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Wonders & Worries: A randomized clinical trial of a psychosocial intervention for children who have a parent with cancer

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Abstract

Objective: The aim of this study was to test the effectiveness of Wonders & Worries, a psychosocial intervention for children who have a parent with cancer. Primary goals were to improve family quality of life, functioning and communication skills as reported by parent and child, enhance children's emotional/behavioral adjustment and parenting efficacy, while decreasing parenting concerns and ill parents' depression and anxiety.

Methods: Sixty families were recruited from a community based non-profit agency. Parents diagnosed with Stage I-III cancer and their children ages 5–14 years were enrolled and randomized into intervention ($n = 32$) or wait-list control groups ($n = 28$). Families received 2 parent consults, six weekly 1-h individual child sessions, and 1 treatment center tour. The intervention was comprised of an age-appropriate understanding of cancer and expression of feelings, coping skills to ease feelings related to parent's cancer and enhanced ability to communicate about the disease. Controls received parent consult and access to W & W resources. Data were obtained from standardized measures at baseline; 6 and 10 weeks follow up.

Results: Intervention group significantly improved on parenting concerns, parenting self-efficacy, and family quality of life. Children in the intervention group had significantly lower emotional and behavioral problems and worries related to cancer compared to controls. The intervention failed to significantly affect ill parent's anxiety, depressed mood, family functioning and child's anxiety.

Conclusions: The Wonders & Worries intervention promoted positive adaptation for ill parents and their children. This intervention is promising enough to warrant further refinement and testing with larger, more diverse samples.

KEYWORDS
cancer, child adjustment, clinical trial, oncology, parental cancer, psychosocial functioning, psychosocial intervention

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Trial Registration: ClinicalTrials.gov Identifier: NCT02758639

An estimated 18.3% of adults diagnosed with cancer confront their own health uncertainty and the emotional and social impacts of their illness on their minor children.[1] They yearn to shield their children from trauma by managing the disclosure of information about their illness, as well as children's exposure to their emotional distress.[2] They worry how potential changes in their appearance, stress, physical function, energy, and time will impact their child's daily routine and mental health.[3] Additionally, studies indicate that parents diagnosed with cancer lack confidence and parenting skills to navigate these dialogues and report limited resources available to foster their parenting efficacy.[4]

The influx of worries about one's own and familial well-being create overwhelming distress for the ill parent which can lead to reduced functioning among the entire family system. In a multinational study of the association between parental cancer and family function, Schmitt and colleagues found that the parents depressed mood emerged as the most significant factor associated with family functioning.[5] The ill parents' emotional well-being permeated throughout the family leaving their children at an increased likelihood of developing depression and anxiety.[6,7] This struggle with their parent's cancer often results in psychosocial problems[8,9] which can reach or exceed clinical levels of distress on measures of behavioral-emotional adjustment.[10] Moreover, even children who are not clinically distressed are often left to understand and cope with these changes in the family alone. Children report worrying about changes in routines, the ill parent dying, and frequently have misconceptions of the cause of cancer and their role in causing the disease.[11,12]

Parenting concerns appear greater among those who have less confidence in knowing how to interact with their children and among parents experiencing their own emotional distress.[4] Initial interventions with parents have found that by increasing parental confidence through support of practical concerns and familial communication,[13-15] parents experienced an improvement in parental skills and depressive symptoms.[13] Research suggests that psychological interventions can lead to improved mood, quality of life, stress management, and enhanced family coping.[16,17] Although interventions available for children whose parents have cancer are growing, few of these have been systematically evaluated to test the effects on children's psychosocial adjustment.[15,18,19]

There is a growing need for empirical evidence to guide interventions for these families. The Wonders & Worries (W&W) program is a child-centered psychosocial intervention designed to address the issues raised in prior descriptive research and to respond to the limitations of current research. The W&W curriculum was based upon previous research and clinical work of Child Life Specialists with hospitalized children and child development and family systems theories.[20,21] Detailed intervention description has been previously published.[16] The W&W intervention was informed by a theoretical model of factors influencing children's adjustment to parental cancer (adapted from the resiliency model of family stress, adjustment and adaptation), that focused on assessing the vulnerabilities of each individual child and family, followed by offering activities focused on influencing the factors that have been shown to impact children's adjustment to parental cancer.[22] The goals of the program are to provide children an age-appropriate understanding of the illness, its treatment, and side effects, and to help children cope with the stress and fear related to illness (Table 1). In addition, the intervention seeks to improve parenting quality and self-efficacy and increase family communication about illness. The aim of the current study was to evaluate the effectiveness of the Wonders & Worries manualized intervention on child and parent outcomes within a randomized wait-list control trial (RCT).

1 | METHOD

1.1 | Participants

Study participants were families who had a parent diagnosed with any type of early-stage solid tumor cancers (Stage 0-III) and had a child 5–14 years old living in the home. Participants who were non-English speaking, had children not living in the home at least 50% of the time, or had a parent diagnosed with recurrent, advanced or metastasized cancers were excluded from the study.

1.2 | Research design and procedures

Eligible parents and families were recruited from Wonders & Worries Inc., a community based non-profit agency that provides support for children who have a parent with a serious illness from November 2016- March 2018. W&W program coordinator screened new families and referred interested participants to the university study team. The study team reached out to parents to provide detailed study information before enrolling and collecting baseline data prior to the initial parent consultation. Computer generated block randomization was used to randomize families to intervention or wait-list control group. Families who declined enrollment continued to have access to other W&W services including parent consultations and emergency financial aid.

