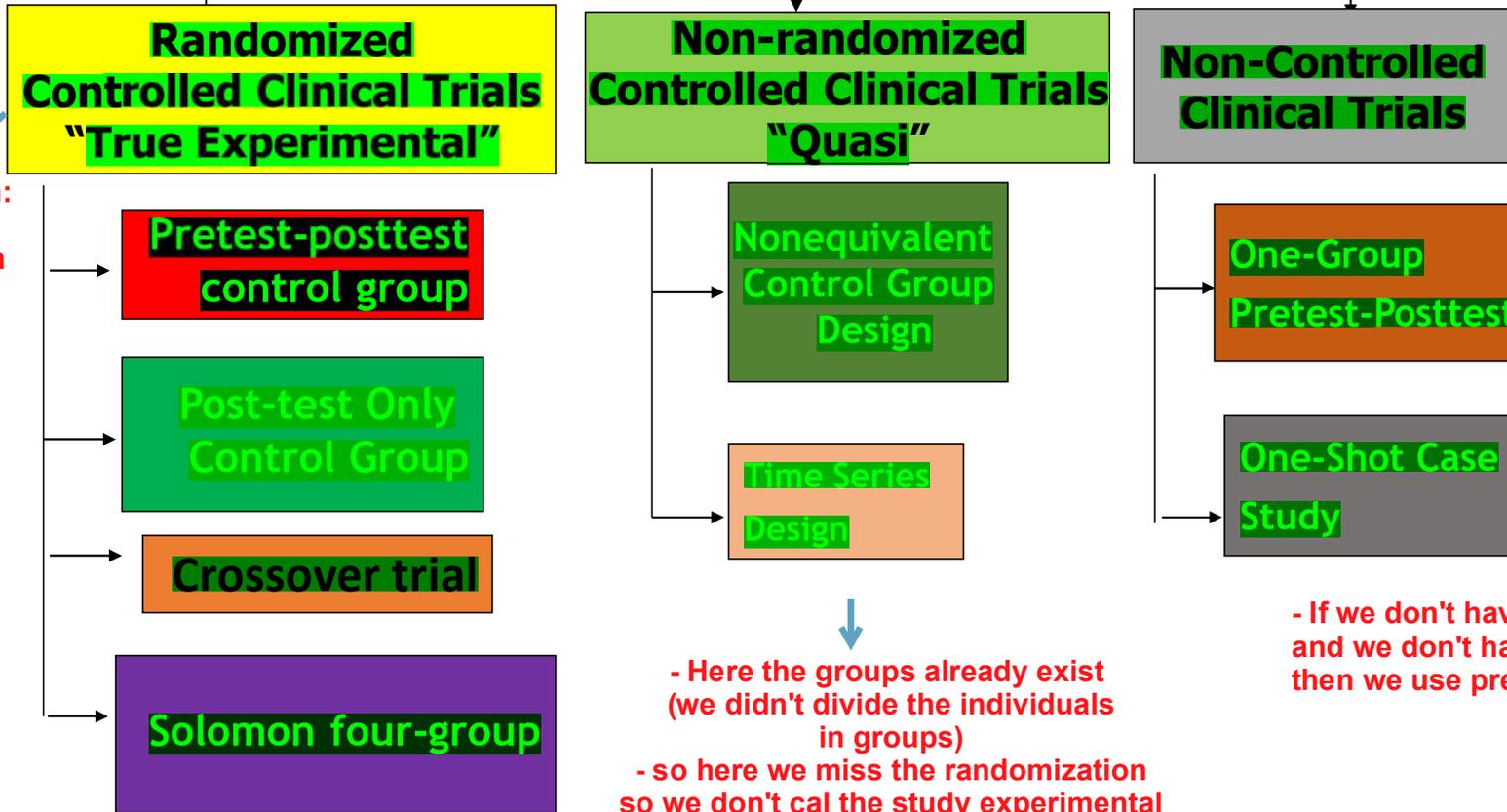


- if the sample contained animals --> Experimental
- If the sample contained humans --> Clinical
- If the sample contained any of them and we want to apply therapy --> interventional

Clinical Trial Designs

- Control group --> must be homogenous
- Comparison Group --> Shouldn't be homogenous
- in comparison group we can't bring 2 groups that are both exposed to the risk factor and compare between them.



