Treatment Fidelity in Intervention Research

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Why is treatment fidelity important??????
Treatment Fidelity

- Key methodological strategies to enhance validity and reliability of behavioral interventions.
- Integral to both the interpretation and generalization of research findings (internal & external validity).
Implications for Internal Validity

- **Significant results**: Due to an effective treatment or unknown contaminants added to treatment?
- **Type 1 error**

- **Non-significant results**: Due to an ineffective treatment or a treatment that was inadequately administered?
- **Type II error**
External Validity & Other Benefits

• Replication of treatment in other studies.
• Generalization of treatment to applied settings.
• Dissemination
• Cost of low fidelity: rejection of effective programs or acceptance of ineffective programs.
Statistical Power

- Internal validity in outcome studies is highly correlated with effect size ($r=0.88$).

- Lack of standardization within and between providers, and variation in treatment intensity and content across participants:
  - inflates error variance
  - decreases power
  - increases chance of Type II error
Other Benefits of Treatment Fidelity

- Promotes “course correction” or the early detection of errors
  - Reduces costs and improves treatment.

- Inadequate treatment delivery may lead to higher rates of attrition.

- Improved theory development and testing

- Poor tx fidelity – your results go up in the air like balloons!
Where we headed? I don’t know!
BCC Treatment Fidelity Model

- Design of study
- Training providers
- Delivery of treatment
- Receipt of treatment
- Enactment of treatment skill
Study design
Study Design -- Definition

- Treatment fidelity processes that ensure that a study can adequately test its hypotheses in relation to underlying theory.
How can a study be designed to maximize treatment fidelity?
Designing a study to maximize treatment fidelity

(1) Explicitly identify and use a theoretical model or models or clinical guidelines as the basis for the intervention
Designing a study to maximize treatment fidelity

(2) Ensure that treatment “dose” (treatment intensity, measured by number, frequency, length of contact) is the same for each subject within a particular treatment condition.
Designing a study to maximize treatment fidelity

(3) Ensure that treatment “dose” is the same across interventions that include multiple behavioral targets and across treatment and control/comparison groups
Designing a study to maximize treatment fidelity

(4) Include design features that control for or minimize contamination across treatment/comparison/control conditions
Designing a study to maximize treatment fidelity

(5) Address possible setbacks in implementation by designing “back-up” systems or remedies to be applied prior to implementing the study
Training Providers
Training

• Treatment fidelity processes that assess and improve the training of treatment providers to ensure that they have been satisfactorily trained to deliver the intervention to study participants
Ensuring Treatment Fidelity Through Provider Training Involves:

- Standardization of training
- Skill acquisition
- Measuring provider skill acquisition
- Maintenance of skills over time
Ensuring Treatment Fidelity: Training

Skill Acquisition - training providers

General Examples

1. Didactic sessions
2. Modeling
3. Use of videotaped materials
4. Training manuals
5. Role plays
Ensuring Treatment Fidelity: Training

**Standardized training:**
- to ensure that all providers are trained in the same manner
- to prevent differential outcomes by provider
- to decrease provider by treatment interactions
Ensuring Treatment Fidelity: Training

- Measurement of skill acquisition after training
  - understanding demonstrated
  - performance criteria determined and performance documented
Treatment Fidelity: Delivery
Delivery - Definition

- Treatment fidelity processes that monitor and improve delivery of the intervention so that it is delivered as intended
  - ensure the intervention protocols are being administered accurately and consistently.
- DRIFT???
Monitor and control for subject perceptions of nonspecific treatment effects (e.g., perceived warmth, credibility of therapist)
Delivery - What to Assess

Ensure that providers are delivering the same intervention.
Delivery – Assessment Tools

- Scripted intervention protocols
- Treatment manuals
- Checklist
- Self-Report Questionnaire from Subject
- Providers work with all treatment groups
- Qualitative interviews
- Audio-taped sessions
- Direct observation
Ensure that providers adhere to the treatment protocol
- content
- dose
Delivery – Tricks to Improve Delivery

- Computerized prompts
- Audio or video tape encounter
- Behavioral checklist of intervention components
- Random observation of encounters
- Use treatment-specific handouts, presentation materials, manuals (color code)
- Ongoing training
Treatment Receipt

- Are you in the mood to Party?
- Yeah, I need to use the Potty.
- Thanks! I guess I am a Hottie!
What is Treatment Receipt?

