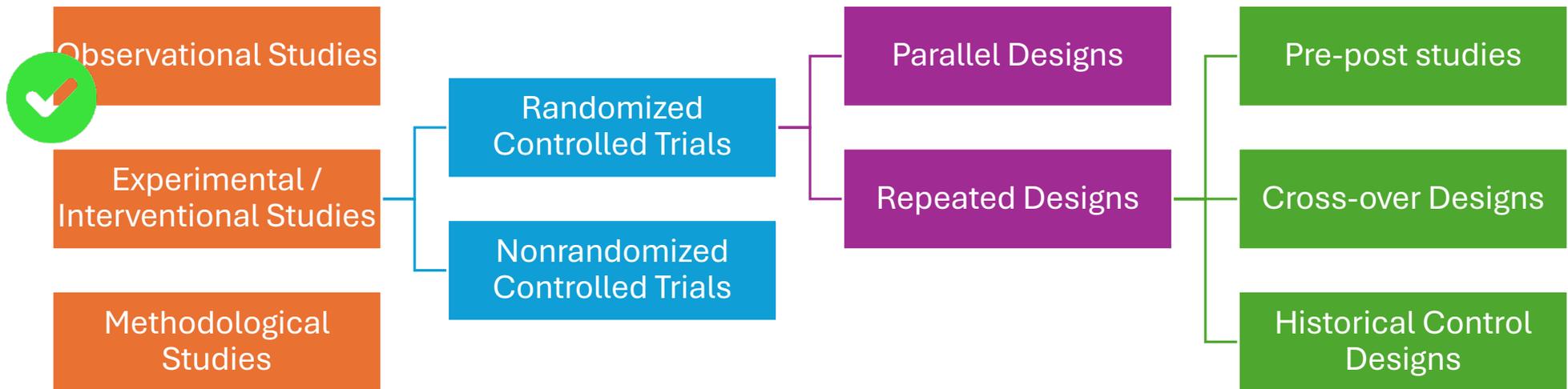


Week 9

Experimental (Interventional) Studies

Assoc. Prof. Dr. Dođukan ÖZEN

Research Designs



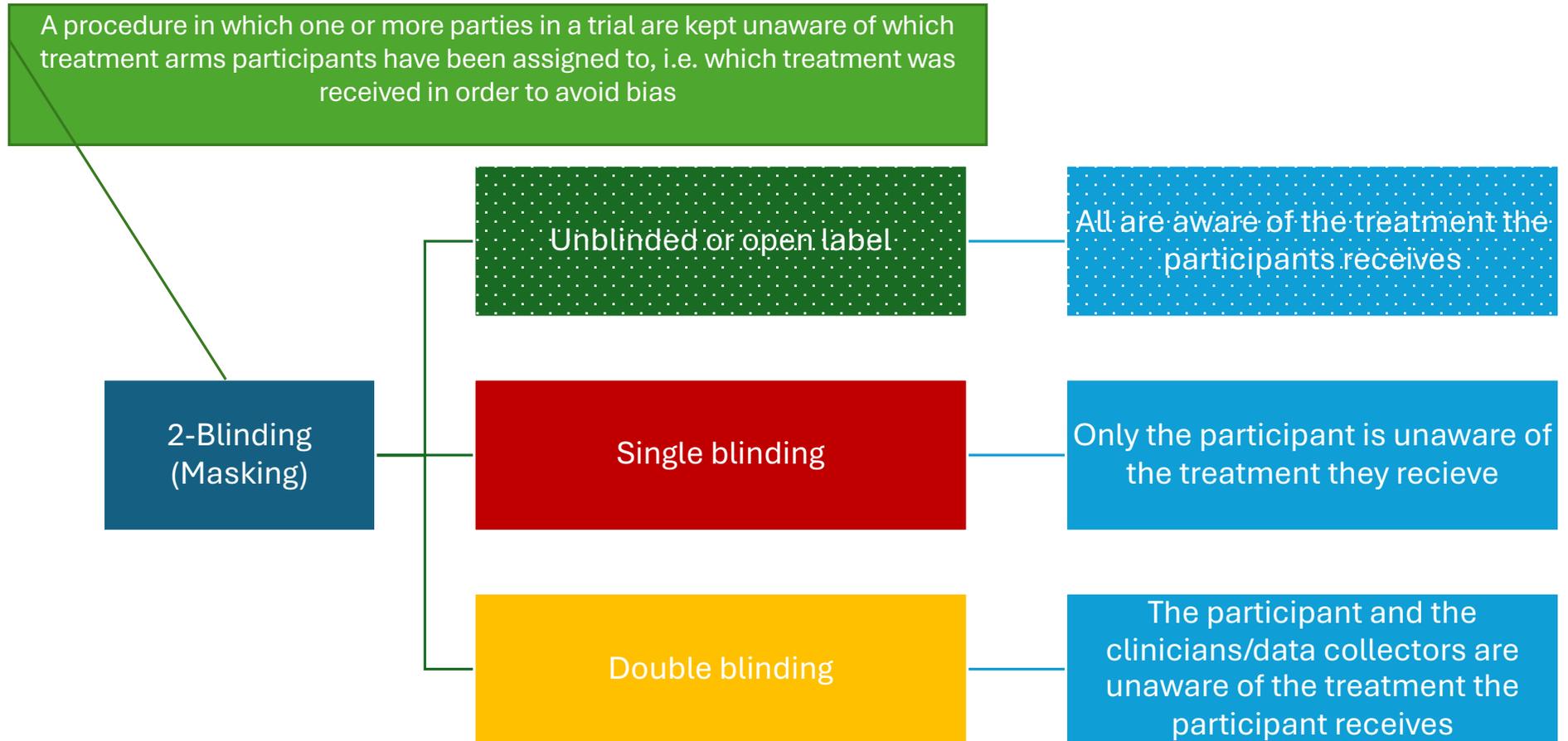
Some Concepts of Experimental Research



1-Randomization

- A method based on chance alone by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms.
- After the reference population and the experimental population are determined, the subjects included in the study are divided into at least two groups with equal probability using the appropriate randomization method. Which intervention method (vaccine, drug, etc.) will be applied to which of these groups is also determined by the randomization method.

