Randomized Controlled Trial

Am J Clin Nutr

. 2017 Mar;105(3):746-757.

 doi: 10.3945/ajcn.115.127555. Epub 2017 Jan 18.

# Efficacy of iron-supplement bars to reduce anemia in urban Indian women: a cluster-randomized controlled trial

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* PMID: **28100507**

* DOI: [10.3945/ajcn.115.127555](https://doi.org/10.3945/ajcn.115.127555)

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## Abstract

**Background:** India's high prevalence of iron-deficiency anemia has largely been attributed to the local diet consisting of nonheme iron, which has lower absorption than that of heme iron.**Objective:** We assessed the efficacy of the consumption of iron-supplement bars in raising hemoglobin concentrations and hematocrit percentages in anemic (hemoglobin concentration <12 g/dL) Indian women of reproductive age.**Design:** The Let's be Well Red study was a 90-d, pair-matched, cluster-randomized controlled trial. A total of 361 nonpregnant women (age 18-35 y) were recruited from 10 sites within Mumbai and Navi Mumbai, India. All participants received anemia education and a complete blood count (CBC). Random assignment of anemic participants to intervention and control arms occurred within 5 matched site-pairs. Intervention participants received 1 iron-supplement bar (containing 14 mg Fe)/d for 90 d, whereas control subjects received nothing. CBC tests were given at days 15, 45, and 90. Primary outcomes were 90-d changes from baseline in hemoglobin concentrations and hematocrit percentages. Linear mixed models and generalized estimating equations were used to model continuous and binary outcomes, respectively.**Results:** Of 179 anemic participants, 136 (76.0%) completed all follow-up assessments (65 intervention and 71 control participants). Baseline characteristics were comparable by arm. Mean hemoglobin and hematocrit increases after 90 d were greater for intervention than for control participants [1.4 g/dL (95% CI: 1.3, 1.6 g/dL) and 2.7% (95% CI: 2.2%, 3.2%), respectively]. The anemia prevalence at 90 d was lower for intervention (29.2%) than for control participants (98.6%) (OR: 0.007; 95% CI: 0.001, 0.04).**Conclusions:** The daily consumption of an iron-supplement bar leads to increased hemoglobin concentrations and hematocrit percentages and to a lower anemia prevalence in the target population with no reported side effects. This intervention is an attractive option to combat anemia in India. This trial was registered at clinicaltrials.gov as [NCT02032615](http://clinicaltrials.gov/show/NCT02032615).

**Keywords:**Indian diet; Let’s be Well Red; hematocrit; hemoglobin; iron-deficiency anemia; iron-supplement bar; women.