

Clinical Trials

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Outline

- Clinical trials?
- Randomization
- Control
- Reliability
- Validity

Pre-test
(baseline)

Experimental
group

Control
group

No intervention
Sham



Post-test

Clinical Trials

```
graph TD; A[Clinical Trials] --> B[Randomization]; A --> C[Control];
```

Randomization

Control

Randomization

- = the way participants are allocated to the experimental or control groups
- To create groups that are as similar as possible

Randomization

- To ensure that the results are attributable to the intervention rather than to some other variable
(e.g., age, socioeconomic status, disease duration)

Randomization

```
graph TD; A[Randomization] --- B[Computer-generated numbers]; A --- C[Stratification]
```

Computer-generated
numbers

Stratification

Types of control in research

- Five types of control are common:
 1. Control of the implementation of the independent variable:
 - The investigator must have a rationale to govern the implementation of the variable and a mechanism to monitor the implementation

1. Control of the implementation of the independent variable

- Problem: effect of heat on R.O.M of the low back —————> The use of heat must be standardized:
 - Does heat mean hot pack, ultrasound, or other modality?
 - If hot pack, should all hot packs be the same size, or adjusted to the size of the patient?
 - If ultrasound, what is the duration and frequency? Area of application?

2. Control of subject selection

- **Inclusion / exclusion criteria:** for admission of subjects to the study
 - Example: age, gender, pain (chronic or acute)
- ***Homogeneous sample:*** tight selection criteria reducing the variability between subjects
- ***Heterogeneous sample:*** broad selection criteria increasing the variability between subjects

3. Control of extraneous variables

- **Extraneous** or ***confounding*** variables = factors that may influence the dependent variable (other than the independent variable)
 - Example: temperature, time of the day for testing, lighting, learning effect
- You must rule out the effect of the confounding variables (related to the setting & subjects)

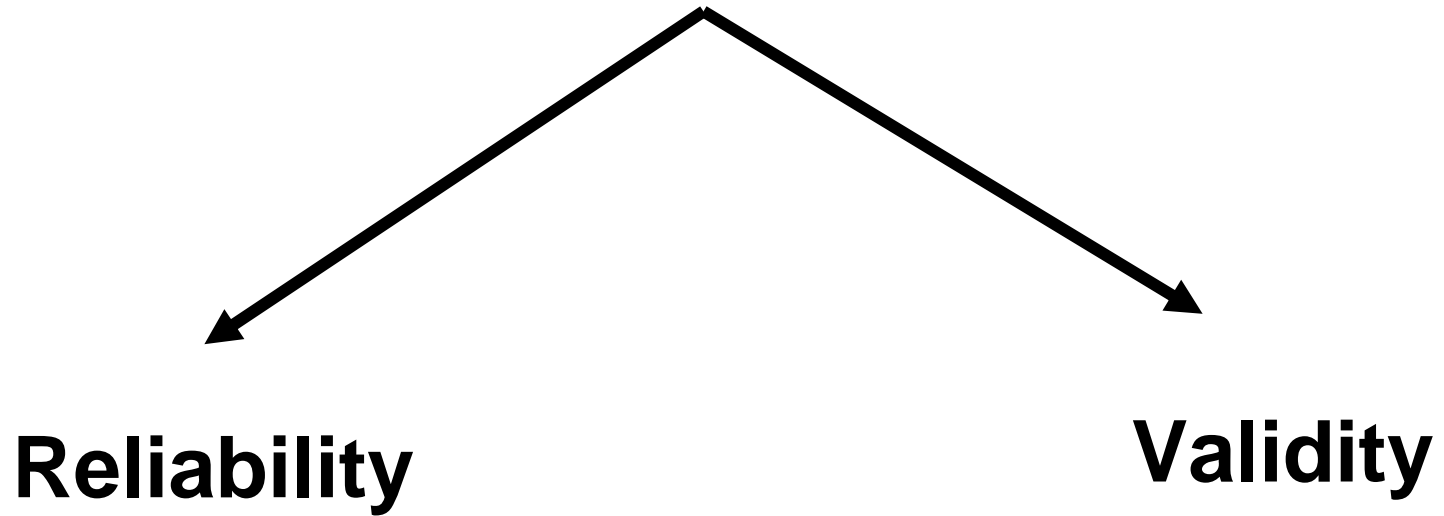
4. Control of information given to subjects & researchers

