, nutrition counseling, and food support [7]. The program requires that nutritional assessment, which can be complex and time consuming, be made available to all PLWH and include anthropometric measures at a minimum (such as weight, height and Mid Upper Arm Circumference (MUAC)), and include assessments of food security and diet whenever possible [7]. Based on the nutritional assessment conducted, the person living with HIV should then be counselled on dietary practices to improve their nutritional status [7]. Finally some food support in the form of therapeutic

foods and micronutrient supplements should be provided to treat malnutrition or other nutritional conditions which were noted during the nutrition assessment and counseling portions of NACS [7].

NACS was introduced into Ghana by the U.S. Agency for International Development (USAID) through the Food and Nutrition Technical Assistance (FANTA) project in October 2009 [8]. The program is active in 83 health facilities nationwide that provide antiretroviral therapy (ART) services across the country as of 2013 [8]. NACS training materials and learning sites have been developed and set up for Ghana and about 903 health care providers and managers trained on NACS as of 2013 [8].

The objective was to evaluate whether receiving care in a NACS designated HIV clinic was associated with a change in BMI among PLWH six months after enrollment into the study.

Methods

Study population and design

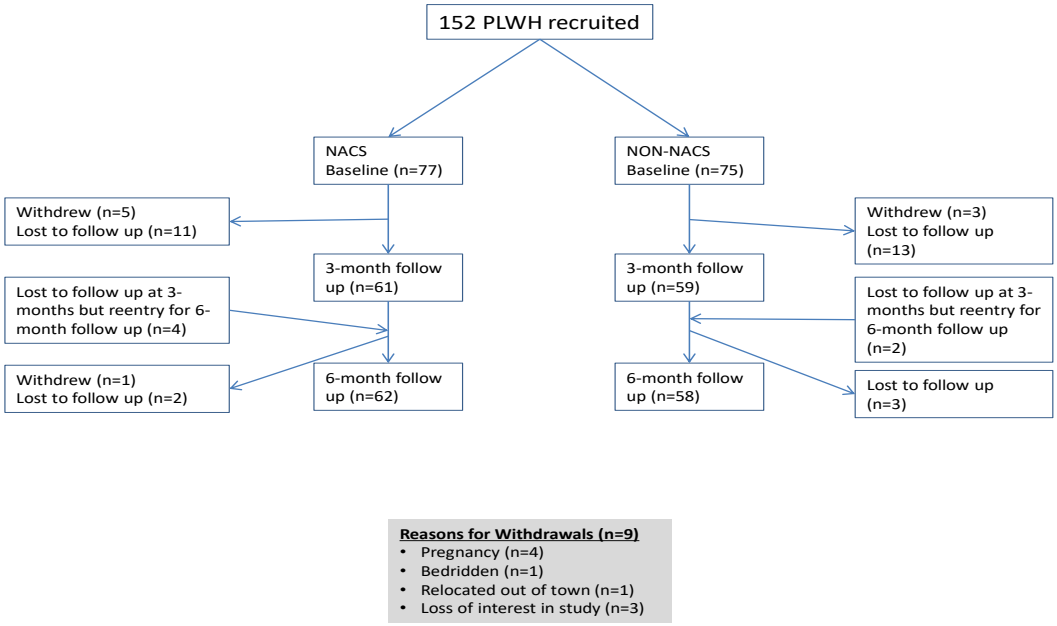
The study population is PLWH between 18-65 years who attended the HIV clinics of six hospitals in the Greater Accra Region of Ghana (three NACS and three non-NACS HIV clinics). The list of HIV clinics implementing NACS was obtained from the NACS program office of the Ghana Health Service. The names of the hospitals have been anonymized to protect the identities of the staff of the HIV clinics who allowed us to directly observe their counseling sessions, since some of the clinics have as few as two staff members, and using the hospital name will identify them. Participants had to be non-pregnant HIV positive women or men who had been on anti-retroviral therapy (ART)

drugs for at least six months. The Tufts Health Sciences IRB and the Ghana Health Service Ethical Review Committee GHSERC approved the study. All participants and HIV clinic staff provided written informed consent.

For this pilot study, one hundred and fifty-two participants were recruited between November and December 2015 (25 in each HIV clinic) and were followed up for six months (Figure 1). Study visits were scheduled at baseline, three, and six months.

One hundred and twenty (78.9%) participants returned at both the three and six months study visits, with similar rates of loss to follow-up between participants who attended NACS and non-NACS clinics at three months (20.8 vs. 21.3%) and six months (19.5 vs. 22.7%). Of the nine participants who self-withdrew during the follow-up, four were due to pregnancy and three lost interest in continuing participation.

Figure 1 Showing study participant flow over 6 months



Study procedures

At each study visit, participants filled out a self-administered questionnaire Computer-Assisted Personal Interview (CAPI) [9] about their demographic background and socioeconomic status among others. Their weight and height were measured using a digital weighing scale and a stadiometer to the nearest 0.1kg and 0.01m respectively at each visit.

In each HIV clinic, five counseling sessions (between a staff of the HIV clinic and the study participant) were randomly selected and directly observed by a member of the research team to determine whether any nutritional counseling was offered. Using a scale developed by the investigators we assessed the level of implementation of NACS interventions in all study sites and scored them from zero to eight, with a higher score indicating better implementation of NACS.

Statistical analysis

SAS 9.3 (SAS Institute Inc.) was used to perform all statistical analyses. Continuous variables were analyzed using means ± SDs whilst percentages were used to describe categorical variables.

BMI was the outcome of interest. Separate repeated measures models were used to estimate the association between NACS status and BMI between baseline and the three month study visits and between the three and six month study visits. The maximum likelihood estimation method with CS (compound symmetry) as the covariance structure was used. NACS status (whether the participant received care in a NACS designated HIV clinic or not), age (continuous), time from HIV diagnosis (continuous), baseline BMI (continuous), sex (categorical) and monthly income (categorical) were fixed factors in the models. NACS status was treated as a repeating factor. Subject nested within HIV clinic was analyzed as a random effect. A binary variable was created out of the NACS implementation score with low implementation (1-4) and high implementation (5-8). The regression analysis was then repeated using this binary NACS implementation score variable as the main independent variable. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 152 participants were recruited at baseline, with 77 from NACS designated HIV clinics and 75 from non-NACS HIV clinics. The mean age of all participants was 40 years, and 84% were female (Table 3 in Chapter 3). The mean interval from HIV diagnosis at study enrollment was 3.5 years. At baseline, the mean BMI was 25.8kg/m^2,

with 3.3% being underweight, 26.5% being overweight, and 20.5% being obese. Baseline characteristics did not differ significantly between participants who attended the NACS designated clinics and non-NACS HIV clinics.

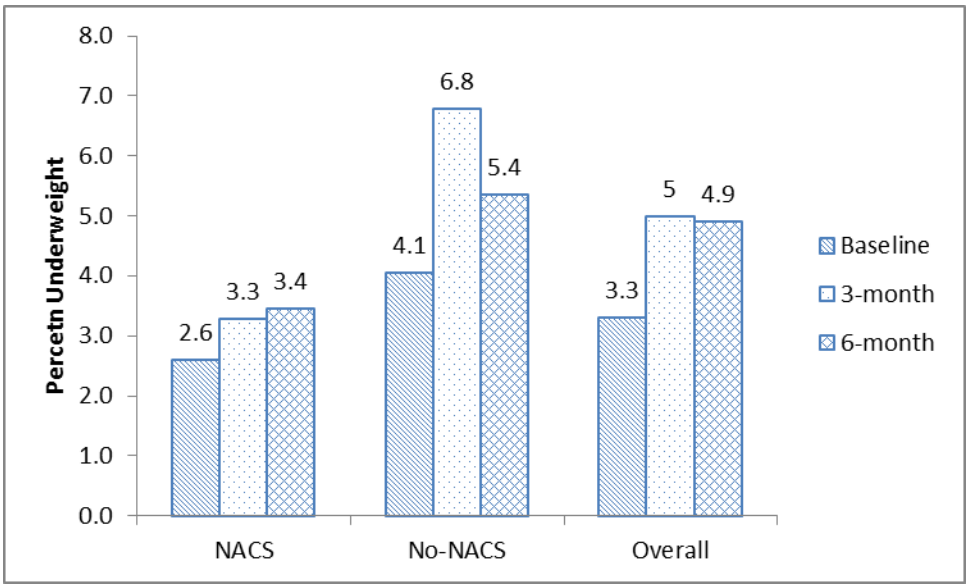
The change in BMI at the 3-month follow up visit was 0.2 kg/m^2 (p=0.77) and 0.01 kg/m^2 (p=0.99) for NACS and non-NACS participants respectively and this difference was not statistically significant. The change in BMI between the 3-6 month study visits were 0.6 kg/m^2 (p=0.55) and 0.1 kg/m^2 (p=0.89) for NACS and non-NACS participants respectively (Table 1) and these were not statistically significant. The changes in BMI for the overall populations were also not statistically significant over time (Table 1).
The proportion of participants who had normal weight decreased among those from NACS (51.9%, 45.9%, 44.8%) and non-NACS (47.3%, 39%, 39.3%) facilities over time (Figure 3). The proportion of participants who were overweight only increased among those from non-NACS HIV clinics (Figure 4) and that of obesity only increased among participants from NACS designated HIV clinics (Figure 5) with none of these trends being significant. None of these changes was significant.

Table 1 Longitudinal changes in BMI over time[1]

Mean BMI, kg/m^2	NACS (N=77)[2]	Non-NACS (N=75)	Total population (N=152)
Baseline	25.1±4.7	26.6±6.5	25.84± 5.67
3-months	25.3±4.4	26.6±6.1	25.96± 5.31
6-months	25.9±5.1	26.7±6.4	26.31± 5.78
Change (baseline – 3 months)	0.2	0.01	0.12
Change (3-6 months)	0.6	0.1	0.35
p for trend	0.36	0.87	0.50

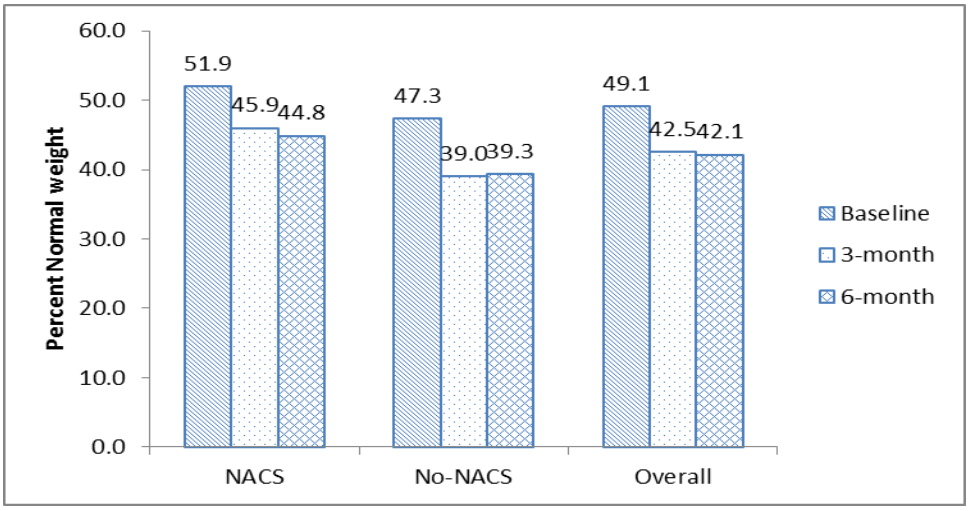
[1]Values are mean±SD. NACS, Nutrition Assessment Counseling and Support program; PLWH, People Living with HIV.
[2] N is baseline value.