Families randomized into the waitlist-control group received the initial parent consult and after completion of the follow-up measures were provided the opportunity to participate in the W&W intervention. Families randomized to the intervention received 9 sessions (see Experimental Intervention) provided by a master's prepared W&W certified child life specialists (CCLS). Child life specialists are professionals trained to help children and their families understand and manage challenging life events and stressful health care experiences.[20]

1.3 | Experimental Intervention

The W&W intervention, a manualized nine-session curriculum was designed to be individualized to each family's needs (Table 1). Families received an initial parent consult, six weekly 1-h individual child

TABLE 1 Description of Wonders & Worries Intervention Sessions & Rationale

Parent Consultations: The goal is to increase parents' understanding of W&W services and philosophy for supporting children as well as to increase CCLS's understanding of the family situation and parents' concerns for their child (ren).
Objectives include: (a) Share information regarding the illness in the family including the child (ren)'s current understanding of the illness, treatment, and side effects; (b) provide parents with suggestions for talking with their child (ren) about the illness; (c) to discuss each child's individual needs, personality and coping skills; (d) increase the CCLS's knowledge of each child's strengths and unique challenges; (e) provide parents with suggestions regarding how to best meet their individual child (ren)'s emotional needs; and (f) provide parents with information regarding the variety of ways children process information, express emotions and build coping skills
Parent letters: are provided after each child session to (a) increase parent's understanding of the topics covered and activities implemented during W&W's child sessions; (b) increase parent's knowledge and understanding regarding their child (ren)'s experience during sessions while maintaining confidentiality for the child (ren); and (c) improve communication within the family
Child session 1: Getting to know each other: The goal is to build rapport and a sense of safety within the group so that the children will feel comfortable discussing difficult topics. The activities promote self-expression and self-discovery and provide the CCLS with an initial assessment of the child (ren)'s perception of their family functioning, anxiety level, and temperament.
Session 1: Activities
M&M/Skittle- game (describe things that make you happy, sad, laugh, scared, etc.)
All my friends and neighbors –game (what you have in common with other children in the group)
Book – When Eric's Mom fought cancer
Art activity- family Totem pole
Child session 2: Cancer education: Focus on providing developmentally appropriate education about the illness, treatment, and side effects. The CCLS will frequently allow for questions, reflections, and concerns the child (ren) may voice.
Session 2: Activities
Worry box – children write worries, questions, and concerns about parent's cancer and place in box to be decorated and taken home.
Cancer teaching/psycho-education- using real medical equipment such as a doll with a port-o-cath, photo books, and anatomy books, and other visual teaching tools
Book – Sammy's Mom has cancer
Medical collage – art activity using real medical materials, IV tubing, gauze, syringes, band-aids
Child session 3: Feelings: Helps children label and identify various feelings that may occur while a family is dealing with cancer. Focus is expression and validation of all feelings the child (ren) may experience.
Session 4: Activities
Book – My rainbow feelings of cancer
Feelings Bingo – game – helps children be able to identify and label feelings
Feelings garden – art activity to facilitate children in labeling and expressing feelings related illness.
Child session 4 & 5: Stress and coping: Discussion of the definition of stress and ways people cope. Child (ren) identify activities they already do in their lives to cope when stressed. Ideas may include sports, playing with pets, talking to loved ones, journaling, art.
Session 4 & 5: Activities
Coping kits– provide items for child (ren) to include in their kit such as stress balls, bubbles, journals, magic wands, stuffed animals, etc.
Book – Be the boss of your stress, Don't pop your Cork on Monday's
Targets – game – draw a target on poster board with things that make you mad about your parent's cancer. Child (ren) then use a dart gun or wet toilet paper to throw at the target. Physical yet safe way for child (ren) to express strong negative emotions.
Stress/Coping review (including body, mind, spirit meter) relaxation and breathing techniques
Child session 6: Hopes for the future/Closure: Focus on child (ren)'s hopes for the future. An emphasis is made on the idea that positive things may evolve from the most difficult circumstances. Closure activity is provided for child (ren) as a way to remember their time with the group and each other.
Session 6: Activities
Book – The hope Tree
Hope Tree- art activity – write things you are hopeful for on leaves to be placed on a tree.

(Continues)

TABLE 1 (Continued)

Closing activity with exchange of silver hearts
Child session 7: Cancer treatment center tour: The treatment center tour will include education about the treatment plan involved in ill parent's care. This includes tour of chemo infusion rooms, radiation machine, CT scanner, MRI machine, and laboratory to view blood cells under a microscope. This hands-on experience helps to clear up misconceptions and alleviate fears around parent's treatment plan. This session will occur at previously scheduled times according to tour schedule.

sessions, 1 treatment center tour (group session parents and children) and a final parent consult. Scheduled sessions were conducted at W&W locations at time/day that was convenient for the family. All parents (intervention and control) received information during the initial parent consult to assist with understanding children's reaction to illness and to support positive parenting techniques. The study protocol was created for school age children to limit the heterogeneity of the intervention. The activities provided in each session revolve around similar themes but can be individualized to the child's developmental level and preferences.

1.4 | Ethics

The study protocol was approved by the University of Texas at Austin Institutional Review Board (#2015-04-0029) and registered with ClinicalTrials.gov Identifier: NCT02758639. The study team obtained signed informed consent and child assent/consent. Potential risks of this research were minimal psychological ones. If participants were upset by discussing the topics of the study, the interventionists were able to assist the participant at that moment. To minimize risks, participants were reminded that they may decline to answer any questions, and that they may terminate their participation at any time.

1.5 | Study measures

Demographic information and illness-related variables were obtained through parent self-report at baseline. Standardized survey instruments with recognized validity and reliability were utilized to determine study outcomes from parent and child respondents at baseline, post-intervention, and 10 weeks after enrolment. Research assistants collected study data from participants on provided iPad and/or links sent to parents. Data was managed using Qualtrics electronic data capture tools hosted at the University.

1.6 | Ill parent measures

Parent's concerns correlated with psychological distress were measured using two subscales of the Parenting Concerns Questionnaire (PCQ), practical and emotional impact.[21] Internal consistency reliability for the current study sample was 0.83 for both subscales.

