

Fidelity to Intervention Protocol

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Organization of Session

- Overview of Issues related to Fidelity
- Examples from Two Trials: ACTIVE & ENRICHED
- Discussion

Fidelity:

- Adherence by staff to intervention protocol
- Reduction in excess variability in carrying out intervention protocol
- Monitoring fidelity over multiple replicates of a trial
- Procedures for assessment of fidelity to the intervention protocol

Fidelity: Prior to Intervention

- Specification of Intervention Protocol
 - Development of comprehensive & user-friendly Intervention Manuals
- Selecting Interventionists
 - Setting criteria & procedures for selection
- Centralized Training of Interventionists
- Piloting of Intervention
- Develop procedures for monitoring fidelity

Selecting Interventionists:

- Criteria for selecting interventionists
 - Match with intervention population
 - Age, prior experience with population
 - Match with intervention protocol
- Selection Process: Multiple levels
 - Site
 - Intervention Center/intervention developer
 - Intervention supervisor

Intervention Manuals: Comprehensive & User Friendly

- Clear, precise definitions, language, and directions
- Integration of interventionist & participant materials
- Scripted Protocol
- Dosing criteria for each session
- Fidelity AND Flexibility: Individual differences

Centralized Training

- Conceptual Understanding of Phenomenon
- Procedures for Training Interventionists
- Early Evaluation of Interventionist x Intervention Fit
- Working with Multicultural Populations
- Interventions with Behavioral & Pharmaceutical Arms

Centralized Training: Procedures for Training

- Modeling of Intervention Procedure - live or video
- Use of scripts
- Observation of trainees & checklists
- Audio tapes & checklists
- Trial with “sample” participant & feedback
- Trial run at site

Centralized Training:

Early Evaluation of Interventionist

- Understanding & ability to execute intervention protocol
- Match with subject population
- Match with site & intervention protocol

Quality Assurance in the Intervention: Intervention Environment

- Setting criteria for Environment prior to the Intervention
 - Environmental demands of intervention protocol
- Quality assurance of Environment during the Intervention
 - Checklists
- Special Considerations:
 - Interventions in the home
 - Interventions in public settings

Fidelity: Quality Assurance during the Intervention

- Assuring fidelity across sites
 - Equivalence in Dosing level, feedback, incentives, etc.
- Maintaining contact with staff
- Schedule for monitoring of fidelity
- Procedures for monitoring fidelity
 - Observation, audio tapes, session records, etc.

Fidelity in Special Circumstances

- Multiple Interventions
- Booster following the Intervention
- Replacing Interventionists

Fidelity: Multiple Interventions

“Bleeding” across interventions

- Identifying possible commonalities among interventions
- Contact between subjects in different interventions
- Contact among Interventionists & Training of Interventionists

Fidelity:

Boosters following Interventions

- Maintaining Intervention staff across time
- Relation of protocol for initial intervention & for booster intervention
- Monitoring fidelity across multiple, temporally space replicates of intervention