Figure 2 Showing longitudinal changes in percent underweight over time



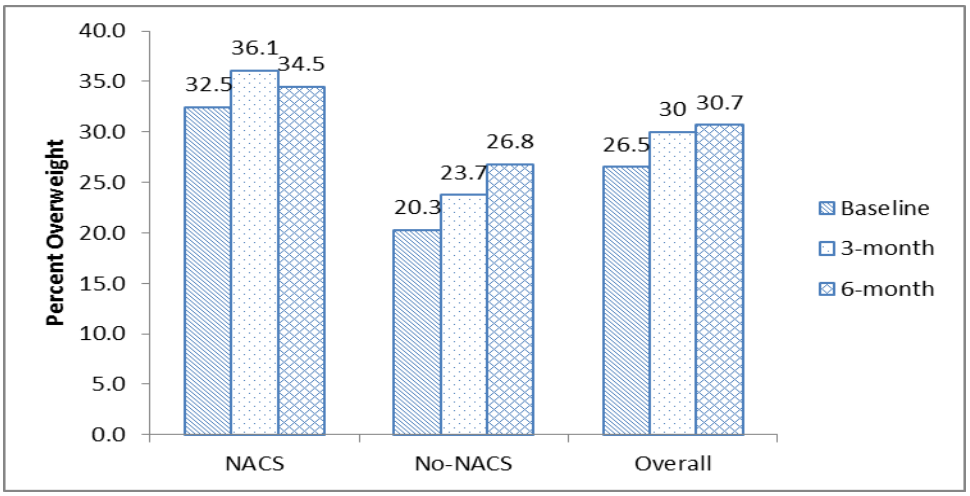
p for trend=0.97

Figure 3 Showing longitudinal changes in percent normal weight over time



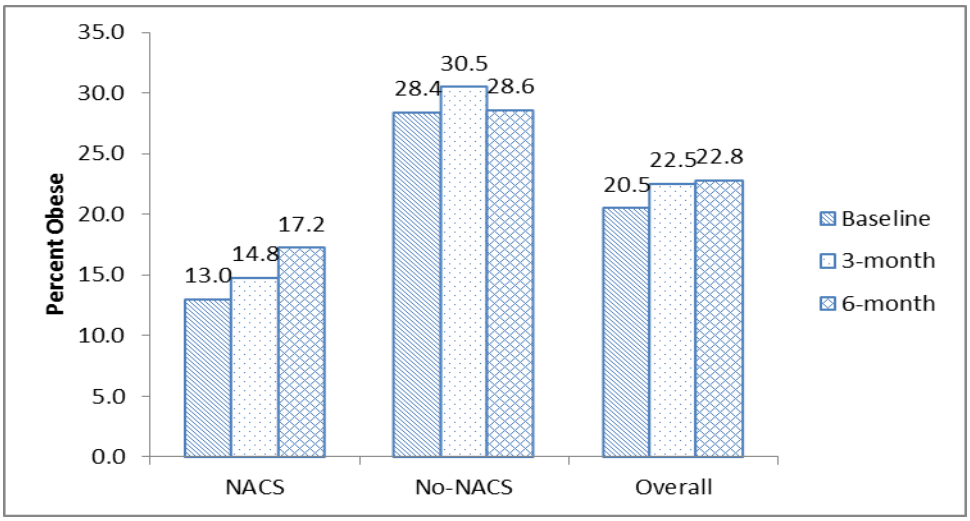
p for trend=0.98

Figure 4 Showing longitudinal changes in percent overweight over time



p for trend=0.89

Figure 5 Showing longitudinal changes in percent obese over time



p for trend=0.87

In multivariate regression models adjusting for age, sex, monthly income, time since HIV diagnosis, and baseline BMI, receiving care in a NACS designated HIV clinic was not associated with changes in BMI from baseline to 3 months (β= -0.05, 95% CI: -0.27, 0.17), nor from 3 months to 6 months (β= -0.05, 95% CI: -0.41, 0.32) (Table 2). Older age was negatively associated with changes in BMI at 3 months (β=-0.02, 95% CI: -0.03, -0.01) and 6 months (β= -0.05, 95% CI: -0.07, -0.02). Higher BMI at baseline was positively associated with changes in BMI at 3 months and 6 months (β= 0.97, 95% CI: 0.95, 0.99) and (β= 0.95, 95% CI: 0.97, 0.98) respectively (Table 2). Lower monthly income was marginally positively associated with changes in BMI at 3 months (β= 0.25, 95% CI: 0.003, 0.50) but no significant association was found at 6 months (β= 0.40, 95% CI: -0.01, 0.80) (Table 2). Sex and time from HIV diagnosis were not associated with changes in BMI over time. Repeating this analysis using the binary NACS implementation score as the main independent variable did not change the outcome (Supplemental Table 1).

Table 2 Repeated measures models for change in BMI during six months follow-up in PLWH

	From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)	*p*	β (95% CI)	*p*
NACS status (Yes vs No)	-0.05 (-0.27, 0.17)	0.67	-0.05 (-0.41, 0.32)	0.78
Sex (Female vs Male)	-0.19 (-0.49, 0.12)	0.23	-0.08 (-0.57, 0.42)	0.76
Baseline BMI, kgm^2	0.97 (0.95, 0.99)	<0.0001	0.95 (0.91, 0.98)	<0.0001
Age, y	-0.02 (-0.03, -0.01)	0.001	-0.05 (-0.07, -0.02)	<0.0001
Time from HIV diagnosis, y	0.004 (-0.03, 0.03)	0.77	-0.02 (-0.06, 0.03)	0.54
Monthly income (Low vs High)[1]	0.25 (0.003, 0.50)	0.047	0.40 (-0.01, 0.80)	0.054

NACS, Nutrition Assessment Counseling and Support program; PLWH, People Living with HIV.
[1] Low= GHS 0-299 (equivalent of US$0-77), High= GHS >300(> US$78)

Discussion

This analyses found that among this cohort of PLWH with 47% being overweight/obese, receiving care in a NACS designated HIV clinic was not associated with changes in BMI over 6 months. When the analyses was repeated using a binary variable of the NACS implementation score of the HIV clinic as the main independent variable, it did not change the conclusion. NACS was not being implemented per protocol in NACS designated HIV clinics. It was also revealed that there was no significant change in the proportions in each weight category over time.

Although undernutrition still represents an important concern in PLWH, over nutrition is being increasingly recognized in this population. Almost half of the participants from both NACS designated and non-NACS HIV clinics were either overweight or obese with very little underweight. This could be due to the fact that many newly diagnosed PLWH may be coming into care earlier without experiencing substantial weight loss. This is plausible considering the fact that Ghana has adopted an opt-out strategy to HIV testing during pregnancy whereby all pregnant women are routinely offered HIV testing with the right to refuse [10]. Anecdotally, a majority of this study population found out their HIV positive status this way and so had not lost any weight at diagnosis. This opt-out HIV testing during pregnancy also accounts for the overrepresentation of women in this study.

The high BMIs observed could also have been a result of the inclusion criteria of the study, one of which was that a participant had to be on ARTs for at least six months before being eligible to participate. Initiating ARTs has been associated with initial weight gain which could contribute to overweight or obesity among PLWH [11, 12]. ART coverage for adult PLWH in Ghana was 35.3% in 2014, down from 58.2% in 2011, and

this downward trend is due to a lack of resources and logistics [13]. Throughout the follow up of the study, we did not observe a significant change in BMI over time, and this could contribute to the lack of association between NACS and change in BMI observed in this study, since no significant change was observed. The marginally significant association between those reporting a lower income and a positive change in BMI only within the first half of the follow up was unexpected. We earlier showed (Table 5, Chapter 3) that those of the lower income bracket had lower odds of being overweight or obese, and it is possible that with time these people gained weight faster than those of the higher income bracket leading to the positive association with BMI observed after three months of follow up.

The high BMIs observed are very similar to other another study done among PLWH in Accra where 35% of PLWH sampled were either overweight or obese [14]. This follows a recent trend where more PLWH are overweight and obese than underweight [15]. This is in contrast to the beginning of the HIV epidemic, where it was associated with wasting and called the 'Slim' disease in Africa [16, 17]. This high level of overweight and obesity among PLWH, if confirmed, calls for shifting of the paradigm of HIV care from focusing solely on undernutrition to addressing the co-existence of over-and-undernutrition in PLWH. Overweight/obesity adds additional risks to the already elevated burden of cardiovascular diseases and diabetes due to treatment in this population [4, 18]. Even though NACS as designed initially focused on preventing and treating undernutrition, it should be able to handle over-nutrition if nutrition assessment is conducted and nutrition counseling provided to promote the achievement and maintenance of healthy weight in the NACS designated HIV clinics. Further studies are needed to investigate the weight status of

PLWH in Ghana in larger sample sizes and in more parts of the country to facilitate recommendations aimed at helping PLWH achieve and maintain a healthy weight.

It could be beneficial to re-examine the nutrition training offered to NACS practitioners and to simplify the message enough that they will be able to provide basic nutrition counseling to their patients. Currently there is no financial motivation for a health worker to take on the additional burden of providing nutrition counseling and this may be a de-motivator to some health workers in NACS designated HIV clinics who do not consider nutrition their core responsibility. Addressing this innovatively in a resource limited environment can be challenging but not inhibitive. For example discharging NACS duties well may be a promotion booster. In addition, NACS practitioners could be given special T-shirts or lapel pins to identify them and boost their pride in the program.

