CLINICAL STUDIES

ANALYSIS OF MOST RELEVANT CLINICAL TRIALS PERTAINING TO AIO INGREDIENTS OF RED YEAST RICE, PLANT STEROLS & CO Q10

Study Name	**PI, CRO**	**Study design (no of patients, duration)**	**Claims / Results** **LDL/ Triglycerides, HDL elevation**
Red Yeast Rice for Dyslipidemia in Statin-Intolerant Patients	Annals of Internal Medicine June 2009 Author: David J Becker	Randomized, controlled trial. 62 patients with dyslipidemia and history of discontinuation of statin therapy due to myalgias.	In the red yeast rice group, LDL cholesterol decreased by 1.11 mmol/L (43 mg/dL) from baseline at week 12 and by 0.90 mmol/L (35 mg/dL) at week 24. **Red yeast rice and therapeutic lifestyle change decrease LDL cholesterol level without increasing CPK or pain levels and may be a treatment option for dyslipidemic patients who cannot tolerate statin therapy.**
Red yeast rice lowers cholesterol in physicians	BMC Complementary & Alternative Medicine July 2013 Author: Veronique Verhoeven	Double blind, placebo controlled randomized trial. 52 physicians and their spouses with a total cholesterol level of > 200 mg/dL w 8 weeks.	A commercially available RYR product showed to be efficient in lowering cholesterol values, with a mean LDL difference of 22%.

A meta-analysis of red yeast rice – an effective and relatively safe alternative approach for dislipidemia	Public Library of Science (PLos One) June 2014 Author: Liy Y	13 randomized, placebo-controlled trials 804 participants	RYR showed to lower LDL effectively with no side effects
Tolerability of red yeast rice (2,400 mg twice daily) versus pravastatin (20 mg twice daily) in patients with previous statin intolerance.	Americal Journal of Cardiology January 2010 Author: albert SC	43 adults with dyslipidemia with history of statin discontinuation 12 weeks	The low-density lipoprotein cholesterol level decreased 30% in the red yeast rice group and 27% in the pravastatin group. **In conclusion, red yeast rice was tolerated as well as pravastatin and achieved a comparable reduction of low-density lipoprotein cholesterol in a population previously intolerant to statins.**
Simvastin V's therapeutic lifestyle changes and supplements:	Mayo Clinic Author Becker DJ	Randomised primary prevention trial 74 patients with hypercholesterolemia	Lifesytle changes with RYR and fish oil reduced LDL in proportions similar to standard therapy with simvastatin
Statin alternatives or just placebo – an objective review of omega-3 red yeast rice an garlic in cardiovascular therapies	Chinese Medical Journal Author: Ong HT	A review of a group of randomised, placebo-controlled studies 2000 patients 2-year follow up	Omega 3 in modest doses reduces cardiac deaths and in high doses reduces non-fatal cardiovascular events. RYR reduces adverse cardiac events to a similar degree as the statins. It is unlikely garlic is useful in preventing cardiovascular disease
A combined natural supplement lowers LDL cholesterol in subjects	International Journal for Food Science	Randomised, double-blind placebo-controlled	Reduction of LDL cholesterol [-0.22 g/L (95% confidence interval, CI: -0.31 to -0.12) corresponding

with moderate untreated hypercholesterolemia:	Nutrition November 2013 Author: Barret E	trial 100 people 16 weeks	to -14.3% from baseline (95% CI: -21.5 to -7.2) compared to placebo], as well as total cholesterol, apolipoprotein B100 and apolipoprotein B100/apolipoprotein A-I ratio, were observed after 16 weeks of supplementation with NCLS. These effects were already observed at Week 4 and 10 of supplementation. No significant changes were observed in HDL, triacylglycerol, creatine kinase, lactate dehydrogenase and coenzyme Q10 levels **The NCLS was effective in reducing LDL cholesterol and apolipoprotein B100 in subjects with moderate hypercholesterolemia, without modifying safety parameters.**
A multicentre study of nutraceutical drinks for cholesterol (evaluating effectiveness and tolerability)	Journal of Clinical Lipidology March 2012 Author: Karl M	Randomized, double blind placebo trial 79 subjects 59 completed 8 weeks	Reduced LDL 17.8% with no side effects The nutraceutical drink with RYR reduced total cholesterol at week 4 by 13% (-35 mg/dL) and week 8 by 14% (-46 mg/dL). LDL cholesterol decreased 17.1% at 4 weeks (-28 mg/dL) and 17.8% at week 8 (-30 mg/dL). No side effects, bar 1 who experienced a headache **A nutraceutical drink with RYR can be effective natural alternative to pharmacologic therapies for people intolerant or refusing statins**
Cholesterol-lowering effects of proprietary Chinese RYR dietary	American Journal of Clinical Nutrition	Double blind placebo controlled trial	Total cholesterol, LDL cholesterol and total triacylglycerol were reduced with the supplement.

supplement	February 1999 Author: Heber D	83 subjects with hyperlipidemia (currently untreated) 12 weeks	HDL cholesterol did not change significantly. **Red yeast rice significantly reduces total cholesterol, LDL cholesterol, and total triacylglycerol concentrations compared with placebo and provides a new, novel, food-based approach to lowering cholesterol in the general population.**
Effects of Xuezhikang in patients with dyslipidemia	Journal of Clinical lipilology November 2014 Author: Moriarty PM	Multi-centre randomized placebo controlled study 116 subjects 4-12 weeks	Decreases in non-HDL-C (∼24% reduction) and LDL-C (∼27% reduction) compared with placebo. XZK treatment at either dose enabled approximately 50% of subjects to reduce their LDL-C levels by ≥ 30%. Doubling the XZK daily dose from 1200 to 2400 mg at treatment week 8 caused an additional 4.6% reduction in LDL-C **Reduced non-HDL-C and LDL-C, and was well tolerated.**
Red yeast rice improves lipid pattern, high-sensitivity C-reactive protein, and vascular remodeling parameters in moderately hypercholesterolemic Italian subjects.	Nutrition Research August 2013 Author: Cicero AF	Crossover, double-blind, placebo-controlled randomized clinical trial 25 people 4 weeks	Monacolins-treated patients change in total cholesterol (-12.45%, 95% CI -16.19 to -8.71), low-density lipopotein cholesterol (-21.99%, 95% CI -26.63 to -17.36), non-high-density lipoprotein cholesterol (-14.67%, 95% CI -19.22 to -10.11), matrix metalloproteinase 2 (-28.05%, 95% CI -35.18 to -20.93), matrix metalloproteinase 9 (-27.19%, 95% CI -36.21 to -18.15), and hs-CRP (-23.77%, 95% CI -30.54 to -17.01). **Monacolins-treated patients experienced a more favourable percent change in total cholesterol.**

			No significant differences were observed in regards to triglycerides, HDL cholesterol, and safety parameters.
Effect on LDL-**cholesterol** of a large dose of a dietary supplement with plant extracts in subjects with untreated moderate hypercholesterolaemia: a randomised, double-blind, placebo-controlled study.	European Journal of Nutrition December 2013 Author: Barrat E	Randomised, double-blind, placebo-controlled study 4 weeks 45 subjects with untreated hypercholesterolaemia	After 4 weeks of supplementation, LDL-C was significantly lower in 6-TAB (-0.21 g/l; 95 % CI -0.38 to -0.03 g/l; p = 0.0217) and 3-TAB (-0.25 g/l; 95 % CI -0.42 to -0.07 g/l; p = 0.0071) compared to PLA, although no difference in LDL-cholesterol was observed between the two groups, while no effect was seen on triacylglycerol and HDL-cholesterol. Four weeks after the end of supplementation, no difference in LDL-C was seen between the PLA group and the DS-treated groups. **Supplementation with twice the recommended dose of the dietary supplement including red yeast rice was effective in reducing LDL-cholesterol and appeared safe, but according to the present results, no additional benefit could be achieved compared to the recommended dose.**
Powdered **red yeast rice** and plant stanols and sterols to lower **cholesterol**.	Journal of Dietary Supplements June 2012 Author: Feuerstein JS	Case series 18 subjects with hypercholesterolemia despite therapeutic lifestyle change through diet and exercise	Statistically significant reduction ($p < .05$) in the following mean variables was seen: total cholesterol 19% (46 mg/dL) and LDL 33% (53 mg/dL) after 6 weeks using the blend. There was no significant difference in body mass index (BMI), triglyceride, high-density lipoprotein (HDL) cholesterol levels, or systolic and diastolic blood pressure over the same period. No side effects reported.

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HypoCol (**red yeast rice**) lowers plasma **cholesterol** -.	Scandinavian Cardiovascular Journal August 2010 Author: Bogsrud MP	Randomized placebo controlled study 16 weeks Subjects had LDL-cholesterol between 3.0 and 6.0 mmol/L, fasting triglyceride level less than 4.5 mmol/L.	Patients receiving RYR experienced a significant reduction in LDL-cholesterol (23.0%) and total cholesterol (15.5%) compared to placebo after 16 weeks of treatment ($p<0.001$). **The tested red yeast rice product demonstrated a significant cholesterol lowering effect compared to placebo, and was well tolerated in this Caucasian population.**
Effect of Xuezhikang, an extract from red yeast Chinese rice, on coronary events in a Chinese population with previous	American Journal of Cardiology June 15 2008	Multicenter study 5,000 patients with average low-density	Treatment with XZK significantly decreased CV and total mortality by 30% and 33%, the need for coronary revascularization by 1/3, and lowered total and low-density lipoprotein cholesterol and

