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Empowering Practice: Validating Outcomes in Evidence-Based Clinical Practice

Lisa K. Kenyon PT, DPT, PhD, PCS
PhysicalTherapy.com Webinar
January 9, 2018

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Acknowledgment

Thank you to the families who have given their permission to show photographs of their children, to use the children's first names, and to describe the children's condition and abilities during this presentation

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Objectives

As a result of this course, participants will be able to:

- 1) Identify five elements of an effective single-subject research design.
- 2) Describe at least three key points in the clinical application of single-subject research designs within seating and mobility practice.
- 3) Describe the seven steps in designing a single-subject research study to evaluate specific seating and mobility outcomes within clinical practice.

Why Evaluate Clinical Outcomes???

What is an SSRD?

- **A research design**
- Study of a single individual or system (e.g., a particular hospital, department, etc.)
- Involves repeated measurement of the dependent variable(s) under rigorous, controlled conditions
 - The dependent variable (AKA the target behavior)
- Includes systematic introduction of the independent variable/intervention
 - Sometimes withdrawing or varying independent variable

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Why an SSRD?

- Allows a clinical question to be answered or an hypothesis(es) to be tested
- Can be used to study comparisons between
 - Several interventions
 - Components of interventions
 - Intervention and no-intervention conditions

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The primary purpose of an SSRD is to determine whether there is a causal or functional relationship between a clinician-manipulated independent variable (intervention) and a meaningful change in the dependent variable (target behavior).

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Purpose: To compare physiological functioning, switch activation, and response accuracy in a 19-year-old student with quadriplegic cerebral palsy and neurologic scoliosis using 2 different seating systems

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Purpose: To compare physiological functioning, switch activation, and response accuracy in a 19-year-old student with quadriplegic cerebral palsy and neurologic scoliosis using 2 different seating systems

A custom-molded seating system resulted in:
 ↑SaO₂, ↓HR, RR, and BT fluctuations, ↓time to activate a switch, slight improvement in accurately responding to “yes/no” questions

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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This ability to establish a causal relationship is one of the ways that SSRDs differs from case reports. A case report is a “pre-scientific” report of practice that cannot establish a causal or functional relationship.

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Knowledge Check

What distinguishes a single-subject research design (SSRD) from a case report?

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Why an SSRD?

- Allows us to
 - Address real clinical questions in real clinical situations
 - Accommodate specific client-related factors
 - These factors to become part of the outcome assessment process
 - Explore outcomes in small client-groups
 - Clients with “rare” conditions/diagnoses or atypical/complex presentations

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Why an SSRD?

- Allows us to
 - Address real clinical questions in real clinical situations
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 - These factors to become part of the outcome assessment process
 - Explore outcomes in small client-groups
 - Clients with “rare” conditions/diagnoses or atypical/complex presentations
 - **Validate practice**

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What is an SSRD?

- Two core features distinguish an SSRD from other research designs and from case reports
 - Repeated, systematic measurement of the dependent variable(s)/target behavior(s) over time
 - At frequent and regular intervals
 - Design phases
 - Baseline phase
 - Intervention phase

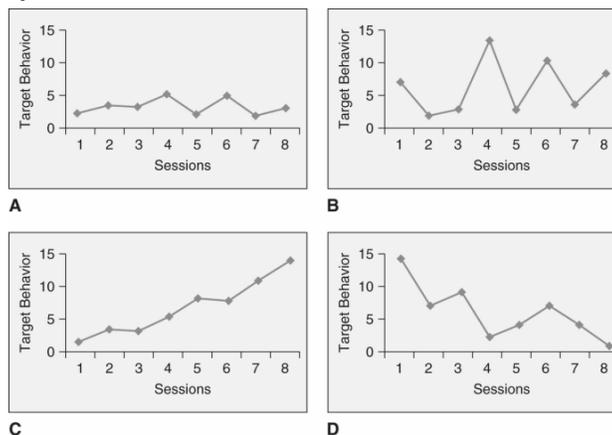
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Baseline (A) Phase

- Period without the intervention - reflects natural state
- Provides a standard for evaluating possible intervention effects
- Repeated measurement of the target behavior
 - Ideally until stability is demonstrated
- **Ideally should consists of 5 or more data points**
- Subject acts as his/her own control
 - Subject-specific characteristics become part of the research process

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Sample Baselines



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Intervention (B) Phase

- The intervention (independent variable) is introduced
- Repeated measurement of dependent variable/target behavior continues
- Intervention phase should be at least as long as the baseline phase
 - **Ideally consists of 5 or more data points**

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Purpose: To compare physiological functioning, switch activation, and response accuracy in a 19-year-old student with quadriplegic cerebral palsy and neurologic scoliosis using 2 different seating systems

