



## The Discerning (SI) Research Consumer

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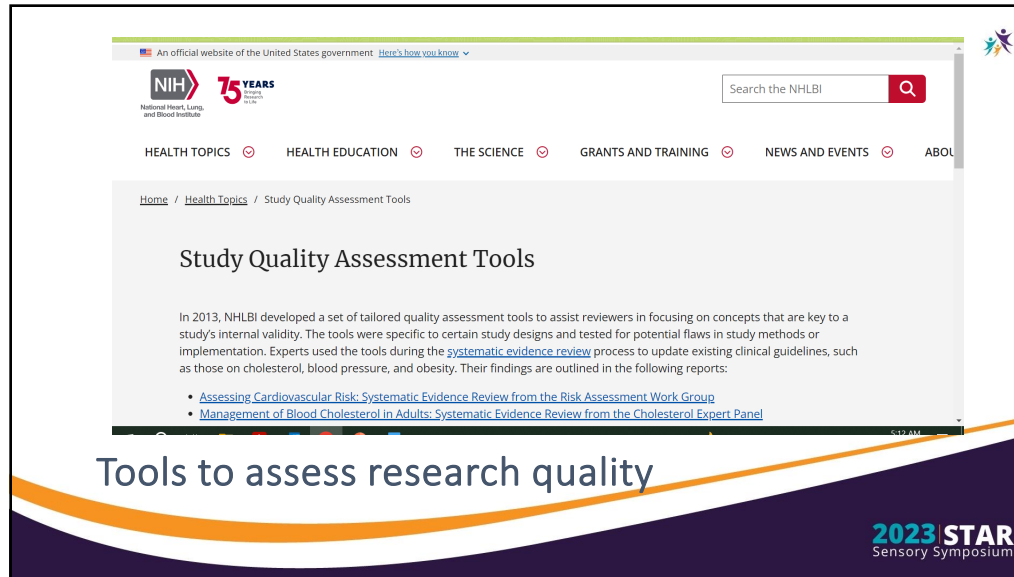
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### What is "good" research?

- Theory based
- Grounded in previous research
- Guided by well considered research question
- Structured by appropriate methodology
- Matches data with statistical analysis, research question, study design
- Produces generalizable and representative results
- Identifies limitations
- Generates new questions

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An official website of the United States government. Here's how you know

NIH 75 YEARS  
National Heart, Lung, and Blood Institute

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Home / Health Topics / Study Quality Assessment Tools

## Study Quality Assessment Tools

In 2013, NHLBI developed a set of tailored quality assessment tools to assist reviewers in focusing on concepts that are key to a study's internal validity. The tools were specific to certain study designs and tested for potential flaws in study methods or implementation. Experts used the tools during the [systematic evidence review](#) process to update existing clinical guidelines, such as those on cholesterol, blood pressure, and obesity. Their findings are outlined in the following reports:

- [Assessing Cardiovascular Risk: Systematic Evidence Review from the Risk Assessment Work Group](#)
- [Management of Blood Cholesterol in Adults: Systematic Evidence Review from the Cholesterol Expert Panel](#)

## Tools to assess research quality

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### "Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies"

- ✓ 1. Was the research question or objective in this paper clearly stated?
- 👥 2. Was the study population clearly specified and defined?
- 📊 3. Was the participation rate of eligible persons at least 50%?
- 👤 4. Were all participants recruited from similar populations? Were inclusion and exclusion criteria delineated and applied uniformly to all participants?
- 📈 5. Was a sample size justification, power description, or variance and effect estimates provided?...

<https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools>

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## And more...



- Was baseline performance established?
- Did the intervention last long enough?
- Did investigators consider the impact of differences in number of sessions between participants?
- Were control and outcome variables defined, valid, reliable, and implemented consistently?
- Were potential confounding variables considered?
- Were treatment effects measured more than once?
- Were the outcome assessors blinded to participant group membership?
- Did investigators consider the impact of loss of participants?

