Published in final edited form as:

*J Consult Clin Psychol*. 2015 February ; 83(1): 12–23. doi:10.1037/a0038219.

# The Enhancing Connections Program: A 6-State Randomized Clinical Trial of a Cancer Parenting Program

**Frances M. Lewis**,
University of Washington

**Patricia A. Brandt**,
University of Washington

**Barbara B. Cochrane**,
University of Washington

**Kristin A. Griffith**,
University of Washington

**Marcia Grant**,
City of Hope Cancer Research Center

**Joan E. Haase**,
Indiana University School of Nursing

**Arlene D. Houldin**,
University of Pennsylvania

**Janice Post-White**,
University of Minnesota

**Ellen H. Zahlis**, and
University of Washington

**Mary Ellen Shands**
University of Washington

## Abstract

**Objective—**The purpose of this study was to test the efficacy of a cancer parenting program for child-rearing mothers with breast cancer, the *Enhancing Connections Program.* Primary goals were to decrease maternal depressed mood and anxiety, improve parenting quality, parenting skills and confidence, and enhance the child's behavioral-emotional adjustment to maternal breast cancer.

**Method—**A total of 176 mothers diagnosed within 6 months with Stage 0–III breast cancer and their 8–12 year old child were recruited from medical providers in 6 states: Washington, California, Pennsylvania, Minnesota, Arizona and Indiana. After consenting and obtaining baseline measures, study participants were randomized into experimental or control groups. Experimental mothers received five, 1-hour educational counseling sessions at 2- week intervals; controls received a booklet and phone call on communicating and supporting their child about the mother's cancer. Outcomes were assessed at 2 and 12 months.

**Results—**Compared to controls, at 2 months experimental mothers significantly improved on depressed mood and parenting skills; experimental children improved on behavioral-emotional adjustment: total behavior problems, externalizing problems, and anxiety/depressed mood significantly declined. At 1 year, experimental children remained significantly less depressed than controls on both mother- and child-reported measures. The intervention failed to significantly affect parenting self-efficacy or maternal anxiety.

**Conclusions—**The *Enhancing Connections Program* benefitted mothers and children in specific areas and warrants refinement and further testing.

## Keywords

breast cancer; parent education; randomized clinical trial; educational counseling; self-efficacy; child behavioral-emotional adjustment

An estimated 232,340 women were newly diagnosed with invasive or *in situ* breast cancer in the U.S (ACS, 2013) and approximately 18%–22% had minor children residing in their households (Weaver, Rowland, Alfano, & McNeel, 2010). This means that approximately 53,456 children were newly impacted by maternal breast cancer in the U.S. but that number does not reflect the multiple thousands of additionally affected children in other countries.

Results from a growing body of studies show that children are negatively affected by their mother's breast cancer. The majority of school-age children show regression, withdrawal, and anxiety about family stability and integrity and fear their mother will die from the cancer, even early stage disease (Brown et al., 2007; Grabiak, Bender, & Puskar, 2007; Huizinga, van der Graaf, Visser, Dijkstra, & Hoekstra-Weebers, 2003; Nelson & While, 2002; Osborn, 2007; Visser et al., 2005; Zahlis, 2001). An estimated 22–33% of children reach or exceed clinical levels of distress (Huizinga et al., 2003; Nelson & While, 2002; Osborn, 2008; Visser et al., 2005; Watson et al., 2006).

Children watch their mothers struggle with extended months of treatment and disease-related symptoms. Side effects from polychemotherapy, hormonal therapy, and surgical or radiation treatment can produce sleep alterations, mood alterations, and extreme fatigue, all of which can impact the child (Rauch & Muriel, 2003). Treatment demands or concerns about the cancer as well as high rates of depressed mood and anxiety in the diagnosed mother can make her less physically or emotionally available to the child (Brown et al., 2007; Compas, Worsham, Ey, & Howell, 1996; Fann et al., 2008; Lewis, 2011; Lewis et al., 2000; Shands, Lewis, & Zahlis, 2000; Sigal, Perry, Robins, Gagne, & Nassif, 2003; Vannatta, Ramsey, Noll, & Gerhardt, 2010; Watson et al., 2006). Parental non-availability, especially during maternal illness, is a known risk factor for children's behavioral-emotional adjustment. Interactions with the child and mothers with breast cancer are known to be strained, limited, and infrequent (Armsden & Lewis, 1993; Behar, 2000; Behar & Lewis, 2015; Lewis & Darby, 2004; Lewis & Hammond, 1996; Sigal et al., 2003; Vannatta et al., 2010).

In interview studies involving small samples, recently diagnosed mothers report that their own anxiety and worries about symptoms keep them from being responsive to their child

(Shands et al., 2000; Zahlis & Lewis, 1998). They describe themselves as being in survival mode and report difficulty in knowing what to do or say to help their child, fearing that talking about the cancer will add to the child's burden (Lewis, 2010; Lewis, Casey, Brandt, Shands, & Zahlis, 2006; Rauch & Muriel, 2003; Zahlis & Lewis, 1998). Mothers state they do not feel confident they can allay the child's concerns, deal with their child's emotional state, and do not want to face the child's questions or emotions, especially about death (Barnes et al., 2000; Barnes et al., 2002; Shands et al., 2000). When mothers do communicate with their child about the breast cancer, one interview study with 19 diagnosed mothers documented that mothers focused on the medical aspects of the cancer, not on the child's worries or concerns (Shands et al., 2000). In that same study, their conversations included emotionally laden terms for which the child had limited or no understanding (Shands et al., 2000).

There is an additional dilemma. Children, even children with nightmares and crying spells, hold back disclosing their questions, fears or worries to their ill mother, not wanting to further burden an already distressed parent (Lewis, 2010; Lewis et al., 2000). They instead tend to protect or hide their thoughts and feelings from their ill mother. As this 9-year old girl reported, "I went on the couch in front of the TV so she'd think that I'd been watching it, but I closed my eyes and I was thinking about her illness" (Issel, Ersek, & Lewis, 1990, p. 9).

