

# Assessing the Strength and Integrity of an Intervention

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**Purpose/Objectives:** To evaluate the strength and integrity of a pilot behavioral intervention designed to assist mothers with breast cancer and their children.

**Research Approach:** A single-group analysis of the strength and integrity characteristics of an intervention developed for a pilot research study.

**Setting:** Homes of study participants in an urban area.

**Participants:** Seven households with a mother and father and one household with a single mother.

**Methodologic Approach:** Observer-reported checklists, audiorecorded intervention session data, and structured interview data obtained from study participants.

**Main Research Variables:** Strength of the intervention included dimensions such as the theoretical foundation, competence of the interventionist, and specificity to the breast cancer experience in the family. Intervention integrity consisted of adherence by the interventionist and participants to the intervention plan.

**Findings:** The strength of the intervention was determined to be an asset. Careful planning had included a framework, a defined set of scripted sessions, a competent interventionist, and content specific to the breast cancer experience. In regard to integrity, the protocol content was delivered as scripted. Improvements in the dosage and purity dimensions were found to be needed. Homework assignments and in-session skill-building approaches with the mothers were refined.

**Conclusions:** An intervention can be examined carefully for strength and integrity with established criteria to determine improvements needed.

**Interpretation:** A clinical research protocol can be improved through an assessment of an intervention's strength and integrity.

## Key Points . . .

- ▶ An analysis of the strength and integrity of an intervention assists the researcher and clinician in learning what works about the intervention and what needs improvement.
- ▶ When an intervention is monitored to ensure that it is provided uniformly and treatment errors are reduced, the consumer obtains a more consistently delivered intervention.
- ▶ Standards of care that evolve through careful planning and evaluation of interventions will ensure a better match of an intervention to the needs of the designated population.

experienced. Strength indicators include whether the type, number, and duration of sessions needed to integrate the theory into practice were considered during the planning phase, as well as what skills are needed by interventionists. Through analysis of these elements of strength, the specifications of the intervention are understood more clearly by the study researchers. Having an estimate of the strength of an intervention assists in the interpretation of study results (Scott & Sechrest, 1989).

Questions such as the following are relevant to the analysis of the strength of an intervention: Was the content developed with a theoretical framework as a guide? Was a plan developed for the number and duration of sessions? What

Each year, thousands of children's life experiences are changed as a result of the diagnosis and treatment of maternal breast cancer. Case-intensive interview studies have revealed that many children have fears that their mothers will die and that they have little help in managing information about breast cancer (Shands, Lewis, & Zahlis, 2000; Zahlis, 2001; Zahlis & Lewis, 1998). A pilot study of a behavioral intervention was developed to help mothers respond to their school-age children's cancer-related concerns and enhance the quality of mother-child relationships (Lewis, Casey, Brandt, Shands, & Zahlis, 2004). The purpose of this article is to summarize the methods used to analyze the strength and integrity of that intervention and to report the results obtained.

What does the strength of an intervention mean? An intervention that has characteristics of strength is one that has been constructed with a theoretical foundation and directly addresses concerns of the study population or is specific to the situation

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competencies of the clinicians were needed to implement the intervention? Did the participants believe that the intervention was specific to their issues?

What does the integrity of an intervention mean? Integrity is defined as the degree to which an intervention actually was delivered as planned (Scott & Sechrest, 1989). The integrity of an intervention involves its implementation stage. To understand whether adherence to integrity occurred, a review of whether each participant had similar exposure to the intervention is needed. Researchers who design an intervention are interested in whether the content of the intervention was delivered as planned and whether all of the participants received the same dosage.

Why is studying the strength and integrity of an intervention important? Designers of an intervention become more fully informed of what works and what does not work by studying the elements of strength and integrity. They learn whether to continue the intervention as originally designed or to make changes as needed. See Figure 1 for definitions of key words and phrases.