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## Clinically relevant



- Answers your clinical question*
- Applicable/relevant to your practice*
- Supports your clinical reasoning, reflection, and clinical decision making*
- Supports your efforts to be an evidence-based practitioner*

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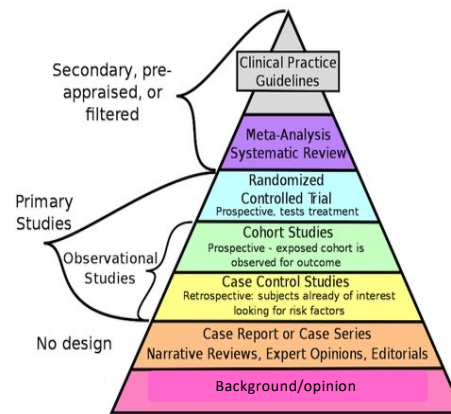
## Evidence-based Practice

- Evidence from research
- Evidence from practice
- Client expertise and preferences
- Expertise of other professionals
- Contextual evidence

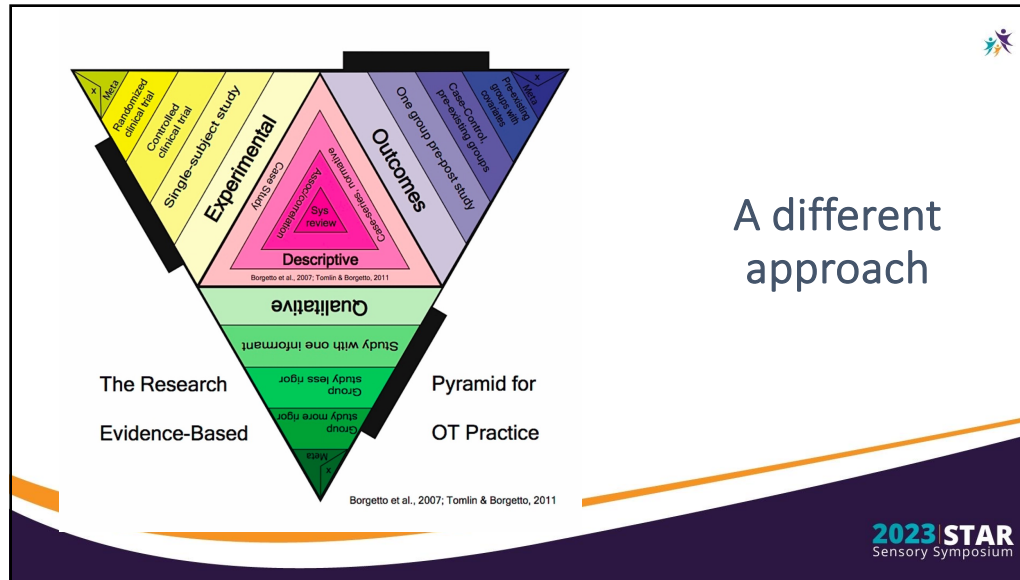


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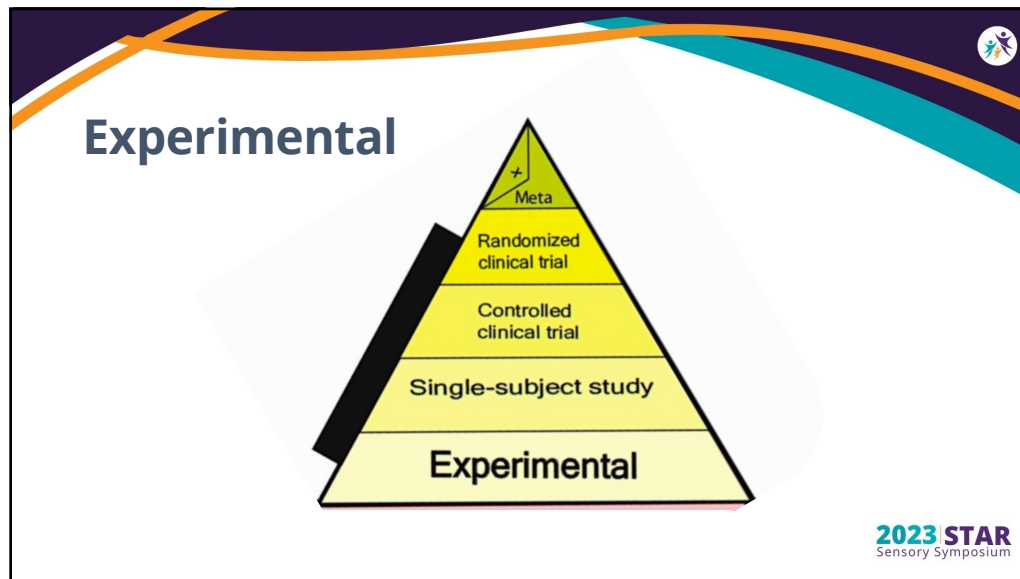
## Classic evidence pyramid



