Appendix A

Summary of Canola Oil Intervention Studies

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Baudet, M.F. and Jacotot, B. Dietary fats and lecithin-cholesterol acyltransferase activity in healthy humans. *Ann. Nutr. Metab.* 1988; 32:352	Randomized, cross-over study with 6-week treatment periods. Blinding not specified.	N=20 healthy (T-C=208 mg/dl), women (26-49 years) who had lived in a monastery and maintained the same baseline diet for several years.	Test fats provided 15.6% of energy. All diets provided 54% CHO, 16% protein, 30% total fat. Chol=400mg/d for milk (SF diet) and 300 mg/d for all others. *Composition of test fats:* <u>Sat fat (milk)</u> SFA 70% (wt. basis); MUFA 27.8%; PUFA 2.2% <u>Canola oil (Low Erucic Rapeseed)</u> SFA 7.0%; MUFA 58.4%; PUFA 33.4% <u>Sunflower oil</u> SFA 10.9%; MUFA ~17%; PUFA 70.8% <u>Peanut oil</u> SFA 21% (including long-chain forms); MUFA ~42%; PUFA ~35.8%	*Lipid values (mg/dl)* <u>Canola oil</u> T-C: 185* LDL-C: 114** HDL-C: 63 TG: 68 <u>Sat fat</u> T-C: 223 LDL-C: 148** HDL-C: 61 TG: 72*** <u>Sunflower oil</u> T-C: 195* LDL-C: 128** HDL-C: 66 TG: 53*** <u>Peanut oil</u> T-C: 205 LDL-C: 135*** HDL-C: 66 TG: 55 *p<0.01 vs sat fat **p<0.01 vs canola ***p<0.0q vs sat fat and canola	There were no changes in body weight. Canola oil resulted in significantly lower T-C than the sat fat diet and lowered LDL-C compared to all other fats with no difference in HDL-C.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
McDonald, B.E., Gerrard, J.M., Bruce, V.M. and Corner, E.J. Comparison of the effect of canola oil and sunflower oil on plasma lipids and lipoproteins and on in vivo thromboxane A_2 and prostacyclin production in healthy young men. *Am. J. Clin. Nutr.* 1989; 50:1382	Radnomized, cross-over study with 18 day treatment periods. The baseline diet was fed for 6 days.	N=8 noromochol-esterolemic (T-C=3.08-4.82 mmol/l) male students (19-32 years)	The test fats provided 28% of total energy and constituted 75% of total dietary fat. All diets provided ~3,000 kcal, 14.5% protein, 49.5% CHO and 28% fat. Cholesterol intake was not reported. <u>Baseline (high sat fat)</u> SFA (%en) 14; MUFA 15; PUFA 7 <u>Canola oil</u> SFA 5; MUFA 20; PUFA 10 <u>Sunflower oil</u> SFA 7; MUFA 7; PUFA 22	Average of the two canola oil treatments vs. baseline: T-C: -17.7%* LDL-C: -23.8%** HDL-C: -7.8%** *p<0.05 vs, baseline for both treatment periods **p<0.05 vs. baseline for one of the two treatment periods There were no significant differences in lipid endpoints between the canola and sunflower oil groups.	Body weight data were not presented but the paper noted that calorie intakes were adjusted to maintain constant body weight. The intervention periods were slightly shorter than three weeks and a difference in dietary cholesterol may have affected the results, but the macronutrient composition of the diets was very well controlled and the magnitudes of decreases in serum lipids between the canola and baseline diets were large.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Wardlaw, G.M., Snook, J.T., Lin, M-C., Puangco, M.A. and Kwon, J.S. Serum lipid and apolopoprotein concentrations in healthy men on diets enriched in either canola oil or safflower oil. *Am. J. Clin. Nutr.* 1991; 54:104.	Randomized, single-blind, parallel study with an 8-week treatment period followed by a 3-week baseline diet.	N=32 moderately hypercholesterolemic (T-C >5.17 mmol/l) men (mean age =33 years)	The test fats provided 80% of total fat. The primary source of fat in the baseline diet was butter. Energy, CHO, protein and alcohol intakes were similar between the three diets. Cholesterol was slightly higher in the baseline diet (360 mg/d) compared to the experimental diets (320 mg/d). <u>Baseline diet (high sat fat)</u> SFA (%en) 15; MUFA 14; PUFA 9 <u>Canola oil (MUFA) diet</u> SFA 7; MUFA 22; PUFA 11 <u>Safflower oil (PUFA) diet</u> SFA 7; MUFA 9; PUFA 22	Changes vs. baseline: <u>Canola oil</u> T-C: -9%* LDL-C: -12%* HDL-C: +1% <u>Safflower oil</u> T-C: -15%* LDL-C: -20%* HDL-C: -3% *p<0.01 vs. baseline	Body weight did not change during the study. Canola and safflower oils significantly lowered T-C and LDL-C compared to a high saturated fat diet without changing HDL-C.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Seppänen-Laakso, T., Vanhanen, H., Laakso, I., Kohtamäki, H. and Viikari, J. Replacement of butter on bread by rapeseed oil and rapeseed oil-containing margarine: effects on plasma fatty acid composition and serum cholesterol. *Br. J Nutr.* 1992; 68:639.	Randomized, parallel study with a 6-week intervention period. A control group consumed the baseline diet throughout the study. All experimental subjects returned to the baseline diet for a 6-week follow-up period. Blinding not specified.	