This study had some limitations. First, the length of follow up was relatively short, although logistical constraints were faced that limited the ability to extend the length of follow-up. Secondly, the lack of sufficient implementation of NACS in NACS designated HIV clinics limited the ability to detect the effect of NACS implementation on BMI. A better implementation of NACS could have revealed whether the program could have an impact on BMI or not. Loss to follow up could have influenced the results obtained but when we assessed this, there was no difference in the rate of loss to follow up between NACS and non-NACS study participants.

The prospective nature of the study allowed us to longitudinally observe any associations if they were present. The availability of a natural control group of similar HIV clinics which had not yet implemented the NACS program also should have allowed

comparisons to be made between participants exposed to the program and those not exposed to the program, but due to the non-implementation, these comparisons did not reveal differential impact of NACS. However, NACS score (how well NACS was implemented irrespective of its designation) also was not associated with change in BMI.

In conclusion, this study showed that receiving care in an HIV clinic supposed to be implementing NACS but not implementing it per protocol was not associated with BMI or with any changes in BMI. Health policymakers should ensure that the NACS program is being implemented as designed by providing the logistical support the HIV clinics need and supervising the staff to be sure they are implementing the program.

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Supplemental Table 1 Repeated measures models for change in BMI during six months of follow up using binary NACS implementation score as main independent variable

	From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)	*p*	β (95% CI)	*p*
NACS implementation score (High vs Low)	-0.20 (-0.42, 0.02)	0.08	-0.31 (-0.67, 0.06)	0.10
Sex (Female vs Male)	-0.17 (-0.47, 0.13)	0.23	-0.05 (-0.55, 0.45)	0.85
Baseline BMI, kgm^2	0.98 (0.96, 0.10)	<0.0001	0.95 (0.92, 0.99)	<0.0001
Age, y	-0.02 (-0.04, -0.01)	0.001	-0.05 (-0.07, -0.03)	<0.0001
Time from HIV diagnosis, y	0.002 (-0.03, 0.03)	0.88	-0.02 (-0.07, 0.03)	0.45
Monthly income				
GHS 0-299 (equivalent of US$0-77)	0.23 (-0.02, 0.47)	0.07	0.35 (-0.05, 0.76)	0.08
GHS >300(> US$78)	Ref			

NACS, Nutrition Assessment Counseling and Support program; PLWH, People Living with HIV.

CHAPTER 5: RECEIVING CARE IN AN HIV CLINIC DESIGNATED TO PROVIDE NUTRITION ASSESSMENT COUNSELING AND SUPPORT IS ASSOCIATED WITH FEWER DEPRESSION SYMPTOMS BUT NOT HEALTH-RELATED QUALITY OF LIFE OVER TIME AMONG PEOPLE LIVING WITH HIV IN ACCRA, GHANA

Abstract

Background:

People living with HIV (PLWH) face many nutrition related problems and at the same time depression and health-related quality of life (HRQol) issues. The nutrition assessment counseling and support (NACS) program was introduced to address access to nutrition services by PLWH, but since its introduction into Ghana, its impact on health outcomes such as depression and HRQol has not been evaluated. The objective of this study was to examine the impact of NACS on change in depression symptoms and HRQol among a cohort of PLWH in Accra, Ghana.

Method: 152 adult PLWH from six HIV clinics (3 NACS and 3 non-NACS) were followed prospectively with data collection at three time-points over a six month period. Depression, health-related quality of life (HRQol), as well as demographic data were collected at each visit. Separate repeated measures models were used to estimate the association between NACS status and depression and HRQOL between baseline and three month and between the three and six month study visits.

Results: At the three month visit, receiving care in a NACS designated HIV clinic was not associated with a change in either depression symptoms (β; 95% CI= -0.90; -2.31, 5.0) or HRQol [(β; 95% CI= 0.01; -0.01, 0.03) (β; 95% CI= 1.77; -0.52, 4.07)]. Between the three and six month visits however, receiving care in a NACS designated HIV clinic was associated with fewer depression symptoms (β; 95% CI= -2.31; -4.53, -0.10) and increasing HRQol [(β; 95% CI=0.04; 0.009, 0.08) (β; 95% CI= 6.91; 2.74, 11.08)]. Additional analysis using the NACS implementation score did not change the results.

Conclusions: High HRQol and low depression symptoms were found in this cohort of PLWH. Compared to PLWH in non-NACS HIV clinics, those receiving care in NACS designated HIV clinics reported reduced depression symptoms and improved HRQol scores between three- and six-month follow-up. These differences are unlikely to be attributable to NACS, since NACS designation was not associated with NACS implementation. Future studies are warranted to further evaluate the impact of the NACS program on psychosocial outcomes of PLWH.

Keywords: NACS, nutrition assessment counseling support, Ghana, HIV, depression, quality of life, CES-D, EQ-5D

Introduction

Among people living with HIV (PLWH), depressive symptoms are quite common, and being diagnosed HIV positive can itself lead to depression [1-4]. This could be due to the high level of stigmatization associated with HIV by both the community and even health care professionals [5-8]. This stigma could be due to the fact that unlike other diseases,

society usually puts the responsibility of developing HIV on the PLWH and attributes avoidable practices such as unsafe sex as the cause of infection [8]. Since it is not a visible condition, depression usually is under-diagnosed and may not be a treatment priority for PLWH [2]. PLWH who are depressed are at risk of poorly adhering to their Highly Active Antiretroviral Therapy (HAART) medications and may have an unhealthy dietary pattern as well as poor quality of life [2, 3, 9].

Since the introduction of HAART has brought about longer survival times among PLWH, maintaining and improving Health-related quality of life (HRQol) has become an important aspect of HIV management [10-12]. HRQol describes people's perception of their well-being and how they can function physically [13, 14]. HRQol has been shown to be negatively associated with an increase in viral load and HIV disease progression, whether the PLWH is on antiretroviral therapy (ART) or not [15].

The nutrition assessment counseling and support (NACS) program evolved from the Food by Prescription (FBP) program, which started Kenya in 2006 [16]. NACS's aim is to prevent and treat undernutrition among PLWH, and it was introduced into Ghana in 2009 [16-18]. The nutritional assessment component of NACS includes making anthropometric measures (such as weight and height) and dietary assessment available to all PLWH. Nutrition counseling should then be provided to the client based on the assessments done, and where undernutrition is detected, food support in the form of food rations provided [17]. Within Ghana, about 903 health care providers and managers have been trained and equipped to implement NACS [19]. Treatment of depression and quality of life issues is not part of NACS training nor explicitly part of the NACS program.

There are few studies that have prospectively evaluated the impact of nutrition assessment, counseling, and food support on depression and quality of life outcomes among PLWH in resource-limited settings such as Ghana. Our objective was to evaluate the impact of receiving care in a NACS designated HIV clinic on changes in depression and HRQol among PLWH in Accra, Ghana.

Methods

Study design:

A prospective design was used with data collection at baseline, three and six months after recruitment into the study. This pilot study was carried out in the HIV clinics of six of the eleven district hospitals in the Greater Accra Region of Ghana with an HIV clinic for adults (3 NACS and 3 non-NACS HIV clinics). The Ghana Health Service NACS program office provided the list of HIV clinics implementing NACS at the time of data collection. In order to protect the identities of the staff of the HIV clinics where we conducted this study, we anonymized the names of the hospitals. This was necessary because some of these clinics had few staff members and using the clinic name was equivalent to identifying the staff by name. For this pilot study we recruited 152 participants (25 PLWH per clinic).

To be eligible for this study, participants had to be HIV positive, above 18 years, and be stable on ART medications. Being pregnant, breastfeeding or not being able to physically have weight and height measured excluded participants from the study. This study was conducted according to the guidelines laid down in the Declaration of Helsinki and approved by the Tufts Health Sciences IRB and the Ghana Health Service Ethical Review

Committee. Written informed consent was obtained from all subjects and staff of the HIV clinics surveyed. The data collection spanned November 2015 to July 2016, and recruitment took approximately two weeks per clinic. Of the 152 participants recruited at baseline, 79% of participants in both NACS and non-NACS HIV clinics returned at three months. Six months after recruitment, 81% of the participants recruited from NACS HIV clinics at baseline returned compared to 77% of participants from non- NACS HIV clinics. Loss to follow-up between participants from both groups were similar at three months (20.8 vs. 21.3%) and six months (19.5 vs. 22.7%).

Study measures:

In each study site an interviewer-administered structured questionnaire was used to collect information on demographic characteristics, socio economic status, depression symptoms and quality of life from interested and eligible PLWH.. Depression symptoms, quality of life and weight and height measurements were assessed at each study visit. Data was collected at baseline, three, and six months after recruitment.

Depression symptoms were measured using the Center for Epidemiologic Studies Depression Scale (CES-D) [20]. The CES-D is a 20-item self-report tool designed to measure depression symptoms over the previous week in nine symptom groups [21]. The responses to each item question range from 0 [rarely or none of the time (<1 day)] to 3 [all the time (5-7 days)]. Four of the 20 questions measure positive feelings such as 'I was happy' and these four questions are reverse scored to calculate total depression symptoms scores [22, 23]. Total scores from the CES-D can range from 0-60, with higher

scores indicating higher degrees of depression symptoms [24]. Any score 16 or more is suggested to indicate depressive symptoms [25-27].

HRQol was derived from the EQ-5D-3L instrument after obtaining approval [28]. The EQ-5D-3L is made up of two components; a descriptive system and a visual analogue scale (EQ-VAS) [28]. The descriptive system is made up of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each with three severity levels [28]. The responses to the descriptive system places an individual into one of 243 health states which can be converted to an EQ-5D utility scale from a tariff set [29]. The Zimbabwean EQ-5D tariff set was used in this study since there is no Ghanaian EQ-5D tariff. This assumes that Ghanaians and Zimbabweans will value health comparably [29]. The EQ-5D utility scores obtained ranged from -0.29 (severe problems in all five dimensions) to 1.0 (no problems in all five dimensions) [29].

The EQ-VAS looks like a thermometer and asks respondents to self-rate their health state for that day on a scale ranging from 0 (worst imaginable health state) to 100 (best imaginable health state) [28, 29]. It can be used as a quantitative measure of health outcome from the perspective of the individual respondent [28].

Statistical analyses:

SAS 9.3 (SAS Institute Inc.) was used in all data analyses. Independent samples t-test was used to compare continuous variables, whilst chi-squared tests were used for categorical variables. Repeated measures models were used to analyze the data using the maximum likelihood estimation method with compound symmetry as the covariance structure. To best utilize the data collected at three time points, two separate models

estimating the association between NACS status and change in depression and HRQOL between baseline and the three month study visits and between the three and six month study visits are presented.

