

Table B Studies in 2010 NEL review of saturated fats

| Study   | Participants   | Duration                                       | Purpose  | Design  | Location        | Met NEL selection criteria. Why not?  | Findings  | Provides Evidence that SFAs cause heart disease? |
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| <b>Trials that should not have been included because they did not meet inclusion criteria</b> |  |  |  |   |                 |   |   |  |
| Berglund et al, 2007  | 110 recruited age 21-65, 83 finished (52 men and 33 women age 21-61) with adverse metabolic feature(s) other than high LDL | 7 wks. per diet (3 diets) with 4-6 wk recovery | RCT that compared MUFA with or CHO as a replacement for SFA in subjects with a high metabolic risk profile.  | randomized, double blind, crossover   | U.S.            | No. <80% retention rate. Also, this trial did not test saturated fats (all diets had 7% of calories as saturated fats; therefore saturated fats were not a variable). | N/A   | No   |
| Bourque et al, 2007   | 22 healthy, overweight women (17 completed) 44 +/- 4 yrs   |  | Determine effects of a specialty oil with medium-chain saturated fatty acids (MCTs), phytosterols, n-3 PUFA on circulating lipids and FA metabolism. | Randomized, single-blind, partially controlled, inpatient clinical trial. Crossover: Two 27 day feeding interventions separated by 8 week washout | Canada (McGill) | No. <80% retention rate; only 17 women completed  | Consumption of the specialty oil with saturated fats <i>had an overall positive effect on lipids:</i> "substantially lowers plasma total and LDL cholesterol concentrations, but does not affect circulating TAG or HDL cholesterol | No   |

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| <a href="#">Lefevre et al, 2005:</a>  | 86 healthy men, 22-64 yrs. (120 recruited, 87 finished, 1 dropped)            | 6 wks. diet                         | Effect of diets varying in total/SFAs on plasma lipids  | RCT, double blind, 3 period crossover (1 diet each period). | U.S. | No. <80% retention rate   | "Persons who are insulin resistant respond less favorably to Step II diets [those very low in saturated fats] than do those who are insulin sensitive."          | No  |
| Azadbakht et al, 2007   | 46 Adolescents 10-18 yrs. w/ hypercholesterolaemia (2 drop outs, 44 finished) | 3 week run-in, 3 month intervention | Determine effect of NCEP step 2 diet on HDL/LDL particle size in dyslipidaemic adolescents                    | RCT, blinded to all but nutritionist                        | Iran | No. Study population had hypercholesterolaemia, a rare genetic condition that affects only 1% of the population.                        | Step 2 diet decreased LDL-C, TC and increased LDL particle size. Also reduced presence of hypercholesterolaemia after 3 months (68% vs 100%). Did not change HDL | No  |
| <b>Trials that should not have been included because they did not test normally occurring saturated fats or saturated fats at all</b> |   |                                     |   |   |      |   |  |     |
| Lichtenstein et al, 2006  | 30 middle aged hypercholesterolemic men and women (12 drop outs, 10 replaced) | 35 d per diet (5 total)             | Assess the efficacy of soybean oils (SO) with modified fatty acid profiles, compared to soybean and partially | randomized, double blind, crossover                         | U.S. | No. Did not test normally occurring saturated fats (tested a novel vegetable oil instead). Also appears to have had <80% retention rate | LDL highest in partially hydrogenated and LoALA soybean oil groups. Only low SFA reduced LDL compared to regular soybean oil.                                    | No. |

