A Pilot Trial of a Stress Management Intervention for Primary Caregivers of Children Newly Diagnosed With Cancer: Preliminary Evidence That Perceived Social Support Moderates the Psychosocial Benefit of Intervention

Anna L. Marsland,1 PhD, RN, Kristin A. Long,1 MS, Chelsea Howe,2 MA, Amanda L. Thompson,3 PhD, Jean Tersak,4 MD, and Linda J. Ewing,2 PhD, RN

1Department of Psychology, University of Pittsburgh, 2Department of Psychiatry, University of Pittsburgh School of Medicine, 3Departments of Pediatrics and of Psychiatry and Behavioral Sciences, George Washington University Medical School, and 4Department of Pediatrics, University of Pittsburgh School of Medicine

All correspondence concerning this manuscript should be addressed to Anna L. Marsland, PhD, Department of Psychology, University of Pittsburgh, 3943 O’Hara Street, Pittsburgh, PA 15260, USA. E-mail: marsland@pitt.edu

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Objectives (1) To examine the acceptability and feasibility of a stress management intervention for caregivers of children recently diagnosed with cancer. (2) To explore whether caregivers with lower baseline perceived social support derive greater benefit from the intervention than those with higher perceived support. Methods 45 primary caregivers were randomly assigned to intervention or standard care. Of these, 37 completed measures of social support, depression, anxiety, and perceived stress at both pre-intervention (T1; mean = 24 days post-diagnosis) and post-intervention time points (T2; mean = 165 days post-diagnosis). Results Enrollment, retention, and satisfaction data support feasibility and acceptability of the intervention. There was no overall significant impact of participation in the intervention on levels of distress at T2. However, T1 social support moderated intervention response, with caregivers who perceived lower T1 support showing greater psychological benefit from the intervention. Conclusions Primary caregivers with lower levels of perceived social support may benefit from preemptive stress management intervention.

Key words caregivers; childhood cancer; social support; stress management intervention.

Introduction

Primary caregivers of children diagnosed with cancer confront a multitude of cancer-related stressors, including threat to their child’s life, repeated hospitalizations and clinic visits, caring for other family members, and alteration of roles and responsibilities (Long & Marsland, 2011). Research on the psychosocial adjustment of parents (predominantly mothers) of children with cancer reveals feelings of guilt, anger, helplessness, anxiety, and depression that are experienced shortly after their child’s diagnosis (Jantien Vrijmoet-Wiersma et al., 2008; Norberg & Boman, 2008; Pai et al., 2007; Poder, Ljungman & von Essen, 2008) but that generally fall to pre-diagnosis levels within a year (Dolgin et al., 2007; Patino-Fernandez et al., 2008; Poder et al., 2008). However, 25–30% of parents experience more persistent psychological adjustment difficulties, including anxiety, depression, marital difficulties, loneliness, and cancer-related post-traumatic stress, regardless of time since diagnosis (Bruce, 2006; Kazak, Boeving, Alderfer, Hwang, Reilly,
Evidence suggests that prolonged parental distress predicts increased behavioral, emotional, and social difficulties among both children with cancer and their siblings (Bruce, 2006; Colletti et al., 2008; Gerhardt et al., 2007; Maurice-Stam et al., 2008). Accordingly, recent recommendations advocate for the identification of factors associated with parental risk that can be targeted by preemptive intervention (Kazak et al., 2007).

To date, three studies have examined preemptive psychosocial interventions designed to promote adjustment among parents of children newly diagnosed with cancer. The largest study showed that 217 mothers who participated in an eight-session problem-solving intervention in the months after their child’s diagnosis reported significantly enhanced problem-solving skills and lower levels of negative affect than 213 mothers who received usual psychosocial care (Sahler et al., 2005). These findings replicated results of an earlier feasibility trial conducted by the same group (Sahler et al., 2002). To date, this group has not examined individual difference factors that may moderate intervention benefit, which was a focus of the current study. The third study did not show any psychological benefit of a brief intervention designed to promote healthy family adjustment; however, as noted by the authors, difficulties with recruitment and retention compromised the scientific rigor of these findings (Stehl et al., 2009).

During the past 10 years, our research group has developed a supportive stress management intervention designed to be administered to the primary caregiver shortly following his/her child’s cancer diagnosis. In an initial uncontrolled trial, we recruited primary caregivers of children (aged 6–17 years) within 6–8 weeks of being diagnosed with leukemia or lymphoma. Twenty-eight caregivers were eligible during a 15-month recruitment period; 20 (71%) agreed to participate, and 13 (65%) completed all six intervention sessions (unpublished data). Feedback from caregivers was uniformly positive. These findings provided support for the current controlled pilot trial, which examined feasibility, acceptability, and preliminary efficacy.