N=54 moderately hypercholesterolemic (mean baseline T-C =6.32 mmol/l) men and women (28 female) with a mean age of ~43 years	The participants replaced butter on bread with margarine made from canola oil (fat content =650 g/kg) or a margarine containing rapeseed, sunflower, coconut and partially hydrogenated soybean oils (fat content =800 g/kg). The canola oil group consumed a mean of 18g/d (20%en) and the margarine group consumed a mean of 23g test fat/d (22%en). There were no significant differences in energy, total fat, CHO, alcohol or gel-forming fiber between the baseline and canola oil diets. The baseline diet had more protein (15.6 vs. 12.9 g/d) and cholesterol (377 vs. 293 mg/d) than during the canola intervention. <u>Baseline diet for canola group</u> SFA (%en) 17.4; MUFA 12.2; PUFA 5.6 <u>Canola diet</u> SFA 14.0; MUFA 15.1; PUFA 8.1	Change from baseline in canola oil group: <u>Three weeks</u> T-C: -7.8%** LDL-C: -13.4%*** HDL-C: -1.3% <u>Six weeks</u> T-C: -3.0% LDL-C: -6.3%* HDL-C: +2.0% *p<0.05 **p<0.01 ***p<0.001 There were no significant changes in serum lipids among subjects who consumed the control diet, but results were not statistically compared to the canola oil group.	Body weight did not change during the study. Substitution of canola oil (in the form of an oil in water emulsion) significantly reduced serum LDL-C after six weeks and did not affect serum HDL-C compared to baseline.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Truswell, A.S., Choudhury, N. and Roberts, C.C.K. Double blind comparison of plasma lipids in healthy subjects eating potato crisps fried in palmolein or canola oil. *Nutr. Res.* 1992; 12 (Suppl. 1):S43. Identical data were also reported in: Truswell, A.S. Comparing palmolein with different predominantly monounsaturated oils: effect on plasma lipids. *Int. J. Food Sci. Nutr.* 2000; 51:S73.	Randomized, double-blind, cross-over study with 2- and 3-week intervention periods in a study conducted in 1990. A similar design was used in an experiment conducted in 1991 but the intervention periods were extended to 3 and 5 weeks.	<u>1990 experiment</u> N=21 (9 women) normocholesterolemic (baseline T-C =4.90 mmol/l) subjects (age not reported) <u>1991 experiment</u> N=30 (17 women), normocholesterolemic (T-C ~5.0 mmol/l) subjects (age not reported)	Composition of the test diets not reported. Subjects were randomized to consume potato crisps containing either canola oil or palmolein oil as part of a low fat diet. Women consumed 35g/d of the test oil and men consumed 53g/d. Fatty acid composition (% of total fatty acids) for the test oils were: <u>Canola oil</u> 16:0 5% 18:0 3% 18:1 63% 18:2 20% 18:3 8% <u>Palmolein</u> 14:0 1% 16:0 39% 18:0 5% 18:1 45% 18:2 11% 18:3 0%	Serum lipids (mmol/l) at the end of the intervention periods (combined): *1990 experiments* <u>Canola</u> T-C: 4.51* HDL-C: 1.34** <u>Palmolein</u> T-C: 5.04* HDL-C: 1.46** LDL-C was not different between the two groups (values not provided) *p<0.001 **stated to be statistically significant but p-value not reported *1991 experiments* <u>Baseline diet</u> T-C: 5.0 LDL-C: 3.80 HDL-C: 1.17* <u>Canola</u> T-C: 4.82 LDL-C: 3.57 HDL-C: 1.27 <u>Palmolein</u> T-C: 5.14 LDL-C: 3.83 HDL-C: 1.27 *Paper reported that HDL values were sig. different (p-value not provided). Differences for other comparisons were not provided.	Body weight did not change during the 1990 study but increased slightly during the experimental periods during the 1991 studies. The canola oil used in the 1991 study was contaminated with palmolein. This study suggests that canola oil is hypocholesterolemic compared to palmolein and may decrease HDL, but the study did not report diet composition and many statistics were not provided.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Valsta, L.M., Jauhiainen, M., Aro, A., Katan, M.B. and Mutanen, M. Effects of a monounsaturated rapeseed oil and polyunsaturated sunflower oil diet on lipoprotein levels in humans. *Arterioscler. Thromb.* 1992; 12:50.	Randomized, double-blind, cross-over study with 25-day treatment periods after a 2-week baseline diet.	N=59 (30 women), healthy (baseline T-C =5.03 mmol/l) subjects (18-65 years)	The baseline diet was high in SFAs. Test fats were provided as special margarine, salad dressing, ice cream and specially prepared baked goods. All diets were similar in energy content, total fat, cholesterol, protein, CHO, dietary fiber and alcohol. The fatty acid content of the diets were: <u>Baseline (high SFA)</u> SFA 18.9% en MUFA 11.0% PUFA 3.7% <u>Canola oil</u> SFA 12.4% en MUFA 16.2% PUFA 7.6% <u>Sunflower oil</u> SFA 12.7% en MUFA 10.2% PUFA 13.3%	Changes in serum lipids due to the canola oil diet compared to baseline: T-C: -15%** LDL-C: -6%* HDL-C: no change *p<0.01 **p<0.001 There were no differences between the canola and sunflower oil diets in T-C or HDL-C, but the canola oil diet lowered LDL-C significantly more (p<0.01) than the sunflower oil diet.	The paper did not report body weight but noted that diets were adjusted to maintain constant weight. This paper provide strong evidence that canola oil has beneficial effects on serum lipids compared to diets higher in SFAs.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Lichtenstein A.H., Ausman L.M., Carrasco W., Jenner J.L., Gualtieri L.J., Goldin B.R, Ordovas J.M., Schaefer E.J. Effects of canola, corn, and olive oils on fasting and postprandial plasma lipoproteins in humans as part of a National Cholesterol Education Program Step 2 Diet. *Arterioscler. Thromb.* 1993;13:1533-42. Identical data for serum lipids was also reported in: Jones, P.J.A., *et.al.* Effect of dietary fat selection on plasma cholesterol synthesis in older, moderately hypercholesterolemic humans. *Arterioscler. Thromb.* 1994; 14:542. Lichtenstein, A.H. *et.al.* Rice bran oil consumption and plasma lipid levels in moderately hypercholesterolemic humans. *Arterioscler. Thromb.