Depression symptoms (CES-D) and HRQol (EQ-5D and EQ-VAS) were the dependent variables. Fixed factors in the model were NACS status (whether the participant received care in a NACS designated HIV clinic or not), time from diagnosis with HIV, sex, visit number, and monthly income. NACS status was treated as a repeating factor. The individual subject nested within HIV clinic was analyzed as a random effect. A p-value of less than 0.05 was considered statistically significant.

Results

At baseline, the study population had been diagnosed with HIV for an average of 3.5 years and were mainly female (84%). They were on average 40 years of age and a majority earned 77USD or less in the previous month. There were no statistically significant differences in the responses to 19 of the 20 depression symptom questions by participants between arms of the study (Table 1).

In response to the question; 'In the past week, could you motivate yourself to start things you had to do in the past seven days', 96.1% of participants receiving care in NACS designated HIV clinics responded 'rarely or none of the time' compared to 88% of participants from non-NACS HIV clinics (p=0.007). The overall mean depression score of the study population was 12.9±9.3 (lower than the threshold for diagnosing depression), with no significant differences between the two groups (p=0.28) (Table 1). When CES-D scores were categorized, 66.4% of the entire study population was classified not depressed at baseline (Table 1).

Table 1: Selected depression symptoms at baseline by groups[1]

Depression symptoms	Overall	NACS	Non-NACS	p
I did not feel like eating; my appetite was poor				
Rarely or none of the time (<1 day)	107 (70.9)	56 (73.7)	51 (68.0)	
Some or a little of the time (1-2 days)	14 (9.2)	5 (6.6)	9 (12.0)	0.68
Occasionally or a moderate amount of time (3-4 days)	19 (12.6)	9 (11.8)	10 (13.3)	
All of the time (5-7 days)	11 (7.3)	6 (7.9)	5 (6.7)	
My sleep was restless				
Rarely or none of the time (<1 day)	107 (70.9)	50 (65.8)	57 (76.0)	
Some or a little of the time (1-2 days)	10 (6.6)	8 (10.5)	2 (2.7)	0.13
Occasionally or a moderate amount of time (3-4 days)	22 (14.6)	10 (13.2)	12 (16.0)	
All of the time (5-7 days)	12 (7.9)	8 (10.5)	4 (5.3)	
I was happy				
Rarely or none of the time (<1 day)	13 (8.6)	7 (9.2)	6 (8.0)	
Some or a little of the time (1-2 days)	26 (17.2)	11 (14.5)	15 (20.0)	0.84
Occasionally or a moderate amount of time (3-4 days)	45 (29.8)	23 (30.3)	22 (29.3)	
All of the time (5-7 days)	67 (44.4)	35 (46.0)	32 (42.7)	
I could not motivate myself to start things I had to do				
Rarely or none of the time (<1 day)	139 (92.1)	73 (96.1)	66 (88.0)	
Some or a little of the time (1-2 days)	6 (4.0)	0 (0.0)	6 (8.0)	0.007
Occasionally or a moderate amount of time (3-4 days)	4 (2.6)	1 (1.3)	3 (4.0)	
All of the time (5-7 days)		2 (2.6)	0 (0.0)	
Overall mean depression symptoms score[2]	**12.9±9.3**	**12.0±9.7**	**13.7±8.8**	**0.28**
Depression symptoms score categorized				
Not depressed (CES-D<16)	101 (66.4)	53 (68.8)	48 (64.0)	0.53
Depressed (CES-D≥16)	51 (33.6)	24 (31.2)	27 (36.0)	

[1] Values are n(%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program; CES-D, Center for Epidemiologic Studies Depression Scale.
[2] Higher CES-D score indicates more depression symptoms.

At baseline, there were no significant differences in the HRQol as measured by the EQ-5D descriptive scale and EQ-VAS between the two groups (p=0.24 and p=0.31 respectively) (Table 2). Within the pain/discomfort domain of the EQ-5D, 66.2% of participants from NACS designated HIV clinics reported no problems compared to 44% of those from non-NACS HIV clinics (p=0.007) (Table 2). There were no statistically significant differences in the responses to the other four domains of the EQ-5D (Table 2).

Table 2 Domains of Health-Related Quality of Life by NACS status at baseline[1]

Responses	Overall	NACS	Non-NACS	p
Mobility				
No problems	125 (82.2)	62 (80.5)	63 (84.0)	0.57
Some problems	27 (17.8)	15 (19.5)	12(16.0)	
Severe problems	0 (0.0)	0 (0.0)	0 (0.0)	
Self-care				
No problems	152(100)	77 (100)	75(100)	0.9
Some problems	0 (0.0)	0 (0.0)	0 (0.0)	
Severe problems	0 (0.0)	0 (0.0)	0 (0.0)	
Usual activities				
No problems	150(98.7)	75 (97.4)	75(100.0)	0.26
Some problems	2(1.3)	2(2.6)	0	
Severe problems	0 (0.0)	0 (0.0)	0 (0.0)	
Pain/discomfort				
No problems	84(55.3)	51(66.2)	33(44.0)	0.007
Some problems	58(38.2)	20(26.0)	38(50.7)	
Severe problems	10(6.5)	6(7.8)	4(5.3)	
Anxiety/depression				
No problems	67(44.1)	37(48.1)	30(40.0)	0.60
Some problems	75(49.4)	35(45.5)	40(53.3)	
Severe problems	10(6.5)	5(6.4)	5(6.7)	
Mean EQ-5D scores	0.84±0.13	0.85±0.14	0.82±0.11	0.24
Mean EQ-VAS scores	81.19±17.15	79.81±18.7	82.64±15.41	0.31

[1] Values are n(%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program; EQ-5D, EuroQol Five Dimensions Questionnaire; EQ-VAS, EuroQol Five Dimensions Questionnaire Visual Analogue Scale.

Among both NACS designated and non-NACS participants, there was no significant trend observed in the individual domains of depression symptoms between baseline and the three month visits (Tables 3&4). Between the three and six month visits, there was a significant trend in the 'I was happy during the past week' domain among participants from NACS designated HIV clinics (p=0.07) (Table 3). The proportion of PLWH who reported feeling happy all the time in the previous week increased from 59% to 75.9% (Table 3). Mean depression symptoms score decreased significantly between the baseline and three month visits by 3.9 (p=0.009) and 3.5 (p=0.02) among NACS and non-NACS participants respectively (Tables 3&4) (not comparing NACS designated to non-NACS). During the second half of the follow up, there was an insignificant decrease in symptoms

between both groups When the depression scores were categorized according to depressed or not, the only significant trend was observed between the baseline and the three month visits among participants from NACS designated HIV clinics (p=0.046) (Table 3).

Table 3 Longitudinal changes in selected depression symptom domains over time among NACS designated study participants[1]

Depression symptoms	Baseline	3 month	p	3 month	6 month	p
	NACS					
	I did not feel like eating; my appetite was poor					
Rarely or none of the time (<1 day)	56 (73.68)	40 (65.57)		40 (65.57)	42 (72.41)	
Some or a little of the time (1-2 days)	5 (6.58)	8 (13.11)		8 (13.11)	6 (10.34)	
Occasionally or a moderate amount of time (3-4 days)	9 (11.84)	11 (18.03)	0.27	11 (18.03)	6 (10.34)	0.49
All of the time (5-7 days)	6 (7.89)	2 (3.28)		2 (3.28)	4 (6.90)	
	My sleep was restless					
Rarely or none of the time (<1 day)	50 (65.79)	47 (77.05)		47 (77.05)	48 (82.76)	
Some or a little of the time (1-2 days)	8 (10.53)	1 (1.64)	0.19	1 (1.64)	5 (8.62)	0.10
Occasionally or a moderate amount of time (3-4 days)	10 (13.16)	7 (11.48)		7 (11.48)	3 (5.17)	
All of the time (5-7 days)	8 (10.53)	6 (9.84)		6 (9.84)	2 (3.45)	
	I was happy					
Rarely or none of the time (<1 day)	7 (9.21)	4 (6.56)		4 (6.56)	0 (0.00)	
Some or a little of the time (1-2 days)	11 (14.47)	6 (9.84)	0.50	6 (9.84)	2 (3.45)	0.07
Occasionally or a moderate amount of time (3-4 days)	23 (30.26)	15 (24.59)		15 (24.59)	12 (20.69)	
All of the time (5-7 days)	35 (46.05)	36 (59.02)		36 (59.02)	44 (75.86)	
	I could not motivate myself to start things I had to do					
Rarely or none of the time (<1 day)	73 (96.05)	61 (100.00)		61 (100.00)	58 (100.00)	
Some or a little of the time (1-2 days)	0 (0.00)	0 (0.00)	0.29	0 (0.00)	0 (0.00)	-
Occasionally or a moderate amount of time (3-4 days)	1 (1.32)	0 (0.00)		0 (0.00)	0 (0.00)	
All of the time (5-7 days)	2 (2.63)	0 (0.00)		0 (0.00)	0 (0.00)	
Overall mean depression symptoms score	12.0±9.7	8.1±6.9		8.1±6.9	6.5±6.6	
Change in mean depression symptoms score	-3.9		0.009	-1.6		0.20
	Depression symptoms score categorized					
Not depressed (CES-D<16)	53 (68.83)	51 (83.61)	0.046	51 (83.61)	51 (87.93)	0.50
Depressed (CES-D≥16)	24 (31.17)	10 (16.39)		10 (16.39)	7 (12.07)	

[1]Values are n (%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program; CES-D, Center for Epidemiologic Studies Depression Scale.