Measurement and analysis of an intervention's strength and integrity are particularly important when pilot testing a newly developed intervention. Formative changes in the treatment itself and in the plan for monitoring integrity should be completed in a pilot test before implementing the intervention with a wider audience recruited for a clinical trial. Without pertinent data and responsible decision making throughout all of the phases of intervention research, the dissemination and utility of the intervention are jeopardized. As research programs progress from pilot studies to clinical trials, the intervention should be refined and monitored continually. Testing an intervention is aimed at ensuring its safety related to dosage and side effects (National Institutes of Health, 2001) and its effectiveness in producing expected outcomes (Yeaton, 1994).

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**Strength:** characteristics of the intervention that contribute to its overall quality; the theoretical foundation and planning of the intervention's dosage, including frequency and number of sessions

**Integrity:** the degree to which the intervention is delivered as designed

**Intervention as a variable:** the procedures involved in the intervention and its implementation

**Intervention errors:**

- **Type 1:** Intervention is interpreted as effective when it is not.
- **Type 2:** Intervention is interpreted as ineffective when it is effective.
- **Type 3:** Intervention is not understood or contains inappropriate measurements, designs, or conceptualizations of variables.

**Competence of the interventionist:** the alliance between the mother and the interventionist in respect to the mutuality of goals

**Dosage as integrity:** the number of sessions and percentage of homework completed

**Purity as strength:** intervention content and strategies developed with a theoretical basis before implementing the intervention

**Purity as integrity:** intervention delivered as planned

**Specificity of the intervention:** relevance of the intervention to the breast cancer experience in respect to the mother and child relationship

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**Figure 1. Definitions of Key Words and Phrases**

Mistakes in conclusions about treatments occur because of type 1, 2, or 3 errors. A type 1 error occurs when an intervention is interpreted as effective when it is not. By reviewing intervention integrity, for example, a researcher would be able to identify participants who obtained the expected outcomes yet participated in only a few of the sessions. As treatment-delivery errors are reduced, the likelihood of a type 2 error (false negative) is reduced and, thus, an intervention is less likely to be viewed as ineffective when, in fact, it was effective (Costner, 1989). When an intervention is monitored to ensure that it is delivered uniformly and treatment errors subsequently are reduced, the variability of the intervention received is decreased. The statistical power to detect significant intervention effects is strengthened when the variability of the intervention and the within-group variance are decreased.

Type 3 errors are minimized when a study has theoretical validity. Theoretical validity occurs when an understanding of the study variables, including the intervention and its attributes, exists (Smith & Sechrest, 1998). The unique qualities of each independent variable, including the intervention, contribute to theoretical validity. A type 3 error occurs when an intervention is not understood or when inappropriate measurements, designs, or conceptualizations of the variables occur (Smith & Sechrest). Type 3 errors have received minimal attention by researchers because interventions typically are inadequately described or evaluated. As a consequence of inadequate descriptions, the essence of the treatment and its relationship to study outcomes are unclear; thus, the practical and theoretical significance of an intervention often is questionable (Smith & Sechrest).

## Pilot Intervention Study

A pilot intervention study was designed to provide a cognitive-behavioral approach to improve the quality of mother-child relationships and children's adjustment to their mothers' breast cancer during the acute phase of treatment. A one-group pre/post-test design was used to evaluate efficacy in the five one-hour educational sessions delivered to the mothers in their homes over a 10-week period (Lewis et al., 2004). This intervention was conducted with a highly scripted protocol. Between sessions, the mothers and their school-age children interacted to complete specific homework activities such as reading a booklet together about the mothers' breast cancer treatment and the mothers listening to the children's concerns about breast cancer.

Social cognitive theory guided the development of the content and approaches used in the intervention (Bandura, 1986, 1997, 2001). Social cognitive theory addresses behavioral capability and self-efficacy. Behavioral capability is addressed through skill-enhancing approaches. Self-efficacy is increased as a person develops self-confidence in performing certain skills (Bandura, 1986).

The content of the intervention included an emphasis on the mothers' self-care and their listening skills with a focus on the children's concerns and coping efforts related to the breast cancer experience. Efficacy approaches, such as modeling and practice of specific parenting behaviors, were integrated throughout the intervention.

