**Table . Corn Oil: Effect on Blood Lipids, Design Type 1 Studies**

| Author/ Year | De-sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| **HEALTHY SUBJECTS** | | | | | | | |
| **Wagner et al., 2001** | **RCT, DB, CO** | **A** | **+** | **Purpose:**<br>To evaluate effects of plant oil mixture high in oleic acid but also showing moderate content of PUFA in comparison with single, PUFA-rich corn oil used in normal, balanced diet on human plasma and lipoprotein metabolism<br><br>**Sample:**<br>28 healthy, Australian males (19-31 y of age)<br><br>**Inclusions:**<br>Normolipidemic; non-smoker; free from acute or chronic illness; BMI within normal range<br><br>**Exclusions:**<br>Use of meds or vit/mineral supplements 4 wk | **Run-in Period:**<br>Adjustment diet: olive/sunflower/butter mixture (ave: 11.6 MJ, 105 g fat, 12 mg α-tocopherol equivalents/d)<br><br>2 wk<br><br>**TX/Duration:**<br>Subj randomized to 1 of 2 diets for 2 wk than CO to other diet for 2 wk<br><br>42 d with 35-d follow-up<br><br>Subj followed usual diet after both CO periods for 5-wk follow-up period<br><br>**Dose/Form:**<br>1) PUFA-rich diet (corn oil) = 80 g corn oil/d (SFA/MUFA/PUFA = 28:33:39, 20 mg $\alpha$-tocopherol, 100 mg $\gamma$-tocopherol/d); N=14<br>2) MUFA-rich diet (mixed oil) = 68 g olive oil, 12 g sunflower oil/d | **Outcome Measures:**<br>Lipids<br>Plasma and LDL $\alpha$-tocopherol and $\gamma$-tocopherol<br><br>**Results:**<br>TC conc (mmol/L) higher after olive oil diets ($P$< 0.01) than corn oil diet<br>Corn 4.9 $\pm$ 0.9 to 4.3 $\pm$ 0.7<br>Olive 4.9 $\pm$ 0.9 to 4.5 $\pm$ 0.7<br><br>LDL conc (mmol/L) higher after olive oil diets ($P$< 0.01) than corn oil diet<br>Corn 3.91$\pm$0.87 to 3.06$\pm$0.88<br>MUFA rich diet 3.91 $\pm$0.87 to 3.88$\pm$0.74<br><br>VLDL sig lower with corn oil diet than with MUFA-rich mixed oil diet after 1st test period ($P$<0.01)<br><br>NS change for HDL bet groups or test periods<br><br>Plasma and VLDL TG conc sig reduced after 1st test period with corn oil diet compared with mixed oil diet (0.8$\pm$0.3 vs 1.1$\pm$0.4, | **Author's Conclusions:**<br>"The results show that during the intervention of two weeks for each diet and the following cross over the corn oil diet had more influence on lipoprotein metabolism than the MUFA-rich diet. The hypocholesterolemic effect of the PUFA-rich diet must also be connected with the high amount of unsaponifiable substances, mainly phytosterols in the corn oil"<br><br>***Reviewer's Comments:***<br>*None* |

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| | | | | before study initiation | (SFA/MUFA/PUFA = 28:49:23, 24 mg $\alpha$-tocopherol, 2.4 mg $\gamma$-tocopherol); N=14<br><br>**Dietary Intake During Study:**<br>Total fat: 30-35% TE; 110 g/d fat; test oils main fat source (80 g of 110 g/d)<br>PUFA (% TE):<br>Corn oil: 12.0<br>Mixed oil: 7.2<br>Adjustment: 7.1<br><br>Oils incorporated into meals; 90% of total food prepared by researchers; 10% of energy chosen by subj (tocopherol-free)<br><br>**Dietary Intake Assessment/Frequency:**<br>Weighed dietary records completed during entire study; dietary compliance monitored by FA analysis of lipoprotein fractions LDL and HDL<br><br>**Study Visits/ Measurements:**<br>Fasting blood samples | *P*<0.05; 0.25±0.09 vs 0.35±0.09, *P*<0.01) and baseline diet (*P*<0.01)<br><br>Sig correlation bet LDL-chol and incr levels of LDL-PUFA in corn oil group (*r*=0.69, *P*<0.01)<br><br>Corn oil predominated diet incr LDL transported $\gamma$-tocopherol relatively (41% after adjustment period vs 49% after 1st test period) and absolutely (*P*<0.001) to 4-fold amt compared with adjustment period<br><br>Highly sig correlation ($r^2$=0.73; *P*<0.001) bet plasma and LDL $\gamma$-tocopherol conc in corn oil group<br><br>Sig correlation bet plasma and LDL levels for $\alpha$-tocopherol ($r^2$=0.71; *P*<0.05) in mixed oil group<br><br>**% change and absolute change not provided** | |

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| | | | | | collected at 0, 2, 4, 6 and 11 wk<br><br>24-h stool samples collected throughout study to determine excretion of tocopherols | | |
| **Schwab et al., 2000** | **RCT** | **A** | **Ø** | **Purpose:**<br>To examine effect of supplemental dietary chol added to reduced fat diets (30% energy from fat) enriched with either corn oil (high in PUFA) or beef tallow (high in SFA) on in vitro susceptibility of LDL to oxidation<br><br>**Sample:**<br>13 subj (7 females, 6 males)<br><br>**Inclusions:**<br>LDL chol conc >3.36 mmol/L while consuming habitual diets<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>Subj consumed test diets in following order:<br>1) Corn oil-enriched diet<br>2) Beef tallow-enriched diet<br>3) Beef tallow-enriched diet with supplemental chol<br>4) Corn oil-enriched diet with supplemental chol<br><br>Supplemental chol provided in form of cooked egg yolk<br><br>4 diet periods for 32 d each<br><br>**Dose/Form:**<br>Corn oil – 2/3 of total fat (20% of total kcals) | **Outcome Measures:**<br>Lipids, lipoproteins and apolipoproteins<br>LDL lag time, particle score and LDL $\alpha$-tocopherol conc<br>Plasma antioxidant content<br><br>**Results:**<br>Lipid values higher after corn oil + chol diet compared with corn oil diet:<br>TC (mmol/L; $P<0.05$)<br>Corn oil + chol: 5.29$\pm$0.67<br>Corn oil: 5.01$\pm$0.53<br>LDL (mmol/L; $P<0.05$)<br>Corn oil + chol: 3.48$\pm$0.63<br>Corn oil: 3.24$\pm$0.54<br>HDL (mmol/L; $P<0.05$)<br>Corn oil + chol: 1.21$\pm$0.29<br>Corn oil: 1.14$\pm$0.25<br>TG (mmol/L; $P<0.05$)<br>Corn oil + chol: 1.12$\pm$0.32<br>Corn oil: 1.24$\pm$0.36<br>LDL ApoB (mmol/L; $P=0.07$)<br>Corn oil + chol: 90$\pm$17 | **Author's Conclusions:**<br>"In conclusion, a moderate amount of dietary cholesterol added to diets high in both saturated and polyunsaturated fatty acids resulted in an increase in the susceptibility of LDL to oxidation in middle-aged and elderly subjects with moderate hypercholesterolemia. These data suggest that within the context of normal variations in dietary patterns small but potentially significant alterations in the susceptibility of LDL to oxidation can occur…" |

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| | | | | DS; use of meds known to affect plasma lipid conc | **Dietary Intake During Study:**<br>Total fat: 30% TE with 2/3 fat from corn oil or beef tallow<br>PUFA (% TE):<br>Corn oil: 11.2±0.5<br>Corn oil + chol: 11.9±0.2<br>Beef tallow: 2.6±0.4<br>Beef tallow + chol: 3.4±0.2<br>Chol (mg/4.2 MJ):<br>Corn oil: 85±4<br>Corn oil + chol: 197±13<br>Beef tallow: 109±12<br>Beef tallow + chol: 226±21<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Fasting blood samples collected<br><br>**Washout Period:**<br>Consumed habitual diet | Corn oil: 80±18<br><br>Effect of fat type (corn oil vs beef tallow) NS on susceptibility of LDL to oxidation, but addition of moderate amt of chol resulted in incr susceptibility of LDL to oxidation (decr lag time): 69±22 min vs 96±24 min in corn oil diet with vs without supplemental chol, respectively, *P*=0.006<br><br>82±20 min vs 96±26 min in beef tallow diet with vs without supplemental chol, respectively, *P*=0.025<br><br>Stepwise equation indicated that as plasma oleic acid conc incr and/or linoleic acid conc decr, lag time incr (decr susceptibility to oxidation), whereas as dietary chol conc incr, lag time decr (incr susceptibility to oxidation)<br><br>**% change and absolute change not provided** | ***Reviewer's Comments:***<br>*None* |

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| **Howell et al., 1998** | **RCT, CO** | **A** | **+** | **Purpose:**<br>To examine whether phytosterols in polyunsaturated oils account for their differential action on lipid metabolism compared with monounsaturated oils<br><br>**Sample:**<br>16 normolipidemic subj (8 females; 8 males)<br><br>**Inclusions:**<br>Plasma TC levels <4.9 mmol/L, LDL <3.0 mmol/L and TG <2.4 mmol/L; BMI <27<br><br>**Exclusions:**<br>Smoker; use of meds known to affect lipid metabolism | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>3 diet TX of 10 d each separated by washout period<br><br>Solid food diet (50% TE as CHO, 35% fat and 15% PRO) with 2/3 fat as either:<br>1) Corn oil<br>2) Olive oil<br>3) Olive oil + phytosterol mixture<br><br>**Dose/Form:**<br>1) Corn oil (56.8% of total fat PUFA, 27.8% MUFA, 13.9% SFA, 830 mg/100 phytosterols)<br>2) Olive oil (9.3% of total fat PUFA, 72.9% MUFA, 17.8% SFA, .63g phytosterols /1000 kcal)<br>3) Olive oil plus phytosterol mixture (0.4 g phytosterol/1000 kcal – double that contained in corn oil mixture) | **Outcome Measures:**<br>Plasma lipids<br>Free cholesterol fractional synthetic rates<br>Deuterium incorporation rates into esterified chol<br><br>**Results:**<br>TC conc (mmol/L) higher after olive oil diets ($P$=0.0001) than corn oil diet:<br>Corn oil: 3.32±0.11<br>Olive oil: 3.71±0.15<br>Olive oil + phytosterol: 3.65±0.13<br><br>NS diff bet olive oil and olive oil + phytosterol diets (mean diff: 0.06 mmol/L; 95% CI, -0.13 to 0.25 mmol/L)<br><br>LDL conc (mmol/L) higher after olive oil diet ($P$<0.05) than corn oil diet:<br>Corn oil: 1.99±0.12<br>Olive oil: 2.17±0.12<br>Olive oil + phytosterol: 2.11±0.12 (NS diff from corn diet or olive oil diet)<br><br>Plasma TG conc (mmol/L) higher after olive oil diet ($P$<0.05) than corn oil diet: | **Author's Conclusions:**<br>"These results suggest that phytosterols are partly responsible for the differences in plasma cholesterol levels and synthesis observed between polyunsaturated and monounsaturated oils"<br><br>***Reviewer's Comments:***<br>*None* |