Table 4 Longitudinal changes in selected depression symptom domains over time among non-NACS study participants[1]

Depression symptoms	Baseline	3 month	p	3 month	6 month	p
	Non-NACS					
	I did not feel like eating; my appetite was poor					
Rarely or none of the time (<1 day)	51 (68.00)	38 (64.41)		38 (64.41)	46 (82.14)	
Some or a little of the time (1-2 days)	9 (12.00)	7 (11.86)	0.78	7 (11.86)	3 (5.36)	0.15
Occasionally or a moderate amount of time (3-4 days)	10 (13.33)	7 (11.86)		7 (11.86)	5 (8.93)	
All of the time (5-7 days)	5 (6.67)	7 (11.86)		7 (11.86)	2 (3.57)	
	My sleep was restless					
Rarely or none of the time (<1 day)	57 (76.00)	41 (69.49)		41 (69.49)	37 (66.07)	
Some or a little of the time (1-2 days)	2 (2.67)	5 (8.47)	0.40	5 (8.47)	8 (14.29)	0.80
Occasionally or a moderate amount of time (3-4 days)	12 (16.00)	8 (13.56)		8 (13.56)	7 (12.50)	
All of the time (5-7 days)	4 (5.33)	5 (8.47)		5 (8.47)	4 (7.14)	
	I was happy					
Rarely or none of the time (<1 day)	6 (8.00)	3 (5.08)		3 (5.08)	3 (5.36)	
Some or a little of the time (1-2 days)	15 (20.00)	8 (13.56)	0.64	8 (13.56)	5 (8.93)	0.73
Occasionally or a moderate amount of time (3-4 days)	22 (29.33)	21 (35.59)		21 (35.59)	17 (30.36)	
All of the time (5-7 days)	32 (42.67)	27 (45.76)		27 (45.76)	31 (55.36)	
	I could not motivate myself to start things I had to do					
Rarely or none of the time (<1 day)	66 (88.00)	58 (98.31)		58 (98.31)	54 (96.43)	
Some or a little of the time (1-2 days)	0 (0.00)	0 (0.00)	0.06	0 (0.00)	0 (0.00)	0.59
Occasionally or a moderate amount of time (3-4 days)	6 (8.00)	0 (0.00)		0 (0.00)	1 (1.79)	
All of the time (5-7 days)	3 (4.00)	1 (1.69)		1 (1.69)	1 (1.79)	
Overall mean depression symptoms score	13.7±8.8	10.2±8.4		10.2±8.4	8.6±8.0	
Change in mean depression symptoms score	-3.5		0.02	-1.6		0.29
	Depression symptoms score categorized					
Not depressed (CES-D<16)	48 (64.00)	44 (74.58)	0.19	44 (74.58)	48 (85.71)	0.14
Depressed (CES-D≥16)	27 (36.00)	15 (25.42)		15 (25.42)	8 (14.29)	

[1]Values are n (%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program; CES-D, Center for Epidemiologic Studies Depression Scale.

Within the five domains of the HRQol, the only significant trend over time was observed in the anxiety/depression domain among NACS participants where the proportion of participants who reported having no problems in the domain increased over time (p=0.047 and p=0.04 Table 5). Mean HRQol scores measured using the EQ-5D scale between the baseline and three month visits increased by 0.05 among participants from both NACS designated and non-NACS HIV clinics (p=0.009 Tables 5 and 6). Assessing HRQol using the visual analogue scale of the EQ-5D only increased by 8.35 among participants from NACS designated HIV clinics between the baseline and three month visits (p=0.005 Table 5).

Table 5: Longitudinal changes in Health-Related Quality of Life domains over time among NACS designated participants[1]

Domains	Baseline	3 month	p	3 month	6 month	p
	Mobility					
No problems	62 (80.52)	55 (90.16)		55 (90.16)	54 (93.10)	
Some problems	15 (19.48)	6 (9.84)	0.12	6 (9.84)	4 (6.90)	0.57
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Self-care					
No problems	77 (100.00)	60 (98.36)		60 (98.36)	57 (98.28)	
Some problems	0 (0.00)	1 (1.64)	0.26	1 (1.64)	1 (1.72)	0.97
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Usual activities					
No problems	75 (97.40)	60 (98.36)		60 (98.36)	58 (100.00)	
Some problems	2 (2.60)	1 (1.64)	0.70	1 (1.64)	0 (0.00)	0.33
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Pain/discomfort					
No problems	51 (66.23)	46 (75.41)		46 (75.41)	40 (68.97)	
Some problems	20 (25.97)	14 (22.95)	0.22	14 (22.95)	17 (29.31)	0.73
Severe problems	6 (7.79)	1 (1.64)		1 (1.64)	1 (1.72)	
	Anxiety/depression					
No problems	37 (48.05)	42 (68.85)		42 (68.85)	50 (86.21)	
Some problems	35 (45.45)	16 (26.23)	0.047	16 (26.23)	8 (13.79)	0.04
Severe problems	5 (6.49)	3 (4.92)		3 (4.92)	0 (0.00)	
Mean EQ-5D scores	0.85±0.14	0.90±0.11		0.90±0.11	0.92±0.11	
Change in mean EQ-5D	0.05		0.009	0.02		0.34
Mean EQ-VAS scores	79.81±18.7	88.16±14.8		88.16±14.8	91.43±12.2	
Change in mean EQ-VAS	8.35		0.005	3.27		0.19

[1]Values are n (%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program ; EQ-5D, EuroQol Five Dimensions Questionnaire ; EQ-VAS, EuroQol Five Dimensions Questionnaire Visual Analogue Scale

Table 6: Longitudinal changes in Health-Related Quality of Life domains over time among non-NACS participants[1]

Domains	Baseline	3 month	p	3 month	6 month	p
	Mobility					
No problems	63 (84.00)	49 (83.05)		49 (83.05)	49 (87.50)	
Some problems	12 (16.00)	10 (16.95)	0.88	10 (16.95)	7 (12.50)	0.50
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Self-care					
No problems	75 (100.00)	59 (100.00)		59 (100.00)	56 (100.00)	
Some problems	0 (0.00)	0 (0.00)	-	0 (0.00)	0 (0.00)	-
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Usual activities					
No problems	75 (100.00)	59 (100.00)		59 (100.00)	55 (98.21)	
Some problems	0 (0.00)	0 (0.00)	-	0 (0.00)	1 (1.79)	0.30
Severe problems	0 (0.00)	0 (0.00)		0 (0.00)	0 (0.00)	
	Pain/discomfort					
No problems	33 (44.00)	36 (61.02)		36 (61.02)	31 (55.36)	
Some problems	38 (50.67)	23 (38.98)	0.051	23 (38.98)	22 (39.29)	0.19
Severe problems	4 (5.33)	0 (0.00)		0 (0.00)	3 (5.36)	
	Anxiety/depression					
No problems	30 (40.00)	32 (54.24)		32 (54.24)	37 (66.07)	
Some problems	40 (53.33)	26 (44.07)	0.15	26 (44.07)	15 (26.79)	0.08
Severe problems	5 (6.67)	1 (1.69)		1 (1.69)	4 (7.14)	
Mean EQ-5D scores	0.82±0.11	0.87±0.09		0.87±0.09	0.86±0.13	
Change in mean EQ-5D	0.05		0.009	-0.01		0.67
Mean EQ-VAS scores	82.64±15.41	87.03±13.5		87.03±13.5	82.11±17.4	
Change in mean EQ-VAS	4.39		0.09	-4.92		0.09

[1]Values are n (%) and mean±SD. NACS, Nutrition Assessment Counseling and Support program; EQ-5D, EuroQol Five Dimensions Questionnaire; EQ-VAS, EuroQol Five Dimensions Questionnaire Visual Analogue Scale

Between the baseline and three month study visits, receiving care in NACS designated HIV clinic was not associated with change in depression symptoms after adjusting for other covariates (p=0.20 Table 7). Between the three and six month study visits however, receiving care in a NACS designated HIV clinic was significantly associated with a decrease in depression symptoms (p=0.04) after adjusting for time from HIV diagnosis, sex, baseline depression symptom score and monthly income (Table 7). Within both time frames, baseline depression symptom score was independently associated with an increase in subsequent depression symptoms (p<0.0001 Table 7). We arrived at the same conclusions when we used the binary NACS implementation score as the main independent variable (Supplementary Table 1).

Table 7 Repeated measures models for change in Depression symptoms over six months follow-up in PLWH

	From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)[1]	*p*	β (95% CI)	*p*
NACS status (yes vs no)	-0.90 (-2.31, 0.50)	0.20	-2.31(-4.53, -0.10)	0.04
Time from HIV diagnosis, y	-0.09 (-0.29,0.10)	0.32	-0.10(-0.41, 0.20)	0.50
Sex (female vs male)	1.00 (-0.93, 2.94)	0.30	1.29 (-1.82, 4.41)	0.41
Baseline depression symptom score	0.70 (0.62, 0.79)	<.0001	0.30 (0.16, 0.44)	<.0001
Monthly income (Low vs High)[2]	-0.21 (-1.78, 1.35)	0.78	0.26(-2.17, 2.7)	0.83

NACS, Nutrition Assessment Counseling and Support program.
[1] Adjusted for NACS status, time from HIV diagnosis, sex, baseline depression symptom score and monthly income.
[2] Low= GHS 0-299 (equivalent of US$0-77), High= >GHS 300 (>US$78)

Over the study follow up, receiving care in a NACS designated HIV clinic was not significantly associated with change in HRQol as determined by the descriptive scale of the EQ-5D between baseline and three months (p=0.20) but was associated with an increase in HRQol between the three and six month study visits (p=0.01 Table 8). In both time periods, baseline HRQol was significantly associated with changes in HRQol scores. When we used the binary NACS implementation score as the main independent variable, it was also not significantly associated with a change in EQ-5D at either time period (Supplementary Table 2).

Between baseline and three months, receiving care in a NACS designated HIV clinic had no significant effect on HRQol (as determined by the EQ-VAS) after adjusting for other covariates (p=0.13) but being female and a higher baseline EQ-VAS were independently associated with a higher HRQol (p=0.01 and p<0.0001 respectively Table 8). Between the three and six month study visits, receiving care in a NACS designated HIV clinic was significantly associated with an increase in HRQol (p=0.001) after adjusting for other covariates (Table 8). Baseline EQ-VAS was also significantly associated with an increase in EQ-VAS between during this time frame. When we used the binary NACS implementation score as the main independent variable, it was not significantly associated with a change in EQ-5D at both time periods (Supplementary Table 2).

Table 8 Repeated measures models for change in Health-Related Quality of Life over six months follow-up in PLWH

	EQ-5D				**EQ-VAS**			
	From baseline to 3-month visit		From 3-6month study visit		From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*
NACS status (yes vs no)	0.01 (-0.01,0.03)	0.20	0.04 (0.009, 0.08)	0.01	1.77 (-0.52,4.07)	0.13	6.91 (2.74,11.08)	0.001
Time from HIV diagnosis, y	0.0005 (-0.002, 0.003)	0.73	-0.001 (-0.004, 0.006)	0.64	-0.11 (-0.43,0.21)	0.51	-0.09 (-0.66,0.48)	0.75
Sex (female vs male)	-0.02 (-0.04, 0.009)	0.22	-0.04 (-0.08,0.01)	0.15	3.78 (0.59, 6.97)	0.02	3.06 (-2.84,8.96)	0.31
Baseline EQ-5D or EQ-VAS	0.66 (0.60, 0.73)	<0.0001	0.23 (0.11,0.37)	0.0005	0.69 (0.62,0.76)	<0.0001	0.26 (0.13,0.39)	0.0001
Monthly income (Low vs High)[2]	-0.001 (-0.02, 0.02)	0.90	0.01 (-0.03,0.04)	0.72	-1.28 (-3.86,1.30)	0.33	-0.56 (-5.16,4.05)	0.82

NACS, Nutrition Assessment Counseling and Support program; EQ-5D, EuroQol Five Dimensions Questionnaire; EQ-VAS, EuroQol Five Dimensions Questionnaire Visual Analogue Scale.

