EXPERIMENTAL EPIDEMIOLOGY
OR
RANDOMIZED CONTROLLED TRIALS

Definition

Experimental studies involve some action, intervention or manipulation such as deliberate application or withdrawal of the suspected cause or changing one variable in the causative chain in the experimental group while making no change in the control group , and observing and comparing the outcome of the experiment in both the groups.

Aims:

1) To provide "scientific proof " of etiological factors which may permit the modification or control of those diseases
2) To provide a method of measuring the effectiveness and efficiency of health services for the prevention, control and treatment of disease and improve the health of the community.

Basic steps of randomized controlled trials

1. Drawing up a protocol

2. Selecting reference and experimental population

3. Randomization

4. Manipulation or intervention

5. Follow up

6. Assessment of outcome.

1) The protocol Study is conducted under strict protocol. The protocol specifies the aims, objectives of the study. Questions to be answered. Criteria for the selection of study and control groups. Size of the sample. Standardization of working procedures and schedules up to stage of evaluation of outcome of the study.

2) Selecting reference and experimental population.

a) Reference or target population
b) Experimental or study population
c) Participants should fulfill
d) informed consent
e) should be representative of the population to which belong.

f) should be qualified or eligible for the trial

3) Randomization: It is a statistical procedure by which the participants are allocated into groups usually called " study " and control groups, to receive or not to receive an experimental preventive or therapeutic procedure, or intervention.

4) Manipulation – It is to intervene or manipulate the study group by the deliberate application or withdrawal or reduction of the suspected causal factor as laid down in the protocol.

5) Follow up – Examination of groups subjects at defined intervals. Under the same given circumstances, in the same time frame till final assessment of outcome.

6) Assessment

a) **Positive results –** that is benefits of the experimental measure such as reduced incidence or severity of the disease, cost to health service or other appropriate outcome in the groups.
b) **Negative results –** severity and frequency of side effects and complication, including death.

Bias in experimental study: Participants bias, Observer bias, Evaluation bias.

Blinding –

a) **Single blinding-** participant is not aware whether he belongs to the study**.**
b) **Double blind –** neither the doctor nor the patient is aware.
c) **Triple blind –** investigator, doctor, participant doesn't know about the study.

EXPERIMENTAL STUDY DESIGNS

Concurrent parallel study designs: Comparisons are made between two randomly assigned groups, one group exposed to specific treatment, other group not exposed.

Cross over type study designs: The patients are randomly assigned to a study group & control group. The study group receives the treatment under investigation. The control group receives some alternate form of active treatment or placebo.

Types of randomized controlled trials

1. Clinical trails(clinics)

2. Preventive trails(vaccines)

3. Risk factor trails

4. Cessation experiments

5. Trial of etiological agents

6. Evaluation of health services.

Non randomized trials

1. Uncontrolled trials.
2. Natural experiments.
3. Before and after comparison studies.

a. Before and after comparison studies without control

b. Before and after comparison studies with control.

NATURAL HISTORY OF DISEASE

The natural history of disease consists of two phases:

Prepathogenesis (i.e. the process in the environment)

Pathogenesis (i.e. the process in man)

Prepathogenesis phase:

- This refers to the period preliminary to the onset of disease in man.
- The disease agent has not entered man, but the factors which favor its interaction with the human host already exist in the environment.
- This situation is frequently referred to as "man in the midst of disease" or "man exposed to the risk of disease".

Pathogenesis phase:

The pathogenesis phase begins with the entry of the disease "agent" in the susceptible human host. Here the disease agent multiplies and induce tissue and physiological changes, the disease progresses through a period of incubation and later through early and late pathogenesis.

The final outcome of the disease may be recovery, disability or death.

1) Agent factors

- Biological agents
- Nutrient agents
- Physical agents
- Chemical agents
- Mechanical agents
- Social agents

HOST FACTORS

- ✓ Demographic characteristics
- ✓ Biological Characteristics
- ✓ Social and economic characteristic
- ✓ Life style factors

ENVIRONMENTAL FACTORS

- ❑ Physical environment
- ❑ Biological environment
- ❑ Psychosocial environment