The population used for the analysis of strength and integrity included eight families recruited for the pilot intervention study. By performing the analysis early in the study, the researchers could assess the strength and integrity of the inter-

vention and make revisions in the study protocol early in the pilot phase as needed. The assessment included seven households with a mother and father and one household with a single mother. Eight mothers and five fathers were included with six male children and two female children. Mothers were diagnosed with stage 0, I, or II breast cancer. The time since diagnosis ranged from one to seven months with a median of five months. Five of the eight women had had a partial or modified mastectomy, and six of the eight had received chemotherapy. Four of the eight mothers had had radiation treatment. At the time of the study, the majority of mothers experienced fatigue and discomfort related to treatment. Annual household income ranged from \$32,499 to more than \$70,000 and averaged \$54,686. In four of the eight families, mothers worked full-time, and all of the fathers worked full-time. The average age of the mothers was 40 years, and the fathers' average age was 39 years. The families were Caucasian except for one Asian American family. Sample recruitment occurred at oncology outpatient clinics.

## Analysis and Results of the Strength and Integrity of the Pilot Intervention

The primary dimensions included in this analysis of strength and integrity involve purity, dosage, competence of the interventionist, and specificity of the intervention for the sample. See Table 1 for an outline of the method, source, and time point for each dimension. Focusing on strength characteristics is particularly important to the planning phase of the intervention. Integrity is directed toward the implementation phase of the intervention and adherence to what was planned (Scott & Sechrest, 1989).

The purity of an intervention determines whether its content and strategies were conceptualized (strength) and delivered as planned (integrity). In regard to strength, the investigators developed and then reviewed the content and approaches of each intervention session to ensure that the social cognitive framework was integrated throughout the sessions as conceptualized. A scripted protocol was developed to enhance the uniformity of the delivery of the intervention to each family.

Purity as a measure of integrity or adherence to the scripted protocol was obtained by reviewing audiotapes from two of the

five audiotaped intervention sessions for each family. Intervention delivery was taped by the interventionist using a handheld audio recorder. Two raters reviewed 20% of the audiotapes of sessions 2 and 4. These sessions were chosen for the audit because they provided a sample of an early and late intervention session. A detailed checklist was developed for this review. Because of the specificity and clarity of the checklist items, the training needed by the raters was minimal. After about three hours of training, adequate reliability occurred. The checklist operated as an audit trail to ensure that the protocol was implemented as designed (Lincoln & Guba, 1985) and provided the documentation needed for any formative changes required during the implementation phase of the intervention. The items on the checklist were developed by the grant team members to represent the unique themes covered in each session. In addition, the items selected were congruent with the social cognitive framework. Examples of items on the checklist include "Was the designated role-playing exercise delivered?" and "Was each page of the workbook reviewed with the mother?"

The checklist criteria had an inter-rater reliability of 100% agreement. Neither of the raters of the checklist delivered the intervention. Each rater was responsible for an independent review of adherence to the protocol, which occurred by completing the checklist. The high level of agreement probably was a function of the specificity and clarity of the items on the checklist. No errors were found in the delivery of the content as outlined in the protocol. Skill-building omissions by the interventionist were detected in the majority of audited sessions. These skill-building approaches were not explicitly scripted in the protocol but instead were written as overall guidelines for the interventionist's use.

Dosage was an indicator of the intervention's integrity. Information from previous intervention research was used during the planning phase to determine the dosage, in this case the number and duration of sessions (Lewis, 1996). In addition, a minimum number of hours had to be established to accomplish the outcomes because the majority of mothers recruited for the intervention would have some fatigue as a result of ongoing breast cancer treatment.

