The Evidence for Tailoring Behavioral Interventions: What Works, Why and How

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Model for Tailoring Biobehavioral Interventions

Understand

1. Identify individual’s explanatory model of the illness

Assess

2. Identify and select potential etiologies for illness

3. Identify and understand critical patient characteristics for tailoring the intervention

Plan

4. Adapt/develop instruments to assess the critical patient characteristics

5. Adapt/develop instruments to assess the outcomes

Implement

6. Plan the tailored intervention:
   • What
   • Where
   • When
   • How
   • To Whom
   • How Much

7. Implement the tailored intervention
   • Maintain intervention fidelity

Evaluate

8. Evaluate Outcomes
Understand
Sleep Problems in Dementia

*Caregiver ($n = 18$)

- Decreased sleep
- Increased stress
- Disrupted social and familial interaction
- Difficulty managing own health problems
- Loss of work
“He doesn’t sleep through the night. . . But we both work and it’s very difficult for us. We’re so tired at night. We don’t sleep much.”

“He began to get up and wander around the house. So I got a monitor. I have put everything dangerous up high, put the matches up so he won’t try to light a fire in the kitchen. I had to put the things I don’t want broken in the basement. I have put locks on the doors in the house.”

“I have two small children so it is very difficult. Some nights we never know if we will get any sleep at all.”
We hypothesized that nighttime behavioral disturbance may be associated with obstructive sleep apnea syndrome, periodic limb movements, and restless legs syndrome (RLS).
60 elders with dementia residing at home

**Methods**

- 2 nights polysomnography
  - Obstructive sleep apnea syndrome
  - Periodic limb movements

**Assess**: RLS diagnosis – 2 experts

1. Chief sleep complaint (from caregiver and/or elder)
2. RLS diagnostic interview per caregiver
3. Polysomnography data including apnea–hypopnea index (AHI) and periodic limb movement index (PLMI)
4. RA observations of RLS signs
5. Medical diagnoses and medications
**Understand: Sleep and Behavioral Disturbance in Dementia**

- **Behavioral Disturbance**
  - 3 nights of every 5 minute behavioral observations using the Cohen–Mansfield Agitation Inventory for direct observation (19 hours) to calculate the Behavioral Disturbance Index (BDI)
  - BDI – frequency of behaviors per hour of observation
Results

Possible-RLS Diagnosis

- 76%
- 24%

p-RLS Diagnosis
### Understand: Sleep and Behavioral Disturbance in Dementia

Best fitting multiple linear regression model predicting Behavioral Disturbance Index

<table>
<thead>
<tr>
<th>Predictor</th>
<th>$r$ ($p$-value)</th>
<th>Coeff</th>
<th>SE</th>
<th>t</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-RLS</td>
<td>0.31 (0.02)</td>
<td>0.70</td>
<td>0.23</td>
<td>3.0</td>
<td>0.004</td>
</tr>
<tr>
<td>MMSE</td>
<td>-0.33 (0.012)</td>
<td>-0.04</td>
<td>0.007</td>
<td>-2.79</td>
<td>0.012</td>
</tr>
<tr>
<td>Log AHI</td>
<td>-0.37 (0.004)</td>
<td>-0.32</td>
<td>0.11</td>
<td>-3.0</td>
<td>0.004</td>
</tr>
<tr>
<td>Intercept</td>
<td></td>
<td>2.95</td>
<td>0.39</td>
<td>7.51</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Adjusted $R^2 = 0.31; p = 0.0000$

The specific aims are to determine: the sensitivity, specificity, and optimal cut–off values (scores that indicate a positive RLS diagnosis) for the: a) behavioral indicators index assessed by the Behavioral Indicators Test–Restless Legs (BIT–RL); b) the leg movement index assessed by the Periodic Activity Monitor–Restless Legs, c) serum ferritin, and d) selected demographics/medical history.
Methods

• Sample
  – Cognitively intact
  – 100 with RLS, 100 without RLS
  – Aged 40–90

• 3 in-laboratory stays (5 pm – 8 am)
Methods (continued)

- Periodic Activity Monitor – RLS
  - Triaxial accelerometer, worn on both legs
  - 3 nights

- Behavioral Indicators Test – RLS
  - Trained observers
    - 2 days of training using videos of persons with and without RLS
    - Gold standard rater – 95% or greater
    - Interrater reliability – 95% or greater
  - 20 minute observations in early morning, afternoon, after a short exercise period
  - 1 hour observation at bedtime
  - 3 days

