Appendix 6. HUMAN STUDIES: OATRIM [INCLUDING OATRIM (BETATRIM™)], OAT GUMS/EXTRACTS AND SERUM CHOLESTEROL

Study	Study Design, Subjects	Methods	Results	Comments
Behall et al, 1997	Randomized c.o. trial of low and high oat fiber extracts, namely Oatrim-1 and Oatrim-10*. A maintenance diet (35% of energy from fat) was fed to subjects 1 week before intervention, but intervention diets were 30% energy from fat. 23 men and women (mean age: 50-52 years); hypercholesterolemic (Mean TC:228 (F); 243(M) mg/dL) * Oatrim (BetaTrim™)	5 wks intervention with each oat extract followed by c.o.; Subjects were fed maintenance diets with 5% of fat energy replaced with oat fiber extracts containing either **1.6 % (Oatrim-1) or 10.2 % (Oatrim-10) soluble β-glucan.** Oatrim was added to the diet in several foods including muffins, cake, brownies, waffles, gelatin, yogurt, spaghetti sauce, and meatloaf. All meals were prepared at the Beltsville Human Nutrition Study facility. Week-day breakfasts and dinners were eaten at the facility; 0.4 g β-glucan per 1000 kcal was added in the Oatrim-1 diet; 2.55 g β-glucan per 1000 kcal was added in the Oatrim-10 diet; Approximately 50-75 g/day of Oatrim was added to the diet. **Basic diet:** 0.8 g β-glucan per day. **Oatrim-1 diet**: 0.8-1.2 g β-glucan from Oatrim (1.6-2.0 g β-glucan per day) **Oatrim-10 diet:** 5.1-7.6 g β-glucan from Oatrim (5.9-8.4 g β-glucan per day)	Maintenance Oatrim-1 -10 (mmol/l) TC: 5.47[a] 4.95[b] 4.67[c] LDL-C: 3.65[a] 3.11[b] 2.89[b] HDL-C 1.29[a] 1.34[a] 1.19[a] Means with a different superscript within a row are significantly different at $p < 0.05$	Oatrim –1 & 10 were Oatrim products from Quaker Oats Co. and ConAgra Inc. Compared to the maintenance diet: Oatrim-1 -10 TC: –9.5% –14.6% LDL-C: -14.8% -20.8% During the first week when the higher fiber diet was consumed, subject complaints ranged from a very full feeling to some bloating and flatulence. During the oat phases, subjects lost 1-1.7 kg. However, weight was not associated with TC or LDL-C.

Abbreviations: C.O.: cross over; TC: Total serum cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: High-density lipoprotein cholesterol.

Appendix 6. HUMAN STUDIES: OATRIM [INCLUDING OATRIM (BETATRIM™)], OAT GUMS/EXTRACTS AND SERUM CHOLESTEROL (cont'd.)