Parenting self-efficacy was measured by the Cancer Self-Efficacy scale (CASE).[23,24] The Help Child subscale (9 items) measures the confidence of the parent to communicate with and assist the child in dealing with cancer-related concerns. The Deal and Manage subscale (13 items) measures the ability of the parent to help the family deal with the demands and challenges of having cancer. The Stay Calm subscale (6 items) measures the ability of the parent respondent to remain calm while having interactions with the child about cancer. The internal consistency reliability by subscale for the current study sample was 0.94, 0.93 and 0.95, respectively.

Parent Depressed mood was measured using the Center for Epidemiologic Studies Short Depression scale (CES-D-R).[25] Internal consistency reliability for the current study sample was 0.85.

Anxiety was measured by the Spielberger State-Trait Anxiety Inventory for Adults (STAI), comprised of two self-rated surveys: the State Anxiety Inventory and the Trait Anxiety Inventory.[26] Internal consistency reliability by subscale for the current study was 0.94 and 0.93, respectively.

1.7 | Ill parent & child measures

Family Quality of life. The Beach Center Family Quality of Life Survey (FQOL) was used to evaluate satisfaction with various aspects of living.[27] The 5 subscales included Family Interaction (6-items), Parenting (6-items), Emotional Well-being (4-items), Physical/Material Well-being (4-items) Disability-Related Support (4-items). The internal consistency reliability by subscale for the current study was 0.88, 0.85, 0.85, 0.71 and 0.86, respectively. Internal consistency reliability for the child responses in this study was 0.72 for subscales.

Family Functioning/Communication was measured using the McMaster Family Assessment Device (FAD).[28] The internal consistency reliability by subscale for the current study was 0.93 for general functioning and 0.80 for communication. Child respondents also answered the same items as the parent respondents from the General Functioning subscale, with an internal consistency reliability in this study of 0.78.

Child behavioral-emotional adjustment were measured using the parent-reported Child Behavior Check List (CBCL).[29] Behavior problem items consisted of 114 questions in 20 subscales. Internal consistency for all subscales ranged from 0.94 to 0.99.

1.8 | Child measures

Child anxiety was measured with The Revised Child Manifest Anxiety Scale – Second Edition (RCMAS-2).[30] Internal consistency reliability for the current study by subscale was 0.81, 0.73, 0.86. And 0.80, respectively, and 0.92 for the total score.

Illness-Related Pressures About My Mommies Illness (AMMI) Scale was used to measure the pressures on the child and the worries that the child attributes to the parent's cancer.[24] Internal consistency reliability for the current study was 0.81.

1.9 | Statistical methods

The sample size was determined to be adequate based upon a power analysis incorporating the effect size for change in CBCL total subscale observed in an RCT.[13] The final sample size of 60 families was established (adjusted upwards by 20% to account for expected attrition). This provided 80% power for detecting an absolute T-score change of four in the intervention group versus the control group with a type 1 error rate of 5%.

We compared baseline demographic and survey measures using independent samples *t*-tests for continuous variables and Pearson X^2 for categorical variables. We analyzed repeated measures for all survey responses from participants as part of their original random group assignment following intention-to-treat principles. To assess changes over time for each survey outcome between intervention and control groups, linear mixed-models including a group-by-time interaction term and covariates for age, race, gender, cancer diagnosis, cancer stage and duration of disease (months) were used.[31] Surveys results from adult respondents were analyzed using a two-level model with a random intercept [Level 1: Adult Respondent; Level 2: Study Group]. Surveys addressing child measures/responses were analyzed using a three-level model to account for familial clustering [Level 1: Child; Level 2: Family; Level 3: Study Group]. The mixed-model methodology utilized maximum likelihood estimation to obtain parameter results. All available data for each study participant was used for analyses. The AMMI child reported illness pressures scale was utilized to evaluated responses for children 9 years of age and older. Effect sizes to indicate standardized differences between study group means for each outcome were calculated using Cohen's *d* [small $d = 0.2$; medium $d = 0.5$; large $d = 0.8$]. We used Stata Statistical Software: Release 15 (StataCorp, College Station, TX) for all analyses.

2 | RESULTS

A total of 154 families were offered study participation by the study team. Of these 60 (39%) consented and 32 were randomized to the intervention group and 28 to control (See Figure 1). Parents were primarily in their early 40s, with the majority being Caucasian (72%), privately insured (90%), and married (82%), with an annual income higher than \$50,000 (68%). The person with illness was most often the mother (90%) with breast cancer (82%). Most children were between the ages of 8–11 years (56%), and Caucasian (54%). There was no significant difference in child gender distribution. Ten families were lost to follow-up, thus $n = 50$ families were included in the final analysis. Baseline demographic information for control and intervention groups can be found in Table 2.

Tables 3 and 4 contain adjusted means for ill parents and children at baseline and at six and 10 weeks, using estimated values for missing data calculated using maximum likelihood estimation.

2.1 | Parent outcomes

There were significant improvements for intervention parents compared to controls on parenting concerns and parenting self-efficacy. All significant changes occurred at post-intervention (6 weeks) and parenting concern improvements remained significant at 10 weeks. Adjusted mean changes for all child outcomes can be found in Table 3.

Parenting concerns. Parenting Concerns Questionnaire Factors 1 and 2 did not differ significantly at baseline between the intervention and control groups. Parenting concerns regarding the practical impact of the illness on the child (Factor 1) were significantly lower at 6 weeks ($p = 0.001$, Cohen's $d = 0.76$), and at 10 weeks ($p = 0.004$, Cohen's $d = 0.65$) in the intervention group compared with the control group. Parenting concerns regarding the emotional impact of the illness on the child (Factor 2) were significantly lower at 6 weeks ($p < 0.001$, Cohen's $d = 0.93$) and at 10 weeks ($p = 0.006$, Cohen's $d = 0.61$) in the intervention group compared with the control group.