Plasma clearance of lovastatin versus chinese **red yeast rice** in healthy volunteers.	Journal of Alternative & Complementary Medicine December 2005 Author: Li Z	Randomized crossover study taking 2400 mg CRYR or 20 mg of lovastatin. 11 subjects	The Cmax and area under the curve (AUC) of lovastatin were 22.42 ng/mL, and 80.47 higher than CRYR (p = 0.001 and 0.002, respectively). The Cmax for lovastatin hydroxy-acid was 36.63 ng/mL higher than the Cmax of CRYR hydroxy-acid (p = 0.001). The AUC of lovastatin hydroxy-acid was 258.5 greater than that of CRYR (p = 0.001). **The results suggested that the effect of CRYR on the cholesterol concentration might be caused by the additive and/or synergistic effects of monacolin K with other monacolins and substances in CRYR. It may lead to the ultimate development of a botanical supplement based on CRYR.**
[Intervention of xuezhikang on patients of acute coronary syndrome with different levels of blood lipids].	Chinese Journal of Integrated & traditional medicine December 2004 Wang WH	Double blind randominsed controlled study 105 subjects	Serum levels of TC, TG and LDL-C in the treated group lowered significantly. HDL-C level in patients with HL increased significantly while in those with NBL, it showed a trend of increasing but with no statistical significance. **Applying XZK in ACS patients in early stage, either with NBL or with HL, could improve the endothelial function, antagonize inflammatory response to stabilize the atheromatous plaque.**
Effects of xuezhikang, an extract of cholestin, on lipid profile and C-reactive protein: a short-term time course study in patients with stable angina.	International Journal of Clinical Chemistry February 2005	A short term course study 48 subjects with stable angina	Both doses of Xuezhikang induced significant reductions in total cholesterol (TC, 13% and 22%), and low-density lipoprotein (LDL) cholesterol (23% and 32%) compared with baseline at day 14. The higher dose of Xuezhikang (2400 mg/day) resulted in

	Author: Li JJ		significantly greater reductions in TC and LDL cholesterol compared with 1200 mg/day group ($p<0.05$, $p<0.01$, respectively). A less significant reduction was observed in triglycerides (TG) level (13% and 23%) compared with TC and LDL cholesterol. There was no significant difference in mean high-density lipoprotein (HDL) cholesterol levels compared with baseline in both groups. **Xuezhikang resulted in rapid reduction of CRP within 24 h and lipid profile within 2 weeks, which may be clinically important for patients with coronary artery disease.**
Herbs for serum **cholesterol** reduction: a systematic view.	Journal of Family Practice June 2003 Author: Thompson Coon	A systematic review of 25 randomized clinical trials of herbal medicinal products used to lower serum cholesterol	Many herbal medicinal products have potential hypocholesterolemic activity and encouraging safety profiles.
An analysis of nine proprietary Chinese **red yeast rice** dietary supplements: implications of variability in chemical profile and contents.	Journal of Alternative and Complementary Medicine April 2001 Author: Heber D	Analysis	Total monacolin content varied from 0% to 0.58% w/w and only 1 of 9 preparations had the full complement of 10 monacolin compounds. Citrinin was found at measurable concentrations in 7 of the 9 preparations.
Cholesterol-lowering effects of a proprietary Chinese **red-yeast-rice**	American Journal of Clinical Nutrition	Double blind placebo controlled prospectively	Total cholesterol concentrations decreased significantly between baseline and 8 wk in the red-

dietary supplement.	February 1999 Author: Heber D	randomized trial 12 weeks 83 healthy subjects with hyperlipidemia	yeast-rice-treated group compared with the placebo-treated group [(x+/-SD) 6.57+/-0.93 mmol/L (254+/-36 mg/dL) to 5.38+/-0.80 mmol/L (208+/-31 mg/dL); P < 0.001]. LDL cholesterol and total triacylglycerol were also reduced with the supplement. HDL cholesterol did not change significantly. **Red yeast rice significantly reduces total cholesterol, LDL cholesterol, and total triacylglycerol concentrations compared with placebo and provides a new, novel, food-based approach to lowering cholesterol in the general population.**
Red yeast rice and coenzyme Q10 as safe **alternatives** to surmount atorvastatin-induced myopathy in hyperlipidemic rats.	Canadian Journal of Physiology & Pharmacology June 2014 Author: Adbelbaset M	90 days	RYR and CoQ10 had the advantage over atorvastatin in that they lower cholesterol without elevating creatine kinase, a hallmark of myopathy. RYR maintained normal levels of heart ubiquinones, which are essential components for energy production in muscles. **In conclusion, RYR and CoQ10 may offer alternatives to overcome atorvastatin-associated myopathy.**
PLANT STEROLS			
[Risk management of	Nutrición hospitalaria	Randomised controlled	There are significant differences between placebo

cardiovascular disease through milk enriched with **sterols** in a young-adult population; randomized controlled **clinical trial**].	(Spanish study) October 2014 Author: San Mauro Marin I	clinical trial 19 subjects	and milk with sterols for LDL (p=0.009) and total Cholesterol (p=0.003). **Sterols supplied in a functional food, such as milk, can be a strategy for non- pharmacological treatment of hypercholesterolemia and therefore a tool for cardiovascular risk reduction globally.**
Plant sterols-enriched diet decreases small, dense **LDL**-cholesterol levels in children with hypercholesterolemia: a prospective study.	Italian Journal of Pediatry May 2014 Author: Garoufi A	Prospective Study 59 Children	The consumption of plant sterols reduced sdLDL-C significantly ($p < 0.001$), but levels remained higher compared with controls ($p < 0.001$). TC, LDL-C, non high density lipoprotein-cholesterol (NonHDL-C) and apolipoprotein B (ApoB) levels also decreased significantly ($p < 0.05$). The median reduction of sdLDL-C and LDL-C was 16.6% and 13%, respectively. These variables decreased >10% in sixteen children (64%), independently from baseline levels, sex, age and body mass index (BMI). High density lipoprotein-cholesterol (HDL-C), lipoprotein a [Lp(a)], and triglycerides (TGs) levels remained unaffected. **Plant sterols decrease sdLDL-C significantly and may be beneficial for children with hypercholesterolemia.**
LDL-cholesterol-lowering effect of **plant sterols** and stanols across different dose ranges:	British Journal of Nutrition July 2014 Author: Ras RT	Meta-analysis of random controlled studies to investigate the combined and separate effects of plant sterols and	Studies were searched and selected based on predefined criteria. Relevant data were extracted. Average LDL-cholesterol effects were calculated when studies were categorised by dose, according to random-effects models while using the variance as weighing factor. This was done for plant sterols

		stanols when classified into different dose ranges.	and stanols combined and separately. In total, 124 studies (201 strata) were included. Plant sterols and stanols were administered in 129 and fifty-nine strata, respectively; the remaining used a mix of both. The average PS dose was 2.1 (range 0.2-9.0) g/d. PS intakes of 0.6-3.3 g/d were found to gradually reduce LDL-cholesterol concentrations by, on average, 6-12%. When plant sterols and stanols were analysed separately, clear and comparable dose-response relationships were observed. Studies carried out with PS doses exceeding 4 g/d were not pooled, as these were scarce and scattered across a wide range of doses. **In conclusion, the LDL-cholesterol-lowering effect of both plant sterols and stanols continues to increase up to intakes of approximately 3 g/d to an average effect of 12%.**
Plant sterols and **plant** stanols in the management of dyslipidaemia and prevention of cardiovascular disease.	Atherosclerosis Nov 13 Author: Gylling H	This EAS Consensus Panel critically appraised evidence relevant to the benefit to risk relationship of functional foods with added plant sterols and/or plant stanols, as components of a healthy lifestyle, to reduce plasma low-density lipoprotein-cholesterol (LDL-C)	Based on LDL-C lowering and the absence of adverse signals, this EAS Consensus Panel concludes that functional foods with plant sterols/stanols may be considered 1) in individuals with high cholesterol levels at intermediate or low global cardiovascular risk who do not qualify for pharmacotherapy, 2) as an adjunct to pharmacologic therapy in high and very high risk patients who fail to achieve LDL-C targets on statins or are statin-intolerant, 3) and in adults and children (>6 years) with familial hypercholesterolaemia, in line with current guidance.

		levels, and thereby lower cardiovascular risk.	
A softgel dietary supplement containing esterified **plant sterols** and stanols improves the blood lipid profile of adults with primary hypercholesterolemia: a randomized, double-blind, placebo-controlled replication study.	Journal of the Academy of Nutrition and Dietetics. February 2014 Author: McKenney	Randomised double-blind placebo controlled replication study	Mean placebo-adjusted reductions in plasma lipid levels were significant (P<0.01) for LDL cholesterol (-4.3%), non-HDL cholesterol (-4.1%), and total cholesterol (-3.5%), but not for triglycerides or HDL cholesterol. **These results support the efficacy of 1.8 g/day esterified plant sterols/stanols in softgel capsules, administered as an adjunct to the National Cholesterol Education Program Therapeutic Lifestyle Changes diet, to augment reductions in atherogenic lipid levels in individuals with hypercholesterolemia.**
Consumption of **plant** sterol-enriched foods and effects on plasma **plant** sterol concentrations--a meta-analysis of randomized controlled studies.	Atherosclerosis October 13 Author: Raz RT	Meta-analysis of 41 randomized controlled studies 2084 subjects	The average dose of PS from enriched foods was 1.6 g/d (range: 0.3-3.2 g/d). Plasma sitosterol and campesterol concentrations were increased by on average 2.24 µmol/L (31%) and 5.00 µmol/L (37%), respectively, compared to control. Total- and LDL-cholesterol were reduced by on average 0.36 mmol/L (5.9%) and 0.33 mmol/L (8.5%), respectively. The increase in sitosterol and campesterol was impacted by the dose of PS, the baseline PS concentration and the PS composition of the test products. In the highest PS dose category (2.0-3.2 g/d), increases in sitosterol and campesterol were on average 3.56 and 7.64 µmol/L, respectively.