• Treatment fidelity processes that monitor and improve the ability of participants to understand & perform treatment-related behavioral skills and cognitive strategies during treatment delivery.
  – Participant’s comprehension?
Assessment of Treatment Receipt

- **Direct methods**
  - Objective methods of assessing treatment receipt
    - knowledge assessment
    - Physiological monitoring (heart rate and skin temperature)

- **Indirect methods**
  - Subjective methods of self-reports
    - Questions inquiring about client’s confidence in applying skills delivered
The best way to achieve good health is to take care of yourself.

Your lifestyle is destroying you.

You should change your eating habits, and stop smoking and drinking.

Start an exercise program. Get plenty of rest. Learn how to handle stress.

You're right, doc. Thanks!

Man! I've got to find another doctor!
• Treatment fidelity processes which monitor and improve the ability of participants to perform treatment-related behavioral skills and cognitive strategies in relevant real life settings.
Enactment

- May seem to be confounded with adherence or efficacy
- Should include:
  - Evidence skill was implemented
  - Right time
  - Right setting
Enactment

- Enactment differs from the focus on ultimate outcomes of a study as it is considered throughout the course of the research.....
  - might be same “measure” considered but the timing is different.
  - A snapshot versus a video!
Enactment

- For example....
  - Fills pill organizer (ultimate outcome improved BP)
  - Uses a behavioral strategy
  - Tries out new healthy recipes (Ultimate outcome weight loss)
Enactment

- It is best to assess enactment by collecting data from various perspectives:
  - Direct observation of both participants and interventionists
  - Self-report from participants
  - Interventionist report of participant’s behavior
Enactment

OY VEY!

ARE THEY DOING IT??
Treatment Fidelity: Rewards for your efforts?

- Stronger support for outcomes
- Forces retraining
- Helps to explain findings
- Helps to identify where problems are
How to Describe Treatment Fidelity???

• In manuscripts
  - Report appropriately* - just before discussion

• In grant submission
  - at the end of design section/after description of the intervention
  - Can describe in a table

It will only add to your already stellar grant proposal!
Where we Need to GO

- Rigorous methods to evaluate treatment fidelity.
- Tx fidelity plans that are intervention relevant.
Where we need to go

- examples of set treatment fidelity plans for well tested interventions.
  - Assertive community treatment (ACT), which is an intensive and comprehensive treatment for clients with severe mental illness has the Dartmouth Assertive Community Treatment Fidelity Scale.
  - Eye Movement Desensitization and Reprocessing (EMDR) has treatment fidelity protocols.
Restorative Care Work

• Consistently we use the same approach for:
  – Res-Care in the nursing home
  – Res-Care-AL
  – Res-Care-PD
  – Res-Care-CI
  – Res-Care-AC
Table: Treatment Fidelity Plan

<table>
<thead>
<tr>
<th>Focus Area</th>
<th>Information Used to Evaluate Treatment Fidelity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Evidence that groups are separate</td>
</tr>
<tr>
<td></td>
<td>No contamination</td>
</tr>
<tr>
<td>Training</td>
<td>Training manual</td>
</tr>
<tr>
<td></td>
<td>Observation &amp; Checklist</td>
</tr>
<tr>
<td>Delivery</td>
<td>Observation</td>
</tr>
<tr>
<td></td>
<td>Attendance sheets</td>
</tr>
<tr>
<td>Receipt</td>
<td>Paper and pencil test</td>
</tr>
<tr>
<td>Enactment</td>
<td>Daily logs</td>
</tr>
</tbody>
</table>