Assess: Restless Legs Syndrome
– Interim Results

• Diagnostic Indicators of RLS
  – BIT–RL
    » 20 minute afternoon observation
  – Serum ferritin (45 cut point)
  – History of iron deficiency
  – History of cardiovascular disease
  – History of depression
**Purpose:** Test the effect of an individualized daytime social activity intervention on daytime napping and nighttime sleep

**Methods:**
- Randomized Controlled Trial
  - Individualized Social Activity Intervention
  - Usual Care Control
- 139 nursing home residents with dementia who napped
Methods (continued)

• Individualized social activity intervention
  – Replace excessive napping with meaningful social activities
  – Project nursing assistants conducted, 1 hour daily for 21 days
  – Critical characteristics
    » Past interests and preferences
    » Cognitive and functional status
    » Patterns of daytime napping
  – 123 activities – games, music, dancing, reminiscence
  – Fidelity – training, gold standard, videotaping
  – Prescription Algorithm

• Baseline and days 17–21 – actigraphy
• Data Analysis: 2-factor repeated measures analysis of variance, first factor was between subjects (intervention vs. control), second factor was within subjects, time (pre vs. post), hypothesis of interest was the interaction between the 2 factors
Research: Social Activity and Excessive Daytime Napping

Daytime Minutes Slept (n = 139)

$p = .001$
Research: Social Activity and Excessive Daytime Napping

Day/Night Sleep Ratio (n = 139)

$\text{Baseline Post}$

\[ p = .04 \]
Individualized social activity, when compared to a control condition

- Reduced excessive daytime sleep
  - More alert, active
  - More involved in the world around them
- More normal 24–hour sleep/wake rhythm

Clinical Trial – 194 participants

Determine the effect of

1) progressive resistance muscle strength training and walking
   Critical characteristics: cognitive status and 1-repetition max
2) individualized social activity
3) combined progressive resistance muscle strength training, walking, and individualized social activity
4) usual care control

Primary Outcome Measure: Total Sleep Time

Results: Effect of Activities and Exercise on Sleep in Dementia

Significant Pairwise comparison:
Mean difference (Combined Group – Control) = 35.23; SE =13.72; p = .011
Results: Effect of Activities and Exercise on Sleep in Dementia

Significant Pairwise comparison:
Mean difference (Combined Group – Control) = 4.77; SE = 2.015; \( p = .019 \)
Results: Effect of Activities and Exercise on Sleep in Dementia

Significant Pairwise comparisons:
Mean difference (Combined Group – Control) = 32.64; SE = 12.19; \( p = .008 \)
(Combined Group – ISA) = 31.52; SE = 11.93; \( p = .009 \)
(Combined Group – PRT) = 28.11; SE = 11.69; \( p = .017 \)
Understand: Obstructive Sleep Apnea
• MCI is characterized by memory impairment but little or no decline in everyday function.
• 60% of older adults with cognitive impairment have OSA compared to only 7–18% of older adults in general population.
• OSA causes:
  • Hypoxia
  • Sleep fragmentation
  • Daytime sleepiness
  • Cognitive dysfunction
  • Brain Damage
Specific Aims:

1) Estimate the effect size associated with active continuous positive airway pressure (CPAP) compared to sham CPAP on cognitive and everyday function in older adults with amnestic mild cognitive impairment and OSA.

We hypothesize that the active CPAP group will have significantly better cognitive and everyday function at 6 months than the sham CPAP group.

2) Estimate the effect size associated with CPAP treatment adherence, controlling for OSA severity at baseline, neuroimaging evidence of pre-existing cerebrovascular disease and hypoxic ischemic brain injury, and previously identified demographic and other patient factors, on cognitive and everyday function after 1–year of active CPAP.
Plan, Implement, and Evaluate: Obstructive Sleep Apnea (OSA) and Mild Cognitive Impairment (MCI)

* Sample:
  * 110 older adults with amnestic mild cognitive impairment (single or multiple domain) and moderate to severe obstructive sleep apnea

* Design:
  * Phase 1: 6 month double-blind placebo-controlled randomized controlled trial
    * Active Continuous Positive Airway Pressure (CPAP)
    * Sham CPAP
  * Phase 2: 6 month open-label CPAP trial
Plan, Implement and Evaluate: Obstructive Sleep Apnea (OSA) and Mild Cognitive Impairment (MCI)

* Tailored CPAP adherence intervention
  * Motivational Interviewing
    * Critical characteristics
      * Transtheoretical Model Stage of Change
      * Self-efficacy
  * Fidelity
    * Manualized
    * Competency validation
    * Quarterly reassessment of competency