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The U.S. Government's Global Hunger & Food Security Initiative

SPECIFYING AN INTERVENTION

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TWO TYPES OF INTERVENTIONS

- **Controlled clinical trial** with exposure at the individual level. These are called randomized clinical trials (RCT).
- **Community interventions** in which the intervention is assigned to an entire group. Generally a cluster randomized trial.



CONTROLLED CLINICAL TRIAL

- Hypothesis: Subjects fed trans fatty acid containing diets will have elevated plasma lipid parameters.
 - Must do a pilot study decide length of time for the diet intervention.
 - Know that elevated blood lipids are associated with increased cardiovascular disease.
 - Decide to measure change in total and LDL cholesterol over time in subjects fed trans fats vs those that are not.
 - Did a 24 week study to see how long it took for total and LDL cholesterol to change when subject fed a new lipid vs the control.



FINAL STUDY DESIGN

- Answer: 3-4 weeks. Study done at 5-6 weeks.
- Final Study:
 - Randomized clinical trial
 - 3-day menu cycle enriched in trans 18:1 vs 18:1. All food components the same.
 - Subjects live in a metabolic research center for duration of study OR all food packaged for takeout for duration of study
 - Anthropometric and blood biochemical measurements taken every few days.



COMMUNITY INTERVENTION

- **Community interventions** in which the intervention is assigned to an entire group - a cluster randomized trial.
- Hypothesis: The vitamin B12 intervention group will take active steps to improve their vitamin B12 status.
 - Intervention - Adult elderly in 12 senior centers (20 in each center) are provided information on B12 + macronutrients
 - Control – Adult elderly in a separate 12 senior centers (20 subjects per center) are provided information on diet planning and macronutrients.
 - All other procedures are exactly the same.



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