* 1994; 14-459	Randomized, doubly-blind, cross-over metabolic trial with 32-day interventions and a 1 to 2 week washout between each treatment. All subjects consumed the baseline diet for 32 days and were then randomized to one of the test diets. The baseline diet was consumed during washout periods.	N=15 (8 female), moderately hypercholesterolemic (mean T-C = 237 mg/dl) aged 44-78 years	Baseline diet (typical American diet) was higher in total fat (35.4 vs. ~30%en) and cholesterol (81 vs. 128 mg/1000 kcal) compared to the test diets, and slightly lower in protein (16.5 vs. 17.2%en) and CHO (48.1 vs. 53%en). The test diets were similar in macronutrient content and equivalent to AHA Step II diets. Two-thirds of the fat in the test diets was contributed by the test fats. <u>Baseline</u> SFA 12.9%en; MUFA 12.7%; PUFA 7.9% <u>Canola Oil Diet</u> SFA 5.4%; MUFA14.5%; PUFA 6.7% <u>Corn Oil Diet</u> SFA 6.9%; MUFA 9.0%; PUFA 11.2% <u>Olive Oil Diet</u> SFA 6.9%; MUFA 17.0%; PUFA 3.9%	Change in serum lipids vs. baseline: <u>Canola oil</u> T-C: -12.2%*** LDL-C: -16%*** HDL-C: -8.3%* TG: NSD <u>Olive oil</u> T-C: -7.8%** LDL-C: -13.2%*** HDL-C: -4.2% TG: NSD <u>Corn oil</u> T-C: -12.2%*** LDL-C: -13.2%*** HDL-C: -8.3%** TG: NSD *p<0.05 **p<0.01 ***p<0/001 T-C was significantly lower (p<0.01) after the canola oil and corn oil diets compared to the olive oil diet. No other lipids were significantly different between the test fats.	Body weight did not change during the study. All three test fats lowered serum T-C and LDL-C compared to a typical American diet. The canola oil diet lowered T-C significantly more than the olive oil diet, but the latter did not lower HDL-C. There were no significant differences between the three oils in serum LDL-C or HDL-C at the end of the treatment periods.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Nydahl, M., Gustafsson, I-B., Őhrvall, M. and Vessby, B. Similar serum lipoprotein cholesterol concentrations in healthy subjects on diets enriched with rapeseed and with sunflower oil. *Eur. J. Clin. Nutr.* 1993; 48:128.	Randomized, double-blind, cross-over study with 3-week intervention periods and a 3-week washout.	N=101 (64 female) healthy (mean baseline T-C = 4.79 mmol/l) subjects (mean age =29.2 years).	Macronutrient composition of the test diets was similar (data not provided). No dietary information was provided for the baseline diet, which was a typical Swedish diet for most participants. The test fats were fed as oils and specially formulated margarines. Neither the specific fat content of the diets or the amount of test fats provided were reported. *Fatty acid content of test diets (wt. %)* <u>Canola oil</u> 14:0 4.4% 16:0 19.4% 18:0 8.0% 18:1 41.6% 18:2 16.0% 18:3 5.1% <u>Sunflower oil</u> 14:0 4.3% 16:0 21.1% 18:0 9.2% 18:1 30.6% 18:2 28.9% 18:3 1.7%	Differences between test diets and baseline: <u>Canola oil</u> T-C: -4%*** LDL-C: -5%** HDL-C: +2% LDL/HDL-C: -6%** <u>Sunflower oil</u> T-C: -4%** LDL-C: -7%** HDL-C: -1% LDL/HDL-C: -4%* *p<0.01 **p<0.001 There were no significant differences in serum lipids between the canola or sunflower oil diets.	Body weight did not change during the study. Both canola and sunflower oil decreased T-C and LDL-C without significantly affecting HDL-C compared to baseline similarly. The lack of dietary information about the baseline diet and fat content of the experimental diets limits the quantitative conclusions that can be drawn from this study.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Seppänen-Laakso, T., Vanhanen, H., Laakso, I. Kohtamäki, H. and Viikari, J. Replacement of margarine on bread by rapeseed and olive oils: effects on plasma fatty acid composition and serum cholesterol. *Ann. Nutr. Metab*. 1993; 37:161.	Randomized (alphabetically), controlled, parallel feeding study of 6 weeks duration.	N=57 (27 females), middle aged (average age in the three groups ranged from 41.7 to 45.5), normo- to moderately-hypercholesterolemic (T-C 5.0 – 8.5 mmol/L) subjects.	Control group (N=11) Maintained usual diet throughout the experiment but was not used for comparative purposes. Canola oil Substituted canola oil (mean 17g/d given as a water-oil emulsion) for margarine on bread. The energy, protein, total fat, cholesterol, CHO, alcohol and gel-forming fiber content of the baseline and canola oil diets were statistically similar although moderate differences were noted. ▪ Baseline diet SFA 15.8%en MUFA 14.0% PUFA 6.8% ▪ Test diet SFA 14.9%en MUFA 15.7% PUFA 9.4% Olive oil Substituted olive oil (mean 19g/d given as water-oil emulsion) for margarine on bread. The energy, protein, total fat, cholesterol, CHO, alcohol and fiber content of the baseline and olive oil diets were statistically similar, although moderate differences were noted. ▪ Baseline diet SFA 15.2%en MUFA 13.1% PUFA 7.1% ▪ Test diet SFA 13.6%en MUFA 16.8% PUFA 6.0%	Change from baseline in the test groups. *Canola oil* Three weeks: T-C: -3.3% LDL-C: -6.5% HDL-C: +6.0%* Six weeks: T-C: -4.7% LDL-C: -6.5% HDL-C: +3.0* *Olive oil* Three weeks: T-C: -4.5% LDL-C: -7.5%* HDL-C: NC Six weeks: T-C: -2.2% LDL-C: -4.0% HDL-C: NC *p<0.01 There were no significant changes in any serum lipid in subjects consuming the control diet.	