A secondary goal of the current study was to identify caregivers who are at increased psychological risk and who may derive greater benefit from targeted early intervention. Our conceptual model of risk is guided by Lazarus and Folkman’s (1984) theory of stress and coping. In this model, psychological stress is defined as a relationship between an individual and the environment that is appraised as being beyond the individual’s ability to cope, given available resources (Lazarus & Folkman, 1984). One such resource is perceived social support, which plays a key role in an individual’s belief in his/her ability to cope with a stressful event such as cancer, and in turn, in the magnitude of the psychological response. Among parents of children with cancer, perceived social support has a larger impact on psychological adjustment than child- or disease-related factors (Fotiadou, Barlow, Powell, & Langton, 2008; Greening & Stoppelbein, 2007; Kazak et al., 1998; Morrow, Carpenter & Hoagland, 1984; Norberg, Linblad, & Boman, 2006; Wijnberg Williams, Kamps, Klip, & Hoekstra-Weebers, 2006), with higher levels of perceived support at the time of diagnosis protecting parents from future psychological difficulties (Grootenhuis & Last, 1997).

Despite calls for stepped levels of care (Kazak et al., 2007), previous intervention studies have not targeted individuals who are at increased psychosocial risk. Given that the majority of parents cope well with their child’s diagnosis and treatment, a more cost- and time-effective approach may be to identify modifiable vulnerability factors and target those factors for intervention. Thus, we aimed to (a) examine the acceptability and feasibility of a stress management intervention for caregivers of children recently diagnosed with cancer, and (b) explore whether caregivers with lower perceived social support derive greater benefit from the intervention than those with higher perceived support. It was hypothesized that parents with lower perceived social support at the time of their child’s diagnosis would be at risk for prolonged distress and would gain greater benefit from the intervention.

**Methods**

**Design**

This controlled pilot study was designed to assess the feasibility and acceptability of a randomized clinical trial of a new multimodal intervention (“Connections to Coping”) for primary caregivers of a child with cancer. We also intended to offer a parallel intervention to the child with cancer. Eligibility criteria were English-speaking biological or adoptive primary caregivers of a child who (a) was between 7 and 17 years, (b) was newly diagnosed with a non-central nervous system (CNS) cancer that required chemotherapy, (c) had no diagnosis of intellectual disability or pervasive developmental disorder, and (d) had a life expectancy of >4 months, which corresponds to the average length of the intervention in our preliminary work and removes potential confounds related to end-of-life and palliative care. Inclusion criteria were selected to ensure that child participants would be cognitively able to participate in the intervention. Primary caregivers were defined as
those who self-identified as responsible for the majority of direct care for the child with cancer. No exclusion criteria were based on gender, race, or ethnicity.

We planned to recruit participants within 1 month of the child’s diagnosis and conduct a time 1 (T1) assessment before randomly assigning them in a ratio of 2:1 to the intervention (N = 30) or a treatment-as-usual (TAU) control condition (N = 15). The intervention period was expected to last 4–6 months, with time 2 (T2) data collection 2 weeks following the final intervention session and at a yoked time point among control participants. In addition to assessing feasibility and acceptability, preliminary outcome measures included caregiver symptoms of depression, anxiety, perceived stress, and social support.

**Participants**

Forty-nine eligible primary caregivers were recruited from Children’s Hospital of Pittsburgh and enrolled in the study between February 2006 and April 2008 (See Figure 1). Four caregivers did not complete baseline questionnaires, resulting in a sample of 45 (42 mothers, 2 fathers, and 1 grandmother) at T1 who were randomized to the intervention (N = 30) or the TAU control condition (N = 15). We quickly found that the majority of child participants were too unwell to participate in an active intervention at this stage of treatment; therefore, we dropped this component of the study. All participants received $75 for taking part in the study. Informed consent was acquired in compliance with guidelines of the University of Pittsburgh Institutional Review Board.

**Procedure**

The “Connections to Coping” intervention is a manualized, multimodal stress management and coping enhancement intervention. It was developed to address the specific needs identified by primary caregivers of children newly diagnosed with cancer who took part in focus groups led by the principal investigators (A.M. and L.E.) in 2001/2002 (data unpublished). The intervention uses a cognitive behavioral stress management approach and includes six face-to-face sessions, six telephone contacts, and access to a study web site. All sessions were scheduled at the convenience of the caregivers and took place in the outpatient clinic (54% of all sessions), inpatient unit...
(36%), or the caregiver’s home (10%). One Masters-level clinician (C.H.) conducted all sessions. Her training included education in the conceptual foundations of the intervention and the stressors and burdens commonly experienced by families of children with cancer, along with training in conducting each of the sessions, with role plays to assure standard delivery. Treatment fidelity was monitored during weekly supervision provided by licensed pediatric psychologists (L.E. and A.M.). Primary components of the intervention included the following:

1. Face-to-face sessions: Six sessions (one session every 2–3 weeks) comprised the core content and skills training of the intervention. Sessions were psychoeducational and experiential and included opportunities for caregivers to: (a) identify specific stressors, (b) learn skills to manage emotional and physical responses to stress, (c) address methods of handling stress within the family system, (d) obtain social and emotional support, and (e) learn several different methods of relaxation, with audiotapes provided for home practice (see Table I).