Parenting self-efficacy. No differences were found between the intervention and control groups for any of the CASE subscales (Help Child, Deal and Manage and Stay Calm) at baseline. Compared with control group parents, intervention group parents at 6 weeks were significantly more confident in their ability to help the child deal with cancer-related concerns ($p = 0.007$, Cohen's $d = 1.0$), better able to deal and manage the demands of having cancer ($p = 0.001$, Cohen's $d = 0.94$), and able to stay calm to a greater degree while interacting with the child about cancer ($p = 0.005$, Cohen's $d = 0.59$).

There were no significant differences between intervention and control groups on the Parent Depressed Mood & Anxiety either six or 10 weeks. Maternal depressed mood Adjusted CES-D was significantly lower at baseline in the intervention group ($p = 0.05$).

2.2 | Family outcomes (Ill parent & child reported)

Family quality of life. Adjusted means for the intervention and control groups differed significantly at baseline for FQOL subscales Family Interaction ($p = 0.01$), Parenting ($p = 0.01$) and Physical/Material Well-being ($p = 0.002$). Parents in the intervention group reported higher emotional well-being at 6 weeks compared with control group parents ($p = 0.02$, Cohen's $d = 0.89$).

Family Functioning/Communication. The adjusted FAD communications subscale was significantly lower at baseline in the

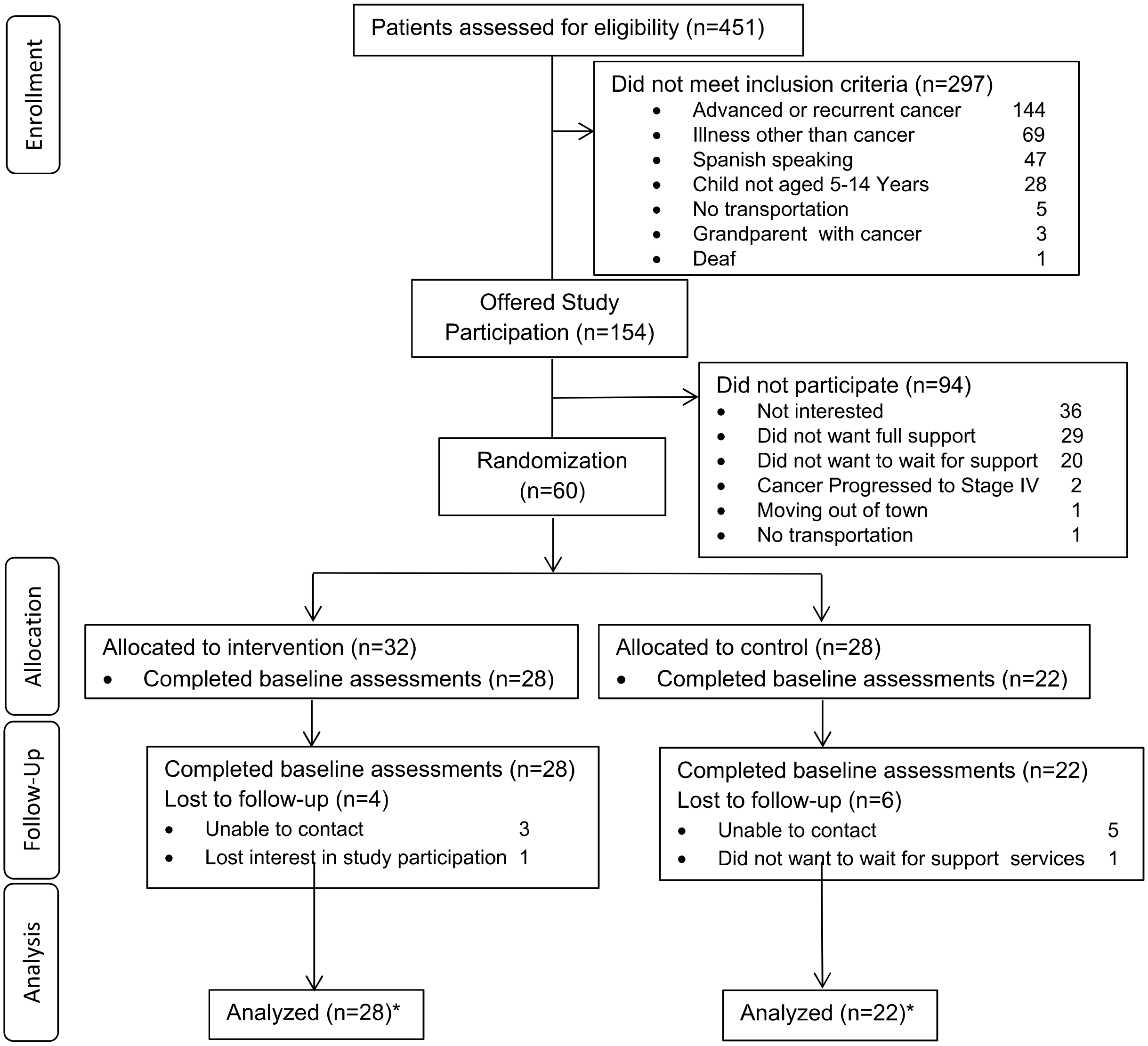

FIGURE 1 Study participant flow diagram of enrollment and loss to follow-up. *intention-to-treat analysis

intervention group (p = 0.02). There were no significant differences between intervention and control groups at either six or 10 weeks.

2.3 | Children's outcomes

There were significant improvements for children in the intervention compared to control group on both parent and child reported measures of behavioral and emotional adjustment. Adjusted mean changes for all child outcomes can be found in Table 4.

Child Behavioral-emotional adjustment. At baseline no significant differences were found between the intervention and control groups for any of the 20 CBCL subscales. Internalizing problems were significantly lower for the intervention group children at 10 weeks (p = 0.04, Cohen's d = 0.57) compared with control group children. There were no significant differences in externalizing problems and total score between intervention and control groups.