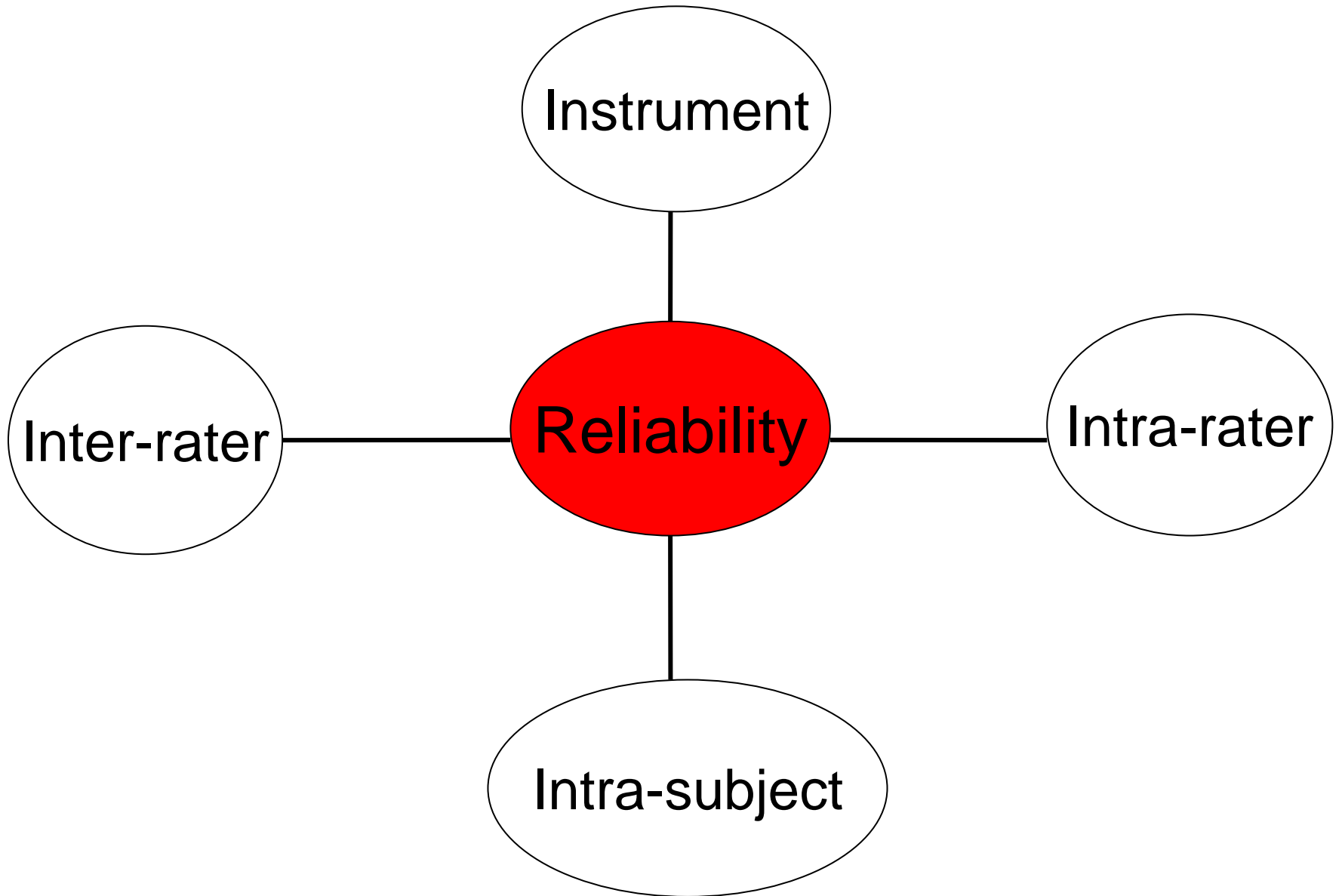
- **Incomplete information:** about the purpose of the study to control the effect of expectations (BUT be aware of ethics)
- **Subject blinding:** to withhold information about which of several treatments the patient is receiving (not applicable to physical therapy)
- **Researcher blinding:** to the treatment received by the patients, to control the effect of the researcher expectations

4. Control of information given to subjects & researchers

- **Single-blind study:** either the subject OR the researcher is blind to the treatment or group assignment
- **Double-blind study:** both subject and researcher are blind

5. Control of measurement





Reliability

- **Reliability** (consistency) = the degree to which test scores are free from error
 - ***Instrument reliability*** = measurement error
 - ***Intra-rater reliability*** = consistency with which one rater assigns scores to the same thing on two occasions

Reliability

- ***Inter-rater reliability*** = consistency among different raters in assigning scores to the same thing
- ***Intra-subject reliability*** = related to change in subject performance from time to time

5. Control of measurement

- **Validity** = the appropriateness and usefulness of the specific inferences made from test scores

Research validity

- The extent to which the conclusions of the research are believable and useful

Instrument validity

- = the ability to measure what should be measured
- Example: using a goniometer with surface landmarks to measure R.O.M.
(gold standard: radiographs)
- Today's gold standard may not be tomorrow's