The interventionist measured the dosage by tracking the number of sessions and homework assignments completed. The mothers who completed all five sessions of the intervention and all of the homework assignments obtained the full

**Table 1. Intervention Strength and Integrity: Dimensions, Methods, Sources, and Time Points**

| Dimension                           | Method                     | Example  | Source   | Time Point          |
|-------------------------------------|----------------------------|--|--|---------------------|
| <b>Strength</b>                     |                            |  |  |                     |
| • Purity                            | Scripted protocol          | "Since our last visit, what would you want to add to how you take care of yourself?"           | Social cognitive theory literature                           | Planning phase      |
| • Competence of the interventionist | Working Alliance Inventory | "We are working on mutually agreed upon goals."  | Participant and interventionist                              | After intervention  |
| • Specificity                       | Structured interview       | "Did information in this session have personal usefulness to your experience with your child?" | Mother and father  | After intervention  |
| <b>Integrity</b>                    |                            |  |  |                     |
| • Purity                            | Intervention audit         | Completed in-session exercise: yes or no   | Audiotaped interventions at sessions 2 and 4 for each family | During intervention |
| • Dosage                            | Checklist                  | Number of sessions and assignments completed   | Interventionist  | During intervention |

dose of the intervention. The interventionist logged this information after completion of each intervention session. By exploring the dosage of an intervention, the investigator identified hypotheses for testing in future studies and determined, for example, whether a large effect may be achieved by a small dose (Yeaton & Sechrest, 1992).

With regard to dosage as an integrity dimension, the analysis indicated that all eight of the families completed all of the intervention sessions. Six of the eight families completed all of the homework assignments. One of the eight families completed 80% of the assignments and all sessions, and another family completed 60% of the assignments and all sessions.

The competence of the interventionist reflected the degree to which the interventionist was sufficiently skilled to implement the treatment. Competence is an essential characteristic of the strength of an intervention (Scott & Sechrest, 1989). Experience and training are not sufficient measures of competence (Waltz, Addis, Koerner, & Jacobson, 1993). Mutuality of goals and understanding has been found to be essential to treatment outcomes (Horvath & Symonds, 1991) and important predictors of success for psychosocial-oriented interventions (Marmar, Weiss, & Gaston, 1989). Self-report measures of the interpersonal relationship between client and interventionist have been found to be more accurate than data obtained by an observer (Hartley, 1985; Horvath & Symonds). The **Working Alliance Inventory (WAI)** was used as the indicator of the competence of the interventionist in this study (Horvath & Greenberg, 1989). The WAI is a self-report measure of mutuality and collaboration between the client and interventionist on goals and tasks. The WAI measures the generic interpersonal process between client and interventionist. Thus, it is useful across various contexts and philosophical frameworks. Horvath and Greenberg reported the Cronbach alpha reliabilities on the WAI to be 0.95 (client version) and 0.87 (interventionist version). Convergent and discriminate validity have been established on the WAI (Horvath & Greenberg). The short version of 12 items was used in this study because it has similar psychometric properties to the 36-item form (Tracey & Kokotovic, 1989). A Likert rating scale was used (1 = never to 7 = always). A high score indicates a high alliance. Item examples on this measure are "We agree on what is important to work on" and "We are working on mutually agreed upon goals."

For competence of the interventionist, descriptive statistics of WAI scores were calculated to determine the mutuality of goals experienced by the mother and interventionist. The Wilcoxon signed ranks test (two-tailed) was used to evaluate the dimension of competence of the interventionist. Power efficiency of the Wilcoxon signed ranks test for small samples is almost 95% (Siegel & Castellan, 1990). When sample distributions are likely not to meet the assumptions of normality, typical of small samples, nonparametric statistics are useful. One such procedure is the Wilcoxon signed ranks test. One of the advantages of the Wilcoxon signed ranks test is that the procedure considers the direction and magnitude of the differences (Munro, 1997; Siegel & Castellan). Results of the mother and interventionist pair showed no statistically significant differences. This result indicated that the mother and interventionist had comparable perceptions about the working alliance formed with each other. Mean scores on the WAI further indicated that the alliance between the mother and the interventionist was formed at a high level.

Specificity is the relevance of the intervention to a particular population (in this situation, mothers and children in the con-

text of breast cancer). Specificity is an important dimension of the strength of an intervention because the more targeted an intervention is to the needs of a specific population, the better the outcomes (Scott & Sechrest, 1989). Information on the specificity dimension was obtained using semistructured interviews conducted by a predoctoral student who had knowledge of but did not deliver the intervention. Mothers and fathers were interviewed separately after the program. The mothers in the study were asked about the timing of the intervention. Fifty percent reported that they would have preferred to have participated in the program closer to their diagnosis. The number of sessions designed for the intervention was reported to be sufficient by all of the mothers.