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| | | | | | **Dietary Intake During Study:**<br>Total fat: 35% TE with 2/3 fat as test oil<br>PUFA (% TE):<br>Corn oil: 17.0<br>Olive oil: 4.3<br>SFA: ~7% TE<br>Chol: 129 mg/1000 kcal<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Wt measured daily<br>Fasting blood samples collected on d 9 and 10 of each dietary phase<br><br>**Washout Period:**<br>Habitual ad lib diet consumed for $\geq$ 2 wk | Corn oil: 0.70$\pm$0.04<br>Olive oil: 0.85$\pm$0.07<br>Olive oil + phytosterol: 0.80$\pm$0.06 (NS diff from corn diet or olive oil diet)<br><br>NS diff bet HDL conc after any diets<br><br>Females had consistently higher (*P*=0.03) plasma HDL conc than males over each TX period, but both genders responded similarly to diet TX with no within-group diff<br><br>Fractional synthetic rates after corn oil TX (0.061$\pm$0.009 pools/d) higher (*P*<0.05; 0.034 pools/d; 95% CI, 0.008 to 0.059 pools/d) than those after olive oil TX (0.028$\pm$0.004 pools/d), but NS diff from olive oil + phytosterol TX<br><br>Deuterium incorporation rates into esterified chol NS diff bet TX<br><br>**% change not provided** | |
| **Schwab et al., 1998** | **RCT** | **A** | **Ø** | **Purpose:**<br>To examine effect of FA composition of reduced-fat diet on in vitro oxidation of LDL | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>5 reduced-fat diets | **Outcome Measures:**<br>Lipids<br>LDL lag time<br>Antioxidant constituents in LDL particles | **Author's Conclusions:**<br>"In conclusion, in middle-aged and elderly moderately |

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| | | | | **Sample:**<br>14 moderately hypercholesterolemic middle-aged and elderly subj (8 females, 6 males)<br><br>**Inclusions:**<br>LDL chol conc >3.36 mmol/L<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of meds known to affect plasma lipid levels; use of DS or HRT | enriched with test oils provided in randomized order for 32-d each<br><br>Each diet separated by washout period in which habitual diet consumed<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Canola oil<br>3) Olive oil<br>4) Rice bran oil<br>5) Beef tallow<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE; 2/3 fat from experimental fats<br>PUFA (% TE):<br>Corn oil: 11.21±0.51<br>Canola oil: 6.69±0.17<br>Olive oil: 3.85±0.34<br>Rice bran oil: 8.83±0.43<br>Beef tallow: 2.62±0.35<br>SFA (% TE):<br>Corn oil: 6.90±0.60<br>Canola oil: 5.40±0.67<br>Olive oil: 6.90±0.66<br>Rice bran oil: 7.44±0.61<br>Beef tallow: 13.69±0.58<br>Chol (mg/4.2 MJ):<br>Corn oil: 85±4 | Plasma FA patterns<br><br>**Results:**<br>Plasma TC conc sig higher after beef tallow (5.63 ±0.79 mmol/L; *P*<0.05 compared to all other oils except olive oil), intermediate after olive oil (5.32±0.51 mmol/L) and lowest after canola- (5.05±0.53 mmol/L), corn- (5.00±0.51 mmol/L) or rice bran- (5.00±0.49 mmol/L) enriched diets<br><br>Plasma LDL conc sig higher after beef tallow (3.62 ±0.70 mmol/L; *P*<0.05 compared to all other oils except olive oil), intermediate after olive oil (3.42±0.51 mmol/L) and lowest after canola- (3.24±0.51 mmol/L), corn- (3.24±0.49 mmol/L) or rice bran- (3.16±0.44 mmol/L) enriched diets<br><br>HDL and TG levels similar among diet phases<br><br>NS diff among diet phases in in vitro susceptibility of LDL to oxidation; however mean data suggested that LDL isolated after subj consumed diets higher in | hypercholesterolemic subjects, the consumption of reduced-fat diets enriched in animal fat or vegetable oils with a relatively wide range of fatty acid profiles did not alter the in vitro susceptibility of LDL to oxidation. The advantages of reducing the saturated fat content of the diet were reflected in lower total and LDL cholesterol levels"<br><br>***Reviewer's Comments:***<br>*None* |

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| | | | | | Canola oil: 81±5<br>Olive oil: 84±3<br>Rice bran: 83±7<br>Beef tallow: 109±12<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Subj reported to research unit ≥3x/wk for measurement of BP and wt and to consume 1 meal | MUFA (e.g., canola and olive oils) had longer lag times than LDL isolated after subj consumed other test diets (e.g., corn and rice bran oils)<br><br>Resistance of LDL to oxidation sig correlated with LDL α-tocopherol conc (*r*=0.30, *P*=0.01), and correlation with plasma 18:1/18:2 ratio approached sig (*r*=0.22, *P*=0.08)<br><br>**% change and absolute change not provided** | |
| **Insull et al., 1994** | **RCT, DB** | **A** | **+** | **Purpose:**<br>To compare plasma lipid changes due to PUFA in partially hydrogenated soybean oil, corn oil and sunflower oil fed in reduced fat diet<br><br>**Sample:**<br>61 healthy adults (26 male, 35 female)<br><br>**Inclusions:**<br>Healthy; free-living; adult | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>7 successive 5-wk feeding periods<br><br>Each TX period followed by CNTL, self-selected, ad lib diet; TX diet order randomized<br><br>TX diets consisted of lunch and dinner; supplemented with low fat foods for breakfast and | **Outcome Measures:**<br>Lipids<br><br>**Results:**<br>% change in lipoproteins with each diet relative to ad lib diet:<br>TC<br>Corn: -10.8 (*P*<0.0001)<br>Sunflower: -12.6 (*P*<0.0001)<br>Soybean: -9.2 (*P*<0.0001)<br>LDL<br>Corn: -12.0 (*P*<0.0001)<br>Sunflower: -15.2 (*P*<0.0001)<br>Soybean: -12.3 (*P*<0.0001)<br>HDL<br>Corn: -11.0 (*P*<0.0001) | **Author's Conclusions:**<br>"The main conclusions drawn from this study are: 1) at a fat intake of 22-26% of total energy, a diet of natural foods with SFA at 5.4-7.4% of energy is effective for lowering plasma TC and LDL-C; 2) increasing the PUFA from 4.7% to 9.7% of energy, while decreasing MUFA |

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| | | | | **Exclusions:**<br>Use of lipid lowering meds | snacking<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Sunflower oil<br>3) Partially hydrogenated soybean oil<br><br>Amt not provided<br><br>**Dietary Intake During Study:**<br>Test diets:<br>Total fat: 22.3-25.7% TE<br>PUFA (% TE):<br>Corn oil: 7.5-9.3<br>Sunflower oil: 7.8-9.7<br>Soy oil: 4.7-5.6<br>SFA (% TE):<br>Corn and soy oils: 5.4-5.9<br>Sunflower oil: 6.4-7.1<br>Chol: 258-278mg/d<br>Calories: 1549-2010 kcal/d<br><br>Ad lib diets:<br>Total fat: 32.4-38.8% TE<br>PUFA: 4.3-5.1% TE<br>SFA: 12.1-13.5% TE<br>Chol: 284-368mg/d<br>Calories: 1678-2367 kcal/d | Sunflower: -10.5 ($P$<0.0001)<br>Soybean: -8.6 ($P$<0.0001)<br><br>Plasma chol (TC, LDL, HDL) on test diets decr sig from ad lib feeding by ave of 11%, 13% and 10%, respectively ($P$<0.001)<br><br>Plasma TG conc NS change bet ad lib diet and test diets<br><br>Males showed greater response than females in lowering TC ($P$<0.01) and LDL ($P$<0.02) | from 14.2-8.9% of energy produces modest further lowering of plasma TC; and 3) the fat-modified diet must be sustained in order to maintain the reduced-cholesterol concentrations…. However, these data indicate that the proportion of the diet's PUFA must be an important consideration in designing low-fat, low-SFA diets for studies to prevent coronary artery disease and cancer"<br><br>***Reviewer's Comments:***<br>*None* |

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| | | | | | **Dietary Intake Assessment/Frequency:** Recorded intake of low fat food supplements daily<br><br>3- and 5-d food records kept during several test and ad lib periods<br><br>**Study Visits/ Measurements:** Fasting blood samples collected at end of wk 4 and 5 of each diet period<br><br>**Washout Period:** Habitual diet eaten ad lib | | |
| **Jones et al., 1994** | **RCT, DB** | **A** | **+** | **Purpose:** To examine (1) influence of MUFA/PUFA ratio on circulating chol levels and plasma chol synthesis rates in moderately hypercholesterolemic subj and (2) assoc bet FA and plant sterol contents of oils consumed and plasma chol synthesis | **Run-in Period:** Baseline diet: 35.4% kcal as fat (15% SFA, 15% MUFA, 6% PUFA), 128 mg chol/1000 kcal<br><br>**TX/Duration:** Diets provided in randomized order with 2/3 dietary fat from test oil<br><br>32 d each with 7-14 d washout periods | **Outcome Measures:** Lipids<br>Chol fractional synthesis rate<br>Absolute synthesis rate<br><br>**Results:** TC levels sig lower on plant oil diets than baseline diet ($P<0.005$):<br>Corn oil: 194±5 mg/dL<br>Canola oil: 194±5 mg/dL<br>Olive oil: 205±5 mg/dL<br>Baseline diet: 221±8 mg/dL | **Author's Conclusions:** "These data suggest a more rapid rate of cholesterol synthesis with consumption of corn oil versus olive oil diets, indicating differential mechanisms that control circulating cholesterol level control across plant oil types" |

