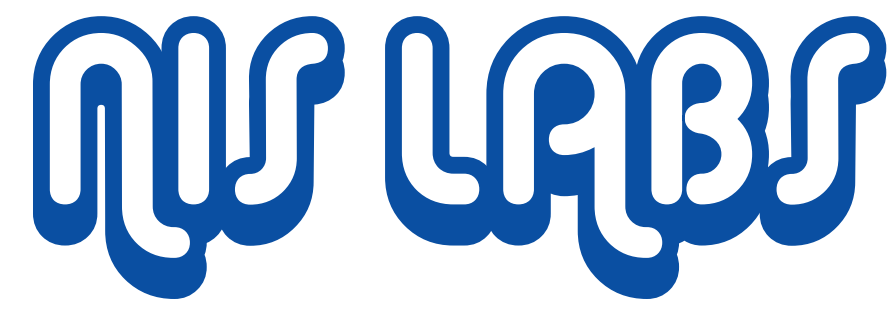


# Significant improvements in blood lipid profile after 2 weeks consumption of Wholemega®, a salmon oil of wild-caught Alaskan salmon, containing a broad-spectrum of omega fatty acids.



## Results from a randomized double-blinded placebo-controlled human clinical trial.



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### Purpose

The purpose of this study was to evaluate the effects of Wholemega® consumption on blood lipids, using a double-blinded, randomized, placebo-controlled study design, to explore the effects of consumption on HDL cholesterol levels, LDL levels and particle size, and triglycerides.

Due to the multiple negative health impacts of elevated levels of ultra-small LDL particles and triglycerides, it was of particular interest to examine whether consumption of Wholemega would support beneficial changes over a short study period.

### Background

Wholemega is a fish oil product based on wild salmon, sustainably harvested in protected Alaskan waters, and extracted using extra-virgin processing. Wholemega is a food-grade unrefined oil, with a broad spectrum of fatty acids, as well as a high content of the naturally occurring antioxidant Astaxanthin that is present in wild salmon. The omega-3, 5, 6, 7, and 9 belong to a group of fatty acids often referred to as 'good' fats. They help build healthy cell membranes, increase fluidity within the cell membrane, and thus aid proper cellular signaling processes. A previous clinical study showed that consumption of Wholemega results in rapid changes in the fatty acid composition in cellular membranes. Also, a positive shift was seen in reduced arachidonic acid and increased levels of EPA and DHA.

### THE BALANCE of omega3 and omega6 in our food affects the pro- versus anti-inflammatory outcomes.

- ✓ The human body cannot produce the most beneficial EFAs\*
- ✓ The metabolic conversion of EFAs from food is competitive
- ✓ An unbalanced food intake of EFAs can contribute to a variety of health problems

However balanced EFA intake can influence:

- Pro/anti-inflammatory responses
- Vascular health
- Cellular integrity
- Cellular communication
- Hormonal production
- Insulin responsiveness

\*Essential Fatty Acids



### Clinical Study Protocol

A total of 60 healthy subjects of both genders were recruited for this double-blinded, placebo-controlled, randomized human clinical study. All 60 people completed the study. Written informed consent, as approved by Sky Lakes Institutional Review Board, was obtained from all participants. Wholemega® and the placebo (a plant-based oil) were encapsulated in gel caps and sealed in dark glass bottles, labeled with study code and lot number. Twenty-nine people were randomized to the Wholemega group, and thirty-one people to the placebo group. Statistical analysis included 'within-subject' analysis, where the changes within the 'paired' data sets for the same subject are analyzed before and after 'treatment', i.e. consumption, for each group.

#### Inclusion criteria

Healthy adults of both genders; Age 18 - 85 years of age; BMI 20-30; Willing to comply with dietary and nutritional supplement restrictions for 2-4 weeks (depending on whether a wash-out period was needed prior to study start)

#### Exclusion criteria

Previous major gastrointestinal surgery, such as bariatric surgery, because absorption of test product could be affected; Currently on cholesterol-lowering medication; Regular consumption of fish oil unless committing to a 10 day washout period; Regular consumption of fatty fish unless committing to avoid consumption of fatty fish for 10 days before study start, as well as during the study; Undergoing stressful life events that would compromise compliance; Ongoing medical treatment for other diseases (cancer, viral disease); Pregnant, lactating, or trying to become pregnant; Food allergies related to compounds in test products.

