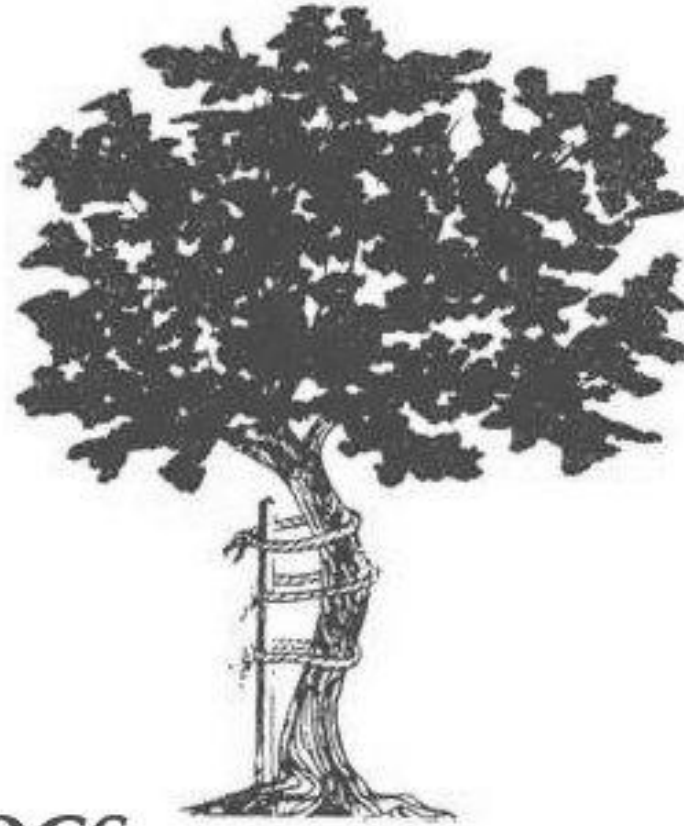
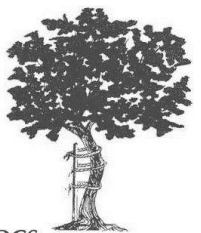


RESEARCH DESIGN *and* STATISTICS



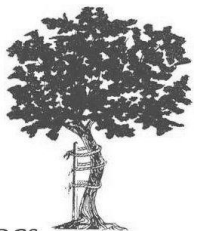
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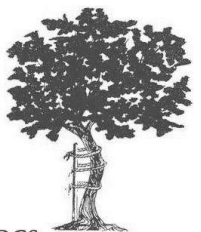
Research Design

- **Dependent variable:** what you measure in an experiment and what is affected during the experiment
- **Independent variable:** what you vary or manipulate as the researcher.
- **Control group:** the group in the study that does not receive the new or different treatment. (treated as usual)
- **Experimental group:** the group in the study that received the new or novel treatment under investigation.



Types of Studies

- Case Series and Case Reports: consist of collections of reports on the treatment of individual patients or a report on a single patient. Because they are reports of cases and use no control groups to compare outcomes, they have little statistical validity.



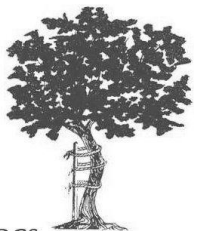
Types of Studies

- **Case controlled Studies:** studies in which patients who already have a specific condition are compared with people who do not have the condition. The researcher looks back to identify factors or exposures that might be associated with the illness. They often rely on medical records and patient recall for data collection. These types of studies are often less reliable than randomized controlled trials and cohort studies because showing a statistical relationship does not mean that one factor necessarily caused the other. For instance, researchers could identify workers who currently have back pain and those that do not, and then look back in time to compare both groups' exposure to heavy lifting. The researchers could then determine if exposure to heavy lifting is related to back pain.



