MeSH Evidence Table: State of the Science: CVD Risk Factors and the Development of Atherosclerosis in Childhood-RCT

<table>
<thead>
<tr>
<th>Type</th>
<th>Study Design</th>
<th>Setting</th>
<th>Country</th>
<th>Setting</th>
<th>Interventions</th>
<th>Intervention Details</th>
<th>Comparison</th>
<th>SpecificOutcomes</th>
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<tbody>
<tr>
<td>RCT</td>
<td>Phase I: Interventions</td>
<td>Germany</td>
<td>Clinical</td>
<td>None/NR</td>
<td>6 mo</td>
<td>Assess effect of a 6 mo exercise program in obese children on FMD, a marker of vascular function in young people</td>
<td>Q12a (RF5)</td>
<td>RF8, RF11,</td>
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<tr>
<td>RCT</td>
<td>Intervention</td>
<td>Australia</td>
<td>Clinical</td>
<td>Other</td>
<td>28 wk</td>
<td>Determine whether simvastatin preceding an exercise intervention in obese children on FMD, a marker of vascular function in young people</td>
<td>Q12a (RF5)</td>
<td>RF8, RF11,</td>
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**Characterize the impact of obesity and obesity-related diseases in children and determine whether an intervention is effective in reducing disease risk.**

**Methods:**

- **Participants:** Young children aged 9-18 years with obesity (BMI > 97th percentile) who are not taking any medications that could affect cholesterol levels.
- **Interventions:**
  - Exercise training: A 6-month supervised exercise program involving aerobic and strength training sessions.
  - Simvastatin: A 6-month regimen of simvastatin followed by an exercise intervention.

**Outcomes:**

- **Primary Outcomes:**
  - FMD: A measure of endothelial function and arterial compliance.
  - BMI: A measure of body mass.
- **Secondary Outcomes:**
  - Blood pressure:
  - Total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglycerides (TG).

**Results:**

- **FMD (Atherosclerosis Risk in Young Adults [ARIC] Study):**
  - **Primary:**
    - No change in either group.
  - **Secondary:**
    - **BMI:**
      - No change.
      - **TC:**
        - No change.
      - **HDL-C:**
        - No change.
      - **LDL-C:**
        - No change.
      - **TG:**
        - No change.
      - **Systolic Blood Pressure (SBP):**
        - No change.
      - **Diastolic Blood Pressure (DBP):**
        - No change.

**Conclusion:**

The study provides evidence that a 6-month supervised exercise program and a 6-month regimen of simvastatin are not effective in reducing disease risk in children with obesity. Further research is needed to identify effective interventions for this population.