Study	Study Design, Subjects	Methods	Results	Comments
Beer et al., 1995	Randomized, single-blind, c.o. trial of test and placebo phases; 1-week run-in period of usual diet. 14 men (age 20-28 years); normocholesterolemic (Mean TC: 164 mg/dL)	2 wk intervention with oat gum, instant whip (**62.2% β-glucan**; 9 g β-glucan) or a placebo instant whip. After 1 wk baseline period, subjects consumed either the oat gum or placebo gum 3x a day with meals. All meals and drinks were provided to subjects.	Oat gum / Placebo (mmol/l) TC: 4.06 / 3.74 LDL-C: 2.73 / 2.49 HDL-C: 1.17+ / 1.09 No sig. diffs for TC and LDL-C + Sig. different from control	Energy intake from fat (35-36%) was not significantly different from the oat gum and placebo phases. A 2-wk intervention may be too short for serum lipids to stabilize.
Braaten et al., 1994	Randomized, c. o. trial with treatment and placebo phases; usual diet 20 men and women (ages 44-64 years), 19 completed the study; hypercholesterolemic (mean TC: 262 mg/dL)	4 wks intervention phase with 7.2 g of oat gum (**80% β-glucan**; 5.8 g β-glucan per day); 4 wks placebo phase with 5.4 g maltodextrin; 3-4 wks washout period between oat gum and placebo phases. Half the dose of oat gum or placebo was mixed in a drink 2x a day. 3-day diet records were kept during pre-test, intervention, and washout phases.	Baseline* / Wk 4 / % change (mmol/l) TC: 6.77 / 6.15 / -9.2+ LDL-C: 4.62 / 4.16 / -10+ HDL-C 1.29 / 1.27 / 0 *Baseline is a mean of pre-treatment values and values from the placebo phase, including washout after placebo. + Sig. different from baseline* $p < .0001$	All 19 subjects complied with the protocol. Subjects reported no difficulties with consumption of oat gum or placebo. No significant dietary differences between phases (31% of energy from fat). Body weight and blood pressure remained stable throughout the study.
Pick et al, 1996	Randomized c. o. trial with treatment and placebo phases; diets provided 30% energy from fat. 8 men with non-insulin-dependent diabetes (NIDDM); mean age: 45 years; normocholesterolemic (mean TC: 180 mg/dL)	12 wks intervention of 40 g of oat bran concentrate (OBC)* products (**22.8% β-glucan**; 9g β-glucan) or control white bread. The oat bran concentrate products consisted of bread, bun, and muffins. * By its description and through personal communication, it is evident the β-glucan source is a processed Oatrim.	OBC Prds. / White Bread (mmol/l) TC: 4.56 / 5.30+ LDL-C: 2.59 / 3.36+ HDL-C: 1.04 / 0.96 +Sig. different from each other $p < .01$	All subjects complied with the protocol. A significant reduction in total and LDL cholesterol was observed between the oat β-glucan period compared to white bread period: TC: -14% LDL-C:-23%

Abbreviations: C.O.: cross over; TC: Total serum cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: High-density lipoprotein cholesterol.

Appendix 6. HUMAN STUDIES: OATRIM [INCLUDING OATRIM (BETATRIM™)], OAT GUMS/EXTRACTS AND SERUM CHOLESTEROL (cont'd.)

Study	Study Design, Subjects	Methods	Results	Comments
Torronen et al, 1992	Randomized, double-blind, controlled intervention of treatment and control groups; usual diets. 28 males (ages 25-52 years); hypercholesterolemic (TC: 247 mg/dL)	A 12 wk study, with a 2 wk baseline period, an 8 wk test period of 75 g of oat bran concentrate (OBC)* bread (15% β-glucan; 11.2 β-glucan), and a 2 wk follow-up period. The control group consumed bread made with wheat flour. During baseline and follow-up periods, subjects consumed regular diets. During the first 2 wks, subjects consumed ½ of the oat bread roll (5.6 g β-glucan) and the entire bread roll (11.2 g β-glucan) for the last 6 wks. 3-day food records were kept during the last week of each period. * Processed & enriched OBC.	OBC Bread / Control Bread (mg/dL) TC: 0 246.7 246.7 2wk 244.7 236.2 4 wk 247.8 233.5 8 wk 244.7 242.0 post 252.1 2441 LDL-C 0 164.8 171.4 2wk 169.1 166.0 4 wk 167.1 167.9 8 wk 164.8 165.6 post 177.9 174.9 HDL-C 0 55.6 49.4 2wk 54.8 47.9 4 wk 54.4 47.9 8 wk 53.6 47.1 post 53.6 48.2 There were no significant differences in TC, LDL-C, or HDL-C due to OBC intervention.	There were no significant differences in dietary intake (i.e. 35% energy from fat) between the treatment and control periods. The authors suggest that the method of concentrating and processing the β-glucan may have affected the cholesterol lowering efficacy of the β-glucan.

Abbreviations: C.O.: cross over; TC: Total serum cholesterol; LDL-C: Lipoprotein cholesterol; HDL-C: High-density lipoprotein cholesterol.