			Intake of PS-enriched foods increases plasma sitosterol and campesterol concentrations. However, total PS remains below 1% of total sterols circulating in the blood.
The effects of **plant** stanol ester consumption on arterial stiffness and endothelial function in adults:	BMC cardiovascular disorders Author: Gylling H	Randomized, controlled, double-blind, parallel trial 6 months 92 subjects	Lowering LDL and non-HDL cholesterol by 10% with staest for 6 months reduced arterial stiffness in small arteries. In subgroup analyses, staest also had a beneficial effect on arterial stiffness in large arteries in men and on endothelial function. Further research will be needed to confirm these results in different populations.
Phytosterol capsules and serum cholesterol in hypercholesterolemia:	Atherosclerosis June 2013 Author: Ottestad I	Randomized controlled trail	Daily intake of capsules containing 2 g phytosterols did not reduce total- or LDL-cholesterol significantly in a highly relevant target group for the use of phytosterol products. The present results may emphasize the importance of choosing a suitable dosage-delivery system in order to achieve optimal cholesterol lowering effect.
Lipid effects of a dietary supplement softgel capsule containing **plant sterols**/stanols in primary hypercholesterolemia.	Nutrition Jan 2013 Author: Maki KC	Randomised, placebo-controlled crossover trial 12 weeks 28 subjects	The mean baseline lipid concentrations (milligrams per deciliter) were 223 for total cholesterol (TC), 179 for non-high-density lipoprotein cholesterol (non-HDL-C), 154 for low-density lipoprotein cholesterol, 44 for HDL-C, 125 for triacylglycerols, and 5.2 for TC/HDL-C. Differences from the control responses (plant sterol/stanol minus control) in the per-protocol sample were significant ($P < 0.05$) for LDL-C (-9.2%), non-HDL-C (-9.0%), TC (-7.4%), TC/HDL-C (-5.4%), and triacylglycerols (-9.1%). The HDL-C responses were not significantly different between

			treatments. **The incorporation of softgel capsules providing esterified plant sterols/stanols 1.8 g/d into the NCEP TLC diet produced favorable changes in atherogenic lipoprotein cholesterol levels in these subjects with hypercholesterolemia.**
A spread containing bioactive milk peptides Ile-Pro-Pro and Val-Pro-Pro, and **plant sterols** has antihypertensive and cholesterol-lowering effects.	Food & Function Jund 2012 Author: Turpeinen AM,	Randomized, placebo-controlled double blind intervention	The results thus suggest that milk peptides IPP and VPP and plant sterols, in a low-fat spread matrix, produce a clinically significant reduction in systolic blood pressure as well as serum total and LDL cholesterol without adverse effects. Functional foods that affect 2 major risk factors offer a safe and convenient way to reduce the risk of cardiovascular disease by supporting lifestyle intervention.
Reduction of **LDL**-cholesterol in mildly hypercholesterolemic Thais with **plant** stanol ester-fortified soy milk.	Journal of the Medical Association of Thailand = Chotmaihet thangphaet. November 2011 Author: Kriengsinyos W	120 mildly hyperchoestrolemic thai subjects	The mean reduction in total cholesterol was 8.2 % in the stanol group ($p < 0.0001$) and 0.6% in the control group. LDL-cholesterol declined in both groups at week two, but the reduction was maintained to week six only in the stanol group. The mean reduction in LDL-cholesterol was 13.5% in the stanol group ($p < 0.0001$) at week 6, compared to a 4.6% decrease in the control group. Adjusted serum beta-cryptoxantene and beta-carotene levels decreased at week six for the stanol group. Serum sex hormone levels in both groups remained unchanged. **Consumption of stanol-ester-containing soymilk for six weeks significantly reduced LDL-cholesterol in mildly hypercholesterolemic Thais.**

			No adverse effect on sex hormones was observed However, stanol-ester consumers are at risk of fat-soluble-vitamin deficiencies if the vitamin intake from foods is inadequate.
Lipid-altering effects of a dietary supplement tablet containing free **plant sterols** and stanols in men and women with primary hypercholesterolaemia: a	International Journal of Science Nutrition June 2012 Author: Maki	randomized, placebo-controlled crossover trial 6 weeks 32 subjects	Differences from control in responses (plant sterol/stanol - control) were significant ($p < 0.05$) for LDL-C (- 4.9%), non-HDL-C (- 3.6%) and TC (- 2.8%). HDL-C and TG responses were not significantly different between treatment conditions. **These results indicate that 1.8 g/day free plant sterols/stanols administered in a tablet produced favourable lipoprotein lipid changes in men and women with hypercholesterolaemia.**
A comparison of the LDL-cholesterol lowering efficacy of plant stanols and plant sterols over a continuous dose range: results of a meta-analysis of randomized, placebo-controlled trials.	Prostaglandins Leukot Essent Fatty Acids July 2011 Author: Musa-Veloso K	113 publications and 1 unpublished study report (representing 182 strata)	Intakes of plant stanols in excess of the recommended 2g/day dose are associated with additional and dose-dependent reductions in LDL-CH, possibly resulting in further reductions in the risk of coronary heart disease (CHD).
The effect of **plant sterols** on serum triglyceride concentrations is dependent on baseline concentrations: a pooled analysis of 12 randomised controlled trials.	European Journal of Nutrition February 2013 Author: Demonty I	Analysis of 12 randomised controlled trials included in total 935 hypercholesterolaemic subjects not preselected based on their baseline TG	In most studies, the PS dose ranged between 1.6 and 2.5 g/day. PS intake significantly lowered serum TG by 6.0% (95% CI: -10.7, -1.2) or 0.12 mmol/L (95% CI: -0.20, -0.04). No significant interaction was observed between PS intake and baseline TG concentrations on relative changes, but, on absolute changes, interaction was significant with larger TG decreases observed with higher TG concentrations

		concentrations.	at baseline. No effects were observed on HDL-C concentrations. **These results show that PS exert a modest TG-lowering effect which is dependent on baseline concentrations.**
Effects of **plant** sterol esters in skimmed milk and vegetable-fat-enriched milk on serum lipids and non-cholesterol **sterols** in hypercholesterolaemic subjects:	British Journal of Nutrition June 2012 Author: Casas-Agustench	Placebo-controlled crossover study 4 weeks 43 hypercholesterolaemic subjects	Compared to control, LDL-C decreased by 8·0 and 7·4 % (P < 0·015, both) in the PS-SM and PS-VFM periods, respectively. Serum lathosterol:cholesterol (C) ratios increased by 11-25 %, while sitosterol:C and campesterol:C ratios increased by 70-120 % with both the PS-fortified milk. Adjusted LDL-C reductions were variably enhanced in participants with basal low serum lathosterol/C or conversely high sitosterol/C and campesterol/C. Subjects with post-treatment serum PS:C ratios above the median showed mean LDL-C changes of - 5·9 to - 10·4 %, compared with 1·7 to - 2·9 % below the median. **Consumption of 2 g/d of PS as PS-SM and PS-VFM lowered LDL-C in hypercholesterolaemic subjects to a similar extent. Basal and post-treatment changes in markers of cholesterol metabolism indicating low cholesterol synthesis and high cholesterol absorption predicted improved LDL-C responses to PS.**
Effects of dietary phytosterols on cholesterol metabolism and atherosclerosis: clinical and experimental evidence	American Journal of Medicine December 1999	16 published trials 590 subjects	Phytosterol therapy was accompanied by an average 10% reduction in total cholesterol and 13% reduction in LDL cholesterol levels.

	Author: Mohammed H Moghadasian		
Lipid responses to plant-sterol-enriched reduced-fat spreads incorporated into a National Cholesterol Education Program Step I diet[1,2,3]	American Journal of Clinical Nutrition July 2001 Author: Kevin C Maki	Randomized, double-blind 3 group parallel controlled study	Subjects in the low- and high-sterol groups who consumed ≥80% of the scheduled servings (per-protocol analyses) had total cholesterol values that were 5.2% and 6.6% lower, LDL-cholesterol values that were 7.6% and 8.1% lower, apolipoprotein B values that were 6.2% and 8.4% lower, and ratios of total to HDL cholesterol that were 5.9% and 8.1% lower, respectively, than values for the control group ($P < 0.001$ for all). Additionally, triacylglycerol concentrations decreased by 10.4% in the high-sterol group. **A reduced-fat spread containing plant sterol esters incorporated into a low-fat diet is a beneficial adjunct in the dietary management of hypercholesterolemia.**
Phytosterols supplementation decreases plasma small and dense LDL levels in metabolic syndrome patients on a westernized type diet.	Nutrition, Metabolism & Cardiovascular Diseases October 2012 Author: Sialvera TE	Randomised, placebo-controlled design 2 months 108 patients with metabolic syndrome	After 2 months supplementation with phytosterols, a significant reduction in total cholesterol, LDL-cholesterol, small and dense LDL (sdLDL) levels, as well as, apoB and triglycerides concentrations were observed in the intervention group ($P < 0.05$) compared to the control group. In addition, phytosterol supplementation lowered serum total cholesterol by 15.9%, LDL-cholesterol by 20.3% and triglyceride levels by 19.1% ($P = 0.02$, $P < 0.001$ and $P < 0.001$, respectively), although the patients kept their habitual westernized type diet. No differences

			were observed in HDL cholesterol, apoA1, glucose, C-reactive protein, fibrinogen levels and blood pressure. **Phytosterol supplementation improves risk factors of coronary artery disease even if the diet is a westernized type.**
Plant stanol esters lower LDL cholesterol level in statin-treated subjects with type 1 diabetes by interfering the absorption and synthesis of cholesterol.	Athesclorosis August 2011 Author: Hallikainen M	Randomized double-blind parallel study 24 subjects 4 weeks	Serum total, LDL and non-HDL cholesterol concentrations were decreased by 9.6, 16.4 and 15.3% compared with the baseline concentrations in the STAEST group (P<0.05 for all). The respective reductions were 7.8, 14.8 and 12.2% compared with the controls (P<0.05 for all). No effects on HDL cholesterol or serum triglyceride concentrations were found. The STAEST consumption significantly decreased serum plant sterol concentrations and the ratios to cholesterol by 30-32 and 25-27% (P<0.05 for all) compared with the baseline levels, respectively. **STAEST significantly decreased serum total, LDL and non-HDL cholesterol concentrations and thus offers an additional benefit to cholesterol lowering in patients with type 1 diabetes who are on statin treatment.**
Action of plant sterol intervention on sterol kinetics in hypercholesterolemic men with high versus low basal circulatory plant sterol concentrations.	Journal of the American College of Nutrition April 2011	Randomised cross-over trial 82 hypercholesterolemic	For both phases of dietary intervention, the endpoint cholesterol absorption index was positively correlated with campesterol ($r = 0.5864$, $p < 0.0001$) and β-sitosterol ($r = 0.4676$, $p < 0.0001$) absorption indices; inversely, endpoint cholesterol FSR