Body weight did not change during the experiment. The test fats prompted small positive changes in serum lipids during 6 weeks of feeding, but the differences between their respective baseline and test diets were small (SFA intakes were not statistically different), so the results are difficult to interpret. Changes in other foods during the course of the experiment may have affected the results. No statistical comparison of the effect of canola and olive oils was provided.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Gustafsson, I-B., Vessby, B., Őhrvall, M and Nydahl, M. A diet rich in monounsaturated rapeseed oil reduces the lipoprotein cholesterol concentration and increases the relative content on n-3 fatty acids in serum in hyperlipidemic subjects. *Am. J. Clin. Nutr.* 1994; 59:667.	Randomized, parallel design study with 3-week duration. Subjects consumed a typical Swedish baseline diet for 7 days prior to the study.	N=95 (22 female), moderately hypercholesterolemic (T-C 6.5-9.0 mmol/l) subjects (mean age = 44.4-48.2)	The test diets were similar in energy, protein, total fat, cholesterol, CHO, dietary fiber and alcohol content. The baseline diet was lower in energy, dietary fiber and CHO and higher in total fat and alcohol than the experimental diets. The fatty acid compositions of the diets were: <u>Baseline</u> SFA 16.0%en MUFA 13.0% PUFA 5.7% <u>Canola oil</u> SFA 7.2%en MUFA 14.0% PUFA 6.5% <u>Sunflower oil</u> SFA 7.6%en MUFA 9.6% PUFA 10.5%	Serum lipid changes compared to baseline diets: <u>Canola oil</u> T-C: -15%** LDL-C: -16%** HDL-C: -11%** LDL/HDL: -6* <u>Sunflower oil</u> T-C: -16%** LDL-C: -14%** HDL-C: -13%** LDL/HDL: 0 *p<0.05 **p<0.001 There were no significant differences in the above parameters between the two test oils.	The subjects lost weight (~1kg) in both groups during the study. These data suggest canola oil and sunflower oil are equivalent with respect to their affect on major serum lipids. The difference in baseline and experimental diets make it difficult to determine if the effect is entirely due to the fatty acid composition of the diets.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Miettinen, T.A. and Vanhanen, H. Serum concentration and metabolism of cholesterol during rapeseed oil and squalene feeding. *Am. J. Clin. Nutr.* 1994; 59:356.	This study was a 4-phase parallel design study intended to examine the effect of adding squalene to a diet containing canola oil. The initial phase of this study compared a baseline diet to a canola oil-enriched diet without randomization.	N=18 male, moderately hypercholesterolemic (mean T-C at baseline = 7.1 mmol/l) subjects (mean age =50 years)	50 g of dietary fat was replaced by 50g canola oil mayonnaise during the first phase of the study. Complete dietary information for the baseline diet was not collected, but intakes of animal fat and cholesterol were reported as "reduced" in the canola oil vs. baseline diet, and cholesterol intakes were similar. <u>Canola oil diet</u> Energy 2,392 kcal SFA 10.5%en MUFA 19.5% PUFA 10.4%	Serum lipids on the canola oil diet compared to baseline: T-C: -9%* LDL-C: -10%* HDL-C: +9%* TG: -19%* *$p<0.05$	The addition of canola oil to the diet did not result in significant weight gain. The data suggest that canola oil reduces serum lipids when it replaces animal fat, but lack of dietary data make interpretation of the data difficult. This study was designed primarily to examine the effect of squalene on the diet.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Sundram, K., Hayes, K.C. and Siru, O. Both dietary 18:2 and 16:0 may be required to improve the serum LDL/HDL cholesterol ratio in normocholesterolemic men. *J. Nutr. Biochem.* 1995; 6:179.	Randomized, cross-over study in which all subjects began with a habitual diet for 3 weeks, followed by a Step I diet prior to randomization. The experimental periods were 4 weeks each.	N=23 male, healthy, normocholesterolemic (mean T-C = 174 mg/dl), members of the Malaysian military aged 19-24 years. The subjects were very lean (mean BMI=21.3).	There were no significant differences among the baseline, Step 1 or experimental diets in energy, protein, CHO, total fat (~30%en) or cholesterol. The fatty acid content of the diets were: <u>Baseline</u> SFA 12.2%en MUFA 12.0% PUFA 3.8% <u>Step 1</u> SFA 10.1%en MUFA 12.9% PUFA 8.3% <u>Canola</u> SFA 6.0%en MUFA 17.5% PUFA 7.7% <u>Palmolein</u> SFA 13.0%en MUFA 14.3% PUFA 4.1%	Statistical comparisons between the experimental and baseline diets were not provided. Differences in serum lipids between the Step 1 and the experimental diets were: <u>Canola oil</u> T-C: -1.5% LDL-C: 1.2% HDL-C: -14.6%* <u>Palmolein</u> T-C: 0.1% LDL-C: 6.2% HDL-C: -14.6% *$p<0.01$ compared to Step 1 by repeated measures ANOVA, but not by students t test at $p<0.05$	Body weight did not change during the experiment. The data suggest that the effect of palmolein on serum lipids is similar to that of canola oil compared to a Step 1 diet. However, the low saturated fat content of the Step 1 diet and the fact that the unsaturated fat content of these diets was similar may explain these differences. The very fit nature of the subjects in this study as well as the low fat content of their habitual diet limits the applicability of this study to general American population.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Uusiiupa, M., Schwab. U., Mäkimattila, S., Karhapää, P., Sarkkinen, E., Maliranta, H., Ågren, J. and Penttilä, I. Effects of two high-fat diets with different fatty acid compositions on glucose and lipid metabolism in healthy young women. *Am. J. Clin. Nutr.