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A PILOT RANDOMIZED TRIAL OF NUTRITIONAL SUPPLEMENTATION IN FOOD INSECURE PATIENTS RECEIVING ANTIRETROVIRAL THERAPY (ART) IN ZAMBIA

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BACKGROUND: In many parts of sub-Saharan Africa, where the need for ART is most urgent, there is also widespread hunger. Whether food supplementation can improve clinical and adherence outcomes of food insecure populations on ART has been widely debated, but not yet tested.

METHODS: In the context of a home-based adherence support program attached to 8 government clinics in Lusaka, we randomly assigned 4 clinics to provide a monthly household food ration (micronutrient-fortified corn-soya blend, from World Food Programme) to food insecure patients starting ART; 4 clinics served as controls. Weight and CD4+ change were measured at 6 and 12 months. Adherence was assessed by timeliness of pharmacy visits.

RESULTS: At baseline, the median age, BMI, CD4+ count, WHO stage, hemoglobin, or gender distribution did not differ significantly between 375 food recipients versus 161 non-recipients. For those receiving food, median number of rations received was 9 (IQR: 6-10); median time between starting ART and first ration was 70 days (IQR: 44-125). We observed negligible differences in weight gain (kg) at 6 months (+5.6 vs. +5.0; p=0.48) and 12 months (+6.2 vs. +5.5; p=0.44) between food recipients and non-recipients. However, food recipients had a substantially greater increase in CD4+ count at 12 months than did non-recipients (+185 vs. +113; p=0.017). The mean number of days late for pharmacy visits per month was lower among food recipients versus non-recipients (2.4 vs. 3.4; p=0.008). Both the CD4+ and adherence findings remained statistically significant in multivariate analyses adjusting for sex, WHO Stage, and BMI at entry.

CONCLUSIONS: In this pilot study, a monthly household food ration for food insecure patients commencing ART improved adherence by 40% and resulted in a better CD4+ response at 12 months of therapy. Further study is warranted of food supplementation as an adjunct to ART in food insecure patients.

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