Treatment Fidelity in Yoga Research

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What is Treatment Fidelity?

• “Methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions.” (Bellg et al., 2004)
  – Emphasis mainly on the intervention rather than participant adherence.

• “Extent to which an intervention’s core components have been delivered as prescribed and differentiated from the comparison condition.” (Nelson et al., 2012)
What is Treatment Fidelity?

• Or simply stated:
  – “Was the intervention delivered as intended? How was this monitored and measured?” (Davidson et al., 2003)

• Little work on treatment fidelity in yoga research. (Sherman et al., 2012)
Why Treatment Fidelity Matters
(Borrelli, 2011)

• Increases **confidence** in results.
  – Were effects from the intervention or unknown factors?
• Enhances both **internal validity** (tx is delivered as intended) and **external validity** (tx can be replicated and applied in real-world settings).
• Allows **early detection of errors** to prevent protocol deviations.
• Ensures that treatments are **operationalized in the same way** (in multi-site studies).
  – Reduces chance of site by treatment interactions.
Strategies to Enhance Treatment Fidelity

• Presenting strategies recommended by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium

• Their goal: Identify and recommend treatment fidelity strategies for health behavior intervention research

(Bellg et al., 2004; Borrelli et al., 2005; Borrelli, 2011)
Strategies to Enhance Treatment Fidelity

• Five Aspects of treatment fidelity:
  – **Study design**
  – Provider training
  – Treatment delivery
  – Treatment receipt
  – Enactment of treatment skills
# Strategies to Enhance Treatment Fidelity

## Study Design

<table>
<thead>
<tr>
<th>Recommended Steps</th>
<th>Specific Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify dose in treatment and comparison conditions.</td>
<td>Specify and measure frequency and length of interventions (each session and total length).</td>
</tr>
<tr>
<td>Describe treatment</td>
<td>Provide a detailed and standardized manual.</td>
</tr>
<tr>
<td>Give both (all) study groups same focus</td>
<td>Varies depending on study groups (e.g., focus will be on reducing symptoms, improving comfort, etc.).</td>
</tr>
<tr>
<td>Indicate interventionist credentials</td>
<td>Select only qualified interventionists who meet pre-specified standards.</td>
</tr>
<tr>
<td>Articulate theoretical model clearly</td>
<td>Specify and include “active ingredients” of intervention; experts/protocol review group determine whether protocol reflects model.</td>
</tr>
<tr>
<td>Include plan to address setbacks</td>
<td>Pre-specify backup interventionists. Train backup interventionists.</td>
</tr>
</tbody>
</table>
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## Provider Training

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<tr>
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<tr>
<td>Be selective in hiring interventionists.</td>
<td>Hire providers with similar credentials and experience. Ensure “buy in” to treatment, theory, and randomization.</td>
</tr>
<tr>
<td>Standardize interventionist training</td>
<td>Train interventionists using a standardized study-specific manual. For multiple sites, conduct centralized training.</td>
</tr>
<tr>
<td>Measure interventionist knowledge</td>
<td>Test interventionists to confirm understanding of study procedures. Use role plays with standardized patients and provide feedback.</td>
</tr>
<tr>
<td>Build in method to maintain skills</td>
<td>Regular meetings between interventionists and study staff to prevent “drift.” Study staff to review audio or videotapes of sessions. Provide regular and timely feedback.</td>
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## Strategies to Enhance Treatment Fidelity
### Treatment Delivery

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<tr>
<td>Include method to ensure content is delivered.</td>
<td>Use a treatment manual and checklist of intervention components.</td>
</tr>
<tr>
<td>Include method to ensure dose</td>
<td>Record intervention and practice time.</td>
</tr>
<tr>
<td>Include method to assess interventionist nonadherence</td>
<td>Review audio- or video-taped sessions and offer feedback to interventionists.</td>
</tr>
<tr>
<td>Assess nonspecific treatment effects</td>
<td>Include measures of participant expectations and ratings of interventionists.</td>
</tr>
<tr>
<td>Minimize treatment contamination</td>
<td>Provide checklist of non-allowed intervention components for interventionists.</td>
</tr>
</tbody>
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**Treatment Receipt**

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<tr>
<td>Assess participant ability to perform intervention skills</td>
<td>Request feedback that includes self-assessment of ability to do the intervention.</td>
</tr>
<tr>
<td>Build in strategy to improve performance of skills</td>
<td>Provide materials to encourage intervention practice outside of formal supervised sessions. Schedule follow-up visits or calls to check in on understanding of skills.</td>
</tr>
<tr>
<td>Consider multicultural factors in the development and delivery of intervention</td>
<td>e.g., Provide intervention in native language; ensure protocol consistent with values of the target group; written materials with appropriate level of health literacy.</td>
</tr>
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Enactment of Treatment Skills

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<td>Assess use and performance of skills in an applied setting</td>
<td>Assess participants’ use of intervention skills outside of study sessions via direct observation, self-report, and/or interventionist report.</td>
</tr>
</tbody>
</table>

Distinguishes what is taught (treatment delivery), what is learned (treatment receipt), and what is actually used (enactment).
Suggested *Minimum* Treatment Fidelity Strategies for Yoga Studies *(Sherman, 2012)*

- Observe at least some classes to ensure delivered as designed.
- Develop checklists that specify critical and minimum intervention components (e.g., all elements of a sequence).
- Include other important/less tangible aspects of instruction in checklist
  - e.g., Principle of truthfulness – doing what body can actually do at that moment
Examples

• **BreathEasy Trial** (yoga for smoking cessation)  *(Bock et al., 2014)*
  – Section on Quality Control and Assurance

• **Mindfulness-Based Cognitive Therapy Adherence Scale** *(Segal et al., 2002)*
  – See Appendix for sample items

• **MsFLASH** (yoga, exercise, and omega-3 fatty acids for menopausal symptoms) *(Sternfeld et al, 2013)*
  – Section 2.7. Centralized training, detailed manuals, mock classes conducted, written materials and CD/DVDs created, “Yoga Fidelity Monitoring Form” (for each yoga class by study staff member), site visits.
An Example of Proposed Treatment Fidelity Strategies

• Proposed study of yoga and physical activity in a group of hospitalized cancer patients.
• Strategies:
  – Train interventionists with detailed manual.
  – Test interventionists for knowledge of content.
  – Ask interventionists to complete a checklist of components for every session.
  – Report any deviations from the planned protocol.
  – Videotape all sessions (focus on interventionist); view randomly selected 10%.
  – Meet regularly with interventionists to discuss experiences and facilitate consistency.
References


References


• Sherman K. Guidelines for developing yoga interventions for randomized trials. *Evidence-Based Complementary and Alternative Medicine*; 2012 (Article ID 143271).