

# **Treatment Fidelity in Yoga Research**

**Suzanne Danhauer, Ph.D.  
Wake Forest School of Medicine**

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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

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



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# Strategies to Enhance Treatment Fidelity

## Provider Training

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



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# Strategies to Enhance Treatment Fidelity

## Treatment Delivery

Recommended Steps	Specific Approaches
Include method to ensure content is delivered.	Use a treatment manual and checklist of intervention components.
Include method to ensure dose	Record intervention and practice time.
Include method to assess interventionist nonadherence	Review audio- or video-taped sessions and offer feedback to interventionists.
Assess nonspecific treatment effects	Include measures of participant expectations and ratings of interventionists.
Minimize treatment contamination	Provide checklist of non-allowed intervention components for interventionists.

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# Strategies to Enhance Treatment Fidelity

## Treatment Receipt

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

# Strategies to Enhance Treatment Fidelity

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  - **Enactment of treatment skills**

# Strategies to Enhance Treatment Fidelity

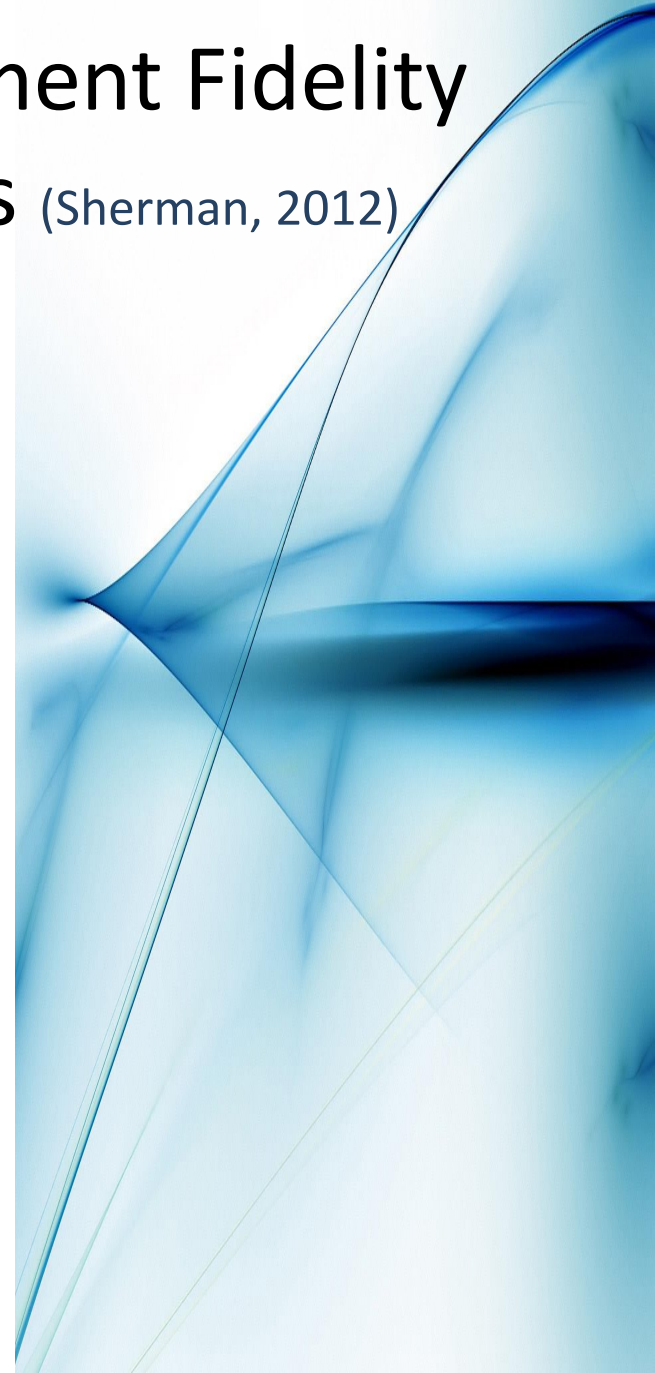
## Enactment of Treatment Skills

Recommended Steps	Specific Approaches
Assess use and performance of skills in an applied setting	Assess participants' use of intervention skills outside of study sessions via direct observation, self-report, and/or interventionist report.