	Author: Zhao HL	men 2 x 4 weeks	correlated negatively with the absorption indices of campesterol (r = -0.5004, p < 0.0009), β-sitosterol (r = -0.4154, p < 0.05), and cholesterol (r = -0.4056, p < 0.0001). PS intervention reduced absorption indices of campesterol, β-sitosterol, and cholesterol by 36.5% ± 2.7%, 39.3% ± 2.9%, and 34.3% ± 1.9%, respectively, but increased cholesterol FSR by 33.0% ± 3.3% relative to control. Endpoint circulatory PS levels (cholesterol adjusted) were positively associated with endpoint absorption indices of campesterol (r = 0.5586, p < 0.0001, for placebo; r = 0.6530, p < 0.0001, for PS intake) and cholesterol (r = 0.3683, p < 0.001 for placebo; r = 0.3469, p < 0.002, for PS intake) and were negatively associated with cholesterol FSR (r = -0.3551, p < 0.002, for placebo; r = -0.3643, p < 0.001, for PS intake). The cholesterol-lowering effect of PS was most pronounced among individuals falling within the 50th-75th percentiles of basal PS concentrations. **These data suggest that basal PS concentrations indicate not only sterol absorption efficiency but also the extent of PS-induced cholesterol reduction and thus might be clinically useful to predict the extent of cholesterol response to PS intervention within a given individual.**
Primary hyperlipidemias in children: effect of **plant** sterol supplementation on plasma lipids and markers of cholesterol synthesis and absorption.	Acta diabetologica. (Germany) June 2011	Study 12 weeks 58 subjects wtith familia	A significant reduction was observed in LDL-cholesterol in the three groups (10.7, 14.2 and 16.0% in FH, FCH and UH, respectively). Lathosterol concentrations were unchanged, reflecting a lack of increased synthesis of cholesterol. Of the two

	Author: Guardamagna O	hypercholestrolemia	absorption markers, only sitosterol showed a slight but significant increase. **Daily consumption of plant sterol dairy products favorably changes lipid profile by reducing LDL-cholesterol.**
The metabolic effects of omega-3 **plant** sterol esters in mixed hyperlipidemic subjects.	Cardiovascular drugs and therapy / sponsored by the International Society of Cardiovascular Dece 2010 Author: Bitzur R	Randomized double blind study 12 weeks Subjects with mixed hyperlipidemia (not clear how many)	n-3-PSE treatment did not result in a significant change in LDL-C levels. Triglyceride levels were reduced significantly by 19% (51 mg/dL, $p < 0.0001$) in the n-3-PSE group in comparison with the placebo group ($p = 0.025$). Diastolic blood pressure and hsCRP were reduced by 7% (5.9 mmHg) and 7.8% (0.6 mg/L), respectively, and were significantly different from the placebo group ($p = 0.036$ and $p = 0.018$, respectively). I**n patients with mixed hyperlipidemia, n-3-PSE treatment may offer a safe and effective therapy for triglyceride level reduction while avoiding the typical increase in LDL-C levels associated with n-3 fatty acid treatment. The observed reduction in blood pressure and inflammation markers warrants further evaluation. The positive effect of n-3-PSE treatment was preserved at the end of the follow up phase.**
Effects of phytosterol ester-enriched low-fat milk on serum lipoprotein profile in mildly hypercholesterolaemic patients are	British Journal of Nutrition Oct 2010	Randomised trial 3 months	After PS therapy, patients receiving the healthy diet+PS or a free diet+PS exhibited a similar reduction in total cholesterol (6.7 and 5.5 %), LDL-cholesterol (9.6 and 7.0 %), non-HDL-cholesterol

not related to dietary cholesterol or saturated fat intake.	Author: Hernández-Mijares A	64 subjects	(12.2 and 8.9 %) and apo B-100/apo A-I ratio (11.5 and 11.6 %), respectively. In patients following the healthy diet, (β-carotene concentration rose by 26.9 %, whereas the β-carotene and lycopene levels dropped by 21.0 and 22.8 % in the group receiving the free diet+PS, respectively. No change was observed in carotenoid levels in healthy diet+PS group. **The efficacy of PS in relation to lipoprotein profile is not influenced by saturated fat or dietary cholesterol intake, which confirms the positive effect of healthy diet therapy in improving the negative effects that PS exert on carotenoid levels.**
The effect of adding **plant sterols** or stanols to statin therapy in hypercholesterolemic patients: systematic review and meta-analysis.	Journal of the American College of Nutrition July 2010 Author: Scholle JM	Meta-analysis of 8 randomised controlled trials 306 subjects on concurrent statin therapy	Upon meta-analysis, the use of plant sterols/stanols in combination with statin therapy significantly lowered total cholesterol (WMD, -14.01 mg/dL [95% CI, -18.66 to -9.37], $p < 0.0001$) and LDL cholesterol (WMD, -13.26 mg/dL [95% CI, -17.34 to -9.18], $p < 0.0001$) but not HDL cholesterol or triglycerides. **Based upon the current literature, plant sterols/stanols, when administered in addition to statins, favorably affect total and LDL cholesterol with 95% confidence. Randomized trials examining the impact of plant sterols/stanols in combinatation with statins on patient morbidity and mortality are needed.**
The comparative efficacy of **plant**	Journal of the	A meta-analysis of 14	Upon meta-analysis, the results showed that there is

sterols and stanols on serum lipids: a systematic review and meta-analysis.	American College of Nutrition May 2010 Author: Talati R	randomized controlled trials 531 healthy patients with hypercholesterolemia	no statistically or clinically significant difference between plant sterols and plant stanols in their abilities to modify total cholesterol (WMD -1.11 mg/dL [-0.0286 mmol/L], 95% confidence interval [CI] -4.12 to 1.90, P=0.47), low-density lipoprotein cholesterol (WMD -0.35 mg/dL [-0.0091 mmol/L], 95% CI -2.98 to 2.28, P=0.79), high-density lipoprotein cholesterol (WMD -0.28 mg/dL [-0.00073 mmol/L], 95% CI -1.18 to 0.62, P=0.54), or triglycerides (WMD -1.80 mg/dL [-0.0203 mmol/L], 95% CI -6.80 to 3.21, P=0.48). **Plant sterols and plant stanols do not have statistically or clinically relevant differing effects on total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, or triglyceride levels. The selection of plant sterols vs plant stanols should then be based on potential differences in safety parameters and further study is required to elucidate such differences.**
Effect of a **plant** stanol ester-containing spread, placebo spread, or Mediterranean diet on estimated cardiovascular risk and lipid, inflammatory and haemostatic factors.	Nutrition, Metabolism & Cardiovascular Diseases March 2011 Author: Athyros VG	Randomized, placebo-controlled study 4 months 150 mildly hypercholestoralaemic subjects	Placebo had no significant effect on risk factors or eCVD risk. Mediterranean diet gradually induced a significant reduction in total cholesterol (TC), LDL-C, triglycerides, high sensitivity C-reactive protein (hsCRP), blood pressure and eCVD risk (24-32%). The plant stanol ester spread reduced (by 1 month) TC (-14%), LDL-C (-16%), hsCRP (-17%), and estimated CVD risk (26-30%). eCVD risk reduction was sustained at 4th months when the gradual Mediterranean diet eCVD risk reduction became

			comparable to that of the stanol group. **Plant stanol esters yielded an early, by 1st treatment month, reduction of eCVD risk that resulted from a TC, LDL-C, and hsCRP decrease. eCVD risk reduction on the Mediterranean diet resulted from a change in several CVD risk factors and equaled that of plant stanol at 4 months. The consumption of plant stanol esters by moderately hypercholesterolaemic patients may be a useful option to reduce CVD risk in those who do not adopt a Mediterranean diet.**
Plant stanol supplementation decreases serum triacylglycerols in subjects with overt hypertriglyceridemia.	Lipids Dec 2009 Author: Theuwissen E	Randomised placebo controlled parallel study 28 subjects	After a 1-week run-in period during which a control margarine was used, subjects consumed for 3 weeks either control or PSE-enriched margarine (2.5 g/day of plant stanols). Serum plant stanol concentrations increased in all subjects receiving the PSE-enriched margarines, demonstrating good compliance. PSE supplementation significantly decreased serum total (6.7%, P = 0.015) and LDL cholesterol (9.5%, P = 0.041). A significant interaction between baseline TAG concentrations and PSE intake was found; PSE intake lowered TAG concentrations, particularly in subjects with high baseline TAG concentrations (>2.3 mmol/L; P = 0.009). Additionally, a significant interaction between baseline total number of LDL particles (LDL-P) and PSE intake was found (P = 0.020). PSE consumption lowered LDL-P, primarily in subjects with elevated baseline values; this was mainly due to a non-significant decrease in the number of

			atherogenic small LDL-P. Circulating levels of hs-CRP, glucose, and insulin were not changed after PSE intake. **Taken together, PSE supplementation not only lowered LDL cholesterol, but also serum TAG concentrations, especially in subjects with overt hypertriglyceridemia.**
Evaluation of cardiovascular risk and oxidative stress parameters in hypercholesterolemic subjects on a standard healthy diet including low-fat milk enriched with **plant sterols**.	Journal of Nutritional Biochemistry Sept 2010 Author: Bañuls C	Randomized parallel trial 40 subjects 2 x 3 month intervention phases	PS induced a significant decrease in total cholesterol (6.4%), LDL (9.9%) and the apolipoprotein B100/apolipoprotein A1 ratio (4.9%), but led to a decrease in cryptoxanthin level (29%) without any change being observed in the antioxidant capacity of LDL cholesterol particles, total antioxidant status or lipid peroxidation. **After 3 months, we observed the positive effect of including a PS supplement in dietary measures, as the lipoprotein-mediated risk of cardiovascular disease was reduced. Despite a decrease in the concentration of cryptoxanthin, no evidence of a global impairment of antioxidative defenses or an enhancement of oxidative stress parameters was found.**
Low and moderate-fat **plant** sterol fortified soymilk in modulation of plasma lipids and cholesterol kinetics in subjects with normal to high cholesterol concentrations: report on two randomized	Lipids in Health & Disease Oct 2009 Author: Rideout TC	2 x 28 day studies Study 1: 33 normal cholesterolemic subjects	In comparison with the 1% dairy milk control, the low-fat soy beverage reduced ($P < 0.05$) total and LDL-cholesterol by 10 and 13%, respectively. Consumption of the moderate-fat PS-enriched soy beverage reduced ($P < 0.05$) plasma total and LDL-cholesterol by 12 and 15% respectively. Fasting

