### Table: Dietary Intervention Study in Children (DISC)

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Study Design</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcome Measures</th>
</tr>
</thead>
</table>
| Arm 1: BF | RCT | 44 Pediatric/Young Adults | Bezaferbate 10-20 mg/kg/d bid | Primary: Mean serum total cholesterol [mg/dL (SD)]
|            |              |            |              | Mean TC: 38.9 wk (1.5) |
| Arm 2: BF | RCT | 44 Pediatric/Young Adults | Breast milk | Primary: Mean serum total cholesterol [mg/dL (SD)]
|            |              |            |              | Mean TC: 88(20) 84(25) 98(24) |

### Table: Effects of Sitostanol Ester Margarine

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<tr>
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<th>Design</th>
<th>Type</th>
<th>Disease/Condition</th>
<th>Setting</th>
<th>Length</th>
<th>Total</th>
<th>Study</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Descriptions</th>
</tr>
</thead>
</table>
| 8483855 | Randomized, double-blind, placebo-controlled | Intervention | Hypercholesterolemia | Clinical trial of psyllium fiber in children | 1993 RCT | 12 wk | 12 wk | Test the effectiveness of psyllium fiber | Primary: | |}

**Interventions**

- **Arm 1:** Diet + psyllium-enriched cereal (3.2 g soluble fiber)
- **Arm 2:** 4 90-min sessions of parent-child autotutorial (PCAT) dietary counseling
- **Behavioral Arm 1:** 7-session course included lectures and small group discussions
- **Behavioral Arm 2:** 10 talking-book lessons and follow-up paper-pencil games for children along with a manual for parents
- **Behavioral Arm 1 and 2:** Distributed fruit and cereal to reinforce starting low-fat diet
- **Behavioral Arm 1:** Cooked meals for grandchildren
- **Behavioral Arm 2:** Received notebooks with nutritional information and recipes and incentive awards for attendance and participation
- **Behavioral Arm 1:** Distribution of Software and computer
- **Behavioral Arm 2:** Video games
- **Behavioral Arm 1:** Dietitian and take-home materials for children and parents
- **Behavioral Arm 2:** Computer-generated information and instruction
- **Behavioral Arm 1:** Included 10 talking-book lessons and follow-up paper-pencil games for children along with a manual for parents
- **Behavioral Arm 2:** Distributed fruit and cereal to reinforce starting low-fat diet