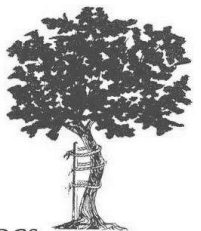
Types of Studies

- Cohort study: a cohort is any group of people who are linked in some way and followed over time. Researchers observe what happens to one group that has risk factors (positive physical examination findings), and compare them to a similar group that does not have the risk factors (normal physical examination). Cohort studies are observational and not as reliable as randomized controlled studies, since the two groups may differ in ways other than in the variable under study.



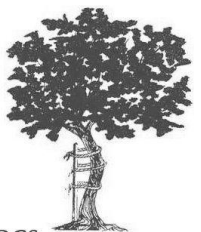
Types of Studies

- Randomized controlled trials: are carefully planned experiments that introduce a treatment or exposure to study its effect on real patients. They include methodologies that reduce the potential for bias (randomization and blinding) and that allow for comparison between intervention groups and control (no intervention) groups. A randomized controlled trial is a planned experiment and can provide sound evidence of cause and effect.



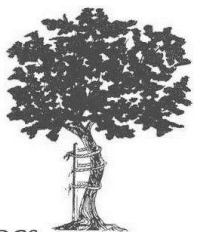
Types of Studies

- **Systematic Reviews:** focus on a clinical topic and answer a specific question. An extensive literature search is conducted to identify studies with sound methodology. The studies are reviewed, assessed for quality, and the results summarized according to the predetermined criteria of the review question.



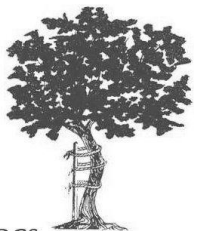
Types of Studies

- Meta-analysis: will thoroughly examine a number of valid studies on a topic and mathematically combine the results using accepted statistical methodology to report the results as if it were one large study.



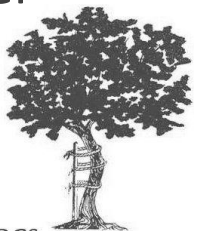
Levels of Evidence

- I. Evidence obtained from high quality randomized controlled trials, prospective studies, or diagnostic studies.
- II. Evidence obtained from lesser quality randomized controlled trials, prospective studies, or diagnostic studies (improper randomization, no blinding, < 80% follow-up)
- III. Case controlled studies or retrospective studies
- IV. Case series
- V. Expert Opinion



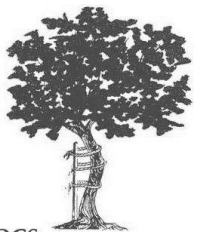
Types of Data

- Nominal: Mutually exclusive categories
 - Gender, Positive or Negative, Handedness, Hair Color
- Ordinal: Data is ranked with unequal intervals between rankings
 - Verbal pain scale, Rate your health (Good, Fair, Poor)
- Interval: Data is ranked with equal intervals between rankings
 - Temperature
- Ratio: Data is ranked with a true zero point and equal intervals between numbers
 - ROM, Height, Weight, Strength from a hand held dynamometer



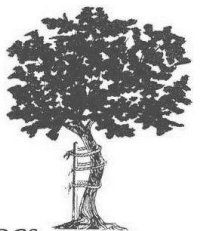
Descriptive Statistics

- Mean: the arithmetic average of the scores, appropriate for interval or ratio data
- Median: the midpoint, 50% of scores are above, 50% are below, appropriate for ordinal data
- Mode: the most frequently occurring score. Appropriate for nominal data
- Range: the difference between the highest and lowest score
- Standard Deviation (SD): a determination of variability of scores (difference) from the mean.



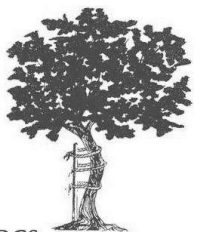
Inferential Statistics

- **ANOVA:** is used to test for differences among two or more independent groups. Typically, however, the One way ANOVA is used to test for differences among three or more groups, with the two group case relegated to the t-test.