- If we don't have randomization and we don't have control groups then we use pre-experimental

- An exam Question : VERY IMPORTANT:
 The most likely used Design option is ?
DOUBLE BLINDED

Design Options

- Controls:** Use of a comparison or control group.
- Randomization:** the random (by chance) assignment of participants into exposure groups.
- Manipulation:** Manipulation of the independent variable
- Blinding:**

| Sponsor's Clinician / Analysis Team | Investigator | Patient | | |
|---|--------------|---------|---|----------------|
| No | No | No | → | open/unblinded |
| No | No | Yes | → | single blinded |
| No | Yes | Yes | → | double blinded |
| Yes | Yes | Yes | → | triple blinded |

- Randomization means that the scientist can assign experimental group and control group but those groups must be randomized.

- The groups must be homogenous
 - so for example we can take 1000 participants and but people with an odd number in experimental group and people with an even number in control group.
 - Or we can use simple random table where we choose numbers randomly.

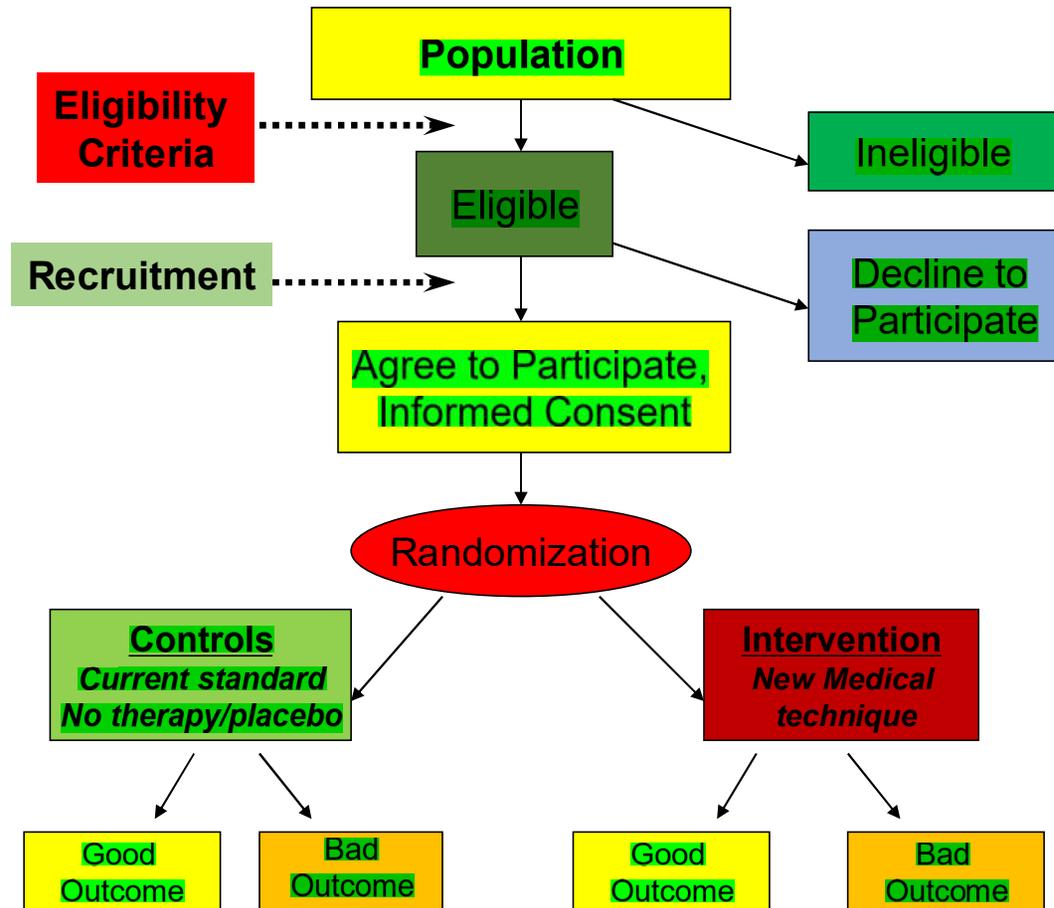
- To check if the group is hetro or homogenous we use leven's test.
 - This test give us the F value - The smaller this value , the larger the P value -
 - So in homogenous group the F must be small and the P must be big

The Basic design of randomized Controlled Clinical Trial

- Population :

1- Access population :
the people who are available to take the sample from them

2- Reference population :
People on which we can generalize the conclusion on them.