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| | | | | rate<br><br>**Sample:**<br>15 healthy subj<br><br>**Inclusions:**<br>LDL levels >130 mg/dL; postmenopausal (women)<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of meds known to affect plasma lipid levels | **Dose/Form:**<br>1) Corn oil<br>2) Canola oil<br>3) Olive oil<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE with 2/3 fat from test oil<br>PUFA: 2.12% TE (baseline), not specified for TX oils<br>SFA: ≤7% TE<br>P/S ratio:<br>Corn oil: 1.625<br>Canola oil: 1.239<br>Olive oil: 0.558<br>Baseline diet: 0.616<br>Chol: 224±12.7 mg/d<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Blood samples collected at end of each period | TC levels higher on olive oil diet ($P$<0.01) than corn and canola phases<br><br>LDL levels sig lower on plant oil diets than baseline diet ($P$<0.001):<br>Corn oil: 125±5 mg/dL<br>Canola oil: 126±5 mg/dL<br>Olive oil: 132±5 mg/dL<br>Baseline diet: 152±8 mg/dL<br><br>HDL levels sig lower on corn ($P$<0.01), and canola ($P$<0.05) oil diets compared with baseline diet:<br>Corn oil: 44±2 mg/dL<br>Canola oil: 44±3 mg/dL<br>Olive oil: 46±2 mg/dL<br>Baseline diet: 48±3mg/dL<br><br>TG levels NS diff<br><br>Fractional synthesis rates higher ($P$<0.05) for corn oil (0.0665±0.0097 pool/d) compared with baseline (0.0412±0.0060 pool/d) and olive oil (0.0409±0.0052 pool/d), but not canola oil (0.0492±0.0072 pool/d)<br><br>Mean absolute synthesis rates for corn oil (1697±271 mg/d) elevated ($P$<0.05) relative to | ***Reviewer's Comments:***<br>*None* |

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| | | | | | | baseline (1080±170 mg/d) and olive oil (1034±140 mg/d) but not canola oil (1169±137 mg/d)<br><br>**% change and absolute change not provided** | |
| **Lichtenstein et al., 1994(a) (Rice bran oil consumption and plasma lipid levels in moderately hyperchol-esterolemic humans)** | **RCT, DB, CO** | **A** | **+** | **Purpose:**<br>To study effects of substituting rice bran oil for other more commonly used and recommended veg oils, i.e., canola, corn and olive, within context of National Cholesterol Education Panel guidelines<br><br>**Sample:**<br>15 middle-aged and elderly subj (8 female; 7 male)<br><br>**Inclusions:**<br>LDL levels ≥130 mg/dL; postmenopausal (women)<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of | **Run-in Period:**<br>Rice bran oil diet; 32 d<br><br>**TX/Duration:**<br>Diets provided in randomized order with 2/3 of fat (20% of kcals) from test oils<br><br>32 d each<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Canola oil<br>3) Olive oil<br>4) Rice bran oil<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE with 2/3 from test oil<br>PUFA (% TE):<br>Corn oil: 11.21±0.52<br>Canola oil: 6.69±0.17<br>Olive oil: 3.85±0.34<br>Rice bran oil: 8.83±0.43 | **Outcome Measures:**<br>Lipids<br>Lipoproteins<br><br>**Results:**<br>Plasma TC conc similar and stat indistinguishable following rice bran oil- (192±19 mg/dL), canola- (194±20 mg/dL) and corn oil- (194±19 mg/dL) enriched diets and lower than olive oil-enriched diet (205±19; *P*=0.001)<br><br>Plasma LDL conc similar and stat indistinguishable following rice bran- (122±17 mg/dL), canola- (126±17 mg/dL) and corn oil- (125±19 mg/dL) enriched diets and lower than olive oil-enriched diet (132±19; *P*=0.01)<br><br>NS diff in VLDL, HDL, TG, LDL apolipoprotein B, apolipoprotein A-I and lipoprotein(a), TC/HDL ratio and LDL apolipoprotein B:apolipoprotein A-I ratios bet diff | **Author's Conclusions:**<br>"From this study we conclude that consumption of a diet enriched in rice bran oil,…corn or canola oil within the context of current NCEP guidelines has comparable advantages in terms of lowering plasma lipid levels or improving the cardiovascular risk profile"<br><br>**Reviewer's Comments:**<br>None |

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| | | | | meds known to affect plasma lipid levels | SFA (% TE):<br>Corn oil: 6.90±0.60<br>Canola oil: 5.40±0.67<br>Olive oil: 6.90±0.66<br>Rice bran oil: 7.44±0.61<br>Chol: 80-85 mg/1000 kcal<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Blood samples collected at end each period | veg oil-enriched diets<br><br>**% change and absolute change not provided** | |
| **Lichtenstein et al., 1994(b) (Hypercholesterolemic effect of dietary cholesterol in diets enriched in polyunsaturated and saturated fat)** | **RCT, DB, CO** | **A** | **+** | **Purpose:**<br>To study effects of adding modest amts of chol to reduced fat diets enriched in commonly consumed source of SFA relatively high in stearic acid<br><br>**Sample:**<br>14 middle-aged and elderly women and men | **Run-in Period:**<br>Baseline diet: typical U.S. diet [35% TE as fat (13% SFA, 12% MUFA, 8% PUFA), 128 mg chol/1000 kcal]<br><br>32 d<br><br>**TX/Duration:**<br>Reduced-fat diets enriched with test fats (1/3 of fat derived from natural foods and 2/3 of fat from designated fat) | **Outcome Measures:**<br>Lipids<br>Lipoproteins<br><br>**Results:**<br>% change in fasting plasma lipoproteins with each reduced-fat diet relative to baseline diet:<br>TC<br>Corn oil: -13 ($P$<0.05)<br>Beef tallow: -2 (NS)<br>LDL<br>Corn oil: -17 ($P$<0.05)<br>Beef tallow: -8 ($P$<0.05)<br>HDL<br>Corn oil: -9 ($P$<0.05) | **Author's Conclusions:**<br>"The results indicated that within the context of a reduced-fat diet and independent of the cholesterol content of the diet, the current recommendation of limiting the source of SFAs relatively high in stearic acid seems valid and prudent" |

| Author/ Year | De-sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| | | | | **Inclusions:**<br>LDL levels >130 mg/dL; >40 y of age; postmenopausal (women)<br><br>**Exclusions:**<br>Evidence of chronic illness, including hepatic, renal, thyroid or cardiac dysfunction; smoker; use of meds known to affect plasma lipid levels | 32 d each<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Beef tallow<br>3) Corn oil plus chol (eggs added)<br>4) Beef tallow plus chol (eggs added)<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE; 2/3 from test oil<br>PUFA (% TE):<br>Corn oil: 11.21±0.52<br>Corn oil + chol: 11.91±0.15<br>Beef tallow: 2.62±0.35<br>SFA (% TE):<br>Corn oil: 6.90±0.60<br>Corn oil + chol: 7.37±0.38<br>Beef tallow: 13.69±0.58<br>Beef tallow + chol: 12.07±1.09<br>Chol (mg/1000 kcal):<br>Corn oil: 85±4<br>Corn oil + chol: 197±13<br>Beef tallow: 109±12<br>Beef tallow + chol: 226±21 | Beef tallow: -7 (*P*<0.05)<br>TG<br>Corn oil: 4 (NS)<br>Beef tallow: 10 (NS)<br>LDL apolipoprotein B<br>Corn oil: -20 (*P*<0.05)<br>Beef tallow: -5 (NS)<br>Apolipoprotein A1<br>Corn oil: <1 (NS)<br>Beef tallow: <1 (NS)<br><br>% change in fasting plasma lipoproteins bet reduced-fat diets and chol added diets:<br>TC<br>Corn oil: 6 (*P*<0.05)<br>Beef tallow: 5 (*P*=0.05)<br>LDL<br>Corn oil: 8 (*P*<0.05)<br>Beef tallow: 11 (*P*<0.01)<br>VLDL<br>Corn oil: -4 (NS)<br>Beef tallow: -15 (*P*<0.01)<br>HDL<br>Corn oil: 7 (*P*<0.05)<br>Beef tallow: 2 (NS)<br>TG<br>Corn oil: -9 (*P*<0.05)<br>Beef tallow: 13 (NS)<br>LDL apolipoprotein B<br>Corn oil: 16 (NS)<br>Beef tallow: 5 (NS)<br>Apolipoprotein A1 | **Reviewer's Comments:**<br>None |

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| | | | | | **Dietary Intake Assessment/Frequency:** Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:** Report to research unit ≥3x/wk for measurement of BP and wt<br><br>Fasting blood samples collected 4x during last wk of each period | Corn oil: 4 (NS)<br>Beef tallow: 5 ($P$<0.05)<br><br>Lipoprotein(a) unaffected by dietary TX | |
| **Lichtenstein et al., 1993(a) (Hydrogena-tion impairs the hypolipid-emic effect of corn oil in humans)** | **RCT, DB, CO** | **A** | **+** | **Purpose:** To assess effects on plasma lipoproteins and apolipoproteins of replacing corn oil with corn-oil margarine in stick form as 2/3 of fat in National Cholesterol Education Program Step 2 diet in middle-aged and elderly women and men with moderate hypercholesterolemia<br><br>**Sample:** 14 middle-aged and | **Run-in Period:** Baseline diet: typical U.S. diet [35% kcal as fat (13% SFA, 12% MUFA, 8% PUFA), 128 mg chol/1000 kcal]<br><br>32 d<br><br>**TX/Duration:** National Cholesterol Education Program Step 2 diet enriched with test oils (2/3 of fat as test oil; 20% of kcals)<br><br>32 d each diet with 1 wk | **Outcome Measures:** Lipids<br>Apolipoproteins<br>Lipoprotein (a)<br><br>**Results:** % change in lipoproteins with each diet relative to baseline diet:<br>TC<br>Corn oil: -13±6 ($P$=0.001)<br>Corn margarine: -7.4±10 ($P$=0.006)<br>LDL<br>Corn oil: -17±8 ($P$=0.001)<br>Corn margarine: -10.4±12 ($P$=0.003)<br>HDL | **Author's Conclusions:** "The consumption of either test diet, both of which approximated the current dietary recommendations with respect to total fat, saturated fat, and cholesterol, resulted in significant declines in the plasma cholesterol concentrations of middle-aged and older women and men with mildly elevated |