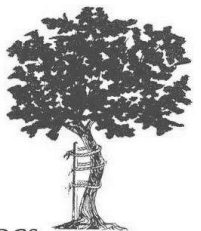
Inferential Statistics

- **T-Test:** A test of the null hypothesis that the means of two normally distributed populations are equal. Given two data sets, each characterized by its mean, standard deviation and number of data points, we can use some kind of t test to determine whether the means are distinct, provided that the underlying distributions can be assumed to be normal. If the p -value that is calculated is below the threshold chosen for statistical significance (usually the 0.05 level), then the null hypothesis that the two groups do not differ is rejected in favor of an alternative hypothesis, which typically states that the groups do differ.



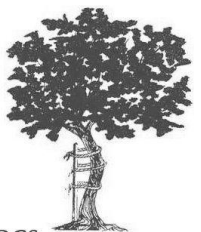
Inferential Statistics

- **Chi Square:** tests a null hypothesis that the relative frequencies of occurrence of observed events follow a specified frequency distribution. The events are assumed to be independent and have the same distribution, and the outcomes of each event must be mutually exclusive. A simple example is the hypothesis that an ordinary six-sided die is "fair", i.e., all six outcomes occur equally often. chi-square is used to assess two types of comparison: tests of goodness of fit and tests of independence. A test of goodness of fit establishes whether or not an observed frequency distribution differs from a theoretical distribution. A test of independence assesses whether paired observations on two variables, expressed in a contingency table, are independent of each other – for example, whether people from different regions differ in the frequency with which they report that they support a political candidate.



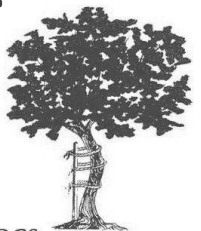
Inferential Statistics

- **Regression analysis:** a statistical technique for determining the relationship between a single dependent (criterion) variable and one or more independent (predictor) variables. The analysis yields a predicted value for the criterion resulting from a linear combination of the predictors.



Reliability

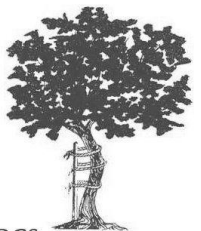
- The reproducibility of a test or measurement. If a measurement is reliable it will produce a consistent response when repeated.
- **Intrarater Reliability:** a test that is reproducible or consistent when the **SAME** examiner performs the test on multiple occasions.
- **Interrater Reliability:** a test that is reproducible when **DIFFERENT** examiners perform the measurement.



Assessing Reliability

Nominal Data: Percent agreement beyond chance is determined with the Kappa statistic

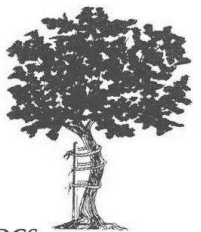
- < 0.00 Poor
- 0.00 to 0.20 Slight
- 0.21 to 0.40 Fair
- 0.41 to 0.60 Moderate
- 0.61 to 0.80 Substantial
- 0.81 to 1 Almost Perfect



Assessing Reliability

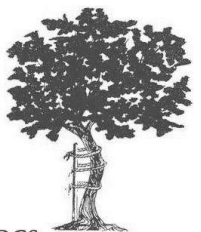
Ordinal, Ratio, Interval Data: Intraclass Correlation Coefficient (Measures Correlation and Agreement)

- < 0.50 Poor
- 0.50 to 0.75 Moderate
- > 0.75 Good
- > 0.90 Excellent



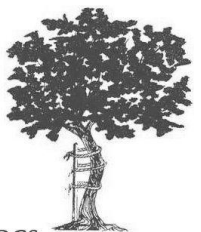
Interpretation of Change

- Is the change a result of error or limitations in the test reproducibility?
- Does the change represent a true difference?
- Does the change represent a clinically important change to the patient?



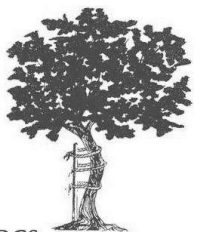
Minimum Detectable Change

- The amount of change that will exceed the threshold of error.
- Takes into account reliability values and measurement error.