2. Between session telephone contact: Caregivers received a telephone call from the interventionist between each face-to-face session. The goals of the phone contact were to provide emotional support, to enhance caregiver coping, and to maintain the participants’ relationship with the clinician.

3. Web-based component: In addition, all families were given access to a secure study web site (see Ewing et al., 2009, for further details). The web site was modeled after other supportive internet-based programs (e.g., CHESS; Gustafson, Bosworth, Hawkins, Boberg, & Bricker, 1992; Rotondi, Sinkule, & Spring, 2005) and was designed to offer social support and informational resources to all members of the family. Key features included the following: (a) Information about methods of coping along with guided relaxation exercises, (b) five separate monitored discussion/support groups for caregivers, older (13–17 years) and younger (7–12 years) children with cancer, and older and younger siblings, (c) electronic mail connections to research team members who were available for non-medical questions or discussion and a library of anonymous responses to questions, and (d) links to available local resources.

Caregivers randomized to TAU did not receive additional psychological support beyond that offered as part of routine care, which includes as-needed access

Table I. Overview of “Connections to Coping” Intervention Sessions

<table>
<thead>
<tr>
<th>Session</th>
<th>Content</th>
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</table>
| I. Telling the story | Introduction and overview of program  
Structural discussion of cancer experience, current stressors, and coping resources  
Session duration: 60 min |
| II. Emotional responses to stress; Relaxation training using breathing | Discussion of emotional/behavioral responses to cancer and methods of reducing family distress  
Introduction of family meetings with guidelines for family discussion  
Introduction of relaxation training (diaphragmatic breathing)  
Session duration: 45 min |
| III. Responses to stress; progressive muscle relaxation training | Discussion of stress: physical responses, causes, methods of coping  
Relaxation training: progressive muscle relaxation  
Session duration: 30 min |
| IV. Active coping strategies; relaxation training using visual imagery | Coping skills training including active cognitive and behavioral techniques  
Cognitive and behavioral techniques exercises tailored to cancer-related stressors  
Relaxation training: visual imagery and autogenic training  
Session duration: 45 min |
| V. Communicating effectively/accessing social support | Discussion of communication skills and styles (passive, aggressive, assertive)  
Exercise to identify and problem solve the social network  
Session duration: 30 min |
| VI. Parenting a chronically ill child; review of skills | Discussion of issues related to parenting a chronically ill child (normalizing experiences, modeling, favoring the ill child, reinforcing positive behavior, etc.)  
Review of skills and discussion of application of skills to specific situations and concerns  
Session duration: 45 min |
to a hospital-based social worker, but no preemptive psychosocial intervention. “Connections to Coping” focuses on issues faced by families early in treatment; for this reason, caregivers in the control condition were not offered the intervention following the T2 assessment.

**Psychosocial Measures**

All caregivers completed psychosocial questionnaires at T1 and T2. Psychological outcome measures included the following: (1) the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961), a 21-item measure of depressive symptoms with good internal consistency (Cronbach’s α at T1 = .92 and at T2 = .87); (2) the State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), a 40-item measure, including 20 items assessing state and 20 items assessing trait anxiety, with excellent internal consistency (state α = .95 and .94 and trait α = .95 and .91 at T1 and T2, respectively); (3) the Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983), a 14-item measure that assesses the degree to which caregivers perceive that current demands exceed their abilities to cope, which has acceptable internal consistency (state α = .80 and at T2 = .78); and (4) the Impact of Event Scale (IES; Horowitz, Wilner, & Alvarez, 1979), a 15-item scale that assesses intrusive and avoidant experiences that occur in response to a traumatic incident, which has good internal consistency (α at T1 = .81 and at T2 = .91). Finally, to examine perceived social support as a moderator of distress and treatment response, caregivers completed the Interpersonal Support Evaluation List (ISEL; Cohen, Mermelstein, Kamarck & Hoberman, 1985), a 40-item scale assessing perceived availability of four types of social support (appraisal, informational, self-esteem, and tangible) that has been shown to buffer stress-related psychological distress (Cohen, 1991). This measure had good internal consistency (α at T1 = .87 and at T2 = .89). All measures are well validated and widely used in psychosocial research.

**Program Evaluation Measures**

To assess satisfaction with the intervention, the Client Satisfaction Questionnaire-8 (CSQ-8; Larsen, Arklsson, Hargreaves, Nguyen, 1979) was administered. Participants also completed open-ended questions regarding the components of the intervention that they found to be most helpful and additional topics that might enhance coping abilities. Finally, rates of session attendance were tracked.