crossover studies.		Study 2: 23 hypercholesterolemic sjubects	triglycerides were reduced by 9.4% following consumption of the moderate-fat soy beverage in comparison with the 1% dairy milk. Both low and moderate-fat PS-enriched soy varieties reduced ($P < 0.05$) LDL:HDL and TC:HDL ratios compared with the 1% dairy milk control. Consumption of the moderate-fat PS-enriched soymilk reduced ($P < 0.05$) cholesterol absorption by 27%, but did not alter cholesterol synthesis in comparison with 1% dairy milk. **Compared to 1% dairy milk, consumption of low and moderate-fat PS-enriched soy beverages represents an effective dietary strategy to reduce circulating lipid concentrations in normal to hypercholesterolemic individuals by reducing intestinal cholesterol absorption.**
The effects of **phytosterols**/stanols on blood lipid profiles: a systematic review with meta-analysis.	Asia Pacific Journal of Clinical Nutrition 2009 Author: Wu T	Meta-analysis of 20 studies	The results of the systematic review indicated that phytosterols/stanols could significantly decrease low density lipoprotein cholesterol, total cholesterol and triacylglycerol in treatment groups compared with control groups and that the mean differences were [-0.35 mmol/L, 95%CI(-0.47, -0.22), p<0.00001], [-0.36 mmol/L, 95%CI(-0.46, -0.26), p<0.00001] and [-0.1 mmol/L, 95%CI(-0.16, -0.03), p=0.004] respectively. Foods enriched with 2.0 g of phytosterols/stanols per day had a significant cholesterol lowering effect.
Stearate-enriched **plant** sterol	Journal of Nutrition	Randomized double-	Serum LDL cholesterol concentration significantly

esters lower serum **LDL** cholesterol concentration in normo- and hypercholesterolemic adults.	August 2009 Author: Carr TP	blind 2 group parallel, placebo-controlled study 64 subjects 4 weeks	decreased 0.42 mmol/L (11%) and the LDL:HDL cholesterol ratio decreased 10% with PS ester supplementation, whereas LDL particle size and lipoprotein subclass particle concentrations (as measured by NMR) were not affected. The percent change in LDL cholesterol was positively correlated with baseline lathosterol concentration (r = 0.729; P = 0.0014), indicating an association between the magnitude of LDL change and the rate of whole-body cholesterol synthesis. Serum campesterol (but not sitosterol) concentration significantly increased in the PS ester group. Serum tocopherol, retinol, and beta-carotene concentrations were not affected by PS ester supplementation. **Thus, our findings demonstrate the usefulness of a novel stearate-enriched PS ester compound in decreasing LDL cholesterol in both normo- and hypercholesterolemic adults. The extent to which PS ester fatty acid composition affects intestinal micelle formation and cholesterol absorption in humans requires further study.**
A **plant** stanol yogurt drink alone or combined with a low-dose statin lowers serum triacylglycerol and non-HDL cholesterol in metabolic syndrome patients.	Journal of Nutrition June 2009 Author: Plat J	Subjects with metaboli syndrome so at increased risk of CHD	TAfter 9 wk, we evaluated the effects on serum lipids, low-grade inflammation, and endothelial dysfunction markers. In metabolic syndrome patients, stanol esters (2.0 g/d), simvastatin, or the combination lowered non-HDL-C by 12.8% (P = 0.011), 30.7% (P < 0.001), and 35.4% (P < 0.001), respectively, compared with placebo. **This study shows that in metabolic syndrome**

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Independent and interactive effects of **plant sterols** and fish oil n-3 long-chain polyunsaturated fatty acids on the plasma lipid profile of mildly hyperlipidaemic Indian adults.	British Journal of Nutrition Sept 2009 Author: Khandelwal S	Randomised 200 mildy hypercholesteroleaemic Indian adults 4 weeks	The main effects of plant sterols were a 4.5 % reduction in LDL-cholesterol and a 15 % reduction in TAG without a significant change in HDL-cholesterol. Overall, fish oil n-3 LC-PUFA did not significantly affect cholesterol concentrations but reduced TAG by 15 % and increased HDL-cholesterol by 5.4 %. The combination significantly lowered TAG by 15 % v. control. **Once-a-day intake of 2 g plant sterols/d in a yoghurt drink, 2 g fish oil n-3 LC-PUFA/d in capsules, and their combination had beneficial effects on the lipid profile of mildly hypercholesterolaemic Indian adults.**

Effects of yoghurt enriched with free **plant sterols** on the levels of serum lipids and **plant sterols** in moderately hypercholesterolaemic subjects on a high-fat diet.	International Journal for Food Science Nutrition August 2008 Nittlynen LH	Randomised double-blind cross over trial 8 weeks 42 subjects	Meta-analysis: the pooled treatment difference was -0.34 mmol/l (5.2%, P=0.173) in total cholesterol and was -0.26 mmol/l (-5.8%, P=0.261) in LDL cholesterol, when the sterol yoghurt was compared with the placebo. A low-fat yoghurt enriched with 1-2 g/day plant sterols reduced serum cholesterol levels in moderately hypercholesterolaemic subjects. Campesterol and sitosterol serum levels increased, but their concentration remained in the range of normal values.
Effects of long-term **plant** sterol or stanol ester consumption on lipid and lipoprotein metabolism in subjects on statin treatment.	British Journal of Nutrition December 2009 Author: de Jong A	Randomised, double blind trial 85 weeks 54 subjects	Compared with the control group, plant sterol and stanol ester consumption reduced LDL-cholesterol by 0.28 mmol/l (or 8.7 %; P = 0.08) and 0.42 mmol/l (13.1 %; P = 0.006) respectively after 85 weeks. No effects were found on plasma concentrations of oxysterols or 7 alpha-hydroxy-4-cholesten-3-one, a bile acid synthesis marker. **Long-term consumption of both plant sterol and stanol esters effectively lowered LDL-cholesterol concentrations in statin users.**
Cholesterol lowering effect of a soy drink enriched with **plant sterols** in a French population with moderate hypercholesterolemia.	Lipids in Health & Disease October 2008 Author: Weidner C	Randomized, placebo-controlled double-blind mon-centric study 8 weeks 50 subjects	Regular consumption of the soy drink enriched with plant sterols for 8 weeks significantly reduced LDL-C by 0.29 mmol/l or 7% compared to baseline ($p < 0.05$). TC and non-HDL-C concentrations decreased by 0.26 mmol/l and 0.31 mmol/l (each $p < 0.05$), respectively. Mean reductions in total, LDL and non-HDL cholesterol were significantly greater than in the placebo group ($p < 0.05$). HDL-C and triglycerides were not affected. Compliance was very high

Cholesterol lowering effect of a soy drink enriched with **plant sterols** in a French population with moderate hypercholesterolemia.	Lipids in Health & Disease October 2008 Author: Weidner C	Randomized, placebo-controlled double-blind mon-centric study 8 weeks 50 subjects	Regular consumption of the soy drink enriched with plant sterols for 8 weeks significantly reduced LDL-C by 0.29 mmol/l or 7% compared to baseline ($p < 0.05$). TC and non-HDL-C concentrations decreased by 0.26 mmol/l and 0.31 mmol/l (each $p < 0.05$), respectively. Mean reductions in total, LDL and non-HDL cholesterol were significantly greater than in the placebo group ($p < 0.05$). HDL-C and triglycerides were not affected. Compliance was very high (>96%), and products were well tolerated. **Daily consumption of a plant sterol-enriched soy drink significantly decreased total, non-HDL and LDL cholesterol and is therefore an interesting and convenient aid in managing mild to moderate hypercholesterolemia.**
The lipid-lowering effects of **phytosterols** and (n-3) polyunsaturated fatty acids are synergistic and complementary in hyperlipidemic men and women.	Journal of Nutrition June 2008 Author: Micallef MA	Randomised, double-blind, placebo controlled 2 x 2 factorial trial in 4 parallel groups 3 weeks 60 hyperlipidemic subjects	The combination of phytosterols and (n-3) LCPUFA reduced plasma total cholesterol by 13.3% ($P = 0.001$), which differed from (n-3) LCPUFA alone ($P < 0.001$). LDL-cholesterol concentrations followed the same pattern as that of plasma cholesterol with a 12.5% decrease ($P = 0.002$) in the combination group. The HDL-cholesterol concentration was increased by (n-3) LCPUFA (7.1%; $P = 0.01$) alone and in combination with phytosterols (8.6%; $P = 0.04$), whereas phytosterol treatment alone had no effect. Plasma triglyceride concentration was lowered by (n-3) LCPUFA (22.3%; $P = 0.004$) alone