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| | | | | elderly moderately hypercholesterolemic subj (8 women; 6 men)<br><br>**Inclusions:**<br>Middle-aged and elderly; LDL levels >130 mg/dL<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of meds known to affect plasma lipid levels | washout period<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Corn oil margarine<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE with 2/3 from test oil<br>PUFA (%TE):<br>Corn oil: 9.45±2.55<br>Corn oil margarine: 8.30±0.16<br>Baseline diet: 7.94±0.75<br>SFA (% TE):<br>Corn oil: 6.41±1.45<br>Corn oil margarine: 7.73±0.13<br>Baseline diet: 12.90±1.97<br>*Trans* fat: 12.4±2.8 g/person/d ave during margarine phase (range: 9.2-18.5)<br>Chol: <100mg/1000 kcals<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit | Corn oil: -9±7 (*P*=0.002)<br>Corn margarine -11.1±9 (*P*=0.002)<br>LDL apolipoprotein B<br>Corn oil: -20±15 (*P*=0.001)<br>Corn margarine -9.8±12 (*P*=0.01)<br><br>Stat sig incr in VLDL conc relative to baseline for margarine-enriched diet only (21±31; *P*=0.03)<br><br>NS effect on plasma TG, apolipoprotein A-I, and lipoprotein(a) bet diet phases<br><br>Diet enriched with margarine not as efficacious as similar diet enriched with corn oil in reducing plasma TC (*P*=0.039), LDL (*P*=0.058) and LDL apolipoprotein B (*P*=0.068) conc<br><br>Margarine diet resulted in sig higher TC/HDL ratio compared with corn oil diet (5.54±1.94 vs 4.58±1.04; *P*=0.037)<br><br>Plasma lipids measured at 24 h stat indistinguishable from those measured at 0-h time point | plasma lipid levels. The use of commercially available corn-oil stick margarine, when compared with liquid corn oil, resulted in significantly higher plasma cholesterol concentrations. The differences, whether attributable to differences in either the fatty acid profiles or the *trans* fatty acid contents of the two preparations of corn oil, were of a magnitude that over the long term would be predicted to have a physiologically significant impact on cardiovascular risk"<br><br>***Reviewer's Comments:***<br>*Authors noted that their study design "had the disadvantage of not being able to isolate the biological effects of trans fatty* |

| Author/ Year | De-sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| | | | | | **Study Visits/ Measurements:**<br>Visits to metabolic research unit ≥3x/wk for measurement of BP and wt<br><br>Fasting blood samples collected 4x during last wk of each period<br><br>Last d of each period, subj consumed test meals in metabolic research unit and had blood samples drawn at 0, 5, 8, 10 and 24 h | | *acid consumption independent of any other changes resulting from hydrogenation"* |
| **Lichtenstein et al., 1993(b) (Effects of canola, corn, and olive oils on fasting and postprandial plasma lipoproteins in humans as part of a National Cholesterol** | **RCT** | **A** | **+** | **Purpose:**<br>To assess effects of consuming oils relatively high in MUFA or PUFA as part of National Cholesterol Education Program Step 2 diet in middle-aged and elderly women and men<br><br>**Sample:**<br>15 middle-aged and | **Run-in Period:**<br>Baseline diet: typical U.S. diet [35.4% kcal as fat (13% SFA, 12% MUFA, 8% PUFA), 128 mg chol/1000 kcal]<br><br>32 d<br><br>**TX/Duration:**<br>National Cholesterol Education Program Step 2 diets enriched with test oils (2/3 fat as test oil; | **Outcome Measures:**<br>Lipids<br>Apolipoproteins<br>Lipoprotein (a)<br><br>**Results:**<br>% change in lipoproteins with each diet relative to baseline diet:<br>TC<br>Corn oil: -13±6 (*P*=0.001)<br>Canola oil: -12±9 (*P*=0.001)<br>Olive oil: -7±7 (*P*=0.01)<br>LDL<br>Corn oil: -17±8 (*P*=0.001) | **Author's Conclusions:**<br>"The major finding of this study is that significant reductions in LDL-C and apoB levels can be achieved in middle-aged and elderly women and men with initial LDL levels >130 mg/dL by reducing dietary saturated fat and cholesterol intake |

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| **Education Program Step 2 diet)** | | | | elderly subj (14 completed – 8 females, 6 males)<br><br>**Inclusions:**<br>Middle-aged and elderly; LDL-C levels >130 mg/dL<br><br>**Exclusions:**<br>Evidence of chronic illness; smoker; use of meds known to affect plasma lipid levels | 20% of kcals)<br><br>32 d each diet with 1-2 wk washout period<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Canola oil<br>3) Olive oil<br><br>**Dietary Intake During Study:**<br>Total fat: 30% TE with 2/3 from test oil<br>PUFA (% TE):<br>Corn oil: 11.21±0.52<br>Canola oil: 6.69±0.17<br>Olive oil: 3.85±0.34<br>Baseline diet: 7.94±0.75<br>SFA: ≤7% TE<br>Chol: <100 mg/1000 kcal<br><br>**Dietary Intake Assessment/Frequency:**<br>Meals provided by metabolic research unit<br><br>**Study Visits/ Measurements:**<br>Blood samples collected at end of each period | Canola oil: -16±3 (*P*=0.001)<br>Olive oil: -13±8 (*P*=0.001)<br>HDL<br>Corn oil: -9±7 (*P*=0.01)<br>Canola oil: -7±3 (*P*=0.05)<br>Olive oil: -4±9 (NS)<br>LDL apolipoprotein B<br>Corn oil: -21±4 (*P*=0.001)<br>Canola oil: -20±11 (*P*=0.001)<br>Olive oil: -16±11 (*P*=0.001)<br><br>NS diff in LDL among oil-enriched diet periods<br><br>NS effect on plasma TG, apolipoprotein A-I, lipoprotein(a) or TC/HDL ratio among diet phases<br><br>Apolipoprotein B:apolipoprotein A-I ratios sig reduced after veg oil-enriched diets (*P*=0.001) | and by incorporating vegetable oils rich in either monounsat-urated fatty acids (canola and olive oil) or polyunsaturated fatty acids (corn oil) as part of an NCEP Step 2 diet. Although differential effects were seen after the consumption of the three different oil-enriched diets in some plasma lipid measures, none of these oils had a significant advantage in terms of altering the overall lipoprotein profile"<br><br>***Reviewer's Comments:***<br>*None* |

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| **Ng et al., 1991** | **RCT, DB** | **A** | **+** | **Purpose:**<br>To compare effect of diets enriched with refined, bleached and deodorized palm olein, refined, bleached and deodorized corn oil, on serum lipid conc in healthy human volunteers and refined, bleached and deodorized coconut oil during usual cooking practices<br><br>**Sample:**<br>83 subj (80 completed; 58 males, 22 females)<br><br>**Inclusions:**<br>Normolipidemic; normotensive; nondiabetic; free from cardiac, hepatic, renal or bleeding disorders; BMI <26 kg/$m^2$; willing to adhere to provided dietary guidelines<br><br>**Exclusions:**<br>None given | **Run-in Period:**<br>3 daily hostel meals with at least half of fat from palm olein cooking oil<br><br>**TX/Duration:**<br>Randomly assigned to 1 of 3 dietary sequences:<br>1) Group 1: Coconut-Palm-Coconut<br>2) Group 2: Coconut-Corn-Coconut<br>3) Group 3 (CNTL): Coconut oil throughout study<br><br>5 wk each period (15 wk total)<br><br>**Dose/Form:**<br>Oils used as cooking oils<br><br>**Dietary Intake During Study:**<br>Subj provided with daily meals<br><br>Cooking oils about 75% of total dietary fat<br><br>Total fat: 32% TE (ave)<br>PUFA (% TE):<br>Corn oil: 35.6 | **Outcome Measures:**<br>Lipids<br><br>**Results:**<br>After 1st phase of coconut oil, serum chol incr >10% above entry level for all groups<br><br>% change in chol conc after 2nd period relative to 1st period of coconut oil:<br>TC<br>Corn oil: -36 (*P*=0.001)<br>Palm oil: -19 (*P*<0.001)<br>LDL<br>Corn oil: -42 (*P*<0.001)<br>Palm oil: -20 (*P*<0.001)<br>HDL<br>Corn oil: -26 (*P*<0.001)<br>Palm oil: -20 (*P*<0.001)<br><br>% change in chol conc after 2nd period compared to baseline values:<br>TC<br>Corn oil: -29 (*P*<0.001)<br>Palm oil: -9 (*P*<0.001)<br>LDL/HDL ratio<br>Corn oil: -25 (*P*<0.001)<br>Palm oil: -8 (NS)<br><br>When responses in serum TC in male and female subj considered | **Author's Conclusions:**<br>"The corn-oil enriched diet produced a dramatic hypocholesterolemic effect in the subjects, yielding serum cholesterol concentrations (3.15±0.59 mmol/L) that were well below the lower limit for the range usual found in the general population.…The substitution of coconut oil with either palm olein or corn oil as the major dietary fat significantly reduced HDL-cholesterol. However, due to the greater concomitant proportionally greater reductions in LDL-cholesterol, the LDL-HDL ratio was decreased 3% and 25% by palm olein and corn oil, respectively. Corn oil showed a |

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| | | | | | Palm oil: 11.4<br>Coconut oil: 2.8<br>SFA (% TE):<br>Corn oil: 30.4<br>Palm oil: 45.6<br>Coconut oil: 75.1<br>P/S ratio:<br>Corn oil: 35.6<br>Palm oil: 45.6<br>Coconut oil: 75.1<br>Chol: 200 mg<br>Calories: 9.62 MJ (males) and 8.04 MJ (females)<br><br>**Dietary Intake Assessment/Frequency:**<br>Dietary compliance monitored visually by dietitians (plate waste)<br><br>**Study Visits/ Measurements:**<br>Wt measured weekly<br><br>Fasting blood samples collected at baseline and end each dietary period | separately for palm olein and corn oil periods, males found to exhibit slightly greater response than females<br><br>Actual change in HDL after 2nd period compared to baseline values:<br>Palm: -0.27 mmol/L ($P$<0.001)<br>Corn: -0.35 mmol/L($P$<0.001)<br><br>Serum TG unaffected during palm olein period but sig reduced during corn oil period when compared with preceding coconut oil period (-0.08 mmol/L; $P$<0.01) or with conc at baseline (-0.20 mmol/L; $P$<0.02) | hypotriglyceridemic effect that was not observed for palm olein or coconut oil"<br><br>***Reviewer's Comments:***<br>*None* |
| **Wardlaw and Snook, 1990** | **RCT, CO** | **A** | **+** | **Purpose:**<br>To determine if diet of typical American foods with corn oil as major source of fat | **Run-in Period:**<br>High butter diet - 85% of fat from butter<br><br>2 wk | **Outcome Measures:**<br>Lipids<br>Apolipoproteins | **Author's Conclusions:**<br>"These data suggest that when men on diets high in saturated |