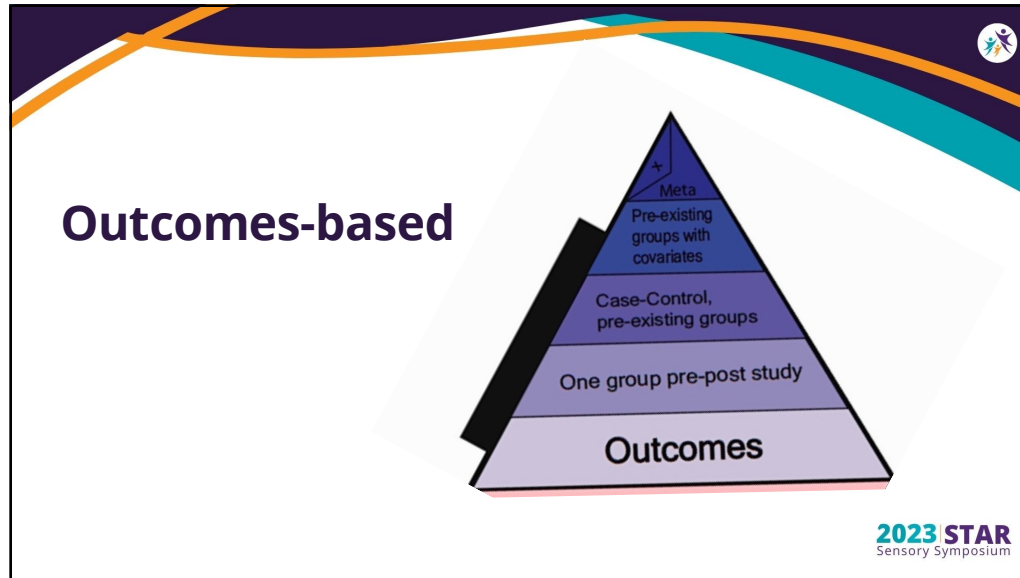
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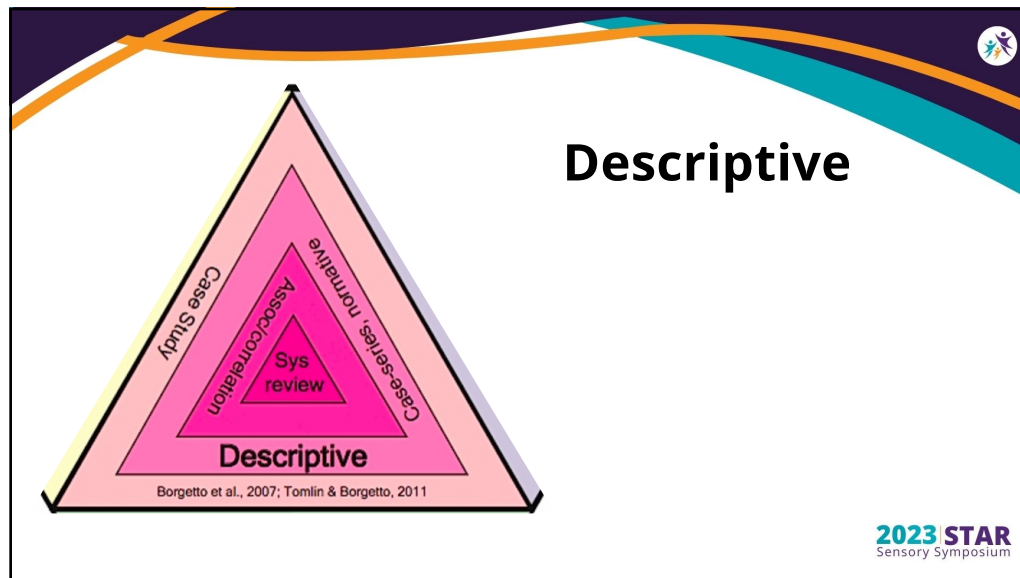
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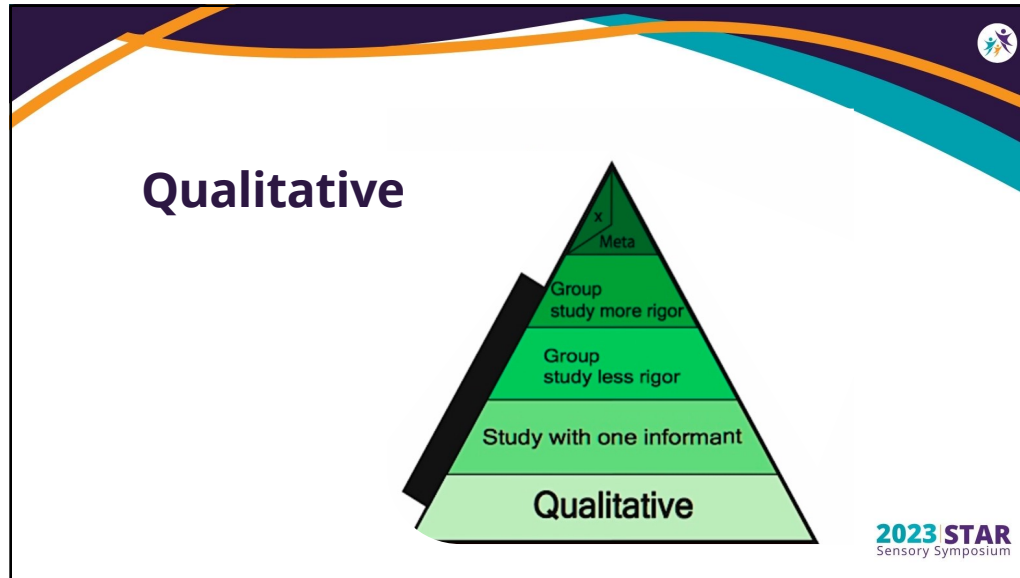
