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Title: Effect of ready-to-use-therapeutic food supplementation on the nutritional status, mortality and morbidity of children 6 to 60 months in Niger: a cluster randomized trial

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Background: Ready-to-use-therapeutic foods (RUTF) are becoming an important component of the effective outpatient treatment of severe wasting. Their utility for prevention of wasting, however, has not been evaluated. Further, some findings of adverse health effects due to iron and folic acid supplementation suggest that iron supplementation in settings where the prevalence of malaria and other infectious diseases is high should be proceeded with cautiously. We evaluate the effect of a 3-month preventative supplementary feeding using RUTF on the nutritional status, mortality and morbidity of children 6 to 60 months.

Methods: A cluster randomized trial of 12 villages in Maradi, Niger. Six villages were randomized to intervention and 6 to no intervention. Villages were visited monthly from August 2006 to March 2007. All children in the study villages between 6 and 60 mo of age were eligible for recruitment. The monthly distribution consisted of one packet per day of RUTF (PlumpyNut®, 500kcal/day) to each eligible child with weight-for-height ³ 80% of the NCHS reference median from August to October 2006. Our main outcome was change in weight-for-height Z (WHZ) score according to the WHO Standards and incidence of wasting (WHZ < -2) over 8 months of follow up.

Results: The adjusted overall effect of the intervention on WHZ change was 0.18 Z (95% CI: 0.09, 0.27) over 8 mo. This effect was strongest in children 24 mo or younger at baseline. The intervention resulted in a 36% (95% CI: 20% - 49%) reduction in the incidence of wasting and a 57% (95% CI: 43% - 68%) reduction in the incidence of severe wasting. There was no evidence of increased risk of malaria associated with RUTF supplementation. There was a non-significant 49% reduction in mortality associated with the intervention.

Conclusions: In a setting of acute food insecurity, short-term preventative supplementation with RUTF reduced the decline in WHZ and incidence of wasting and severe wasting. This study suggests that this product fortified with 11.5 mg of iron/100g did not aggravate malaria but further research is needed.

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