Despite the toll of the mother's breast cancer on the mother and child, programs and services lag far behind need. There is only one published intervention study in the English language, exclusive of a study by the current authors: Thastum's study (Thastum, Munch-Hansen, Wiell, & Romer, 2006). Using a quasi-experimental design, 24 mothers and 17 fathers with cancer and 34 children were in either a counseling program or in a control group. The content of the intervention was not specified; the duration of the intervention varied between 3 to 10 months; the number of intervention sessions ranged from 3 to 8; and none of the sessions were monitored for dosage or fidelity. Time since diagnosis and disease staging of the ill parent varied between 1 to 153 months. Results showed a significant reduction in parental depressed mood but no significant changes on other parent or child outcomes compared to controls. This means that there is no known cancer parenting intervention that has been tested for efficacy in a randomized control trial in the published literature except that to be reported in the current study.

## Specific Aims

The *Enhancing Connections Program (EC)*, to be described below, is a cancer parenting program that was designed to address the communication and parenting issues raised in prior descriptive research and to respond to the limitations of current research. The goals of the program are to decrease maternal depressed mood and anxiety; improve parenting behavior (parenting quality, skills and self-efficacy); and improve children's behavioral-emotional adjustment to their mother's breast cancer. The aim of the current study was to evaluate the efficacy of the EC program on maternal and child outcomes within a randomized clinical trial.

## Method

### Participants

Study participants were women recently diagnosed with non-metastatic breast cancer and their school-age child, recruited from six states in the U.S., including community based comprehensive cancer centers, community cancer centers, private medical practices, and self-referral. Women were eligible if they were diagnosed with breast cancer (Stage 0, I, IIA, IIB, or III) within the past six months; were married or in an intimate heterosexual relationship; read and wrote English among their languages of choice; and had a school-age child between 8 and 12 years of age. Mothers with more than one age-eligible child were asked to choose one referent child for the study.

### Procedures & Design

After IRB approval at the core study center and in each recruitment site, intermediaries contacted potentially eligible mothers. Site intermediaries were nurses working at that site but not a member of the study team. Pending mothers' approvals, intermediaries gave contact information to the study team. Mothers were then contacted by phone by the study team, read an IRB-approved enrollment script, and, if interested, were asked to obtain their school-age child's interest in participating. Pending the child's acceptance, the study team obtained signed informed consent, child assent/consent, and baseline data in participants' homes. See Figure 1. Recruitment and randomization were managed at each state and enrollees from each recruitment site were randomized in blocks of two.

A total of 116 eligible mothers declined enrollment: 50% said they did not want or need the study; 20% said they were too busy to participate; 9% were not interested in a research study; 5% claimed they had too much stress to participate; 2% said they were too ill to participate; and 14% offered other reasons, e.g., the mother did not want to tell her child about the breast cancer diagnosis.

Mothers randomized to intervention received five parent education counseling sessions; see Experimental Intervention. Mothers randomized to the alternative treatment control group were mailed a printed booklet which focused on ways the mother could be supportive to her child about the breast cancer. After receiving the booklet, mothers were contacted by a specially trained Masters-prepared patient educator who used a script to review key points in the booklet and ways to get the most from the booklet. Each call lasted 10 or fewer minutes and was digitally recorded. One third of these calls were randomly chosen and assessed for fidelity, dosage, and potential drift for the duration of the study. There was no evidence of drift or contamination for the entire trial.

Dosage and fidelity of the experimental intervention were monitored for the duration of the trial by the core study team and by each state's site investigator. Session-specific performance criteria were developed for the current study, against which the audio-recorded intervention sessions were reviewed. There were 20–35 session-specific performance criteria against which the patient educator's behavior was evaluated. After initial training, the core team evaluated 100% of the first 25 recorded sessions for each intervention session from each state for each patient educator and provided feedback to the patient educator and site

co-investigator. Following that, a random sample of 1/3 of all subsequent intervention sessions were reviewed by the core study team for intervention fidelity. Fidelity was defined as a score of 3 [out of a perfect score of 3] on each performance criterion for each intervention session. A score of 1 or 2 on a single criterion resulted in contacting the patient educator to review the score and to retrain.

Members of the data collection team were masked on the randomization status of each study participant for the duration of the trial. They also met separately from the intervention team to protect against drift and contamination.

## Experimental Intervention

The intervention consisted of five fully-scripted patient education counseling sessions delivered at 2-week intervals to the mother; an interactive booklet about breast cancer to be read by the mother to the child; a mother's workbook containing didactic text as well as in-session and at-home assignments to be completed by the diagnosed mother, most with her child; "My Story," a child-completed activity booklet in which the child's interests and ways of dealing with stress were drawn or written by the child; and access by phone pager to the patient educator for 12 hours each day between the scheduled intervention sessions. (The pager was never used by study participants during the study except to reschedule appointments.)

The Enhancing Connections Program derived from 3 theories: the Transtheoretical Model of Coping (Compas, Howell, Phares, Williams, & Giunta, 1989; Compas, Malcarne, & Fondacaro, 1988; Compas et al., 1994; Compas et al., 1996; Welch, Wadsworth, & Compas, 1996; Wenzel, Glanz, & Lerman, 2002); the Contextual Model of Parenting (Collins, Harris, & Susman, 1995; Collins & Laursen, 2004; Lerner, Castellino, Terry, Villarruel, & McKinney, 1995); and Bandura's Social Cognitive Theory (Bandura, 1982, 1986, 1997, 2001, & 2004). All of the intervention materials, including the in-session and at-home assignments, were designed to articulate with these theories. See Table 1.

The first 2 theories informed the content of the intervention, including ways to communicate with the child which were child-centered and responsive to the child, using appropriate language, and staying within the child's frame of reference. Within this contextual parenting model, the diagnosed mother was offered ways to match her behavior and language to the cues of the child, including eliciting the child's ways of coping with the cancer and what the mother could do to support her child's coping.