Some Concepts of Experimental Research



Experimental / Interventional Studies

Randomized Controlled Trials

Nonrandomized
Controlled Trials

Parallel Designs

Repeated Designs

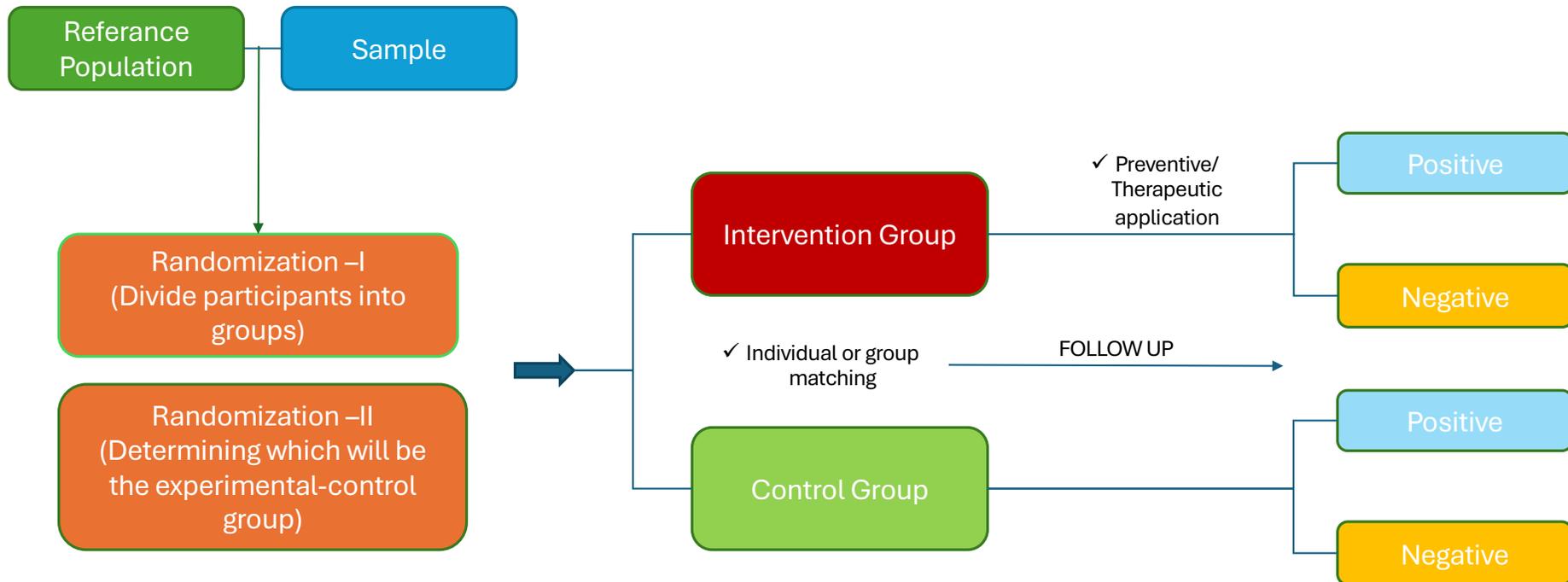
Pre-post studies

Cross-over
Designs

Historical
Control Designs

Parallel (Simultaneous) Controlled Studies

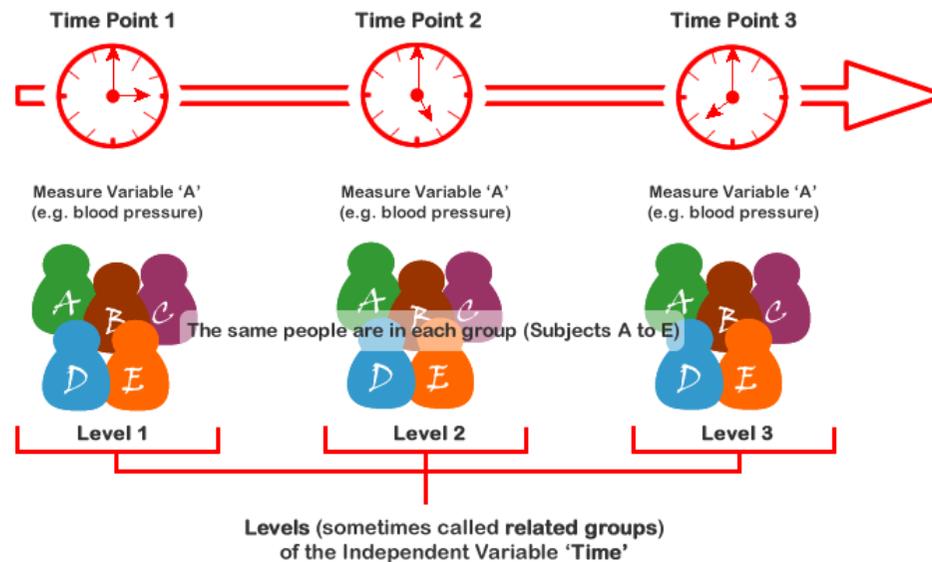
- ✓ Diagnosis and selection criteria should be determined
- ✓ Selection should be made with the appropriate sampling method.