**Control Variables**

Control variables that might provide alternative explanations for intervention-related changes in psychological function were assessed, including demographic factors (e.g., number of people in the household, number and ages of other children, and caregivers’ employment status, age, and race). In addition, information regarding the child’s disease type and stage, illness severity, treatment protocol, and treatment response was obtained from the child’s medical chart and used to derive an index of treatment intensity (see Kazak et al., 2005). The intensity rating was assigned by Dr. Jean Tersak, a Pediatric Oncologist who was blinded to treatment condition. Owing to previous research documenting improved caregiver mental health over time, length of time since diagnosis in days was used as a standard covariate in all analyses.

**Data Analysis**

To assess intervention acceptability and feasibility, the percentage of eligible caregivers who were enrolled and retained in the study was examined. We also explored whether retention was related to demographic factors, disease factors (child’s disease type, stage, severity, and treatment intensity), or scores on baseline psychosocial measures, using a series of Chi-square and independent samples T-tests comparing caregivers who remained in the study with those who withdrew. Finally, descriptive information regarding acceptability was provided based on CSQ-8 responses, open-ended program evaluation questions, and rates of attendance at the face-to-face and telephone sessions.

To ensure that randomization yielded comparable groups, we compared intervention and control groups on demographic characteristics, disease factors, and baseline psychosocial functioning using a series of Chi-square and independent samples T-tests. To evaluate the overall effect of the intervention on the different measures of caregiver distress, we used linear mixed effects regression. In separate models predicting T2 measures of depression, anxiety, perceived stress, and impact of events, we entered the T1 measure of distress and time since diagnosis in step 1, followed by group status (intervention versus standard care) in step 2. To examine risk among caregivers with lower perceived social support, we examined Pearson correlations of T1 social support with caregiver distress at both time points. Finally, we examined whether T1 social support moderated the effect of intervention participation on caregiver changes in distress from T1 to T2. Here, T1 measures and time since diagnosis were entered into step 1,
group status and T1 social support were entered in step 2, and the interaction of group X T1 social support was entered in the final step of separate models predicting T2 measures of caregiver distress. All analyses were performed using SPSS for Windows (version 18).

Our power to detect significance in this small pilot sample was limited. For any T2 outcome, with two covariates in the regression model (i.e., T1 levels of the outcome and days since diagnosis) in addition to the group effect, we had power of .34 to detect as significant at .05 a medium-sized difference between the intervention and control groups (estimated using Power and Precision: http://www.power-analysis.com). A total sample size of 120 would be needed to yield power of 80% to detect a medium effect in any of the T2 measures.

Results
Feasibility and Acceptability
During the recruitment period, 276 children were newly diagnosed with non-CNS cancers at the Children’s Hospital of Pittsburgh. Of these families, 73 were eligible to participate in the current study. Reasons for ineligibility were the child’s age (N = 168), treatment regimen that did not include chemotherapy (N = 18), treatment at a different facility (N = 8), poor prognosis or relapse (N = 5), developmental delay (N = 3), and outside the recruitment window (N = 1). In all, 57 of the 73 eligible families (78%) agreed to be approached about the study, and 49 caregivers consented to participate (enrollment rate = 67%; Figure 1). The eight caregivers who were not interested in participating reported either feeling too overwhelmed to take part or having sufficient available support.

A total of 11 caregivers (22%) dropped out after providing consent. Four dropped out before completing T1 measures and were not randomized to the intervention or control condition. The remaining seven who withdrew before T2 were all randomized to the intervention condition (Figure 1). Reasons for discontinuation included the following: (a) death of child (N = 2), (b) the child being too ill (N = 4), and (c) the child responding so well to treatment that the family believed the intervention was not needed (N = 1). Individuals who dropped out did not differ from those who completed both assessments with respect to caregiver age, gender, race, years of education, employment status, marital status, number and ages of other children, days since child’s diagnosis, child’s disease type, stage, severity, or treatment intensity, or scores on baseline psychosocial measures (p’s > .05). One mother who was assigned to the control group had a T1 BDI score of 57 (>4 SDs above the mean) and was referred for evaluation and treatment of depression. She was excluded from data analysis, resulting in a final sample of 44 caregivers at T1 and 37 caregivers who completed both T1 and T2 measures (23 intervention, 14 controls).

All caregivers assigned to the intervention condition who completed the T2 assessment took part in all six intervention sessions. Adherence rate to phone calls conducted between face-to-face sessions was 92%; self-reported adherence to daily relaxation practice was 60%. In addition, all caregivers assigned to “Connections to Coping” were given access to the study-specific web site. Twenty-one percent of them logged onto the site, with the “Discussion Groups” component being accessed most often (40% of all hits). See Ewing et al. (2009) for further details regarding use of the study web site.