* 1994; 59:1310.	Randomized, blinded, cross-over study with 3-week treatment periods and a 2-week washout. The habitual diet was consumed before the study and during the washout period.	N=10, female, healthy (T-C = 5.21 mmol/l), young (mean age = 23 years) students.	The experimental diets were similar in energy, protein, total fat (~39%en), CHO and dietary fiber. Both diets were low in cholesterol, but the canola oil diet was lower (109 vs. 213 mg/d). The baseline diet was lower in total fat and probably different in several other nutrients although statistical comparisons were not provided. The fatty acid content of the experimental diets were: <u>High saturated fatty acid diet</u> SFA 20.4%en MUFA 12.0% PUFA 3.9% <u>Canola oil (high MUFA)</u> SFA 8.5% MUFA 19.0% PUFA 10.3%	Changes in serum lipids for the canola oil diet vs. the SFA diet: T-C: -21.6* LDL-C: -29%* HDL-C: -1.8% Changes in serum lipids for the canola oil diet vs. the baseline diet: T-C: -18.0* LDL-C: -26.6%* HDL-C: -5.5% *$p<0.001$	Body weights decreased slightly during both experimental periods, but there were no differences in weight loss between the two diets. This study confirms that diets high in unsaturated fatty acids lower serum lipids when fed at the expense of SFAs.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Nydahl, M., Gustafsson, I-B., Őhrvall, M. and Vessby, B. Similar effects of rapeseed oil (Canola oil) and olive oil in a lipid-lowering diet for patients with hyperlipoproteinemia. *J. Am. Coll. Nutr.* 1995; 14:643	Randomized, cross-over design with 3.5-week treatment periods and no washout. Blinding was not stated.	N=22 (10 female), hypercholesterolemic (mean baseline T-C =307 mg/dl) subjects (mean age =54.2 years).	No quantitative information was provided for the baseline diet, which was a traditional Swedish diet. The experimental diets were similar in protein, total fat (30%en), CHO, cholesterol and dietary fiber. The fatty acid content of the experimental diets was: <u>Canola oil</u> SFA 8%en MUFA 13% PUFA 7% <u>Olive oil</u> SFA 8%en MUFA 15% PUFA 5%	Changes in serum lipid values compared to baseline: <u>Canola oil</u> T-C: -17* LDL-C: -20* HDL-C: -5% <u>Olive oil</u> T-C: -14%* LDL-C: -16%* HDL-C: -4% *p<0.001 There were no significant differences in lipid responses between the two experimental diets.	There were no changes in body weight between the two diets. This study suggests that canola oil and olive oil have similar hypocholesterolemic properties when compared to a traditional Swedish diet in hypercholesterolemic subjects.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Valsta, L.M., Jauhiainen, M., Aro, A., Salminen, I. and Mutanen, M. The effects on serum lipoprotein levels of two monounsaturated fat rich diets differing in their linoleic and α-linolenic acid contents. *Nutr. Metab. Cardiovasc. Dis.* 1995; 5:129.	Randomized, double-blind, cross-over study with 6-week treatments and washout periods. The subjects consumed the habitual diet for 6 weeks prior to randomization.	N=40 (20 female), normocholesterolemic (mean baseline T-C = 4.66 mmol/dl) subjects aged 20-46 years.	There were no significant differences between the experimental diets in energy, protein, total fat, SFA, MUFA, PUFA, cholesterol or alcohol. The habitual diet appeared to be lower in total fat (33%en vs. ~40%en), MUFA (11.2% vs. ~17.5%) and %), PUFA (5.1% vs. ~8.4%) and higher in SFA (13.0% vs. ~11.5) and cholesterol (348 vs. 270 mg/d) compared to the canola oil diet, but comparative statistics were not provided.	Lipid changes of the test fats compared to baseline: <u>Canola oil</u> T-C: -9.4%* LDL-C: -22%* HDL-C: 0% <u>Trisun-Sunflower oil</u> T-C: -8.5% LDL-C: -21%* HDL-C: 0% *p<0.001	Changes in body weight were not reported, but diets were adjusted to maintain constant body weight. The study suggests that UFAs form canola oil and tri-sun sunflower oil are equally hypo-cholesterolemic when fed to healthy men and women compared to a habitual Swedish diet.
Matheson, B., Walker, K.Z., Taylor, D.M., Peterkin, R., Lugg, D. and O'Dea, K. Effect on serum lipids of monounsaturated oil and margarine in the diet of an Antarctic Expedition. *Am. J. Clin. Nutr.* 1996; 63:933.	Non-randomized cross-over study with 13-week intervention periods. Subjects consumed their habitual (high SFA) diet for 15 weeks followed by 12 weeks of a high canola oil diet and then returned to 12 weeks of the habitual diet.	N=23 (1 female) moderately hypercholesterolemic (mean T-C at baseline =5.82 mmol/l) subjects aged 25-50. Subjects were members of an Antarctic expedition that spent the winter in that continent.	The baseline diet was similar (p>0.05) to the canola oil diet at the end of the 12-week intervention period in energy, total fat (~37.5% en), protein, CHO, dietary fiber, and cholesterol. <u>Baseline</u> SFA 15.9%en MUFA 13.4% PUFA 4.9% <u>Canola</u> 13.3% MUFA 16.2% PUFA 5.3%	Baseline (week 16) vs. the canola diet: T-C: -7.0%* LDL-C: -10.0%* HDL-C: +5.6% *p<0.016	Body weight increased slightly throughout the experiment (+0.8 kg from the beginning of the study to the end of the canola diet. This study confirms that diets higher in UFAs are hypocholesterolemic compared to diets higher in SFAs.