Plant sterol consumption frequency affects plasma lipid levels and cholesterol kinetics in humans.	European Journal of Clinical Nutrition June 2009 AbuMweis SS	Randomised, placebo-controlled, three – phase (6 days) cross-over feeding trial 19 subjects	Relative to control, end point plasma low-density lipoprotein (LDL) cholesterol concentrations were lower (P<0.05) after consuming plant sterols three times per day but were not different when consumed once per day (3.43+/-0.62, 3.22+/-0.58 and 3.30+/-0.65 mmol/l, control, three times per day and single-BF, respectively). Relative to the control, end point LDL level was 0.21+/-0.27 mmol/l (6%) lower (P<0.05) at the end of the three times per day phase. Cholesterol fractional synthesis rate was highest (P<0.05) after the three times per day phase (0.0827+/-0.0278, 0.0834+/-0.0245 and 0.0913+/-0.0221 pool/day, control, single-BF and three times per day, respectively). Cholesterol-absorption efficiency decreased (P<0.05) by 36 and 39% after the three times per day and single-BF phase, respectively, relative to control. **Present data indicate that to obtain optimal cholesterol-lowering impact, plant sterols should be consumed as smaller doses given more often, rather than one large dose.**
The baseline serum lipoprotein profile is related to **plant** stanol induced changes in serum lipoprotein cholesterol and triacylglycerol concentrations.	Journal of the American College of Nutrition February 2008 Author: Naumann E	Data of five studies performed here	After plant stanol ester consumption, higher baseline serum concentrations of total and LDL cholesterol resulted in larger absolute decreases in their respective serum concentrations. For the ratio of total to HDL cholesterol and triacylglycerol, higher baseline serum levels resulted in larger absolute and relative decreases in their serum levels. HDL cholesterol concentrations increased in subjects with low baseline concentrations and decreased in those

The baseline serum lipoprotein profile is related to **plant** stanol induced changes in serum lipoprotein cholesterol and triacylglycerol concentrations.	Journal of the American College of Nutrition February 2008 Author: Naumann E	Data of five studies performed here	After plant stanol ester consumption, higher baseline serum concentrations of total and LDL cholesterol resulted in larger absolute decreases in their respective serum concentrations. For the ratio of total to HDL cholesterol and triacylglycerol, higher baseline serum levels resulted in larger absolute and relative decreases in their serum levels. HDL cholesterol concentrations increased in subjects with low baseline concentrations and decreased in those with high baseline concentrations. Effects however were small. No relationships were observed with baseline serum cholesterol-standardized lathosterol and campesterol concentrations, although LDL cholesterol concentrations tended to decrease more at higher baseline sitosterol concentrations. No effects of other baseline characteristics were found. **People with an unfavorable serum lipid and lipoprotein profile benefit even more of plant stanols than people with a more favorable profile.**
Plant sterol-enriched fermented milk enhances the attainment of **LDL**-cholesterol goal in hypercholesterolemic subjects.	European Journal of Nutrition February 2008 Author: Plana N	Randomised, double-blind, placebo-conrolled parallel clinical trial 42 days 83 hypercholesterolemic patients not at goal	Patients on phytosterols attained an average LDL-C reduction of more than 10% (12.2% after 3 weeks; 10.6% after 6 weeks) (P = 0.001; 95% CI: 4.03-19.00) regardless of statin therapy compared to the control group. About 50% of the subjects on phytosterols, as compared to 20% of controls, attained their LDL-C target values (<3.3 or <2.6 mmol/l for primary and secondary prevention, respectively) at the end of the study (P < 0.001). HDL-cholesterol (HDL-C) did not change and

Examination of encapsulated phytosterol ester supplementation on lipid indices associated with cardiovascular disease.	Nutrition September 2007 Author: Earnest CP	Randomised, double blind parallel group clinical intervention 54 subjects	Total cholesterol (TC) levels at baseline (mean +/- SD) were 6.29 +/- 0.7 mmol/L in the phytosterol group and 6.00 +/- 0.7 mmol/L in the placebo group. Baseline LDL-C levels were 4.27 +/- 0.7 mmol/L in the treatment group and 4.00 +/- 0.8 mmol/L in the placebo group. Analysis of variance and Tukey's least significant difference post hoc analyses revealed a significant within-group reduction in TC (-0.23 +/- 0.4 mmol/L, P < 0.05) and LDL-C (-0.22 +/- 0.5 mmol/L, P < 0.05) for the phytosterol treatment group. Mean reductions in TC and LDL-C were greater than placebo (P < 0.05). Percentages of change from baseline for TC were -3.52% (95% confidence interval -6.44 to -0.40) for phytosterol treatment and 2.64% (95% confidence interval 0.30-5.60) for placebo. Those for LDL-C were -5.00% (95% confidence interval -9.92 to -0.08) for phytosterol and 4.89 (95% confidence interval 0.24-9.5) for placebo. No other significant effects were observed. **Encapsulated phytosterol ester ingestion appears to positively modulate LDL-C. Given that the reduction in LDL-C was not as extensive as in food-based trials, future investigations should examine potential timing and dose issues relative to encapsulated delivery.**
[Changes in lipid profile after regular intake of canned fish. The influence of addition of isoflavones, omega-3 fatty acids and	Medicina Clinica June 2007	Randomized, single blind study 3 months	The mean age of the study population was 53 years, 45% of them being males. In all 4 groups a significant reduction of total cholesterol, low-density lipoprotein (LDL)-cholesterol levels and total

fitosterols].	Author: Otero-Raviña F	400 subjects	cholesterol/high-density lipoprotein (HDL)-cholesterol ratio was observed after 3 months of follow-up; there were no significant changes of triglycerides nor HDL-cholesterol levels. The comparison between different types of supplementation revealed that only phytosterols addition reached a greater reduction of total cholesterol and LDL-cholesterol levels than canned tuna in olive oil alone ($p < 0.05$), **Regular intake of enrichment with canned tuna supplementation is associated with improvement of lipid profile. The addition of isoflavones, omega-3 fatty acids or phytosterols supplementations increases fish consume effect, although only the enrichment with phytosterols reaches significantly better results.**
The lipid lowering effect of **plant** sterol ester capsules in hypercholesterolemic subjects.	Lipds in Health & Disease April 2007 Author: Acuff RV	Double-blind, placebo-controlled sequential study with 4 week placebo phase 16 subjects	In comparison to placebo, LDL-cholesterol was significantly reduced by 7% and 4% ($P < 0.05$) at both week 3 and week 4; HDL at week 3 of the treatment was significantly increased by 9% ($P < 0.01$), but not at week 4 (4%); total cholesterol was not significantly different from placebo throughout the period, TC/HDL and LDL/HDL were significantly reduced by (8%, 8%, 6%, 10%, respectively) ($P < 0.01$) at both week 3 and week 4. CRP and triglycerides did not differ either between the two phases or during the treatment phase. **Plant sterol ester capsule is effective in improving lipid profiles among**

			hypercholesterolemic subjects in a free-living setting at the minimum dosage recommended by FDA. The significant improved lipid profiles were reached after three weeks of administration. To achieve better lipid lowering results, higher dosages and combination with diets low in saturated fat and cholesterol are recommended.
Plant stanol esters in low-fat milk products lower serum total and **LDL** cholesterol.	European Journal of Nutrition March 2007 Author: Seppo L	Meta-analysis of 4 unpublished sub studies (yoghurt, yoghurt single-shot drinks or milk 5 weeks 199 hypercholesterolemic subjects	The pooled treatment difference in total cholesterol was -3.8% (95% CI -6.0 to -1.7, p < 0.001) when stanol was compared to placebo. In LDL cholesterol, the pooled treatment difference was -4.9% (95% CI -7.8 to -1.8, p = 0.002). There were no significant differences between the groups in pooled HDL cholesterol or triacylglycerol concentrations. The results tended to be more pronounced when we were certain that the yoghurt single-shot drink was ingested with lunch, and when the baseline LDL-cholesterol concentration was > or = 3.5 mmol/l. **These results imply that low-fat milk products enriched with plant stanol esters lower both total cholesterol and LDL cholesterol statistically significantly in subjects with mild or moderate hypercholesterolemia. The changes tended to relate to the baseline LDL-cholesterol concentration.**
Fish-oil esters of **plant sterols** improve the lipid profile of dyslipidemic subjects more than do fish-oil or sunflower oil esters of	American Journal of Clinical Nutrition December 2006	Semi-randomised, single-blind, 4 period crossover study including 4	Fish oil and FO-PS resulted in fasting and postprandial plasma triacylglycerol concentrations that were markedly lower than those observed with OO and SU-PS (P = 0.0001), but to a different

plant sterols.	Author: Demonty I	experimental isoenergetic diets of 4 wk each and 4-wk intervening washout periods. 21 hyperlipidemic subjects	extent. LDL cholesterol was significantly lower after supplementation with FO-PS and SU-PS than at the end of the control OO diet (P = 0.0031 and 0.0407, respectively). HDL cholesterol was not affected. FO-PS and SU-PS resulted in a lower ratio of total to HDL cholesterol and lower apolipoprotein (apo) B concentrations than did OO and fish oil. The ratio of apoB to apoA was significantly lower after SU-PS consumption than after consumption of OO (P = 0.0126) and fish oil (P = 0.0292). FO-PS and SU-PS resulted in similar ratios of apoB to apoA. HDL2 and the ratio of HDL2 to HDL3 were significantly higher at the end of the FO-PS treatment than at the end of the OO (P = 0.0006), fish oil (P = 0.0036), and SU-PS (P = 0.0016) treatments. **Supplementation of an OO-based diet with FO-PS may reduce cardiovascular disease risk more than does supplementation with fish oil or SU-PS.**
Plant sterol-fortified orange juice effectively lowers cholesterol levels in mildly hypercholesterolemic healthy individuals.	Arteriosclerosis, Thrombosis, and Vascular Biology. March 2004 Author: Devaraj S	Randomised placebo controlled trial 8 weeks 72 mildly hypercholesterolemic subjects	Sterol OJ supplementation significantly decreased total (7.2%), LDL (12.4%), and non-high-density lipoprotein (HDL) cholesterol (7.8%) compared with baseline and compared with placebo OJ (P<0.01). Apolipoprotein B levels were significantly decreased (9.5%) with sterol OJ. There were no significant changes in HDL cholesterol or triglycerides with the sterol OJ. While folate and B12 levels significantly increased, homocysteine levels were unchanged. **Orange juice fortified with plant sterols are**