Acceptability was assessed through responses to the CSQ-8 and open-ended program evaluation questions. Mean ratings from these measures indicated satisfaction with the intervention (Table II), with all participants indicating that the intervention was good or excellent overall. In open-ended questions, caregivers indicated that they appreciated the help they received to cope with the many stressors faced during the early stages of their child’s cancer treatment. When asked if there was anything they would like to change, the two most frequent responses were as follows: (a) a desire for more sessions extending for a longer period and (b) a request that the intervention be offered even earlier in the course of their child’s treatment.

<table>
<thead>
<tr>
<th>Satisfaction questions</th>
<th>Mean (standard deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To what extent has participation in the program helped you?</td>
<td>3.43 (.73)</td>
</tr>
<tr>
<td>2. How would you rate the whole program?</td>
<td>3.83 (.39)</td>
</tr>
<tr>
<td>3. Would you tell a friend that they should take part in this program?</td>
<td>3.74 (.54)</td>
</tr>
<tr>
<td>4. Have the things you have learned in this program helped you to deal with upsetting events (stress) in your life?</td>
<td>3.43 (.39)</td>
</tr>
<tr>
<td>5. Are you happy with the help you received in the program?</td>
<td>3.30 (1.06)</td>
</tr>
<tr>
<td>6. Did you enjoy the training?</td>
<td>3.74 (.62)</td>
</tr>
</tbody>
</table>

Note. Scores are based on a 0 (poor) to 4 (excellent) rating scale (N = 23).
Table III. Demographic and Child Disease Characteristics of Intervention and Control Groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention group (N = 23)</th>
<th>Standard care control group (N = 14)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caregiver age (years)</td>
<td>42.8 (9.21); range: 28–73</td>
<td>39.5 (7.48); range: 30–54</td>
<td>NS</td>
</tr>
<tr>
<td>Caregiver gender</td>
<td>91.3% female</td>
<td>100% female</td>
<td>NS</td>
</tr>
<tr>
<td>Caregiver education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some high school</td>
<td>8.7%</td>
<td>7.1%</td>
<td>NS</td>
</tr>
<tr>
<td>High school diploma/GED</td>
<td>34.8%</td>
<td>35.7%</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>30.4%</td>
<td>14.3%</td>
<td></td>
</tr>
<tr>
<td>College</td>
<td>21.7%</td>
<td>21.4%</td>
<td></td>
</tr>
<tr>
<td>Advanced degree</td>
<td>4.3%</td>
<td>21.4%</td>
<td></td>
</tr>
<tr>
<td>Caregiver marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/partnered</td>
<td>56.5%</td>
<td>64.3%</td>
<td>NS</td>
</tr>
<tr>
<td>Separated/divorced/widowed</td>
<td>34.8%</td>
<td>21.4%</td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>8.7%</td>
<td>14.3%</td>
<td></td>
</tr>
<tr>
<td>Caregiver ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>82.6%</td>
<td>92.9%</td>
<td>NS</td>
</tr>
<tr>
<td>African-American</td>
<td>17.4%</td>
<td>7.1%</td>
<td></td>
</tr>
<tr>
<td>Child age (years)</td>
<td>13.2 (2.6), range: 8–17</td>
<td>12.9 (3.4), range: 7–17</td>
<td>NS</td>
</tr>
<tr>
<td>Child gender</td>
<td>43.5% female</td>
<td>57.1% female</td>
<td></td>
</tr>
<tr>
<td>Days from diagnosis</td>
<td>24 (15.4); range: 5–56</td>
<td>25 (14); range: 4–55</td>
<td>NS</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukemia/Lymphoma</td>
<td>18</td>
<td>11</td>
<td>NS</td>
</tr>
<tr>
<td>Solid tumors</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Treatment intensity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>8.7%</td>
<td>0%</td>
<td>NS</td>
</tr>
<tr>
<td>Moderate</td>
<td>69.6%</td>
<td>85.7%</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>21.7%</td>
<td>14.3%</td>
<td></td>
</tr>
</tbody>
</table>

Equivalency of Intervention and Control Groups

A total of 44 primary caregivers completed T1 assessments. The caregivers ranged in age from 28 to 73 years (\( M = 41 \) years, SD = 8), and the majority were female (98%) and European-American (84%). The children with cancer ranged in age from 7 to 17 years (\( M = 13 \) years, SD = 3), were evenly split among gender (50% female), and were mostly European-American (83%). For the full T1 sample (\( N = 44 \)), the timing of the T1 assessment ranged from 2 to 85 days (median = 23) from the child’s diagnosis. For the subsample that completed T1 and T2 data (\( N = 37 \)), the range was 4–56 days (median = 22).