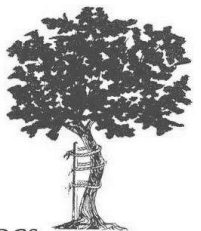
Minimum Clinically Important Difference

- The smallest change that represents an important difference for the patient
- May be a statistic based on research or determined by expert consensus



Validity

- The degree to which an instrument measures what it is intended to measure.
- Criterion-Related Validity: determined by comparing a clinical test to a known gold or reference standard. How well does the results of the clinical test match the gold standard



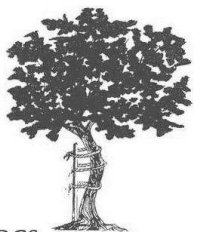
True Positive

- A positive clinical finding on a special test that is positive when tested against the gold standard.

False Positive

- A positive clinical test finding that has a negative diagnosis when using the gold standard.

Type I Error = False Positive



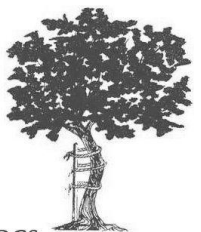
True Negative

- A test that is negative in the clinic and negative when using the gold standard

False Negative

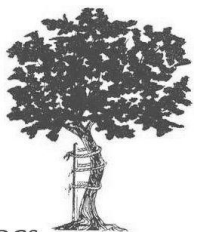
- A test that is negative in the clinic but has a positive diagnosis when using the gold standard

Type II Error = False Negative



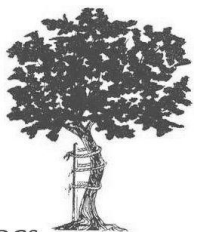
Validity results are commonly reported based on the test's:

- Sensitivity
- Specificity
- Likelihood Ratio



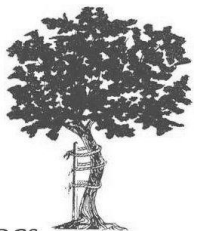
Sensitivity

- A test's ability to obtain a positive result when the condition is truly positive
- Valuable in ruling out a disorder or condition, SnNout
- A test with high sensitivity indicates a low number of false negatives
- When a test has high sensitivity, a negative result rules out the diagnosis



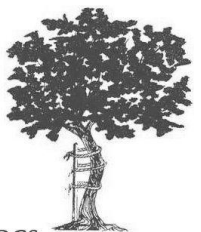
Specificity

- A test's ability to obtain a negative result when the condition is truly negative
- Valuable in ruling in a disorder or condition, SpPin
- A test with high specificity indicates a low number of false positives
- When a test has high specificity, a positive result rules in the diagnosis



Likelihood Ratios

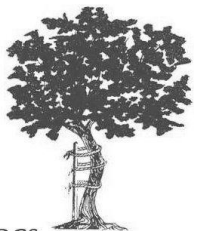
- Tells us how much more likely a person is to have a condition after the test is performed
- Incorporates sensitivity and specificity and offers greater utility than either alone



Positive likelihood ratio (+LR)

- Indicates how much the odds of the disease increases when a clinical test is positive
- The higher the +LR, the greater the value of a positive diagnosis

- +LR Interpretations
 - 1 to 2: Alters post test probability minimally
 - 2 to 5: Alters post test probability to a small degree
 - 5 to 10: Alters post-test probability to a moderate degree
 - >10: Significantly alters post-test probability



Negative likelihood ratio (-LR)

- Indicates how much the odds of the disease decreases when a clinical test is negative
- The lower the -LR, the greater the value of a negative diagnosis
- -LR Interpretations
 - 0.5 to 1: Alters post test probability minimally
 - 0.2 to 0.5: Alters post test probability to a small degree
 - 0.1 to 0.2: Alters post-test probability to a moderate degree
 - < 0.1 : Significantly alters post-test probability