Children in the intervention group were reported to have significantly lower T-scores than those in the control group for subscales Withdrawn/depressed (p = 0.001, Cohen's d = 0.68) and Depressive problems (p = 0.01, Cohen's d = 0.46) at 6 weeks, and similarly at 10 weeks for Withdrawn/depressed (p = 0.006, Cohen's d = 0.52) and Depressive problems (p = 0.01, Cohen's d = 0.45). T-scores for somatic complaints were significantly lower for intervention group children at both 6 weeks (p = 0.04, Cohen's d = 0.23) and 10 weeks (p = 0.002, Cohen's d = 0.42) than control group children. T-scores for Social problems were significantly lower for intervention group children at 6 weeks (p = 0.04, Cohen's d = 0.57) compared with control group children. Thought problems were reported to be significantly lower for intervention group children compared with control group children at 6 weeks (p = 0.002, Cohen's d = 0.46) and

TABLE 2 Family, person with cancer, and child demographics

	Control group (n = 22)	Intervention group (n = 28)	p-Value
Parent/Caregiver age (Years): Mean ± S.D.[a]			
Mother	43.2 ± 6.58	41.9 ± 5.84	0.50
Father	44.8 ± 8.4	44.9 ± 8.13	0.95
Primary caregiver (Grandmother-stepmother)	---	52.3 ± 8.08	---
Income: n (%)[b]			
≤14,999	3 (13.6)	2 (7.14)	
$25,000-$49,999	4 (18.2)	3 (10.71)	
$50,000-$74,999	3 (13.6)	3 (10.71)	
$75,000-$99,999	3 (13.6)	2 (7.14)	
≥$100,000	7 (31.8)	16 (57.14)	
Declined to answer	2 (9.2)	2 (7.14)	0.64
Insurance status: n (%)[b]			
Uninsured	2 (9.1)	3 (10.7)	
Private	20 (90.9)	25 (89.3)	0.85
Marital status: n (%)[b]			
Married	17 (77.3)	24 (85.7)	
Separated	2 (9.1)	1 (3.6)	
Divorced	3 (13.6)	2 (7.1)	
Single	---	1 (3.6)	0.57
Person with cancer: n (%)[b]			
Mother	21 (95.5)	24 (85.7)	
Father	1 (4.5)	1 (3.6)	
Primary caregiver	---	3 (10.7)	0.28
Person with cancer age (Years): Mean ± S.D.[a]			
Mother	43.6 (6.48)	41.6 (5.72)	0.29
Father	36 (--)	66 (--)	---
Primary caregiver	---	52.3 (8.08)	---
Race person with cancer: n (%)[b]			
White	14 (63.6)	22 (78.7)	
African American	2 (9.1)	2 (7.1)	
Hispanic	2 (9.1)	2 (7.1)	
Other	4 (18.2)	2 (7.1)	0.63
Cancer stage: n (%)[b]			
0	1 (4.55)	---	
I	3 (13.64)	7 (25)	
II	11 (50)	14 (50)	
III	7 (31.82)	7 (25)	0.52
Cancer diagnosis: n (%)[b]			
Breast	19 (86.4)	22 (78.6)	
Genito-urinary	2 (9.1)	3 (10.7)	
Other	1 (4.5)	3 (10.7)	0.70
Time since diagnosis (duration) (Months): Mean ± S.D.[a]	4.23 (9.19)	3.57 (8.78)	0.79

(Continues)

TABLE 2 (Continued)

Children	Control group (n = 38)	Intervention group (n = 49)	
Age (Years): Mean ± S.D.[a]	9.58 (2.5)	9.27 (2.53)	0.57
Age: *n* (%)[b]			
5–7 Years	6 (15.8)	13 (26.5)	
8–11 Years	23 (60.5)	26 (53.1)	
12–14 Years	9 (23.7)	10 (20.4)	0.49
Race: *n* (%)[b]			
White	19 (50)	28 (57.1)	
African American	---	3 (6.1)	
Hispanic	4 (10.5)	6 (12.2)	
Other	15 (39.5)	12 (24.6)	0.25
Gender: *n* (%)[b]			
Male	23 (60.5)	23 (46.9)	
Female	15 (39.5)	26 (53.1)	0.21
	Male (n = 46)	**Female (n = 41)**	
Age: *n* (%)[b]			
5–7 Years	12 (26.1)	7 (17)	
8–11 Years	24 (52.2)	25 (61)	
12–14 Years	10 (21.7)	9 (22)	0.58
Race: *n* (%)[b]			
White	24 (52.2)	23 (56.1)	
African American	3 (6.5)	---	
Hispanic	5 (10.9)	5 (12.2)	
Other	14 (30.4)	13 (31.7)	0.43

[a] Independent samples *t*-test.

[b] Pearson X^2.

at 10 weeks ($p = 0.04$, Cohen's $d = 0.22$). T-scores for Children in the intervention group were reported to have less Oppositional defiant problems than control group children at 6 weeks ($p = 0.02$, Cohen's $d = 0.58$). T-scores for Conduct problems were significantly lower for intervention group children at 10 weeks ($p = 0.047$, Cohen's $d = 0.60$) compared with control group children. Obsessive-compulsive problems were reported to be significantly lower for intervention group children at 6 weeks ($p = 0.02$, Cohen's $d = 0.37$) compared with control group children. Stress was reported to be reduced for intervention group children at 6 weeks ($p = 0.03$, Cohen's $d = 0.61$) compared with control group children.

Illness related pressures. No differences between the intervention and control groups for children ages 9 years and older were found at baseline. The intervention group had significantly lower scores for the AMMIE-EC3 at 10 weeks ($p = 0.03$, Cohen's $d = 0.19$) than control group children.

Child anxiety. There were no significant differences between intervention and control groups on the RCMAS-2 at either six or 10 weeks.