[1] Adjusted for NACS status or NACS implementation score, time from HIV diagnosis, sex, quality of life score and monthly income.

[2] Low= GHS 0-299 (equivalent of US$0-77), High= >GHS 300 (>US$78)

Discussion

The significant changes in depression symptoms and HRQol observed between PLWH receiving care in NACS designated HIV clinics and non-NACS HIV clinics not offering NACS between the three and six months study visits was unexpected since there was virtually no implementation of NACS in the NACS designated HIV clinics sampled throughout the course of the study. Weight and height measurements took place in both NACS designated and non-NACS HIV clinics but no nutrition counseling was provided nor was food support available on site in either group of clinics. A similar pattern was found when the NACS implementation score was used as the main independent variable. The significant changes in depression symptoms and HRQoL between the three and six month study visit period in NACS designated HIV clinics could be due to some unmeasured activities that was present in NACS designated HIV clinics but not in non-NACS HIV clinics. An example is the presence of Models of Hope in two of the three hospitals that had NACS designated HIV clinics, but only one of the hospitals with non-NACS HIV clinics. Models of Hope are peer HIV counsellors who go to certain HIV clinics to encourage their fellow PLWH to adhere to their medications and to have hope that once they stay in care, their viral loads will become and remain undetectable and they could lead a relatively normal life. These Models of Hope were present for every clinic visit in two NACS designated HIV clinics but only one non-NACS HIV clinic. Their presence could be an encouraging factor to study participants, and this could lead to them feeling less depressed. The presence of the Models of Hope could also impact HRQol through the anxiety depression domain, where there was a significant trend in more NACS participants reporting no problems with anxiety/depression over time.

The levels of depressed (CES-D ≥ 16) participants at baseline (31% NACS, 36% non-NACS) was within the range observed among PLWH in other Sub-Saharan African countries studied using the same scale (54% Uganda, 21.1% South Africa and 21.3% Nigeria) [30-32]. This indicates that interventions to reduce depression among this population in Ghana is warranted. Increasing HRQol scores and decreasing rates of depression symptoms were observed among both groups of participants over the study period, and this could be due to a number of factors such as effectiveness of the ART medications, buildup of resilience and optimism with time, and early diagnosis of HIV. Current ART medications are more potent, easier to take and have fewer side effects and will lead to undetectable viral loads in most PLWH especially when they are diagnosed earlier [33]. With Ghana adopting an opt-out strategy for testing all pregnant women for HIV, more female PLWH are being diagnosed and brought into the continuum of HIV care earlier and prioritized for ARTs. This increases their likelihood of remaining healthy without the weight loss traditionally associated with HIV/AIDS and can contribute to the high HRQol scores observed in the study. Another indication of the good health of the participants was the fact that within the five domains of the EQ-5D quality of life scale, no study participant reported having severe problems with mobility, self-care, and or performing the usual activities over the entire study period. This could be due to the inclusion criterion of being on ART for at least six months. However, the study participants mirrored the majority of PLWH we observed in the study sites who did not participate in our study in terms of visible general health. All study sites had ready and enough ART's in stock to meet the needs of their clients, and these life-saving medications were almost free of charge to PLWH. The high EQ-VAS score (81.2)

observed in this study is similar to another study conducted among PLWH on ARTs in South Africa (90) [34]. These high scores indicate a high self-reported quality of life among HIV populations and could be a manifestation of better management of the virus.

The strategy for HIV testing during pregnancy also accounts for the imbalance in the study population with 84% being women. All pregnant women in Ghana are offered HIV testing and have to opt-out if they don't want it [35]. This has led to many more women finding out their HIV status and hence the gender imbalance observed.

Another contributing factor that could help explain the low depression and high HRQol observed in this study could be the Christmas holidays and faith. Ghana, especially the southern part where this study was conducted, is majority Christian (71%) [36], and the Christmas holiday is a period of family reunion and feasting that generally is joyful. Anecdotally, some of the study participants reported feeling renewed hope that once they made it to Christmas with their HIV under control and didn't die, they had faith and hope that they will survive the coming year in spite of their HIV positive status. This mix of faith and optimism could manifest in low depression and high quality of life scores. This is in contrast to European settings where the Christmas holidays may be associated with a decrease in emotional wellbeing and mental health [37]

In conclusion, a trend of increasing HRQol and decreasing depression symptoms over time was found irrespective of whether the PLWH received care in a NACS designated HIV clinic or not. Between the three and six month study visits, there was a significant association between receiving care in a NACS designated HIV clinic and HRQol and

depression symptoms despite the fact that there was virtually no implementation of NACS in the NACS designated HIV clinics.

The health authorities will need support to improve the implementation of nutrition programs (especially provision of nutrition counseling) such as NACS. This could help retain PLWH in care and in the long run help fight against the spread of the disease. Further studies need to be done on how to simplify the message of nutrition for non-nutrition professionals such as nurses who come into the most contact with PLWH. A simplified message may improve the implementation of NACS and other nutrition programs.

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Supplementary Table 1 Repeated measures models for change in Depression symptoms over six months using binary NACS implementation score as main predictor

	From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)[1]	*p*	β (95% CI)	*p*
NACS implementation score (High vs Low)	0.07 (-1.38, 1.52)	0.92	-1.87 (-4.16, 0.42)	0.11
Time from HIV diagnosis, y	-0.10 (-0.30,0.09)	0.30	-0.14 (-0.45, 0.17)	0.37
Sex (female vs male)	0.87 (-1.09, 2.83)	0.38	1.28 (-1.86, 4.41)	0.42
Baseline depression symptom score	0.71 (0.62, 0.79)	<.0001	0.33 (0.19, 0.46)	<.0001
Monthly income (Low vs High)[2]	-0.14 (-1.74, 1.47)	0.87	-0.007 (-2.51, 2.49)	0.99

NACS, Nutrition Assessment Counseling and Support program.
[1] Adjusted for NACS status, time from HIV diagnosis, sex, baseline depression symptom score and monthly income.
[2] Low= GHS 0-299 (equivalent of US$0-77), High= >GHS 300 (>US$78)

Supplementary Table 2 Repeated measures models for change in Health-Related Quality of Life over six months follow-up in PLWH using binary NACS implementation score as main independent variable

	EQ-5D				**EQ-VAS**			
	From baseline to 3-month visit		From 3-6month study visit		From baseline to 3-month visit		From 3-6month study visit	
	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*	β (95% CI)	*p*
NACS implementation score (High vs Low)	-0.003 (-0.022, 0.015)	0.72	0.001 (-0.04, 0.04)	0.96	-0.48 (-2.87, 1.92)	0.69	1.76 (-2.80, 6.31)	0.45
Time from HIV diagnosis, y	0.0005 (-0.002, 0.003)	0.69	0.002 (-0.003, 0.006)	0.54	-0.10 (-0.43, 0.22)	0.54	-0.02 (-0.63, 0.59)	0.95
Sex (female vs male)	-0.01 (-0.04, 0.01)	0.29	-0.03 (-0.08, 0.02)	0.25	4.12 (0.87, 7.36)	0.01	3.70 (-2.59, 9.99)	0.25
Baseline EQ-5D or EQ-VAS	0.67 (0.60, 0.74)	<.0001	0.25 (0.11, 0.39)	0.0004	0.69 (0.61, 0.76)	<.0001	0.24 (0.11, 0.38)	0.0006
Monthly income (Low vs High)[2]	-0.003 (-0.02, 0.02)	0.79	0.004 (-0.04, 0.04)	0.83	-1.55 (-4.20, 1.10)	0.25	-0.77 (-5.76, 4.22)	0.76

NACS, Nutrition Assessment Counseling and Support program; EQ-5D, EuroQol Five Dimensions Questionnaire; EQ-VAS, EuroQol Five Dimensions Questionnaire Visual Analogue Scale.

[1] Adjusted for NACS status or NACS implementation score, time from HIV diagnosis, sex, quality of life score and monthly income.

[2] Low= GHS 0-299 (equivalent of US$0-77), High= >GHS 300 (>US$78)

CHAPTER 6: SUMMARY

The main objective of this thesis was to assess the implementation and impact of NACS on BMI, depression and HRQol among PLWH in Accra, Ghana.

At the end of the study we found that:

- The only nutrition assessment being offered to PLWH was BMI with no dietary, clinical or food security assessments being offered.
- In NACS designated HIV clinics, NACS was not being implemented as it should be; in particular the nutrition counseling component.
- The lack of implementation meant that there was no significant difference in NACS implementation scores between NACS designated and non-NACS HIV clinics and the NACS implementation scale was not associated with higher odds of having a normal BMI.
- Receiving care in a NACS designated HIV clinic was not associated with change in BMI over the study period.
- We found a study population with a mean BMI of 25.8 kg/m^2 with 26.5% of them overweight and 20.5% of them obese and only 3.3% underweight.
- We found an HIV population with high quality of life scores [(mean EQ-5D 0.84 out of 1) and (mean EQ-VAS 81.2 out of 100)] and relatively low levels of depression (31.2% in NACS vs 36% in non-NACS).
- We also found that over time, depression symptoms decreased and health related quality of life scores increased in both groups of participants.

- Among PLWH who received care in NACS designated HIV clinics, there was a significant decrease in depression symptoms and increase in HRQol scores between the third and sixth month study visits.
- This unexpected association could be due to the presence of peer HIV counsellors in more NACS designated than non-NACS HIV clinics or some unmeasured activity in NACS designated HIV clinics during the second half of this follow up period.

Future research directions: Further studies covering more HIV clinics in more regions are need to needed to confirm the true state of the implementation of the NACS program in Ghana. If confirmed, there needs to be more research on how to improve the implementation of the program. This could involve research into how to repackage the nutrition education messages in order to encourage more nutrition counseling. Possible interventions to achieve this could include developing simple, less complicated nutrition messages that nurses and other non-nutrition health workers could confidently and quickly use to provide basic nutrition information to help PLWH eat a healthy diet and achieve or maintain a healthy weight. It could also involve making short videos on good nutrition practices on CDs and distributing them to the HIV clinics, the majority of whom have television sets. It could also take the form of simple colorful posters explaining the concept of a nutritionally balanced diet which could be posted in HIV clinics. We could then examine whether any of these interventions alone or in combination with another would lead to a better and sustained implementation of NACS and whether a better implementation of NACS would have an impact on various health outcomes. As a follow up to this thesis, I will like to investigate the levels of overweight and obesity among

PLWH and at the same time assess the presence of risk factors for cardiovascular diseases such as type 2 diabetes, hypertension and dyslipidemia in this population.