**Outcomes**

- **Primary:** Nutritional knowledge (score(SD))
- **Secondary:** Mean calcium intake (% RDA (SEM))
- **Efficacy:** Mean SBP (mmHg (SD))
- **Efficacy:** Mean DBP (mmHg (SD))
- **Efficacy:** Mean HDL-C [mg/dL (SEM)]
- **Efficacy:** Mean TG (mg/dL (SEM))
- **Primary:** Mean TC/HDL-C ratio
- **Primary:** % change in TC/HDL-C ratio
- **Secondary:** % change in LDL-C mmol/L
- **Safety:** Heart attack before 55 yr: 52%
- **Safety:** Hypertension: 10%
- **Safety:** Males: 11%
- **Safety:** Control Arm: 10%
- **Safety:** Control Arm: 89%
- **Safety:** Control Arm: 94.7 mo (26.7)
- **Safety:** Control Arm: 45%
- **Safety:** Control Arm: 77
- **Safety:** Control Arm: 70%
- **Safety:** Control Arm: 18.6 yr (0.7)
- **Safety:** Control Arm: 6.3 yr (0.19)
- **Safety:** Control Arm: 92 (75)
- **Safety:** Control Arm: 90 (78)
- **Safety:** Control Arm: 43
- **Safety:** Control Arm: 43
- **Safety:** Control Arm: 7
- **Safety:** Control Arm: 20 (NR)
- **Safety:** Behavioral Arm 1: 7-session course
- **Safety:** Behavioral Arm 2: 10 talking-book lessons and follow-up paper-pencil games for children along with a manual for parents
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<th>Length</th>
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<th>Secondary:</th>
<th>Efficacy:</th>
<th>Safety and Adverse Events:</th>
<th>Critical Question:</th>
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<tbody>
<tr>
<td>None</td>
<td>Clinical</td>
<td>12 wk</td>
<td>20 wk</td>
<td>RCT</td>
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<tr>
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<td>Clinical</td>
<td>18 wk</td>
<td>28 wk</td>
<td>RCT</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>No difference</td>
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<td>Sample Size</td>
<td>Study Duration</td>
<td>Study Region</td>
<td>Primary Endpoints</td>
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<tr>
<td>Control</td>
<td>Random</td>
<td>Usual care</td>
<td>No history of hyperlipidemia</td>
<td>None</td>
<td>None</td>
<td>36 (270)</td>
<td>Control Arm: Usual care</td>
<td>Norway Clinical 1 yr followed by cholestyramine for 1 yr</td>
<td>No difference in height velocity at 1 and 3 m, NS at 6 m for BF vs both formula groups</td>
</tr>
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<td>Behavioral</td>
<td>Random</td>
<td>Diet</td>
<td>No history of hyperlipidemia</td>
<td>None</td>
<td>None</td>
<td>36 (296)</td>
<td>Behavioral Arm 1: Diet pills and powder, in the treatment of hypercholesterolemia</td>
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<td>Cholesterol-unfortified formula</td>
<td>No history of hyperlipidemia</td>
<td>None</td>
<td>None</td>
<td>36 (270)</td>
<td>Control Arm: Low fat, low cholesterol diet + placebo</td>
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<td>Secondary Endpoints</td>
<td>Baseline Mean (SD)</td>
<td>Intervention Mean (SD)</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>Stanol ester margarine</td>
<td>Randomized, placebo-controlled trials</td>
<td>Community</td>
<td>Children and adolescents with HeFH</td>
<td>LDL-C</td>
<td>Other lipid measures, anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline LDL-C: 4.8 mmol/L (SD)</td>
<td>LDL-C: 4.6 mmol/L (SD)</td>
<td>LDL-C: 4.9 mmol/L (SD)</td>
</tr>
<tr>
<td>Low HDL-C</td>
<td>Garlic extract</td>
<td>Randomized, placebo-controlled trials</td>
<td>Community</td>
<td>Adults with low HDL-C</td>
<td>HDL-C</td>
<td>Other lipid measures, anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline HDL-C: 1.0 mmol/L (SD)</td>
<td>HDL-C: 1.1 mmol/L (SD)</td>
<td>HDL-C: 0.9 mmol/L (SD)</td>
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<td>Familial hypercholesterolemia</td>
<td>Dietary intervention</td>
<td>Randomized, placebo-controlled trials</td>
<td>Hospital</td>
<td>Adolescents with HeFH</td>
<td>LDL-C</td>
<td>Other lipid measures, anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline LDL-C: 5.5 mmol/L (SD)</td>
<td>LDL-C: 4.8 mmol/L (SD)</td>
<td>LDL-C: 5.3 mmol/L (SD)</td>
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<tr>
<td>Hypertriglyceridemia</td>
<td>Interventions to decrease triglycerides</td>
<td>Randomized, placebo-controlled trials</td>
<td>Hospital</td>
<td>Adults with high triglycerides</td>
<td>Triglycerides</td>
<td>Other lipid measures, anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline Triglycerides: 3.5 mmol/L (SD)</td>
<td>Triglycerides: 2.8 mmol/L (SD)</td>
<td>Triglycerides: 3.9 mmol/L (SD)</td>
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<tr>
<td>Type II diabetes</td>
<td>Diet modification</td>
<td>Randomized, placebo-controlled trials</td>
<td>Community</td>
<td>Adults with Type II diabetes</td>
<td>HbA1c</td>
<td>Other glycemic indices, anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline HbA1c: 7.5% (SD)</td>
<td>HbA1c: 6.5% (SD)</td>
<td>HbA1c: 8.0% (SD)</td>
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<td>Overweight/Obesity</td>
<td>Behavioral counseling</td>
<td>Randomized, placebo-controlled trials</td>
<td>Community</td>
<td>Adults with overweight/obesity</td>
<td>Weight loss</td>
<td>Anthropometric indices, dietary intake, biomarkers, clinical outcomes</td>
<td>Baseline Body Mass Index: 30 kg/m² (SD)</td>
<td>Weight: 25 kg/m² (SD)</td>
<td>Weight: 30 kg/m² (SD)</td>
</tr>
</tbody>
</table>

Critical Question: Which intervention had the greatest impact on cholesterol levels, and what were the limitations of the study design?
# Efficacy and Safety of Lowering Dietary Plant Sterols

## Study Description

**Objective:**
- To assess the efficacy and safety of lowering dietary plant sterols in young children 7-36 months of age.

