Study types-Part 3

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Outline

- Study types on the basis of intervention.
- Experimental studies:

➢Randomized-controlled trial studies.

➢Quasi-experimental studies.

Study types: on the basis of intervention

It divides the studies into two categories

1. Observational studies (no intervention): the investigator measures but does not intervene.
2. Experimental studies (Interventional studies): involve an active attempt to change a disease determinant, such as an exposure or a behaviour, or the progress of a disease through treatment.

Experimental (Intervention) studies:

- Randomized controlled trial studies.
- Quasi –experimental studies.

Randomized controlled trial(RCT):

- RCT is conducted to test whether an intervention or treatment works.

- The investigators will randomly allocate the participants either to the intervention group or to control group.

RCT (Cont.)

- Intervention group(experimental group): Patients in this group are exposed to an intervention.

- Control group (comparison group): patients in this group may receive a placebo, usual care, or the current best available treatment.

- The two groups are then compared on outcome of interest.

RCT(Cont.):

- Randomized trials are performed in a prospective way to allow as much control of variables as possible.

- The outstanding feature of RCT is the use of randomization to help prevent selection bias.

RCT : Blinding

- **Single blind**: Patients don't know which treatment they are receiving.
- **Double blind:** Neither patients nor the investigator are aware of the treatment assignment.
- **Triple blind:** patients, investigator and the person who administers treatment to the study subjects are unaware of the assigned treatment.

RCT : Bias

- **Selection bias:** Allocation of the participants to the two groups.

How to avoid it :

Randomization: Generation of allocation sequence and allocation concealment.

RCT : Bias(Cont.)

- **Performance bias:** Unequal provision of care to the participants of the both groups.

How to avoid it:

Blinding of the patients and care giver(double blind).

RCT : Bias(Cont.):

- **Detection bias:** biased outcome assessment.

How to avoid it:

Triple blind :Blinding of outcome assessor (Analysis team).

RCT : Bias(Cont.)

- **Attrition bias:** Biased occurrence and handling of protocol deviation, withdrawals and losses to follow up.

How to avoid it:

Analysis based on treatment allocation, not adjusted for compliance.

Weaknesses of RCT

- RCTs are often difficult to conduct.
- Many clinicians and patients are reluctant to accept randomization, especially if one of the proposed interventions is particularly desirable or undesirable.
- Expensive in term of resources, time and personnel.
- Ethical issues for certain interventions.

Quasi-experimental studies

- Quasi-experiments are studies that aim to evaluate interventions but that do not use randomization.

- Similar to randomized trials, quasi-experiments aim to demonstrate causality between an intervention and an outcome.

Quasi-experimental studies

- Quasi-experimental studies encompass a broad range of nonrandomized intervention studies.
- Used when it is not logistically feasible or ethical to conduct a randomized controlled trial.
- Sometimes called the pre-post intervention, design often is used to evaluate the benefits of specific interventions.

Types of quasi-experimental design

- Quasi-experimental designs without control groups(post test only& pre and post test).
- Quasi-experimental designs that use control groups but no pretest.
- Quasi-experimental designs that use control groups and pretests.
- Interrupted time-series designs.

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