

Attenuating the Micronutrient Malnutrition of Over-Nutrition.

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Synopsis:

In collaboration with the U.S. Department of Agriculture, we have developed a unique, palatable and inexpensive dietary supplement -- the CHORI-Bar -- which has been formulated to treat the micronutrient malnutrition associated with caloric overnutrition. The CHORI-Bar is formulated with vitamins, minerals, and other nutrients such as omega-3 fatty acids and choline, in a whole food, high fiber matrix. We hypothesize that this bar will correct micronutrient deficiencies in obese adults, improve insulin sensitivity, attenuate indices of the MetS, decrease DNA damage, and possibly promote weight loss. We propose to conduct a 6 month pilot study in obese adults with MetS to test the efficacy of eating this bar twice a day. The CHORI-bar will not only provide micronutrients and fiber, but, taken as a morning and afternoon snack, may have the dual purpose of helping to distribute caloric intake over the course of the day, which has been shown to be associated with a lower risk of obesity^{37,38}. If the proposed pilot study is successful, results will provide the basis for the design of a larger randomized controlled trial.

PHASE 1 AIM:

To characterize the effect size on lipid profile, indices of inflammation, insulin resistance, total plasma antioxidant capacity, micronutrient levels, hunger and satiety, BMI, waist circumference, and blood pressure with a new fruit blend CHORI-bar taken twice daily for 2 weeks in 6 healthy normal weight adult volunteers and to compare these results with a previous informal 2 week trial of a 100% blueberry-based bar in the same 6 adults.

PHASE 2 AIM:

If the effects measured in Ph 1 approximate the changes previously observed, then to characterize the effect size on indices of inflammation, insulin resistance, total plasma antioxidant capacity, micronutrient levels, hunger and satiety, BMI, waist circumference, and blood pressure with the new fruit blend CHORI-bar taken twice daily for 4 weeks in 6 overweight adult volunteers and any adolescent children of participating adults. If the new fruit blend bar does not yield comparable changes to those previously observed in normal weight, healthy adults, Phase 2 will use the original 100% blueberry-based bar.

PHASE 3 AIM:

To evaluate the efficacy of the bar with maximum efficacy selected from the Phase 1 & 2 preliminary studies in a sample of 30 overweight adolescents, randomized to bid CHORI -bars or a placebo pill for 3 mos.

- a) Characterize the physical (BMI, waist circumference, blood pressure), metabolic (glucose and insulin homeostasis, inflammatory indices, micronutrient levels, and hunger and satiety hormones), and behavioral (diet and activity by questionnaire) status in a consecutive cohort of 30 obese adolescents.
- b) Evaluate the effect of the CHORI-bar vs. placebo above and beyond the effect of standard of care lifestyle counseling for weight management on all study measures, the primary out come being insulin resistance.

In all three phases, we will also evaluate novel exploratory assays for gut inflammation, redox status, tissue metals, and DNA integrity, that may serve as markers for micronutrient malnutrition and chronic disease risk.