Spinal Cord Outcomes S C P E Partnership Endeavor

THE INTERNATIONAL SPINAL CORD INJURY PHYSICAL THERAPY - OCCUPATIONAL THERAPY BASIC DATA SET: *RATIONALE, EVIDENCE, AND VALIDATION*

Shepherd Center
2020 Peachtree Road, NW, Atlanta, GA 30309-1465
404-352-2020

1

ISCS PHYSICAL THERAPY – OCCUPATIONAL THERAPY BASIC DATA SET WORK GROUP

- Kim Anderson (co-Chair)
- Fin Biering-Sorensen
- Anne Bryden
- Edelle Field-Fote (co-Chair)
- Lisa Harvey
- Linda Jones
- MJ Mulcahey
- Sara Mulroy
- Vanessa Noonan
- Marcel Post
- Ruediger Rupp
- Mary Schmidt-Read

Shepherd Center

2

KEY CONCEPTS:

- Multimodal interventions may be associated with complex interactions
- Rehab (exercise, training, practice) is a powerful intervention
- There is a need to track when it is delivered concurrently with an experimental intervention

Shepherd Center

3

IN THE CLINICAL WORLD MULTIMODAL INTERVENTIONS ARE THE RULE RATHER THAN THE EXCEPTION

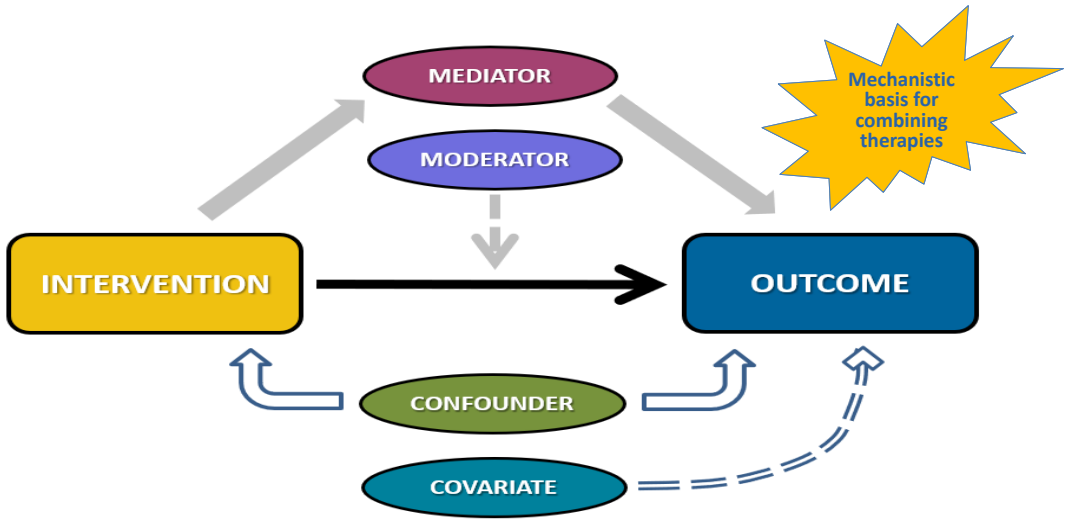
- Surgical
- Cellular (stem cells)
- Biologics (growth factors)
- Pharmacologic
- Electrotherapeutic
- Etc

OFTEN combined with Activity / Training / Exercise

Shepherd Center
2020 Peachtree Road, NW, Atlanta, GA 30309-1465
404-352-2020

4

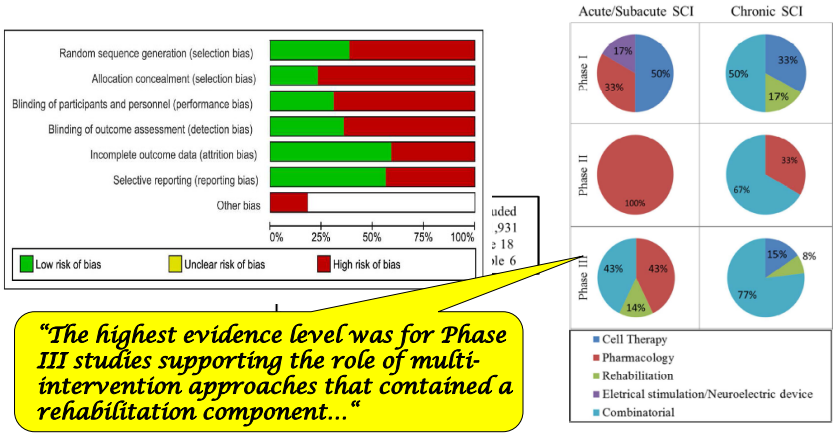
Interactions Among Interventions Can Be Complex



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. 2019;43(2):83-84.

5

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



"The highest evidence level was for Phase III studies supporting the role of multi-intervention approaches that contained a rehabilitation component..."