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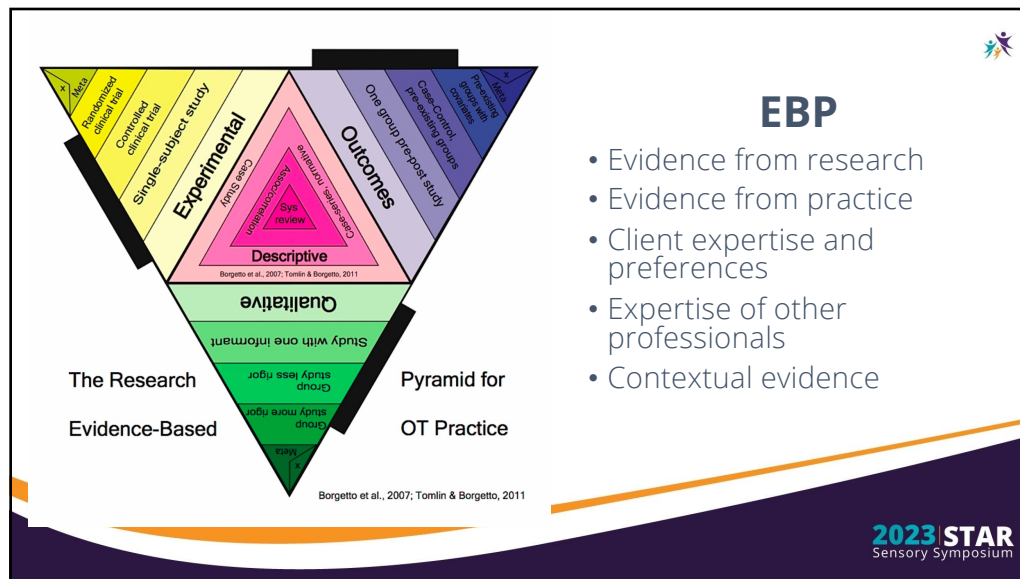
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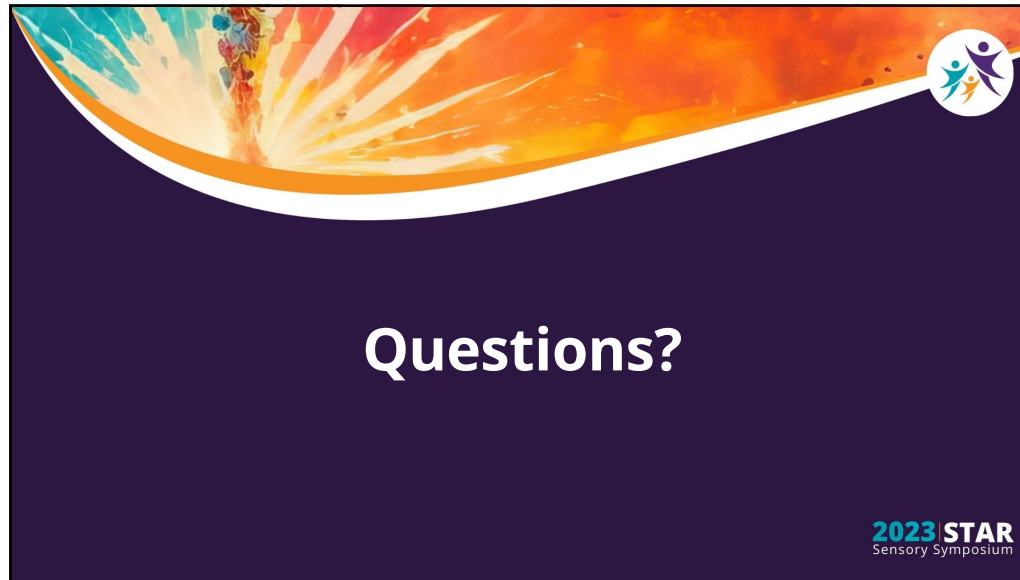
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# Questions?