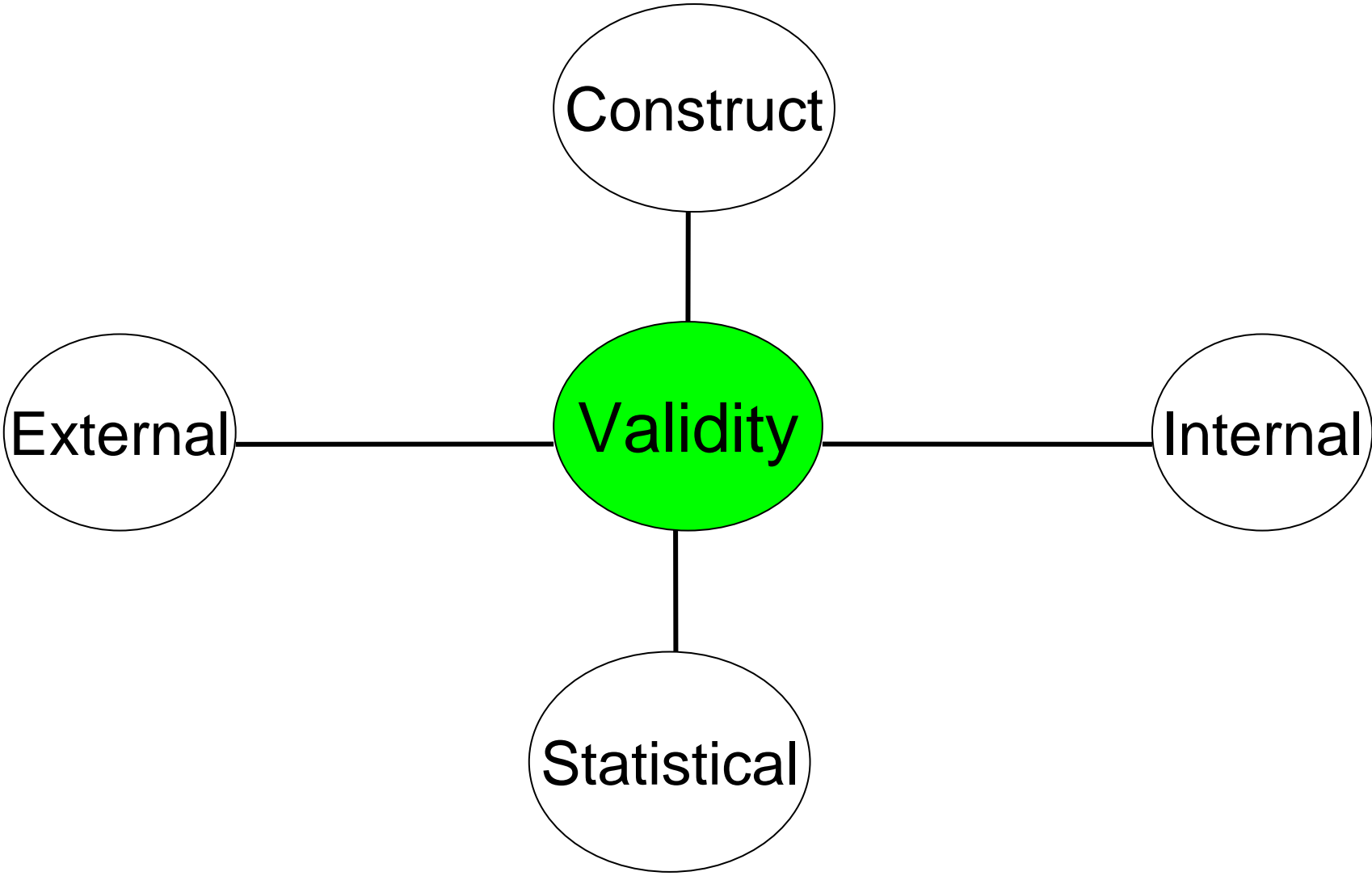
Construct

Validity

Internal

Statistical

External



Types of validity

Internal validity:

- The extent to which the results demonstrate that a causal relationship exists between the independent and dependent variables
- Is the research designed so that there are only few alternative explanations for changes in the dependent variable other than the effect of the independent variable?

Types of validity

Internal validity:

- To increase internal validity —————> maximize the control over all aspects of the study
- Example: eliminating ***confounding*** (extraneous) variables through *control* of the experimental setting to eliminate their effects on the dependent variable
- Should be planned as early as the proposal

Types of validity

Construct validity:

- Concerned with the meaning of variables within the study
- Are the research constructs defined so that the research can be placed in the framework of other research within the field?

Types of validity

Construct validity:

- *Labeled* versus *implemented* construct
- Example: using active range of motion as a dependent measure of shoulder function. Labeled construct is “function”, and implemented construct is “range of motion”

Types of validity

External validity:

- To whom, in what settings, and at what times can the results be ***generalized?***
- To whom can the results of this research be ***applied?***

Types of validity

External validity:

- Requires thoughtful consideration of the population to whom the results of the study can be applied

Types of validity

Statistical conclusion validity:

- Are statistical tests used correctly to analyze the data?

Validity

↑ Internal validity



↓ External validity

Validity Example

- To achieve a high level of *internal validity*, researchers standardize the experimental treatment to control confounding variables.
- Such standardization compromises *external validity* because the results can be applied only to settings in which the treatment can be controlled.