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

Shepherd Center

6

Consensus Process 1st Step – Match

Matched like items from the SCI-ICS and SCIRehab taxonomies

- 28 interventions matched

1. SCI-ICS: van Langeveld SA, Post MW, et al *J Neurol Phys Ther*. 2008;32:2-7.

2. NIH Rehab Therapies Common Data Elements (Form 1723) https://commondataelements.ninds.nih.gov./crf-library

	Spinal Cord Injury Interventions Classification System (SCI-ICS[1])	Rehabilitation Therapies CRF 1723 (NIH Common Data Elements [CDEs])[2]
Body Functions	101 Muscle power	12. Strengthening
	102 Muscle length	9. ROM / stretching
	103 Muscle tone	9. ROM / stretching
	104 Joint mobility	9. ROM / stretching
	105 Sensory functions	31. Other therapeutic activities
	106 Neuropathic pain	44. Psychotherapeutic intervention; 51. Education not covered by other activities; 54. Psychosocial support
	107 Musculoskeletal pain	13. Musculoskeletal treatments/modalities; 32. Modalities; 51. Education not covered by other activities
	108 Skin and related structures	14. Skin management; 15. Wound care
	109 Cardiovascular system	11. Endurance
	110 Respiratory system	11. Endurance; 18. Airway / respiratory management
Basic Activities	201 Arm and hand use	20. Self-feeding
	202 Positions and movements	2. Bed mobility; 10. Balance
	203 Transfers	3. Transfers
	204 Standing	6. Upright activities
	205 Walking	7. Pre-gait; 8. Gait
	206 Handrim wheelchair/ (Bi)cycle	4. Wheelchair mobility - manual
	207 Powered wheelchair/ transportation	5. Wheelchair mobility - power
	208 Swimming	19. Aquatic exercises/hydrotherapy
Complex Activities	301 Moving around inside	4. Wheelchair mobility - manual; 5. Wheelchair mobility - power; 7. Pre-gait; 8. Gait
	302 Moving around outside	4. Wheelchair mobility - manual; 5. Wheelchair mobility - power; 7. Pre-gait; 8. Gait
	303 Washing oneself	22. Bathing
	304 Caring for body parts	21. Grooming
	305 Toileting	26. Bowel management; 27. Bladder management
	306 Dressing	23. Dressing - lower; 24. Dressing - upper
	307 Eating and drinking	20. Self-feeding; 62. Swallowing interventions/feeding trials; 63. Swallowing interventions/exercises
	308 Communication	28. Communication interventions; 42. Motor speech and/or voice disorder interventions; 43. Cognitive-communication interventions
	309 Domestic life	30. Home management skills
	310 Recreation and leisure	33. Community re-integration outing; 38. Leisure skills in center; 39. Leisure skills outing; 40. Social activity

7

Consensus Process 2nd Step – Rank

Each member of the working group independently ranked the top 10 interventions he/she believed most likely would directly influence change in the ISNCSCI score (initially)

SCI-ICS (Interventions Classification System)	Rehabiliation Therapies form (F1723)	Ranks
11 Muscle power	12. Strengthening	1
25 Walking	7. Pre-gait; 8. Gait	2
21 Arm and hand use	2. Self-feeding	3
24 Standing	6. Upright activities	4
31 Moving around inside	4. Wheelchair mobility - manual; 5. Wheelchair mobility - power; 7. Pre-gait; 8. Gait	4
22 Positions and movements	2. Bed mobility; 1. Balance	6
32 Moving around outside	4. Wheelchair mobility - manual; 5. Wheelchair mobility - power; 7. Pre-gait; 8. Gait	7
23 Transfers	3. Transfers	8
13 Muscle tone	9. ROM / stretching	9
33 Washing oneself	22. Bathing	10
15 Sensory functions	31. Other therapeutic activities	11
17 Musculoskeletal pain	13. Musculoskeletal treatments/modalities; 32. Modalities; 51. Education not covered by other activities	12
12 Muscle length	9. ROM / stretching	13
14 Joint mobility	9. ROM / stretching	13
36 Dressing	23. Dressing - lower; 24. Dressing - upper	13
16 Neuropathic pain	44. Psychotherapeutic intervention; 51. Education not covered by other activities; 54. Psychosocial support	16
19 Cardiovascular system	11. Endurance	16
	13. Musculoskeletal treatments/modalities	18
26 Handrim wheelchair/ (Bi)cycle	4. Wheelchair mobility - manual	19
28 Swimming	19. Aquatic exercises/hydrotherapy	20
34 Caring for body parts	21. Grooming	20

8

CONSENSUS PROCESS 3RD STEP – CONSOLIDATE

The time and effort require to record individual interventions could be burdensome in the clinical enrivornment, thus we decided to:

- **Group like items together and focus on categories rather than individual elements**
- **Focus on the interventions that might be influencing outcomes frequently documented in clinical trials**

Shepherd Center

9

Split Interventions into Two Categories

1. Bed/seated activities
2. Standing activities
3. Walking, stairs (inside, outside)
4. Gross motor UE
5. Fine motor UE

- Activity-directed

1. Strength training (including electrical stimulation for strength)
2. Endurance training (including electrical stimulation for endurance)

- Impairment-directed

Shepherd Center

10

	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

11

Content validity PT-OT Data Set

- Content validity: does the scale adequately covers the domain under investigation (Streiner & Norman 2008)
- What did we do to ensure content validity:
  - Developed by expert group
  - Pilot phase, Nine therapists completed form for a single therapy session
    - Was the intended use of the form clear?
    - Were the instructions about how to complete the form clear?
    - Were the treatment time intervals appropriate?
    - Did it cover everything you did?
  - Public call for comments
  - Approval by relevant organizations (ASIA, ISCoS)

12

Inter-rater reliability (ongoing)

- Process of data collection
  - Therapist works with patient, another therapist observes
  - Therapist records afterwards
    - Classify activities performed in appropriate category
    - Estimates (or times) time spend per category
- Research questions
  - Do PT/OT classify interventions in the same treatment category?
  - Do PT/OT select the same time category?

Shepherd Center

13

ISCS Physical therapy – Occupational Therapy Basic Data Set Validity Study Sites

- **Magee**
- **Shepherd Center**
- **Metro**
- **Heidelberg**
- **Denmark**
- **Rancho**
- **Swiss Paraplegia Center**
- **Beijing**
- **Oslo**
- **Marcel Post**
- **National Rehab Hospital (Ireland)**
- **QE SCI Center (Glasgow)**

Shepherd Center

14