Comparative Effectiveness of Rehabilitation Interventions for TBI: Update on Findings

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Learning Objectives

At the conclusion, the participant will be able to:

1. Understand how we can compare rehabilitation interventions in a non-experimental setting
2. Be able to categorize therapies within acute rehabilitation as contextualized, quasi-contextualized and decontextualized
3. Describe preliminary findings on the relative effectiveness of different therapeutic approaches
4. Describe preliminary findings on the effects of family involvement in therapy
5. Identify how the findings can be applied to the delivery of therapy today

A RANDOMIZED CONTROLLED TRIAL (RCT) is the Holy Grail of Research

- Assumption: If the two groups are similar before treatment, then any differences after treatment must be due to the treatment
- People are randomized into Treatment A or Treatment B group
- Because of randomization, usually the two groups look similar re: participant characteristics
- But….not always. One group may lose people early or later, and that may make the groups unbalanced

Randomized Trials are hard to complete..

- Difficult to find adequate comparison groups
- May be unethical to withhold a treatment thought to work
- People with TBI are very different from each other and they change over time, so need large samples to accomplish equality/balance between groups
- A 'controlled' trial often means one that does not fit the real environment or has been applied to only a select sample of people

Mimic RCT using Propensity Score Methods

- Collect as much information as possible on the patient population. Try to obtain information that could effect the outcomes, in addition to treatment.
- Use propensity score methods to create groups of people who are balanced on measured characteristics
- Like RCT: If we create groups that are equal on important characteristics prior to treatment, then any differences after treatment must be due to treatment

Cautions with Propensity Score Analysis

- Can still have unknown differences between groups
- While generally the samples will be more representative of the population than RCTs, can still have some subjects excluded (generally because of characteristics that would make them unsuited for intervention, but not always).

Aim 1: Determine the **comparative effectiveness of different therapeutic approaches** used in inpatient TBI rehabilitation.

We hypothesize:

- Patients who receive a greater proportion of therapy time in **Advanced Training** will achieve better outcomes.
- Patients with the **greatest initial levels of disability will experience larger effects** from Advanced Training therapeutic approaches in comparison to the effects experienced by patients with less disability at admission.
- Patients who receive a greater proportion of therapy in **Contextualized** treatment (versus **Decontextualized**) will achieve better outcomes.

Aim 2: Determine the **comparative effectiveness of differences in delivery of therapy.**

We hypothesize:

- The **level of effort** (from effort ratings made during each rehabilitation session) that patients are able to apply in treatment moderates the effectiveness of time in treatment (days receiving 3 or more hours of treatment).
- **Family involvement** in treatment is associated with better outcomes. Family involvement is defined as whether the family attended at least 10% of the therapy minutes.

Data Used to Evaluate Hypotheses

- TBI Practice-Based Evidence Study database
- 1845 participants with detailed inpatient rehabilitation intervention data from 9 US sites
- Outcomes measured by interview at 3 and 9 months post-discharge:
  - Community participation: Participation Assessment with Recombined Tools-Objective (PART-O)
  - Functional Independence: FIM™ Motor and Cognitive subscales (also discharge)
  - Depression signs: Patient Health Questionnaire-9
  - Life satisfaction: Satisfaction with Life Scale (SWLS)

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Practice Based Evidence (PBE) Design

- Prospective
- Multi-site observational
- Naturally occurring practice variations
- Large data set
- Designed by providers and consumers

Horn, Corrigan, Dijkers (2015) Traumatic Brain Injury Rehabilitation: Introduction to the Traumatic Brain Injury – Practice Based Evidence *Archives* Supplement. Archives PM&R, 96(8 Supple 3):S173-7.

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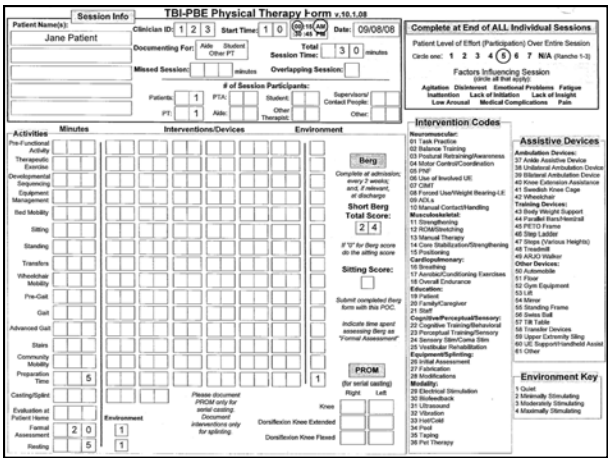

Therapy Classifications

- Content:
  - Contextualized
  - Quasi Contextualized
  - Decontextualized
- Complexity:
  - Advanced
  - Not Advanced