Social Cognitive Theory, the 3rd theory, influenced the structure for each session and the in-session and at-home assignments, including the skill-building exercises (Bandura, 1982, 1986, 1997, 2001, & 2004). The theory also influenced the sequence of each intervention session and the scripted text that the patient educator used to interact with the diagnosed mother.

## Study Measures

Standardized questionnaires with well established validity and reliability with comparable populations were used to measure study outcomes. Data on demographic and treatment-

related variables were obtained through self-report and medical records. See Table 2 for the correlation matrix of study measures at baseline.

**Depressed mood—**Maternal depressed mood was measured by the Center for Epidemiologic Studies-Depression Scale (CES-D) (Conerly, Baker, Dye, Douglas, & Zabora, 2002; Radloff, 1977). This 20-item scale measures the recent occurrence of symptoms of depression. For each reported symptom, the respondent indicates the frequency of that symptom in the past week, from "rarely or none of the time (less than 1 day)" to "most or all of the time (5–7 days).” Internal consistency in three samples from the general population ranged between .84 and .85 (Radloff, 1977) and was 0.85 or higher in more recent studies with cancer patients (Conerly et al., 2002; Given et al., 2004). The validity of the measure is well-established, including its association with the broader concept of “distress” in cancer-related research (Benazon & Coyne, 2000; Coyne et al., 1987; Coyne & Smith, 1991). Internal consistency reliability for the current study sample was 0.90.

**Anxiety—**Maternal anxiety was measured by the state component of the Spielberger State-Trait Anxiety Inventory (STAI), a 20-item self-report questionnaire which evaluates feelings of apprehension, tension, nervousness, and worry “right now, at this moment” (Spielberger, 1983; Spielberger & Rickman, 1991; Spielberger, Sydeman, Owen, & Marsh, 1999). Response options range from “Not at all” (1) to “Very much so” (4). Items indicating positive feelings are reverse coded for scoring so that a higher score indicates greater anxiety. Internal consistency reliability for the current study sample was 0.96.

**Parenting self-efficacy—**Parenting self-efficacy was measured by three subscales on the Cancer Self-Efficacy Scale (CASE): Help Child, Deal & Manage, & Stay Calm subscales (Lewis et al., 2006; Lewis, 2011). Response options range from “Not at all confident” (1) to “Very confident” (10). Higher scores denote higher self-efficacy.

The Help Child subscale (9 items) measures the mother’s confidence in being able to talk with her child about the child’s cancer-related concerns and ways to manage those concerns; e.g., “I can assist my child to talk out his/her worries about my cancer.” The Deal and Manage subscale (13 items) measures the mother’s confidence in helping herself and her family deal with the demands and challenges of the cancer, e.g.,“I am able to take care of my family even as I experience pressures from the cancer.” The Stay Calm subscale (6 items) measures the mother’s confidence in remaining calm during difficult interactions with the child about the cancer, e.g., “I have the skills to keep myself calm about the cancer, even in highly charged talks with my child.” The internal consistency reliabilities for the current study sample were: 0.97 for Help Child, 0.96 for Deal and Manage, and 0.96 for Stay Calm subscales.

**Parenting quality—**Parenting quality was measured by 6 items on the Family-Peer Relationship Scale (FPRQ), the mother’s report of the type of interpersonal communication she has with her child (Ellison, 1983 & 1985). The measure has two theoretical dimensions relevant to the current study: Disclosure of Negative Feelings, e.g., “How likely is it that the child will share if s/he is feeling mad or angry?” and Disclosure of Bad Things Happening, e.g., “How likely is it that the child will share if something bad happens to the child?” The

internal consistency reliabilities were 0.89 and 0.86, respectively, for the current study sample.

**Parenting skills—**The mother's parenting skills were measured by a 14-item self-report Parenting Skills Checklist that was developed for the current study that measures the interactional behaviors mothers use to assist their child disclose, discuss, and cope with the breast cancer. The measure consists of two subscales: the Elicitation scale, e.g., "I draw out my child's concerns about the breast cancer," and the Connecting and Coping scale, e.g., "I set up private times to talk to my child about the breast cancer." The internal consistency reliabilities for these two subscales were 0.74 and 0.90, respectively for the study sample.

**Child behavioral-emotional adjustment—**The child's behavioral-emotional adjustment was measured by two mother-reported and two child-reported measures. The Behavior Problems Checklist of the CBCL, a mother-reported scale, consists of 118 items that measure a broad range of behavior problems in children ages 6–18 (Achenbach & Edelbrock, 1987; Achenbach & Rescorla, 2001). Items are rated from 0 to 2 from "Not True (as far as you know)" to "Somewhat or Sometimes True" to "Very True or Often True." The Externalizing score measures aggressive, antisocial, and under-controlled behavior and the Internalizing score measures fearful, inhibited, and over-controlled behavior. The internal consistency reliabilities for the current study sample were 0.97 for Total Behavior Problems, 0.90 for the Internalizing score, and 0.94 for the Externalizing score (Achenbach & Edelbrock, 1987; Achenbach & Rescorla, 2001).

**Child anxiety—**The child's anxiety was measured by the Revised Child Manifest Anxiety Scale (RCMAS), a 28-item child self-report measure of specific aspects of anxiety brought on by feelings or actions of the child. Items ask the child to rate an item as yes or no. The internal consistency reliability coefficient averaged 0.83 from prior studies and the scale's convergent validity was 0.85 with the State-Trait Anxiety Inventory for Children (STAIC) (Compas et al., 1996). The internal consistency reliability for the total scale was 0.90 for the study sample.

**Child depression—**Children's depression was measured by a child-reported and a mother-reported standardized questionnaires. The child-reported measure was the Child Depression Inventory (CDI), a 27-item child self-report measure of affective, cognitive, and behavioral symptoms of depression such as tiredness, aloneness, and appetite in children aged 7 to 17 years (Hodges, 1990; Kovacs, 1992; Mattison, Handford, Kales, Goodman, & McLaughlin, 1990). Elements assessed on the CDI include decreased interest in activities and feelings of worthlessness occurring over the two weeks prior to assessment. Higher scores denote greater depressive symptoms. The internal consistency reliability for the total scale for the study sample was 0.84. The total scale of the CDI correlated 0.72 (p=.0001) with the RCMAS in the current study.