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Jenkins, D.J.A., Wolever, T.M.S., Vidgen, E., Kendall, C.W.C., Ransom, T.P.P., Mehling, C.C., Mueller, S., Cunnane, S.C., O'Connell, N.C., Setchell, K.C.R., Lau, H., Teitel, J.M., Garvey. M.B., Fulgoni, V., Connelly, P.W., Patten, R. and Corey, P.N. Effect of psyllium in hypercholesterolemia at two monounsaturated fatty acid intakes. *Am. J. Clin. Nutr.* 1997; 65:1524.	Randomized, cross-over study with 1-month intervention periods separated by 2- to 6-week washout periods during which an *ad libitum* Step 2 diet was consumed.	Study 1 N=32 (17 female) moderately hypercholesterolemic (mean T-C = 7.06 mmol/l) subjects (mean age =57.5 years). Study 2 N=27 (15 female) moderately hypercholesterolemic (mean T-C =7.05 mmol/l) subjects (mean age =58.0 years).	The main purpose of this study was to determine the effect of psyllium at two levels of dietary MUFAs, however, data comparing the serum lipid changes between psyllium-containing diets at 6% and 12% MUFA were presented. The 12% MUFA diet was made by adding canola oil to the 6% MUFA diet. The 6% MUFA diet was fed in Study 1 and the 12% MUFA diet was fed in Study 2. The two MUFA diets were roughly similar (statistics not provided) in protein, CHO, dietary fiber and alcohol. The 12% MUFA diet contained more total fat than the 6% diet (72 vs. 46 g/d) and less cholesterol (22 vs. 31 mg/MJ). The fatty acid content of the two diets were: 6% MUFA SFA 11 g/d MUFA 15 g/d PUFA 19 g/d 12% MUFA SFA 15 g/d MUFA 31 g/d PUFA 25 g/d	Changes in serum lipids compared to baseline after 4-week interventions between 6 and 12% MUFA diets containing psyllium: 6% MUFA T-C: -9.7%*** LDL-C: -12.3%*** HDL-C: -10.9%** LDL/HDL: 0% 12% MUFA T-C: -12.1%*** LDL-C: -15.3%*** HDL-C: -8.1%*** LDL/HDL: -7.3%** Analogous data for the non-psyllium-containing diets: 6% MUFA T-C: -4.9%** LDL-C: -4.3% HDL-C: -3.4% LDL/HDL: 0.8% 12% MUFA T-C: -10.2%*** LDL-C: -7.4%** HDL-C: -1.6% LDL/HDL: -4.2% *p<0.05 **p<0.005 ***p<0.001	Body weight did not change during the studies. The paper noted a significant negative correlation (r= -3.1, p=0.035) for serum T-C with dietary MUFA content for combined psyllium and control data. A similar correlation was observed for the T-C/HDL-C ratio (r= -0.44, p=0.002) This study suggests that addition of canola oil to a 6% MUFA-containing diet causes favorable changes in serum lipids, however differences in composition between the two diets limits the conclusions that can be drawn.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Noakes, M. and Clifton, P.M. Oil blends containing partially hydrogenated or interesterified fats: differential effects on plasma lipids. *Am. J. Clin. Nutr.* 1998; 68:242.	Randomized, cross-over study with 3-week intervention periods following a 2-week run-in segment during which a low-fat diet was consumed. Blinding status was not reported and the paper did not specify whether there was a wash-out period between interventions.	N=18 (6 female), moderately hypercholesterolemic (mean baseline T-C ~6.5 mmol/l) subjects (mean age ~53 years). These subjects participated in the MUFA (canola oil) arm of the study. The study also included a separate group of 20 subjects who were fed PUFA-containing diets, but these data will not be summarized.	After consumption of the baseline diet subjects were randomized to one of three treatments: a butter diet, a canola + *trans* fat (TFA) diet or a canola diet without TFA. There were no significant differences between the butter and canola without TFA diets in energy, protein, total fat, CHO, alcohol or dietary fiber. The cholesterol content of the butter diet was greater ($p<0.01$) than the canola oil diet (298 vs. 195 mg/d). <u>Butter</u> SFA 15.5%en MUFA 10.1% PUFA 2.8% <u>Canola</u> SFA 8.7% MUFA 14.5% PUFA 6.0%	Differences in serum lipids when substituting canola for butter: T-C: -8.4%* LDL-C: -12.8% HDL-C: 0% Total/HDL-C: -13.5%* *$p<0.01$	Body weight did not change during the experiment. This study confirms that canola oil has favorable changes on serum lipids when compared to a high SFA diet. The similarity of the test diets in non-fatty acid components (with the exception of cholesterol) suggests that the effect is due to differences in UFA intakes.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Sarkkinen, E.S., Uusitupa, M.I.J., Gylling, H. and Miettinen, T.A. Fat-modified diets influence serum concentrations of cholesterol precursors and plant sterols in hypercholesterolemic subjects. *Metabolism* 1998; 47:744.	Randomized, parallel design feeding study of 6 months. Subjects consumed their habitual diet during a 2-week run-in period. The subjects were double-blinded with respect to serum lipid values collected during the study.	N=160 (83 female), moderately hypercholesterolemic (baseline mean T-C ~6.5 mmol/l) mean age ~45 years. N=77 (41 female) subjects participated in the control and canola oil arms of the study.	