Introduction to Research Design

ISSUES RELEVANT TO REHABILITATION

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...by the end of this presentation you should be able to

Formulate a research question relevant to rehabilitation research.
Identify common research designs utilized in rehabilitation research.
Identify common outcomes measures utilized in rehabilitation research.
You must first take stock of these things:

What do you want to study? What is interesting to you?
What is your skill set? Prior experience?
What kind of passion and persistence do you bring to this enterprise?
What kind of scholarly “identity” do you want to have?

Your Answers Are Important Because…

You have to develop realistic goals for what you want to do and what you can realistically accomplish
You will have to work with others and communicate effectively to others
This may require a research mentor and/or a research team
All of this requires an important investment of your valuable time
For Many of Us, Rehabilitation Research is Exciting

Interface of the physiological, psychological, social and biological; of the theoretical and the practical
In real-life settings, in the clinic and the community
Dynamic field -- always facing new challenges and opportunities
All research methods are acceptable in the quest to advance scientific knowledge, to develop meaningful and effective interventions, services and policies to improve the quality of life of those we serve

Back to Basics:

The Classic Approach

The Scientific Method

1. Ask a question
2. Do background research
3. Construct a hypothesis
4. Test your hypothesis by doing an experiment
5. Analyze your data and draw a conclusion
6. Report your results (Was your hypothesis correct?)
The More Likely Scenario:

Where Do You Get A Research Question?

From Clinical Observations
A complex case, several issues at once occurring
What will work with this person? What is going on with these people? How this turn out?

From Clinical Anecdotes
“I know this works!” (or its corollary: “That never works”)
“These people always do this”

From Prior Research and Theory
Somewhere, someone has done relevant work
What remains to be done? Has been applied to the problem/condition you face?
Real theories specify testable hypotheses
“Naïve Observer” vs “Academic Theory”

False dichotomy
We need to understand complex issues, and identify effective interventions at every level
But we also need to understand the mechanisms of change, and the conditions under which change occurs
We need to establish evidence for our practices, but we also need to challenge assumptions that we make about our practices to advance knowledge and refine our knowledge base

A scientific theory comprises a collection of concepts, including abstractions of observable phenomena expressed as quantifiable properties, together with rules (called scientific laws) that express relationships between observations of such concepts. A scientific theory is constructed to conform to available empirical data about such observations, and is put forth as a principle or body of principles for explaining a class of phenomena.
Good science is not about maintaining the status quo

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

There is nothing new about this point: 
*Skepticism is required, but speculation is not science.*

"I thought I felt a paradigm shift, but it was just my undershorts riding up."
Background Work is Required to Formulate A Good Research Question

You have to hit the library
What have others found about this issue that concerns you?
Some things have been studied **A LOT**
  - Depression and SCI (Caveat: description, yes; interventions, no)
Some things have NOT been studied much **AT ALL**
  - PTSD and multiple limb loss, or with TBI, polytrauma
  - Another example: Equine “therapy” for veterans with PTSD

How to Use Previous Work to Develop A Research Question or Hypothesis

FROM A THEORETICAL PERSPECTIVE
Example: Hope
  - **KNOWN:** High hope, low distress in disability (1991)
  - **UNKNOWN:** Does a “hope” intervention have any positive effect in rehabilitation? According to the theoretical model, it should.

FROM A CLINICAL PERSPECTIVE
Example: Equine Therapy
  - **KNOWN:** People say it works!
  - **UNKNOWN:** Does it? What do the clients really say? *Empirically, we don’t know these things.*
IMPORTANT! A Research Question IS NOT the Same as a Hypothesis

A RESEARCH QUESTION  Is NOT theory-driven
Ex: Do people get better after equine therapy?
You do not have a theoretical model explaining why they would get better, or under what conditions. This is more of a "what's this like" or "are these related" type of questions. Often exploratory.

A HYPOTHESIS  Is theory-driven
Ex: Veterans receiving cognitive processing therapy will report less PTSD symptomology at the end of treatment than veterans who received equine therapy.
This is a statement based on a premise of existing theoretical models of CPT and PTSD, and informed by the empirical literature to date.

Refine the Question*

So it can be studied
Change
“Is equine therapy helpful for veterans with PTSD” to
“Does a manualized equine therapy reduce PTSD symptoms reported by veterans?”

A good question will lead to specifics
The therapy is manualized (sessions, protocol, etc.)
We know a variable of concern (PTSD symptoms)
Gives us idea of the design (over time) and even analyses (to detect change in symptoms)

*A theory-driven hypothesis would state a testable proposition about why the change would occur
How Do We Study Your Research Question?

**Designing The Study**

- Depends on the question
- Depends on the sample required
  - Small number required?
  - Lots and lots?
  - Somewhere in between?
- Depends on the variables required
  - Demographics? Which ones?
  - Self-report measures?
  - Observable data? Recording the frequency of certain behaviors?

**Independent and Dependent Variables**

- **Independent variable (IV):** any variable that is presumed to influence a second variable (i.e., the dependent variable)

- **Dependent variable (DV):** the effect/outcome
Design Strategies

Experimental Strategy
Different values of the IV are created

Observational Strategy (non-experimental)

Combination

Controlling for Alternative Explanations

Confounding Variable: A variable that is related to the independent variable (the presumed influence) and that affects the dependent variable (the presumed effect), rendering a relational inference between the IV and the DV ambiguous.

