University of Maryland School of Nursing

NRSG 790: Methods for Research and Evidence Based Practice

Module 4: Understanding Results

Controlling Potential Threats to Internal Validity

* Potential threats to the internal validity of a study are listed in the table below. Contributory Design Aspects that make the threat more likely to occur, and Design Strategies to Limit the impact of this potential threat are offered.

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| **Potential Threat to Internal Validity** | **Contributory Design Aspects** | **Design Strategies to Limit** |
| **Selection/sample Bias** | * No control group * Non-random assignment to intervention & control groups * Observational designs | * Random assignment to intervention & control groups * Analyze differences between groups at baseline * Case/control matching |
| **History** | * Longitudinal designs * Designs using repeated measures * Long time period between pre- and post-measures | * Measure potential intervening variables & include in analysis * Limit time between pre- and post- observations * Random assignment to intervention and control groups (assuming that outside events impact both groups equally) |
| **Maturation** | * Longitudinal designs over a long time period, especially those involving children or individuals with conditions that progress naturally without intervention | * Measure/account for disease progression or development & other factors * Random assignment to control or intervention group |
| **Attrition/Mortality** | * Longitudinal designs * Lack of placebo, standard care or control group   demanding participation parameters | * Analyze characteristics of drop-outs; compare to rest of sample * Plan for attrition in sample size * Appropriate control conditions * Minimize participation burden |
| **Lack of Intervention Fidelity** | * Multiple intervention providers * Complexity and interactive nature of the intervention | * Observe/analyze random sample of intervention sessions to assess fidelity * Train providers how to deliver the intervention * Have a clear process and directions |
| **Testing** | * Use repeated measures and pre- test post-test designs, particularly if the same tool is used repeatedly * Longitudinal designs lacking a control group * Test battery administration | * Multiple measures and different tool versions * Mixed method design * Use of random assignment to intervention and control group |
| **Instrumentation** | * Changes to measures or instruments during the study * Biomedical instruments & calibration needs * Biological samples – obtaining, storing and testing * Instrument reliability, validity, sensitivity, specificity | * Use same instruments for pre-test and post-test data * Select instruments with known reliability & validity * Educate data collectors in use of the instrument(s) * Logical score groupings in analysis to account for floor and ceiling effects * Blinding of data collectors |
| **Contamination/Diffusion of Treatments** | * Studies involving two or more groups in the same location * Cross-over designs involving patient psychoeducation and behavior change interventions * Designs in which the intervention is not sufficiently different from standard treatment | * Plan approaches to minimize study group interactions * Use of attentional control condition * Designs with interventions sufficiently different from control or standard treatment |
| **Compensatory Rivalry between Treatment Groups** | * Two or more intervention groups with no active or attentional control or comparison to usual care only * Participants know if they have been assigned to a particular treatment or placebo group | * Use of placebo, attentional or active control groups * Blinding participants to knowing to which group (intervention or control) they have been assigned |
| **Compensatory Equalization of Treatment by Research Team Member(s)** | * Two or more intervention groups with no active or attentional control or comparison to usual care only * Members of the research team know to which group each participant has been assigned | * Use of active and attentional control conditions * Blinding members of the research team to which group participants have been assigned |
| **Statistical Regression** | * Pretest posttest designs * Repeated measures designs * Sample with extreme high and low scores * Use of instruments that do not differentiate well or capture response variation within the sample * Homogeneity of samples | * Observe changes in extreme scores * Recruit samples with sufficient diversity * Use instruments capable of differentiating between levels of knowledge, attitudes, etc. * Random assignment to control and intervention groups |
| Polit, D.F. & Beck, C.T. (2017). *Nursing Research: Generating and Assessing Evidence for Nursing Practice* (10th ed.). Philadelphia, PA: Lippincott Williams and Wilkins. | | |