

A Randomized Trial of Iron-Biofortified Pearl Millet-Based Complementary Feeding in Children Aged 12 to 18 Months Living in Urban Slums in India

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Objectives: To determine the efficacy of iron-biofortified pearl millet (FePM, Dhanashakti, ICTP-8203Fe)-based complementary feeding on iron status and growth, in children living in urban slums of Mumbai, India.

Methods: This randomized controlled feeding trial of FePM was conducted among 223 children aged 12 to 18 months who were not severely anemic (hemoglobin (Hb) ≥ 9.0 g/dL) (Clinicaltrials.gov ID: NCT02233764). Children were randomized to receive either complementary foods prepared from FePM or conventional non-biofortified pearl millet (CPM) daily for 9 months. Iron status (Hb,

serum ferritin (SF)), and anthropometric indicators (i.e., length, weight, head, mid-upper arm circumferences, triceps and subscapular skinfolds) were evaluated at enrollment and throughout the trial. World Health Organization (WHO) anthropometric Z-scores were calculated using WHO growth standards. Primary outcomes were Hb and SF concentrations, and growth, defined as WHO Z-scores. An intent to treat approach was used for analyses. We used the Hodges–Lehmann–Sen test to assess the change in primary outcomes between baseline and the last visit and report corresponding 95% confidence intervals.

Results: At baseline, 67.7% of children were anemic (Hb < 11.0 g/dL) and 59.6% were iron-deficient (SF < 12.0 $\mu\text{g/L}$). FePM did not significantly increase iron biomarkers or improve growth, compared to CPM. In subgroup analyses, FePM improved hemoglobin concentrations in male children, and in children with iron deficiency or iron depletion (SF < 25.0 $\mu\text{g/L}$) at baseline, compared to CPM.

Conclusions: Daily consumption of FePM-based complementary foods did not significantly improve iron status or growth in children living in this population. However, the intervention significantly improved hemoglobin concentrations among male children and individuals who were iron-deficient or iron-depleted at baseline.

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