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The Death of the oat bran fad. (Murdered by a poorly conceived study.)

The oat bran fad passed with the publication of a flawed study.

There was an article¹ in the medical literature which received wide media attention that effectively killed the oat bran craze. Years back, many people were making and eating oat bran muffins to lower cholesterol. details The fad aspect of oat bran ended when an article was published claiming to indicate that oat bran did not significantly lower cholesterol. The article was a significantly flawed study. (see right column)

See right column for details of problems in this study:

Letters written pointing out the flaws in this study:

Subsequent letters to <u>The New England Journal of Medicine (NEJM)</u> (citations) noted the inadequacy of the study. A letter² by the Robenoubonoffs, M.D. and R. D. suggests, "The authors have managed to confuse the American public further with a poorly designed and underpowered trial that draws erroneous conclusions." A letter³ by James Burrous, M.D. published in the same issue of The New England Journal of Medicine asked, "What does a small ... study of dietitians with desirable cholesterol levels ... tell us about the population of the American public at risk?"

A later different study documents the cholesterol lowering effect of oat bran:

A subsequent study⁴ was performed on 84 middle aged men and women who were placed on metabolic diets

Problems with the study which incorrectly concluded that oat bran did not significantly lower cholesterol:

On closer examination, <u>The New</u>

<u>England Journal of Medicine article</u>¹

was a seriously flawed study.

- 1. The primary problem with this study is that there were insufficient numbers of participants to exclude a cholesterol lowering effect. There were only 20 participants. To prove an effect is not present, a large number of participants need to be studied. A trial demonstrating a positive effect generally requires fewer participants than a trial trying to reliably prove that no difference exists.
- 2. Cholesterol lowering drug interventions tend to have a lesser magnitude effect on patients who have a very low cholesterol intake and start out with low cholesterol levels. The individuals in the trial had a very low fat and low cholesterol intake compared to the rest of the U.S. population, and had low cholesterol levels and LDL cholesterol at the time of initiation of the study. Many of these subjects for this trial were dietitians with a baseline low fat diet different from the average older individual at high

risk for heart disease.

comparing wheat bran to oat bran. This study showed a statistically significant 5% reduction in total cholesterol for oat bran beyond what was found for wheat bran. details

Multiple studies were later combined and analyzed to further assess the effects of oat bran on cholesterol:

There were at least two subsequent meta-analyses (analyses combining multiple other studies):

One meta-analysis⁵ concluded that oat bran modestly reduced cholesterol. details

A second meta-analysis⁶, this one written by the senior author of the initial flawed oat bran study, illustrates how the conclusions of a meta-analysis can be slanted. This meta-analysis presented the conclusions of the meta-analysis in a way as consistent as possible with the initial suboptimal study. details.

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- 2. Roubenoff RA, Roubenoff R. Letter to the Editor, Oat Bran and Serum Cholesterol. N Engl J Med 1990; 320:1746-47.
- 3. Burris, J. Letter to the Editor, Oat Bran and Serum Cholesterol. N Engl J Med 1990; 320:1748.
- 4. Wheat-bran and oat-bran supplements' effects on blood lipids and lipoproteins. Kashtan H, Stern H, Jenkins D, Jenkins A, Hay K, Marcon N, Minkin S, Bruce W. Am J Clin Nutr 1992;55:976-80.
- 5. Oat Products and Lipid Lowering. A Meta-analysis. Ripsin CM, Keenan J, Van Horn L, et al. JAMA 1992; 267:3317-25.
- 6. Brown L, Rosner B, Lillett W, Sacks F. Cholesterollowering effects of dietary fiber: a meta-analysis. Am J Clin Nutr 111; 69:30-42