The mother-reported measure of child depression was the 13-item Anxiety/Depressed subscale of the CBCL. Example items read: "Cries a lot," "Feels or complains that no one loves him/her," "Nervous, high strung, or tense," "Too fearful or anxious," and "Feels worthless or inferior." The internal consistency reliability for the current sample was 0.84.

## Data Analytic Strategy

Prior to evaluating efficacy, data were inspected for sampling distributions, outliers, covariates, and floor and ceiling effects. The Child's Depression Inventory (CDI) required data transformation because it did not approximate a normal distribution; all other variables were normally distributed.

Pre-treatment equivalence was examined at baseline on mother and child variables using 2-tailed t-tests for interval variables and Chi-square tests for nominal variables; groups were comparable at baseline on all demographic, treatment, and outcome measures. Comparisons were also made between study drops and completers. There were no significant differences between groups between baseline and 2 months or between 2 and 12 months on demographic, treatment, or outcome variables.

The sample size was calculated *a priori* to detect an Effect size of 0.5 on all mothers' and children's outcomes assessed at 2 months. Sustained changes were to be described at 12 months. A two-tailed power calculation required a sample size of 128 (64 per group) for 80.0% power to detect an Effect size of $d$=0.5, $p$=.05.

Linear Mixed Models were used to test intervention efficacy within an intent to treat analysis. Random effects models are based on Maximum Likelihood Estimation in which an iterative method estimates a trajectory for each study participant based on all available data for that participant supplemented by data obtained from the total sample (De Leeuw & Meijer, 2008; Twisk, 2004; West, Welch, & Galecki, 2007). The Maximum Likelihood Estimation Method has two advantages over more traditional analysis of variance models: it uses all available data from all participants rather than dropping participants with missing data. Second, it incorporates serial correlations among observations over time, thereby reducing bias.

## Sample

A total of 452 mothers were approached by site intermediaries and agreed to be contacted by the study team. Of these, 176 (38.9%) consented and completed baseline measures, of which 90 (51.1%) were randomized to intervention and 86 (48.9%) to control. Of the 176 participants who completed baseline data, 157 (89.2 %) completed measures at 2-months and 123 (69.9%) completed measures at 12 months.

Diagnosed mothers were primarily Caucasian (84.7%); 12 (6.7%) were Hispanic, 6 (3.4%) were Asian, 5 (2.8%) were African American and 4 (2.3%) were other ethnicities including Native American and Pacific Islander. Mothers had one or more dependent children living at home, were primarily college educated (68.6%), averaged 43 years of age (SD 4.9), and were married an average of 16.4 (SD 6.0) years; range: 1 to 32 years. Mothers had been diagnosed an average of 3.7 months (SD 1.9) at time of entry into study and 53.5% were treated with non-breast conserving surgery. Mothers had primarily Stage II breast cancer (N=87, 49.4%); an additional 52 had Stage I (29.5%); 20 had Stage III (11.4 %); and 17 had Stage 0 (9.7 %). More than three-quarters (78.9%) of the diagnosed mothers received adjuvant chemo- or radiation therapy or a combination of both during the course of the

study. At baseline, 40.6% scored at or above 16 on the CES-D and 39.2% scored at or above 40 on the STAI, scores denoting caseness.

## Results

Tables 3 and 4 contain adjusted means for mothers and children at baseline and at 2 and 12 months, using estimated values for missing data calculated using Maximum Likelihood Estimation, maintaining the sample size across all assessment periods. Tests were computed for the overall model for differences between baseline, 2, and 12 months by randomization group and for planned comparisons between baseline and 2 months and baseline and 12 months. Outcomes by state were also calculated; there were no differential outcomes by state.

### Mothers' Outcomes

There were significant improvements for intervention mothers compared to controls on two measures: depressed mood and parenting skills. All significant changes occurred at 2 months but improvements were not significant at 12 months. There were also statistical tendencies worthy of note.

**Depressed mood—**Mothers in the intervention group had significantly diminished depressed mood compared to controls at 2 months (mean score 9.46 vs. 13.85, $p$=.039; Cohen's $d$ = 0.29).

**Parenting skills—**There were significant improvements in parenting skills. Mothers in the intervention group scored significantly higher on Connecting and Coping Skills than controls at 2 months (mean score 23.49 vs. 22.04, $p$=.018; Cohen's $d$=0.32). They also tended to have higher scores on Elicitation Skills compared to controls at 2 months (mean score 8.34 vs. 8.14, $p$=.10; $d$=0.23).

**Anxiety—**Intervention mothers tended to have lower anxiety than controls at 2 months (mean score 30.61 vs. 36.16, $p$=.057; Cohen's $d$=0.26).

**Parenting self-efficacy—**Mothers in the intervention group tended to have greater confidence than controls at 2 months on the Help Child subscale (mean score 85.41 vs. 80.33, $p$=.064; Cohen's $d$ = 0.25). There were no significant differences at 2 or 12 months on the other two subscales, Stay Calm or Deal and Manage.

**Parenting quality—**Intervention mothers tended to score higher on parenting quality on Disclosure of Negative Feelings at 2 months compared to controls (mean score 14.99 vs. 14.18, $p$=.10, Cohen's $d$= 0.30). There were no significant changes on Disclosure of Bad Things Happening.

### Children's Outcomes

There were significant improvements for children in the intervention compared to control group on both mother- and child-reported measures of behavioral-emotional adjustment.