Jaccard & Becker, 2010
Controlling for Confounding and Disturbance Variables

1. Hold the variable constant;  
2. Use matching strategy;  
3. Random assignment to experimental groups.  
4. Reduce sampling error  
   Increase sample size  
   Define groups to limit variability

Between-Subjects Design  
(aka independent groups design)

Condition A  
Condition B

The two groups include different individuals.
Advantages/Disadvantages of Between-Subjects Designs

If use random assignment, attempt to equalize the two groups on all variables, except the IV.
- Chance that could find between-groups differences.

Not susceptible to carry-over effects.

Within-Subjects Design
(aka correlated groups design or repeated measures design)

All values of the variable occur for each participant.
Advantages/Disadvantages of Within-Subjects Designs

More economical in terms of participants
- Very important when high amount of time, effort or money is needed to recruit and train research participants.

Control of confounding variables
- Participants are identical except for the IV (e.g., treatment received).

Carry-over effects
- First condition may influence performance in the second condition.
- Counterbalance.

Two Way Within-Subjects OR Mixed Between- and Within-Subjects Design

2 X 2 (Condition X Time)
Exercise

Evaluation of a new treatment for PTSD

Need: Only ~50% of patients respond to existing empirically-supported treatments.

Issues to consider for design:
- Literature: Well-established, empirically-supported treatments already exist.
- What is an appropriate control condition for the new treatment?

Possible Research Questions

- Does the new treatment work (i.e., help PTSD/functioning)?
- Is the new treatment better than a control treatment?
- Is the new treatment better than existing (established treatment)?
- Does the new treatment work for nonresponders to existing treatments?
- Do certain people respond better to new treatment versus existing treatments (i.e.,...
Example 1: Between-Subjects Design

New Mindfulness Treatment versus Education Control

Is the new treatment better than a control treatment?

Example 2: Between-Subjects Design (non inferiority/equivalence design)

New Mindfulness Treatment versus Prolonged Exposure

Is the new treatment better than existing (established treatment)?
Example 3: Cross-Over Design

Is the new treatment a viable 2nd line treatment for non-responders? Does the order of treatment matter?

Example 4: Mixed Between- and Within-Subjects Design

Does the new treatment work for nonresponders to existing treatments?
Summary

Design of study depends on the question you are asking.
Question you are asking depends on your homework (i.e., where is the literature at?)
Existing data and theory will drive your hypotheses.
Important to control for alternative explanations in the design to increase confidence in the question you are answering.

Choosing the Right Assessments

Strongly depends on your research question.
Depends on your design (e.g., length of questionnaire, frequency, feasibility).
Look to the literature to facilitate cross-study communication across measures.
Avoid “kitchen sinking”
Characterizing the Sample

Demographics

Population-specific measures (i.e., factors that characterize the sample you are studying, e.g., military history)

Outcomes

Defining how you want to measure outcomes:
- How will you know a treatment works?
- What is the important effect you want to measure?
Factors that Influence Outcomes

Should be hypothesis/theory-driven.

**Mediators**: explain *why* there is a relationship between two variables.

**Moderators**: explain *how* and *under what conditions* a relationship exists.

Sample Assessment for Mindfulness PTSD Study:
Sample Characteristics

*Demographic questionnaire* (age, gender, race/ethnicity, education, etc)

*Military history form* (rank, branch, deployments)

*Trauma History Questionnaire* (Green, 1996)
Sample Assessment for Mindfulness PTSD Study:

Assessing PTSD

*Clinician Administered PTSD Scale* (CAPS; Blake et al., 1995)

*PTSD Checklist: Military and Civilian Versions* (PCL; Weathers et al., 1993)

Need to decide timing and frequency of administration based on design and hypotheses.

Sample Assessment for Mindfulness PTSD Study:

Assessing Mindfulness

*Mindful Attention Awareness Scale* (Brown & Ryan, 2003)

*Acceptance and Action Questionnaire-II* (AAQ-II; Bond et al., 2011)
Sample Assessment for Mindfulness PTSD Study:
Assessing Other Factors

*Beck Depression Inventory-II (BDI-II; Beck et al., 1996)*

*Alcohol Use Disorders Identification Test (AUDIT; Babor et al., 2001)*

*Traumatic brain injury interview/Neuropsychological testing*

*World Health Organization Disability Assessment Schedule II (WHODAS II; World Health Organization)*

### Common Outcomes in Rehabilitation Research

**Broad Assessment of Functioning**
- General
- Mental Health (diagnosis, mood)
- Social/Relationships
- Family
- Work (employment status, days worked)
- Physical (health/injuries, pain)
- Cognitive (neuropsych, TBI)
Summary

It is important to develop a clear research question. From this, you can design your study and hypotheses. Choose assessments based on the characteristics of your sample and hypotheses.

Choosing and Working with a Mentor

Background complementary
Has established research career
  publications, grants
Committed, generally, and to you, specifically
Understands and shares your goals and expectations congruence
Personal compatibility must match on several levels
Reciprocal relationship you deliver
Pursuing Grant Funds

Not all studies are fundable
Grant funds are provided
  - to address priorities
  - in areas where research is needed now
To be competitive
  - must have a track record
  - must have prior work relevant to the priority area
Your research ideas may still be very important to the field! priorities change over time

Let’s talk about the questions you are interested in studying

(Relationships? Outcomes? Is something effective?)
Designing your study

What is your question?
What do you know about the field?
What are your hypotheses?
How will you design your study to answer your question/hypotheses?
Are there any possible alternative explanations that could result from your study?
How will you measure the question to be answered?

Questions or Comments?
References


WHODAS-II