3 | DISCUSSION

The results of the Wonders & Worries intervention reported here contribute to the limited body of evidence regarding community based interventions designed specifically for children who have a parent with cancer. Recent, systematic reviews have concluded that most "existing studies do not meet the methodological rigor to make conclusions about intervention effectiveness, with studies that lack standardization, randomization and sufficient study control".[32] To our knowledge, this is the first randomized clinical trial study of a manualized child-centered intervention for families who have a parent diagnosed with cancer.[15] The W&W intervention significantly improved parenting concerns, parenting self-efficacy, and family emotional well-being; effect sizes range from moderate to large: 0.59 to 1.0. In addition, the W&W intervention significantly improved the child's behavioral-emotional adjustment and illness related worries; effect sizes range from small to large: 0.22 to 0.68. It should be noted that children and parents had baseline scores that often fell within normal clinical limits

TABLE 3 Ill Parent measures showing adjusted mean change over time by randomization group[a]

	Baseline			6 Weeks				10 Weeks			
Study measure	**Control *M (SE)***	**Intervention *M (SE)***	***p***	**Control *M (SE)***	**Intervention *M (SE)***	***d***	***p***	**Control *M (SE)***	**Intervention *M (SE)***	***d***	***p***
Parenting concerns questionnaire (PCQ)											
Factor 1	3.03 (0.18)	3.19 (0.16)	0.51	3.33 (0.18)	2.69 (0.16)	0.76	0.001	2.91 (0.18)	2.36 (0.16)	0.65	0.004
Factor 2	2.86 (0.18)	2.99 (0.16)	0.61	2.72 (0.18)	1.94 (0.16)	0.93	0.000	2.46 (0.18)	1.94 (0.16)	0.61	0.006
Total score	2.95 (0.16)	3.09 (0.14)	0.52	3.03 (0.16)	2.32 (0.14)	0.95	0.000	2.69 (0.17)	2.15 (0.14)	0.70	0.001
Maternal Depressed Mood (CES-D-R)[b]	15.58 (1.2)	12.38 (1.1)	0.05	13.67 (1.2)	10.38 (1.1)	0.59	0.96	12.87 (1.2)	9.24 (1.1)	0.64	0.80
Parenting efficacy (CASE)											
Help child subscale	56.86 (3.1)	61.52 (2.68)	0.26	57.22 (3.1)	72.73 (2.68)	1.0	0.007	63.49 (3.1)	73.63 (2.68)	0.70	0.18
Deal & manage subscale	91.67 (3.6)	93.62 (3.2)	0.69	88.44 (3.6)	104.23 (3.2)	0.94	0.001	94.69 (3.7)	103.41 (3.17)	0.51	0.12
Stay calm subscale	48.67 (1.9)	46.84 (1.63)	0.47	45.98 (1.9)	51.09 (1.63)	0.59	0.005	48.14 (1.9)	51.13 (1.63)	0.34	0.054
FQOL											
Family interaction subscale	3.63 (0.14)	4.13 (0.12)	0.01	3.63 (0.14)	4.32 (0.12)	1.1	0.20	3.68 (0.14)	4.21 (0.12)	0.84	0.83
Parenting subscale	3.59 (0.13)	4.06 (0.11)	0.01	3.62 (0.13)	4.17 (0.11)	0.92	0.59	3.77 (0.13)	4.08 (0.11)	0.52	0.33
Emotional well-being subscale	3.57 (0.15)	3.73 (0.13)	0.42	3.48 (0.15)	4.1 (0.13)	0.89	0.02	3.51 (0.16)	4.0 (0.13)	0.68	0.09
Physical/Material well-being subscale	3.83 (0.11)	4.3 (0.09)	0.002	3.9 (0.11)	4.37 (0.09)	0.95	0.98	3.99 (0.11)	4.45 (0.09)	0.92	0.96
Disability-related support subscale	3.77 (0.11)	4.03 (0.1)	0.08	3.75 (0.11)	4.24 (0.1)	0.94	0.18	3.82 (0.11)	4.24 (0.1)	0.81	0.37
Family functioning (FAD)											
General functioning subscale	2.03 (0.1)	1.87 (0.09)	0.22	2.07 (0.1)	1.77 (0.09)	0.65	0.19	1.93 (0.1)	1.75 (0.09)	0.37	0.94
Communication subscale	2.35 (0.07)	2.13 (0.06)	0.02	2.32 (0.07)	1.97 (0.06)	1.1	0.17	2.27 (0.07)	2.1 (0.06)	0.53	0.58
State-Trait anxiety inventory											
SSAI	48.38 (2.64)	43.83 (2.32)	0.20	44.38 (2.64)	37.26 (2.32)	0.58	0.50	44.11 (2.72)	37.36 (2.32)	0.54	0.57
STAI	43.55 (2.23)	40.37 (1.95)	0.29	44.33 (2.23)	37.73 (1.95)	0.64	0.13	42.38 (2.26)	36.66 (1.95)	0.55	0.27

Note: CES-D-R: Center for Epidemiologic Studies Short Depression Scale.[26] CASE: Cancer Self Efficacy Scale.[25] FQOL: Family Quality of Life Survey.[28]

[a] Adjusted means from linear mixed-models including group × time interaction and covariates age, gender, race, cancer diagnosis, cancer stage, duration of illness.

