Validation of the International Spinal Cord Injury PT-OT Basic Data Set

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ISCS Physical therapy – Occupational Therapy Basic Data Set Work Group

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In the Clinical Research World Multimodal Interventions Are The Rule Rather Than The Exception

- Surgical
- Cellular (stem cells)
- Biologics (growth factors)
- Pharmacologic
- Electrotherapeutic
- Etc

OFTEN combined with Activity / Training / Exercise

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Key Concepts:

- Multimodal interventions may be associated with complex interactions
- Some interactions are beneficial (some not)
- Exercise, training, practice is a powerful intervention

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Common Types of Interactions

Mediators
- Variable necessary to reveal intervention effects

Moderator (aka Effect Modifier)
- Variable that changes the size/direction of the effect of the intervention on the outcome

Covariate
- Variable that influences outcome but not associated with intervention or outcome

Confounder
- Variable that correlates (+ or -) with both intervention and outcome (nuisance variable)

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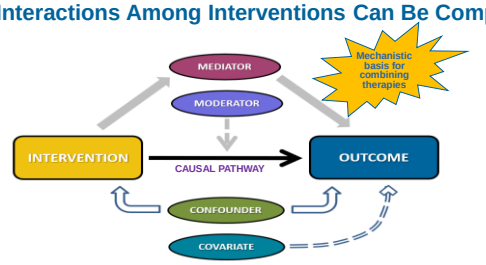
Interactions Among Interventions Can Be Complex



Adapted from: Field-Fote EC. *J Neurol Phys Ther*. Mediators and Moderators, Confounders and Covariates: Exploring the Variables That Illuminate or Obscure the "Active Ingredients" in Neurorehabilitation.

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Use / Training / Practice Has Powerful Effects

- May be necessary to reveal treatment effects (mediator)
- May influence the size/direction of the intervention effect (moderator)
- May be more beneficial for functional restoration than the experimental intervention of interest (covariate)

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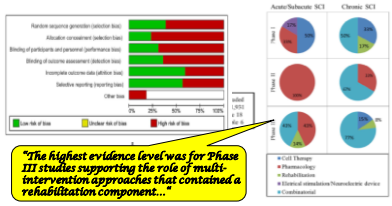
Strongest Evidence for SCI Rx Effects (Motor) is for Multimodal Interventions that Include Rehabilitation



Gomes-Osman et al.
J Neurotrauma. 2016: 33;245-38.

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Steps in the PT-OT BDS Validation Process

- Recruit site leaders at 10 Centers
  - 4 USA, 1 each in Denmark, Germany, Ireland, Norway, Switzerland, UK
- Ethics approval or waiver
- Recruit therapist participants (PTs or OTs)
- Review study syllabus, participate in training session
- Formatted data collection workbook provided
- PT and/or OT pairs (treating/observing) recorded data

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Key Point: Study Design Note

- The intent is that <u>in real-world use</u> the Treating therapist would use BDS form to collect data on the PT-OT interventions that are received by an individual who is participating in an SCI clinical trial. The use of an Observing therapist in this study was simply a design requirement as the goal was to validate the PT-OT BDS based on its reliability.

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ISCI PT-OT BDS

	ITEM	TIME (in minutes)					
ACTIVITY-DIRECTED INTERVENTIONS							
A	Bed/seated control activities: balance, seated transfers, bed mobility	<10	10-19	20-29	30-44	45-60	>60
B	Standing control activities: standing, balance, standing transfers weight bearing	<10	10-19	20-29	30-44	45-60	>60
C	Walking, stairs (inside, outside)	<10	10-19	20-29	30-44	45-60	>60
D	Gross motor UE: dressing, washing, manual wheelchair mobility	<10	10-19	20-29	30-44	45-60	>60
E	Fine motor UE: grooming, self-feeding, buttoning, zipping, adjustment of clothing	<10	10-19	20-29	30-44	45-60	>60
IMPAIRMENT-DIRECTED INTERVENTIONS							
F	Strength training (including electrical stimulation for strength)	<10	10-19	20-29	30-44	45-60	>60
G	Endurance training (including electrical stimulation for endurance)	<10	10-19	20-29	30-44	45-60	>60
TOTAL INTERVENTION TIME							
Sum of time spent on individual items		<10	10-19	20-29	30-44	45-60	>60

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Agreement between therapists

Intervention	Observations Included*	Category Agreement Percentage	Time Agreement Percentage	ICC (95% CI)**
A Bed/seated control activities	125	80.0%	79.2%	0.815 (0.736, 0.870)
B Standing control activities	74	75.7%	74.3%	0.549 (0.285, 0.716)
C Walking, stairs (inside, outside)	48	93.8%	93.8%	0.748 (0.553, 0.859)
D Gross motor upper extremity	59	66.1%	65.5%	0.470 (0.112, 0.685)
E Fine motor upper extremity	41	78.0%	73.2%	0.728 (0.492, 0.854)
F Strength training (including electrical stimulation for strength)	109	78.9%	78.0%	0.656 (0.497, 0.764)
G Endurance training (including electrical stimulation for endurance)	53	50.9%	50.9%	0.105 (-0.546, 0.482)

*Number of data entries for which at least one rater provided data for duration of intervention.
**Run as a One-way random effects model

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Key Points: Agreement between therapists

- **Category agreement was high ≥ 75% for 5 of the 7 categories**
- ***Exceptions:*** **Gross UE & Endurance Training (≥ 50% and <75%)**
- **Time agreement was high ≥ 75% for 3 of the 7 categories**
- ***Exceptions:*** **standing control, gross UE, fine motor UE, endurance training**

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Influence of Other Factors

Topic	Groupings	Observations Pairs Included	Agreement Percentage	Pearson Chi-Square
Discipline Pairings	Both OT	26	76.9%	$p = 0.255$
	Both PT	74	87.8%	
	OT with PT	100	89.0%	
Years of Experience	≥ 3 years	73	90.4%	$p = 0.277$
	< 3 years	127	85.0%	
Degree of Impairment	Motor-Incomplete Tetraplegia	82	86.6%	$p = 0.327$
	Motor-Complete Tetraplegia	26	76.9%	
	Motor-Incomplete Paraplegia	53	88.7%	
	Motor-Complete Paraplegia	39	92.3%	
Setting	Inpatient	164	87.8%	$p = 0.470$
	Outpatient	36	83.3%	
Location	US Center	80	83.8%	$p = 0.264$
	Non-US Center	120	89.2%	

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Key Points: Influence of Other Factors

- **No differences identified due to …**
  - **Discipline**
  - **Experience**
  - **Impairment**
  - **Setting**
  - **Location**

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Conclusions

- **The ISCI PT-OT BDS is reliable for use based on % agreement**
- **ISCI PT-OT BDS can be used in the clinical setting**
  - The treating therapist should complete the form
  - The treating therapist should time the intervention components
- **Syllabus revisions related to power WC and standing/walking**

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