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# Randomized Control Trials

Roseann C. Schaaf, PhD., OTE/L, FAOTA  
Research Director, Collaborative Leadership in Ayres Sensory Integration  
Professor, Thomas Jefferson University

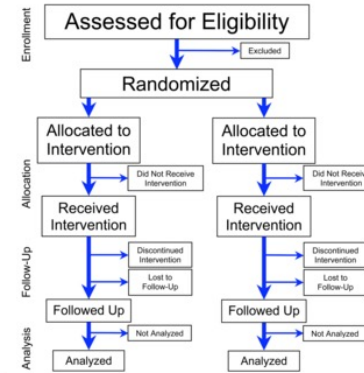
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## What is an Randomized Control Trial (RCT)

- A study that randomly assigns participants to an experimental group and a control group
- One of the best ways to study efficacy of treatment
  - Excludes bias and controls variability
  - Examines cause-effect relationship
- Considered one of the highest levels of evidence
- Referred to as gold standard in intervention research

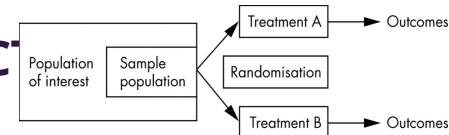


Hariton, et al. (2018)

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## Designing and RCT




- Carefully select the population
  - Randomly assigned to either intervention or control/comparator group
    - Balances participant characteristics between groups
  - Concealment of participants (no knowledge of which group participants are allocated to) – often computer generated
  - Number of participants based on power calculation which determines how many are needed to reliably determine if outcome is related to intervention
- Must keep evaluators (and interventionists) blind to intervention arm
- Clearly describe the intervention in a replicable way
- Choose outcomes that are psychometrically sound, meaningful
- Follow-up at a specific interval

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## Components of a High Quality RCT

(Cook, et al., 2015 CEC Quality Standards)





Article  
**CEC's Standards for Classifying the Evidence Base of Practices in Special Education**  
Journal of Special Education, 2015, Vol. 49, No. 2, 104-114  
 Copyright © Council for Exceptional Children, 2014  
 DOI: 10.1177/0022022114264819  
 SAGE

- Clearly and comprehensively describes context and setting
- Clearly describes participants: demographics, diagnosis and related conditions
- Clearly describes the intervention, its active ingredients who will deliver it, any special training needed, replication, and the procedures (use a manual!)
- Internal validity: Evidence that the independent variable (ASI) causes change in the dependent variable (participation in tasks and activities)
- Outcome measures are relevant and with adequate psychometrics
- Data analysis is appropriate to evaluate outcomes and measures effect size




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## Challenges of RCTs

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- Costly
- Time intensive
- Requires upfront time to train intervention
- Must have fidelity measure
- Obtaining a clean sample
- Controlling for variables
- Choosing outcomes that are sensitive and meaningful (and psychometrically sound)
- Loss to follow-up

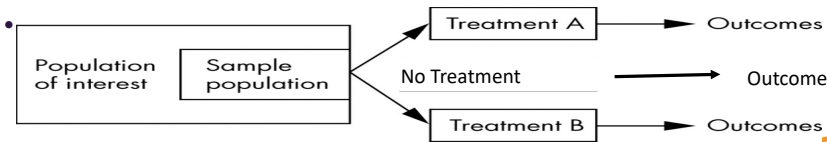


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## Comparative Effectiveness (CER) RCT's



- Comparison of two interventions (may include a no-treatment group)
- Aims to generate evidence from real life setting
- Allows examination of effectiveness (rather than efficacy) – which works best?



Williams, et al, 2016 **2023 STAR**  
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## RCTs and CER's on ASI



- Miller, Coll, et al 2007 (SI vs control)
- Pfeiffer, et al, 2011 (SI vs group activities)
- Iwanaga, et al, 2013 (group activities vs. SI)
- Schaaf, et al, 2014 (ASI vs no treatment)
- Kashefimehr, et al, 2017 (SIT vs control)
- Omairi, et al, 2022 (ASI vs control)
- Randell, et al, 2022 (senITA: ASI vs control)
- Schaaf, et al., in press (ASI vs. ABA vs contrc



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## Current status of research

- A manualized, systematic protocol for OT-ASI
  - Describes intervention in detail
- Active ingredients of ASI are outlined
- A validated fidelity measure
- A sensitive, meaningful outcome measure (GAS, PEI)
- OT-ASI improves participation in individualized goals
- OT-ASI improves socialization
- OT-ASI may improve independence in daily living skills (PEDI)
- OT works!