TABLE 4 Children's outcomes showing adjusted mean change over time by randomization group[a]

	Baseline			6 Weeks				10 Weeks			
Study measure	**Control *M (SE)***	**Intervention *M (SE)***	***p***	**Control *M (SE)***	**Intervention *M (SE)***	***d***	***p***	**Control *M (SE)***	**Intervention *M (SE)***	***d***	***p***
Child behavior checklist (CBCL) scale (III parent Report)											
Anxious/Depressed	57.47 (1.44)	56.84 (1.22)	0.75	58.79 (1.47)	55.79 (1.23)	0.45	0.09	56.81 (1.47)	55.06 (1.23)	0.26	0.43
Withdrawn/Depressed	56.41 (1.52)	57.13 (1.29)	0.73	59.59 (1.55)	54.79 (1.3)	0.68	0.001	58.28 (1.55)	54.62 (1.3)	0.52	0.006
Somatic complaints	55.39 (1.26)	56.31 (1.07)	0.60	55.6 (1.27)	54.28 (1.08)	0.23	0.04	55.96 (1.27)	53.51 (1.08)	0.42	0.002
Social problems	56.81 (1.27)	55.65 (1.08)	0.51	57.76 (1.29)	54.4 (1.08)	0.57	0.04	56.87 (1.29)	53.98 (1.08)	0.49	0.11
Thought problems	55.91 (1.19)	57.06 (1.0)	0.49	57.36 (1.21)	54.85 (1.01)	0.46	0.002	55.53 (1.21)	54.29 (1.01)	0.22	0.04
Attention problems	57.86 (1.5)	56.84 (1.27)	0.62	58.76 (1.52)	55.36 (1.28)	0.49	0.07	57.27 (1.52)	54.89 (1.28)	0.34	0.29
Rule-breaking behavior	54.5 (0.99)	53.32 (0.84)	0.39	55.34 (1.01)	53.45 (0.84)	0.41	0.44	55.28 (1.01)	52.92 (0.84)	0.51	0.20
Aggressive behavior	55.94 (1.25)	54.71 (1.06)	0.48	57.28 (1.27)	54.44 (1.06)	0.49	0.16	56.44 (1.27)	53.62 (1.06)	0.49	0.17
Internalizing problems	54.7 (2.07)	53.31 (1.76)	0.63	55.85 (2.1)	51.57 (1.77)	0.45	0.14	54.41 (2.1)	48.95 (1.77)	0.57	0.04
Externalizing problems	51.45 (1.9)	48.79 (1.61)	0.32	52.52 (1.94)	48.61 (1.61)	0.44	0.47	50.83 (1.94)	46.36 (1.61)	0.51	0.29
Depressive problems	57.63 (1.36)	58.1 (1.15)	0.81	59.03 (1.39)	56.11 (1.15)	0.46	0.01	58.15 (1.39)	55.36 (1.15)	0.45	0.01
Anxiety problems	58.07 (1.59)	56.55 (1.35)	0.49	58.97 (1.61)	55.35 (1.35)	0.49	0.19	57.49 (1.61)	54.85 (1.35)	0.36	0.48
Somatic problems	53.97 (1.27)	55.92 (1.08)	0.26	53.93 (1.28)	54.12 (1.08)	0.03	0.14	54.16 (1.28)	53.6 (1.08)	0.10	0.03
Attention deficit	55.84 (5.3)	65.98 (4.6)	0.16	56.01 (5.59)	54.37 (4.62)	0.06	0.23	55.96 (5.59)	53.98 (4.62)	0.08	0.22
Oppositional defiant problems	55.47 (1.16)	54.87 (0.98)	0.71	57.46 (1.18)	54.32 (0.99)	0.58	0.02	56.08 (1.18)	54.15 (0.99)	0.36	0.22
Conduct problems	54.55 (1.08)	53.52 (0.91)	0.49	56.09 (1.1)	53.76 (0.92)	0.47	0.19	55.75 (1.1)	52.73 (0.92)	0.60	0.047
Sluggish cognitive Tempo	55.69 (1.19)	55.99 (1.01)	0.85	56.63 (1.22)	54.29 (1.02)	0.42	0.07	55.13 (1.22)	53.79 (1.02)	0.24	0.26
Obsessive-compulsive problems	57.12 (1.45)	57.65 (1.24)	0.79	58.9 (1.48)	56.39 (1.24)	0.37	0.02	56.64 (1.48)	54.94 (1.24)	0.25	0.09
Stress problems	58.54 (1.49)	57.4 (1.27)	0.58	59.72 (1.52)	55.5 (1.27)	0.61	0.03	57.99 (1.52)	54.54 (1.27)	0.50	0.10
Total problems	53.68 (2.22)	51.23 (1.89)	0.42	54.04 (2.25)	49.61 (1.89)	0.43	0.30	52.23 (2.25)	46.84 (1.89)	0.52	0.13
AMMI-EC3[b] (Child report)	25.41 (1.45)	27.83 (1.17)	0.22	23.81 (1.45)	25.7 (1.17)	0.29	0.74	23.72 (1.5)	22.49 (1.17)	0.19	0.03
RCMAS-2 (Child report)											
Defensiveness subscale	51.39 (1.65)	50.69 (1.46)	0.76	48.15 (1.65)	46.99 (1.46)	0.15	0.81	46.2 (1.69)	47.66 (1.46)	0.19	0.27
Physiological anxiety subscale	50.94 (1.89)	51.4 (1.67)	0.76	49.05 (1.89)	49.56 (1.68)	0.06	0.90	48 (1.94)	48.94 (1.68)	0.15	0.95
Worry subscale	50.69 (1.66)	52.43 (1.47)	0.45	49.93 (1.66)	49.25 (1.47)	0.09	0.26	48.96 (1.71)	46.65 (1.47)	0.29	0.06
Social anxiety subscale	48.98 (1.8)	49.37 (1.59)	0.88	47.42 (1.8)	47.05 (1.6)	0.04	0.71	47.61 (1.85)	45.57 (1.6)	0.23	0.25

TABLE 4 (Continued)