**Behavioral-emotional adjustment—**Children in the intervention group had significantly fewer Behavioral Problems on the total scale compared to controls at 2 months (mean score 44.47 vs. 46.63; $p$=.001; Cohen's $d$=0.52) and Externalizing scores also significantly decreased at the same time (mean score 44.38 vs. 46.48; $p$=.003; $d$= 0.45). Internalizing scores also tended to diminish compared to controls (mean score, 47.58 vs. 48.33, $p$=.084; $d$ = 0.25).

**Child depression—**There were significant changes in both the child- and mother-reported measures of child depression. Children in the experimental group scored significantly lower on depressed mood on the mother-reported measure at both 2 and 12 months compared to controls (mean score 52.97 vs 53.22, $p$=.001; Cohen's $d$= 0.46) and (mean score 53.11 vs. 52.70, $p$=.05; $d$= 0.30), respectively. Children in the experimental group also scored significantly lower on the child-reported measure of depressed mood at 12 months (mean score 1.05 vs 1.47, $p$=.025; $d$= 0.34).

**Child anxiety—**There were no significant differences between intervention and control groups on the RCMAS at either 2 or 12 months.

## Discussion

The Enhancing Connections Program (EC) is the first randomized clinical trial of a cancer parenting education program that resulted in improvements in both ill parents' and children's outcomes. The program significantly improved mothers' and children's depressed mood, mothers' parenting skills, and children's behavioral-emotional adjustment; effect sizes ranged from small to moderate: 0.29 to 0.52. Significant improvements in the children's adjustment at both 2 and 12 months are noteworthy because these effects occurred by directly intervening with the mother, not the child. That the sustained changes in the children's depressed mood were evident at 1 year were based on both mother- and child-report add to our confidence that the program helped the children.

Mothers significantly benefitted from the intervention in two areas: they became less depressed and they gained parenting skills that specifically enabled them to interpersonally connect with and assist their child to cope with the impact of the cancer [Connecting & Coping scale]. In reducing maternal depressed mood and augmenting parenting skills, the intervention appeared to decrease the mother's inaccessibility to her child, a known risk factor for poorer behavioral-emotional adjustment in children (Lewis & Darby, 2004; Weissman et al., 2006). Mothers' improved skills in drawing out their child's concerns and questions [Elicitation Skills scale] and their child's disclosure of sad or angry feelings [Disclosure of Negative Feelings scale] reinforces this interpretation. Mothers also tended to gain confidence in knowing what to do to help their child manage [CASE: Help Child scale]. Taken together, results suggest that the intervention helped mothers create an interpersonal environment in which their child could express questions and feelings and receive support. The intervention appears to be parent empowering and child-protective. Caution is also in order. Gains made in parenting skills and maternal depressed mood at 2 months were not maintained at 12 months. Future studies need to consider booster education to prevent or minimize backsliding.

Current study results compare favorably with those obtained by Thastum's team (Thastum, Munch-Hausen, Wiell & Romer, 2006). The current program involved briefer and fewer intervention sessions and significantly improved both parent and child outcomes. Thastum's program involved longer and more frequent sessions but significantly improved only one outcome: parental depression. Their program had no effect on child outcomes or other parent outcomes.

The intervention significantly affected parenting skills but had limited impact on maternal self-efficacy. Admittedly the intervention emphasized the mother's skill acquisition and contained fewer efficacy-enhancing exercises. Future studies need to add more self-efficacy enhancing exercises in the in-session and at-home assignments (Bandura, 1982, 1986, 1997, 2001, & 2004).

The intervention had limited impact on both maternal and child anxiety. Recall that maternal anxiety tended to decrease, but did not significantly decrease. Nothing in the EC Program was powerful enough to significantly reduce maternal anxiety, even though it tended to do so. These results suggest that maternal anxiety during early diagnosis and treatment is mutable but future studies need to incorporate additional methods to reduce it.

The absence of changes in child-reported anxiety may be due to the child's limited capacity for self-reflective or introspective behavior (Lewis et al., 2006) We do not think it reflects intervention failure given the significant improvements in the child's depressed mood and behavioral problems.

There are arguably other factors that could have influenced outcomes. The choice of an alternative treatment control group, not an attention control group, may have affected results. However, the behavioral-emotional changes in the children and in the mothers' specific skills suggest that changes could be potentially attributable to gains from the content of the intervention.

It is possible that the mother's report of her child's behavioral-emotional adjustment was confounded by improvements in her own mood or parenting skills. That is, less depressed or more skilled mothers could have viewed their children's behavior in more positive terms. However, results from Weissman's team, using objective rather than self-report, measures of child-outcomes, suggest that diminished maternal depressed mood can significantly predict children's mood and does not reflect mothers' reporting bias (Weissman et al., 2006). There is also evidence in the current study that mothers at least attempted to be accurate reporters of their child's behavior. Recall that mothers' report of their children's internalizing behavior only tended to improve whereas their report of their child's externalizing behavior significantly improved. If mothers were merely biased reporters of their children's behavior, improvements in both internalizing and externalizing behavior would have been expected. Instead, mothers' ability to distinguish between these two types of behavior suggests they may be discerning observers, not merely biased reporters.

The current study was limited by sampling bias and attrition at 1 year. The sample was biased toward primarily well-educated, middle class mothers in mostly long-term heterosexual marriages. Future research needs to include single parent households, same-sex

parents, and less resourced and less well-educated parents (Behar & Lewis, 2015). Mothers' choice of the referent child in households with more than one eligible child may have introduced bias; they may have systematically chosen the most or the least distressed child. Future studies need to use a researcher-generated method for selecting the referent child. Attrition from the study was high at 1-year: only 60% of the study sample completed measures at 1-year follow-up. Even though the use of Maximum Likelihood Estimation methods generated the least-biased estimates for study outcomes across all occasions, future studies need to consider additional methods to minimize attrition at follow-up.

Despite these limitations, this trial provides reason for optimism in directly intervening with recently diagnosed child-rearing mothers during the early months of diagnosis and treatment for breast cancer. The positive outcomes for the child at both 2- and 12 months suggests that child-rearing mothers are able to gain parenting and communication competencies that can benefit their children, even when dealing with a potentially life-threatening disease.

