

Paper highlights best practices for omega-3 clinical trials with cardiovascular outcomes

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A paper published this week in the journal *Prostaglandins, Leukotrienes and Essential Fatty Acids* sheds new light on recent neutral studies questioning the benefits of omega-3s for heart health. The paper titled, "Conducting Omega-3 Clinical Trials with Cardiovascular Outcomes: Proceedings of a Workshop Held at ISSFAL 2014," identifies experimental design issues in recent studies that have not demonstrated significant effects of EPA and DHA omega-3s on cardiovascular disease outcomes and suggests that it is too early to conclude that EPA and DHA do not provide cardiovascular health benefits.

The data from the paper, which was presented at a workshop sponsored by the Global Organization for EPA and DHA Omega-3s (GOED) at the International Society for the Study of Fatty Acids and Lipids 2014 Congress, found that recent neutral findings may have been due to a number of design issues, rather than a lack of substantiated clinical benefits in cardiovascular disease. The issues include such things as:

- aggressive cardiovascular drug treatment overshadowing the benefits of long-chain omega-3s
- high background long-chain omega-3 intake at study initiation
- too few subjects in the study
- treatment duration too short
- insufficient LC omega-3 dosage
- increase in omega-6 fatty acid intake during the study
- failure to assess the LC omega-3 status of the subjects prior to and during treatment

- lack of clarity concerning which mechanisms were expected to produce benefits

"It's very important that researchers consider these issues when designing [clinical trials](#) and discussing the results of studies that show non-significant effects of omega-3s in [cardiovascular outcomes](#)," said Dr. Harry Rice, vice president of regulatory and scientific affairs for GOED and lead author on the paper. "Some of these studies have been heavily publicized in mainstream media, often without the necessary context. This leads consumers to believe omega-3s are not heart healthy and to possibly eat less fish or stop taking an omega-3 supplement."

It is possible the recent studies show neutral results for omega-3 intake because there are no associated cardiovascular benefits, but with multiple large-scale clinical trials ongoing in this area, it is premature to conclude omega-3s do not reduce [cardiovascular disease](#) risk. The existing body of gold-standard research showing [omega](#)-3s may reduce cardiovascular death risk, maintain healthy blood pressure and improve triglyceride levels also makes it difficult to conclude that EPA and DHA consumption does not contribute to a healthy heart.

More information: Harry B. Rice et al. CONDUCTING OMEGA-3 CLINICAL TRIALS WITH CARDIOVASCULAR OUTCOMES: PROCEEDINGS OF A WORKSHOP HELD AT ISSFAL 2014, *Prostaglandins, Leukotrienes and Essential Fatty Acids (PLEFA)* (2016). [DOI: 10.1016/j.plefa.2016.01.003](https://doi.org/10.1016/j.plefa.2016.01.003)

Provided by GOED

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