Design: Single-subject design

- Baseline phase: original seating (standard planar inserts)
- Intervention phase: a custom-molded seating
- Baseline phase: original seating (standard planar inserts)

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Evaluating Outcomes: Steps in Conducting an SSRD

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Steps in Conducting an SSRD

1. Identify the clinical question
2. Describe the proposed client/clients
3. Identify the target behavior
4. Determine how to measure the target behavior
5. Describe the intervention
6. Determine the schedule & sequence of testing and intervention
7. Analyze the data

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Step 1: Identify the Clinical Question

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Step 1: Identify the Clinical Question

- What is it that you want to investigate?
- Clearly identify the clinical problem
- Make sure that your question is
 - Not too broad
 - Not too narrow

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Step 1: Identify the Clinical Question

- What is it that you want to investigate?
 - Example: Notice that certain clients “do” better in custom-molded seating. But is a custom-molded seating “better” than commercially available, standard seating?
- Clearly identify the clinical problem
 - Need to identify what is it that is “better”
 - Iterative process until a workable question is reached

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Step 1: Identify the Clinical Question

- What is it that you want to investigate?
 - Example: Notice that certain clients “do” better in custom-molded seating. But is a custom-molded seating “better” than commercially available, standard seating?
- Clearly identify the clinical problem
 - Need to identify what is it that is “better”
 - Iterative process until a workable question is reached

Clinical Question: Is there a difference in oxygen saturation levels when a client is positioned in a custom-molded seating system versus a standard seating system?

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Other Sample Clinical Questions

- **General Question:** Would power mobility training be beneficial for this client?

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Other Sample Clinical Questions

- **General Question:** Would power mobility training be beneficial for this client?
 - **Clinical Question:** Does power mobility training improve cause and effect skills in a child who has multiple, severe disabilities?

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Other Sample Clinical Questions

- **General Question:** Would power mobility training be beneficial for this client?
 - Clinical Question: Does power mobility training improve cause and effect skills in a child who has multiple, severe disabilities?
- **General Question:** Which access method would be best for this client?

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Other Sample Clinical Questions

- **General Question:** Would power mobility training be beneficial for this client?
 - Clinical Question: Does power mobility training improve cause and effect skills in a child who has multiple, severe disabilities?
- **General Question:** Which access method would be best for this client?
 - Clinical Question: Is a joystick or a switch a better access method for this client?

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Step 2: Describe the Proposed Client/Clients

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Step 2: Describe the Proposed Client/Clients

- What type or types of clients should I focus on in this question?
 - If you have a specific client in mind, describe that client!
 - Example:
 - I have a teenager with CP who uses a head array to drive his PWC
 - He wants to try a joystick
 - Decide to use SSRD to explore this possibility
 - I describe this teenager using functional classification scales (GMFCS, MACS, CFCS, etc.)

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Step 2: Describe the Proposed Client/Clients

- Helps to develop your inclusion/exclusion criteria
 - But in SSRDs, these are often broader and less restrictive than in other studies
 - Remember!!! Individual client characteristics are embraced and retained in SSRDs!

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Sample Inclusion

- Diagnosis of **cerebral palsy** - Gross Motor Function Classification System (GMFCS) Level IV or V
- ≤ **4 years** of age
- A manual **wheelchair** or adaptive stroller
- Parental/guardian **permission** to participate in the study

Sample Exclusion

- Power mobility training or use within **previous 12 months**
- Inability to tolerate sitting in the manual wheelchair/adaptive stroller **for a 60-minute period**

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Description: a 19-year-old young man diagnosed with spastic quadriplegic CP, GMFCS level V, who had received school-based PT for 16 years.

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Description: a 19-year-old young man diagnosed with spastic quadriplegic CP, GMFCS level V, who had received school-based PT for 16 years.

How could this description be improved?

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Step 3: Identify the Target Behavior

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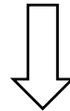
Step 3: Identify the Target Behavior

- What is it that you are trying to change or improve?

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Step 3: Identify the Target Behavior

- What is it that you are trying to change or improve?



That's the
target
behavior!!!!
!

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Step 3: Identify the Target Behavior

- Must be quantifiable
 - Could be an overt behavior (Functional performance, frequency of a behavior, etc.)
 - Could be a physiological response (Oxygen saturation levels, etc.)
 - Could be a subjective report (Pain reports, etc.)
- May have one or more target behavior

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Target variables:

- ❖ Cardiopulmonary functioning – SaO₂, HR, RR, BT (**ICF Domain: Body function and structure**)
- ❖ Time to activate communication switches (**ICF Domain: Activity**)
- ❖ Accuracy of answering questions (**ICF Domain: Participation**)

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Knowledge Check

In single-subject research design, what term is used to indicate the dependent variable?