There were no significant differences in demographic characteristics, family composition, disease characteristics (type, stage, severity, or treatment intensity), or time since diagnosis of T1 or T2 assessments between individuals randomly allocated to the intervention versus control groups (Table III). Caregivers assigned to the intervention group scored significantly higher on the Impact of Event scale at T1 than those in the control group \( t(42) = 2.13; p = .04 \). Otherwise, there were no significant group differences in T1 levels of distress or perceived social support.

Across all caregivers, 21% at T1 and 19% at T2 endorsed levels of depressive symptoms in the clinical range (BDI scores >18). On the measure of perceived stress, 26 caregivers (58%) at T1 and 17 caregivers (45%) at T2 scored more than one SD above the adult female norm of 19.3 (SD = 7.5; Cohen & Williamson, 1987). Similarly, on the measure of state anxiety, 27 caregivers (60%) at T1 and 18 caregivers (47%) at T2 scored more than one SD above the adult female norm of 34.2 (SD = 9.87; Spielberger et al., 1983).

Treatment Efficacy

T2 assessments were conducted on an average of 165 days following the child’s diagnosis (median = 153; range = 86–341 days) and 141 days following the T1 assessment (median = 130; range = 44–322 days). Mean values of caregiver distress at T1 and T2 are presented in Table IV. Paired t-tests showed a significant decrease in state anxiety from T1 to T2 across all participants, with similar trends toward decreased perceived stress and Impact of Events total scores across time points (Table IV). Magnitude of change in caregiver distress measures between T1 and T2 were not significantly associated...
with time since the child’s diagnosis at T2 or time between T1 and T2 assessments.

Next, we examined the effect of the intervention on each measure of caregiver distress using linear mixed effects regression. The two groups did not differ on demographic or disease factors; therefore, they were not used as covariates in the multivariate models. However, variability in days since diagnosis at T2 was included as a covariate in all analyses. We observed no significant main effect of group (intervention versus standard care) on T2 symptons of depression (BDI: β = .14, p = .45), impact of events (IES: β = −.06, p = .70), perceived stress (PSS: β = .06, p = .71), or state or trait anxiety (STAI-trait: β = .07, p = .53; STAI-state: β = .18, p = .15). There was a marginally significant association of group with total perceived social support score (β = .19, p = .07), reflecting an increase in perceived social support from T1 to T2 among the intervention group, but not the standard care control group.

Social Support as a Moderator of Treatment Efficacy

Our secondary hypothesis was that primary caregivers with lower levels of perceived social support at the time of their child’s diagnosis would (a) be at higher risk for prolonged distress and (b) derive greater benefit from a supportive intervention than those with greater baseline perceived support. To examine risk among caregivers with lower perceived social support, we first examined bivariate associations of T1 social support with caregiver distress at both time points. As expected, T1 perceived social support covaried inversely with both concomitant and future measures of caregiver distress (Table V). Further, caregivers with low perceived support (below the median score of 94 on the ISEL) who were randomized to the control condition endorsed greater distress at T2 than those with higher baseline perceived support [BDI: t(12) = 2.79, p = .01; PSS: t(12) = 1.92, p = .06; STAI-state t(12) = 2.06, p = .06; STAI-trait: t(12) = 3.38, p = .005]. These findings confirm that caregivers who perceive low levels of social support following their child’s diagnosis are at increased risk for prolonged distress.

To determine whether individuals with lower social support gained greater benefit from the intervention, we examined T1 social support as a moderator of intervention response. After controlling for T1 levels of distress and social support, time since diagnosis, and group assignment, results revealed significant interactions of group by T1 social support in the prediction of T2 depression (β = −2.30, ΔR² = .12, p = .03), impact of events (β = −2.16, ΔR² = .11, p = .02), perceived stress (β = −3.29, ΔR² = .24, p = .001), state anxiety (β = −1.74, ΔR² = .07, p = .02), and trait anxiety (β = −1.42, ΔR² = .04, p = .02) scores, with models accounting for 42, 32, 37, 57, and 79% of the total variance in the respective T2 measures of distress (Figure 2). Examination of simple slopes at one SD above and below the mean of T1 social support showed that the intervention was associated with decreased state anxiety at low levels of

Table IV. Mean Levels of Distress at Time 1 (T1) and Time 2 (T2) (Standard Deviations in Parentheses) and Results of t-Tests Examining Changes in Measures of Distress From T1–T2 Across All Study Completers