## Acknowledgments

Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number R01-CA-78424. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors want to acknowledge the anonymous reviewers of this manuscript, Gail M. Houck, physicians whose patients were enrolled into the study, and Kimberly Yee and Tessa Floyd for assistance with manuscript preparation. The authors dedicate this paper to Cynthia Foss Brunk.

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## Public Health Significance Statement

The Clinical Trial results show that a brief intervention to mothers with breast cancer can significantly reduce the burden of cancer on both the child and the ill parent.

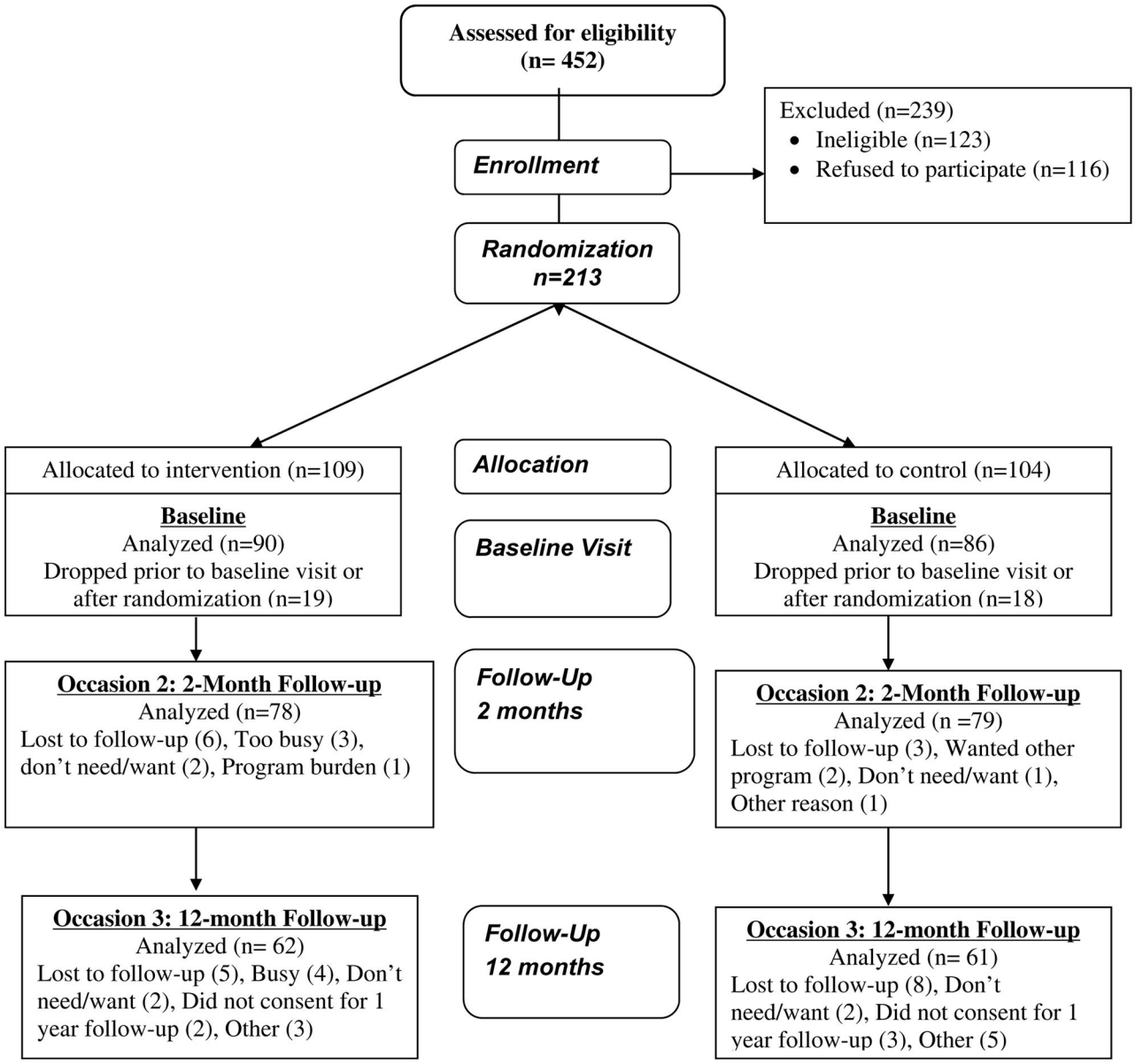


**Figure 1.**
Flowchart of study participants.

## Table 1

Description of Enhancing Connections Intervention Sessions & Rationale

| |
|---|
| **Session 1: Anchoring yourself to help your child:** This session helps the diagnosed mother define the child's experience with the cancer as distinct from the mother's and add to the mother's cognitive- behavioral methods to manage their own cancer-related emotions to prevent emotionally flooding the child. The session positions the parent to be a more attentive listener to the child as well as add to the parent's self-care skills. *Rationale*: Diagnosed mothers are able to be more attentive to their child if they are able to emotionally control their own affect. An overly emotive parent is unable to fully attend to the child's words, maintain healthy interpersonal boundaries, or be emotionally accessible to the child. Overly charged interactions between the mother and child can emotionally flood the child, risking further disconnection with the ill parent. |
| **Session 2: Adding to your listening skills:** This session assists the ill mother develop skills to deeply listen and attend to the child's thoughts and feelings, complementing the parent's tendency to be a teacher or problem-solver, not an attentive listener, of the child's thoughts, concerns or worries. *Rationale*: Diagnosed mothers typically function like biology teachers, offering their child biomedical facts about the cancer using highly charged information that is not developmentally appropriate. By focusing on the child's view of the cancer, the ill mother is more informed and able to strategically support the child in ways that articulate with the child's views and concerns. |
| **Session 3: Building on your listening skills:** This session builds on Session 2 and adds to the mother's abilities to elicit and assist the child elaborate the child's concerns or feelings, even a reticent child. It is one thing to interact with a talkative child (Session 2); it is a distinct skill to help a child talk who is not forth coming. *Rationale*: Ill mothers need communication and parenting skills that enable them to initiate difficult cancer-related conversations and to interact with an upset child or one who is not forthcoming. |
| **Session 4: Being a detective of your child's coping:** This session helps the ill mother interpret and respond to the child's ways of coping with the cancer in non-judgmental ways. It includes helping the parent relinquish negative assumptions about the child's coping behavior related to the mother's cancer. By giving away negative assumptions, the session enables the diagnosed parent to positively interpret, not negatively evaluate, their child's behavior. The session also offers the ill parent ways to elicit their child's report of what the parent can do to support the child's coping with the child's cancer-related pressures. R*ationale*: Listening and drawing out the child's concerns is one thing (Sessions 2 & 3); carrying out behavior that the child finds supportive is a different skill. All skills are important to reduce the child's cancer-related distress. |