One limitation of this thesis was the non-randomized nature of the NACS intervention and the small number of hospital sites. Another was the relatively short follow up time although we faced logistical constraints to extend the length of follow-up to a longer period. Finally loss to follow up of the cohort could have influenced the results obtained but when we assessed this, there was no difference in the rate of loss to follow up between NACS and non-NACS study participants.

This study also had several strengths. The slowdown in expansion of the NACS program made available a natural control group not exposed to it and made assessing the impact of the program possible between PLWH exposed and not exposed to the program. In addition, the prospective nature of the study with multiple measurements over time allowed us to longitudinally observe any associations if they were present.

Significance of the thesis: To the best of our knowledge, this is the first study to evaluate the implementation and impact of NACS in Ghana. The results of this dissertation provide data which the Ghana Ministry of Health could utilize to objectively assess the implementation of the NACS program. The high prevalence of overweight and obesity in PLWH in Ghana suggest future NACS programs need to incorporate nutrition support and counseling to reduce obesity and obesity-associated chronic health conditions in this population. Donor agencies such as USAID could use this study to not only assess the implementation of NACS and other nutrition assistance programs in Sub-Saharan Africa

but to find out if such programs are having the necessary impact and if modifications are needed to have the expected impact.

APPENDIX

Appendix 1 Informed Consent form for patients (version 11/09/2015)

TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Friedman School of Nutrition Science and Policy
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Evaluating the Implementation Impact and Marginal Cost-Effectiveness of NACS in the Greater Accra Region of Ghana

Principal Investigator: Dr. Christine Wanke
Co-Investigators: Joachim Sackey, Dr. Beatrice Rogers, Dr. Fang Fang Zhang,
Study team telephone number: 0245-638-917 or +1-617-636-4076

INTRODUCTION

We are inviting you to take part in a research that will assess how a programme called the Nutrition Assessment and Counseling Support programme which we will call NACS from here on is being implemented among people with HIV. We are recruiting you because you receive HIV care in a hospital. This research will also study the impact and cost-effectiveness of the NACS programme on the weight and height of people with HIV in the Greater Accra Region.
Taking part in this research study is entirely your choice. You can decide to refuse to participate in this study. If you decide to participate in this study, you can then choose to stop taking part in the study at any time for any reason. If you refuse to participate in the study or stop being in this study, it will not affect your health care benefits.

Please read all of the following information carefully. Ask Joachim Sackey, or his research assistant, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.
New things might be learned during this study that you should know about. We will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and decide to be in the study, we may still choose to stop your participation in this study if we think it is in your best medical interest.
If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

As a participant in this study, your identity and data relating to this study will be kept confidential, except as required by law.

If you have questions about your rights as a research study subject, call the Ghana Health Service Ethical Review Committee (ERC) at 0302-681109 or the Tufts Health Sciences Institutional Review Board (IRB) at +1-617-636-7512. The IRB and ERC are a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by Ghana Health Service Ethical Review Committee and the IRB of Tufts Health Sciences.

CONFLICT OF INTEREST

Under Tufts University Conflict of Interest in Research Policy, Joachim Sackey, a member of the research team, is obligated to disclose to you and to all subjects of this study that he is the recipient of a fellowship funded by Fogarty, the funding source of this study.

PURPOSE OF STUDY

This research study is being conducted because ever since NACS was introduced in the care management of people with HIV, its impact and cost-effectiveness hasn't been studied. This research will study how NACS is being implemented in 11 District hospitals in the Greater Accra Region. We will study the weight and height of patients like you who attend hospitals offering NACS services and hospitals not currently offering NACS services in 6 of the selected hospitals. We will also study how cost-effective NACS is. In total we will recruit 150 patients to participate in this research study.

PROCEDURES TO BE FOLLOWED

Before being enrolled in this study, we will screen you to make sure you are eligible to participate in this study. The screening process involves us asking you some questions about: whether you are taking HIV medications and if yes how long you have been taking them. We will also ask about your age, pregnancy and breastfeeding status (if you are a woman) and whether you are willing to participate in the study for the 6 month duration. We will take your word as the answer to these questions and won't look into your medical folder. This study will have 3 study visits spread over 6 months: 1st visit (today), 2nd visit (approximately 3 months after today's visit) and the 3rd visit (approximately 6 months after today's visit). We will contact you a week or two before your next two visits to confirm a date for your appointment with us that coincides with your routine visit to the hospital.

On each study visit, we will administer a questionnaire to you using a computer-assisted software and we will also measure your weight and height. You can choose not to answer a particular question on the questionnaire.

We may decide to sit in and observe your interaction with the nurse one time when you are being weighed and counseled. If this will be done, we will inform you ahead of time. No information will be collected from your medical record.
To participate in our study you **must** agree to have your weight and height measured; **and** to fill out the questionnaire **and** possibly have your session with the nurse observed. It will take about 15 minutes to complete the questionnaire and 5-10 minutes to measure your weight and height and so in total you may spend an average of 20-25 minutes for this research for each of 3 study visits. Your participation may also include the observation of your usual clinic interaction with the nurse of the HIV clinic which will vary in length.

RISKS
There is minimal physical risk to you if you agree to participate in this research. There is minimal risk of loss of confidentiality if you participate in this study. To prevent that risk, we will keep any paper records under lock and key and use passwords to protect any electronic data.

BENEFITS
If you agree to participate in this study, your weight and BMI or body mass index (which is calculated from your weight and height) will be provided to you at the end of each study visit if you request this from us.

Aside this you will not receive any direct benefits by participating in this research. Indirectly you will be contributing to important research whose results may be used by health authorities to improve and guide the rollout of the NACS program in other hospitals.

ALTERNATIVES

The alternative to participating in this study is to choose not to participate in the questionnaire or the observation. You will receive your standard clinic care.

RESEARCH RELATED INJURY

There are no known physical risks to participating in this study, therefore no payments for research related injury will be made.

COSTS
There are no costs to you if you decide to participate in this study.

PAYMENT
If you agree to participate in this study you will be compensated GH¢15 cash for every visit you attend to help with your transportation, up to a total of GH¢45 cash.

PRIVACY AND CONFIDENTIALITY

All questionnaires and data collection forms will be kept securely in a locked cabinet in Accra. They will also be scanned and backed up electronically together with any recruitment and reimbursement documentation in a password-protected folder on secure network drives of Tufts University.

If you agree to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it.
We will make every effort to keep your information private, but it cannot be completely guaranteed. The Institutional Review Board of Tufts Health Sciences and the Ghana Health Service Ethical Review Committee may check records that identify you to make sure we the investigators are following all rules and guidelines.

WHOM TO CONTACT
In case you have any problem or questions call Joachim Sackey on (0245-638-917 or +1-617-636-4076), Dr. Wanke on +1-617-636-3811, or Hannah Frimpong (GHS-ERC Administrator) on (0302681109 or 0243235225

Documentation of Consent
I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____

Date Participant's Signature/ Witness signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature

Appendix 2 Informed consent form for health workers (version 11-09-2015)

TUFTS MEDICAL CENTER
TUFTS UNIVERSITY
Friedman School of Nutrition Science and Policy
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Evaluating the Implementation Impact and Marginal Cost-Effectiveness of NACS in the Greater Accra Region of Ghana

Principal Investigator: Dr. Christine Wanke
Co-Investigators: Joachim Sackey, Dr. Beatrice Rogers, Dr. Fang Fang Zhang,
Study team telephone number: 0245-638-917 or +1-617-636-4076

INTRODUCTION

We are inviting you to take part in a research that will assess how a programme called the Nutrition Assessment and Counseling Support programme which we will call NACS from here on is being implemented among people with HIV. You are being invited to participate in this study because you are a health provider for patients receiving HIV care at a hospital. This research will also study the impact and cost-effectiveness of the NACS programme on the weight and height of people with HIV in the Greater Accra Region.

Taking part in this research study is entirely your choice. You can decide to refuse to participate in this study. If you decide to participate in this study, you can then choose to stop taking part in the study at any time for any reason.

Please read all of the following information carefully. Ask Joachim Sackey, or his research assistant, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

As a participant in this study, your identity and data relating to this study will be kept confidential, except as required by law.

If you have question about your rights as a research study subject, call the Ghana Health Service Ethical Review Committee (ERC) at 0302-681109 or the Tufts Health Sciences Institutional Review Board (IRB) at +1-617-636-7512. The IRB and ERC are a group of doctors, nurses, and non-medical people who review human

research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.
This research study has been reviewed and approved by Ghana Health Service Ethical Review Committee and the IRB of Tufts Health Sciences.

CONFLICT OF INTEREST
Under Tufts University Conflict of Interest in Research Policy, Joachim Sackey, a member of the research team, is obligated to disclose to you and to all subjects of this study that he is the recipient of a fellowship funded by Fogarty, the funding source of this study.

PURPOSE OF STUDY
This research study is being conducted because ever since NACS was introduced in the care and management of people with HIV, its impact and cost-effectiveness hasn't been studied. This research will study how NACS is being implemented in some District hospitals in the Greater Accra Region. We will study the weight and height of HIV patients who attend hospitals offering NACS services and hospitals not currently offering NACS services. We will also study how cost-effective NACS is. In total, we will recruit 5 HIC clinic staff per hospital (55 in total) to participate in this study.

PROCEDURES TO BE FOLLOWED
If you agree to participate in this study, we will ask you to fill out a short questionnaire using a computer-assisted software which will take about **5 minutes to complete**. We will also sit in and observe how you interact with 1-2 patients.

RISKS
There are no physical risks to you if you agree to participate in this research. We won't collect any identifying information from you and so there will be no loss of confidentiality or risks to your employment by participating in this study.

BENEFITS
There are no direct benefits to you for participating in this research. Indirectly you will be contributing information that can be used by the Ghana Health Service and donor organizations to improve and guide the rollout of the NACS program in hospitals.

ALTERNATIVES

The alternative to participating in this study is to choose not to participate in the questionnaire or the observation.

RESEARCH RELATED INJURY

There is no risk of injury if you participate in this study.

COSTS
There are no costs to you if you decide to participate in this study.