<table>
<thead>
<tr>
<th>Measure</th>
<th>Total sample</th>
<th>Intervention completers N = 23</th>
<th>Control completers N = 14</th>
<th>Change T1–T2 N = 37</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1 N = 44</td>
<td>Time 2 N = 37</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time 1</td>
<td>Time 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time 1</td>
<td>Time 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSSa</td>
<td>28.2 (7.8)</td>
<td>26.0 (7.2)</td>
<td>28.4 (7.2)</td>
<td>25.6 (4.7)</td>
</tr>
<tr>
<td>BDIb</td>
<td>12.2 (8.1)</td>
<td>12.1 (8.7)</td>
<td>13.6 (8.2)</td>
<td>11.5 (8.5)</td>
</tr>
<tr>
<td>STAI-state</td>
<td>47.8 (13.6)</td>
<td>43.7 (13.1)</td>
<td>50.8 (12.8)</td>
<td>43.1 (11.4)</td>
</tr>
<tr>
<td>STAI-trait</td>
<td>40.6 (11.2)</td>
<td>40.6 (9.9)</td>
<td>42.2 (10.5)</td>
<td>41.0 (8.1)</td>
</tr>
<tr>
<td>IES-total</td>
<td>35.2 (11.7)</td>
<td>30.6 (17.6)</td>
<td>39.0 (11.8)</td>
<td>34.3 (15.6)</td>
</tr>
<tr>
<td>ISEL-total</td>
<td>91.8 (19.8)</td>
<td>90.8 (21.1)</td>
<td>88.5 (20.6)</td>
<td>91.4 (20.6)</td>
</tr>
</tbody>
</table>

*PSS = Perceived Stress Scale; **BDI = Beck Depression Inventory; ‘STAI = StateTrait Anxiety Inventory; †IES = Impact of Events Scale; ‡ISEL = Interpersonal Support Evaluation List.

**p = .002, *p = .06.

Table V. Correlations of Time 1 Perceived Social Support With Time 1 and Time 2 Measures of Distress Across All Study Completers (N = 37)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDI</td>
<td>−0.70***</td>
<td>−0.50**</td>
</tr>
<tr>
<td>IES</td>
<td>−0.40**</td>
<td>−0.34*</td>
</tr>
<tr>
<td>PSS</td>
<td>−0.47**</td>
<td>−0.40*</td>
</tr>
<tr>
<td>STAI-trait</td>
<td>−0.60***</td>
<td>−0.49**</td>
</tr>
<tr>
<td>STAI-trait</td>
<td>−0.54**</td>
<td>−0.48**</td>
</tr>
</tbody>
</table>

*BDI = Beck Depression Inventory; †IES = Impact of Events Scale; ‡PSS = Perceived Stress Scale; §STAI = StateTrait Anxiety Inventory. 
***p < .001; **p < .01; *p < .05.
The relationship between baseline social support [t(33) = 2.37, p = .02] and the intervention was examined. There was no benefit of the intervention at high levels of social support [t(33) = .01, p = .99]. A similar pattern of effects was observed for the other measures of distress (Figure 2).

**Discussion**

In the current pilot study, we examined evidence for the feasibility, acceptability, and preliminary efficacy of a stress management intervention for caregivers of children recently diagnosed with cancer. The feasibility results are encouraging. We recruited 67% of eligible primary caregivers of children who were within 8 weeks of a new diagnosis of any cancer (excluding CNS tumors), resulting in an initial sample of 45 caregivers (42 mothers, 2 fathers, and 1 grandmother). We obtained baseline psychosocial data on 92% of this sample within 6 weeks of the child’s diagnosis, and 82% of this sample completed all aspects of the study. These results are inconsistent with those of Stehl et al. (2009), who recruited 23% of eligible caregivers within 2 months of their child’s cancer diagnosis to participate in a randomized trial of a three-session family function intervention. In contrast to the Stehl et al. (2009) study, which required that two caregivers participate, the current study recruited only one primary caregiver per family. This may have increased the practical aspects of participation, especially given the multiple schedule demands that confront caregivers of children newly diagnosed with cancer and the tendency for parents to assume complementary, non-overlapping roles in the face of their child’s cancer (e.g., one parent being responsible for caring for the child with cancer and the other parent...
The current findings also support the acceptability of early intervention. Feedback from participants was uniformly positive and indicated satisfaction with the intervention and a belief that it was helpful. Here, our findings are consistent with the findings of others (Kazak et al., 2005; Stehl et al., 2009) and suggest that supportive interventions offered during the early stages of diagnosis and treatment are well received by caregivers.

Consistent with the existing literature (e.g., Poder et al., 2008; Jantien Vrijmoet-Wiersma et al., 2008), primary caregiver distress assessed 4–56 days following diagnosis was higher than normative values, with 21% of caregivers endorsing clinical levels of depressive symptoms. Mean levels of perceived stress and anxiety also were significantly higher than population norms, with 58 and 60%, respectively, falling above a cut-off of one SD above normative values. Although mean levels of caregiver distress declined during the subsequent 4–5 months, levels of distress remained elevated at the T2 follow-up when compared with population norms. Overall, the intervention group did not differ significantly from the control group in the main effect of decreased distress between T1 and T2. However, further research is warranted, given the low power to detect effects in the current small sample.