| **Session 5: Celebrating your success:** This session focuses on gains the ill mother attributes to her participation in prior sessions in parenting their child about the cancer. Both self-monitoring and self- reflection are key elements to enhance the parent's self-efficacy in parenting their child. This session structures specific self-reflective exercises to help the parent internalize their accomplishments into a new self-view as an efficacious parent and assists the ill parent to identify available resources to be used after program completion to maintain the program gains. *Rationale*: This final session helps the mother internalize a new view of the self as a skilled and confident parent, anchoring the parent's new identity as an efficacious of the parent, not just a parent with new skills. |

**Table 2**

Correlation Matrix of Mothers' Reported Measures at Baseline

| | | CBCL Internal T-score | CBCL External T-score | CBCL Total T-score | Maternal Anxiety (STAI) | Maternal Depressed Mood (CES-D) | CASE Help Child subscale | CASE Deal and manage subscale | CASE Stay calm subscale | Disclosure of Negative Feelings | Disclosure of Bad Things Happening | Elicitation skill |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CBCL External T- score | Pearson Correlation | .621 | | | | | | | | | | |
| | Sig. (2-tailed) | .000 | | | | | | | | | | |
| | N | 176 | | | | | | | | | | |
| CBCL Total T- score | Pearson Correlation | .831 | .877 | | | | | | | | | |
| | Sig. (2-tailed) | .000 | .000 | | | | | | | | | |
| | N | 176 | 176 | | | | | | | | | |
| Maternal Anxiety (STAI) | Pearson Correlation | .326 | .222 | .252 | | | | | | | | |
| | Sig. (2-tailed) | .000 | .003 | .001 | | | | | | | | |
| | N | 176 | 176 | 176 | | | | | | | | |
| Maternal Depressed Mood (CES-D) | Pearson Correlation | .305 | .228 | .244 | .724 | | | | | | | |
| | Sig. (2-tailed) | .000 | .002 | .001 | .000 | | | | | | | |
| | N | 175 | 175 | 175 | 175 | | | | | | | |
| CASE Help child subscale | Pearson Correlation | −.253 | −.225 | −.237 | −.392 | −.348 | | | | | | |
| | Sig. (2-tailed) | .001 | .003 | .002 | .000 | .000 | | | | | | |
| | N | 175 | 175 | 175 | 175 | 175 | | | | | | |
| CASE Deal and manage subscale | Pearson Correlation | −.319 | −.286 | −.269 | −.607 | −.619 | .665 | | | | | |
| | Sig. (2-tailed) | .000 | .000 | .000 | .000 | .000 | .000 | | | | | |
| | N | 175 | 175 | 175 | 175 | 175 | 175 | | | | | |
| CASE Stay calm subscale | Pearson Correlation | −.239 | −.240 | −.212 | −.464 | −.438 | .774 | .711 | | | | |
| | Sig. (2-tailed) | .001 | .001 | .005 | .000 | .000 | .000 | .000 | | | | |
| | N | 175 | 175 | 175 | 175 | 175 | 175 | 175 | | | | |
| Disclosure of Negative Feelings | Pearson Correlation | −.140 | −.055 | −.072 | −.031 | .075 | .254 | .119 | .151 | | | |
| | Sig. (2-tailed) | .064 | .467 | .344 | .686 | .326 | .001 | .116 | .047 | | | |

| | | CBCL Internal T-score | CBCL External T-score | CBCL Total T-score | Maternal Anxiety (STAI) | Maternal Depressed Mood (CES-D) | CASE Help Child subscale | CASE Deal and manage subscale | CASE Stay calm subscale | Disclosure of Negative Feelings | Disclosure of Bad Things Happening | Elicitation skill |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | N | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | | | |
| Disclosure of Bad Things Happening | Pearson Correlation | −.161 | −.094 | −.111 | −.108 | .050 | .244 | .133 | .144 | .575 | | |
| | Sig. (2-tailed) | .033 | .214 | .143 | .156 | .510 | .001 | .079 | .057 | .000 | | |
| | N | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | | |
| Elicitation skill | Pearson Correlation | −.074 | −.141 | −.097 | −.148 | −.026 | .519 | .262 | .462 | .319 | .252 | |
| | Sig. (2-tailed) | .328 | .062 | .202 | .051 | .733 | .000 | .000 | .000 | .000 | .001 | |
| | N | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | |
| Connecting & Coping | Pearson Correlation | −.113 | −.165 | −.151 | −.212 | −.058 | .535 | .279 | .405 | .319 | .254 | .629 |
| | Sig. (2-tailed) | .138 | .029 | .047 | .005 | .443 | .000 | .000 | .000 | .000 | .001 | .000 |
| | N | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 | 175 |

