# Introduction: Nutritional Supplements and the Quest to Improve Human Performance—the Need for the Strictest Standards and Rigor When Reporting Clinical Trials

Inherent in the concept of nutrient supplementation is that a deficiency exists. The addition of the specific nutrient, or combination of nutrients, addresses a deficiency so that human performance is normalized or even enhanced. The quest to improve mental and physical performance, even in the absence of a recognizable or diagnosable deficiency, is as old as mankind. In the hieroglyphic records of the Ptolemaic Dynasty, evidence exists of a pharaoh specifically eating grapes in the belief that this would enhance his performance.[1] Similar evidence comes from the Greeks who ate a variety of different foods to enhance their performance during the early Olympics.

A glance at the shelves of present-day drugstores, chemists, convenience stores, and supermarkets attests to the strong societal acceptance of nutritional supplements of every type. The thriving health food industry and the constant subliminal or overt reinforcement of this message by the media further underscore the conventional wisdom that supplementing one's diet with compounds, ranging from vitamins to herbs to single macronutrients, provides the consumer with a performance advantage, in addition to generating a billion dollar market. However, because the oral ingestion of these products is classified as a "food" and not a drug, the U.S. Food and Drug Administration does not require efficacy data to supplement the manufacturers' often exaggerated claims. The enticing claims of these products, the sheer number of similar products, and the desire for immortality, enhanced performance, and prevention of the onset of terrifying diseases not only entice the gullible consumer but also bewilder them as to their choice of products. This is not helped by the extensive range of books and articles in the popular press and programs on television. Many of these are an outlet for personal prejudices or "hobby horses," or even worse—for the financial gain of the author, rather than for presentation of a balanced opinion, based on the best evidence available, to assist the public in reaching informed decisions.

In this climate, a scientific paper, particularly one based on randomized prospective studies, that claims an advantage of a compound is a welcome endorsement for a widely marketed nonprescription product. *Nutrition*, like other journals, in keeping with its mission of providing scientific evidence to its readers, has published in good faith such papers, which support or refute the efficacy of a tested supplement. Such a single-author paper was recently published[2] and attracted attention from the media[3] and intense scrutiny from the scientific and medical communities, thereby becoming quite controversial[4,5]

We follow this Review with a Letters to the Editor section. In the first letter, the personal viewpoints about the paper published in *Nutrition*[2] and a related study previously published in the *Lancet*[6] are expressed.

Dr. Chandra's response to the viewpoints is also provided. It is with regret that we feel this response of the author, despite repeated requests from others and us, has failed to address the specific issues that have been raised and that are discussed in the correspondence section. Nor has the author provided the raw data requested by Professor Carpenter, a peer who wanted to enable the statistics to be checked.

As a journal, we regret that our peer review process failed to identify these problems before publication. While the CONSORT guidelines were not introduced until 1996 and subsequently revised in 2001, this episode confirms our impression that in all fields, but especially those where there is controversy, the strictest standards of rigor in reporting clinical trials should be adopted. Sufficient details of study design, drop-outs, methodology, and statistical methods must be given to allow the study to be fully evaluated and to be repeated elsewhere. After all, the public uncritically believes the claims emanating from such studies, and fellow scientists and funding agencies divert precious resources to attempt to reproduce or verify published data. In future, this journal will expect authors to report their clinical trials according to the CONSORT guidelines.[10]

In an effort to obtain guidance as to the optimal supplement to take to enhance mental acuity, the American Psychological Society (APS) is frequently approached to provide recommendations concerning widely marketed non-prescription compounds for the amelioration of naturally occurring age-related memory loss. The public has turned to the APS for guidance as to which products are indeed useful. In the public interest, the APS convened a group of scientists, led by Mark A. McDaniel, PhD, from the Department of Psychology at the University of New Mexico in Albuquerque. McDaniel and colleagues from the universities of Colorado and South Carolina reviewed the experimental evaluation of double-blind, placebo-controlled studies concerning several widely marketed, non-prescription compounds claimed to enhance memory and treat age-related memory decline. The committee's work was published in a journal belonging to the society.[8] However, this being a relatively new journal, and one with a potentially limited readership, *Nutrition*'s editorial board, at a recently convened meeting, agreed to republish this significant work to reach a wider audience. *Nutrition* also considers this publication to be in the realm of public service, especially because the analytical criteria used to assess the efficacy of a product, including study design and sample size, and the generality of the treatment across different memory tests and populations are particularly useful. Such a study serves as a template for assessing past and future data wherein the efficacy of a product is claimed.

We encourage our readers and researchers engaged in this challenging but promising field to submit manuscripts on this topic.

**Michael M. Meguid, MD, PhD**
*Editor-in-Chief,* Nutrition
*Department of Surgery*
*SUNY Upstate Medical University*
*Syracuse, New York, USA*

Correspondence to: Michael M. Meguid, MD, PhD, FACS, FACN, Editor-in-Chief, *Nutrition*, Director of Surgical Research, Department of Surgery, SUNY Upstate Medical University, 750 East Adams Street, Syracuse, NY 13210, USA. E-mail: meguidm@upstate.edu

Nutrition 19:955–956, 2003

0899-9007/03/$30.00

**Alan Shenkin, PhD, FRCP, FRCPath**
*European Editor*, Nutrition
*Department of Clinical Chemistry*
*University of Liverpool*
*Liverpool, United Kingdom*

## REFERENCES

1. Joachim H. *Papyros Ebers: das alteste Buch uber Heilkunde*. Berlin: Georg Reimer, 1890
2. Chandra RK. Effect of vitamin and trace-element supplementation on cognitive function in elderly subjects. Nutrition 2001;17:709
3. Brody JE. Nutrition a key to better health for elderly. *New York Times*, August 21, 2001, p 8
4. Shenkin SD, Whiteman MC, Alison P, Deary IJ. Supplementation and the elderly: dramatic results? Nutrition 2002;18:364
5. Roberts, S, Sternberg, S. Do nutritional supplements improve cognitive function in the elderly? Nutrition 2003;19:976
6. Chandra RK. Effect of vitamin and trace-element supplementation on immune responses and infection in elderly subjects. Lancet 1992;340:1124
7. Moher D, Schultz KF, Altman DG, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Lancet 2001;357:1191
8. McDaniel MA, Maier SF, Einstein GO. "Brain-specific" nutrients: a memory cure? Psychol Sci Public Interest 2002;3:12

doi:10.1016/S0899-9007(03)00023-6