

# Supplementary feeding in the care of the wasted HIV infected patient

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## Abstract

Wasting and food insecurity are commonly seen in patients receiving antiretroviral treatment (ART) programs in sub-Saharan Africa and south Asia, and supplementary feeding is often offered in conjunction with ART. Evidence for the effectiveness of such supplementary feeding is scant. A randomised, investigator-blinded, controlled clinical trial of two types of supplementary food, corn/soy blended flour and a ready-to-use peanut butter-based lipid paste, in wasted adults in Blantyre, Malawi is described and the results summarised. A historical control group who did not receive supplementary food is described as well. Provision of about half of the daily energy requirement as a supplementary food for 14 weeks resulted in more rapid restoration of a normal BMI; and the energy-dense, ready-to-use paste was associated with more rapid weight gain than the blended flour. Survival was similar among the 3 groups. The strong association between lower BMI and survival indirectly suggests that there may well be clinical benefit from supplementary feeding in this population. No differences were seen in ART adherence or quality of life with more rapid restoration of BMI. Further research is urgently needed concerning the widespread practice of supplementary feeding in HIV/AIDS care to most effectively utilize this intervention.

## Wasting and the supplementary food commonly used in ART care

The prevalence of wasting, defined as a body mass index (BMI) <18.5 kg/m<sup>2</sup> in adults, in patients with advanced HIV infection in sub-Saharan Africa is 20-40%.<sup>1,2</sup> Wasting can be the result of inadequate nutrient intake, either from anorexia or food insecurity associated with poverty, a catabolic state induced by opportunistic infection or malignancy, or poor absorption of nutrients secondary to diarrhea and malabsorption. Because food insecurity is common in sub-Saharan Africa,<sup>3,4,5</sup> and an adequate diet is believed to be important for adherence with antiretroviral therapy (ART),<sup>6,7</sup> supplementary feeding in conjunction with ART is advocated as the standard of care in the treatment of wasted HIV infected adults in many settings in sub-Saharan Africa. In addition, mortality during the first months of ART in sub-Saharan African settings is very high and a low BMI is an independent risk factor for this early mortality.<sup>8</sup> Supplementary feeding may therefore be seen as an intervention to improve outcomes of patients on ART because it ameliorates food insecurity. However, evidence to support the effectiveness of this practice is limited.<sup>9</sup>

## Supplementary foods

The most commonly available supplementary food in food aid programs is corn-soy blend (CSB), an inexpensive, fortified cereal legume combination that has been widely used in Africa for decades. However, CSB has been associated with disappointing results in supplementary feeding programs among children, pregnant women and HIV infected adults in sub-Saharan Africa.<sup>10,11</sup> In a study in urban Malawi among adults with late stage HIV infection and not receiving ART, CSB had no effect on mortality nor on

clinical complications<sup>12</sup>. Specialized, energy-dense ready-to-use fortified spreads (RUFs) have also been recommended for feeding wasted HIV infected adults. RUFs is a pre-cooked, energy dense, lipid paste made from peanuts that resists bacterial contamination<sup>13</sup>. A fortified spread has been formulated to deliver the same nutrients as the therapeutic food F-100 for severely malnourished children and its use has been associated with better outcomes in therapeutic and supplementary feeding of malnourished children with and without HIV<sup>14,15</sup>.

## Supplementary feeding trial among HIV infected adults in Malawi

Given the widespread practice of supplementary feeding among wasted HIV infected adults and the vociferous attestations of the importance of supplementary feeding by AIDS advocacy groups, we conducted a randomized controlled trial in Blantyre, Malawi to test the hypothesis that among wasted, non-pregnant adult Malawians starting antiretroviral therapy (ART), patients who receive food supplementation with ready-to-use fortified spread (RUFs) for 14 weeks will have a greater increase in body mass index (BMI) and fat-free body mass than those receiving corn/soy blend (CSB).<sup>16,17</sup> All patients received free nevirapine, lamivudine and stavudine. The investigators were blinded in this trial, which was conducted at large, public ART clinic at Queen Elizabeth Central Hospital, Blantyre. Subjects were followed for 9 subsequent months after completion of the supplementary feeding to assess the longer term effects of the intervention. The primary outcomes were changes in BMI and the fat-free body mass after 14 weeks, while the secondary outcomes were survival, CD4 count, HIV viral load, quality of life and ART adherence. The original study design included an additional group of subjects who would not receive supplementary feeding, but the ethical review panel asked that this group be removed from the study as the standard of care in Malawi was to offer supplementary feeding to wasted adults.

