Experimental Design and Statistical Analysis Seminar

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EXPERIMENTAL DESIGN AND STATISTICAL ANALYSIS SEMINAR:
STUDY DESIGNS

1. Classification of Study Designs
2. Essential Design Features of a Controlled Clinical Trial
3. Quality Assurance
4. Computer Facility
5. Data Security Precautions
6. Preparation of Analysis Files
7. Broader classifications of study designs
8. Randomization
9. Activities By Stage Of Clinical Trial

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EXPERIMENTAL DESIGN AND STATISTICAL ANALYSIS SEMINAR:
3: Essential Design Features of a Controlled Clinical Trial

Any controlled clinical trial requires specification of:

1. Choice of the test and control treatments.
2. Selection of the outcome measure.
3. Establishing comparable study groups.
4. Blinding and bias control.

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3: Essential Design Features Of a Controlled Clinical Trial

1: Choice of the test and control treatments.

1) There must be a reasonable doubt regarding the efficacy of the test treatment
2) The test treatment must be different from the control treatment
3) They must be distinguishable from one another
4) The method of treatment administration must be the same for all treatments
5) The method of treatment administration must be similar to real-world

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3: Essential Design Features Of a Controlled Clinical Trial

1. Choice of the test and control treatments.

6) They must be medically justifiable
7) There must be an ethical basis for use of either treatment
8) Use of the treatments must be compatible with the health care needs of the study patients
9) Both treatments must be acceptable to study patients and to the physicians administering them

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1. Choice of the test and control treatments.

- Active Treatment: Transcranial magnetic stimulation (TMS), which uses electromagnetic principles to produce small electrical currents in the cortex to treat headache and depression.
- Sham-TMS: Subjects hear the sound and feel the vibration of the stimulation.
- Two Active Treatments: The Mediterranean Diet and Whole Plant-Based Food.
- Active Treatment and TAU.

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2: Essential Design Features Of a Controlled Clinical Trial

2. Principles in the selection of the outcome measure

1. The outcome could be:
   - A. Surrogate outcome measure (a score on a psychological test).
   - B. Clinical Event (death, recurrence of a disease, re-admission, length of stay)
2. The rate of occurrence of the outcome event will affect the power of the study and the length of time it is required to run.

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2: Essential Design Features Of a Controlled Clinical Trial

2. Principles in the selection of the outcome measure:

3. Chosen before the start of data collection
4. Clinically relevant
5. Easy to diagnose or observe
6. Free of measurement or ascertainment errors
7. Capable of being observed independent of treatment assignment

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1. Choice of the test and control treatments.

- Concussive or mild Traumatic Brain Injury (MTBI) related to blast injury is the most common form of combat-related injury in the Iraq and Afghanistan Wars.
- Among many physical symptoms, headache (HA) is the most debilitating clinical symptom associated with MTB.
- Transcranial magnetic stimulation (TMS) is a safe, new technology which uses electromagnetic principles to produce small electrical currents in the cortex. Sham-rTMS: The patients receiving the sham treatment can visualize the movement of coil and treatment beam over their own cortices on the monitor, and hear the sound and feel the vibration of the stimulation just like the patients receiving the active treatment except they will not receive any magnetic flux.
- Headache assessment will consist
  1. The location of the headache,
  2. Rating of the average intensity of headache (M-VAS scale),
  3. The frequency and duration (hours) of headache per exacerbation episode.
  4. A daily headache diary to document their daily average headache level on a 0-10 Numerical Pain Scale (NPS), along with frequency, duration and severity of headache exacerbation. The data from the daily headache diary will be averaged and compared to the headache NPS obtained from the Brief Pain Inventory.

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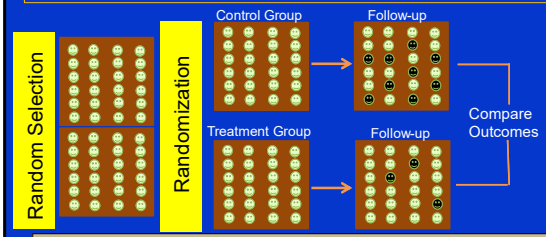
CONTROLLED INTERVENTIONAL STUDIES:
1: Studies with Independent Concurrent Controls



Study of Acupuncture to Treat Osteoarthritis Knee Pain:
- Control Group: Sham Treatment.
- Treatment Group: Acupuncture Treatment.
- Outcome: Group differences on their Pain level at the of study

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2: Essential Design Features Of a Controlled Clinical Trial

3. Principles of establishing Comparable study groups:

1) The baseline characteristics of the test and control treated groups must be more or less similar.
2) The assignment should be randomized and remain blinded until it is needed.
2) The process used for generation has known mathematical properties.
3) Future assignments cannot be predicted from past assignments.
4) The order of allocations is reproducible.
5) Methods for the generation and administration of the schedule are documented.
6) The process provides a clear audit trail.
7) Departures from the established sequence of assignments can be detected.

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2: Essential Design Features Of a Controlled Clinical Trial

4. Principles of Blinding and Bias Control:

1) One of the goal for any trial should be to collect data that are free of bias, especially treatment-related bias.
2) Blinding or masking is a procedure used to protect against treatment-related bias.
3) The treatment assignment, or some other item of information, is withheld from some individual or group of individuals in the study as a means of improving the objectivity of the treatment, data collection, reporting, or analysis processes.

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2: Essential Design Features Of a Controlled Clinical Trial

4. Principles of Blinding and Bias Control:

1) A double-blinded trial is one in which neither the patient nor the physician responsible for treatment is informed of the patient's treatment assignment
2) A single-blinded trial is one in which the patient is not informed of the treatment assignment, but the treating physician is
3) Un-Blinded/Open trial is one in which both the patient and the physician are informed of the treatment assignment

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2: Essential Design Features Of a Controlled Clinical Trial

4. Principles of Blinding and Bias Control:

1) Use a treatment allocation scheme that meets the blinding criteria listed above.
2) Administer treatments with the highest level of blinding feasible
3) Blind Rater
4) Do not require blinded treatment administration if doing so requires study patients to assume measurable risks in order to achieve or maintain the blinding

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