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## We still need to learn

- What are the mechanisms of action?
- Which aspects of the intervention are useful for which outcomes
- Which characteristic benefit most and from which interventions
  - sensory characteristics
  - Cognitive level
  - Family and socioeconomic situations
- Adequate dosage: intensity and frequency
- Can it work in settings other than clinics
  - Evidence for school-based ASI



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## Guidelines for Discerning Consumers of Research



- Evaluate quality of research study
  - Use CEC or other quality indicators for RCTs and CER
- Is the sample clearly described and are groups comparable?
- Is the intervention described in a replicable manner?
- Determine if outcome measures are psychometrically strong and meaningful
- Are intervention and intervention targets described in a replicable way?
  - Do they follow a manualized or evidence-based approach
- Is the stated relationship between the intervention ingredients and the functional targets clearly described and tested?

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## Better Research → More Precise Therapy = Better Outcomes



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## Single Subject Research Design (SSRD) Studies


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## What is a Single Subject Study



- A type of quantitative research
- Focuses intensely on the behavior of the individual participants (2-10)
- Highly structured data collection
  - quantify change in behavior through experimental manipulation
- SSRD are widely used
  - if they use rigorous methods are considered valid for documenting treatment effectiveness
- Not a case study
  - an in-depth analysis and description of one individual
- Not a group design
  - larger number of subjects
  - reports findings in terms of means and standard deviations

Horner et al., 2005; Tate et al., 2015, 2016

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## Why use SSRD

- Links science to practice and practice to science
- Fits easily into clinical settings
- Considered rigorous
  - Rigor varies depending on the type of design
  - All conditions are held constant except for the introduction of the intervention
- Experimental control occurs within each subject
- Individual serves as their own control
  - Person is both the control and the experimental condition



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## Characteristics of a Single Subject Study

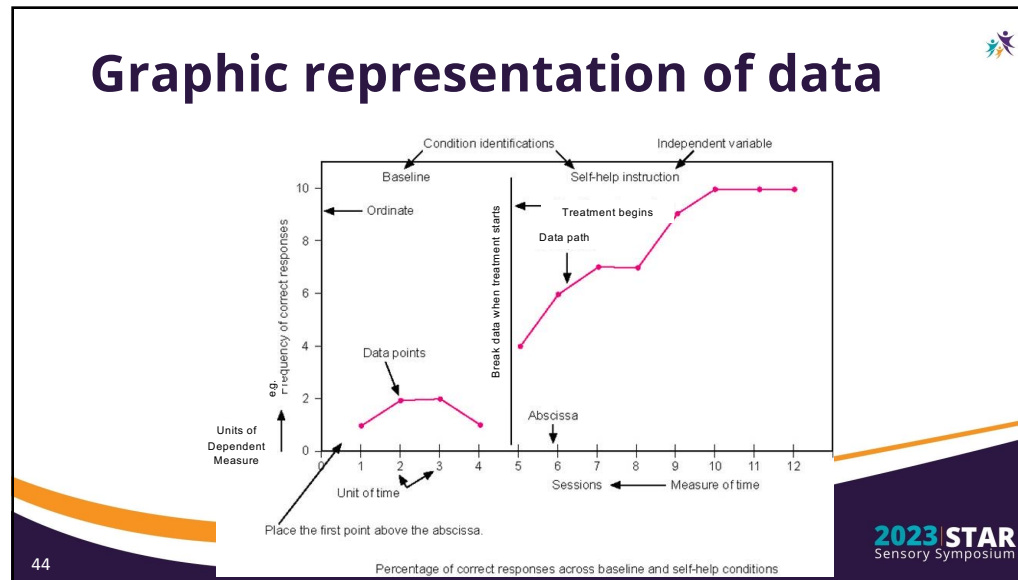
- Behavioral change is individualized , does not rely on standardized measures (e.g. probe)
- Outcome is measured repeatedly over time taken with and without treatment
- Phases or conditions are compared
  - A no intervention Baseline Phase condition followed by the introduction of the Intervention Phase (treatment)
- Change in behavior is represented graphically
- Outcome is plotted on the y axis and time on the x axis (weeks, treatment sessions)



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## Advantages of single subject research