TREATMENT FIDELITY DATA SHOULD NOT BE OUTCOME DATA
<table>
<thead>
<tr>
<th>Focus</th>
<th>Data Obtained</th>
<th>Evidence of Treatment Fidelity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery</td>
<td>Environment and policy assessments</td>
<td>Completion of assessments by Research FFC Nurse</td>
</tr>
<tr>
<td></td>
<td><strong>Percentage of nurses exposed to Component I, Classes 1-4</strong></td>
<td><strong>80% of all nurses working on participating units within the participating hospitals (# exposed/total # nurses)</strong></td>
</tr>
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<td></td>
<td>Goal attainment forms</td>
<td>Forms completed on all recruited patients in treatment hospital</td>
</tr>
<tr>
<td></td>
<td>Patient admission packets</td>
<td>FFC admission information provided to all consented patients.</td>
</tr>
<tr>
<td>Receipt</td>
<td><strong>Knowledge of FFC Test</strong></td>
<td><strong>Mean score of &gt; 80% after exposure to Component I, Classes 1-4.</strong></td>
</tr>
<tr>
<td></td>
<td>Environment and policy assessments</td>
<td>Evidence of change(s) made over the course of the study</td>
</tr>
<tr>
<td></td>
<td>Goal attainment scale</td>
<td>Positive goal attainment scores at discharge in consented patients</td>
</tr>
<tr>
<td>Enactment</td>
<td>FFC Behavior Checklist Nurses</td>
<td>Performance of FFC based on observations of nurses during intervention</td>
</tr>
<tr>
<td></td>
<td><strong>Delirium, pain, fear of falling</strong></td>
<td><strong>Decreased delirium, pain and fear indicate interventions were implemented</strong></td>
</tr>
<tr>
<td></td>
<td>FFC Behavior Checklist Patients</td>
<td>Increased participation in FFC activities by patients admission to discharge</td>
</tr>
</tbody>
</table>

Table 2: Treatment Fidelity [**Bolded** items completed in treatment and control hospitals; items **not bolded** collected in treatment site]
<table>
<thead>
<tr>
<th>Treatment Fidelity Focus</th>
<th>Description of Treatment Fidelity Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>The intervention was developed based on social cognitive theory and the theory of self-efficacy. This was reviewed with experts in cognitive theories and behavior change. Evaluators were kept blinded from treatment intervention and randomization of sites. Different interventions provided the training for the treatment versus the control sites.</td>
</tr>
</tbody>
</table>
| Training                 | RCN Training: (a) training of the RCN was based on a training manual; (b) RCNs met monthly with the principal investigator to discuss intervention process and activities to assure prevent intervention drift.  
NA Training: (a) Each nursing assistant attended the 6 classes or was provided with written material and one-on-one sessions to review the class content. |
| Delivery                 | (a) NA class attendance was recorded as were one-on-one sessions to assure delivery of the intervention; (b) review of daily logs completed by NAs was done on a monthly basis to assure delivery of restorative care activities. |
| Receipt                  | Each NA completed the Nursing Assistants Theoretical Testing of Restorative Care Activities pre and post the 6 week training period. |
| Enactment                | (a) Monthly logs recording the NA restorative care activities were reviewed in the treatment sites to determine daily enactment of restorative care. (b) Direct observation of restorative care based on the Restorative Care Behavior Checklist was done at 4 and 12 months post intervention as evidence that restorative care activities were completed. |
Examples of Assessing Treatment Fidelity

- Hildebrand, Mary W.; Host, Helen H.; Binder, Ellen F.; Carpenter, Brian; Freedland, Kenneth E.; Morrow-Howell, Nancy; Baum, Carolyn M.; Doré, Peter; Lenze, Eric J. Measuring Treatment Fidelity in a Rehabilitation Intervention Study. American Journal of Physical Medicine & Rehabilitation 2012; 91(8): 715-24
Additional Examples


- Spillane V, Byrne MC, Byrne M, Leathem CS, O'Malley M, Cupples ME. **Monitoring treatment fidelity in a randomized controlled trial of a complex intervention.** J Adv Nurs. 2007 Nov;60(3):343-52.


Final Treatment Fidelity Tidbits

- There is no perfect plan
- Don’t get caught in the minutia
- Something is better than nothing