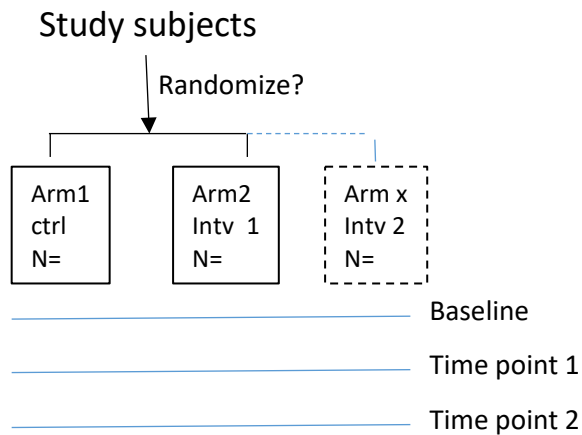


For getting statistical help with intervention trial grant

Please consider/prepare the elements below before getting statistical help with your trial grant preparation.

- 1) A simple study design diagram.



- 2) Make a list of all outcome measurements. Get an estimate of effect sizes (expected changes) and their associated standard deviations backed up either by preliminary data or literature.
 - a. Primary outcome (one), often clinical, determines the sample size of the study.
 - b. Secondary outcomes (often >1), most others, needs estimated power given the sample size.
 - c. Exploratory outcomes for preparing future studies (optional)
- 3) Hypothesis/comparisons
 - a. Primary comparison for the primary outcome is for determining the sample size.
 - b. If you have more than one primary comparisons for the primary outcome, you have to consider multiple testing, which reduces power or increases the sample size.
 - c. Comparisons for secondary outcomes are often in secondary analyses.
- 4) Covariates
Age, sex, race, etc.

Special attention to:

- 1) Is there a maximum sample size you can realistically handle?
- 2) Is there a clinically significant effect size for your primary outcome?
- 3) Attrition rate.
- 4) Is the study a randomized trial? If yes, stratified randomization? If not randomized trial, will the arms be balanced regarding sample size and baseline characteristics?

(all need to be backed up by literature or preliminary results.)