**FBCx® & WEIGHT MANAGEMENT IN ADULTS**

*The Beneficial Effects of FBCx® on Blood Lipids & Weight Management*

**Abstract:** It has previously been reported that early intervention with FBCx® has beneficial effects on weight management, and that in animal studies it may preferentially reduce blood levels of saturated and trans-fats. The current investigation involves overweight but not obese individuals and was intended to confirm the effects of FBCx® on both weight and blood lipid management.

**Methods:** A 2-month, double-blind, placebo-controlled crossover study was conducted with 41 overweight healthy but not obese (Body Mass Index (BMI) 25 to 30kg/m²) adults aged between 18 to 65 years old. Participants took 2 tablets per meal and they were randomized to take either the active (FBCx®) or control tablets. They were instructed not to change eating or activity programs. Participants were tested at baseline, 1 month, and 2 months.

**Results:** In 28 compliant participants (8 males and 20 females), when the active phase was compared to the control phase, there were significant beneficial effects on body weight, lipid profile, and low-density lipoprotein cholesterol (LDL-C). Positive, but not statistically significant effects were also observed on apolipoprotein (ApoB) and insulin levels.

**Conclusions:** Supplementation of 6 g/day of FBCx®, the primary ingredient in Nuvexa™, without any diet or lifestyle changes, supported both healthy weight and blood lipids.


**HUMAN TRIAL WITH FBCX® AND FATTY BREAKFAST**

*Healthy adults consume an egg and sausage breakfast muffin, then have blood tests with and without FBCx®*

**Abstract:** This study tested healthy adults at a range of weights and ages, and for the first time documented post-meal responses to a common, commercially available, fat-containing meal.

**Methods:** A double-blind, placebo-controlled, crossover trial was conducted with 34 healthy adults (28 female and 6 male). Participants were given a commercially available breakfast sandwich as their first meal of the day, along with 8 oz. of bottled water. The sandwich contained 26 g of fat (10 g of saturated fat). They consumed the meal within 10 minutes, followed by immediate ingestion of 2 FBCx® tablets or placebo. Blood samples were collected at baseline, 1, 2, and 3 hours after consumption.

**Results:** Blood triglyceride levels, which ordinarily rise after high-fat meals, remained in the normal range in the post-meal blood profiles for the FBCx® group. Compared to the placebo group, blood TG levels ranged 15% to 20% lower at the 1 and 2 hour marks, increasing to nearly 50% lower at the 3 hour mark.

**Conclusions:** The study showed that taking 2 g of FBCx® with a fat-containing meal supported healthy post-meal blood triglycerides. FBCx® was shown to be effective to decrease the absorption of triglycerides into the bloodstream in the 3 hours following the meal. The effectiveness of FBCx® in supporting healthy blood triglycerides confirms its value as a beneficial ingredient.


**FBCx® & SERUM LIPIDS IN HEALTHY ADULTS**

*The Beneficial Effects of FBCx® on Blood Lipid and Lipoprotein Levels in Healthy Adults*

**Abstract:** This study investigated the effect of oral α-cyclodextrin (soluble dietary fiber) on plasma total cholesterol, triglycerides, LDL, HDL as well as on glucose metabolism.

**Methods:** A double-blind, crossover, placebo-controlled clinical trial was conducted in 75 healthy males and females between the ages of 18 to 75. Individuals in each gender group were randomized into two groups in terms of which treatment arm they received first (placebo vs. α-cyclodextrin, receiving 6 g P.O. a day, for 12 to 14 weeks with a 7 day wash out between arms). The primary outcome variable, plasma total cholesterol, as well as other tests related to lipids and lipoprotein and glucose metabolism, were measured at baseline and at the end of each arm of the study.
Results: After 12 to 14 weeks small-LDL particle number decreased 10% (p<0.045) for subjects on α-cyclodextrin vs placebo. No other statistically significant differences between α-cyclodextrin and placebo were observed in the other measured lipid and lipoprotein parameters. Size distribution of LDL subfractions were different depending if taking α-cyclodextrin or placebo. A small reduction in fasting glucose was seen (-1.6% p<0.05) in subjects when on α-cyclodextrin vs placebo. α-cyclodextrin was generally well tolerated.

Conclusions: α-cyclodextrin was reasonably well tolerated in a healthy population and had some minor beneficial effects in reducing small LDL-particle number and fasting glucose. Further studies are required to understand the consequences of such changes.