PRIVACY AND CONFIDENTIALITY

All data collection forms will be kept securely in a locked cabinet in Accra. They will also be scanned and backed up electronically to a password-protected folder on secure network drives of Tufts University.
If you agree to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it.
We will make every effort to keep your information private, but it cannot be completely guaranteed. The IRB of Tufts Health Sciences and the Ghana Health Service Ethical Review Committee may check records that identify you to make sure we the investigators are following all rules and guidelines.

WHOM TO CONTACT
In case you have any problem or questions call Joachim Sackey on (0245-638-917 or +1-617-636-4076), Dr. Wanke on +1-617-636-3811, or Hannah Frimpong (GHS-ERC Administrator) on (0302681109 or 0243235225

Documentation of Consent
I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____
Date Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____
Date Principal Investigator or Representative's Signature

Appendix 3 Questionnaire for patients (version 10-06-2015)

Study ID: Interviewer: Date: dd-mm-year

	Have you administered the informed consent form to the patient? Yes/ No (*if you haven't, administer the informed consent before screening the participant*)		
	Screening Form For Study Participants		
	Instructions: My name is ……. and I am working on a research project studying how nutrition assessment and counseling can impact the weight and height of people with HIV. Participating in this study is entirely voluntary and your refusal to participate now or decision to drop out of the study later will have no consequences on the care you receive in the hospital. This study involves me asking you some questions and also taking your weight and height today, 3 months and 6 months later. If you think you may be interested in participating in this study I will like to ask you some questions to find out if you are eligible.		
	Interviewer:		
1	Name of hospital:	Code:	
2	Are you taking HIV drugs now? (*if no, participant isn't eligible for this study*) What is the name of the drug(s):	Yes:	No:
3	If yes how long have you been taking the HIV drugs? (*if less than 6 months, participant isn't eligible for this study*)		
4	Are you between 18 and 65 years? (*if no, participant isn't eligible for this study*)	Yes:	No:
5	If female, are you pregnant or breastfeeding? (*if yes to either, participant isn't eligible for this study*)	Yes:	No:
6	This study will take 6 months to complete, and you will need to come back for see us 3 and 6 months from now: Are you willing to do this? (*if no, participant isn't eligible for this study*)	Yes:	No:
If participant is eligible to participate and is willing to participate in the study, assign a unique study ID number from list below .			
7	Date of enrollment:		
8.	Unique ID number:		

	Contact Information (*This contact information sheet should be stored in a* ***locked cabinet separate*** *from other study materials*)
	Instructions for participant: I will now ask you for some information that will allow us to contact you to remind you of follow-up visits. Your information will be kept private and confidential.
1	Last name:
2	First name:
3	Mobile phone number(s)
4.	Unique ID number:

Study ID: Interviewer: Date: dd-mm-year

Participant Demographics and Anthropometry			
Instructions for participant: I will now ask for some information about you and your socioeconomic status to help us understand who you are. Remember that all information provided will be kept private and confidential.			
Demographics			
Visit number: Baseline___ 3-month___ 6-month___			
1	Age in years: ___		
2	What is your marital status	Married	1
		Single	2
		Separated/Divorced	3
		Widowed	4
3	What is your highest level of education (completed?)	None	1
		Primary	2
		Junior/Senior High School (JHS/SHS)	3
		Polytechnic	4
		University	5
4	How many people are in your household (how many people share a pot of food daily)		
5	Of the people in your household, how many of them are above 18 years?		
		Number	
Socioeconomic Status			
6	Are you the main breadwinner of your household?	Yes	
		No	
7	What is your employment status?	Unemployed	1
		Self-employed	2
		Employed by someone else	3
8	What is an estimate of your monthly income?	0-299 GH Cedi	1
		300-599 GH Cedi	2
		600-999 GH Cedi	3
		1000-2000 GH Cedi	4
		More than 2000 GH Cedi	5
9	How long does it take you to get to the hospital from your house by your usual mode of transportation?		
Anthropometry			
10	Height (cm):		
11	Weight (kg):		

Study ID: Interviewer: Date: dd-mm-year

	Medical History and Health Habits		
	Instructions for participant: I will now ask for some information about your medical history and use of drugs and alcohol. Remember that all information provided will be kept private and confidential.		
1	How long have you been diagnosed with HIV:		
2	Have you disclosed your HIV status to your immediate family?	Yes:	No:
3	Has a doctor ever diagnosed you with Tuberculosis (TB)?	Yes:	No:
4	Has a doctor ever diagnosed you with Pneumonia?	Yes:	No:
5	During the past 12 months, how often did you have any alcoholic drink?	Every day	1
		5-6 times a week	2
		3-4 times a week	3
		Twice a week	4
		Once a week	5
		2-3 times a month	6
		Once a month	7
		3-11 times last year	8
		1-2 times last year	9
		Never	10
6	Do you smoke cigarettes now?	Yes	No
7	If yes to Q6, have you smoked at least 100 cigarette sticks in your entire life?	Yes	No
8	Have you ever used drugs like marijuana, cocaine or heroin?	Yes:	No:
9	If yes to Q8, are you currently using these drugs and which one?	Yes:	No:

Study ID: Interviewer: Date: dd-mm-year

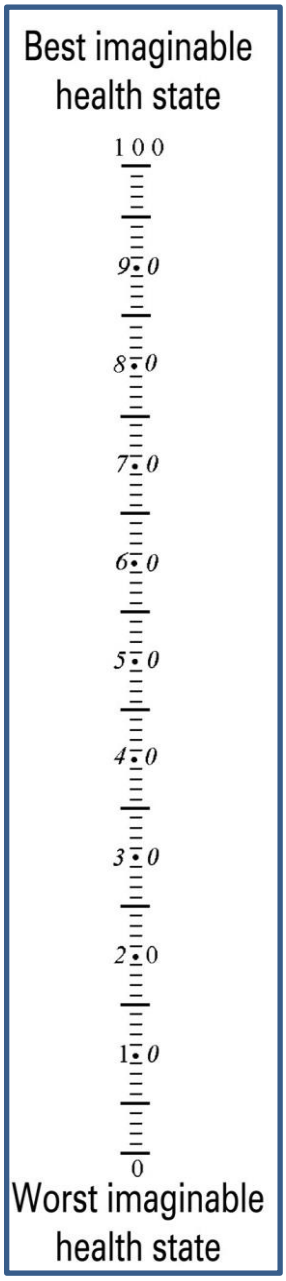
Center for Epidemiologic Studies Depression Scale (CES-D)						
Instructions: Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past **week**						
Visit: Baseline_____ 3 month _____ 6 month_____						
	Place a check mark in the appropriate column. **During the past week….**	Rarely or none of the time (<1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)	Score
1.	I was bothered by things that usually don't bother me	0	1	2	3	
2.	I did not feel like eating; my appetite was poor	0	1	2	3	
3.	I felt that I could not shake off depression even with help from my family or friends.	0	1	2	3	
4.	I felt that I was just as good as other people	0	1	2	3	
5.	I had trouble keeping my mind on what I was doing	0	1	2	3	
6.	I felt depressed	0	1	2	3	
7.	I felt that everything I did was an effort	0	1	2	3	
8.	I felt hopeful about the future	0	1	2	3	
9.	I thought my life had been a failure	0	1	2	3	
10.	I felt fearful	0	1	2	3	
11.	My sleep was restless	0	1	2	3	
12.	I was happy	0	1	2	3	
13.	I talked less than usual	0	1	2	3	
14.	I felt lonely	0	1	2	3	
15.	People were unfriendly	0	1	2	3	
16.	I enjoyed life	0	1	2	3	
17.	I had crying episodes	0	1	2	3	
18.	I felt sad	0	1	2	3	
19.	I felt people disliked me	0	1	2	3	
20.	I could not motivate myself to start things I had to do	0	1	2	3	

Study ID: Interviewer: Date: dd-mm-year

Household Dietary Diversity Scale (HDDS)		
Instructions to interviewer: Read the list of foods. Place a one in the box if anyone in the household ate the food in question, place a zero in the box if no one in the household ate the food **Instructions to respondent**: Now I would like to ask you about the types of foods that you or anyone else in your household ate yesterday during the day and at night.		
Visit: Baseline_____ 3 month _____ 6 month_____		
1	Any food made from millet, maize, rice or wheat like (bread, rice, kenkey, banku, porridge, omotuo, tuo-zaafi, spaghetti, boflot)	No= 0 Yes= 1
2	Any food made from roots or tubers like (gari, fufu, yam, cocoyam, kokonte, sweet potatoes)	No= 0 Yes= 1
3	Any vegetables like (tomatoes, kontomire, aleefu, onions, cabbage, lettuce, okro, garden eggs)	No= 0 Yes= 1
4	Any fruits like (orange, banana, mango, watermelon, apples, tangerine)	No= 0 Yes= 1
5	Any beef, pork, lamb, goat, chicken, liver, kidney, heart, or other organ meats?	No= 0 Yes= 1
6	Any eggs?	No= 0 Yes= 1
7	Any fresh or dried fish or shellfish?	No= 0 Yes= 1
8	Any foods made from beans or nuts like (beans, koose, groundnut soup, groundnut paste, boiled or roasted groundnuts, cashew)	No= 0 Yes= 1
9	Any cheese, yogurt, milk or other milk products?	No= 0 Yes= 1
10	Any foods made with oil, fat, or butter like (palm oil, frytol, soybean oil, any fried food)	No= 0 Yes= 1
11	Any sugar or honey?	No= 0 Yes= 1
12	Any other foods, such as condiments like maggi, salt, coffee, tea?	No= 0 Yes= 1

Study ID: Interviewer: Date: dd-mm-year

EQ-5D (Quality of Life Survey)			
Instructions: You will have 3 options to answer each of the following 5 questions. Please select the best answer that describes your situation.			
Visit: Baseline_____ 3 month _____ 6 month_____			
1	Mobility	I have no problems walking about	
		I have some problems walking about	
		I am confined to the bed	
2	Self-care	I have no problems taking care of myself eg (bathing or dressing myself up with self-care	
		I have some problems bathing or dressing up myself	
		I am not able to bath or dress up myself	
3	Usual activities	I have no problems performing my usual activities like household chores or work	
		I have some problems performing my usual activities	
		I am not able to perform my usual activities	
4	Pain-discomfort	I have no pain or discomfort	
		I have moderate pain or discomfort	
		I have extreme pain or discomfort	
5	Anxiety-Depression	I am not anxious or depressed	
		I am moderately anxious or depressed	
		I am extremely anxious or depressed	



Instructions for respondent: On the vertical scale to the right of this table, please score how good or bad your own health is **today** by placing an (X) on the point of the scale that best describes how you rate your health.
Zero marks the worst imaginable health state you can imagine and ten marks the best imaginable health state.