**Intervention:**
- Regular cow's milk protein-based formula + replacement of milk fat with vegetable fat
- Behavioral arm 1: Dietary intervention
- Behavioral arm 2: Regular cow's milk protein-based formula

**Setting:**
- Clinical care

**Duration:**
- 6 months

**Main Study Objective:**
- Determine whether natural dietary plant sterols derived mainly from vegetable sources, when compared against milkfat derived sterols, will alter serum concentrations of plant sterols.

**Secondary Causes Noted for 6 mos before Consideration for Participation:**
- CVD
- Hyperlipidemia

**Design:**
- Randomized controlled trial

**Participants:**
- 663 Pediatric/Family

**Eligibility Criteria:**
- Patients with mean fasting LDL-C of > 4.15 mg/dL for boys and ≥ 3.51 mg/dL for girls
- Age range: 7-13 months
- TC ≥ percentile for age and sex
- Total N: 334 (295) Behavioral Arm 1: Dietary intervention

**Intervention Strategies:**
- Based on social learning theory

**Fat Intake:**
- Consistently higher in INT group

**Primary Outcome:**
- No difference between groups for any of these measures.

**Secondary Outcomes:**
- No difference between groups for any of these measures.

**Acceptability:**
- Consistently lower in INT group

**Acceptability (%):**
- Not reported

**Data Collection:**
- Hemoglobin, serum folate, serum retinol, and zinc.

**Factors Considered for Study:**
- Gender
- Age
- Smoking status

**Sample Size:**
- 663

**Critical Questions:**
- More effective in LDL lowering, pravastatin with low dose bile acid-binding resin vs. pravastatin alone or pravastatin with high dose bile acid-binding resin.

**Major Problems:**
- Insufficient sample size

**Additional Measures:**
- No adverse events

**Study Sponsor:**
- American Heart Association

**Source:**
- NHLBI Evidence Table: RF5-RCT
<table>
<thead>
<tr>
<th>Study Title</th>
<th>Type</th>
<th>Setting</th>
<th>Study Size</th>
<th>Duration</th>
<th>Main Objective</th>
<th>Participants/Exclusions</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRIP study: Special Turku Coronary Risk Factor Intervention Project</td>
<td>RCT</td>
<td>Young adults</td>
<td>81/41</td>
<td>1 yr</td>
<td>Red cell and plasma plant sterols to cholestanol change differently cholesterol and plant sterols and to increase the intake of saturated fat and cholesterol and to increase the intake of unsaturated fat.</td>
<td>Children with hypercholesterolemia included. Exclusions: FH, &lt;4.1 mmol/L cholesterol, &gt;28% PUFA.</td>
<td><strong>ApoE4+ Boys Decreased 9.1%</strong>, <strong>ApoE4+ Girls Decreased 7.6%</strong>, <strong>ApoE4- Boys Increased 10.6%</strong>, <strong>ApoE4- Girls Increased 7.6%</strong>, <strong>ApoE4- Girls Decreased 4.4%</strong>, <strong>ApoE4- Boys Decreased 5.8%</strong>, <strong>ApoE4- Boys Increased 16.7%</strong>, <strong>ApoE4+ Girls Decreased 24.4%</strong>, <strong>ApoE4+ Boys Increased 7.4%</strong>, <strong>ApoE4- Girls Decreased 7.6%</strong>, <strong>ApoE4- Boys Decreased 7.6%</strong>, <strong>ApoE4+ Girls Decreased 5.8%</strong>, <strong>ApoE4+ Boys Increased 7.4%</strong>, <strong>ApoE4- Girls Decreased 7.6%</strong>, <strong>ApoE4- Boys Decreased 7.6%</strong>, <strong>ApoE4+ Girls Decreased 5.8%</strong>, <strong>ApoE4+ Boys Increased 7.4%</strong>, <strong>ApoE4- Girls Decreased 7.6%</strong>, <strong>ApoE4- Boys Decreased 7.6%</strong>, <strong>ApoE4+ Girls Decreased 5.8%</strong>, <strong>ApoE4+ Boys Increased 7.4%</strong>, <strong>ApoE4- Girls Decreased 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</tr>
<tr>
<td>Study Title</td>
<td>Type of Study</td>
<td>Interventions</td>
<td>Main Outcomes</td>
<td>Duration</td>
<td>Sample Size</td>
<td>Key Findings</td>
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<tr>
<td>Metformin vs Placebo</td>
<td>Randomized Controlled Trial</td>
<td>Metformin, Placebo</td>
<td>Lower fasting glucose, improved insulin sensitivity</td>
<td>24 weeks</td>
<td>120</td>
<td>Metformin significantly improved fasting glucose and insulin sensitivity compared to placebo.</td>
<td></td>
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<tr>
<td>Dietary Intervention</td>
<td>Randomized Controlled Trial</td>
<td>Dietary intervention, control</td>
<td>Improved lipid profile</td>
<td>12 months</td>
<td>200</td>
<td>The dietary intervention significantly improved lipid profile compared to control.</td>
<td></td>
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<tr>
<td>Physical Activity Program</td>
<td>Randomized Controlled Trial</td>
<td>Physical activity program, control</td>
<td>Weight loss, improved cardiovascular health</td>
<td>6 months</td>
<td>100</td>
<td>The physical activity program resulted in significant weight loss and improved cardiovascular health.</td>
<td></td>
</tr>
<tr>
<td>Drug Therapy</td>
<td>Randomized Controlled Trial</td>
<td>Drug therapy, placebo</td>
<td>Reduced blood pressure, improved glycemic control</td>
<td>18 months</td>
<td>300</td>
<td>Drug therapy significantly reduced blood pressure and improved glycemic control compared to placebo.</td>
<td></td>
</tr>
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**Additional Findings**

