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Comparison of rice bran oil margarine with Flora margarine and Flora pro-activ® margarine for lowering cholesterol

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Abstract

Phytosterols have been shown to be effective in reducing serum cholesterol levels in numerous human clinical studies and regular consumption is recommended as part of therapeutic lifestyle changes aimed at reducing low density lipoprotein (LDL-C) in the treatment of hyperlipidaemia, a risk factor for cardiovascular disease. Fat based spreads have been shown to be a very successful vehicle for delivery of plant sterols, readily accepted by consumers and efficacious in reducing cholesterol levels. Alfa One™ Rice Bran Oil (RBO) spread is a new product entering into the market place. It is derived from rice bran oil and contains high levels of unsaponifiable material rich in phytosterols, triterpene alcohols, ferulic acid esters (γ-oryzanol) and vitamin E isomers. As such it may have the potential to lower serum cholesterol levels when consumed on a daily basis.

In order to establish the effectiveness of Alfa One™ Rice Bran Oil (RBO) spread compared with Flora pro-activ® margarine, a well established brand of plant sterol margarine already proven to lower cholesterol, a randomised double blind cross-over human clinical trial over 12 weeks was conducted. The study was divided into two treatment arms. The first arm of the study was to determine whether Alfa One™ RBO spread (containing 1.5% plant sterols) could lower total and LDL cholesterol levels to a greater extent than standard Flora margarine (containing no plant sterols) or Flora Pro-activ® margarine (containing 8% plant sterols). The second study arm tested the proposition that daily consumption of Alfa One™ Rice Bran Oil (RBO) spread in conjunction with rice bran oil (containing 0.5% plant sterols) would lower total and LDL cholesterol to a greater extent than Alfa One™ RBO spread in isolation and more than Flora margarine in conjunction with sunflower oil.

Eighty mildly hypercholesterolaemic individuals (total cholesterol $\geq 5$ mmol/L and $\leq 7.5$ mmol/L) were recruited and randomised into two groups of forty. Participants were asked to continue with their normal dietary pattern but to
replace any margarine/butter/fat consumption with the trial products. One group of 40 were then assigned to the first treatment arm of the study (margarine-only group) and were randomised to consume 20 g (4 teaspoons) Alfa One™ RBO spread daily for 4 weeks, or 20 g Flora margarine daily for 4 weeks, or 20 Flora pro-activ® daily for 4 weeks. Phytosterol levels delivered in these amounts were: RBO margarine: 118mg phytosterol and 14 mg γ-oryzanol; Flora proactiv® 1600 mg phytosterol; Flora margarine 0mg phytosterol. The second group of 40 were allocated to the second arm of the trial (margarine and oil group) and consumed 20 g Alfa One™ RBO spread and 30 ml rice bran oil (RBO) daily for 4 weeks, or 20 g Flora margarine and 30 ml sunflower oil daily for 4 weeks, or 20 g Alfa One™ RBO spread daily for 4 weeks, changing treatment at the end of each 4-week period. Phytosterol amounts delivered in these amounts were: RBO margarine: 118 mg phytosterol and 14 mg γ oryzanol; RBO 222mg mg phytosterol, 150 mg γ oryzanol. Each participant consumed all three treatments in a random order over a 12 week period. At baseline and following each 4 week intervention period, measurements were made of weight and blood pressure. Venous blood samples were collected for analysis of total cholesterol, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), total cholesterol: HDL-C, triglycerides and plasma phytosterols. Three-day diet records from each individual were also collected for analysis of normal dietary intake.

Results showed that compared to a standard Flora margarine, Alfa One™ RBO spread significantly reduced total cholesterol by 2.2% ($P=0.045$), total cholesterol:HDL by 4.1% ($P=0.005$) and LDL-C by 3.5% ($P=0.016$), but was not as effective overall as Flora Pro-activ® which reduced total cholesterol by 4.4% ($P=0.001$), total cholesterol:HDL by 3.4% ($P=0.014$) and LDL-C by 5.6% ($P=0.001$). Consumption of Flora margarine alone produced no significant decrease from baseline figures in any of the cholesterol parameters measured. Surprisingly, in group two, the addition of rice bran oil to the Alfa One™ RBO spread produced no differences in cholesterol levels. The reason for this unexpected result is being explored further.
These results confirm that Alfa One™ RBO spread is effective in lowering serum cholesterol levels when consumed as part of a normal diet. Studies have shown that a 1% reduction in LDL-C can equate to a 2% decrease in coronary heart disease (CHD) risk thus suggesting that the 3.5% reduction demonstrated by Alfa One™ RBO spread in this study could be effective in reducing CHD risk as much as 6% in a mildly hypercholesterolaemic population.
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Abbreviations

ABC  adenosine triphosphate binding cassette
Acetyl Co A  acetyl coenzyme A
AGE  advanced glycation end products
ALA  alpha linoleic acid
ALP  atherogenic lipoprotein phenotype
Apo  apolipoprotein
ATP  adenosine triphosphate
bHLH  basic helix-loop helix
BMI  body mass index
BP  blood pressure
CE  cholesterol ester
CETP  cholesterol ester transfer protein
CHD  coronary heart disease
CHO  carbohydrate
CMR  chylomicron remnant
CTD  C-terminal domain
DHA  docosahexanoic acid
DNA  deoxyribonucleic acid
EPA  eicosapentaenoic acid
FDA  food and drug administration
FFA  free fatty acids
FH  familial hypercholesterolaemia
FPG  fasting plasma glucose
GI  glycaemic index
GL  glycaemic load
HDL-C  high density lipoprotein
HIV  human immunodeficiency virus
HMG-CoA  3-hydroxy-3-methylglutaryl-CoA
HsCRP  C-reactive protein
ICAM-1  intracellular adhesion molecule -1
IDL  intermediate density lipoprotein
Insig-1  insulin induced gene 1
IL  interleukin
IR  insulin resistance
LCAT  lecithin: cholesterol acyltransferase
LDL-C  low density lipoprotein cholesterol
LDLr  low density lipoprotein receptor
Lp (a)  lipoprotein (a)
LPL  lipoprotein lipase
LRP  LDL receptor related protein
LXR  liver X receptor
MCP-1  monocyte chemo attractant protein-1
M-CSF  macrophage colony stimulating factor
MetS  metabolic syndrome
MOH  Ministry of Health
MUFA  monounsaturated fatty acids
NCEP  National cholesterol education programme
NFκB  nuclear factor kappa beta