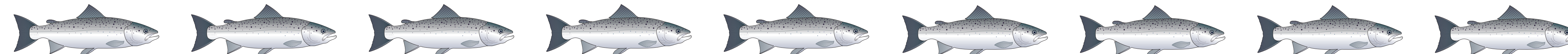
#### Involvement of study participants

Subjects were monitored at baseline, and after 2 weeks. Blood was taken at each visit and tested for HDL and triglyceride levels, LDL sub-fractionation using Segmented Gradient Gel Electrophoresis (LDL SGGE), and also fasting glucose levels (to assess compliance with the fasting requirement).

### Study population

People	Wholemega®		Placebo	
	Males	Females	Males	Females
29			31	
Age Range	21-84 years*		18-69 years	
Mean age	46.2 ± 15.3		44.6 ± 14.9	
Mean age	50.0 ± 7.4	44.1 ± 18.3	41.2 ± 15.4	46.8 ± 14.7
BMI	27.2 ± 2.1	25.7 ± 3.1	26.1 ± 2.8	26.4 ± 3.3

\* if one 84-year old woman is removed, the Wholemega age range is 21-71 years of age.



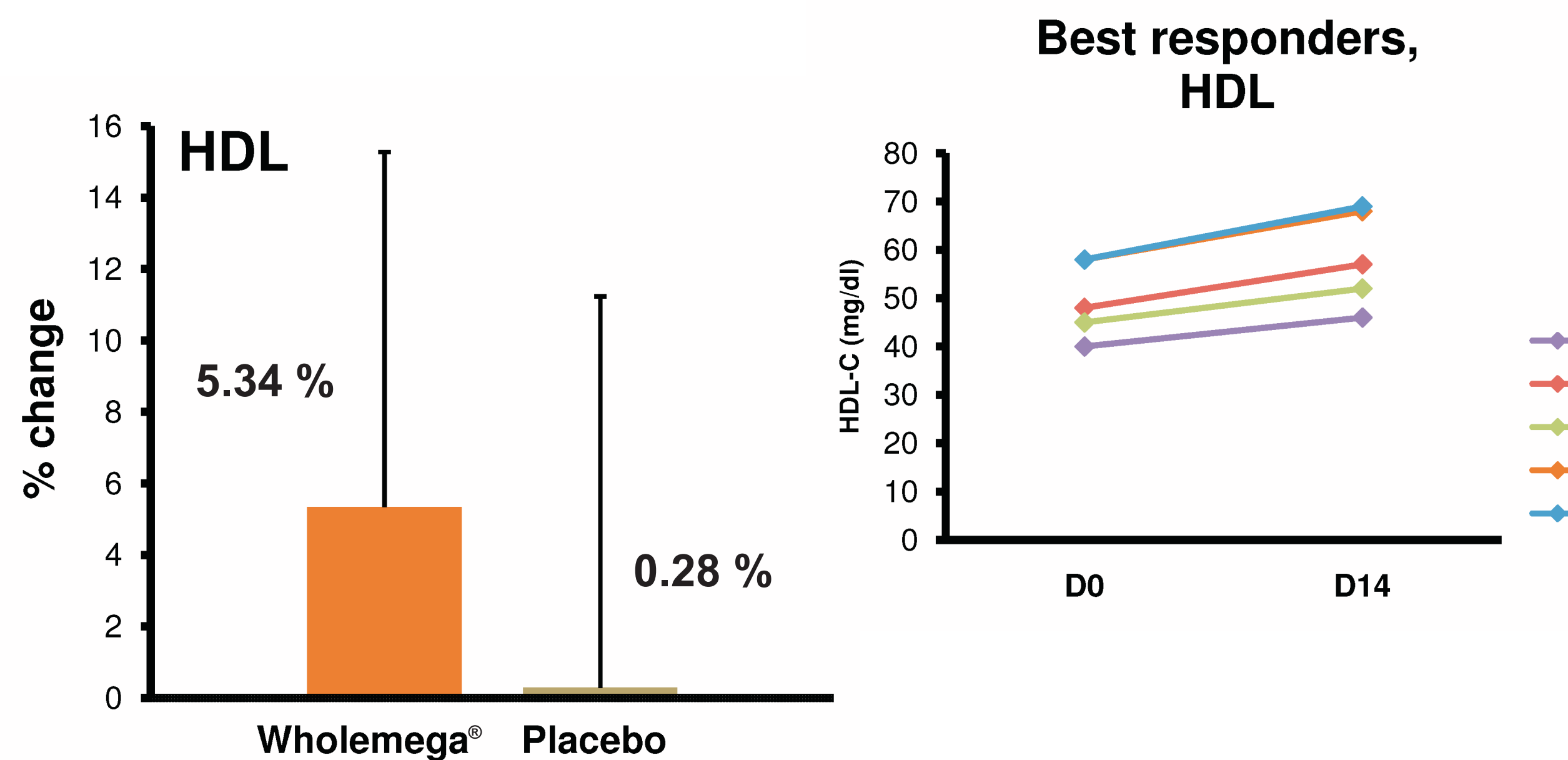
## RESULTS

### Consumption of Wholemega® for 2 weeks resulted in:

- Improvement in blood HDL cholesterol levels;
- A beneficial shift in LDL particle size, with a reduction in the smallest LDL particles, associated with higher cardiovascular risk;
- Reduction of triglyceride levels.