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Step 4: Determine How to Measure the Target Behavior

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Step 4: Determine How to Measure the Target Behavior

- May be through use of a standardized test
 - Examples: Wheelchair Skills Checklist, Seated Postural Control Measure
- May be a frequency count
 - Examples: Number of positive fascial expressions, number of self-abusive episodes, etc.
- Want to avoid a learning effect within the testing

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Target variables:

- ❖ Cardiopulmonary functioning
 - ❖ **SaO2 & HR: Pulse ox**
 - ❖ **RR: Number of breaths per minute**
 - ❖ **BT: infrared thermometer**
- ❖ Time to activate communication switches
 - ❖ **5 "yes/no" questions – 2 switches - Measured time it took to reach a switch**
- ❖ Accuracy of answering questions
 - ❖ **Number of correct answers to the 5 "yes/no" questions**

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Step 5: Describe the Intervention

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Step 5: Describe the Intervention

- The intervention = the independent variable
- Want to be as detailed and specific as possible
 - What will be done?
 - How will it be done?
 - Who will do it?
 - Where will it be done?

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Step 5: Describe the Intervention

- Power mobility training
 - The intervention must be replicable
 - Details important
 - TIDieR checklist and guide for describing interventions
<http://www.equator-network.org/reporting-guidelines/tidier/>

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Step 6: Determine the Schedule & Sequence of Testing and Intervention

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Step 6: Determine the Schedule & Sequence of Testing and Intervention

- How often will the target behavior be measured?
- What combinations of baseline and intervention phases will be used?
- How long will each baseline phase be?
- How long will each intervention phase be?

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Step 6: Determine the Schedule & Sequence of Testing and Intervention

- How often will data on the target behavior be collected?
- What combinations of baseline and intervention phases will be used?
- How long will each baseline phase be?
- How long will each intervention phase be?



Depends on your clinical question!

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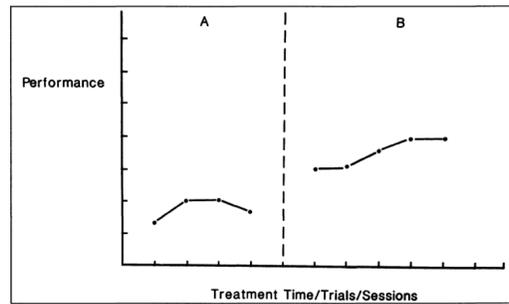
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Basic A-B Design

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Simple SSRD: A-B Design

- 1 baseline phase and 1 intervention phase
- Limitations:
 - **Poor control = threats to internal validity**
- Solutions?
 - Replication (Add phases, repeat across subjects, or add interventions)



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Knowledge Check

In single-subject research design, what letter is used to delineate:

The baseline phase?

The intervention phase?

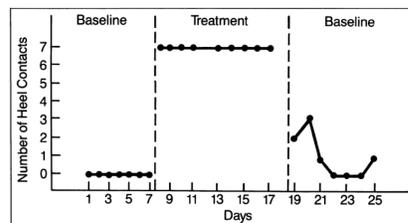
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A-B-A and A-B-A-B Designs

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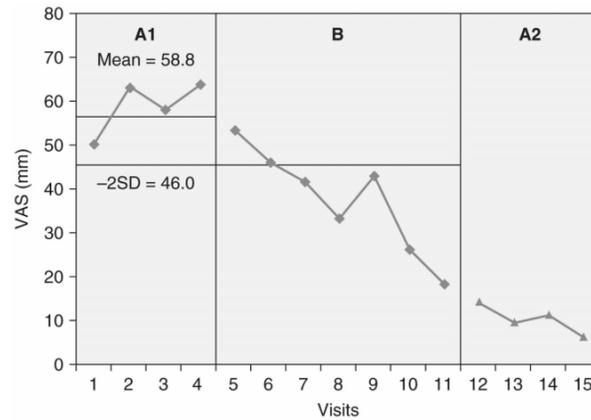
Withdrawal Designs: A-B-A

- Explores the effect of removing the intervention
- Answers the question: Is the change in the target behavior only noted in the presence of the intervention?
- Limitations:
 - Ethics
 - Target behavior must be reversible
 - What if learning is the effect of the intervention?
 - What if symptom resolution is the effect?