In respect to the relevance of the intervention to the breast cancer experience, the interview data from both mothers and fathers indicated that the program was perceived to be useful with no harm or negative consequences identified. Any new program must ensure that unintentional harm does not occur (Dishion, McCord, & Poulin, 1999). Inductive content analytic procedures were used to analyze the postprogram interviews with the mothers and fathers. Units of analysis were determined, then open coding was performed (Strauss & Corbin, 1990). The domains identified in the analysis contributed to understanding the intervention. Fathers indicated that the program "prepared the child" and "created new opportunities" for mothers and children to be together. Mothers indicated that the program assisted them in "taking care of myself," "doing things right," "initiating support," "stopping and thinking," "being cautious" about what to discuss with the children, and "being aware" of the children's thoughts and feelings (Kirsch, Brandt, & Lewis, 2003).

## Changes Needed for the Pilot Intervention

By systematically analyzing the strength and integrity of the pilot intervention, the investigators learned more about the intervention itself. What was working well and what needed improvement also were revealed. Through the evaluation, the intervention was found to have characteristics of both strength and integrity. Careful planning included a framework and a defined number and length of scripted sessions. A mutuality of goals existed between the interventionist and the mothers in the study, and the parents identified benefits of the intervention with no problematic concerns. The delivery of the content followed the scripted protocol.

Improvements were needed in select aspects of the dosage and purity dimensions. In relation to dosage, the few homework assignments that created difficulties for the mothers and children and, therefore, were not completed subsequently were simplified. Directions and formats were improved and tasks reduced. To improve the purity dimension, the investigators revised the script to ensure that the self-efficacy approaches of social cognitive theory were more dominant throughout the program (Bandura, 2001). For example, skill-building approaches to enhance the mothers' self-efficacy in listening and supporting their children were defined for each session, and explicit statements were written into the interventionist's manual. Specific ways for the interventionist to complete role enactment, enhance feedback on homework, and ensure behavioral capability through knowledge and skill training with the mothers were added. Skill-building exercises for each

homework assignment also were included so that the mothers were better prepared to create a comfortable climate for their children during the exercises.

The few modifications made in the intervention protocol ensured that the intervention would be linked more tightly with theory and delivery problems typically found with type 2 errors. Theoretical validity also was enhanced by the analysis and subsequent modifications. Thus, the potential for a type 3 error was decreased. The unique qualities were described more clearly through this evaluation of the intervention's strength and integrity.

## Implications for Clinical Nursing Research and Practice

The analysis of the integrity of the pilot intervention assisted the investigators in preparing for a clinical trial. A clinical trial involves many more families and interventionists than a pilot study. Having a detailed plan for defining and monitoring an intervention provides a form of communication among investigators and interventionists during a clinical trial, which typically is more complex than a pilot study. By learning about an intervention's strength and integrity, its essential elements are better identified and delivery of the protocol can be followed.

A critical condition for the design of population-specific interventions is the congruence of the conceptualization of an intervention and its implementation strategies (Conn, Rantz, Wipke-Tevis, & Maas, 2001). Thus, the investigators had to formulate and incorporate more directive guidelines into the intervention manual that addressed the dominant approaches of social cognitive theory.

The principles of strength and integrity are as essential for nursing practice as for research-oriented interventions. Building intervention content based on a theoretical framework and having knowledge of a population's characteristics and issues are central to planning any intervention. A rationale for the dosage and competence of the interventionist ensures a better match of the intervention to the needs of the designated population. Yeaton (1994) emphasized the value of assessing treatment integrity of services provided to consumers of care. With a greater understanding of the services delivered, the clinical outcomes of services will be clearer. As standards of care increasingly are adopted in practice, clinicians will have more confidence knowing that practice standards evolved through careful evaluation.

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