

Trial testing cocoa flavanol supplement shows promise for reducing cardiovascular risk

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Dietary flavanol sources. Credit: MARS

The first large-scale trial to test the long-term effects of a cocoa flavanol supplement to prevent cardiovascular disease offers promising signals

that cocoa flavanols could have protective cardiovascular effects. In papers published in *The American Journal of Clinical Nutrition*, a team led by Howard Sesso, ScD, MPH, and JoAnn Manson, MD, DrPH, both of the Division of Preventive Medicine at Brigham and Women's Hospital, unpacks the main outcomes of the COcoa Supplement and Multivitamin Outcomes Study (COSMOS), a randomized, placebo-controlled trial that tested a cocoa flavanol supplement and a multivitamin in the prevention of cardiovascular disease and cancer. While neither supplement significantly reduced the primary outcome of total cardiovascular events, people randomized to receive the cocoa flavanol supplement had a 27% lower rate of cardiovascular death, a pre-specified secondary endpoint.

"When we look at the totality of evidence for both the primary and secondary cardiovascular endpoints in COSMOS, we see promising signals that a cocoa flavanol [supplement](#) may reduce important cardiovascular events, including death from cardiovascular disease," said Sesso. "These findings merit further investigation to better understand the effects of [cocoa flavanols](#) on cardiovascular health."

"Previous studies have suggested health benefits of flavanols—compounds in several plant-based foods including cocoa, tea, grapes, and berries," said Manson. "COSMOS was not a chocolate trial—rather, it's a rigorous trial of a cocoa extract supplement that contains levels of cocoa flavanols that a person could never realistically consume from chocolate without adding excessive calories, fat, and sugar to their diet."

Smaller, short-term trials have found cardiovascular benefits for cocoa flavanols on blood pressure and blood vessel dilation. COSMOS offered the first opportunity to study whether a cocoa flavanol supplement might also lead to longer-term reductions in clinical cardiovascular events. Investigators also looked for reductions in risk of cancer. In addition, the

trial was designed to test a common multivitamin in the prevention of cancer and cardiovascular disease.



COSMOS Trial study pills pack. Credit: MARS

The primary cardiovascular outcome for the cocoa flavanol intervention was a composite of total cardiovascular events, including heart attacks, stroke, coronary revascularization, cardiovascular death, carotid artery disease, peripheral artery surgery, and unstable angina. More than 21,000

participants were randomized to take daily capsules that contained 500 mg cocoa flavanols (donated by Mars Edge), a multivitamin tablet (donated by GSK Consumer Healthcare), neither or both.

The study found that cocoa flavanols reduced total cardiovascular events by 10%, but this was not statistically significant. However, several secondary analyses provided broader support for a potential benefit of cocoa flavanols on cardiovascular events. First, those receiving the cocoa flavanol supplement had a significant 27% reduction in death from cardiovascular disease. Second, when the study team took adherence to study pills into account (by looking at those taking their study pills regularly), the team saw a stronger, 15% reduction in total cardiovascular events and a 39% reduction in death from [cardiovascular disease](#). Third, a composite endpoint of major cardiovascular events (heart attacks, strokes, and cardiovascular deaths), although not a trial focus, was also significantly reduced. The authors note in their report that their promising results on cocoa flavanols and cardiovascular events warrant cautious interpretation and underscore the need for additional research.

A daily multivitamin had no significant effect on total or individual cardiovascular events. There were no safety concerns for either cocoa flavanols or a multivitamin.

COSMOS concluded after about 3.6 years, which was likely too short to detect whether the supplements could have affected cancer risk.

Although a daily multivitamin improved levels of several nutritional biomarkers, it had no significant effect on total invasive cancer, the primary outcome for the multivitamin analyses. Cocoa flavanols also had no significant effect on total invasive cancer. The authors note that continuing to follow COSMOS participants may help to clarify any longer-term effects on cancer and death. The investigators and collaborators are also leveraging COSMOS to study cognitive decline, falls, eye disease, and other aging-related outcomes that may be

influenced by the supplements.

"Although our study suggests intriguing signals for cardiovascular protection with [cocoa](#) flavanols, any health benefits due to taking these supplements will need confirmation in a future trial," said Manson. Adds Sesso, "Our message for consumers is to eat a healthy, balanced diet, rich in natural food sources of flavanols, and to stay tuned as we further evaluate other important health outcomes in COSMOS."

More information: OUP accepted manuscript, *The American Journal of Clinical Nutrition* (2022). [DOI: 10.1093/ajcn/nqac055](https://doi.org/10.1093/ajcn/nqac055)

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