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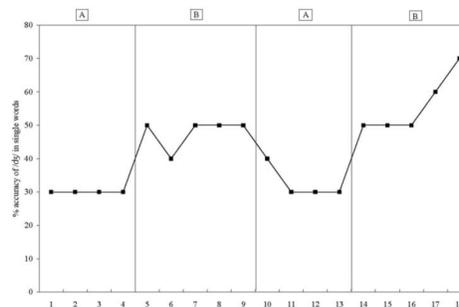
Withdrawal Designs: A-B-A



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Withdrawal Designs: A-B-A-B

- Provides 2 opportunities to evaluate the effect of the intervention
- If effects can be replicated during 2 separate intervention phases, evidence is strengthened



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Sample Clinical Questions Best Addressed with A-B-A or A-B-A-B Designs

- **Clinical Problem:** Child using joystick to drive PWC but is not making much progress. I would like to try switch access but the team is hesitant
- **Clinical Question:** Is a joystick or a switch a better access method for this specific client?
 - Baseline phase: Joystick use
 - Intervention phase: Switch use

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Knowledge Check

In single-subject research design, what designs are often referred to as “withdrawal designs”?

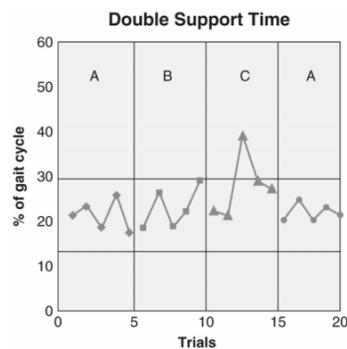
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Multiple Intervention Designs

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Multiple Intervention Designs: A-B-C-A

- B and C may represent 2 different interventions or an intervention and a placebo
- **Only compare adjacent phases (A1-B or C-A2)**



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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

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Step 7: Analyze the Data

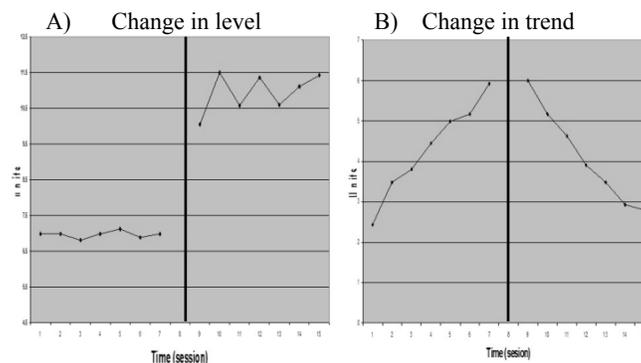
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Step 7: Analyze the Data

- “Plot” data points
- Visually inspect data – assess levels and trends in adjacent phases
 - **Level** – refers to **change in value or magnitude** of the target behavior after intervention
 - **Trend** – refers to **change in direction**
 - Described as accelerating, decelerating, stable or variable

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Step 7: Analyze the Data



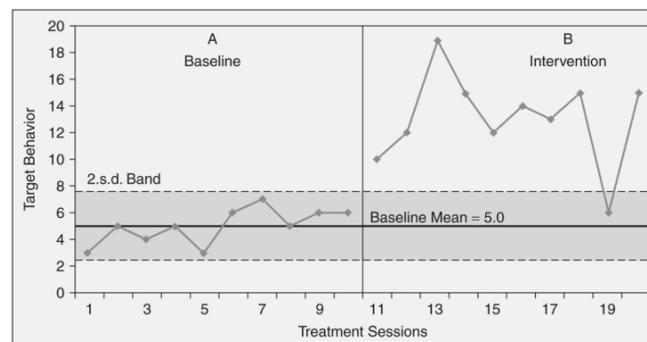
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Step 7: The 2 Standard Deviation (SD) Band Method

- Data points in Baseline 1 are used to determine a mean and SD for Baseline 1
- “Bands” set at ± 2 SD are used to assess the data
 - A minimum of 2 consecutive data points outside of the 2SD band are considered significant an intervention phase

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Step 7: The 2 Standard Deviation (SD) Band Method



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Knowledge Check

In single-subject research design, how many consecutive data points outside of the 2 SD band are needed to achieve significance

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Design: A-B-A

Independent variable: Type of seating system

Target behaviors/dependent variables: SaO₂, HR, RR, BT, time to activate a switch, response accuracy

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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Two Seating Systems' Effects on an Adolescent With Cerebral Palsy and Severe Scoliosis

Kim Lephart, PT, DPT, MBA, PCS; Sandra L. Kaplan, PT, DPT, PhD

Design: A-B-A

NOTE: The A2 phase was terminated after 2 sessions because the subject refused to go back to his old seating system after using the custom-molded seating system.

Independent variable: Type of seating system

Target behaviors/dependent variables: SaO₂, HR, RR, BT, time to activate a switch, response accuracy

Lephart K, Kaplan SL. Two seating systems' effects on an adolescent with cerebral palsy and severe scoliosis. *Pediatr Phys Ther.* 2015 Fall;27(3):258-66.

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In Summary.....

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Review the Objectives: Any Questions?

For a copy of this PPT, please e-mail Lisa at:
kenyonli@gvsu.edu

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