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)

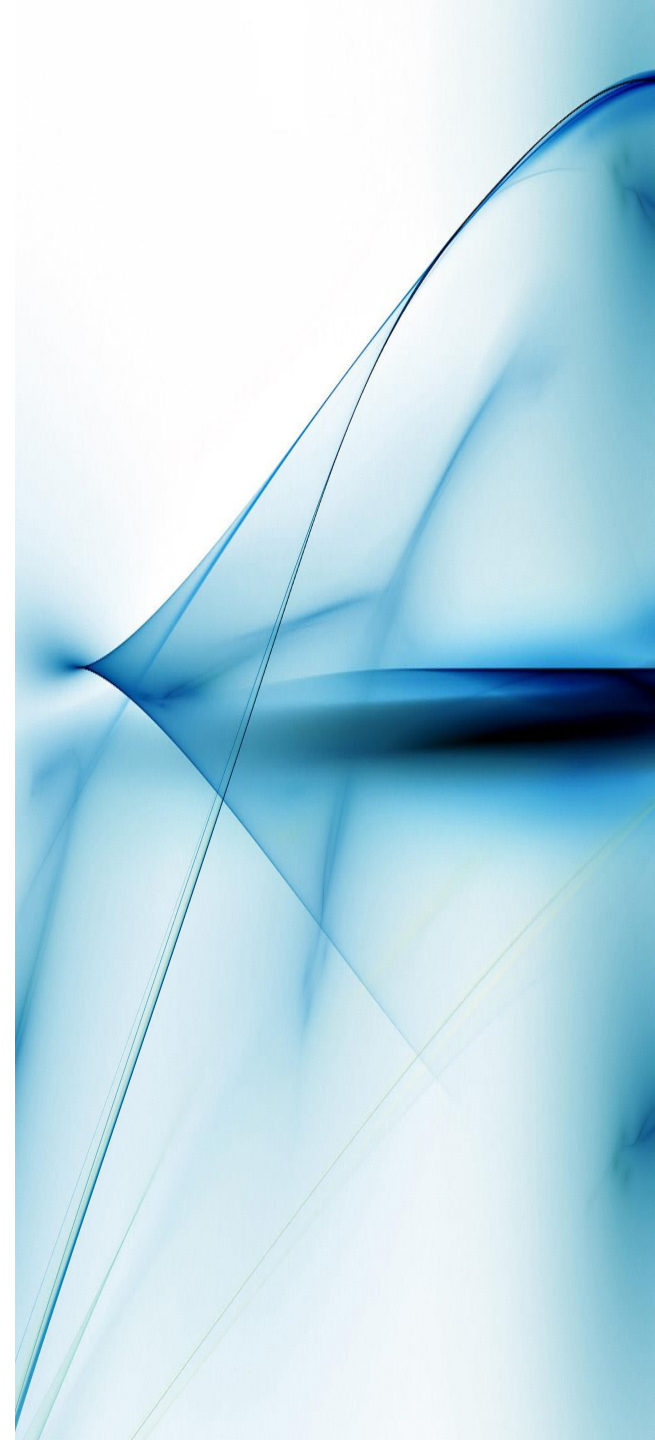
- Observe at least some classes to ensure delivered as designed.
- Develop checklists that specify critical and minimum intervention components (e.g., all elements of a sequence).
- Include other important/less tangible aspects of instruction in checklist
  - e.g., Principle of truthfulness – doing what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