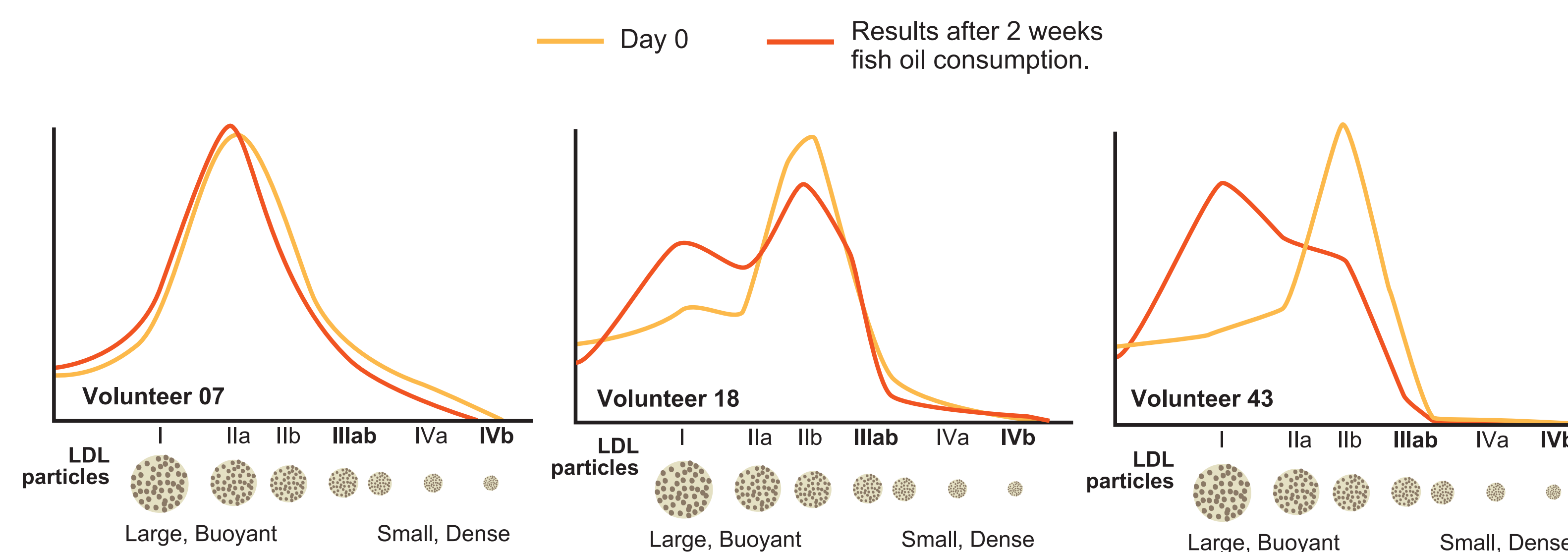
### Increased HDL levels

The increase in HDL seen in the Wholemega® group was statistically significant (P<0.05). In contrast, the group consuming placebo showed no statistically significant changes in HDL levels (P<0.86). The P-values reflect 'within-subject' analysis, where the changes within the 'paired' data sets for the same subject are analyzed before and after 'treatment', i.e. consumption, for each group. The graphs below show the group averages in HDL levels over the 2-week study.



### Reduction in high risk LDL particles

In the Wholemega® group, there was a shift towards a healthier profile of LDL ("bad" cholesterol) particle size. The smallest LDL particles are associated with more severe cardiovascular risks. Thus, 14 days consumption of Wholemega was associated with a beneficial change in the LDL profile (p<0.03).



### Decreased triglyceride levels

Changes in triglyceride levels showed a decrease for the Wholemega® group, in contrast to an increase in the placebo group. In both groups the starting average level of triglycerides was approximately 110 mg/dL. In the placebo group, the triglyceride levels showed a mild but insignificant increase over the study period. In contrast, over the 2-week study period, an eight percent decrease in triglyceride levels in the Wholemega group reached statistical significance (P<0.04).

