

Study raises questions about dietary fats and heart disease guidance

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Dietary advice about fats and the risk of heart disease is called into question in *BMJ* today as a clinical trial shows that replacing saturated animal fats with omega-6 polyunsaturated vegetable fats is linked to an increased risk of death among patients with heart disease.

The researchers say their findings could have important implications for worldwide [dietary recommendations](#).

Advice to substitute vegetable oils rich in [polyunsaturated fatty acids](#) (PUFAs) for animal fats rich in saturated fats to help reduce the risk of heart disease has been a cornerstone of dietary guidelines for the past half century. The most common dietary PUFA in Western diets is [omega-6](#) linoleic acid (n-6 LA for short).

UK dietary recommendations are cautious about high intakes of omega 6 PUFAs, but some other [health authorities](#), including the American Heart Association, have recently repeated advice to maintain, and even to increase, intake of omega 6 PUFAs. This has caused some controversy, because evidence that linoleic acid lowers the risk of cardiovascular disease is limited.

An in-depth analysis of the effects of linoleic acid on deaths from coronary heart disease and cardiovascular disease has not previously been possible because data from the Sydney Diet Heart Study - a [randomised controlled trial](#) conducted from 1966 to 1973 - was missing.

But now, a team of researchers from the US and Australia have recovered and analysed the original data from this trial, using modern statistical methods to compare death rates from all causes, cardiovascular, and coronary heart disease.

Their analysis involved 458 men aged 30-59 years who had recently had a [coronary event](#), such as a heart attack or an episode of angina.

Participants were randomly divided into two groups. The [intervention group](#) was instructed to reduce saturated fats (from [animal fats](#), common margarines and shortenings) to less than 10% of [energy intake](#) and to increase linoleic acid (from safflower oil and safflower oil polyunsaturated margarine) to 15% of energy intake. Safflower oil is a concentrated source of omega-6 linoleic acid and provides no omega-3 PUFAs.

The control group received no specific dietary advice. Both groups had regular assessments and completed food diaries for an average of 39 months. All non-dietary aspects of the study were designed to be equal in both groups.

The results show that the omega-6 linoleic acid group had a higher risk of death from all causes, as well as from cardiovascular disease and [coronary heart disease](#), compared with the control group.

The authors then used the new data to update an earlier meta-analysis (a review of all the evidence). This also showed no evidence of benefit, and suggested a possible increased risk of cardiovascular disease, emphasizing the need to rethink mechanisms linking diet to heart disease.

The researchers conclude that recovery of these missing data "has filled a critical gap in the published literature archive" and that these findings

"could have important implications for worldwide dietary advice to substitute omega-6 linoleic acid (or polyunsaturated fatty acids in general) for saturated fatty acids."

In an accompanying editorial, Professor Philip Calder from the University of Southampton says the new analysis of these old data "provides important information about the impact of high intakes of omega 6 PUFAs, in particular linoleic acid, on cardiovascular mortality at a time when there is considerable debate on this question."

Calder says the findings argue against the "[saturated fat](#) bad, omega 6 PUFA good" dogma and suggest that the [American Heart Association](#) guidelines on omega-6 PUFAs may be misguided. They also "underscore the need to properly align [dietary advice](#) and recommendations with the scientific evidence base."

To coincide with publication of this paper, the *BMJ* is pulling together examples of missing data it has uncovered, as part of its "open data" campaign. We are also asking researchers to tell us about any other documented examples of missing data, to build a picture of the full extent of the problem which is undermining evidence based medicine worldwide.

The current best estimate is that half of all the clinical trials that are conducted and completed are never published. Even when they are, the underlying data that the results are based on is rarely open to external analysis - which is a cornerstone of proper scientific scrutiny. This means doctors cannot be certain that the drugs they are prescribing daily are properly evaluated for safety and efficacy.

More information: www.bmj.com/cgi/doi/10.1136/bmj.e8707
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