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| | | | | would lower serum HDL-chol conc and to document effects on serum lipids of high-oleic acid sunflower oil<br><br>**Sample:**<br>22 men (20 completed CO phases; 17 completed final phase)<br><br>**Inclusions:**<br>TC>4.66 mmol/L<br><br>**Exclusions:**<br>None given | **TX/Duration:**<br>2 phase CO – butter-based diet replaced with veg oil-based diet for 5 wk with 7-wk washout period<br><br>**Dose/Form:**<br>1) PUFA diet – corn oil (85% of fat)<br>2) MUFA diet – high oleic acid sunflower oil (85% of fat)<br><br>**Dietary Intake During Study:**<br>Food provided as 3 meals/d; 1-2 meals/d eaten in lab, other meals provided as carry-out<br><br>Total fat: 40% TE<br>PUFA (% TE):<br>Corn oil: 19±1<br>Sunflower oil: 6±1<br>Butter: 5±1<br>SFA (% TE):<br>Corn oil: 8±1<br>Sunflower oil: 7±1<br>Butter: 21±1<br>Calories: 12 MJ/d | **Results:**<br>% change in mean serum TC after 5 wk relative to prestudy conc:<br>PUFA (corn oil): -14 ($P$<0.01)<br>MUFA: -9 ($P$<0.05)<br><br>% change in mean serum TC after 5 wk relative to butter-based-diet conc:<br>PUFA (corn oil): -21 ($P$<0.001)<br>MUFA diet: -16 ($P$<0.001)<br><br>95% CI for diff bet effect of PUFA (corn oil) vs MUFA diet on TC = 0.21±0.18 mmol/L ($P$<0.03) for changes from butter-based-diet conc<br><br>Extent of change in serum TC conc on veg oil-based diet correlated to butter-based-diet conc for MUFA diet ($r$=0.79, $P$<0.01) and PUFA (corn oil) diet ($r$=0.61, $P$<0.01)<br><br>% change in mean calculated serum LDL after 5 wk relative to prestudy conc:<br>PUFA (corn oil): -13 ($P$<0.05)<br>MUFA: -8 (NS) | fatty acids reduce their saturated fatty acid intake but not their total fat intake, many can still experience a significant lowering in serum total cholesterol….When intake of saturated fatty acids is reduced, either polyunsaturated or monounsaturated fatty acids are an appropriate replacement, although the total drop because of a substitution with polyunsaturated fatty acids may be more consistent and/or greater….Our data with men suggest that…even a diet containing 40 en% from fat can allow for a substantial reduction in blood lipids if intake of saturated fatty acids is minimized" |

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| | | | | | **Dietary Intake Assessment/Frequency:** Daily checklists<br><br>**Study Visits/ Measurements:** Fasting blood samples collected on d 1, 13, 15, 12, 35, 45 and 50<br><br>STUDY 2:<br>Veg oil-based diet continued with an incr in chol intake to match butter-based diet intake (ave incr from 190 to 500 mg/d); N=17<br><br>2 wk | % change in mean calculated serum LDL after 5 wk relative to butter-based-diet conc:<br>PUFA (corn oil): -26 (*P*<0.001)<br>MUFA: -21 (*P*<0.001)<br><br>95% CI for diff bet effect of PUFA (corn oil) vs MUFA diet on LDL = 0.18±0.17 mmol/L (*P*<0.04) for changes from butter-based-diet conc<br><br>% change in mean calculated serum apolipoprotein B-100 after 5 wk relative to butter-based-diet conc:<br>PUFA (corn oil): -28 (*P*<0.001)<br>MUFA: -23 (*P*<0.001)<br><br>Over time, PUFA (corn oil) diet lowered apolipoprotein B-100 at greater rate than did MUFA diet; diet-by-time interaction (*P*<0.05)<br><br>NS changes in HDL and apolipoprotein A-1 conc on either diet, but sig diet-by-time interaction (*P*<0.05) – over time, PUFA (corn oil) diet lowered HDL and apolipoprotein A-1 conc at greater rate than MUFA diet | ***Reviewer's Comments:*** *None* |

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| | | | | | | % change in mean serum TG after 5 wk relative to prestudy conc:<br>PUFA (corn oil): -33 ($P$<0.001)<br>MUFA: -23 ($P$<0.05)<br><br>% change in mean serum TG after 5 wk relative to butter-based-diet conc:<br>PUFA (corn oil): -21 ($P$<0.01)<br>MUFA: -10 (NS)<br><br>95% CI for diff bet effect of PUFA vs MUFA diet on TG = 0.11±0.12 mmol/L (NS) for changes from butter-based-diet conc<br><br>STUDY 2:<br>NS change in mean serum TC, calculated LDL, HDL, TG, apolipoprotein A-1 or B-100 conc when chol intake incr on veg oil-based diets | |
| **Kohlmeier et al., 1988** | **RCT, CO** | **A** | **+** | **Purpose:**<br>To examine effect of typical fat-modified diets on serum lipids, lipoproteins and apolipoproteins and to compare efficacy of 2 commonly used oils with high linoleic acid | **Run-in Period:**<br>2-wk dietary intakes monitored (self-transcribed and dictated protocol methods)<br><br>**TX/Duration:**<br>Randomized to fat-modified diets of either | **Outcome Measures:**<br>Lipids<br>Lipoproteins<br>Apolipoproteins<br>Fecal sterol balance<br><br>**Results:**<br>% median relative diff bet normal and fat-modified diets: | **Author's Conclusions:**<br>"While changes of all measured parameters pointed in the same direction, serum total and LDL cholesterol levels were significantly lower with |

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| | | | | content, sunflower oil and corn oil<br><br>**Sample:**<br>15 nonobese, healthy men<br><br>**Inclusions:**<br>Middle-aged men; higher than ave plasma chol levels (5.2-6.7 mmol/L)<br><br>**Exclusions:**<br>Liver, kidney or metabolic disorder; habitual alcohol consumption >30 g/d | corn oil or sunflower oil TX then CO to other TX<br><br>4 wk each<br><br>TX diets alternated with 4 normal diet periods<br><br>6 wk each<br><br>**Dose/Form:**<br>1) TX 1: 35 g corn oil, 40 g corn-oil margarine and 35 g hidden fat<br>2) TX 2: 35 g sunflower oil, 40 g sunflower-oil margarine and 35 g hidden fat<br><br>Test fats used by subj in normal manner of cooking or as bread spread<br><br>Subj given list of permitted foods<br><br>**Dietary Intake During Study:**<br>Total fat (g/d):<br>Corn oil: 117<br>Sunflower oil: 119<br>Normal diet: 96-111 | TC: -21.6 ($P \leq 0.001$)<br>LDL: -23.3 ($P \leq 0.001$)<br>TG: 5.7 (NS)<br>VLDL: -18.5 (NS)<br>HDL (electrophoresis): -25.5 ($P \leq 0.001$)<br>HDL (precipitation): -3.7 (NS)<br>% median relative diff bet normal and corn oil diets:<br>TC: -25.0 ($P \leq 0.001$)<br>LDL: -29.3 ($P \leq 0.001$)<br>TG: -3.6 (NS)<br>VLDL: -5.0 (NS)<br>HDL (electrophoresis): -14.8 ($P \leq 0.001$)<br>HDL (precipitation): 0.3 (NS)<br>% median relative diff bet normal and sunflower oil diets:<br>TC: -18.2 ($P \leq 0.001$)<br>LDL: -17.3 ($P \leq 0.01$)<br>TG: -1.5 (NS)<br>VLDL: -3.7 (NS)<br>HDL (electrophoresis): -20.5 ($P \leq 0.001$)<br>HDL (precipitation): -2.1 (NS)<br>% median relative diff bet sunflower and corn oil diets:<br>TC: -6.8 ($P \leq 0.01$)<br>LDL: -12.0 ($P \leq 0.01$)<br>TG: 5.4 (NS)<br>VLDL: 0 (NS)<br>HDL(electrophoresis): 2.3 (NS) | corn oil than with the sunflower oil"<br><br>***Reviewer's Comments:***<br>*Counseling always included spouses to assure assistance in meal preparation, compliance and monitoring of intake* |

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| | | | | | PUFA (g/d):<br>Corn oil: 36.3<br>Sunflower oil: 34.7<br>SFA (g/d):<br>Corn oil: 13.4<br>Sunflower oil: 11.6<br>Chol (mg/d):<br>Corn oil: 179<br>Sunflower oil: 166<br>Normal diet: 343-536<br><br>**Dietary Intake Assessment/Frequency:**<br>Self-transcribed and dictated protocol methods throughout study<br><br>24-h recall method used repeatedly<br><br>**Study Visits/ Measurements:**<br>Fasting blood samples collected at end of each diet period along with intravenous fat-tolerance test | HDL (precipitation): 0 (NS)<br><br>Apolipoprotein A-I and A-II NS diff bet each diet<br><br>Fecal bile acid excretion NS diff at end of normal and fat-modified diets<br><br>Fecal sterol balance more negative with use of corn oil than with sunflower oil ($P \leq 0.05$) | |
| **Laine et al., 1982** | **RCT** | **A** | **Ø** | **Purpose:**<br>To compare fully refined, bleached, deodorized corn oil and soy oil, and lightly | **Run-in Period:**<br>Palm oil diet (P/S ratio 0.2)<br><br>3 plasma blood samples | **Outcome Measures:**<br>Plasma lipids | **Author's Conclusions:**<br>"All of the polyunsaturated fat diets produced small |