Repeated Designs

Pre-post or self-controlled studies

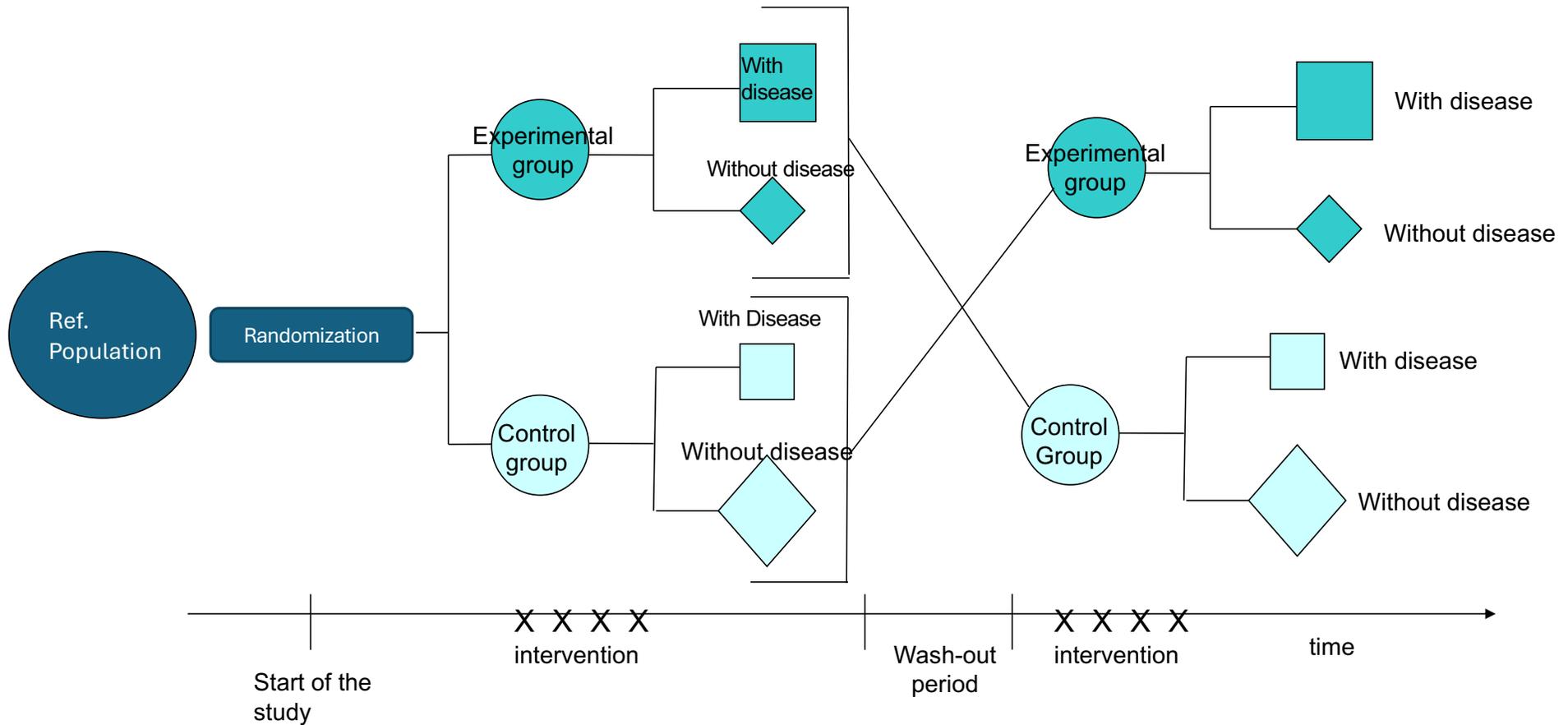
- ✓ In some cases, when there are different individuals in the control and experimental groups, homogeneity may not be achieved between the groups despite randomness. Self-controlled trials are used to eliminate such problems.
- ✓ In such trials, an experimental unit group is used as both a control and an experimental group, that is, each subject becomes his own control.



Repeated Designs: Cross-Over Designs

- ❖ These trials are obtained by properly combining simultaneous (parallel) controlled and pre-post studies.
- ❖ There are two groups in the experiment. Initially, the first group is treated with the investigated treatment, and the other group is treated with a placebo or standard method. The work is interrupted for a period of time, also called the “wash-out period”. At the end of this period, placebo or standard method is applied to the first group, and the method whose effect is investigated is applied to the second group.

Repeated Designs: Cross-Over Designs



Historical controls for clinical trials

In external controlled studies, the results of previous studies by different researchers are used as the control group.

In this type of studies, the control group is a group that belongs to another research group or the researcher has applied another method before. In some cases, it may be unethical to establish a control group. This is especially the case in the field of oncology, and this type of trial is generally used in cancer research. It is better to use an historical control group than to use no control group in situations where ethical problems may occur.

Their drawbacks are that in some cases, they may not be able to expand the control group by randomization and have to work with unbalanced and biased groups.



SOME LIMITATIONS OF EXPERIMENTAL STUDIES

- It may be necessary to wait for a long time to find a sufficient number and quality of cases for research to be carried out in the treatment of very rare diseases.
- In some cases, the intervention method cannot be fully standardized due to the nature of the disease. It may be necessary to apply a different treatment protocol according to each patient.
- Not all participants in the study can be followed.
- Polypharmacy: It can be difficult to objectively measure the effectiveness of the drug, as an intervention, due to the use of too many unnecessary drugs in the community, and over-the-counter drug intake.
- If the drug, as an intervention method, is taken orally, it should be ensured whether it is used regularly or not.