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Contextualized Treatment

"Function-embedded or specific skills training using ecologically valid, real-life tasks that resemble in important ways the patient's environment." Cicerone et al, 2015

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Quasi Contextualized

"The tasks used in treatment may or may not resemble functional / real-life tasks but an important component of the intervention involves the therapist making explicit the relation of the intervention…to the patient's real-life functioning and active promotion of generalization." Cicerone et al, 2015

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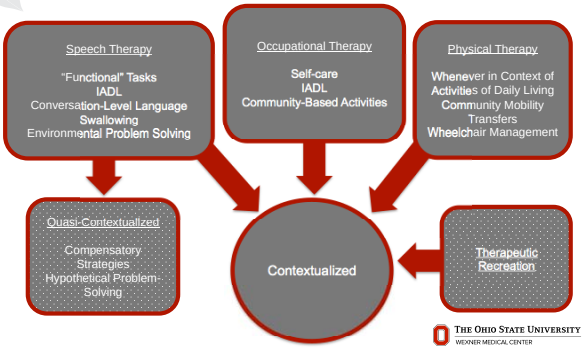
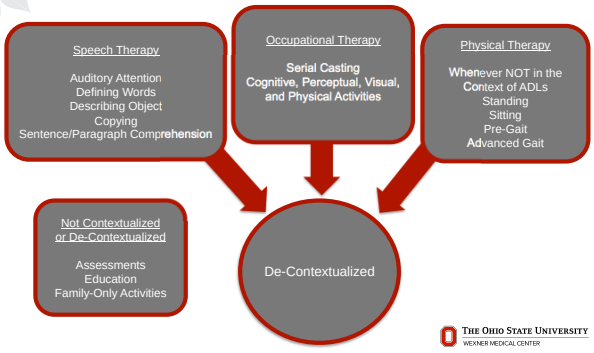
Decontextualized Treatment

"...Specific training in which the emphasis is on repetitive practice of tasks…but do not explicitly share characteristics of more functional activities or tasks, with the assumption that strengthening the underlying… component will transfer…to more functional, real-life activities." Cicerone et al, 2015

Operationalizing Contextualized Therapy



Operationalizing Decontextualized Therapy

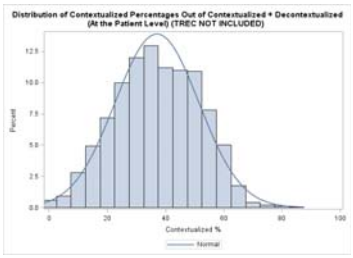


Pop Quiz

On average, what percent of therapy time is spent in contextualized activities?

a. 77%
b. 15%
c. 37%
d. 52%

Treatment Distributions in Determining PSM Method



Normal distribution of "Dose": Use Generalized Propensity Score to evaluate dosage effects

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Results So Far…

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Variables Balanced Prior to Treatment

- Site grouped by avg length of tx session
- Cause of injury
- GCS
- Days injury to rehab
- Adm FIM Cognitive and Motor
- Adm TBI Comprehensive Severity Index (CSI)
- Adm non-TBI CSI
- Average agitation 1st 3 days
- Max pain 1st 3 days
- Weight-bearing precautions 1st 3 days
- Paralysis at admission
- PTA cleared prior to rehab
- Neuroimaging findings (8 variables)
- Admission aphasia or ataxia
- Craniotomy or craniectomy
- Age, age-squared
- Gender
- Race
- Education
- Marital status
- Employment
- Living with and living situation
- Alcohol misuse and/or Illicit drug use
- Premorbid pain
- Driving prior to injury
- Payer source
- Premorbid behavior control problem
- Premorbid learning problems
- Premorbid anxiety or depression
- ADL history

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Those who received larger % of contextualized treatment in inpatient rehab...

- Had greater community participation at 3 and 9 months post-discharge
  - Were more "out and about" in the community at 3 and 9 months post-discharge
  - Were involved in more social activities at 3 months post-discharge
- No differences observed in functional independence, life satisfaction, or depression

PART-O: *Productivity*

- In a typical week, how many hours do you spend working for money, whether in a job or self-employed?
- In a typical week, how many hours do you spend in school working toward a degree or in an accredited technical training program, including hours in class and studying?
- In a typical week, how many hours do you spend in active homemaking, including cleaning, cooking and raising children?

PART-O: *Social Relations*

- In a typical week,how many times do you socialize with friends, in person or by phone? Please do not include socializing with family members.
- In a typical week, how many times do you socialize with family and relatives, in person or by phone?
- In a typical week, how many times do you give emotional support to other people, that is, listen to their problems or help them with their troubles?
- In a typical week, how many times do you use the Internet for communication, such as for e-mail, visiting chat rooms or instant messaging?
- Do you live with your spouse or significant other? Are you currently involved in an ongoing intimate, that is, romantic or sexual, relationship?
- Do you have a close friend in whom you confide?