- At 18 months of age, no difference in growth parameters between groups.
- No significant differences in incidence of adverse events across groups.

**Summary**

The study demonstrated the efficacy of metformin and dietary intervention in improving metabolic parameters. Physical activity programs and drug therapies also showed promising results in improving cardiovascular health and blood pressure control, respectively.
### PMID First Author Title Year Study Design

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Country Setting</th>
<th>Int Type</th>
<th>Specific Intervention</th>
<th>Outcome</th>
<th>Results/CI</th>
<th>Critical Question</th>
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<tbody>
<tr>
<td>RCT</td>
<td>Finland</td>
<td>Dietary + Physical Activity</td>
<td>Pravastatin + low fat diet + physical activity</td>
<td>Carbohydrate intake</td>
<td>Mean gross energy expenditure for walk [kJ/kg body mass (SE)]</td>
<td>No difference between rest &amp; exercise results for either group.</td>
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<tr>
<td>RCT</td>
<td>Finland</td>
<td>Dietary + Physical Activity</td>
<td>Pravastatin + low fat diet + physical activity</td>
<td>Total fat intake</td>
<td>Mean postprandial blood glucose [mmol/L (SE)]</td>
<td>No difference between rest &amp; exercise results for either group.</td>
</tr>
<tr>
<td>RCT</td>
<td>Finland</td>
<td>Dietary + Physical Activity</td>
<td>Pravastatin + low fat diet + physical activity</td>
<td>Protein intake</td>
<td>Mean fasting blood glucose [mmol/L (SE)]</td>
<td>No difference between rest &amp; exercise results for either group.</td>
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<tr>
<td>RCT</td>
<td>Finland</td>
<td>Dietary + Physical Activity</td>
<td>Pravastatin + low fat diet + physical activity</td>
<td>BMI</td>
<td>Mean postprandial blood glucose [mmol/L (SE)]</td>
<td>No difference between rest &amp; exercise results for either group.</td>
</tr>
<tr>
<td>RCT</td>
<td>Finland</td>
<td>Dietary + Physical Activity</td>
<td>Pravastatin + low fat diet + physical activity</td>
<td>Blood lactate [mmol/L (SE)]</td>
<td>Mean fasting blood glucose [mmol/L (SE)]</td>
<td>No difference between rest &amp; exercise results for either group.</td>
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</table>

### Specific Control Outcomes Measured

<table>
<thead>
<tr>
<th>Specific Control</th>
<th>Measured Results/CI</th>
<th>Critical Question</th>
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### Events Additional findings

<table>
<thead>
<tr>
<th>Events</th>
<th>Additional findings</th>
<th>Summary</th>
<th>Main Reported Findings by</th>
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### Notes

This study investigated the impact of dietary intervention and physical activity on various health outcomes among healthy adolescent boys. The results suggest that a combined approach of dietary modification and regular physical activity may be effective in improving metabolic parameters. Further research is needed to confirm these findings and to explore the long-term effects of such interventions.

**Critical Question**

What are the long-term effects of dietary interventions and physical activity on the metabolic health of pre-pubertal and pubertal children and young adults?