	Baseline			6 Weeks				10 Weeks			
Study measure	**Control M (SE)**	**Intervention *M (SE)***	***p***	**Control M (SE)**	**Intervention *M (SE)***	***d***	***p***	**Control M (SE)**	**Intervention *M (SE)***	***d***	***p***
Total anxiety score	49.92 (1.71)	51.67 (1.51)	0.47	49.65 (1.71)	48.95 (1.52)	0.09	0.22	48.19 (1.76)	47.04 (1.52)	0.14	0.16
FQOL (Child report)											
Family interaction subscale	4.31 (0.11)	4.3 (0.09)	0.99	4.27 (0.11)	4.32 (0.09)	0.10	0.69	4.29 (0.11)	4.4 (0.09)	0.22	0.42
Parenting subscale	4.14 (0.1)	4.19 (0.09)	0.70	4.17 (0.1)	4.13 (0.09)	0.09	0.46	4.18 (0.1)	4.28 (0.09)	0.21	0.78
Family Assessment device (FAD) (Child report)											
General functioning subscale	2.06 (0.08)	1.91 (0.07)	0.19	2.02 (0.08)	1.89 (0.07)	0.35	0.79	1.96 (0.08)	1.86 (0.07)	0.27	0.58

Note: CES-D-R: Center for Epidemiologic Studies Short Depression Scale.[26] CASE: Cancer Self Efficacy Scale.[25] FQOL: Family Quality of Life Survey.[28] AMMI-EC3: About My Mommy's Illness.[25] RCMAS-2: Revised Children's Manifest Anxiety Scale.[31]

[a] Adjusted means from linear mixed-models including group × time interaction and covariates age, gender, race, cancer diagnosis, cancer stage, duration of illness.

[b] Child age ≥9 years.

suggesting preventative interventions may be helpful for this population.

Studies published that evaluated parent and family interventions for parental cancer have shown positive impacts upon parental outcomes in areas of parenting skills, mood, and general distress.[13,15,33-35] However, most of these studies have failed to demonstrate a substantial impact upon children's outcomes.[33-35] Qualitative interviews with children suggest this may be due to the interventions provided being too focused on the parent.[11] Most of the counseling sessions were with the parent/family but rarely included individual child sessions. Study results suggest promising outcomes for children's emotional-behavioral issues when a child-centered intervention is used that directly engages children with hands-on activities providing them with a clear understanding of the parent's illness/treatment.

Previous studies demonstrate how open communication about the illness can improve children's coping and adjustment.[2,12,36,37] The favorable improvements described by parents in the intervention group for their children's mood, stress, and somatic complaints may have been mediated by increased communication with parents regarding the cancer.

The ill parent significantly benefited from the intervention in three domains: they reported higher emotional well-being due to perceived support to relieve stress (FQOL), and they had decreased parenting concerns related to the practical and emotional impact of the illness on their child (PCQ). Finally, ill parents gained confidence in, a. Their ability to talk with their child about the child's cancer-related concerns, b. Helping their family deal with the demands and challenges of the cancer, and c. Remaining calm during difficult interactions with the child about the cancer (Help Child, Deal and Manage, and Stay Calm subscales). In improving parents well-being and confidence, the intervention appeared to improve parental adjustment, supportive parenting skills, and perceived social support, all known factors for impacting children's adjustment to parental cancer[6,16] Since improvements in parenting confidence were not maintained at 10 weeks, future studies need to explore the effects of booster sessions to prevent waning effects.

The intervention had limited impact on both child anxiety and parental depressed mood and anxiety. The parental depressed mood and anxiety tended to decrease, but not significantly compared to controls. Future studies need to incorporate targeted methods to reduce anxiety and depressed mood in the ill parent that specifically addresses their own health related worries such as adding direct parent education sessions from the Enhancing Connections program.[13]

The lack of changes in the child-reported anxiety may be due to children's scores on the anxiety measure were within normal limits at baseline so it is possible that anxiety was not decreased enough for the RCMAS-2 to discriminate differences in this population. Two recent trials also did not detect significant differences in child anxiety using this measure.[13,35] Future studies should consider a more sensitive, developmentally appropriate measure for child-reported anxiety. In addition, given that the distress experienced by families facing cancer is normative, not pathological the use of measures to assess "normative" distress and perceived impact of stressful experiences should be considered.

3.1 | Study limitations

It is important to consider study limitations that could have influenced outcomes. The children in the intervention group may have improved due to in person sessions and the therapeutic relationship with the W&W staff. The waitlist control group may have created placebo effects of parents having access to a W&W CCLS. Interpretation of these findings was limited because families who enrolled sought support from the agency and those enrolled in the study may have been demographically dissimilar and/or have had a different overall cancer experience than families who declined. Child outcomes were only reported by the ill parent; future studies should consider triangulating data from the ill parent and an additional primary caregiver to minimize biased reporting. The current sample was limited by bias toward primarily white, middle-class, ill mothers, and married couple households with health insurance. Finally, due to the lack of double-blind design there is potential for therapeutic allegiance of the researcher. It is possible that negative effects due to the intervention may be observed in other more diverse populations. Further study is needed to determine the effectiveness of this intervention in more diverse populations including those subjects with later stage cancers, cancers other than breast cancer, single-parent households and families in which the parent with cancer is the father.

3.2 | Clinical implications

Study results reinforce the potential benefits of child centered intervention for families coping with parental cancer. Psychosocial interventions may impact child mental health in the immediate and long term. Unresolved grief and distress can cause significant mental health and behavioral health concerns well into adulthood,[38,39] interventions that target these issues early may provide preventative effects that can help foster positive coping skills in children as they grow into adulthood. Serious mental and behavioral health concerns are a public health issue with an estimated economic impact in the United States of over 300 billion per year. Interventions that address suffering and anxiety in childhood can be a part of a critical public health strategy. Furthermore, increasing parental competence and quality of life is an essential tool for improving health and mental health outcomes of the child, the ill parent and the rest of the family.

4 | CONCLUSION

While acknowledging the limitations of the results reported here this trial suggests that the Wonders & Worries intervention may have positive effects on child and ill parent's adjustment by addressing parenting concerns and providing a safe environment for children to express their concerns related to their parent's cancer. The goal of community-based programs with preventative interventions such as these is to help families thrive, not merely survive serious illness. An evidence-based, manualized, child-centered intervention such as the one described here is highly replicable and has potential to help children and families cope with the distressing psychological impact of illness in a family.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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