



**Cholesterol Reduction in Statin Unwilling Individuals:
A Simple Food-Based Approach**
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Background: Lipid lowering is a major component of cardiovascular disease care and prevention. Unfortunately, many patients eligible for statin therapy are unwilling to take the drugs. Step One Foods offers a food-based program consisting of ready-to-eat products high in whole grain fiber, omega-3 fatty acids, antioxidants and plant sterols, intended to support cardiovascular care and prevention efforts. In prior controlled eating trials, this type of portfolio dietary approach has been shown to produce LDL lowering commensurate with that attained with pharmacologic treatment.

Purpose: The purpose of the present study was to determine if a simple targeted food intervention deployed in a real-world environment could significantly impact LDL levels of individuals trying to manage their cholesterol through non-pharmacologic means.

Methods: Customers using Step One Foods were invited to voluntarily submit their pre and post lipid profiles. Fasting pre-intervention lab work had to be obtained within 3 months of the food intervention and the fasting post-intervention lipid profile had to be obtained at least 4 weeks after starting the program. Customers were instructed to eat Step One Foods products up until the night before repeat laboratory assessment. As per the standard directions on the Step One Foods website, individuals were encouraged to consume 2 servings per day of any Step One Foods products, ideally as a substitution for something they had been eating before. Two servings per day of Step One Foods supply, on average, 12 grams of whole food fiber, 5 grams of ALA omega-3 fatty acids, 2 grams of plant sterols, and 6000 umol of antioxidants (ORAC scale). No other diet or exercise modifications were required or recommended.

Results: Over the course of 12 months, 51 individuals submitted their pre and post lipid profile results. In 50 of the 51 subjects, the average pre-LDL measured 163 mg/dL and average post-LDL measured 124 mg/dL, representing a 24% cholesterol reduction. One data outlier with familial hypercholesterolemia and a pre-LDL of 317 mg/dL was not included in the analysis. At 36 days of food intervention, her post-LDL measured 221 mg/dL. Except for the twice-per-day structured food substitution, all individuals reported no other lifestyle changes.

Conclusions: A simple targeted dietary intervention can result in a meaningful reduction in LDL cholesterol in a short period of time. Given its simplicity and minimal support requirements, this type of food-based program could be utilized formally as a treatment option in statin unwilling and statin intolerant individuals.

Limitations: This study was based on a self-selected cohort, introducing inherent bias. It is also likely that individuals experiencing little/no LDL change would be less willing to share their results. Although subjects were instructed to make no additional changes to their lifestyle habits, unrecognized or under-reported lifestyle modifications cannot be excluded as contributing to these results. Nevertheless, our data suggest that a simple, structured food intervention can yield significant lipid responses in at least some individuals with high LDL cholesterol.