Experimental Studies (Clinical Trials)

- Individuals are randomly allocated to at least two groups.
- One group is subject to an intervention, or experiment while the other group is not.
- The outcome of the intervention (effect of intervention on the dependent variable/ problem) is obtained by comparing the two groups.
- Must have three elements:
 - **Manipulation**: manipulation of the independent variable
 - **Control**: Introduce controls over the experimental situation, including the use of a control group
 - **Randomization**: assignment to control and experimental groups randomly

4- Blinding

Experimental Studies

Randomised Control Trials

- An experimental study in which subjects are allocated to groups which do or do not receive intervention. Groups are compared for outcome.
- Considered gold standard design
- Thus subjects are enrolled on the basis of exposure
- Control group can be given placebo or standard treatment

Experimental Research Designs

A. True experimental designs

A. Quasi experimental designs

A. Pre-experimental designs

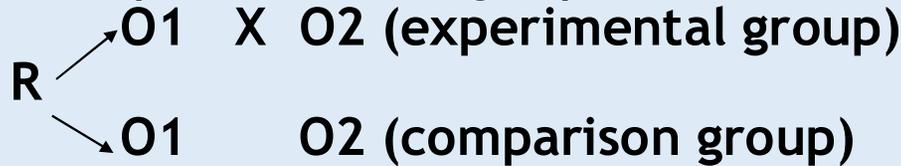
True Experimental Designs

- Studies in which **the researcher has a great deal of control over the research situation.**
- **Minimal internal validity threat** (The degree to which changes in the dependent variable (effect) can be attributed to the independent variable (cause))

True Experimental Designs

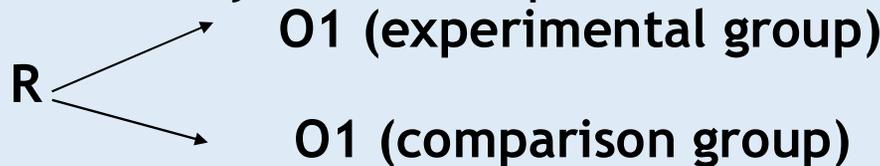
- We first look at the groups and decide if they are homogeneous or heterogeneous
- If the groups are heterogeneous will move to NON-Parametric Techniques
- If the groups are Homogeneous we'll continue using Parametric Techniques

- Pretest-posttest control group



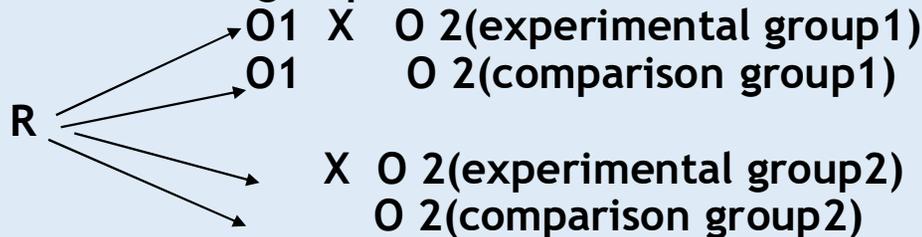
- Here the T-test is False analysis (Type 1 Error) because here alpha is greater than 0.05, so here we use anova test where you can't reject the null hypothesis

- Post-test Only Control Group



- Here we don't have baseline data, so here we work on INDEPENDENT T-TEST

- Solomon four-group



- If the groups are heterogeneous (or not normally distributed) we can't use anova or dependent and independent t-test, so here we use Mann Whitney test.
- Keep in mind that t-test works on the MEAN, while Mann Whitney works on the MEDIAN