Subjects were randomized to one of four diets: control, sunflower-enriched, canola-enriched or reduced fat. The energy, total fat, protein, CHO, alcohol and fiber contents of the control, canola and sunflower-enriched diets were similar. The cholesterol content of the control diet (301 mg/d) was higher than the canola or sunflower-enriched diets (230 mg/d) <u>Control</u> SFA 14.5 %en MUFA 10.0% PUFA 3.6% <u>Canola oil</u> SFA 10.6 % MUFA 11.3% PUFA 3.2% <u>Sunflower oil</u> SFA 10.2 % MUFA 7.9% PUFA 7.9%	Changes in serum lipids at the end of the treatment period compared to the control diet: <u>Canola oil</u> T-C: -3.5% LDL-C: -2.9% HDL-C: -10.3% <u>Sunflower oil</u> T-C: -3.8%* LDL-C: -2.9% HDL-C: -7.8% Changes in serum lipids at the end of the treatment period compared to the beginning: <u>Canola oil</u> T-C: -3.6% LDL-C: -6.5%* HDL-C: +2.2% <u>Sunflower oil</u> T-C: -4.8% LDL-C: -7.2%* HDL-C: +2.8% *$p<0.05$	Body weights did not change during the study. The canola oil diet resulted in a significant decrease in LDL-C compared to baseline after six-months, but there were no significant changes compared to a higher SFA control diet.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Pedersen, A., Baumstark, M.W., Marckmann, P., Gylling, H. and Sandström, B. An olivel oil-rich diet results in higher concentrations of LDL cholesterol and a higher number of LDL subfraction particles than rapeseed oil and sunflower oil diets. *J. Lipid Res.* 2000; 41:1901.	Randomized, double-blind cross-over design with 3-week intervention periods and wash-out periods of 5-12 weeks.	N=18 healthy (baseline mean T-C =4.74 mmol/l) male students age 20-28 years.	The experimental diets were identical in total fat, CHO, protein, fiber and cholesterol contents. <u>Canola oil</u> SFA 9%en MUFA 18% PUFA 7% <u>Olive oil</u> SFA 11%en MUFA 21% PUFA 3% <u>Sunflower oil</u> SFA 10%en MUFA 9% PUFA 15%	Blood lipids at the end of the intervention periods: <u>Canola oil</u> T-C: 3.67 mmol/l LDL-C: 1.73** HDL-C: 0.98 <u>Olive oil</u> T-C: 4.15 mmol/l LDL-C: 2.16 HDL-C: 0.97 <u>Sunflower oil</u> T-C: 3.74 mmol/l LDL-C: 1.89** HDL-C: 0.90 *p<0.05 vs. olive oil **p<0.001 vs. olive oil	Body weight data were not presented. The authors concluded that canola oil and sunflower oil result in lower blood LDL-C concentrations than olive oil. The diets in this study were very well controlled with respect to macronutrient and fatty acid composition.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Hodson, L., Ckeaff, C.M. and Chisholm, W-A.H. The effect of replacing dietary saturated fat with polyunsaturated or monounsaturated fat on plasma lipids in free-living young adults. *Eur. J. Clin. Nutr.* 2001; 55:908	Randomized, cross-over study with 2.5-week treatment periods with no washout phase.	Trial I (PUFA vs. SFA) N=29 (22 female), normo- to moderately hypercholesterolemic (T-C <6.5 mmol/l) students (mean age =22.2 years) Trial II (MUFA vs. SFA) N=42 (35 female), normo- to moderately hypercholesterolemic (T-C <6.5 mmol/l) students (mean age =23.0.	*Trial I* A high SFA (containing butter) diet was compared to a high PUFA diet containing sunflower and safflower oils. The diets did not differ statistically (p>0.05) in protein, total fat, dietary fiber or alcohol. The SFA diet contained more energy and cholesterol (303 mg/d vs. 174 mg/d) compared to the high PUFA diet. The fatty acid contents were: SFA SFA 17.5%en MUFA 9.6% PUFA 2.7% PUFA SFA 8.5%en MUFA 9.5% PUFA 9.1% *Trial II* A high SFA (containing butter) diet was compared to a high MUFA diet containing canola oil. The diets did not differ statistically (p>0.05) in protein, dietary fiber or alcohol. The SFA diet contained more total fat and cholesterol (305 mg/d vs. 168 mg/d) and less CHO compared to the high MUFA diet. The fatty acid contents were: SFA SFA 17.7%en MUFA 9.7% PUFA 3.0% MUFA SFA 8.4%en MUFA 11.6% PUFA 6.1%	Change in serum lipids caused by feeding the canola oil diet compared to the SFA diet: T-C: -12%** LDL-C: -15%** HDL-C: -4%* Change in serum lipids caused by feeding the PUFA diet compared to the SFA diet: T-C: -19%** LDL-C: -22%** HDL-C: -14.4%** *p<0.05 **p<0.001 The difference in change in serum T-C and HDL-C between the two sources of UFAs was significant (p<0.05).	Body weight did not change during the experiment. This study suggests that canola oil has favorable effects on serum lipids compared to saturated fat, however, multiple differences in the macronutrient and cholesterol content of the experimental diets limits the conclusions that can be drawn.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Gulesserian, T. and Widhalm, K. Effect of a rapeseed oil substituting diet on serum lipids and lipoproteins in children and adolescents with familial hypercholesterolemia. *J. Am. Coll. Nutr.* 2002; 21:103.	Non-randomized feeding study of 5 months with comparisons to baseline.	N=17 (11 female) children and adolescents (4-19 years) with a family history of hypercholesterolemia.	