- Focuses intensively on the behavior of the individual participants
- Sensitive to individual differences
- Able to discover causal relationships through manipulation of the intervention (aka the independent variable)
  - Careful measurement of the outcome (aka dependent variable)
  - Control of extraneous variables
- Has social validity
- Group data can hide individual differences
  - Ex. Intervention that has a positive effect on half and negative effect on half, on average would have no effect at all



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## Feasibility of Conducting Single Subject Studies



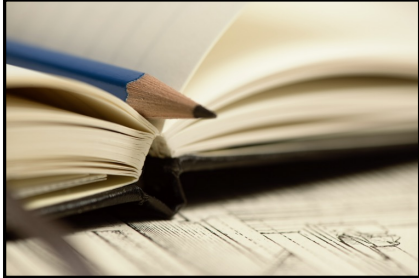

- Best done as a team
- Fewer number of subjects needed
- Multiple baseline design starts the intervention with varying timing without the issues of withdrawal or reversal
- Nonconcurrent design permits intervention to occur at non-overlapping times from the other participants
- Fidelity of program
- Reliable outcome measures linked to occupational engagement



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## Findings from Existing SSRDs Related to ASI

- Kuhaneck et al., 2023
- Whiting et al., 2023
- Andelin et al., 2021
- Schoen et al., 2019
- Preis & McKenna, 2014
- Watling & Dietz, 2007

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## Evidence (Experiential) and Qualitative Research

Melissa Park, MA OT PhD with Keven Lee MSc ergOT PhD  
School of Physical & Occupational Therapy, Faculty of Medicine & Health Sciences, McGill University

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## What is experiential evidence?



Experiential Evidence is used to tailor EBP to particular persons in particular contexts

- Based in **practical knowledge**, experience over time: **1<sup>st</sup> person perspectives (i.e., I/we)** (Friesen, 2012)
- “The collective experience and expertise of those who have practiced or lived in a particular setting, often referred to as **intuitive or tacit knowledge**” (CDC website)
- Attending to **deep** experiential knowledge “helps untangle some of the challenges of EBP” (Noorani, Karlsson, & Borkman, 2019: 217)

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## Qualitative research in occupational therapy

Since the 1970s' **interpretive turn** (Frank & Polkinghorne, 2010)

- **First generation, primary approaches to experience & meaning**
  - ✓ **Anthropology: Ethnography to study culture**
  - ✓ **Psychology: Phenomenology to study conscious experience**
  - ✓ **Sociology: Grounded theory to study experiential dimensions of social processes**
- **Second generation, new approaches to structures/systems**
- **Epistemic plurality & epistemological pluralism** (Kinsella, 2012)

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## Scarcity of qualitative research

### Ayres SI

1. **Grounded theory: Parent perceptions of outcomes and hopes for SI** (Cohn, 2001a, 2001b, 2014).
2. **Ethnography: Clinical reasoning & transformational processes in SI:**
  - **Enacted, emergent narrative practices** (Mattingly, 2000)
  - **Narrative practices of intersubjectivity (e.g., making scenes, embodied metaphors, throwing breaches)** (Park, 2008, 2010, 2012)
  - **Outcomes (e.g., empowerment, joy, embodied pleasure)**

### (A)SI/SP-T (rapid review)

1. **Retrospective, qualitative: Adolescent & adult perceptions of SBI** (Miller, Schoen, Schmitt & Porter, 2023)
2. **Contextual barriers to ASI:**
  - **Phenomenology: Encountered by parents** [South Africa](#) (Smit, Jongh, & Cook, 2018)
  - **Survey: Facing therapists** [Malaysia](#) (Rahman, Kadar & Harun, 2022)
3. **Content analysis: Sensory modulation & schizophrenia** [Australia](#) (Machingura, Lloyd, Murphy, Goulder, Shum & Green, 2021)
4. **Experience & case report** [Brazil](#) / US (Oliveria & Souza, 2022; Rocco, Drobynyk, Bruce & Soumerai, 2023)

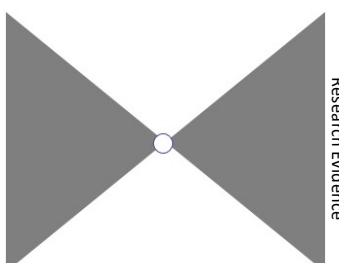
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## “Fit” with emerging trends

Implementation Science


Black Box

Knowledge ‘translation’



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## What are ways of knowing? (Kinsella, 2012)