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|   |  |   | hydrogenated SO, on CVD risk in middle-aged and older moderately hyper-cholesterolemic and postmenopausal women and men.  |   |      |   |     |    |
| Furtado et al, 2008   | 191 Men and women age 30+ completed run-in, 162 eligible for analysis (55% african american, 44% women of which 74% are postmenopausal) 54 +/- 10 yrs (SD). Mostly overweight (BMI 30.4 +/- 6.1) | 6 d run in, 6 wk per diet (3 total), 2 wk. recovery between diets | Examine effects of CHO rich diet (DASH based), low SFA, or high protein on plasma lipid and lipoprotein (essentially, they were testing modifications of DASH by replacing CHO with unsat fat or protein) | blinded, randomized, 3 period crossover | U.S. | No. This trial did not test saturated fats (all diets had 6% of calories as saturated fats; therefore saturated fats were not a variable). And while baseline diets were probably higher in saturated fats, it cannot be assumed that any benefits seen were due to lowering saturated fats (a control group would have been needed). | N/A | No |
| <b>Trials concluding that saturated fats had a neutral or beneficial effect on health</b> |  |   |   |   |      |   |     |    |

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| Dabadie et al, 2005    | 25 benedictine monks, 35-88 yrs. (mean age 61) | 5 wks per diet (2 total) w/ 4 week recovery | Test two different but moderate intakes of myristic acid in otherwise comparable diets on plasma lipids, lipoproteins, fatty acids of phospholipids, and cholesteryl esters.   | 2 period crossover, randomization and blinding not specified. Compared the effects of two moderate intakes of myristic acid on plasma lipids | France | No. selection bias (see 2.4) and not a representative sample of the population. | The diet higher in saturated fat caused positive effects on blood lipids: triglycerides dropped and HDL-C increased; also, DHA [a long-chain omega-3 fatty acid] in cholesterol esters improved more on this diet.   | No |
| Buonacorso et al, 2007 | 30 healthy school employees                    | 4 wk  | Elucidate the effects on lipoprotein composition and rates of cell cholesterol efflux for whole plasma and HDL subfractions during TFA-, SFA-, and PUFA-enriched diets in healthy persons, both in fasting and postprandial conditions | Subjects paired, then randomized.  | Brazil | Probably (selection bias and lack of binding a problem)                         | Blood lipids were unaffected by the diets. TC and TG not affected by any diet. TFA increased HDL2: TC phospholipid, Apo A-1, and Apo A-II and decreased lipids:Apo A. SFA decreased TC, phospholipid, Apo A-1, and Apo A-II and increased lipids:Apo A. PUFA decreased lipids:Apo A. Compared to SFA, TFA showed higher phospholipids and Apo II while PUFA showed higher Apo A-II and lipids:Apo. | No |

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| Chen et al. 2009   | 14 men (1 dropped), 9 women | 23 d per diet (4 total) w/ no recovery | Determine the effect of three daily servings of plant sterol (PS), in the context of two background diets on serum lipids, lipoproteins, retinol, tocopherols and carotenoids.   | randomized, double blind, crossover | U.S. | No. SFA was not an independent variable in this study.                               | N/A This was a trial on plant sterols   | No  |
| <b>Trials with mixed results on blood lipid measures</b> |                             |  |  |                                     |      |  |   |   |
| <a href="#">Chung et al, 2004</a>                        | 16 men and women            | 20 days                                | Examine the acute and chronic effects of consuming a PUFA- or SFA-rich diet on lipoprotein cholesterol levels and the impact of post-prandial TG-rich lipoproteins (TRLs) in determining lipoprotein cholesterol levels. | randomized crossover                | U.S. | Possibly. Not clear if several inclusion criteria are satisfied (2.4, 5.1, 7.6, 8.7) | Saturated fats had a mixed effect on blood lipids: LDL-C (the "bad" cholesterol) dropped on the diet low in saturated fats, but so did HDL-C. Cholesterol clearance rate was lower on SFA diet. | Mixed. HDL-C along with LDL-C, implying neutral risk at best. Only 16 subjects. |

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| <a href="#">Kralova et al, 2008</a> | 14 healthy men 18-55 yrs | 4 wk per diet (2 total) | determine whether the decrease of HDL-C in a diet enriched with PUFA is detrimental with respect to reverse cholesterol transport based on changes in cholesterol efflux | randomized crossover | Czechoslovakia | Yes | This study showed a reduction in HDL-C on the high PUFA diet as great as the reduction of total cholesterol and LDL C. | Mixed. HDL-C drops as much as LDL-C, implying neutral risk at best. Only 14 subjects. |
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