

# VITAL: The VITamin D and Omega-3 Trial (VITAL): Principal Results for Vitamin D and Omega-3 Fatty Acid Supplementation in the Primary Prevention of Cardiovascular Disease and Cancer

**Purpose:** To study the primary prevention role daily supplements of vitamin D3 or omega-3 fatty acids in reducing the risk of developing cancer, heart disease, and stroke in people with no history of cancer, heart disease or stroke.

**Trial Design:** 25,871 U.S. adults (men ≥50; women ≥55); median treatment 5.3 years. Double-blinded, placebo-controlled, randomized, 2x2 factorial: (1) vitamin D3 (cholecalciferol; 2000 IU daily) and marine omega-3 fatty acids (Omacor® fish oil, (eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]), 1 g daily); (2) vitamin D and omega-3 placebo; (3) vitamin D placebo and omega-3 fatty acids; (4) both placebo.

**Primary Endpoints:** (a) MACE (composite MI, stroke, CVD mortality); (b) total invasive cancer.

**Results:** Major CVD events and total invasive cancer were not significantly reduced by Omega-3 or vitamin D3. Omega-3 significantly reduced total MI, especially in African Americans and those with lower fish intake.

	Vit. D3	placebo	O3FA	placebo
<b>MACE composite</b>	396 events	409 events	386 events	419 events
	HR=0.97		8% reduction (HR=0.92); p=0.24	
<b>Total Invasive Cancer</b>	793 events	824 events	820 events	797 events
	HR=0.96		No reduction (HR=1.03)	
<b>Total MI</b>	169 events	176 events	145 events	200 events
	HR=0.96		28% reduction (HR=0.72, p=0.003)	
<b>MI in African Americans</b>			9 events	39 events
			77% reduction, (HR=.23, interaction p=0.001)	