			effective in reducing LDL cholesterol and could easily be incorporated into the therapeutic lifestyle changes dietary regimen.
Reduced-calorie orange juice beverage with **plant sterols** lowers C-reactive protein concentrations and improves the lipid profile in human volunteers.	Journal of Dietary Supplements June 2006	Randomized trial 8 weeks 72 subjects	Sterol Bev supplementation significantly reduced total cholesterol (5%; P < 0.01) and LDL cholesterol (9.4%; P < 0.001) compared with both baseline and Placebo Bev (P < 0.05). HDL cholesterol increased significantly with Sterol Bev (P < 0.02). No significant changes in triacylglycerol, glucose, or liver function tests were observed with Sterol Bev. Sterol Bev supplementation resulted in no significant change in vitamin E and carotenoid concentrations. Sterol Bev supplementation resulted in a significant reduction of CRP concentrations compared with baseline and Placebo Bev (median reduction: 12%; P < 0.005). **Supplementation with a reduced-calorie orange juice beverage containing plant sterols is effective in reducing CRP and LDL cholesterol and could be incorporated into the dietary portion of therapeutic lifestyle changes.**
Effect of **plant** stanol tablets on low-density lipoprotein cholesterol lowering in patients on statin drugs.	American Journal of Cardiology February 2006 Author: Goldberg AC	Double-blind placebo-controlled, parallel clinical trial 9 weeks 26 patients on long-term statin therapy	Stanol tablets reduced LDL cholesterol 9.1% (p = 0.007) or 12.2 mg/dl. Total cholesterol was reduced by 12.9 mg/dl (p = 0.03). A strong inverse correlation (r(s) = -0.82, p = 0.0007) was found between the baseline LDL cholesterol and the percent change in LDL cholesterol observed after stanol treatment. **The additional LDL cholesterol lowering with stanol/lecithin tablets provided a potential**

Effect of **plant** stanol tablets on low-density lipoprotein cholesterol lowering in patients on statin drugs.	American Journal of Cardiology February 2006 Author: Goldberg AC	Double-blind placebo-controlled, parallel clinical trial 9 weeks 26 patients on long-term statin therapy	Stanol tablets reduced LDL cholesterol 9.1% (p = 0.007) or 12.2 mg/dl. Total cholesterol was reduced by 12.9 mg/dl (p = 0.03). A strong inverse correlation (r(s) = -0.82, p = 0.0007) was found between the baseline LDL cholesterol and the percent change in LDL cholesterol observed after stanol treatment. **The additional LDL cholesterol lowering with stanol/lecithin tablets provided a potential adjunctive therapy for patients who have not reached their target LDL cholesterol goal during statin therapy.**
Safety aspects and cholesterol-lowering efficacy of low fat dairy products containing **plant sterols**.	European Journal of Clinical Nutrition May 2006 Author: Korpela R	Parallel double-blind study 6 weeks with 3-week run in 164 mildly or moderately hypercholesterolaemic subjects	During the treatment period, there was a 6.5% reduction in serum total cholesterol in the sterol group while no change was observed in the control group (P<0.0005). Serum low-density lipoprotein (LDL) cholesterol was reduced by 10.4% in the sterol group and by 0.6% in the control group (P<0.00005). There was no change during the trial in serum high-density lipoprotein (HDL) cholesterol or triacylglycerol concentrations. The HDL/LDL cholesterol ratio increased by 16.1% in the sterol group and by 4.3% in the control group (P=0.0001). Serum plant sterol levels increased significantly (P=0.0001) in the sterol group. None of the fat-soluble vitamin levels decreased significantly when changes in serum total cholesterol were taken into account. The hypocholesterolaemic effect of sterol administration was not influenced by apolipoprotein

Intake occasion affects the serum cholesterol lowering of a **plant** sterol-enriched single-dose yoghurt drink in mildly hypercholesterolaemic subjects.	European Journal of Clinical Nutrition March 2006 Author: Doombos AM	Double blind, randomized , placebo-controlled parallel study 4 weeks run-in and 4 weeks intervention period. 184 moderate hypercholesterolaemic subjects	LDL-cholesterol (LDL-C) was significantly lowered when the single-dose drink was taken with a meal independent of its fat content (drink A: -9.5% (P<0.001, 95% CI: -13.8 to -5.2); drink B: -9.3% (P<0.001, 95% CI: -13.7 to -4.9)) as compared to placebo. When consumed without a meal, LDL-C was also significantly decreased (drink A: -5.1% (P<0.05, 95% CI: -9.4 to -0.8); drink B: -6.9% (P<0.01, 95% CI: -11.3 to -2.5) as compared to placebo, however the effect was significantly smaller as compared to the intake with a meal. **These results indicate that a PS-ester-enriched single-dose yoghurt drink effectively reduces LDL-C irrespective of the fat content of the product. A substantially larger decrease in serum cholesterol concentration was achieved when the single-dose drink was consumed with a meal emphasizing the importance of the intake occasion for optimal cholesterol-lowering efficacy.**
Micellar **phytosterols** effectively reduce cholesterol absorption at low doses.	Annals of Nutrition and Metabolism Sept – Oct 2005 Author: Shin MJ	Cross over study 24 healthy subjects	Micellar phytosterols had a significant overall effect on cholesterol absorption (p = 0.0002), reduced cholesterol absorption by 23.3% at a dose of 300 mg phytosterols (p = 0.0004) and by 32.0% at a dose of 500 mg phytosterols (p = 0.0001) compared with the placebo. The effect of 200 mg treatment did not reach statistical significance but there was a tendency (p = 0.052). **Water-dispersible, micellar phytosterols reduced**

			cholesterol absorption effectively at very low doses.
Responsiveness of plasma lipids and lipoproteins to **plant** stanol esters.	American Journal of Cardiology July 2005 Author: Cater NB	3 studies – no more info	Study 1 showed that maximal LDL lowering with plant stanols in the form of esters can be achieved at a dose of 2 g/day. Higher doses do not provide additional efficacy. Study 2 demonstrated that stanol esters can reduce LDL cholesterol levels in postmenopausal women by about 13%, which makes use of stanol esters attractive as a component of nondrug therapy in these women who generally are at relatively low risk for coronary heart disease. Finally, study 3 found that plant stanols provide additional lowering of LDL cholesterol when added to ongoing statin therapy. **This makes plant stanols an attractive dietary component to help to achieve the goals of LDL-lowering therapy in patients requiring an LDL-lowering drug.**
Plant sterols are efficacious in lowering plasma **LDL** and non-HDL cholesterol in hypercholesterolemic type 2 diabetic and nondiabetic persons.	American Journal of Clinical Nutrition June 2005 Author: Lau VW	Double blinded, randomized, crossover, placebo-controlle feeding trial 21 days, separated y a 28 d washout period 29 subjects (15 non diabetic / 14 diabetic)	Plant sterol consumption significantly reduced ($P < 0.05$) LDL-cholesterol concentrations from baseline in both nondiabetic and diabetic subjects by 15.1% and 26.8%, respectively. The diabetic subjects had significantly ($P < 0.05$) lower absolute concentrations of total cholesterol after treatment than did the nondiabetic subjects; however, there was no significant difference in the percentage change from the beginning to the end of the trial. There was also a significant decrease ($P < 0.05$) in absolute non-

			HDL-cholesterol concentrations after treatment in both groups. **The results showed that plant sterols are efficacious in lowering LDL cholesterol and non-HDL cholesterol in both diabetic and nondiabetic persons. Plant sterol consumption may exist as a dietary management strategy for hypercholesterolemia in persons with type 2 diabetes.**
Plant sterol/stanol prescription is an effective treatment strategy for managing hypercholesterolemia in outpatient clinical practice.	Journal of the American Dietary Association Jan 2005 Author: Patch CS	Randomised parallel design Comparitive 12-week interventions 25 hyperlipidaemic subjects	Five of 14 subjects in the intervention group compared with 0 of 11 in the control group achieved a reduction in serum cholesterol of >/=15% (P <.05). Using the number needed to treat index, for each 2.8 patients counseled with routine prescription of plant sterols/stanols, one additional patient would obtain a reduction in cholesterol by >/=15% compared with conventional management. This was achieved without any detrimental effects on the dietary fatty acid profile. **Routine prescription of margarine containing plant sterol/stanol is an effective strategy in the management of hypercholesterolemic patients in the clinical setting.**
Combination of **phytosterols** and omega-3 fatty acids: a potential strategy to promote cardiovascular health.	Current medicinal chemistry. Cardiovascular and hematological agents January 2004	Mini Review	Numerous clinical studies have shown that a daily intake of 1.5-2.0 g of phytosterols can result in a 10-15 % reduction in LDL levels, while consumption of n-3 is associated with a significant reduction in plasma triglyceride (TG) concentrations. Furthermore, n-3 may also beneficially modify a

	Author: Normén L		number of other risk factors of coronary heart disease (CHD). Thus, it is reasonable to suggest that combination of phytosterols and n-3 may further reduce cardiovascular risk factors. In this mini-review, we have critically reviewed and summarized data from clinical and animal studies in which phytosterols and Omega-3 fatty acids, alone or in combination, were used to lower cholesterol and promote . We have also provided information on structure-function relationship for these two natural compounds. Biological properties of several phytosterol derivatives including phytosterol-glucoside have been also discussed. **Although the animal studies are supportive of this combination therapy, human studies are needed to address its long term effects.**
Plant sterol ester-enriched milk and yoghurt effectively reduce serum cholesterol in modestly hypercholesterolemic subjects.	European Journal of Nutrition June 2005 Author: Noakes M	2 studies Study 1 – single blind crossover design with 4 phases of 3 week interventions 39 subjects Study 2 – Full randomized double	In study one, PSteE-milk and PSteE-spread were equally efficacious in lowering total and LDL-cholesterol as compared to placebo by 6-8% and 8-10%, respectively. No significant additional cholesterol-lowering was observed with the combination of PSteE-milk and PSteE-spread (4 g plant sterols/d). PSteE-enriched milk and the combination of PSteE-enriched milk plus spread both lowered lipid-adjusted serum beta-carotene concentrations by 10-14% ($P < 0.02$),while the PSteE-rich spread alone did not significantly alter serum beta-carotene levels. In study two, the PSteE-