**Table 3**

Mothers' Baseline, 2-Month & 12-Month Measures

| | Baseline | | 2 months post- baseline | | | | 12-months post- baseline | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Randomization status | | Randomization status | | | | Randomization status | | | | |
| **Mother's measures** | **Control Mean (SE)** | **Intervention Mean (SE)** | **Control Mean (SE)** | **Intervention Mean (SE)** | ***d*** | ***p*-value[a]** | **Control Mean (SE)** | **Intervention Mean (SE)** | ***d*** | ***p*-value[a]** | **Total Model F (*p*-value)[b]** |
| **Maternal Anxiety** (STAI) | 37.55 (1.24) | 35.09 (1.22) | 36.16 (1.28) | 30.61 (1.28) | 0.26 | *0.057* | 33.92 (1.39) | 29.27 (1.37) | 0.18 | *0.239* | 1.88 (*p*=0.156) |
| **Maternal Depressed** | | | | | | | | | | | |
| **Mood** (CES-D) | 15.35 (1.03) | 13.81 (1.01) | 13.85 (1.06) | 9.46 (1.06) | 0.29 | *0.039* | 9.87 (1.17) | 6.99 (1.17) | 0.06 | *0.440* | 2.23 (*p*=0.111) |
| **Parenting Confidence (CASE)** | | | | | | | | | | | |
| Help child subscale | 70.99 (1.53) | 72.15 (1.50) | 80.33 (1.56) | 85.41 (1.59) | 0.25 | *0.064* | 83.97 (1.73) | 84.87 (1.72) | 0.04 | *0.916* | 2.37 (*p*=0.096) |
| Deal and manage subscale | 106.89 (1.95) | 109.28 (1.92) | 112.19 (2.00) | 118.45 (2.02) | 0.21 | *0.123* | 118.78 (2.18) | 119.30 (2.16) | 0.16 | *0.514* | 2.41 (*p*=0.092) |
| Stay calm subscale | 49.31 (0.80) | 49.36 (0.79) | 51.47 (0.82) | 52.93 (0.83) | 0.20 | *0.178* | 53.07 (0.90) | 53.42 (0.89) | 0.04 | *0.804* | 1.01 (p=0.367) |
| **Parenting Quality (FPRQ)** | | | | | | | | | | | |
| Disclosure of Negative | | | | | | | | | | | |
| Feelings | 14.40 (0.36) | 14.45 (0.35) | 14.18 (0.36) | 14.99 (0.37) | 0.30 | *0.095* | 14.33 (0.39) | 14.64 (0.39) | 0.04 | *0.624* | 1.47 (*p*=0.234) |
| Disclosure of Bad Things | | | | | | | | | | | |
| Happening | 11.91 (0.22) | 12.45 (0.22) | 11.95 (0.23) | 12.81 (0.23) | 0.18 | *0.299* | 11.68 (0.25) | 12.35 (0.25) | 0.06 | *0.680* | 0.54 (*p*=0.582) |
| **Mother's Parenting Skills** | | | | | | | | | | | |
| Elicitation skills | 7.43 (0.16) | 7.19 (0.15) | 8.14 (0.16) | 8.34 (0.17) | 0.23 | *0.101* | 8.03 (0.18) | 7.88 (0.18) | 0.01 | *0.742* | 1.45 (*p*=0.237) |
| Connecting & Coping | 19.90 (0.50) | 19.59 (0.49) | 22.04 (0.51) | 23.49 (0.52) | 0.32 | *0.018* | 21.05 (0.56) | 21.33 (0.56) | 0.10 | *0.436* | 2.86 (p=0.06) |
| **Child Behavioral Checklist (CBCL)** | | | | | | | | | | | |
| Total T-score | 48.08 (1.14) | 49.42 (1.11) | 46.63 (1.15) | 44.47 (1.14) | 0.52 | *0.001* | 45.13 (1.21) | 45.33 (1.20) | 0.07 | *0.362* | 5.89 (*p*=0.003) |
| External T-score | 46.79 (1.01) | 47.72 (0.99) | 46.48 (1.03) | 44.38 (1.03) | 0.45 | *0.003* | 45.76 (1.08) | 45.91 (1.07) | 0.08 | *0.475* | 4.66 (*p*=0.01) |
| Internal T-score | 50.16 (1.09) | 51.48 (1.07) | 48.33 (1.11) | 47.58 (1.11) | 0.25 | *0.084* | 46.62 (1.19) | 46.99 (1.19) | 0.05 | *0.516* | 1.54 (*p*=0.218) |
| Anxious & Depressed T-score | 53.88 (0.65) | 55.78 (0.63) | 53.22 (0.66) | 52.97 (0.65) | 0.46 | *0.001* | 52.70 (0.69) | 53.11 (0.69) | 0.30 | *0.050* | 5.79 (*p*=0.004) |

[a] p-value - change from baseline

[b] Total model shows change over time by randomization group

**Table 4**

Children's Baseline, 2-Month, and 12-Month Measures

| | Baseline | | 2 months post- baseline | | | | 12-months post -baseline | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Randomization status | | Randomization status | | | | Randomization status | | | | |
| **Child Measures** | **Control Mean (SE)** | **Intervention Mean (SE)** | **Control Mean (SE)** | **Intervention Mean (SE)** | ***d*** | ***p*-value[a]** | **Control Mean (SE)** | **Intervention Mean (SE)** | ***d*** | ***p*-value[a]** | **Total Model F (*p*-value)[b]*** |
| **Child Anxiety (RCMAS)** | | | | | | | | | | | |
| Total scale | 9.39 (0.69) | 9.23 (0.68) | 6.53 (0.71) | 6.87 (0.72) | 0.12 | *0.560* | 6.06 (0.77) | 6.19 (0.79) | 0.03 | *0.808* | 0.18 (*p*=0.836) |
| **Child Depression Inventory (CDI)** [c] | | | | | | | | | | | |
| Total scale | 1.61 (0.09) | 1.52 (0.09) | 1.36 (0.09) | 1.21 (0.09) | 0.10 | *0.588* | 1.47 (0.10) | 1.05 (0.10) | 0.34 | *0.025* | 2.81 (*p*=0.063) |

[a] p-value - change from baseline

[b] Total model shows change over time by randomization group

[c] CDI mean and SD are transformed values.

For purposes of mixed model analyses, values were transformed with a natural log transformation.