| Author/ Year | De-sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| | | | | hydrogenated, winterized soy oil, for effectiveness in lowering plasma chol<br><br>**Sample:**<br>24 healthy subj (11 females, 13 males)<br><br>**Inclusions:**<br>Within ±10% ideal wt for ht; normal fasting chol and TG values; ability to maintain routine daily exercise; willingness to complete 3-d food record, eat all meals at research center and consume no other food during 10-wk period; abstention from alcohol for 10-wk period<br><br>**Exclusions:**<br>Use of meds that would interfere with data collection | collected<br><br>7 d<br><br>**TX/Duration:**<br>Subj divided into 4 groups of 6 subj; diets given in randomized order:<br>1) Group 1: palm oil, corn or unhydrogenated soy oil and corn or unhydrogenated soy oil<br>2) Group 2: palm oil, corn or lightly hydrogenated soy oil and corn or lightly hydrogenated soy oil<br>3) Group 3: corn or unhydrogenated soy oil, corn or unhydrogenated soy oil and palm oil<br>4) Group 4: corn or lightly hydrogenated soy oil, corn or lightly hydrogenated soy oil and palm oil<br><br>20 d each study period with no washout period; 10-wk total | **Results:**<br>Ave % change in chol from palm oil regimen:<br>TC<br>Corn oil: -13.2<br>Unhydrogenated soy oil: -12.9<br>Hydrogenated soy oil: -9.2<br>LDL<br>Corn oil: -22.8<br>Unhydrogenated soy oil: -24.3<br>Hydrogenated soy oil: -9.7<br><br>Mean change in mg/dL from palm oil regimen:<br>TC<br>Corn oil (groups 1 & 3): -26.3±3.40 ($P$<0.001)<br>Corn oil (groups 2 & 4): -25.9±2.96 ($P$<0.001)<br>Unhydrogenated soy oil: -25.9±3.84 ($P$<0.001)<br>Hydrogenated soy oil: -16.4±2.50 ($P$<0.001)<br>LDL<br>Corn oil (groups 1 & 3): -27.7±4.64 ($P$<0.001)<br>Corn oil (groups 2 & 4): -23.8±3.79 ($P$<0.001)<br>Unhydrogenated soy oil: -30.3±3.80 ($P$<0.001)<br>Hydrogenated soy oil: -10.8±2.86 ($P$<0.01) | but statistically significant reductions in the cholesterol to protein ratio of all three lipoproteins"<br><br>***Reviewer's Comments:***<br>*None* |

| Author/ Year | De- sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| | | | | | **Dose/Form:**<br>1) Corn oil: 46.0 g (1900 kcals) to 77.5 g (3500 kcals)<br>2) Palm oil: 27.1 g (1900 kcals) to 61.5 g (3500 kcals)<br>3) Unhydrogenated soy oil: 45.4 g (1900 kcals) to 74.5 g (3500 kcals)<br>4) Lightly hydrogenated soy oil: 45.4 g (1900 kcals) to 74.5 g (3500 kcals)<br><br>**Dietary Intake During Study:**<br>Total fat: 35% TE<br>PUFA (g at 3000 kcal level):<br>Corn oil: 52.99<br>Palm oil: 12.28<br>Unhydrogenated soy oil: 52.30<br>Lightly hydrogenated soy oil: 41.90<br>Chol: 700 mg/d<br><br>**Dietary Intake Assessment/Frequency:**<br>None | VLDL<br>Corn oil (groups 1 & 3): 3.8±1.61 ($P$<0.05)<br>Corn oil (groups 2 & 4): -5.6±0.98 ($P$<0.001)<br>Unhydrogenated soy oil: 5.4±2.38 ($P$<0.05)<br>Hydrogenated soy oil: -5.5±1.53 ($P$<0.01)<br>TG<br>Corn oil (groups 1 & 3): -6.3±2.57 ($P$<0.05)<br>Corn oil (groups 2 & 4): -7.4±3.02 ($P$<0.05)<br>Unhydrogenated soy oil: -7.7±2.51 ($P$<0.02)<br>Hydrogenated soy oil: -2.8±3.57 (NS)<br><br>NS change in HDL with any diets<br><br>Corn oil and unhydrogenated soy oil equally effective in reducing plasma TC and LDL conc, but corn oil more effective than lightly hydrogenated soy oil ($P$<0.01 for both total and LDL chol)<br><br>% change in chol/PRO ratio for group 4:<br>Palm to corn:<br>VLDL: -12.33±2.73 ($P$<0.01)<br>LDL: -8.80±0.86 ($P$<0.001) | |

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| | | | | | **Study Visits/ Measurements:**<br>Plasma samples collected on d 10, 18 and 20 of each study period | HDL:-10.50±1.63 (*P*<0.01)<br>Palm to lightly hydrogenated soy:<br>VLDL: -13.15±3.68 (*P*<0.05)<br>LDL: -6.85±1.72 (*P*<0.02)<br>HDL:-7.33±2.01 (*P*<0.05)<br>Corn to lightly hydrogenated soy:<br>VLDL: -0.50±5.18 (NS)<br>LDL: +2.22±2.07 (NS)<br>HDL:+3.63±2.47 (NS) | |
| **Childs et al., 1981** | **RCT** | **A** | **Ø** | **Purpose:**<br>To determine response of plasma lipoproteins to dietary soy lecithin and corn oil and whether response due to PUFA moiety<br><br>**Sample:**<br>STUDY 1: 12 healthy subj (7 females, 5 males)<br><br>STUDY 2: 6 hypercholesterolemic subj (5 females, 1 male)<br><br>**Inclusions:**<br>STUDY 1: No known disorders; normolipidemic (TC | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>STUDY 1:<br>Four 21-d periods (12 wk); 2 periods unsupplemented ad lib intake interposed with periods of supplementation<br><br>Subj divided into 2 matched groups of 6:<br>1) Group A: Soy lecithin then corn oil supplementation<br>2) Group B: Corn oil then soy lecithin supplementation<br><br>STUDY 2:<br>Four 2-mo periods (32 | **Outcome Measures:**<br>Plasma lipids<br><br>**Results:**<br>LDL reduced sig by corn oil (normolipidemics: -12.3±2.3%, *P*<0.002; hypercholesterolemics: -9.8±1.5%, *P*<0.002)<br><br>TC reduced as result of taking corn oil (normolipidemics: -8.4±1.2%, *P*<0.002; hypercholesterolemics: -6.2±1.5%, *P*<0.01)<br><br>TC/HDL reduced as result of taking corn oil (normolipidemics: -7.8±2.0%, 0.05<*P*<0.1; hypercholesterolemics: -9.5±2.1%, *P*<0.001) | **Author's Conclusions:**<br>"The response of both normolipidemic and hypercholesterolemic subjects to the LEC supplementation for 3 weeks and 2 months, respectively...was consistent and significant; slight but statistically significantly increased levels of HDL-CH accompanied slight decreases in LDL-CH levels and resulted in no significant net change in the T-CH levels but in a decrease in the T-CH/HDL-CH ratio….In contrast, corn oil |

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| | | | | and TG levels below age- and sex-specific 95$^{th}$ percentiles<br><br>STUDY 2:<br>Hypercholesterolemic<br><br>**Exclusions:**<br>STUDY 1: Taking meds known to affect lipid metabolism<br><br>STUDY 2:<br>Not provided | wk); soy lecithin supplementation during 2$^{nd}$ period and corn oil supplementation during 4$^{th}$ period<br><br>**Dose/Form:**<br>1) Soy lecithin oil: 36 g (P/S ratio: 2.75)<br>2) Corn oil: 31.8 g (P/S ratio: 4.23)<br><br>**Dietary Intake During Study:**<br>Instructed to follow normal diet<br><br>Supplements consumed as meds; half before morning meal and half before evening meal<br><br>Total diet info not provided<br><br>**Dietary Intake Assessment/Frequency:**<br>STUDY 1:<br>Weekly 3-d food records<br><br>STUDY 2:<br>Monthly 3-d food records | % change in plasma lipids after corn oil relative to baseline:<br>TC:<br>Normolipidemic A: -6.4±1.3 (*P*<0.01)<br>Normolipidemic B: -10.4±1.6 (*P*<0.002)<br>Hypercholesterolemic: -6.2±1.5 (*P*<0.01)<br>LDL:<br>Normolipidemic A: -10.2±2.0 (*P*<0.01)<br>Normolipidemic B: -14.8±4.0 (*P*<0.02)<br>Hypercholesterolemic: -9.8±1.5 (*P*<0.002)<br>HDL:<br>Normolipidemic A: 1.5±2.9 (NS)<br>Normolipidemic B: -4.1±3.9 (NS)<br>Hypercholesterolemic: 1.7±6.1 (NS)<br>TC/HDL ratio:<br>Normolipidemic A: -7.5±1.9 (*P*<0.02)<br>Normolipidemic B: -8.0±3.6 (NS)<br>Hypercholesterolemic: -9.5±2.1 (*P*<0.01)<br>TG:<br>Normolipidemic A: -15.8±4.5 (*P*<0.05) | containing an equal wt of PUFA consistently and significantly lowered LDL-CH in all groups but had no effect on the HDL-CH, and hence lowered the T-CH; it also decreased the T-CH/HDL-CH ratio. We concluded that since the response to the 2 supplements was different, the soy lecithin does not exert its lipoprotein modification because of its PUFA content"<br><br>***Reviewer's Comments:***<br>2 normolipidemic males responded diff than other subj to soy lecithin supplementation - only these 2 subj sig modified diet with incr in total fat |

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| | | | | | **Study Visits/ Measurements:**<br>STUDY 1:<br>Fasting blood samples collected at baseline and on d 14 and 21 of each period<br><br>Wt measured weekly<br><br>STUDY 2:<br>Fasting blood samples collected at baseline and on last d of each mo<br><br>Wt measured monthly | Normolipidemic B: -3.8±4.9 (NS)<br>Hypercholesterolemic: -0.7±5.8 (NS)<br><br>% change in plasma lipids after soy lecithin relative to baseline:<br>TC:<br>Normolipidemic A: -0.3±2.4 (NS)<br>Normolipidemic B: -6.3±2.6 (NS)<br>Hypercholesterolemic: -1.6±3.6 (NS)<br>LDL:<br>Normolipidemic A: -2.5±3.7 (NS)<br>Normolipidemic B: -11.3±3.4 (*P*<0.02)<br>Hypercholesterolemic: -4.4±4.5 (NS)<br>HDL:<br>Normolipidemic A: 5.7±1.9 (*P*<0.02)<br>Normolipidemic B: 2.7±3.6 (NS)<br>Hypercholesterolemic: 8.7±2.4 (*P*<0.02)<br>TC/HDL ratio:<br>Normolipidemic A: -5.8±1.9 (*P*<0.05)<br>Normolipidemic B: -8.4±2.5 (*P*<0.05) | |