Plant sterol ester-enriched milk and yoghurt effectively reduce serum cholesterol in modestly hypercholesterolemic subjects.	European Journal of Nutrition June 2005 Author: Noakes M	2 studies Study 1 – single blind crossover design with 4 phases of 3 week interventions 39 subjects Study 2 – Full randomized double blind crossover design with 2 phases and 3 week interventions 40 subjects	In study one, PSteE-milk and PSteE-spread were equally efficacious in lowering total and LDL-cholesterol as compared to placebo by 6-8% and 8-10%, respectively. No significant additional cholesterol-lowering was observed with the combination of PSteE-milk and PSteE-spread (4 g plant sterols/d). PSteE-enriched milk and the combination of PSteE-enriched milk plus spread both lowered lipid-adjusted serum beta-carotene concentrations by 10-14% ($P < 0.02$),while the PSteE-rich spread alone did not significantly alter serum beta-carotene levels. In study two, the PSteE- and PStaE-enriched yoghurts reduced LDL-cholesterol significantly compared to placebo by 0.27 +/- 0.05 mmol/l (6%) and 0.23 +/- 0.05 mmol/l (5%), respectively. In both studies, there was no effect on HDL-cholesterol and triacylglycerol concentrations. **Plant sterols in the form of their esters when provided in lowfat milk and yoghurt are effective in lowering total and LDL-cholesterol.**
Effect of free **plant sterols** in low-fat milk on serum lipid profile in hypercholesterolemic subjects.	European Journal of Nutrition June 2004 Author: Thomsen AB	Randomisd, placebo-controlled three-arm crossover study 12 weeks 81 patients	The milk product was well tolerated. The placebo-adjusted mean reduction in LDL was 7.13+/-12.31 and 9.59+/-12.44% (mean+/-s.d.) for Lo and Hi groups, respectively ($P<0.0001$); there was no statistically significant difference in LDL lowering for the Lo and Hi groups. There were no significant changes in serum vitamin E or carotenoid concentrations after standardization with LDL

Cholesterol-lowering effects of **plant** sterol esters differ in milk, yoghurt, bread and cereal.	European Journal of Clinical Nutrition March 2004 Author: Clifton PM	Randomised, incomplete crossover, single-blind study consisting of four treatment periods of 3 weeks each, one of which was a control period. 58 subjects	Serum total and LDL cholesterol levels were significantly lowered by consumption of phytosterol-enriched foods: milk (8.7 and 15.9%) and yoghurt (5.6 and 8.6%). Serum LDL cholesterol levels fell significantly by 6.5% with bread and 5.4% with cereal. They were both significantly less efficacious than sterol-enriched milk (P<0.001). Plasma sitosterol increased by 17-23% and campesterol by 48-52% with phytosterol-enriched milk and bread. Lipid-adjusted beta-carotene was lowered by 5-10% by sterols in bread and milk, respectively. **This is the first study to demonstrate that cholesterol-lowering effects of plant sterol esters may differ according to the food matrix. Plant sterols in low-fat milk was almost three times more effective than in bread and cereal. Despite phytosterol-enriched cereal products resulting in lower serum cholesterol reductions compared to sterol-enriched milk, the detection of similar changes in plasma phytosterols demonstrated that such products still delivered and released phytosterols to the gut**.
Plant sterol-fortified orange juice effectively lowers cholesterol levels in mildly hypercholesterolemic healthy individuals.	Arteriosclerosis, Thrombosis, and Vascular Biology. March 2004 Author: Devaraj S	Randomised 8 weeks 72 mildly hypercholesterolemic subjects	Sterol OJ supplementation significantly decreased total (7.2%), LDL (12.4%), and non-high-density lipoprotein (HDL) cholesterol (7.8%) compared with baseline and compared with placebo OJ (P<0.01). Apolipoprotein B levels were significantly decreased (9.5%) with sterol OJ. There were no significant changes in HDL cholesterol or triglycerides with the sterol OJ. While folate and B12 levels significantly

Plant sterol-fortified orange juice effectively lowers cholesterol levels in mildly hypercholesterolemic healthy individuals.	Arteriosclerosis, Thrombosis, and Vascular Biology. March 2004 Author: Devaraj S	Randomised 8 weeks 72 mildly hypercholesterolemic subjects	Sterol OJ supplementation significantly decreased total (7.2%), LDL (12.4%), and non-high-density lipoprotein (HDL) cholesterol (7.8%) compared with baseline and compared with placebo OJ (P<0.01). Apolipoprotein B levels were significantly decreased (9.5%) with sterol OJ. There were no significant changes in HDL cholesterol or triglycerides with the sterol OJ. While folate and B12 levels significantly increased, homocysteine levels were unchanged. **Orange juice fortified with plant sterols are effective in reducing LDL cholesterol and could easily be incorporated into the therapeutic lifestyle changes dietary regimen.**
Co Q10 (STUDIES (2), RESEARCH, REVIEWS)			
The effect of coenzyme Q10 on morbidity and mortality in chronic heart failure	Journal for the American College of Cardiology December 2014 Author: Mortensen SA	Randomised, double-blind, multicentre trial 2 years 420 subjects	There were no significant changes in short-term endpoints. The primary long-term endpoint was reached by 15% of the patients in the CoQ10 group versus 26% in the placebo group (hazard ratio: 0.50; 95% confidence interval: 0.32 to 0.80; p = 0.003) by intention-to-treat analysis. The following secondary endpoints were significantly lower in the CoQ10 group compared with the placebo group: cardiovascular mortality (9% vs. 16%, p = 0.026), all-cause mortality (10% vs. 18%, p = 0.018), and incidence of hospital stays for HF (p = 0.033). In

Red yeast rice and coenzyme Q10 as safe alternatives to surmount atorvastatin-induced myopathy in hyperlipidemic rats	Canadian Journal of Physiology & Pharmacology June 2014 Author: Abdelbaset M	Study in hyperlipidemic rats 90 days	RYR and CoQ10 had the advantage over atorvastatin in that they lower cholesterol without elevating creatine kinase, a hallmark of myopathy. RYR maintained normal levels of heart ubiquinones, which are essential components for energy production in muscles. **In conclusion, RYR and CoQ10 may offer alternatives to overcome atorvastatin-associated myopathy.**
Coenzyme Q10 supplementation decreases statin-related mild-to-moderate muscle symptoms	Medical Science Montior - International Medical Journal of Experimental and Clinical Research Nov 2014 Author: Skarlovnik A	Randomised study 30 days 50 subjects taking statins and reporting muscle pain	The intensity of muscle pain, measured as the Pain Severity Score (PSS), in the Q10 group was reduced from 3.9±0.4 to 2.9±0.4 ($P<0.001$). The Pain Interference Score (PIS) after Q10 supplementation was reduced from 4.0±0.4 to 2.6±0.4 ($P<0.001$). In the placebo group, PSS and PIS did not change. Coenzyme Q10 supplementation decreased statin-related muscle symptoms in 75% of patients. The relative values of PSS and PIS significantly decreased (-33.1% and -40.3%, respectively) in the Q10 group compared to placebo group (both $P<0.05$). From baseline, no differences in liver and muscle enzymes or cholesterol values were found. **The present results show that coenzyme Q10 supplementation (50 mg twice daily) effectively reduced statin-related mild-to-moderate muscular symptoms, causing lower interference of statin-related muscular symptoms with daily activities.**

Reduction of serum ubiquinol-10 and ubiquinone-10 levels by atorvastatin in hypercholesterolemic patients.	Journal of Atherosclerosis & Thrombosis 2005 Author: Macuchi H	Study 8 weeks 14 hypercholesterolemic patients treated with atorvastatin	All patients showed definite reductions of serum ubiquinol-10 and ubiquinone-10 levels, and mean levels of serum ubiquinol-10 and ubiquinone-10 levels decreased significantly from 0.81 +/- 0.21 to 0.46 +/- 0.10 microg/ml ($p < 0.0001$), and from 0.10 +/- 0.06 to 0.06 +/- 0.02 microg/ml ($p = 0.0008$), respectively. Percent reductions of ubiquinol-10 and those of total cholesterol showed a positive correlation ($r = 0.627$, $p = 0.0165$). **As atorvastatin reduces serum ubiquinol-10 as well as serum cholesterol levels in all patients, it is imperative that physicians are forewarned about the risks associated with ubiquinol-10 depletion.**
The clinical use of HMG CoA-reductase inhibitors and the associated depletion of coenzyme Q10	Biofactors – International Union of Biochemistry 2003 Author: Langsjoen PH	Review	Statin-induced CoQ10 deficiency is completely preventable with supplemental CoQ10 with no adverse impact on the cholesterol lowering or anti-inflammatory properties of the statin drugs. We are currently in the midst of a congestive heart failure epidemic in the United States, the cause or causes of which are unclear. **As physicians, it is our duty to be absolutely certain that we are not inadvertently doing harm to our patients by creating a wide-spread deficiency of a nutrient critically important for normal heart function.**

Role of coenzyme Q10 (CoQ10) in cardiac disease, hypertension and Meniere-like syndrome.	Pharmacology & Therapeutics Dec 2009 Author: Kumar A	Review	Significant improvement has been observed in clinical and hemodynamic parameters and in exercise tolerance in patients given adjunctive CoQ10 in doses from 60 to 200 mg daily in the various trials conducted in patients of heart failure, hypertension, ischemic heart disease and other cardiac illnesses. Recently it has been found to be an independent predictor of mortality in congestive heart failure. It has also been found to be helpful in vertigo and Meniere-like syndrome by improving the immune system. Further research is going on to establish firmly its role in the therapy of cardiovascular diseases.
Systematic review of effect of coenzyme Q10 in physical exercise, hypertension and heart failure.	Biofactors 2003 Author: Rosenfeldt F	Randomised double blind placebo-controlled pilot trial 3 months 35 patients	In the CoQ10 patients but not in the placebo patients there were significant improvements in symptom class and a trend towards improvements in exercise time.

FURTHER STUDIES

RED YEAST RICE

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