



Nutritional Research Series Volume 6: Concordance Between the Findings of Epidemiological Studies and Randomized Trials in Nutrition: An Empirical Evaluation and Citation Analysis: Technical Review 17

By U. S. Department of Health and Human Services

Createspace. Paperback. Book Condition: New. This item is printed on demand. Paperback. 64 pages. Dimensions: 11.0in. x 8.5in. x 0.1in. Many randomized controlled trials (RCTs) comparing nutrient interventions with placebo control have failed to replicate the (usually protective) associations between nutrients and risk of chronic disease found in large-scale observational data. High-profile examples of such RCTs found no evidence of intervention effects for fiber and colon cancer, vitamin E and cardiovascular disease, vitamin E and lung cancer, beta-carotene and coronary events, vitamin C and cardiovascular disease, or folate and cardiovascular disease, and even identified adverse effects of nutrient supplementation (e. g. , beta-carotene and cancer). The discrepancies between the findings of RCTs and epidemiological studies raised serious questions about the currently used approach for determining whether the evidence base is adequate to justify launching a large-scale RCT, with hard endpoints as the outcome measure. Deciding which specific nutrient-outcome association to further evaluate in human intervention trials is challenging. Simply having a plausible epidemiological support is probably not enough; all aforementioned negative large RCTs were motivated by hypotheses vetted in epidemiological data or in smaller RCTs examining surrogate outcomes. In previous work we

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