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| | | | | | | Hypercholesterolemic: -9.2±3.7 (NS)<br>TG:<br>Normolipidemic A: -9.2±6.8 (NS)<br>Normolipidemic B: -9.1±5.9 (NS)<br>Hypercholesterolemic: 12.7±4.5 (*P*<0.02)<br><br>Mean weekly dietary lipids of normolipidemics:<br>Total fat: 85±9 g<br>Chol: 346±56 mg<br>P/S ratio: 0.60±0.10 | |
| **Dayton et al., 1969**<br>(Note: Hiscock et al. 1962 described the diet used for the Dayton et al. 1969 study) | **RCT** | **A** | **+** | **Purpose:**<br>To determine whether diet which lowers serum chol conc can prevent overt complications of CHD and other manifestations of atherosclerosis<br><br>**Sample:**<br>846 middle-aged and elderly men (422 CNTL, 424 TX)<br><br>**Inclusions:**<br>Male; living in | **Run-in Period:**<br>Regular institutional diet for ≥4 mo<br><br>Initial electrocardiogram, HX and physical exam performed and 2 baseline blood samples obtained (2 wk apart)<br><br>**TX/Duration:**<br>1) CNTL: Conventional diet – 40% fat kcals mostly of animal origin (iodine value 55; P/S ratio 0.3)<br>2) TX : Veg oil diet – | **Outcome Measures:**<br>Sudden death or MI<br>Atherosclerotic events<br>Serum chol<br><br>**Results:**<br>Diff in sudden death or MI bet groups NS<br><br>When sudden death and MI data pooled with data for cerebral infarction and other secondary endpoints, totals 96 in CNTL group and 66 in TX group; *P*=0.01<br><br>Numbers of fatal atherosclerotic events 70 in CNTL group and 48 | **Author's Conclusions:**<br>"The data of this trial do not suffice for any confident conclusions as to relative effects of the experimental diet upon different end points, but the magnitude of the effect on cerebral infarction was most impressive. At a given age, cerebral atherosclerosis is less advanced than coronary |

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| | | | | Veterans Administration domiciliary unit ≥2 mo<br><br>**Exclusions:**<br>Alcoholic; behavior problems; on therapeutic diets; problems of communication; disease likely to result in death within 5 y; <55 y of age | substitution of veg oil for about 2/3 animal fat using natural foods (iodine value 100; P/S ratio 1.7)<br><br>Both diets ad lib<br><br>8 y past start of 1st subj<br><br>**Dose/Form:**<br>Multiple veg oils used - corn, soybean safflower and cottonseed (in order of decr quantity)<br><br>**Dietary Intake During Study:**<br>Total fat (% TE):<br>TX: 38.9<br>CNTL: 40.1<br>PUFA (linoleic acid % TE):<br>TX: 15.23<br>CNTL: 3.98<br>Chol (mg/1000 kcals):<br>TX: 146<br>CNTL: 262<br>Calories: ~2400 kcals/d<br><br>Egg yolks restricted to 7/wk in TX group | in TX group($P$<0.05)<br><br>For all primary and secondary endpoints combined, 8-y incidence rates 47.7% and 31.3% for CNTL and TX groups, respectively; $P$=0.02<br><br>TX diet induced prompt drop in serum chol and sustained diff bet TX and CNTL groups amounting to 12.7% of starting level<br><br>Estimated that change in saturation of dietary fat accounted for 5/6 of diet-induced lowering of serum chol in TX group; 1/6 due to decr chol intake<br><br>Stratification of data by age demonstrated most prophylactic effect occurred in younger half of study pop, <65.6 y old at start of study<br><br>Stratification of data by baseline serum chol conc revealed most effect in men with starting levels above median (233 mg/dL)<br><br>Gross grading of extent of atheromata in subj who died failed to reveal sig diff bet groups | atherosclerosis and for this reason cerebral complications might be considered more preventable in elderly men.<br><br>Total longevity was not affected favorably in any measurable or significant degree. It may be argued that demonstration of significant results in total mortality rates was too much to hope for in this relatively small trial among older subjects….For this reason, and because of the unresolved question concerning toxicity, we consider our own trial, with or without the support of other published data, to have fallen short of providing a definitive and final answer concerning dietary prevention of heart disease" |

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| | | | | | **Dietary Intake Assessment/Frequency:** Dining room attendance records<br><br>Overall adherence to diet: 56% (CNTL) and 49% (TX)<br><br>**Study Visits/ Measurements:** Fasting blood samples collected and wt measured at 4-mo intervals<br><br>Repeat electrocardiogram, HX and physical exam at 1-y intervals<br><br>Mortality followed for 2 mo past study completion<br><br>Autopsy performed on deceased subj | | ***Reviewer's Comments:*** *Could not CNTL subj adherence to diet – estimated adherence rates from 43-99%; not possible to have baseline measurement of atherosclerosis in subj; preexisting complications of atherosclerosis not disqualifying* |

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| **SUBJECTS WITH HIGH BLOOD CHOLESTEROL OR EXISTING CHD** | | | | | | | |
| **Grundt et al., 2004** | **RCT, DB** | **A** | **Ø** | **Purpose:**<br>To study effect of n-3 PUFA on clinical prognosis and serum lipids<br><br>**Sample:**<br>273 MI pts in TX phase; 89 pts in follow-up phase<br><br>**Inclusions:**<br>Acute MI pts<br><br>**Exclusions:**<br>None listed | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>1) n-3 PUFA x 12-24 mo (median 18 mo)<br>2) Corn oil x 12-24 mo (median 18 mo)<br><br>Clinical events and fasting blood drawn in 89 pts at baseline and 29 mo after TX<br><br>**Dose/Form:**<br>1) 4 capsules/d each 850-882 mg EPA and DHA<br>2) 4 capsules/d each 1 g corn oil<br><br>**Dietary Intake During Study:**<br>Total fat (% TE): not reported<br>SFA (% TE): not reported<br>Chol (mg/d): not reported<br>Calories: not reported<br><br>**Dietary Intake Assessment/Frequency:** | **Outcome Measures:**<br>Blood lipids<br>Cardiac mortality<br><br>**Results:**<br>% change in TC compared to baseline:<br>Corn oil: approx –15 ($P$<0.001)<br>n-3 PUFA: approx –18 ($P$<0.001)<br>NS diff bet groups<br><br>% change in HDL compared to baseline:<br>Corn oil: approx +11 ($P$<0.05)<br>n-3 PUFA: approx +18 ($P$<0.001)<br>NS diff bet groups<br><br>% change in TG compared to baseline:<br>Corn oil: approx +5 (NS)<br>n-3 PUFA: approx –5 (NS)<br>NS diff bet groups<br>TG equal in FO consumers and nonconsumers across TX groups<br><br>Cardiac mortality 10.7% in n-3 PUFA vs 8.0% in corn oil (NS) | **Author's Conclusions:**<br>"In conclusion, no clinical influence or deleterious effects were noted after a prolonged wash-out period following intervention with n-3 PUFAs as compared to corn oil"<br><br>***Reviewer's Comments:***<br>*FO supplementation NS diff bet groups; NS diff seen in meds bet groups; FA conc not measured* |

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| | | | | | Fish meals and FO supplementation assessed; 2 fish meals/wk in n-3 PUFA group, 3 fish meals/wk in corn oil group; 52.8% of n-3 PUFA group took FO, 43.2% in corn oil group | Absolute results not reported | |
| **Sirtori et al., 1992** | **RCT, CO** | **A** | **+** | **Purpose:**<br>To evaluate dietary fat and response of plasma lipids and lipoproteins<br><br>**Sample:**<br>12 hypercholesterol-emic pts<br><br>**Inclusions:**<br>Type II hypercholesterolemia without incr in VLDL-TG<br><br>**Exclusions:**<br>Heavy smokers; BMI >25.0 (males), >23.5 (females); alcohol consumption >30 g ethanol/d; MI in previous 12 mo | **Run-in Period:**<br>Adjustment prudent diet: <10% calories from SFA x 1 mo<br><br>**TX/Duration:**<br>1) Subj randomized to corn oil diet or prudent diet with n-3 FA supplement x 6 wk<br>2) All subj 4 wk on prudent diet<br>3) All subj 6 wk on olive oil diet<br>4) All subj 4 wk on prudent diet<br>5) 6 wk on diet not followed in 1$^{ST}$ randomization<br><br>**Dose/Form:**<br>1) CNTL (prudent): <10% energy from SFA; specific dose not | **Outcome Measures:**<br>Lipids<br>FA conc<br>Apolipoproteins<br><br>**Results:**<br>% change in TC compared to baseline:<br>Corn oil: -2.0 (NS)<br>Olive oil: -2.2 ($P$<0.05)<br>Prudent n-3 supplement: -5.8 ($P$<0.01)<br><br>% change in LDL from baseline:<br>Corn oil: NS<br>Olive oil: -4 ($P$<0.05)<br>Prudent n-3 supplement: -5 ($P$<0.05)<br><br>% change in VLDL compared to baseline:<br>Corn oil: NS<br>Olive oil: NS<br>Prudent n-3 supplement: -25.5- | **Author's Conclusions:**<br>"Dietary unsaturated fatty acids are generally effective on the plasma lipid and lipoproteins in type II patients, but significant differences may be found between the three tested regimens"<br><br>***Reviewer's Comments:***<br>*Subj started with similar baseline lipids; meals provided to subj, included fish 3x/wk; moderate alcohol allowed; pts supplemented with vit E every other d during all TX periods;* |

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| | | | | | identified<br>2) TX 1: Corn oil: 10% MUFA, 10-11% PUFA<br>3) TX 2: Prudent plus n-3 - 6 g n-3 FA (2.8 g/d EPA, 1.7 g/d DHA)<br>4) TX 3: Olive oil: 18% MUFA, 3% PUFA<br><br>**Dietary Intake During Study:**<br>Individual isoenergetic diets based on 1-wk diet recall<br><br>Total fat: approx 30% TE<br>SFA (% TE):<br>Corn oil: 5<br>Olive oil: 5<br>CNTL: 9-10<br>Chol (mg/d):<br>Corn oil: 17-19<br>Olive oil: 17-19<br>CNTL: 24<br>Calories: 1600-2000 all groups<br><br>**Dietary Intake Assessment/Frequency**<br>1-wk diet recall before study<br><br>Direct chemical analysis | 33 ($P$<0.05)<br><br>% change in HDL compared to baseline:<br>Corn oil: NS<br>Olive oil: NS<br>Prudent n-3 supplement: +25 ($P$<0.05), and compared to olive oil ($P$<0.05)<br><br>% change in TG compared to baseline:<br>Corn oil: NS<br>Olive oil: NS<br>Prudent n-3 supplement: -21.4 ($P$<0.001)<br><br>After corn oil TX linoleic conc incr NS; after olive oil TX oleic conc incr NS; n-3 supplementation sig incr EPA ($P$<0.001) and DHA ($P$<0.001) from baseline<br><br>Apolipoprotein AI and A2 change NS with corn oil, olive oil or prudent diets. Corn oil sig decr apolipoprotein B (-3.8%, $P$<0.05) compared to baseline | *changes in FA conc indicate pt compliance* |