**Table 6.1** Knowledge paradigms

	Technical interests ↔	Practical interests ↔	Emancipatory interests	
Habermas (1971)	Empirical-Analytic	Historical-Hermeneutic	Critical-Emancipatory	
Crotty (2003)	Objectivism	Constructionism	Subjectivism	
Guba and Lincoln (2004)	Positivism	Post-Positivism	Constructivism	Critical
Ponterotto (2005)	Positivism	Post-Positivism	Interpretive	Critical
Kezar (2004)		Hermeneutic/ Interpretive	Critical	Post-modernism

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## What is clinical reasoning? (Mattingly, 1991a/b; 1994; 1998)



	Technical interests ↔	Practical interests ↔	Emancipatory interests
Habermas (1971)	Empirical-Analytic	Historical-Hermeneutic	Critical-Emancipatory
Crotty (2003)	To explain or predict (if x, then y)	To understand	To critique
Guba and Lincoln (2004)	Generalities	Particularities	Structures/Systems
Ponterotto (2005)	Function, adaptation	Values, meaning	Advocacy, justice

(Mattingly, 1991a/b 1994, 1998)

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# What is (everyday) research?

	Technical interests	↔ Practical interests	↔ Emancipatory interests
Habermas (1971) Crotty (2003) Guba and Lincoln (2004) Ponterotto (2005) Kezar (2004)	Empirical-Analytic  Biomedical / Rehabilitation Evidence	Historical-Hermeneutic	Critical-Emancipatory

**Hermeneutic understanding invites emancipatory interests.** (Gadamer in Kinsella 2012: 73)

**In the clinic:**  
**"What is the best good?"** (Mattingly, 1998)

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Biomedical Rehabilitation Knowledge


- The inner lifeworld and subjectivities of persons,
- The role of the body as a medium of perception,
- Reflexive attention to processes of interpretation,
- The complexity of context,
- The positionality of scholars,
- The relationship of the researcher to the researched,
- The relationship between objectivity and subjectivity,
- The distinction between fact and value,
- The distinction between explanation and understanding,
- Issues of language and discourse,
- The ethics of representation and voice,
- The complex social dimensions of human life,
- Issues of politics, power, culture and ideology,
- Consideration of gender, race, and sexual orientation, and
- Consideration of knowledge generation as a social practice.

**Practical and emancipatory interests**  
 (Kinsella, 2012: 76)

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## Interpretive challenges & resources

(Park, Bonsall, Fogelberg, 2022)

<p style="text-align: center;"><b>Aporias (impasses)</b></p> <ol style="list-style-type: none"> <li><b>1. How do we interpret the words, experiences of another?</b></li> <li><b>2. How do we know we are not “projecting” our own experiences onto another?</b></li> <li><b>3. How do we resolve the tension between procedures/values (explanation/understanding)?</b></li> </ol>	<p style="text-align: center;"><b>Hermeneutics (systematic methods/meaning)</b></p> <ul style="list-style-type: none"> <li>• <b>Particularities or “peculiarities” in expressions of life</b> (Dilthey, 1927/1977)</li> <li>• <b>“...foregrounding one’s own foreknowledge and prejudices”</b> (Gadamer, 1975/2004: 271)</li> <li>• <b>Distanciation as “not to project but to expose oneself”</b> (Ricoeur, 1981: 106)</li> </ul>
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## Key Considerations in qualitative research

- 1. “Gazing anew”** (Lawlor, 2003)

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## Fundamental difference in “being-with”

Lawlor, M. C. (2003). Gazing anew: The shift from a clinical gaze to an ethnographic lens. *AJOT*, 57(1), 29-39.

Participant observations	Clinical observations
<ul style="list-style-type: none"> <li>• open to vulnerability and the ambiguous implications of a vulnerable stance</li> <li>• absorption in the events, words, and daily lives of others</li> <li>• the need to “understand”</li> </ul>	<ul style="list-style-type: none"> <li>• can mask, delimit or minimize vulnerability.</li> <li>• fix and be helpful</li> <li>• the need to “act” (or explain)</li> </ul>

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## Key Considerations in qualitative research

1. **“Gazing anew”** (Lawlor, 2003)
2. **Epistemic reflexivity** (Kinsella & Whiteford, 2009; Kinsella, 2012)
3. **“Knowing from where I respond”** (Zafran, 2019)

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## Guidelines for rigor

### Framework for design/evaluation

**Figure 1** Three broad types of qualitative health research.

(Rendle et al., 2019:3)

### Quality checklists / tools

- **Consolidated Criteria for Reporting Qualitative Research (COREQ)**
- **Standards for Reporting Qualitative Research (SRQR) in medical education**
- **Mixed methods appraisal tool (MMAT)**

(see also Johnson et al., 2020)

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