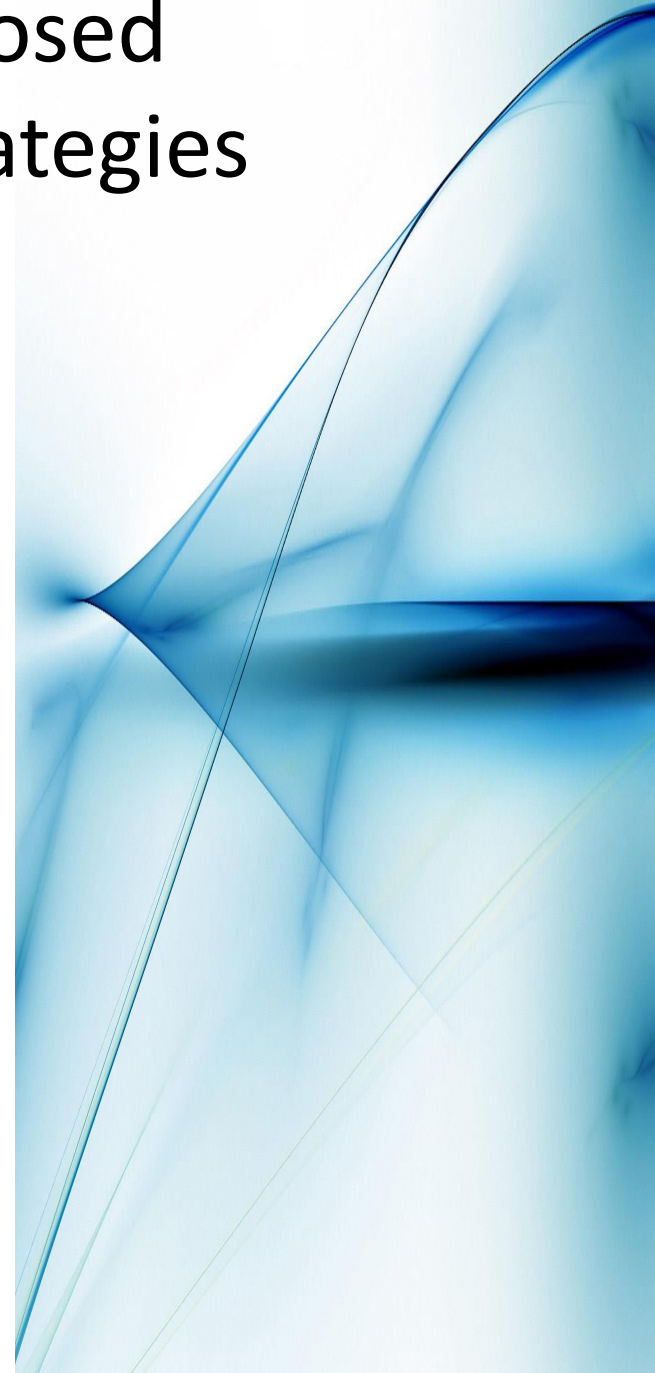
# Examples

- **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.



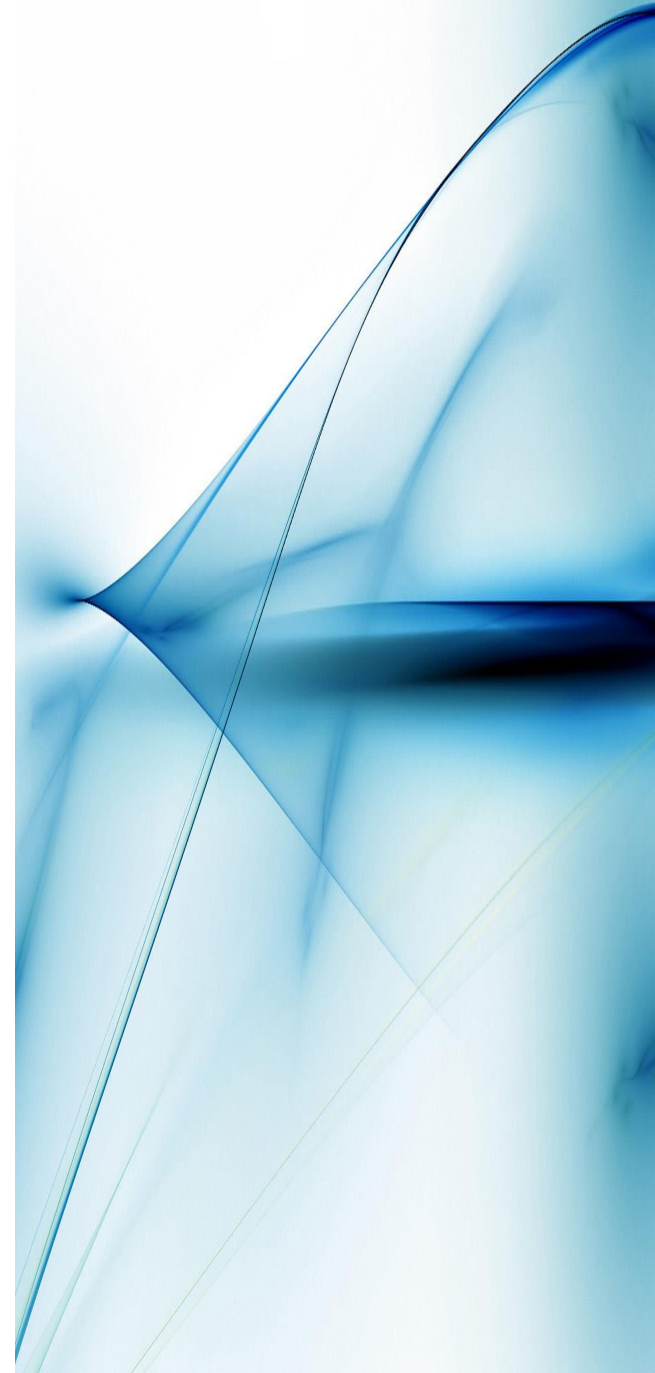
# An Example of Proposed Treatment Fidelity Strategies

- 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.



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