PART-O: *Out and About*

- In a typical week, how many days do you get out of your house and go somewhere? It could be anywhere – it doesn't have to be anyplace "special".

In a typical month,

- How many times do you eat in a restaurant?
- How many times do you go shopping? Include grocery shopping, as well as shopping for household necessities, or just for fun.
- How many times do you engage in sports or exercise outside your home? Include activities like running, bowling, going to the gym, swimming, walking for exercise and the like.
- How many times do you go to the movies?
- How many times do you attend sports events in person, as a spectator?
- How many times do you attend religious or spiritual services? Include places like churches, temples and mosques.

If the amount of contextualized treatment was increased by XX%....

30%	45%	75%
Increase frequency of 1 community activity	Will get out of the house 1-2 additional days per week.	Will get out of the house 3-4 more days per week.

Results for Patients with Greatest Disability

Those who received larger % of contextualized treatment in inpatient rehab...

- Had higher FIM Cognitive scores at discharge (not at follow-up)
- Had higher FIM Motor scores at discharge and 3 months post (not 9 months)
- Were more "out and about" and "productive" at 3 months post (not 9 months)
- No differences in life satisfaction and depression

Examples of effects of increased contextualized on FIM Motor at DC and 3 mos.

Item	Baseline	30%	50%	75% (after / 3 mos)
Feeding	Max	Max	Moderate	Moderate
Grooming	Max	Max	Max	Max
Bathing	Total	Total	Total	Total
Dressing-Upper	Max	Max	Max	Max
Dressing-Lower	Total	Max	Max	Max
Toileting	Total	Moderate	Moderate	Moderate/Min
Bladder	Total	Total	Total	Total
Bowel	Total	Total	Total	Total/Moderate
Transfers:bed/chair	Max	Max	Max	Moderate/Min
Transfers:toilet	Total	Total	Total	Moderate
Transfers:bath	Total	Total	Total	Total
Walking/chair	Max	Max	Moderate	Moderate
Stairs	Total	Total	Total	Total

Examples of effects of increased contextualized on FIM Cognitive at DC

Item	Baseline	30%	*60%*
Comprehension	Maximum	Maximum	Moderate
Expression	Total	Total	Total
Social Interaction	Maximum	Maximum	Maximum
Problem-solving	Total	Total	Total
Memory	Maximum	Maximum	Maximum

Implications

- By increasing the amount of time devoted to contextualized treatment during inpatient rehabilitation, an increase in community participation may be reported at 3 and 9 months post-discharge.
- For patients admitted with the greatest disability, increasing contextualized treatment may lead to better FIM Motor scores at discharge and 3 months, and better FIM Cognitive scores at discharge.

Recommendations

- Today most goals are 'functional', that is they are activities that are required for the individual to resume independent living. The more time in therapy that is spent working directly on real-life activities, the more the person will be participating in the community within the year.
- Sometimes you may identify a component skill that needs to be strengthened before the person can work on the actual goal activity. In these situations, if it is possible to work on the component skill within the context of a real life activity, then greater benefit may be achieved.

Which of the following therapy tasks may be most likely to increase community participation?

- A. Working on basic arithmetic
- B. Drawing a line between numbers and letters on a page in sequence (Trails)
- C. Scanning a bill to identify the amount that is owed
- D. Cancellation task

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A. Putting silverware in appropriate compartments

B. Inserting blocks of different shapes into corresponding holes in board

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B. Walking over poles on ground in gym
C. Walking between objects in gym

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For more information

Contact Jenny Bogner, PhD at bogner.1@osu.edu

References

- Cicerone et al, 2015, Cognitive Rehabilitation Panel, BIAA Guidelines for the Rehabilitation and Chronic Disease Management for Adults with Moderate and Severe TBI
- Koehler, R, Wilhelm,E, Shoulson,I Editors; Committee on Cognitive Rehabilitation Therapy for Traumatic Brain Injury; Institute of Medicine, National Academies
- Beaulieu, Dijkers, Barrett, Horn, Giuffrida, Timpson, Carroll, Smout, Hammond (2015) Occupational, physical, and speech therapy treatment activities during inpatient rehabilitation for traumatic brain injury. Archives PM&R, 96(8 Supple 3):S222-34.
- Horn, Corrigan, Dijkers (2015) Traumatic Brain Injury Rehabilitation: Introduction to the Traumatic Brain Injury – Practice Based Evidence *Archives* Supplement. Archives PM&R, 96(8 Supple 3):S173-7.
- Horn, Corrigan, Beaulieu, Bogner, Barrett, Giuffrida, Ryser, Cooper, Carroll, Deutscher (2015) Traumatic Brain Injury Patient, Injury, Therapy, and Ancillary Treatments Associated with Outcomes at Discharge and 9 Months Post discharge. Archives PM&R, 96(8 Supple 3):S304-29.