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| | | | | | for 6 pts during 1 d in each TX period<br><br>Meals provided to subj | | |
| **Sirtori et al., 1986** | **RCT, CO** | **A** | **+** | **Purpose:**<br>To evaluate changes of lipid-lipoproteins as well as those of platelet aggregability and eicosanoid metabolism, believed to be beneficially affected by diets with elevated P/S ratio<br><br>**Sample**:<br>26 subj with high atherosclerotic risk (23 completed – 12 males; 11 females)<br><br>**Inclusions**:<br>Clinical hyperlipidemia with high atherosclerosis risk and/or evidence of clinical disease (HTN, CHD, peripheral vascular disease); 30-65 y of age; reliable; consuming most | **Run-in Period:**<br>Evaluated daily caloric intake using 48-h recall<br><br>Study visits at 0, 2 and 4 wk:<br>• Dietary intake questionnaire from previous wk submitted<br>• Interviewed by dietitian<br>• Plasma TC, TG, HDL, glucose and uric acid levels monitored<br><br>At 0 and 4 wk, apolipoprotein A1 and B levels determined and platelet-rich plasma collected<br><br>4 wk<br><br>**TX/Duration:**<br>1) TX 1: Olive-corn: olive oil for 8 wk then corn oil for 8 wk; N=13 (6 normolipidemic; 7 hyperlipidemic) | **Outcome Measures:**<br>Lipids<br>Apolipoproteins<br>Glucose<br>Uric acid<br>Platelet function<br><br>**Results:**<br>% change in chol at end of dietary TX relative to baseline:<br>TC<br>Olive-corn:<br>NS after olive oil<br>-7.7 ($P$<0.01) after corn oil<br>Corn-olive:<br>-6.8 ($P$<0.05) after corn oil<br>NS after olive oil<br>LDL<br>Olive-corn:<br>NS after olive oil<br>-9.2 ($P$<0.05) after corn oil<br>Corn-olive:<br>-6.9 ($P$<0.05) after corn oil<br>NS after olive oil<br>HDL<br>Olive-corn:<br>NS after olive oil<br>NS incr after corn oil | **Author's Conclusions*:***<br>"The CORN diet, in both sequences, was associated with significant total- and LDL-cholesterol reductions. OLIVE, when given first, failed to modify these variables, but it did maintain the reduced cholesterolemia after CORN. Apoprotein B levels were reduced in both sequences by OLIVE, less consistently by CORN; triglyceridemia did not change with either diet"<br><br>***Reviewer's Comments:***<br>*None* |

| Author/ Year | De-sign Type | Class | Quality (+,-,Ø) | Purpose/ Population Sample Size | Regimen | Primary Outcome Measures Results | Author's Conclusions/ *Reviewer's Comments (Italicized)* |
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| | | | | meals at home; asymptomatic or stable disease requiring minimal drug TX; dietary HX excluding intake of consistent amt of olive oil or corn oil<br><br>**Exclusions:**<br>Overwt; pharmacological TX for hyperlipidemia ≥3 mo; habitual use of drugs affecting platelet aggregability; physician prescribed linoleic acid-rich diet; instable clinical course of disease | 2) TX 2: Corn-olive: corn oil for 8 wk then olive oil for 8 wk; N=10 (3 normolipidemic; 7 hyperlipidemic)<br><br>16 wk<br><br>**Dose/Form:**<br>1) Corn oil<br>2) Olive oil<br><br>**Dietary Intake During Study:**<br>Menus planned by researchers and prepared by subj<br><br>Total fat: 30% TE<br>PUFA (% TE):<br>Corn oil: 10<br>Olive oil: 2.8<br>SFA (% TE):<br>Corn oil: 7.8<br>Olive oil: 7.4<br>P/S ratio:<br>Corn oil: 1.28<br>Olive oil: 0.33<br>Chol: 100 mg/1000 kcal<br><br>**Dietary Intake Assessment/Frequency:**<br>Dietary compliance | Corn-olive:<br>-4.6 ($P<0.05$) after corn oil<br>NS after olive oil<br><br>NS diff in absolute chol response bet hyperlipidemic and normolipidemic subj, irrespective of diet sequence<br><br>LDL:HDL ratios improved by both diets: base 4.51, olive 4.25, corn 4.25<br><br>% change in apolipoprotein levels:<br>Apolipoprotein A1<br>Olive-corn:<br>+5.2 ($P<0.05$) after olive oil<br>NS after corn oil<br>Corn-olive:<br>NS after corn oil<br>+4.3 ($P<0.05$) after olive oil<br>Apolipoprotein B<br>Olive-corn:<br>NS after olive oil<br>NS after corn oil<br>Corn-olive:<br>-9.5 ($P<0.01$) after corn oil<br>NS after olive oil<br><br>Apolipoprotein A1/B ratio improved with both diets, but more markedly with olive | |

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| | | | | | determined at end of each dietary period by evaluation of FA composition of red blood cell membrane lipids<br><br>**Study Visits/ Measurements:**<br>At 2, 4 and 8 wk:<br>• Dietary intake questionnaire from previous wk submitted<br>• Interviewed by dietitian<br>• Plasma TC, TG, HDL, glucose and uric acid levels monitored<br>• Plasma apolipoprotein A1 and B levels determined<br><br>At 2 and 8 wk, platelet-rich plasma collected | Changes in VLDL, TG and uric acid NS<br><br>Plasma glucose level lowered sig with olive oil (-6.2% vs corn administration, *P*<0.01)<br><br>Changes in platelet function characterized by reduced sensitivity to arachidonic acid (particularly corn oil) and to collagen (particularly olive oil) | |
| **Rose et al., 1965** | **RCT, DB** | **A** | **Ø** | **Purpose:**<br>To study effects of prescribing veg oil and restricted fat diet to pts with IHD<br><br>**Sample:**<br>80 IHD pts (26 CNTL, 28 corn oil, 26 olive oil) | **Run-in Period:**<br>None<br><br>**TX/Duration:**<br>Randomized to 1 of following:<br>1) CNTL: No oil supplement or dietary fat advice | **Outcome Measures:**<br>Serum chol<br>Major cardiac events (sudden death, fatal infarction, definite nonfatal infarction or probable nonfatal infarction) or other significant cardiac pain | **Author's Conclusions:**<br>"It is concluded that under the circumstances of this trial corn oil cannot be recommended as a treatment of ischaemic heart disease" |

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| | | | | **Inclusions:**<br>Either electrocardiograph evidence of infarction or clear HX of angina of effort; <70 y of age<br><br>**Exclusions:**<br>Valvular disease, anemia or syphilis; heart failure or any noncardiac disease likely to threaten life within 2 y; personal or geographical factors likely to interfere with clinic attendance or taking of oil; use of long-term anticoagulant TX prior to study initiation | 2) TX 1: Corn oil with animal fat restricted diet<br>3) TX 2: Olive oil with animal fat restricted diet<br><br>Subj in oil groups advised to restrict intake of milk, eggs and butter and avoid intake of fried foods, fatty meat, sausages, pastry, ice cream, cheese, cakes (except plain sponge), etc<br><br>2 y (planned for 3 y but by end of 2 y ½ of subj dead or lost to follow-up)<br><br>**Dose/Form:**<br>1) Corn oil: 80 g/d supplement (taken in 3 equal doses at mealtime)<br>2) Olive oil: 80 g/d supplement (taken in 3 equal doses at mealtime)<br><br>**Dietary Intake During Study:**<br>Estimated values based on 2 y follow-up data | **Results:**<br>Ave change in serum chol levels (mg/100 mL) at diff time periods compared to baseline:<br>0-6 mo<br>Corn oil: -25.5±8.8 (*P*<0.01)<br>Olive oil: 3.5±9.2 (*P*>0.7)<br>CNTL: 4.4±7.2 (*P*>0.5)<br>6-12 mo<br>Corn oil: -30.8±10.5 (*P*<0.01)<br>Olive oil: 12.0±17.5 (*P*>0.4)<br>CNTL: 0.3±9.2 (*P*>0.8)<br>12-18 mo<br>Corn oil: -30.3.5±9.9 (*P*<0.01)<br>Olive oil: 4.0±20.2 (*P*>0.6)<br>CNTL: -7.9±9.4 (*P*>0.4)<br>18-24 mo<br>Corn oil: -19.9±13.5 (*P*<0.2)<br>Olive oil: -0.9±10.2 (*P*>0.8)<br>CNTL: -2.8±12.1 (*P*>0.8)<br><br>Major cardiac events at diff time periods:<br>0-6 mo<br>Corn oil: 4<br>Olive oil: 4<br>CNTL: 3<br>6-12 mo<br>Corn oil: 1<br>Olive oil: 1<br>CNTL: 0 | ***Reviewer's Comments:***<br>*Only assessed diet during 2nd y of follow-up (diet may have changed plus dietary info collected for only 1/2 to 2/3 of subj who began study); didn't assess dietary oil intake of CNTL subj; placebo not used for CNTL subj; did not address confounding factors* |

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| | | | | | Total fat (g/d):<br>Corn oil: 50<br>Olive oil: 45<br>CNTL: 70<br>Calories (kcals/d):<br>Corn oil: 1505 (2045 with oil)<br>Olive oil: 1475 (2070 with oil)<br>CNTL: 1933<br><br>**Dietary Intake Assessment/Frequency:** Dietary intake assessed during 2nd y of follow-up by self-administered questionnaire<br><br>Attempted to assess supplement intake based on amt returned and subj statements (estimated 90% compliance initially; dropped to 60% ave intake by 1st y)<br><br>**Study Visits/ Measurements:** Standardized HX, physical exams and electrocardiograms performed and wt and serum chol measured at | 12-18 mo<br>Corn oil: 7<br>Olive oil: 2<br>CNTL: 3<br>18-24 mo<br>Corn oil: 0<br>Olive oil: 2<br>CNTL: 0<br><br>Percentage of subj in trial and free of major cardiac events at diff time periods:<br>0-6 mo<br>Corn oil: 86<br>Olive oil: 84<br>CNTL: 88<br>6-12 mo<br>Corn oil: 81<br>Olive oil: 79<br>CNTL: 88<br>12-18 mo<br>Corn oil: 52<br>Olive oil: 68<br>CNTL: 75<br>18-24 mo<br>Corn oil: 52<br>Olive oil: 57<br>CNTL: 75<br><br>2 y from start of TX infarction or death occurred in ¼ more of corn oil group than CNTL group (0.1>*P*>0.05) | |

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| | | | | | follow-up visits (every 1-2 mo) | Likelihood that diff bet CNTL and corn oil groups due to chance 0.05-0.1 (standard error of diff ±13%) | |

AppendixD2CornOilBloodLipidsTypeITable

Corn Oil: Effect on Blood Lipids, Design Type 1 Studies Table