Evidence for the efficacy of structured psychological interventions at reducing distress among caregivers of children early in treatment is mixed, with some studies showing no overall effect (Hoekstra-Weebers, Heuvel, Jaspers, Kamps, & Klip, 1998; Stehl et al., 2009) and others finding relatively small benefits (Kazak et al., 2005; Sahler et al., 2002, 2005). These relatively small or null effects have led to criticism of the “one intervention fits all” model and to the recommendation that interventions be targeted toward individuals at increased psychosocial risk (Kazak et al., 2007). In response to this criticism, a secondary goal of the current study was to identify caregivers at increased psychological risk who may benefit differentially from preemptive intervention. Consistent with findings that social support is associated with better psychological adjustment among parents of children with cancer (Fotiadou et al., 2008; Greening & Stoppelbein, 2007; Kazak et al., 1998; Morrow et al., 1984; Norberg et al., 2006; Wijnberg Williams et al., 2006), our findings confirm that perceived social support measured within 8 weeks of the child’s diagnosis is inversely related to caregiver distress measured 4–5 months later. Indeed, primary caregivers with low perceived social support who were randomized to the control condition showed a significant increase in symptoms of depression, anxiety, and perceived stress across the 4–5 months following their child’s diagnosis, which is inconsistent with the average declines in distress that are typically seen across this period (e.g., Dolgin et al., 2007; Patino-Fernandez et al., 2008).

Our findings also suggest that perceived social support is a marker of psychological risk that can be used to identify individuals who may benefit from early intervention. We provide preliminary evidence that perceived social support in the weeks following the child’s diagnosis is associated with caregivers’ response to a supportive stress management intervention. Caregivers who perceived lower support showed greater levels of distress at baseline and greater intervention-related decreases in depression, anxiety, and perceived stress, whereas caregivers with greater perceived social support derived limited benefit from the intervention.

The mechanism of this effect remains unclear, and caution should be taken before interpreting these findings as the result of individual differences in perceived support. Although we controlled for baseline levels of distress in the multivariate analyses, and our groups did not differ significantly on T1 levels of social support, high inverse correlations of social support with measures of distress at T1 (r’s = -.40 to -.70) prevent examination of the separate effects of these variables as moderators of intervention response. Thus, it is possible that it is the individuals with high baseline levels of distress, alone or in combination with low perceived support, who are at increased risk for future distress and derive greater benefit from stress management intervention. Alternatively, caregivers who perceive greater support may appraise themselves as more able to confront cancer-related stressors as reflected by lower levels of concomitant and future distress.

Limitations of the current pilot intervention study warrant consideration in future, larger-scale trials. A considerable limitation is the use of a TAU control group. Although the choice of an appropriate control condition is a challenge for an intervention that includes a social support component, the use of a TAU control group does not control for non-specific treatment effects such as attention and treatment expectations. Furthermore, the current pilot study is underpowered to examine the efficacy of the...
intervention and the specific components of the multimodal intervention that contribute to observed effects. Anecdotal feedback suggested that face-to-face and telephone sessions were considered useful. In contrast, only 21% of the sample logged on to the study web site, suggesting that this may not be an effective source of support in the early stages of treatment (see Ewing et al., 2009). Future work should match participants on baseline levels of social support and should use larger sample sizes to begin to examine active ingredients, to disentangle the separate effects of baseline social support and level of distress as moderators of treatment response, and to permit the use of intention to treat analyses to control for the possible impact of participant dropout on intervention efficacy. Another limitation of the current study is the relatively short follow-up period; further work is needed to determine whether intervention benefits are maintained for longer periods. Finally, it remains to be determined whether the current findings generalize to caregivers of younger children with cancer or to those with CNS tumors. To address the limitations of this pilot, we are undertaking a larger scale efficacy trial, extending the intervention to caregivers of younger children, recruiting all participants within 6 weeks of diagnosis, following levels of distress and markers of physical health among caregivers across the 12 months following the diagnosis, and exploring whether decreases in caregiver distress are associated with better psychosocial functioning among other family members.

In conclusion, we provide preliminary evidence for the feasibility and acceptability of providing a supportive stress management intervention to primary caregivers of children newly diagnosed with cancer. We also provide some of the first evidence to suggest that primary caregivers with lower levels of perceived social support are at increased risk for prolonged distress following their child’s cancer diagnosis and may benefit more from a preemptive supportive stress management intervention than caregivers who perceive themselves to be more supported. Given evidence that prolonged parental distress is associated with adjustment difficulties among children within the family (Bruce, 2006; Colletti et al., 2008; Gerhardt et al., 2007; Maurice-Stam et al., 2008), the current findings may have clinical implications not only for the psychological health of the primary caregiver but in turn for the emotional health of the child with cancer and his/her siblings. Future research is warranted to examine whether the delivery of psychological interventions to parents results in psychological benefits for the child. Beyond the care of families of children newly diagnosed with cancer, the significance of the current findings includes the potential to identify and treat individuals at increased risk for psychological problems when confronted with life event stress.

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References


