Proceedings of the Nutrition Society (2023), **82 (OCE5)**, E280 doi:10.1017/S0029665123003798

Summer Conference 2023, 3–6 July 2023, Nutrition at key stages of the lifecycle

Impact of consuming zinc-biofortified wheat flour on the growth and morbidity status of children aged 1–5 years: a cluster-randomised, double-blind, controlled trial

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This abstract was presented as the Nutrition and optimum life course Theme highlight.

Wheat biofortification through conventional breeding and/or agronomic methods to increase zinc content may be a promising strategy for addressing zinc deficiency [(1)]. However, evidence on the effectiveness of zinc biofortification interventions on health outcomes are lacking. The aim of the present study was to assess the effectiveness of consuming zinc-biofortified wheat flour (Zincol-2016) on growth and zinc-related morbidity among children (aged 1–5 years), living in a rural community in northwest Pakistan.

Households (N = 486) with at least one adolescent girl aged 10–16 years and one child aged 1–5 years (N = 517) near Peshawar were recruited to a double-blind, cluster-randomised controlled trial (BiZiFED2 RCT)[(2,3)]. During phase 1 of the trial (November 2019 to September 2020), households were provided with locally procured flour from standard wheat varieties (control) to establish a baseline. During phase 2 (September 2020 to March 2021), households received either zinc-biofortified flour or control flour. Anthropometric measurements were collected at the beginning, middle and end of phase 2[(2)]. Data pertaining to incidence and duration of respiratory tract infection (RTI) and diarrhea in the preceding two weeks were collected fortnightly. Analysis was performed using linear mixed models for continuous variables adjusted for baseline, and Pearson's chi-square test for categorical variables.

No significant effect of the intervention was observed on linear growth (height: control 2.3 ± 1.32 cm vs intervention 2.2 ± 1.41 cm; height-for-age Z scores: control -0.21 ± 0.35 vs intervention -0.21 ± 0.38) and weight gain (control 1.7 ± 1.16 kgs vs intervention 1.5 ± 0.98 kgs; weight-for-age Z scores: control 0.39 ± 0.60 vs intervention 0.29 ± 0.54). Caregiver-reported incidence of RTIs were not significantly different for the two study arms between the baseline and midpoint, but towards the end of the trial a lower incidence of RTIs was reported in the intervention arm compared to the control arm (week 26: control 34.7% vs intervention 17.6%, p = 0.036). However, when the longitudinal prevalence of RTI (cumulative days of sickness as a percentage of total days of observations) was considered, no treatment effects were observed (mid-point: control 16.5% [95% CI: 14.1, 18.9] vs intervention 14.8% [95% CI:12.5, 17.2]; endline: control 14.0% [95% CI: 11.5, 16.4] vs intervention 12.2% [95% CI: 9.9, 14.5]). No intervention effects were reported either on the incidence of diarrhea or its longitudinal prevalence (mid-point: control 4.7% [95% CI: 3.2, 6.1] vs intervention 4.9% [95% CI: 3.5, 6.2]; endline: control 3.2% [95% CI: 2.1, 4.3] vs intervention 2.9% [95% CI: 1.6, 4.2]).

Provision of zinc-biofortified wheat flour for 25 weeks did not have a significant effect on growth or morbidity status of children. Longer term interventions are warranted to monitor changes in functional outcomes in response to the ongoing national scale-up of the release of zinc-biofortified wheat varieties.

Acknowledgments

This work is supported by BBSRC Global Challenges Research Fund, Grant Number BB/S013989/1. The authors sincerely thank all the study participants and community members involved in the study. We are grateful to the nutritionists, research assistants and community health workers for their concerted endeavors. We extend our gratitude to the Abaseen Foundation Pakistan for providing facilities and enabling access to the community. We acknowledge the efforts of Helen Bingley, Abaseen Foundation UK for meticulous financial management.

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