Habitual dietary intake data were not provided. The subjects were instructed to consume a low-fat and cholesterol diet including canola oil. Daily intake of canola oil was 15 g/d during the first 2 months and 22 g/d during the remainder of the study. Diet composition during the study was estimated as follows: Energy 1,649 kcal Protein 14.3%en CHO 54.6% Total fat 29.5% Cholesterol 196 mg/d SFA 39 % of fatty acids MUFA 30% of fatty acids PUFA 21% of fatty acids	Dietary changes including addition of canola oil resulted in the following changes in serum lipids: T-C: -9% ($p<0.05$) LDL-C: -6% ($p<0.007$) HDL-C: -3% (NSD)	Body weight distribution (based on weight and length) did not change significantly during the study. This study provides suggestive evidence that substituting canola oil for other sources of fat has favorable changes on serum lipids in children with a family history of hypercholesterolemia, but insufficient dietary information and lack of a control group limit the conclusions that can be drawn.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Karvonen, H.B., Tapola, N.X., Uusitupa, M.I. and Sarkkinen, E.S. The effect of vegetable oil-based cheese on serum total an lipoprotein lipids. *Eur. J. Clin. Nutr.* 2002; 56:1094	Randomized, single-blind, cross-over study with 4-week intervention periods. A 2-week run-in period during which a habitual diet was consumed preceded the intervention periods.	N=31 (14 female) moderately hypercholesterolemic (mean baseline T-C =6.13 mmol/l) subjects (mean age =52.9).	The experimental period consisted of substituting 65 g canola oil-containing cheeses (containing 13 g canola oil) for a similar amount of traditional cheeses. The experimental and control diets were similar (p>0.05) in energy, CHO, cholesterol, dietary fiber and alcohol. The canola oil diet had slightly less total fat (31.1 vs. 32.7 %en) and slightly more protein (18.5 vs. 17.2 g/d) than the control diet. The fatty acid content was as follows: <u>Control (SFA)</u> SFA 14.1%en MUFA 10.4% PUFA 4.7% <u>Canola</u> 9.6% MUFA 12.0% PUFA 6.4%	The effect of substituting canola oil-containing cheese on serum lipids at the end of the intervention periods: T-C: -5.0** LDL-C: -6.4%* HDL-C: -2.3 *p=0.002 **p<0.001	Body weight did not change during the study. Although there were slight differences in the macronutrient content of the diets, these differences were unlikely to significantly affect serum lipids. This study provides strong evidence that canola oil has favorable affects on serum lipids compared to saturated fat.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Kratz, M., Cullen, P., Kannenberg, F., Kassner, A., Fobker, M., Abuja, P.M., Assmann, G. and Warburg, U. Effects of dietary fatty acids on the composition and oxidizability of low-density lipoprotein. *Eur. J. Clin. Nutr.* 2002; 56:72.	Randomized, parallel design with a 4-week treatment period preceded by a 2-week run-in diet high in SFAs. Blinding was not reported.	N=58 (27 female), healthy (mean baseline T-C =4.89 mmol/l) young (mean age =26.0 years) subjects.	There were no significant differences between the high-SFA (run-in) or experimental diets with respect to energy, CHO, protein, total fat, cholesterol or dietary fiber. Fatty acid content of the diets was as follows: <u>High SFA (N=58)</u> SFA 19.1%en MUFA 11.3% PUFA 5.6% <u>Canola oil (N=18)</u> SFA 9.1%en MUFA 19.1% PUFA 9.0% <u>Olive oil (N=20)</u> SFA 10.7%en MUFA 23.3% PUFA 3.4% <u>Sunflower oil (N=20)</u> SFA 10.0%en MUFA 8.7% PUFA 18.5%	Changes in serum lipids compared to the high SFA diet: <u>Canola oil</u> T-C: -14.3** LDL-C: -17.5** HDL-C: -12.6* <u>Olive oil</u> T-C: -9.2** LDL-C: -10.7* HDL-C: -8.0** <u>Sunflower oil</u> T-C: -16.7** LDL-C: -19.7** HDL-C: -12.5** *p<0.01 **p<0.001	Body weights did not change during the study. This well designed study provides strong evidence that canola oil has favorable effects on serum lipids compared to saturated fat. The olive oil diet lowered HDL-C less ($p<0.05$) than the canola oil diet, but the ratio of total to HDL-C was the same for both oils.

Reference	Design and Duration	Population	Dietary Intervention and Intake	Results	Comments
Nielsen, N.S., Pedersen, A., Sandström, B., Marckmann, P. and Høy, C-E. Different effects of diets rich in olive oil, rapeseed oil and sunflower-seed oil on postprandial lipid and lipoprotein concentrations and on lipoprotein oxidation susceptibility. *Br. J. Nutr.* 2002; 87:489.	Randomized, double-blind, cross-over study with 3-week treatment periods separated by 4- to 12-week washout periods.	N=18 male, healthy (baseline T-C 2.46-6.01 mmol/l) subjects (mean age =23.9).	The experimental diets were rich in canola, olive or sunflower-seed oil. All diets were similar in protein, CHO, total fat and dietary fiber. The fatty acid distribution of the test diets was as follows: <u>Canola oil</u> SFA 28.7 mole% of total FAs MUFA 49.5% PUFA 21.8% <u>Olive oil</u> SFA 33.5% MUFA 58.3% PUFA 8.2% <u>Sunflower seed oil</u> SFA 33.4% MUFA 26.2% PUFA 40.4%	Fasting blood lipid values (mmol/l) at the end of the treatment periods for the test oils were as follows: <u>Canola oil</u> T-C: 3.50* LDL-C: 2.20* HDL-C: 1.12 <u>Olive oil</u> T-C: 4.07 LDL-C: 2.73 HDL-C: 1.13 <u>Sunflower seed oil</u> T-C: 3.62* LDL-C: 2.33* HDL-C: 1.09 *p<0.001 vs. olive oil	Body weight changes during the study were not reported. This study suggests that canola oil (and sunflower seed oil) results in lower T-C and LDL-C but similar HDL-C concentrations compared to olive oil when fed in similar diets.