## Trial results

491 adults with BMI < 18.5 kg/m<sup>2</sup> initiating ART participated in the study, 245 receiving RUFs and 246 receiving CSB. The mean enrollment BMI was 16.5 kg/m<sup>2</sup>. After 14 weeks, patients receiving RUFs had a greater increase in BMI and fat-free body mass than those receiving CSB (Table). The mortality rate was 27% for those receiving RUFs and 26% for those receiving CSB. No significant differences in the CD4 count, HIV viral load, quality of life assessment or ART adherence were noted between the two groups during the 14 weeks of supplementary feeding. Twelve weeks after supplementary feeding stopped, 26 weeks after ART was initiated, there were no differences in anthropometric, immunologic, quality of life, ART adherence or clinical characteristics between the two groups of subjects.

## Historical comparison to similar patients who did not receive supplementary feeding

To determine how the outcomes seen in the randomized, controlled trial might compare with outcomes in programs where supplementary food was not given, we compared the trial results with a historical control group receiving no

food supplement that was part of an observational cohort study of outcomes of the same ART regimen in the same clinic one year prior to the supplementary feeding trial<sup>18</sup>. Characteristics on initiation of ART were similar in the three groups, except cotrimoxazole prophylaxis was used more frequently in the food-supplemented groups. The increase in BMI, controlled for differences between the study populations by linear regression, after 14 weeks of supplementary feeding was superior among those receiving RUFs compared to those receiving CSB and CSB users in turn had greater BMI increase than those receiving no supplementary food. Differences in BMI were no longer significant 26 weeks after starting ART. Logistic regression analysis indicated that supplementary food use was not directly associated with improved survival.

### Comparison of our results to other published trials

In spite of the fact that supplementary feeding in HIV treatment programs is a common activity costing literally millions of dollars annually in sub-Saharan Africa, there is a paucity of trials assessing its effectiveness in resource-constrained settings<sup>3</sup>. One trial from Zambia assessed ART adherence among HIV infected patients who received CSB or no food ration, and found that adherence was better among those that received supplementary food<sup>7</sup>. No other controlled trials could be found searching the trial registries or medical literature databases.

### Programmatic and cost considerations of supplementary feeding

The CSB provided in our study cost \$5.4/patient/month, while RUFs was three times as expensive at \$16/patient/month. The Malawian government obtains the first line ART regimen for \$15/patient/month. About one-third of all adults initiating ART in Blantyre are wasted, and provision of supplementary food would be indicated among these individuals. While it was not possible to determine the complete cost of administering ART in Blantyre, the cost of supplementary food is a significant component of this program.

### Conclusions and Future Considerations

It seems clear that supplementary feeding of any type does result in more rapid gain in BMI, and the more energy dense the supplementary food, the more rapid gain in BMI is seen in Blantyre, Malawi. These studies were not powered such that they could detect modest differences in clinical outcomes such as survival, however in both data sets BMI was the strongest predictor of death. Therefore we can speculate that there is a clinical benefit for those individuals who rapidly gain BMI. However, the improvement in survival from supplementary feeding of any type is likely to be < 3%. Quality of life and ART adherence are not better with more rapid gain in BMI.

These studies were not conducted in other settings, such as rural clinics in Africa, better resourced settings such as are seen in South Africa or in Asia, so care must be exercised extrapolating the results to such settings. These studies were not conducted in children, although the large body of evidence that we have comparing blended flours with ready-to-use foods in malnourished children suggests that the RUFs would also be associated with more rapid weight gain in children. Lipid pastes harbor fewer bacteria than water-based porridges and liquid foods; and these hygienic

properties of RUFs are probably more important for children than adults. More research is needed in a variety of settings to understand how to maximize the beneficial effects of supplementary feeding at the lowest cost, since the cost of supplementary food in ART programs is substantial and resources for ART in sub-Saharan may well be subject to even greater constraints in the future.

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## **HIV LEADERSHIP FELLOWSHIP PROGRAM**

The College of Medicine (Community Health Division), in collaboration with the Ministry of Health (MOH) with support from the US Centres for Disease Control and Prevention (CDC), is introducing and implementing an innovative HIV/AIDS leadership and management

Fellowship Program to address challenges inherent in the provision of comprehensive and integrated HIV prevention, care, treatment and support services in Malawi.

The fellowship program gets its policy direction from the National Steering Committee (NSC). The goal of the fellowship program is to build management and leadership capacity in order to support the expansion of national efforts in HIV prevention, treatment, care and support.

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